TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

AGENDA ITEM REQUEST

for Rulemaking Adoption

AGENDA REQUESTED: January 12, 2022

DATE OF REQUEST: December 22, 2021

INDIVIDUAL TO CONTACT REGARDING CHANGES TO THIS REQUEST, IF NEEDED: Gwen Ricco, Rule/Agenda Coordinator, (512) 239-2678

CAPTION: Docket No. 2019-1058-RUL. Consideration of the adoption of proposed amendments to 30 TAC Chapter 335, Industrial Solid Waste and Municipal Hazardous Waste, Sections 335.1, 335.2, 335.9, 335.10, 335.12, 335.13, 335.15, 335.18, 335.19, 335.24, 335.26, 335.27, 335.31, 335.41, 335.46, 335.91, 335.94, 335.112, 335.152, 335.221, 335.241, 335.251, 335.261, 335.272, 335.431, 335.471, 335.474, 335.477, 335.503, 335.504, 335.510, 335.511, 335.513, 335.521, 335.590, 335.602, 335.702, and 335.703; repealed 30 TAC Chapter 335, Sections 335.6, 335.11, 335.14, 335.61 - 335.63, 335.65 - 335.71, and 335.73 - 335.79; and new 30 TAC Chapter 335, Sections 335.6, 335.11, 335.14, 335.51 - 335.61, 335.751, 335.753, 335.755, 335.757, 335.759, 335.761, 335.763, 335.765, 335.767, 335.769, and 335.771.

The adoption will revise state industrial solid waste and hazardous waste management regulations to maintain equivalency with Resource Conservation and Recovery Act revisions promulgated by the United States Environmental Protection Agency, and to formalize the foundry sands exclusion. The proposed rules were published in the July 30, 2021, issue of the *Texas Register* (46 TexReg 4586). (Jarita Sepulvado, Diane Goss; Rule Project No. 2019-086-335-WS)

Director

Division Deputy Director

Gwen Ricco

Agenda Coordinator

Copy to CCC Secretary? NO ☐ YES ☒

Texas Commission on Environmental Quality
Interoffice Memorandum

To: Commissioners **Date:** December 22, 2021

Thru: Laurie Gharis, Chief Clerk
Toby Baker, Executive Director

From: BW Brent Wade, Director
Office of Waste

Docket No.: 2019-1058-RUL

Subject: Commission Approval for Rulemaking Adoption
Chapter 335, Industrial Solid Waste and Municipal Hazardous Waste
Phase II: RCRA Authorization for Parts of Federal Rule Clusters XXIV, XXV, XXVI, XXVII, and XXVIII
Rule Project No. 2019-086-335-WS

Background and reason(s) for the rulemaking:
In order for the State of Texas to be consistent with certain federal solid and hazardous waste requirements and with the Resource Conservation and Recovery Act (RCRA), the Texas Commission on Environmental Quality (TCEQ or commission) periodically incorporates specific United States Environmental Protection Agency (EPA) rule changes into state rules. Parts of the EPA federal rule changes in Rule Clusters XXIV - XXVIII are included in this rulemaking adoption, amending 30 Texas Administrative Code (TAC) Chapter 335.

In addition to incorporating federal rule changes, the rulemaking adoption will update and formalize existing guidance regarding the regulatory status of spent foundry sand from the iron and steel casting industry as a coproduct when reused as a substitute material, including use constituting disposal.

Scope of the rulemaking:

A.) Summary of what the rulemaking will do:
The rulemaking adoption will amend Chapter 335 by adopting federal RCRA revisions and implement state-initiated revisions to clarify the regulatory status of spent foundry sand.

B.) Scope required by federal regulations or state statutes:
This rulemaking initiative will update Chapter 335 to include federal rule changes that are both optional and non-optional. The revisions are set forth in parts of RCRA Clusters XXIV - XXVIII. Each cluster contains one or more checklists, and each checklist explains specific additions and revisions to the rule language.

RCRA Cluster XXIV - Checklist 233

Rule changes in Checklist 233 implement vacaturs of parts of the federal definition of solid waste (DSW) ordered by the United States Court of Appeals for the District of Columbia Circuit by revising several recycling-related provisions associated with the DSW. The purpose of these revisions is to ensure that the hazardous secondary materials recycling regulations encourage reclamation in a way that does not result in increased risk to human health and the environment. The state previously

adopted the 2015 DSW revisions and is recognized as broader in scope than the federal regulations, therefore this checklist is optional.

RCRA Cluster XXV - Checklist 237

Rule changes in Checklist 237 revise the existing hazardous waste generator regulatory program by reorganizing the regulations to improve their usability by the regulated community; providing a better understanding of how the RCRA hazardous waste generator regulatory program works; addressing gaps in the existing regulations to strengthen environmental protection; providing greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner; and making technical corrections and conforming changes to address inadvertent errors and remove obsolete references to programs that no longer exist. The checklist is not optional; however, some provisions are equivalent or less stringent.

RCRA Cluster XXVI - Checklists 238 and 239

Rule changes in Checklist 238 revise existing regulations regarding the export and import of hazardous wastes from and into the United States. Specifically, this rule applies a confidentiality determination such that no person can assert confidential business information claims for documents related to the export, import, and transit of hazardous waste and export of excluded cathode ray tubes. The EPA is making these changes to apply a consistent approach in addressing confidentiality claims for export and import documentation. This checklist is not optional.

Rule changes in Checklist 239 will adopt the methodology the EPA established to determine and revise the user fees applicable to the electronic and paper manifests to be submitted to the national electronic manifest (e-Manifest) system that the EPA developed under the Hazardous Waste Electronic Manifest Establishment Act. Certain users of the hazardous waste manifest are required to pay a prescribed fee to the EPA for each electronic and paper manifest they use and submit to the national system. This checklist is not optional.

RCRA Cluster XXVII - Checklist 241

Rule changes in Checklist 241 establish cost-savings and streamlined standards for handling hazardous waste pharmaceuticals to better fit the operations of the healthcare sector while maintaining protection of human health and the environment. The rule will prohibit disposal of pharmaceuticals into the sewage system, exempt nicotine wastes from classification as a listed hazardous waste, and codify the exemption for unused pharmaceuticals that are expected to be legitimately reclaimed from being classified as a solid waste. This checklist is not optional; however, the provision delisting nicotine wastes is less stringent.

RCRA Cluster XXVIII - Checklist 242

Rule changes in Checklist 242 add hazardous waste aerosol cans to the universal waste program. This change will benefit the wide variety of establishments generating and managing hazardous waste aerosol cans, including the retail sector, by providing a clear, protective system for managing discarded aerosol cans,

easing regulatory burdens, and promoting the collection and recycling of these cans. This checklist is optional.

C.) Additional staff recommendations that are not required by federal rule or state statute:
In addition to federal revisions, revisions are being adopted to the state industrial waste program to codify a 1995 regulatory determination letter and provide an exclusion from the DSW for spent foundry sands generated by the iron and steel casting industries when they are appropriately recycled.

Statutory authority:
The rule change will be adopted under the authority of Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

Effect on the:

A.) Regulated community:
The regulated communities that will be affected by this rulemaking are businesses and industries involved in the generation, treatment, storage, recycling, disposal, import, and/or export of hazardous and industrial solid waste. The impacts to the affected industries will largely be beneficial by providing greater flexibility under the hazardous waste generator regulatory program and for managing or recycling hazardous secondary materials, for managing hazardous waste pharmaceuticals, and for managing hazardous waste aerosol cans.

The regulated community will see a benefit through greater utility of the subject foundry sands as a commodity for an appropriate end user. The market acceptance of the material should increase as the waste moniker is removed and the material is viewed as a valuable coproduct.

B.) Public:
The EPA has concluded that the adoption of these amendments will not present a substantial risk to human health or the environment. The public will benefit from greater compliance with hazardous waste management regulations. The public will also benefit

from the foundry sands exclusion through use of this material as a commodity replacing other more expensive materials in general commerce.

C.) Agency programs:
By adoption of these rules, the state may pursue expanded RCRA authorization from the EPA.

Stakeholder meetings:
Staff received executive management approval to hold an informal advisory group for this rulemaking through an initial Rulemaking Draft Concept and Initiation Memo. A stakeholder meeting to collect informal comments was held July 26, 2019, in Austin. Spent foundry sand was not included in the stakeholder meeting since it was not included in the rule proposal at that time, no stakeholder meeting is planned for it. Additionally, a public hearing was held during the public comment period in Austin.

Public comment:
The commission held a virtual public hearing on August 23, 2021. The comment period closed on August 30, 2021. Timely comments were received from Household & Commercial Products Association, Kyle Beall, Texas Chemical Council, and Texas Industry Project, and untimely comments were received from CVS Health and Texas Molecular Holdings. The executive director considered all comments. Comments focused on the following topics:

- Support for the rulemaking, particularly the inclusion of the pharmaceutical and aerosol can rules.
- Implementation of state small quantity generator notification and renotification requirements.
- Questions and concerns regarding registration and reporting requirements.
- Implementation of adopted federal closure, pre-transport, and quick reference guide requirements.
- Recommendation to retain and enhance the verified recycler exclusion, and a request to clarify that hazardous secondary materials generated in Texas can be shipped out of state to a verified recycler for reclamation.
- Questions regarding the applicability of the pharmaceutical rules.

Significant changes from proposal:
There were no significant rule changes made; however, the following minor revisions were made to rule language in response to comments and to correct a typographical error:

- The catchline in §335.6(a) was revised in response to comments.
- The temporary waste code requirement in §335.13(e)(3) was expanded in response to comments.
- An incorrect citation was corrected in §335.272(b)(9).

Potential controversial concerns and legislative interest:
No controversial matters are anticipated from this rulemaking initiative to adopt federal rule revisions into state rules.

Will this rulemaking affect any current policies or require development of new policies?
No policy issues are anticipated.

What are the consequences if this rulemaking does not go forward? Are there alternatives to rulemaking?
To maintain RCRA authorization, amendments that are not optional must be adopted. The commission may elect to not incorporate the federal amendments that are optional, as the RCRA program authorization from the EPA would not be affected; however, the commission would not be in alignment with the EPA's RCRA program. Such differences may make compliance more difficult for the regulated community, especially for entities with facilities in multiple states. In this rulemaking, all federal rule changes are being included in the adopted rules.

Key points in the adoption rulemaking schedule:
Texas Register **proposal publication date:** July 30, 2021
Anticipated ***Texas Register*** **adoption publication date:** January 28, 2022
Anticipated effective date: February 3, 2022
Six-month ***Texas Register*** **filing deadline:** January 30, 2022

Agency contacts:
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Attachments:
Response to Vacatur of Certain Provisions of the Definition of Solid Waste Rule
Hazardous Waste Generator Improvements Rule
Confidentiality Determinations for Hazardous Waste Export and Import Documents
Hazardous Waste Management System; User Fees for the Electronic Hazardous Waste Manifest System and Amendments to Manifest Regulations
Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine
Increasing Recycling: Adding Aerosol Cans to the Universal Waste Regulations

cc: Chief Clerk, 2 copies
Executive Director's Office
Jim Rizk
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Brody Burks
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Jarita Sepulvado
Diane Goss
Gwen Ricco

ozone and the 1997 and 2006 $PM_{2.5}$ NAAQS requirements of CAA sections 110(a)(2)(A), (B), (C) (enforcement program only), (D)(i)(II) prong 4 (visibility), (E), (F), (G), (H), (J) (consultation and public notification only), (K), (L), and (M).

* * * * *

(b) * * *

(1) * * * Submittal from New Jersey dated October 17, 2014, as supplemented on March 15, 2017, to address the CAA infrastructure requirements of section 110(a)(2) for the 2008 Lead, 2008 8-hour ozone, 2010 NO_2, 2010 SO_2, 2012 $PM_{2.5}$, 2006 PM_{10}, and 2011 CO NAAQS is approved for (A), (B), (C) (enforcement program only), (E), (F), (G), (H), (J) (consultation and public notification only), (K), (L), and (M).

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[FR Doc. 2018–10801 Filed 5–29–18; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260 and 261

[EPA–HQ–OLEM–2018–0185; FRL–9977–56–OLEM]

Response to Vacatur of Certain Provisions of the Definition of Solid Waste Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is revising regulations associated with the definition of solid waste under the Resource Conservation and Recovery Act. These revisions implement vacaturs ordered by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit), on July 7, 2017, as modified on March 6, 2018.

DATES: This final rule is effective on May 30, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2018–0185. All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the EPA Docket Center. See *https://www.epa.gov/dockets/epa-docket-center-reading-room* for more information on the Public Reading Room.

FOR FURTHER INFORMATION CONTACT: Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, MC 5304P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460, Tracy Atagi, at (703) 308–8672, (*atagi.tracy@epa.gov*).

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. General Information

A. Does this action apply to me?

This final rule applies to facilities that generate or recycle hazardous secondary materials (HSM). According to the revisions to the definition of solid waste promulgated in 2015, entities potentially affected by the original rule include over 5,000 industrial facilities in 634 industries (at the 6-digit North American Industry Classification System (NAICS) code level).[1] Most of these 634 industries have relatively few entities that are potentially affected. The top-5 economic sectors (at the 2-digit NAICS code level) with the largest number of potentially affected entities are as follows: (1) 41% in NAICS code 33—the manufacturing sector, which consists of metals, metal products, machinery, computer & electronics, electrical equipment, transportation equipment, furniture, and miscellaneous manufacturing subsectors, (2) 23% in NAICS code 32—the manufacturing sector, which consists of wood products, paper, printing, petroleum & coal products, chemicals plastics & rubber products, and nonmetallic mineral products manufacturing subsectors, (3) 3.0% in NAICS code 92—the public administration sector, (4) 2.9% in NAICS code 61—the educational services sector, and (5) 2.8% in NAICS code 54—the professional, scientific and technical services sector.

[1] 80 FR 1694/2, January 13, 2015.

B. Why is EPA issuing a final rule?

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for revising these provisions without prior proposal and opportunity for comment, because these revisions simply undertake the ministerial task of implementing court orders vacating these rules and reinstating the prior versions. As a matter of law, the orders issued by the United States Court of Appeals for the District of Columbia Circuit on July 7, 2017 and amended on March 6, 2018, (1) vacated the 2015 verified recycler exclusion for hazardous waste that is recycled off-site (except for certain provisions); (2) reinstated the transfer-based exclusion from the 2008 rule to replace the now-vacated 2015 verified recycler exclusion; (3) upheld the containment and emergency preparedness provisions of the 2015 rule; (4) vacated Factor 4 of the 2015 definition of legitimate recycling in its entirety; and (5) reinstated the 2008 version of Factor 4 to replace the now-vacated 2015 version of Factor 4.[2] It is, therefore, unnecessary to provide notice and an opportunity for comment on this action, which merely carries out the court's orders.

In addition, EPA finds that it has good cause to make the revisions immediately effective under section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), and section 3010(b) of RCRA, 42 U.S.C. 6930(b). Section 553(d) provides that final rules shall not become effective until 30 days after publication in the **Federal Register**, ''except . . . as otherwise provided by the agency for good cause,'' among other exceptions. The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.* v. *FCC,* 78 F.3d 620, 630 (D.C. Cir. 1996); *see also United States* v. *Gavrilovic,* 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Thus, in determining whether good cause exists to waive the 30-day delay, an agency should ''balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time

[2] *API* v. *EPA,* 862 F.3d 50 (DC Cir. 2017), *reh'g granted,* No. 09–1038, 2018 U.S. App. LEXIS 5613 (DC Cir. Mar. 6, 2018).

to prepare for the effective date of its ruling.'' *Gavrilovic,* 551 F.2d at 1105. EPA has determined that there is good cause for making this final rule effective immediately because this action merely implements court orders that vacate certain regulatory provisions and reinstate the prior versions. The court issued the mandate for its decision on March 14, 2018, at which point the orders became effective. Delaying the effectiveness of this rulemaking would lengthen the period between the change in the law (*i.e.,* the court's mandate) and the corresponding update to the regulations. Minimizing that time period should reduce the possibility of confusion for the regulated community, state and local governments, and the public. Moreover, the Agency believes that delaying the effectiveness of this rule would not offer any benefits. As a result, EPA is making this rule immediately effective.

II. Statutory Authority

These regulations are promulgated under the authority of sections 2002, 3001, 3002, 3003, 3004, 3006, 3010, and 3017 of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA) This statute is commonly referred to as ''RCRA.''

III. Which regulations is EPA removing and replacing?

A. Removal of the 2015 Verified Recycler Exclusion and Reinstatement of the 2008 Transfer-Based Exclusion, With Modifications

In the 2015 DSW rule, EPA replaced the 2008 DSW rule transfer-based exclusion found at 40 CFR 261.4(a)(24)–(25) with the verified recycler exclusion, found at 40 CFR 261.4(a)(24).[3] (The goal of both exclusions was to exempt from regulation off-site recycling of hazardous waste when certain conditions are met). In promulgating the 2015 verified recycler exclusion EPA made four key changes to the language of the 2008 transfer-based exclusion: (1) Removed a prohibition that had made certain spent petroleum catalysts (hazardous waste codes K171 and K172) ineligible for the new recycling exclusions (*i.e.,* these materials became eligible under the 2015 exclusion); (2) added a specific ''contained'' standard for the management of the materials prior to being recycled; (3) added emergency preparedness and response requirements; and (4) replaced a requirement for generators to make a ''reasonable effort'' to audit the recycling facility prior to sending their material to be recycled with a requirement that the recycling facility obtain a variance from the regulations prior to accepting the recyclable materials.

In its decisions vacating the 2015 verified recycler exclusion and ordering the reinstatement of the 2008 transfer-based exclusion, the court found that the first three provisions noted above were severable from the rest of the verified recycler exclusion and would not be affected by the vacatur. Instead, these provisions are retained in the reinstated transfer-based exclusion found in the revised version of 40 CFR 261.4(a)(24) being finalized with this action. In addition, the export requirements for the transfer-based exclusion found at 40 CFR 261.4(a)(25) are also reinstated.[4] Finally, the following conforming changes are made in response to the vacatur of the verified recycler exclusion and reinstatement of the transfer-based exclusion (1) references to the verified recycler variance process are removed from 40 CFR 260.30 and 40 CFR 260.31, (2) the reference to the financial assurance notification requirement reinstated under the transfer-based exclusion is added back into 40 CFR 260.42(a)(5), and (3) the language in 40 CFR 261.4(a)(25) is updated to reflect the fact that subsequent to the 2015 withdrawal of the transfer-based exclusion, the applicable export definitions were moved to 40 CFR 262.81, and the paper submittal of RCRA export notices and export annual reports was replaced with electronic submittal via EPA's Waste Import Export Tracking System (WIETS). (81 FR 85696, November 28, 2016; 82 FR 41015, August 29, 2017).

B. Removal of the 2015 Factor Four in the Definition of Legitimate Recycling and Reinstatement of the 2008 Factor Four

In the 2015 DSW rule, EPA revised the definition of legitimate recycling found at 40 CFR 260.43, which was originally promulgated in the 2008 DSW rule. In both the 2008 and 2015 versions of the regulation, the legitimacy provision was designed to distinguish between real recycling activities—legitimate recycling—and ''sham'' recycling, an activity undertaken by an entity to avoid the requirements of managing a hazardous secondary material as a hazardous waste. This provision represented the codification of a long-standing policy prohibiting sham recycling which had previously been applied via **Federal Register** preamble and guidance documents, most notably through the 1989 ''Lowrance memo'' which discussed over a dozen factors to be considered.

The existing policy in that 1998 memo was condensed and codified into regulation in 2008 as four separate factors, summarized as follows. Factor 1 addresses the concept that legitimate recycling involves a hazardous secondary material that provides a useful contribution to the recycling process, or to a product or intermediate of the recycling process. Factor 2 addresses the concept that the legitimate recycling process produces a valuable product or intermediate. Factor 3 addresses the concept that under legitimate recycling, the generator and the recycler manages the hazardous secondary material as a valuable commodity when it is under their control. Factor 4 addresses the concept that the product of the recycling process is comparable to a legitimate product or intermediate in terms of hazardous constituents or characteristics. Under the 2008 rule, the first two factors had to be satisfied while the latter two factors had to be considered. In addition, the codified legitimacy test only applied to the then-new Generator-Controlled and Transfer-based exclusions, and to non-waste determinations under 260.34. *See* 40 CFR 260.43(b), (c) (2008).

The 2015 revisions made the following changes to the four legitimacy factors: (1) All four factors were made to apply to all excluded recycling, including recycling exclusions that predated the 2008 rule (2) Factors 3 and 4 became mandatory factors (in the 2008 rule, they were merely factors to be ''considered''), and (3) the substance of Factors 3 and 4 changed to add flexibility since the factors had become mandatory.

In its decisions, the Court vacated Factor 4, but left in place all other 2015 changes to the legitimacy factors. The net result is as follows: (1) The 2015 version of Factor 4 is vacated in its entirety; (2) the 2015 change making the legitimacy factors applicable to all exclusions remains; (3) Factor 3 remains mandatory per the 2015 changes; and (4) the 2008 version of Factor 4 (which

[3] The **Federal Register** citation for the ''2015 DSW rule'' is 80 FR 1694, January 13, 2015, and for the ''2008 DSW rule'' is 73 FR 64668, October 30, 2008.

[4] The court characterized the 2008 transfer-based exclusion this way: ''EPA adopted the first edition, the Transfer-Based Exclusion, as part of its 2008 Rule . . . previously codified at 40 CFR 261.4(a)(24)–(25) (2014).'' *API,* 862 F.3d at 64. The court's citation encompasses both the domestic (*i.e.,* paragraph (a)(24) and export (*i.e.,* paragraph (a)(25)) parts of the exclusion. The court then concluded that ''the [2008] Transfer-Based Exclusion is reinstated.'' *Id.* at 75. Consequently, this action includes both paragraphs (a)(24) and (25).

requires only that the factor be ''considered'') replaces the now-vacated 2015 version. In addition, a reference in 40 CFR 261.4(a)(23)(ii)(E) requiring documentation of how ''all four factors in 40 CFR 260.43(a) are met'' has been revised to conform with the court decisions.

IV. When will the final rule become effective?

The revisions to 40 CFR 260.42, 40 CFR 260.43, 40 CFR 261.4(a)(23) and 40 CFR 261.4(a)(24); the reinstatement of 261.4(a)(25), and the removal of 40 CFR 260.30(f) and 260.31(d) are effective immediately.

V. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize a qualified state to administer and enforce a hazardous waste program within the state in lieu of the federal program, and to issue and enforce permits in the state. A state may receive authorization by following the approval process described in 40 CFR 271.21 (see 40 CFR part 271 for the overall standards and requirements for authorization). EPA continues to have independent authority to bring enforcement actions under RCRA sections 3007, 3008, 3013, and 7003. An authorized state also continues to have independent authority to bring enforcement actions under state law.

After a state receives initial authorization, new federal requirements and prohibitions promulgated under RCRA authority existing prior to the 1984 Hazardous and Solid Waste Amendments (HSWA) do not apply in that state until the state adopts and receives authorization for equivalent state requirements. In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), new federal requirements and prohibitions promulgated under HSWA provisions take effect in authorized states at the same time that they take effect in unauthorized states. As such, EPA carries out the HSWA requirements and prohibitions in authorized states, including the issuance of new permits implementing those requirements, until EPA authorizes the state to do so.

Authorized states are required to modify their programs only when EPA enacts federal requirements that are more stringent or broader in scope than existing federal requirements. Under RCRA section 3009, states may impose standards that are more stringent than those in the federal program (see also 40 CFR 271.1(i)). Therefore, authorized states are not required to adopt new federal regulations that are considered less stringent than previous federal regulations or that narrow the scope of the RCRA program. Previously authorized hazardous waste regulations would continue to apply in those states that do not adopt ''deregulatory'' rules.

B. Effect on State Authorization of D.C. Circuit Court Vacaturs

On March 14, 2018, the D.C. Circuit Court issued its mandate, effectuating the vacaturs as described earlier in this document. The court's vacaturs mean that the vacated provisions of these federal rules are legally null and void and the corresponding regulatory requirements that were previously in effect are reinstated as if the vacated parts of the rules never existed. At the federal level, because the effect of the vacaturs means, in essence, that the vacated provisions of these rules should not have been promulgated, this **Federal Register** action serves to remove the vacated provisions from the federal regulations and replaces them with the regulations that were previously in effect. At the state level, because no state rules were challenged in the litigation, the court decision does not directly affect any state regulations. However, the vacaturs do have an impact on the authorization status of state regulations. The multiple scenarios that exist in the states are discussed below.

1. States Without Final RCRA Authorization

For states and territories that have no RCRA authorization, the vacaturs mean that the reinstated federal rules are now effect in those states and this **Federal Register** action alerts interested parties of the removal of the vacated parts of the rules from the Code of Federal Regulations and their replacement with the previously promulgated provisions.

2. States That Have Final Authorization But Did Not Promulgate Similar Rules

For states and territories that have RCRA authorization but did not adopt the 2015 verified recycler exclusion (and therefore were not authorized for the exclusion), these states are not required to adopt or become authorized for the transfer-based exclusion being reinstated today because the transfer-based exclusion is less stringent than full Subtitle C hazardous waste regulation.

However, states and territories that have RCRA authorization but have not adopted the 2015 definition of legitimate recycling at 40 CFR 260.43 are required to adopt and become authorized for a definition of legitimate recycling that is equivalent to and at least as stringent as the definition being promulgated today.

3. States That Adopted Similar Rules But Are Not Yet Authorized for Them

For states that have adopted rules similar to the verified recycler exclusion and the 2015 definition of legitimate recycling, but have not yet been authorized for them, the vacatur of the federal rules will not change the authorization status of the state programs. The authorization status that was established prior to the adoption of the state counterpart rules remains in effect. The vacaturs and subsequent reinstatement of various provisions of the prior federal rules will result in state provisions that are broader in scope than the federal program as it pertains to the specific vacated provisions.

4. States That Adopted Similar Rules and Have Been Authorized for Them

For states that have previously been authorized for rules similar to the verified recycler exclusion and the 2015 definition of legitimate recycling, and have been authorized for them, the effect of the vacaturs is that those previously-authorized state provisions will be considered broader in scope than the federally program as it pertains to the specific vacated provisions.

VI. Statutory and Executive Order (E.O.) Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), the Office of Management and Budget (OMB) waived review of this action. Because this action is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) or Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (65 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this final rule is not a significant regulatory action under Executive Order 12866, this final rule is not subject to Executive Order 13771, entitled Reducing Regulations and Controlling Regulatory Costs; Executive Order 13211, entitled Actions Concerning Regulations That

Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001); or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This action does not require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

A. Paperwork Reduction Act (PRA)

To implement the court vacatur, EPA submitted an emergency ICR amendment to OMB with OMB control number 2050–0202 (EPA ICR Number 2310.05). You can find a copy of the ICR amendment in the docket for this rule. The ICR amendment reflects changes due to the vacatur, which are expected to affect a total of 105 facilities, resulting in a total net burden reduction of 2,122 hours and $26,132.21 per year. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. Congressional Review Act (CRA)

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the Comptroller General of the United States. Because this final action only implements the court vacatur, and the Agency has made a good cause finding that notice and comment is unnecessary, it is not subject to the Congressional Review Act.

List of Subjects

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Solid waste.

Dated: May 23, 2018.

E. Scott Pruitt,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

§ 260.30 [Amended]

■ 2. Section 260.30 is amended by removing paragraph (f).

§ 260.31 [Amended]

■ 3. Section 260.31 is amended by removing paragraph (d).

■ 4. Section 260.42 is amended by revising paragraph (a) to read as follows:

§ 260.42 Notification requirement for hazardous secondary materials.

(a) Facilities managing hazardous secondary materials under §§ 260.30, 261.4(a)(23), 261.4(a)(24), 261.4(a)(25), or 261.4(a)(27) must send a notification prior to operating under the regulatory provision and by March 1 of each even-numbered year thereafter to the Regional Administrator using EPA Form 8700–12 that includes the following information:

(1) The name, address, and EPA ID number (if applicable) of the facility;

(2) The name and telephone number of a contact person;

(3) The NAICS code of the facility;

(4) The regulation under which the hazardous secondary materials will be managed;

(5) For reclaimers and intermediate facilities managing hazardous secondary materials in accordance with § 261.4(a)(24) or (25), whether the reclaimer or intermediate facility has financial assurance (not applicable for persons managing hazardous secondary materials generated and reclaimed under the control of the generator);

(6) When the facility began or expects to begin managing the hazardous secondary materials in accordance with the regulation;

(7) A list of hazardous secondary materials that will be managed according to the regulation (reported as the EPA hazardous waste numbers that would apply if the hazardous secondary materials were managed as hazardous wastes);

(8) For each hazardous secondary material, whether the hazardous secondary material, or any portion thereof, will be managed in a land-based unit;

(9) The quantity of each hazardous secondary material to be managed annually; and

(10) The certification (included in EPA Form 8700–12) signed and dated by an authorized representative of the facility.

■ 5. Section 260.43 is amended by revising paragraph (a) and adding paragraph (b) to read as follows:

§ 260.43 Legitimate recycling of hazardous secondary materials.

(a) Recycling of hazardous secondary materials for the purpose of the exclusions or exemptions from the hazardous waste regulations must be legitimate. Hazardous secondary material that is not legitimately recycled is discarded material and is a solid waste. In determining if their recycling is legitimate, persons must address all the requirements of this paragraph and must consider the requirements of paragraph (b) of this section.

(1) Legitimate recycling must involve a hazardous secondary material that provides a useful contribution to the recycling process or to a product or intermediate of the recycling process. The hazardous secondary material provides a useful contribution if it:

(i) Contributes valuable ingredients to a product or intermediate; or

(ii) Replaces a catalyst or carrier in the recycling process; or

(iii) Is the source of a valuable constituent recovered in the recycling process; or

(iv) Is recovered or regenerated by the recycling process; or

(v) Is used as an effective substitute for a commercial product.

(2) The recycling process must produce a valuable product or intermediate. The product or intermediate is valuable if it is:

(i) Sold to a third party; or

(ii) Used by the recycler or the generator as an effective substitute for a commercial product or as an ingredient or intermediate in an industrial process.

(3) The generator and the recycler must manage the hazardous secondary material as a valuable commodity when it is under their control. Where there is an analogous raw material, the hazardous secondary material must be managed, at a minimum, in a manner consistent with the management of the raw material or in an equally protective manner. Where there is no analogous raw material, the hazardous secondary material must be contained. Hazardous secondary materials that are released to the environment and are not recovered immediately are discarded.

(b) The following factor must be considered in making a determination as to the overall legitimacy of a specific recycling activity.

(1) The product of the recycling process does not:

(i) Contain significant concentrations of any hazardous constituents found in appendix VIII of part 261 that are not found in analogous products; or

(ii) Contain concentrations of hazardous constituents found in appendix VIII of part 261 at levels that are significantly elevated from those found in analogous products, or

(iii) Exhibit a hazardous characteristic (as defined in part 261 subpart C) that analogous products do not exhibit.

(2) In making a determination that a hazardous secondary material is legitimately recycled, persons must evaluate all factors and consider legitimacy as a whole. If, after careful evaluation of these considerations, the factor in this paragraph is not met, then this fact may be an indication that the material is not legitimately recycled. However, the factor in this paragraph does not have to be met for the recycling to be considered legitimate. In evaluating the extent to which this factor is met and in determining whether a process that does not meet this factor is still legitimate, persons can consider exposure from toxics in the product, the bioavailability of the toxics in the product and other relevant considerations.

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 6. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

Subpart A—General

■ 7. Section 261.4 is amended as follows:

■ a. Republish paragraph (a) introductory text;

■ b. Revise paragraphs (a)(23) introductory text, (a)(23)(ii), and (a)(24); and

■ c. Add paragraph (a)(25).

The revisions and additions read as follows:

§ 261.4 Exclusions.

(a) *Materials which are not solid wastes.* The following materials are not solid wastes for the purpose of this part:

* * * * *

(23) Hazardous secondary material generated and legitimately reclaimed within the United States or its territories and under the control of the generator, provided that the material complies with paragraphs (a)(23)(i) and (ii) of this section:

* * * * *

(ii)(A) The hazardous secondary material is contained as defined in § 260.10 of this chapter. A hazardous secondary material released to the environment is discarded and a solid waste unless it is immediately recovered for the purpose of reclamation. Hazardous secondary material managed in a unit with leaks or other continuing or intermittent unpermitted releases is discarded and a solid waste.

(B) The hazardous secondary material is not speculatively accumulated, as defined in § 261.1(c)(8).

(C) Notice is provided as required by § 260.42 of this chapter.

(D) The material is not otherwise subject to material-specific management conditions under paragraph (a) of this section when reclaimed, and it is not a spent lead-acid battery (see §§ 266.80 and 273.2 of this chapter).

(E) Persons performing the recycling of hazardous secondary materials under this exclusion must maintain documentation of their legitimacy determination on-site. Documentation must be a written description of how the recycling meets all three factors in § 260.43(a) and how the factor in § 260.43(b) was considered. Documentation must be maintained for three years after the recycling operation has ceased.

(F) The emergency preparedness and response requirements found in subpart M of this part are met.

(24) Hazardous secondary material that is generated and then transferred to another person for the purpose of reclamation is not a solid waste, provided that:

(i) The material is not speculatively accumulated, as defined in § 261.1(c)(8);

(ii) The material is not handled by any person or facility other than the hazardous secondary material generator, the transporter, an intermediate facility or a reclaimer, and, while in transport, is not stored for more than 10 days at a transfer facility, as defined in § 260.10 of this chapter, and is packaged according to applicable Department of Transportation regulations at 49 CFR parts 173, 178, and 179 while in transport;

(iii) The material is not otherwise subject to material-specific management conditions under paragraph (a) of this section when reclaimed, and it is not a spent lead-acid battery (see §§ 266.80 and 273.2 of this chapter);

(iv) The reclamation of the material is legitimate, as specified under § 260.43 of this chapter;

(v) The hazardous secondary material generator satisfies all of the following conditions:

(A) The material must be contained as defined in § 260.10. A hazardous secondary material released to the environment is discarded and a solid waste unless it is immediately recovered for the purpose of recycling. Hazardous secondary material managed in a unit with leaks or other continuing releases is discarded and a solid waste.

(B) Prior to arranging for transport of hazardous secondary materials to a reclamation facility (or facilities) where the management of the hazardous secondary materials is not addressed under a RCRA part B permit or interim status standards, the hazardous secondary material generator must make reasonable efforts to ensure that each reclaimer intends to properly and legitimately reclaim the hazardous secondary material and not discard it, and that each reclaimer will manage the hazardous secondary material in a manner that is protective of human health and the environment. If the hazardous secondary material will be passing through an intermediate facility where the management of the hazardous secondary materials is not addressed under a RCRA part B permit or interim status standards, the hazardous secondary material generator must make contractual arrangements with the intermediate facility to ensure that the hazardous secondary material is sent to the reclamation facility identified by the hazardous secondary material generator, and the hazardous secondary material generator must perform reasonable efforts to ensure that the intermediate facility will manage the hazardous secondary material in a manner that is protective of human health and the environment. Reasonable efforts must be repeated at a minimum of every three years for the hazardous secondary material generator to claim the exclusion and to send the hazardous secondary materials to each reclaimer and any intermediate facility. In making these reasonable efforts, the generator may use any credible evidence available, including information gathered by the hazardous secondary material generator, provided by the reclaimer or intermediate facility, and/or provided by a third party. The hazardous secondary material generator must affirmatively answer all of the following questions for each reclamation facility and any intermediate facility:

(*1*) Does the available information indicate that the reclamation process is legitimate pursuant to § 260.43 of this chapter? In answering this question, the

hazardous secondary material generator can rely on their existing knowledge of the physical and chemical properties of the hazardous secondary material, as well as information from other sources (*e.g.,* the reclamation facility, audit reports, etc.) about the reclamation process.

(*2*) Does the publicly available information indicate that the reclamation facility and any intermediate facility that is used by the hazardous secondary material generator notified the appropriate authorities of hazardous secondary materials reclamation activities pursuant to § 260.42 of this chapter and have they notified the appropriate authorities that the financial assurance condition is satisfied per paragraph (a)(24)(vi)(F) of this section? In answering these questions, the hazardous secondary material generator can rely on the available information documenting the reclamation facility's and any intermediate facility's compliance with the notification requirements per § 260.42 of this chapter, including the requirement in § 260.42(a)(5) to notify EPA whether the reclaimer or intermediate facility has financial assurance.

(*3*) Does publicly available information indicate that the reclamation facility or any intermediate facility that is used by the hazardous secondary material generator has not had any formal enforcement actions taken against the facility in the previous three years for violations of the RCRA hazardous waste regulations and has not been classified as a significant non-complier with RCRA Subtitle C? In answering this question, the hazardous secondary material generator can rely on the publicly available information from EPA or the state. If the reclamation facility or any intermediate facility that is used by the hazardous secondary material generator has had a formal enforcement action taken against the facility in the previous three years for violations of the RCRA hazardous waste regulations and has been classified as a significant non-complier with RCRA Subtitle C, does the hazardous secondary material generator have credible evidence that the facilities will manage the hazardous secondary materials properly? In answering this question, the hazardous secondary material generator can obtain additional information from EPA, the state, or the facility itself that the facility has addressed the violations, taken remedial steps to address the violations and prevent future violations, or that the violations are not relevant to the proper management of the hazardous secondary materials.

(*4*) Does the available information indicate that the reclamation facility and any intermediate facility that is used by the hazardous secondary material generator have the equipment and trained personnel to safely recycle the hazardous secondary material? In answering this question, the generator may rely on a description by the reclamation facility or by an independent third party of the equipment and trained personnel to be used to recycle the generator's hazardous secondary material.

(*5*) If residuals are generated from the reclamation of the excluded hazardous secondary materials, does the reclamation facility have the permits required (if any) to manage the residuals? If not, does the reclamation facility have a contract with an appropriately permitted facility to dispose of the residuals? If not, does the hazardous secondary material generator have credible evidence that the residuals will be managed in a manner that is protective of human health and the environment? In answering these questions, the hazardous secondary material generator can rely on publicly available information from EPA or the state, or information provided by the facility itself.

(C) The hazardous secondary material generator must maintain for a minimum of three years documentation and certification that reasonable efforts were made for each reclamation facility and, if applicable, intermediate facility where the management of the hazardous secondary materials is not addressed under a RCRA part B permit or interim status standards prior to transferring hazardous secondary material. Documentation and certification must be made available upon request by a regulatory authority within 72 hours, or within a longer period of time as specified by the regulatory authority. The certification statement must:

(*1*) Include the printed name and official title of an authorized representative of the hazardous secondary material generator company, the authorized representative's signature, and the date signed;

(*2*) Incorporate the following language: ''I hereby certify in good faith and to the best of my knowledge that, prior to arranging for transport of excluded hazardous secondary materials to [insert name(s) of reclamation facility and any intermediate facility], reasonable efforts were made in accordance with § 261.4(a)(24)(v)(B) to ensure that the hazardous secondary materials would be recycled legitimately, and otherwise managed in a manner that is protective of human health and the environment, and that such efforts were based on current and accurate information.''

(D) The hazardous secondary material generator must maintain at the generating facility for no less than three (3) years records of all off-site shipments of hazardous secondary materials. For each shipment, these records must, at a minimum, contain the following information:

(*1*) Name of the transporter and date of the shipment;

(*2*) Name and address of each reclaimer and, if applicable, the name and address of each intermediate facility to which the hazardous secondary material was sent;

(*3*) The type and quantity of hazardous secondary material in the shipment.

(E) The hazardous secondary material generator must maintain at the generating facility for no less than three (3) years confirmations of receipt from each reclaimer and, if applicable, each intermediate facility for all off-site shipments of hazardous secondary materials. Confirmations of receipt must include the name and address of the reclaimer (or intermediate facility), the type and quantity of the hazardous secondary materials received and the date which the hazardous secondary materials were received. This requirement may be satisfied by routine business records (*e.g.,* financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt);

(F) The hazardous secondary material generator must comply with the emergency preparedness and response conditions in subpart M of this part.

(vi) Reclaimers of hazardous secondary material excluded from regulation under this exclusion and intermediate facilities as defined in § 260.10 of this chapter satisfy all of the following conditions:

(A) The reclaimer and intermediate facility must maintain at its facility for no less than three (3) years records of all shipments of hazardous secondary material that were received at the facility and, if applicable, for all shipments of hazardous secondary materials that were received and subsequently sent off-site from the facility for further reclamation. For each shipment, these records must at a minimum contain the following information:

(*1*) Name of the transporter and date of the shipment;

(*2*) Name and address of the hazardous secondary material generator

and, if applicable, the name and address of the reclaimer or intermediate facility which the hazardous secondary materials were received from;

(*3*) The type and quantity of hazardous secondary material in the shipment; and

(*4*) For hazardous secondary materials that, after being received by the reclaimer or intermediate facility, were subsequently transferred off-site for further reclamation, the name and address of the (subsequent) reclaimer and, if applicable, the name and address of each intermediate facility to which the hazardous secondary material was sent.

(B) The intermediate facility must send the hazardous secondary material to the reclaimer(s) designated by the hazardous secondary materials generator.

(C) The reclaimer and intermediate facility must send to the hazardous secondary material generator confirmations of receipt for all off-site shipments of hazardous secondary materials. Confirmations of receipt must include the name and address of the reclaimer (or intermediate facility), the type and quantity of the hazardous secondary materials received and the date which the hazardous secondary materials were received. This requirement may be satisfied by routine business records (*e.g.,* financial records, bills of lading, copies of DOT shipping papers, or electronic confirmations of receipt).

(D) The reclaimer and intermediate facility must manage the hazardous secondary material in a manner that is at least as protective as that employed for analogous raw material and must be contained. An ''analogous raw material'' is a raw material for which a hazardous secondary material is a substitute and serves the same function and has similar physical and chemical properties as the hazardous secondary material.

(E) Any residuals that are generated from reclamation processes will be managed in a manner that is protective of human health and the environment. If any residuals exhibit a hazardous characteristic according to subpart C of 40 CFR part 261, or if they themselves are specifically listed in subpart D of 40 CFR part 261, such residuals are hazardous wastes and must be managed in accordance with the applicable requirements of 40 CFR parts 260 through 272.

(F) The reclaimer and intermediate facility have financial assurance as required under subpart H of 40 CFR part 261,

(vii) In addition, all persons claiming the exclusion under this paragraph (a)(24) of this section must provide notification as required under § 260.42 of this chapter.

(25) Hazardous secondary material that is exported from the United States and reclaimed at a reclamation facility located in a foreign country is not a solid waste, provided that the hazardous secondary material generator complies with the applicable requirements of paragraph (a)(24)(i)–(v) of this section (excepting paragraph (a)(24)(v)(B)(*2*) of this section for foreign reclaimers and foreign intermediate facilities), and that the hazardous secondary material generator also complies with the following requirements:

(i) Notify EPA of an intended export before the hazardous secondary material is scheduled to leave the United States. A complete notification must be submitted at least sixty (60) days before the initial shipment is intended to be shipped off-site. This notification may cover export activities extending over a twelve (12) month or lesser period. The notification must be in writing, signed by the hazardous secondary material generator, and include the following information:

(A) Name, mailing address, telephone number and EPA ID number (if applicable) of the hazardous secondary material generator;

(B) A description of the hazardous secondary material and the EPA hazardous waste number that would apply if the hazardous secondary material was managed as hazardous waste and the U.S. DOT proper shipping name, hazard class and ID number (UN/NA) for each hazardous secondary material as identified in 49 CFR parts 171 through 177;

(C) The estimated frequency or rate at which the hazardous secondary material is to be exported and the period of time over which the hazardous secondary material is to be exported;

(D) The estimated total quantity of hazardous secondary material;

(E) All points of entry to and departure from each foreign country through which the hazardous secondary material will pass;

(F) A description of the means by which each shipment of the hazardous secondary material will be transported (*e.g.,* mode of transportation vehicle (air, highway, rail, water, etc.), type(s) of container (drums, boxes, tanks, etc.));

(G) A description of the manner in which the hazardous secondary material will be reclaimed in the country of import;

(H) The name and address of the reclaimer, any intermediate facility and any alternate reclaimer and intermediate facilities; and

(I) The name of any countries of transit through which the hazardous secondary material will be sent and a description of the approximate length of time it will remain in such countries and the nature of its handling while there (for purposes of this section, the terms ''EPA Acknowledgement of Consent'', ''country of import'' and ''country of transit'' are used as defined in 40 CFR 262.81 with the exception that the terms in this section refer to hazardous secondary materials, rather than hazardous waste):

(ii) Notifications must be submitted electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system.

(iii) Except for changes to the telephone number in paragraph (a)(25)(i)(A) of this section and decreases in the quantity of hazardous secondary material indicated pursuant to paragraph (a)(25)(i)(D) of this section, when the conditions specified on the original notification change (including any exceedance of the estimate of the quantity of hazardous secondary material specified in the original notification), the hazardous secondary material generator must provide EPA with a written renotification of the change. The shipment cannot take place until consent of the country of import to the changes (except for changes to paragraph (a)(25)(i)(I) of this section and in the ports of entry to and departure from countries of transit pursuant to paragraphs (a)(25)(i)(E) of this section) has been obtained and the hazardous secondary material generator receives from EPA an EPA Acknowledgment of Consent reflecting the country of import's consent to the changes.

(iv) Upon request by EPA, the hazardous secondary material generator shall furnish to EPA any additional information which a country of import requests in order to respond to a notification.

(v) EPA will provide a complete notification to the country of import and any countries of transit. A notification is complete when EPA receives a notification which EPA determines satisfies the requirements of paragraph (a)(25)(i) of this section. Where a claim of confidentiality is asserted with respect to any notification information required by paragraph (a)(25)(i) of this section, EPA may find the notification not complete until any such claim is resolved in accordance with 40 CFR 260.2.

(vi) The export of hazardous secondary material under this paragraph (a)(25) is prohibited unless the country of import consents to the intended export. When the country of import

consents in writing to the receipt of the hazardous secondary material, EPA will send an EPA Acknowledgment of Consent to the hazardous secondary material generator. Where the country of import objects to receipt of the hazardous secondary material or withdraws a prior consent, EPA will notify the hazardous secondary material generator in writing. EPA will also notify the hazardous secondary material generator of any responses from countries of transit.

(vii) For exports to OECD Member countries, the receiving country may respond to the notification using tacit consent. If no objection has been lodged by any country of import or countries of transit to a notification provided pursuant to paragraph (a)(25)(i) of this section within thirty (30) days after the date of issuance of the acknowledgement of receipt of notification by the competent authority of the country of import, the transboundary movement may commence. In such cases, EPA will send an EPA Acknowledgment of Consent to inform the hazardous secondary material generator that the country of import and any relevant countries of transit have not objected to the shipment, and are thus presumed to have consented tacitly. Tacit consent expires one (1) calendar year after the close of the thirty (30) day period; renotification and renewal of all consents is required for exports after that date.

(viii) A copy of the EPA Acknowledgment of Consent must accompany the shipment. The shipment must conform to the terms of the EPA Acknowledgment of Consent.

(ix) If a shipment cannot be delivered for any reason to the reclaimer, intermediate facility or the alternate reclaimer or alternate intermediate facility, the hazardous secondary material generator must re-notify EPA of a change in the conditions of the original notification to allow shipment to a new reclaimer in accordance with paragraph (iii) of this section and obtain another EPA Acknowledgment of Consent.

(x) Hazardous secondary material generators must keep a copy of each notification of intent to export and each EPA Acknowledgment of Consent for a period of three years following receipt of the EPA Acknowledgment of Consent. They may satisfy this recordkeeping requirement by retaining electronically submitted notifications or electronically generated Acknowledgements in their account on EPA's Waste Import Export Tracking System (WIETS), or its successor system, provided that such copies are readily available for viewing and production if requested by any EPA or authorized state inspector. No hazardous secondary material generator may be held liable for the inability to produce a notification or Acknowledgement for inspection under this section if they can demonstrate that the inability to produce such copies are due exclusively to technical difficulty with EPA's Waste Import Export Tracking System (WIETS), or its successor system for which the hazardous secondary material generator bears no responsibility.

(xi) Hazardous secondary material generators must file with the Administrator no later than March 1 of each year, a report summarizing the types, quantities, frequency and ultimate destination of all hazardous secondary materials exported during the previous calendar year. Annual reports must be submitted electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system. Such reports must include the following information:

(A) Name, mailing and site address, and EPA ID number (if applicable) of the hazardous secondary material generator;

(B) The calendar year covered by the report;

(C) The name and site address of each reclaimer and intermediate facility;

(D) By reclaimer and intermediate facility, for each hazardous secondary material exported, a description of the hazardous secondary material and the EPA hazardous waste number that would apply if the hazardous secondary material was managed as hazardous waste, the DOT hazard class, the name and U.S. EPA ID number (where applicable) for each transporter used, the total amount of hazardous secondary material shipped and the number of shipments pursuant to each notification;

(E) A certification signed by the hazardous secondary material generator which states: ''I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information including the possibility of fine and imprisonment.''

(xii) All persons claiming an exclusion under this paragraph (a)(25) must provide notification as required by § 260.42 of this chapter.

* * * * *

[FR Doc. 2018–11578 Filed 5–29–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2016–0068]

RIN 0920–AA63

Control of Communicable Diseases; Technical Correction

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule; correcting amendment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) announces a technical correction to the final rule published on July 10, 2017. The July 10, 2017, technical correction provided amendments to a final rule published on January 19, 2017, but contained an error. HHS/CDC is therefore submitting a new correction to correct that error.

DATES: This correcting amendment is effective May 30, 2018.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–E03, Atlanta, Georgia 30329. Telephone: (404) 498–1600.

SUPPLEMENTARY INFORMATION: On January 19, 2017, HHS/CDC published a final rule (82 FR 6890) that included several non-substantive errors. On July 10, 2017, HHS/CDC published a technical correction (82 FR 31728) to correct errors made in the final rule. However, one new error was inadvertently created by including an instruction to change a word in the title of 42 CFR 71.5 dealing with vessels from ''voyage'' to ''flight.'' HHS/CDC therefore, is publishing this correction notice amendment to fix the publication error that was made in the previous technical correction notice.

Section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 257, 258, 260, 261, 262, 263, 264, 265, 266, 267, 268, 270, 271, 273, and 279

[EPA–HQ–RCRA–2012–0121; FRL 9947–26–OLEM]

RIN 2050–AG70

Hazardous Waste Generator Improvements Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: With this action, the United States Environmental Protection Agency (EPA) is finalizing revisions to the Resource Conservation and Recovery Act's (RCRA) hazardous waste generator regulatory program proposed on September 25, 2015. There are several objectives to these revisions. They include reorganizing the hazardous waste generator regulations to make them more user-friendly and thus improve their usability by the regulated community; providing a better understanding of how the RCRA hazardous waste generator regulatory program works; addressing gaps in the existing regulations to strengthen environmental protection; providing greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner; and making technical corrections and conforming changes to address inadvertent errors and remove obsolete references to programs that no longer exist. This final rule responds to the comments of EPA stakeholders, taking into consideration the mission of EPA and the goals of RCRA.

DATES: This final rule is effective on May 30, 2017. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of May 30, 2017.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2012–0121. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jim O'Leary, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304P), 1200 Pennsylvania Ave. NW., Washington, DC 20460, (703) 308–8827, (*oleary.jim@epa.gov*) or Kathy Lett, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304P), 1200 Pennsylvania Ave. NW., Washington, DC 20460, (703) 605–0761, (*lett.kathy@epa.gov*).

SUPPLEMENTARY INFORMATION:

I. Table of Contents

The information presented in this preamble is organized as follows:

II. General Information

A. Does this action apply to me?

Entities potentially affected by this action include between 424,099 and 676,890 industrial entities that generate hazardous waste regulated under the RCRA Subtitle C regulations. Of this universe, between 353,441 and 591,809 are very small quantity generators (VSQGs),[1] previously called conditionally exempt small quantity generators, whose regulatory obligations will only be affected if they choose to take advantage of either of the two voluntary programs being promulgated. Entities potentially affected by this final rule include practically every industrial sector, including printing, petroleum refining, chemical manufacturing, plastics and resin manufacturing, pharmaceutical manufacturing, paint and coatings, iron and steelmaking, secondary smelting and refining, metal manufacturing, electroplating, circuit board manufacturing, and automobile manufacturing, among other industries.

As discussed in section XVI.A, the Regulatory Impact Analysis (RIA) for this action, available in the docket for this action, estimates the future annualized cost to industry to comply with the requirements is between $5.9 and $13.3 million (at a 7% discount rate). The estimated annualized benefits for entities opting to take advantage of two voluntary programs in the final rule (*e.g.,* consolidation of VSQG waste by large quantity generators (LQGs) under the same ownership, and generators who change regulatory status episodically) are between $8.3 and $14.4 million (at a 7% discount rate). This results in a net annualized benefit for the rule of $2.4 million for the low-end estimate and $1.1 million for the high-end estimate at a 7% discount rate.

The Hazardous Waste Generator Improvements Rule is expected to yield a variety of benefits as generators change several of their waste management practices to comply with the regulations. These benefits reflect the rule's focus on enhancing protection of human health and the environment while improving the efficiency of the RCRA hazardous waste generator standards. Ideally, the Agency would prefer to quantify and monetize the rule's total benefits. However, only some categories of benefits are quantifiable; sufficient data are not available to support a detailed quantitative analysis for a majority of the benefit categories. For example, the added flexibility from allowing a large quantity generator accumulating ignitable or reactive hazardous waste to obtain an approval from the authority having jurisdiction (AHJ) over the fire code for the 50-foot property line requirement at 40 CFR 265.176 (provided other safety requirements are met) is difficult to quantify. In addition, quantifying the benefits associated with emergency response due to changes in container labeling would require data on the annual number of emergencies at generator sites, the current risks associated with these incidents, the extent to which more detailed labeling would affect the procedures of emergency responders, and the reduction in risk associated with these changes. Detailed data on these items are not readily available. In this and in similar cases, the benefits are described qualitatively.

B. Incorporation by Reference (IBR)

This final rule is not adding any new IBR material; however, EPA is reorganizing one of the existing requirements containing IBR material to make the regulation easier for the reader to follow. EPA is copying § 265.201(g)(2) to § 262.16(b)(3)(vii)(B). To accommodate this change, EPA is updating § 260.11(d)(1), which is the IBR reference section for these regulations, by adding a reference to § 262.16. The materials being incorporated by reference are for the National Fire Protection Association (NFPA), Flammable and Combustible Liquids Code (NFPA 30), 1977 and 1981. NFPA 30 addresses the fire and prevention codes associated with flammable and combustible liquids. The 1981 edition modifies Chapter 4, Container and Portable Tank Storage of the 1977 edition to address such areas as portable tanks, basement storage areas, cutoff rooms and attached buildings, indoor storage and general purpose warehouses. They are available for inspection through NFPA's Free Access site, *http://www.nfpa.org/freeaccess*. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. (For ordering information, call toll-free 1–800–344–3555 or visit *http://www.nfpa.org/codes-and-standards*.)

III. Statutory Authority

These regulations are promulgated under the authority of sections 2002, 3001, 3002, 3003, 3004, 3005, 3007, and 3010 of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6921, 6922, 6923, and 6924. This statute is commonly referred to as ''RCRA.''

IV. What is the intent of this final rule?

This final rule promulgates over 60 revisions and new provisions to the hazardous waste generator regulatory program. The primary intent of these provisions is to foster improved compliance by hazardous waste generators in the identification and management of the hazardous waste they generate and, as a result, improve protection of human health and the environment. Another major objective of this rule is to support the efficient implementation of the hazardous waste generator regulations by the states.

The Agency intends to achieve these objectives in several ways. For example, the most frequent comment the Agency received when it conducted a program evaluation of the hazardous waste generator regulatory program in 2004 was to improve the user-friendliness of the regulations. Prior to this action, the generator regulations were found in several parts of the Code of Federal Regulations (CFR). This final rule reorganizes and consolidates most of the generator regulatory program into 40 CFR part 262, with exceptions for very technical and lengthy regulations, such as the RCRA air emissions standards and the land disposal restriction requirements.

Another important component of this rule is to explain in greater detail how the hazardous waste generator regulations actually work. As explained later on, there are two types of regulatory standards for the hazardous waste generator program: Conditions that must be met in order to obtain an exemption from permitting (''conditions for exemption'') and requirements that apply to generators regardless of

[1] EPA is finalizing its proposed change to rename ''Conditionally exempt small quantity generators'' as ''Very small quantity generators.'' A discussion of this change can be found in section VII.A.

whether or not they choose to obtain an exemption from the permit requirement (''independent requirements''). The Agency notes that these clarifications regarding the distinction between independent generator requirements and the conditions for exemption do not fundamentally alter the way the generator regulatory scheme has operated over the last 30 years. Similarly, the enforcement consequences of independent requirement violations and non-compliance with conditions for exemption do not signal a change from how the great majority of enforcement efforts have been pursued when violations of these regulations are detected.

This final rule also incorporates numerous clarifications to different components of the hazardous waste generator regulatory program made by the Agency through the years in **Federal Register** notices, guidance, correspondence, and policy. For example, a key component of the program is that generators need to make accurate hazardous waste determinations. While the Agency has stated in **Federal Register** preambles and correspondence from the beginning of the program that solid and hazardous waste determinations must be made at the point of generation before any dilution, mixing, or other alteration of the waste occurs, we have never incorporated such an important concept into regulation. This final rule does so. Also, most generators use knowledge of their processes and feedstocks to determine if they have generated a hazardous waste. In response to comments from the regulated community, this final rule provides additional information and clarity as to what constitutes ''generator knowledge'' to determine whether a listed and/or characteristic hazardous waste has been generated. Providing this information to the regulated community enables the generators to more readily comply with the requirements.

Similarly, this final rule clarifies that a generator can only be in one category for a calendar month and explains how to count the hazardous waste it generates (*i.e.,* acute hazardous waste, non-acute hazardous waste, and residues from the cleanup of acute hazardous waste generated in a calendar month) to determine its regulatory category, and therefore, which set of regulations to comply with. Another important clarification explains the implications of when a generator mixes a solid waste with a hazardous waste, and the regulations a generator must be aware of if it decides to mix wastes. Further clarifications address closure, biennial reporting, waste accumulation, liquids in landfills, emergency response, and the marking and labeling of containers, tanks, drip pads, and containment buildings. All together, these revisions to the generator program provide the generators themselves better access to both the regulations with which they are required to comply and some of the information that was previously only available in guidance.

From experience through the years, the Agency also has identified regulatory gaps resulting in either program inefficiencies or ineffectiveness. For example, prior to this final rule, large quantity generators (LQGs) were not required to notify EPA or most states when they close their facility. Without such information, implementing agencies did not have confirmation a whether or not the generators complied with specified closure performance standards. Generators also were not required to identify and communicate the hazards associated with the hazardous waste they generate and accumulate on-site, nor to ensure working relationships with local emergency authorities. This final rule addresses these concerns.

Similarly, prior to this rulemaking, SQGs were only required to submit a notification when they first identified themselves as a hazardous waste generator to obtain a RCRA identification number, and to be able to ship hazardous waste off-site to a permitted treatment, storage and disposal facility (TSDF). As a result, the Agency and many states databases for this universe of generators became unreliable because there was no notification if the generator went out of business, changed ownership, or changed their regulatory category. This final rule addresses this data gap by requiring SQGs to re-notify every four years.

With this final rule, the Agency also has responded to requests that additional flexibility be provided in the implementation of the program. For example, VSQGs will now be able to send their hazardous waste to LQGs under the control of the same person to allow consolidation and improved management of their hazardous waste. Another provision being added in this final rule will allow VSQGs and SQGs to maintain their existing regulatory category when they generate additional amounts of hazardous wastes as a result of an episodic event, provided they comply with specific conditions. This final rule also will allow an LQG to apply for a site-specific approval from the authority having jurisdiction (AHJ) over the fire code when they are unable to meet the 50 feet property line requirement for the accumulation of ignitable or reactive waste. Together, these provisions that add flexibility to the regulations better represent the real-world conditions that many of the smaller hazardous waste generators operate under and ensure and allow proper management of hazardous waste while under those conditions.

The RCRA hazardous waste generator regulatory program is primarily administered by the states, and therefore, its success is predicated in EPA supporting their inspection, enforcement and permitting activities. The Agency will work with the states to support their efforts in becoming authorized for these program revisions and will support both the regulated community and the implementing agencies in their efforts to comply with these new provisions.

V. Background

A. History of the Hazardous Waste Generator Program

For the most part, the regulations for hazardous waste generators have not changed significantly since 1980, except for three major modifications. First, as a result of the Hazardous and Solid Waste Amendments (HSWA) of 1984, EPA promulgated a rule that created three generator categories; *i.e.,* conditionally exempt small quantity generators, small quantity generators and large quantity generators (51 FR 10146, March 24, 1986). Prior to that rule the regulatory framework for hazardous waste generators consisted of two categories: Small quantity generators and large quantity generators. The 1986 rule split the SQG category in two and created conditionally exempt small quantity generators (CESQG) (now known in this final rule as very small quantity generators).

Second, also as a result of HSWA and the Land Disposal Restriction (LDRs) regulations,[2] hazardous waste generators were required to ensure that their hazardous waste either met a specified treatment standard or performance standard, or, if neither, that the waste was treated to specified concentrations or performance standards prior to land disposal.

Third, the Agency modified the Uniform Hazardous Waste Manifest regulations and associated manifest

[2] There are several regulations associated with LDRs. The more important **Federal Register** notices associated with these regulations include: 51 FR 40636, November 7, 1986; 52 FR 25787, July 8, 1987; 53 FR 31211, August 17, 1988; 54 FR 26647, June 23, 1989; 55 FR 22520, June 1, 1990; 57 FR 37194, August 18, 1992.

document used to track hazardous waste from a generator's site to its ultimate disposition (70 FR 10776, March 4, 2005; 70 FR 35034, June 16, 2005). The revisions to the manifest standardized the content and appearance of the manifest form, made the forms available from a greater number of sources, and adopted new procedures for tracking certain types of hazardous waste shipments with the manifest. Otherwise, the changes that have occurred to the hazardous waste generator regulatory program have been relatively minor.

B. Hazardous Waste Generator Demographics

In 2013, approximately 25,300 generators reported generating approximately 35.2 million tons of hazardous waste. Of the total number of reporting generators, approximately 20,800 were LQGs while 4,500 were non-LQGs, meaning these entities submitted a biennial report but did not report generating sufficient amounts of hazardous waste to be categorized as an LQG.[3]

In 2013, LQGs generated approximately 35.2 million tons of hazardous waste in the aggregate. The 50 largest hazardous waste generators reported generating 29.2 million tons, or 83 percent of the total reported amount. While in total LQGs managed on average 13 waste streams (the mean), approximately 11,000 LQGs (or approximately 53 percent) managed 6 waste streams (the median) or less. Approximately 9600 LQGs (or approximately 46 percent) generated between 1 and 5 waste streams. These generators included sites from the waste treatment industry as well as academic and industrial laboratories. Overall, the Agency estimates that LQGs generate between 6 and 13 hazardous waste streams each year, which represents the median and mean number of wastes streams per LQG.[4]

Of the 35.2 million tons of hazardous waste generated by LQGs in 2013, 33.4 million tons, or 95 percent, were generated in just five industrial sectors: Chemical manufacturing (NAICS 325); petroleum and coal products manufacturing (NAICS 324); waste management and remediation services (NAICS 562); primary metal manufacturing (NAICS 331); and mining (NAICS 212).[5]

Unlike LQGs, who must submit a biennial report every two years describing the types and quantities of hazardous waste generated and its subsequent disposition, SQGs have not been required to provide such information to the Agency. Consequently, EPA lacks the level of detail for SQGs that is available for LQGs. However, based on a review of biennial report data provided by treatment, storage, and disposal facilities[6] (which must report waste received from all hazardous waste generators) and site identification data (from SQGs obtaining an EPA ID number), EPA estimates the number of SQGs to range from approximately 49,900 to 64,300.[7]

Because VSQGs are not required to obtain a RCRA ID, the information available to the Agency is limited to those states that require their VSQGs to obtain a RCRA ID. Therefore, in estimating the size of the VSQG universe, the Agency developed a methodology that extrapolated the size of the VSQG universes based on the data available in those states that require VSQGs to obtain a RCRA ID. We first calculated the ratio of VSQGs to SQGs and VSQGs to LQGs in those states where information was available on the VSQG universe. Wethen used those ratios to estimate the size of a state's VSQG universe where VSQG information was unavailable. Using this methodology, EPA currently estimates the size of the VSQG universe to range from 353,400 to 591,800.[8]

VI. Reorganization of the Hazardous Waste Generator Regulations and Organization of the Preamble

EPA is finalizing its proposal to reorganize the hazardous waste generator regulations to make the regulations more user-friendly, which EPA expects will improve generator compliance. The most frequent stakeholder comment EPA received as part of its 2004 Program Evaluation of the hazardous waste generator program was to improve the user-friendliness of the regulations. EPA proposed a reorganization on September 25, 2015 (80 FR 57918), and took comment on all aspects of that reorganization. The majority of the commenters supported EPA's proposal to reorganize the regulations, stating that they agreed with the Agency that the new framework is easier to understand, simpler, and will facilitate improved compliance by the regulated community. EPA also received some comments opposing the reorganization from commenters who were concerned that the changes would result in confusion for those who already understand the regulations and from commenters concerned about the cost of any necessary changes. After considering the comments, EPA has determined that reorganizing the regulations will result in a better, more straightforward set of regulations that is, on balance, easier for most people to understand, now and in the future of the generator program.

This section serves as an introduction and a reference to the new look and feel of the generator regulations. This section makes passing mention of many of the provisions and revisions that we cover in much more detail later in the preamble. EPA has organized this preamble to correspond with the new organization of the regulations, discussing each provision being changed in its new relative place within the structure of the generator regulations. In addition, after the discussion in this section of where each provision will be found in the reorganized regulations, all following citations to regulatory text in this final rule will use the new citations found in the promulgated regulatory text. If applicable, we are including a note at the end of each section to direct the reader to where the same provision was found before the reorganization.

EPA recognizes that the reorganization of these regulations may be a big adjustment for all those who use them, but has determined that the new structure makes better sense for a generator navigating through the system for the first time. Although many existing generators are familiar with the current regulations, every year many generators either enter the hazardous waste generator program or switch their generator category and therefore need to become familiar with their obligations. Similarly, an existing generator may need to examine a particular regulatory citation to ensure it is complying with the regulations correctly. The Agency believes that providing these generators with a user-friendly regulatory framework is an effective way to make the regulations easier to understand for those who need to comply with them.

EPA intends to work closely with the states and other implementing agencies as well as the regulated community, particularly during the initial implementation period. EPA's efforts

[3] See ''Regulatory Impact Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule.'' A copy of the analysis is available in the docket for this action.

[4] Ibid.

[5] Ibid.

[6] See the Waste Received (WR) form as part of Biennial Report (EPA Form 8700–13A/B).

[7] See ''Regulatory Impact Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule.'' A copy of the analysis is available in the docket for this action.

[8] Ibid.

will be to ensure all stakeholders are trained on the new organization and are given an opportunity to revise forms, guidance, and other materials as necessary. EPA will also be revising its own materials to reflect the new citations in the regulations.

EPA is finalizing the following general organizational changes:

(1) Integrating the generator regulations in § 261.5 into the generator regulations at part 262 by moving § 261.5 (which contains the regulations applicable to VSQGs, counting of hazardous waste, and mixing of hazardous wastes with non-hazardous wastes);

(2) Separating the existing regulations at § 262.34 for SQGs, LQGs and SAAs into three new sections:

(a) Conditions for exemption for satellite accumulation areas (SAA) for small and large quantity generators,

(b) Conditions for exemption for an SQG that accumulates hazardous waste; and

(c) Conditions for exemption for an LQG that accumulates hazardous waste;

(3) Using subtitles in these new sections; and

(4) Where reasonable, incorporating the text of relevant part 265 regulations into these new sections, rather than merely cross referencing them, as was the former approach.

A. Moving and Integrating Regulations From 40 CFR 261.5 Into 40 CFR Part 262

Historically, certain hazardous waste generator regulations have been located in a different part of the regulations (40 CFR 261.5) from the rest of the generator regulations (40 CFR part 262). Many of the commenters on the proposal confirmed what EPA had heard from stakeholders who stated that the location of § 261.5 was confusing and not user-friendly. Many commenters agreed that locating those requirements in part 262 to consolidate all the generator regulations in the same part was a useful revision that will alleviate much confusion in the regulated community and, in the process, will foster greater compliance with the regulations.

Specifically, EPA is moving the definition of a VSQG that generates non-acute hazardous waste at § 261.5(a) into the VSQG definition at § 260.10, moving § 261.5(c) through (e) about counting hazardous waste and § 261.5(h) though (j) about VSQGs mixing waste to a new section at § 262.13 titled ''Generator category determination'' and moving § 261.5(b) and (f) and (g) to a new section at § 262.14 titled ''Conditions for exemption for a very small quantity generator.'' [9]

1. Hazardous Waste Generation Quantity Limits for VSQGs (40 CFR 260.10)

Section 261.5(a) was previously used to set forth the non-acute hazardous waste quantity limits for a VSQG and § 261.5(e) to provide quantity limits for generating acute hazardous waste and any residue or contaminated soil, waste, or other debris resulting from the cleanup of a spill of acute hazardous waste. Under the reorganized regulations, EPA now defines each category of generator at § 260.10, and, thus, § 261.5(a) and (e) are incorporated into those definitions.

2. Determining Generator Category (40 CFR 262.13)

Section 261.5(c) and (d) previously set forth the provisions for a hazardous waste generator to use in making its generator category determination. Every hazardous waste generator must because determine its generator category in order to identify which regulations are applicable to it. Because § 261.5(c) and (d) are applicable to all hazardous waste generators, it makes sense to move them into 40 CFR part 262, with the other hazardous waste generator regulations. To further aid in making the regulations more user friendly, the Agency has promulgated a new section for generator category determination at § 262.13, titled ''Generator category determination.'' This new section is thus located because, after a generator of a solid waste determines it has generated a hazardous waste (§ 262.11), the generator must then determine its hazardous waste generator category for the calendar month.

In addition, § 261.5(h) through (j), regarding the rules that apply for the mixing of hazardous waste with solid waste, including mixtures with used oil by VSQGs, have been relocated to § 262.13, making them independent requirements rather than conditions for exemption. This move is logical in the context of the reorganization because the outcome of any determination a VSQG makes about the consequences of mixing waste ultimately affect its generator category first. In addition, § 262.13 also contains a new citation to the mixing rule in § 261.3 and makes it clear that the mixing rule applies to SQGs and LQGs. These revisions to the generator regulations are all discussed in more depth later in this preamble.

Table 1—Crosswalk of Previous Citations to New Citations for Definitions and General Standards provides a summary of the crosswalk between the previous and new regulatory citations for determining a generator's category.

TABLE 1—CROSSWALK OF PREVIOUS CITATIONS TO NEW CITATIONS FOR DEFINITIONS AND GENERAL STANDARDS

Regulation	Previous citation	New citation	Comment
Definitions of Generator Categories.	§§ 260.10, 261.5 and 262.34	§ 260.10	Previous definition of SQG in § 260.10 was outdated. Generator categories were based on §§ 261.5 and 262.34.
Hazardous Waste Limits for VSQGs.	§ 261.5(a) and (e)	§ 260.10	Included in the new definition of VSQG.
Purpose, Scope, and Applicability	§ 262.10	§ 262.10	Not moved, but expanded significantly.
Hazardous Waste Determination and Recordkeeping.	§§ 262.11 and 262.40(c)	§ 262.11	Content in § 262.11 is expanded and § 262.40(c) is incorporated.

[9] EPA is renaming CESQGs to VSQGs (very small quantity generators). For a detailed discussion on this change, see section VII.A of this preamble.

TABLE 1—CROSSWALK OF PREVIOUS CITATIONS TO NEW CITATIONS FOR DEFINITIONS AND GENERAL STANDARDS—Continued

Regulation	Previous citation	New citation	Comment
Generator Category Determination	§ 261.5(c), (d), and (h)–(j)	§ 262.13	New section that explains how to count hazardous waste to determine generator category.
EPA Identification Numbers	§ 262.12	§ 262.18	Re-notification requirements are also in this section.
Landfill Ban for Liquids	§ 258.28	§ 262.35	For SQGs and LQGs.

3. VSQG Conditions for Exemption (40 CFR 262.14)

Previous sections 261.5(b) and (f) through (j) established the regulations for VSQGs when accumulating acute and non-acute hazardous waste, identified where the acute and non-acute hazardous waste may be managed off site, and explained the implications of mixing hazardous waste with solid waste or used oil. Since these regulations set forth conditions for exemption for VSQGs, similar to how the regulations found in previous § 262.34 set forth conditions for exemption for SQGs and LQGs, EPA is moving § 261.5(b) and (f) and (g) to the newly created § 262.14 titled, ''Conditions for exemption for a very small quantity generator.'' All the conditions for exemption for generators are now located parallel to one another in part 262. Section 262.14 also includes the VSQG landfill ban for liquids and a new VSQG consolidation provision by LQGs under the control of the same person.

In addition, VSQGs who episodically generate higher amounts of hazardous waste may follow the newly promulgated standards for episodic generation in part 262 subpart L in order to maintain their VSQG status while managing these higher amounts of hazardous waste. Table 2—Crosswalk of Previous Citations to New Citations for VSQGs provides a crosswalk between the previous and the new VSQG conditions for exemption.

TABLE 2—CROSSWALK OF PREVIOUS CITATIONS TO NEW CITATIONS FOR VSQGS

Regulation	Previous citation	New citation	Comment
VSQG Definition	§ 261.5(a)	§ 260.10	Moved into new definition of VSQG.
VSQG Mixtures	§ 261.5(h)–(j)	§ 262.13(f)	Moved into Generator category determination.
Conditions for Exemption for a Very Small Quantity Generator.	§ 261.5(b), (f), and (g)	§ 262.14	Included in VSQG conditions for exemption.
VSQG Consolidation by LQGs Within the Same Company.	N/A	§ 262.14(a)(5)(viii)	New provision.
Landfill Ban for Liquids	§ 258.28	§ 262.14(b)	Specific citation for VSQGs.
Episodic Generation	N/A	Part 262 subpart L	New provision.

B. SQG and LQG Conditions for Exemption (40 CFR 262.16 and 262.17)

SQGs and LQGs may accumulate their hazardous waste on site without complying with the storage facility permit and operating requirements, provided they follow all of the conditions for exemption established originally in § 262.34. Section 262.34 became difficult to navigate because the SQG and LQG conditions for exemption were intertwined and contained many cross-references to sections in 40 CFR part 265. Therefore, the Agency is dividing § 262.34 into three new sections at §§ 262.15, 262.16 and 262.17. Section 262.15 lays out the conditions for exemption for SQGs and LQGs operating an SAA, § 262.16 identifies conditions for exemption for SQGs, and § 262.17 identifies the conditions for exemption for LQGs.

1. Satellite Accumulation Area Conditions for Exemption for SQGs and LQGs (40 CFR 262.15)

Many generators use SAAs at their sites. These areas allow generators to accumulate hazardous waste near the point of generation under the control of the operator of the process generating the waste, which provides for efficiency and greater safety in the handling of hazardous waste. When the generator has accumulated 55 gallons of hazardous waste (or one quart of acute hazardous waste) in the SAA, the generator must then move the hazardous waste to the 90- or 180-day central accumulation area within three days. Under the old framework, the conditions for exemption for operating an SAA were located at § 262.34(c), between the hazardous waste accumulation conditions for LQGs and those for SQGs. This created confusion as to whether the provisions apply to LQGs only or to both SQGs and LQGs. In this final rule, the Agency is therefore moving 40 CFR 262.34(c) into its own section at § 262.15 titled, ''Satellite accumulation area regulations for small and large quantity generators.''

Additionally, the Agency is copying the text in §§ 265.171, 265.172 and 265.173(a) (which previously were simply referenced in § 262.34(c)(1)(i)) into § 262.15 in order to eliminate cross-referencing and improve the user friendliness of the regulations. Table 3—Crosswalk of Previous Citations to New Citations for SAAs provides a summary of the crosswalk between previous and new regulations for SAAs.

TABLE 3—CROSSWALK OF PREVIOUS CITATIONS TO NEW CITATIONS FOR SAAS

Regulation	Previous citation	New citation	Comment
Satellite Accumulation Area Provisions.	§ 262.34(c)	§ 262.15	Moved from § 262.34.
Selected Part 265 Subpart I Provisions.	§ 265.171	§ 262.15(a)(1)	Duplicated from part 265.
Selected Part 265 Subpart I Provisions.	§ 265.172	§ 262.15(a)(2)	Duplicated from part 265.
Selected Part 265 Subpart I Provisions.	§ 265.173(a)	§ 262.15(a)(4)	Duplicated from part 265.

2. Conditions for Exemption for an SQG Accumulating Hazardous Waste (40 CFR 262.16)

As previously mentioned, the Agency is promulgating a new section 40 CFR 262.16 titled, ''Conditions for exemption for a small quantity generator that accumulates hazardous waste.'' This reorganization moves § 262.34(d) through (f) and (m) into § 262.16. Specifically, the Agency is moving the bulk of § 262.34(d) to § 262.16(b),[10] § 262.34(e) to § 262.16(c), § 262.34(f) to § 262.16(d) and § 262.34(m) to § 262.16(e). EPA has also added subtitles and eliminated several cross-references to 40 CFR part 265 in order to make the regulations easier to navigate.

a. Addition of subtitles. EPA has added subtitles throughout § 262.16 to highlight to the reader the topic of each section or paragraph. Every subtitle is italicized after the regulatory citation. For example § 262.16(b)(2) addresses ''*Accumulation of hazardous waste in containers.*''

b. Incorporating 40 CFR part 265 subpart I, § 265.201, and part 265 subpart C into 40 CFR 262.16. EPA has integrated three portions of 40 CFR part 265 into § 262.16: Subpart I, § 265.201 and subpart C. First, the regulations previously found at § 262.34(d)(2) stated an SQG must comply with subpart I of part 265 except for §§ 265.176 and 265.178. Therefore, EPA has simply incorporated the text of the appropriate subpart I regulations at § 262.16(b)(2). Second, the regulations previously found at § 262.34(d)(3) stated that an SQG must comply with § 265.201 in subpart J when using a tank. Thus, EPA has incorporated the text of § 265.201—except for paragraph (a)—into § 262.16(b)(3). Incorporation of paragraph (a) of § 265.201 is not necessary because it describes what is already stated in § 262.16—the conditions for exemption for an SQG accumulating hazardous waste in a tank for less than 180 days and accumulating no more than 6,000 kg on site at any time. Third, the regulations previously found at § 262.34(d)(4) stated that an SQG must comply with subpart C of part 265. Therefore, EPA has incorporated the text of subpart C—Preparedness and Prevention—at § 262.16(b)(8) and (9).

c. Other part 262 provisions for SQGs. In addition, part 262 subpart L contains new standards for SQGs who episodically generate higher amounts of hazardous waste to maintain their designation as SQGs during these episodic events. Also, § 262.35 is the landfill ban for liquids that applies to SQGs and LQGs.

Table 4—Crosswalk of Previous Citations to New Citations for SQGs provides a summary of changes between the previous citations in the regulations and new citations for SQGs.

TABLE 4—CROSSWALK OF PREVIOUS CITATIONS TO NEW CITATIONS FOR SQGS

Regulation	Previous citation	New citation	Comment
Definition of Small Quantity Generator.	§ 262.34(d)	§ 260.10	Moved into new definition of SQG.
Accumulation Time Limit	§ 262.34(d)	§ 262.16(b)	Moved.
Accumulation Limit	§ 262.34(d)(1)	§ 262.16(b)(1)	Moved.
Accumulation in Containers	§ 262.34(d)(2) (references part 265 subpart I).	§ 262.16(b)(2)	Duplicated from part 265.
Accumulation in Tanks	§ 262.34(d)(3) (references part 265 subpart J).	§ 262.16(b)(3)	Duplicated from part 265.
Accumulation on Drip Pads		§ 262.16(b)(4) references part 265 subpart W.	No previous regulatory reference for SQGs using drip pads.
Accumulation in Containment Buildings.		§ 262.16(b)(5) references part 265 subpart DD.	No previous regulatory reference for SQGs using containment buildings.
Marking of Tanks and Containers	§ 262.34(d)(4) (references § 262.34(a)(2) and (3)).	§ 262.16(b)(6)	Copied from § 262.34 with some changes.
Preparedness and Prevention	§ 262.34(d)(4) (references part 265 subpart C) and. § 262.34(d)(5)	§ 262.16(b)(8) and (9)	Duplicated from part 265 and moved from § 262.34.
Land Disposal Restrictions	§ 262.34(d)(4) (references part 268).	§ 262.16(b)(7)	There is still a cross reference to part 268.
Transporting Over 200 Miles	§ 262.34(e)	§ 262.16(c)	Moved from § 262.34.
Accumulation Time Limit Extension	§ 262.34(f)	§ 262.16(d)	Moved from § 262.34.
Rejected Loads	§ 262.34(m)	§ 262.16(e)	Moved from § 262.34.
Episodic Generation	N/A	Part 262 subpart L	New provision.

[10] The portions of § 262.34(d) that state what the generation limits are for this category of generator are moved to the definition of ''small quantity generator'' in § 262.10.

3. Conditions for Exemption for an LQG Accumulating Hazardous Waste (40 CFR 262.17)

As previously mentioned, the Agency is promulgating a new section 40 CFR 262.17 titled, ''Conditions for exemption for a large quantity generator that accumulates hazardous waste.'' The Agency is moving § 262.34(a),(b),(g) through (i) and (m) into § 262.17. Specifically, the Agency is moving § 262.34(a) to § 262.17(a), moving § 262.34(b) to § 262.17(b), moving § 262.34(g) to § 262.17(c), moving § 262.34(h) to § 262.17(d), moving § 262.34(i) to § 262.17(e), and moving § 262.34(m) to § 262.16(g). EPA has also deleted paragraphs (j) through (l), which deal with Performance Track, since the program is no longer in operation. EPA has also added subtitles and eliminated some cross-references to part 265 in order to make the regulations easier to navigate.

a. Addition of subtitles. EPA is adding subtitles to § 262.17 to highlight to the reader the central concept addressed by each section or paragraph. Every subtitle is italicized after the regulatory citation. For example § 262.17(a)(1) addresses ''*Accumulation of hazardous waste in containers.*''

b. Incorporating 40 CFR part 265 subpart I into 40 CFR 262.17. EPA is incorporating the 40 CFR part 265 subpart I regulations, which were previously referenced at § 262.34(a)(1)(i), into § 262.17(a)(1). EPA also considered incorporating the text of other subparts of part 265 that contain technical standards for LQGs into the new section § 262.17 (*i.e.,* part 265 subparts J, W, AA, BB, and CC), but ultimately decided not to incorporate the text of these subparts due to their length.

c. Emergency planning and procedures regulations for LQGs in part 265 subpart M. For generator preparedness and planning regulations, EPA removed the reference to part 265 subparts C and D for the preparedness, prevention, and emergency procedure regulations for LQGs and instead incorporated those regulations in part 262 with the other generator regulations. However, due to the length of these subparts, rather than copying the text of these subparts to § 262.17, EPA created a new subpart M in part 262. EPA believes including these provisions in part 262, along with the rest of the generator regulations, will make the regulations easier to navigate.

d. *Other part 262 provisions for LQGs.* In addition, § 262.17(f) contains the newly promulgated standards for LQGs who accept and consolidate hazardous waste from VSQGs. Also, § 262.35 includes the landfill ban for liquids that applies to SQGs and LQGs.

Table 5—Crosswalk of Previous Citations to New Citations for LQGs provides a summary of changes between the previous citations and the new citations for LQGs.

TABLE 5—CROSSWALK OF PREVIOUS CITATIONS TO NEW CITATIONS FOR LQGS

Regulation	Previous citation	New citation	Comment
Definition of Large Quantity Generator.	N/A	§ 260.10	New definition.
Accumulation Time Limit	§ 262.34(a)	§ 262.17(a)	Moved from § 262.34.
Accumulation in Containers	§ 262.34(a)(1)(i) references part 265 subparts I, AA, BB, and CC.	§ 262.17(a)(1) (§ 262.17(a)(1) also references part 265 subparts AA, BB, CC).	There is still a cross-reference to part 265 subparts AA, BB, and CC because of the length of these regulations.
Accumulation in Tanks	§ 262.34(a)(1)(ii) references part 265 subparts J, AA, BB, and CC.	§ 262.17(a)(2) references part 265 subparts J, AA, BB, CC.	There is still a cross- reference to part 265 subparts J, AA, BB, CC because of the length of these regulations.
Accumulation on Drip Pads	§ 262.34(a)(1)(iii) (§ 262.34(a)(1)(iii) also references part 265 subpart W).	§ 262.17(a)(3) (§ 262.17(a)(3) also references part 265 subpart W).	Accumulation time limit and recordkeeping provisions move to § 262.17 and the extensive technical standards remain in part 265.
Accumulation in Containment Buildings.	§ 262.34(a)(1)(iv) (§ 262.34(a)(1)(iv) also references part 265 subpart DD).	§ 262.17(a)(4) (§ 262.17(a)(4) also references part 265 subpart DD).	Accumulation time limit, labeling, and recordkeeping provisions move to § 262.17 and the extensive technical standards remain in part 265.
Marking and Labeling	§ 262.34(a)(2) and (3)	§ 262.17(a)(5)	Moved from § 262.34.
Preparedness, Prevention, and Emergency Procedures.	§ 262.34(a)(4) references part 265 subparts C and D.	§ 262.17(a)(6) references part 262 subpart M.	Cross-references remain but to a new subpart of the generator regulations.
Personnel Training	§ 262.34(a)(4)	§ 262.17(a)(7)	Moved from § 262.34.
Closure	§ 262.34(a)(1)(iv)B) references §§ 265.11 and 265.114. Section 265.111 references other sections in part 265.	§ 262.17(a)(8)	Duplicated from §§ 265.11 and 114 with some revisions.
Land Disposal Restrictions	§ 262.34(a)(4) references applicable parts of part 268.	§ 262.17(a)(9)	There is still a cross-reference to part 268.
Extension of Accumulation Times	§ 262.34(b)	§ 262.17(b)	Moved from § 262.34.
Accumulation of F006	§ 262.34(g) through (i)	§ 262.17(c) through (e)	Moved from § 262.34.
Accepting waste from VSQGs under the control of the same person to consolidate before sending to TSDF.	N/A	§ 262.17(f)	New provision.
Rejected Loads	§ 262.34(m)	§ 262.17(g)	Moved from § 262.34.

C. EPA Identification Number (40 CFR 262.12)

In the interest in keeping the generator regulations in a logical order for a generator proceeding through the process for the first time, EPA has relocated the previous § 262.12—EPA identification number—to § 262.18. Section 262.12 has been reserved to prevent confusion by anyone referring to old guidance documents. EPA believes this move will improve the flow of the hazardous waste generator regulations as it places the section addressing EPA identification number after § 262.13, which addresses how a generator determines its generator category. This sequence is appropriate because a hazardous waste generator must first determine its generator category in order to determine which regulations—including the requirement to obtain an EPA ID number—it must comply with. (For example, SQGs and LQGs must obtain an EPA identification number, but a VSQG does not).

D. What changed since proposal?

In the final rule, EPA is not making any significant changes to the structure of the reorganization in the proposal. The majority of commenters supported the changes EPA proposed and stated the changes would make the regulations more clear to the majority of stakeholders.

One minor change from the proposal that EPA is making in this final rule is to relocate the regulations on mixing solid waste and hazardous waste from each generator category section into § 262.13 for the reasons discussed previously.

E. Guidance and Implementation

As part of the implementation of this final rule, EPA is planning outreach to all stakeholders to discuss the reorganization in particular. The reorganization of the regulations will require adjustment by all parties that rely on EPA's generator regulations and EPA is committed to easing that adjustment through guidance and training.

VII. Detailed Discussion of Revisions to 40 CFR Part 260—Hazardous Waste Management System: General

A. Generator Category Definitions (40 CFR 260.10)

1. Introduction

As part of the reorganization of the regulations and in an effort to make the generator regulations more accessible and easier to understand, EPA proposed to codify definitions for the three categories of hazardous waste generators (VSQG, SQG and LQG) and, in conjunction with those definitions, to also define ''acute hazardous waste'' and ''non-acute hazardous waste'' for the purposes of use in the definitions (80 FR 57925–6).

In the proposal, EPA noted that the term ''small quantity generator'' is codified in the regulations, but is outdated, whereas ''conditionally exempt small quantity generator'' and ''large quantity generator'' have been used within the RCRA hazardous waste community for several decades, but their exact definitions have not been codified. The regulations differentiate among the categories by stating the quantity of hazardous waste generated in a calendar month in each instance, leading to cumbersome phrasing throughout the text.

As a part of the codification of these definitions, EPA also proposed replacing ''conditionally exempt small quantity generator,'' the term for the smallest quantity category of generator, with ''very small quantity generator.'' [11] EPA proposed this revision to remove confusion behind the phrase ''conditionally exempt.'' All three categories of generators are conditionally exempt from storage facility permit, interim status, and operating requirements, not just the smallest category. In addition, the new term is more descriptive of what the definition of the category actually represents. EPA notes this change is consistent with some states, such as Minnesota, that are already using the VSQG term. All regulations previously applicable to a CESQG apply to a VSQG.

VSQGs are generators that generate 100 kilograms or less of non-acute hazardous waste and 1 kilogram or less of acute hazardous waste in a calendar month; SQGs are generators that generate greater than 100 kilograms of non-acute hazardous waste but less than 1,000 kilograms of non-acute hazardous waste and 1 kilogram or less of acute hazardous waste in a calendar month; and LQGs are generators that generate 1,000 kilograms or greater of non-acute hazardous waste and/or greater than 1 kilogram of acute hazardous waste in a calendar month. However, generators often fail to consider residues from the cleanup of a spill of acute hazardous waste or do not count both the non-acute and acute hazardous waste they generate in a calendar month. Codifying definitions for these terms clarifies what categories of waste must be considered in determining generator category.

[11] EPA is finalizing this revision and, therefore, will use this term to refer to the smallest generator category in this preamble discussion.

2. What is EPA finalizing?

EPA is finalizing the generator category definitions as proposed to incorporate all the various categories of hazardous wastes—that is, acute hazardous waste, non-acute hazardous waste, and residues for the cleanup of a spill of acute hazardous wastes. Users of the generator regulations will benefit from the inclusion of the definitions of terms that are commonly used throughout the program. As a part of these revisions, EPA is also finalizing the definitions for ''acute hazardous waste'' and ''non-acute hazardous waste'' and the replacement of ''conditionally exempt small quantity generator'' with ''very small quantity generator.''

The generator category definitions are based solely on the amount of hazardous waste generated. While EPA acknowledges that accumulation limits may trigger different generator regulations, those accumulation limits do not affect a generator's generation category, which is based on how much hazardous waste is generated in a calendar month. Therefore, EPA is adding definitions for each of the generator categories to § 260.10.

A very small quantity generator is a generator who generates less than or equal to the following amounts in a calendar month: (1) 100 kilograms (220 lbs) of non-acute hazardous waste; and (2) 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e); and (3) 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e).

A small quantity generator is a generator who generates the following amounts in a calendar month: (1) Greater than 100 kilograms (220 lbs) but less than 1,000 kilograms (2,200 pounds) of non-acute hazardous waste; and (2) less than or equal to 1 kilogram (2.2 lbs) of acute hazardous wastes listed in § 261.31 or § 261.33(e); and (3) less than or equal to 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e).

A large quantity generator is a generator who generates any of the following amounts in a calendar month: (1) Greater than or equal to 1,000 kilograms (2,200 lbs) of non-acute hazardous waste; or (2) greater than 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e); or (3) greater than 100 kilograms (220 lbs)

of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e).

In the comments addressing these revisions, several commenters suggested that the use of the word ''and'' between the types of waste being considered in the definitions of VSQG and SQG would mean that a generator must generate all three types of waste to qualify for the generator category. EPA disagrees, noting that zero kilograms of acute hazardous waste would qualify as ''less than or equal to 1 kilogram'' and zero kilograms of residue from a spill would qualify as ''less than or equal to 100 kilograms.'' If these ''and''s were changed to ''or''s, as many of the commenters suggested, then a generator could, for instance, qualify as a VSQG just by having less than 1 kilogram of acute hazardous waste regardless of how much non-acute hazardous waste or residues it had generated.

EPA is also finalizing the proposal to replace ''conditionally exempt small quantity generator'' with ''very small quantity generator'' and is replacing all references in the regulations with this term. EPA will also be updating its materials and guidance to take into consideration the new term.

In addition, EPA is adding definitions to § 260.10 for the terms ''acute hazardous waste'' and ''non-acute hazardous waste.'' These terms are necessary because they are used in the definitions of the generator categories discussed above and because they have specific meanings within the hazardous waste generator program. The term acute hazardous waste is used for hazardous wastes that are particularly dangerous to human health and is defined as those hazardous wastes that meet the listing criteria in § 261.11(a)(2) and are therefore listed in § 261.31 and assigned the hazard code of (H) or are listed in § 261.33(e), also known as the RCRA P-list. In this rulemaking, any distinctions between acute and non-acute hazardous wastes are made only in the context of determining generator category. Otherwise, throughout the regulations, preamble, and guidance, the term ''hazardous waste'' refers to both acute and non-acute hazardous waste.

3. What changed since proposal?

EPA is finalizing the definitions for the generator categories as proposed with no changes. EPA is finalizing the replacement of ''conditionally exempt small quantity generator'' with ''very small quantity generator'' with no changes. EPA is finalizing the definitions of acute and non-acute hazardous waste as proposed with no changes.

EPA is making some changes to another area of the regulations as a result of some comments that showed that there is confusion about how the accumulation limits for VSQGs operate. EPA received multiple comments stating that the accumulation limits for VSQGs of 1,000 kg of hazardous waste, 1 kg of acute waste or 100 kg of residues from cleanup of a spill of acute hazardous waste (in § 262.14) and for SQGs of 6,000 kg of hazardous waste (in § 262.16) should be part of the definitions of the generator categories in § 260.10 and a factor in making a generator category determination.

EPA maintains that although these limits are related to the generator definitions, particularly for SQGs, the accumulation limits are not part of the definition of a generator's category, but instead have operated as a separate provision. For SQGs, the accumulation limit has always been a condition for the exemption from permitting and certain other hazardous waste regulations, meaning that if the limit is violated, the generator is no longer exempt from these regulations. The generator category is, as is stated in the statute, based on the amount of waste generated ''during a calendar month.'' [12] An SQG is limited to generating less than 1,000 kg of hazardous waste per month and to shipping that waste off site within 180 days of generation. Therefore, an SQG cannot accumulate more than 6,000 kg of hazardous waste without either generating more than 1,000 kg in one of the past six months (which would make it an LQG) or accumulating its waste beyond the 180-day limit. In this situation, the SQG can choose to become an LQG and manage the hazardous waste as an LQG. Alternatively, the SQG will lose its exemption from regulation as a storage facility and be subject to the requirements in parts 264–268, part 270, and the notification requirements at section 3010 of RCRA.

If a VSQG exceeds the accumulation limit, the exemption can be maintained if the waste is managed under the more extensive conditions for exemption of a larger generator category, but the VSQG does not itself have to become an SQG or LQG. To maintain the exemption, VSQGs that accumulate more than 1,000 kg of non-acute hazardous waste must manage the waste under the conditions for exemption for SQGs, and VSQGs that accumulate more than 1 kg of acute waste or 100 kilograms of any residue from the cleanup of a spill of acute hazardous waste must manage the waste under the conditions for exemption of an LQG.

EPA based the language in the final rule on accumulation limits for VSQGs on the previous regulations in § 261.5(f)(2) and (g)(2), which state the same principle. However, in order to make it more clear how these provisions operate, EPA has included the exact provisions that would apply to the excess waste to clarify this provision in § 262.14(a)(3) and (4). In addition, EPA is clarifying here that when the amount of waste that is accumulated exceeds the accumulation limit, all the accumulated waste at the VSQG must be managed under the requirements for an LQG, as EPA stated in the preamble to the 1980 generator final rule at 45 FR 76621 (November 19): ''The revised regulation also clarifies that once the accumulated amounts exceed *1000* kilograms, all of those wastes and those subsequently added to that accumulation are fully regulated until all the waste is sent to a hazardous waste treatment, storage or disposal facility. This rule means that those wastes remain subject to full regulation even if the quantity of wastes accumulated or stored becomes less than 1000 kilograms.''

4. Major Comments

EPA received support from a variety of stakeholders on its proposal to promulgate definitions for the generator categories in the final rule. Many stakeholders agreed with EPA's assessment that officially defining the commonly-used terms for these generators in the regulations would be a helpful addition.

Some commenters offered additional suggestions, such as revising the SQG threshold to be greater than 100 kg and less than or equal to 1,000 kg to be easier to remember, to use ''less than'' (<) and ''greater than'' (>) signs in the regulations, to change the primary unit of measurement in the regulations to pounds from kilograms and to rely on monthly averages for waste generation rather than actual monthly amounts. EPA is not making changes to the regulations in response to these comments. Although EPA understands that the quantity limits in the regulations for SQGs are not exactly parallel to the other generator categories, EPA sees little or no benefit in making a change that shifts the generator category by a single kilogram of hazardous waste or a revision of the units of measurement in the regulations. Both these revisions would require administrative changes throughout the

[12] The Solid Waste Disposal Act as Amended by the Hazardous and Solid Waste Amendments of 1984, Section 3001(d).

hazardous waste generator system. In addition, EPA believes that the meaning of ''greater than'' and ''less than'' is clear without the use of the arithmetic symbols.

Finally, EPA does not agree with the commenters who stated that it would be appropriate to allow a generator to average hazardous waste generation over several months and use the average to determine its generator category. Beyond the practical implementation concerns with this approach, and despite the commenters' argument that this approach would be consistent with the statute's intent, EPA has long interpreted the RCRA statement that a generator's category be based on the amount of waste generated ''during a calendar month'' at face value: The generator must know the quantity of hazardous waste it generates per month, not as an average of some sort, and be regulated accordingly.[13] EPA rejected similar approaches in the March 24, 1986, final rule that established the current small quantity generator regulations and is not changing that interpretation as a part of this rulemaking.[14]

EPA does agree with the comment that any acute hazardous waste cleaned up in debris is counted as part of the ''residue or contaminated soil, water, or other debris resulting from the cleanup of a spill . . . of any acute hazardous waste'' and is not counted separately as acute hazardous waste.

Regarding ''conditionally exempt small quantity generators,'' EPA received comments on the proposal arguing that the users of the term ''conditionally exempt small quantity generator'' are familiar with its meaning and do not need a revision and that states will need to update materials and forms with the new term, VSQG. EPA has determined that although the users of the regulation are familiar with this term as it is used currently, there is real value in revising it so that those who will be introduced to the RCRA generator program in the future can make more sense of the terms. As stated previously, EPA will be revising its own materials, as necessary, to account for the new term and will work with states to phase in the changed terminology over time.

Effect of the Reorganization: This section is not affected by the reorganization.

B. Generators That Generate Both Acute and Non-Acute Hazardous Waste in the Same Calendar Month (40 CFR 260.10)

1. Introduction

As stated previously in the discussion of the definitions of the categories, when a generator is determining its generator category, it must consider three relevant types of hazardous waste: Hazardous waste (or ''non-acute hazardous waste,'' for purposes of this discussion), acute hazardous waste, and residues from the cleanup of a spill of acute hazardous waste. Historically, the RCRA hazardous waste regulations have not addressed situations involving combinations of wastes and Agency statements about this issue have been inconsistent. This situation led EPA to propose regulations to clarify a generator's category for a calendar month during which it generates any combination of non-acute hazardous waste, acute hazardous waste, and residues from the cleanup of a spill of acute hazardous waste.

EPA discussed its history of statements on this topic in the proposed rule at 80 FR 57927, noting examples of contradictory EPA statements that a generator can have just one category per calendar month and EPA statements that a generator can manage acute hazardous waste as one category of generator and non-acute hazardous waste as a different category of generator in the same calendar month.

EPA proposed a more practical approach that a generator can be in only one generator category in a calendar month and noted that many EPA Regions and states have taken this same approach in implementing the RCRA hazardous waste program.

2. What is EPA finalizing?

EPA is finalizing definitions of the generator categories that expressly state which generator category would apply to hazardous waste generators that generate a combination of non-acute hazardous waste, acute hazardous waste, and/or residues from the cleanup of spills of acute hazardous waste in a calendar month as discussed earlier in this section of the preamble.

In conjunction with these changes, EPA is finalizing a new section § 262.13 explaining how a generator determines its applicable generator category. This topic is fully discussed in section IX.C of this preamble.

EPA's decision to finalize this approach is based partially on developing a practical solution to situations where a generator generates, for example, acute and non-acute hazardous waste in the same month. This approach is analogous to situations in which a generator that generates only non-acute hazardous wastes counts its various hazardous wastes. In those situations, a generator must consider the total amount of all its different kinds of non-acute hazardous waste, not the amount of each type of hazardous waste (*e.g.,* type of waste identified by individual EPA hazardous waste number) separately. Therefore, a generator must similarly follow the same logic in considering the combination of acute hazardous wastes, non-acute hazardous wastes, and residues from the cleanup of a spill of acute hazardous waste generated in a calendar month when determining which category a generator belongs to.

We note that many EPA Regions and states have taken this same approach in implementing the RCRA hazardous waste program and many of the state agencies that commented on the proposed rule stated they were in support of these changes to the regulations for the reasons EPA described in the preamble to the proposed rule, particularly because of the inconsistencies in the guidance.

In practice, five waste generation scenarios exist with different combinations of acute hazardous waste, non-acute hazardous waste, and residues from the cleanup of spills of acute hazardous waste generated in a calendar month. These scenarios are summarized in Table 6—Generator Categories Based on Quantity of Waste Generated.[15]

[13] The Solid Waste Disposal Act as Amended by the Hazardous and Solid Waste Amendments of 1984, Section 3001(d).

[14] 51 FR 10154, March 24, 1986.

[15] This table is being finalized in the regulations as Table 1 to § 262.13.

TABLE 6—GENERATOR CATEGORIES BASED ON QUANTITY OF WASTE GENERATED

Quantity of acute hazardous waste generated in a calendar month	Quantity of non-acute hazardous waste generated in a calendar month	Quantity of residues from the cleanup of spilled acute hazardous waste generated in a calendar month	Generator category
> 1 kg	Any amount	Any amount	LQG.
Any amount	≥ 1,000 kg	Any amount	LQG.
Any amount	Any amount	> 100 kg	LQG.
≤ 1 kg	> 100 kg and < 1,000 kg	≤ 100 kg	SQG.
≤ 1 kg	≤ 100 kg	≤ 100 kg	VSQG.

Note: When calculating generator categories, the quantities of acute hazardous waste and non-acute hazardous waste are considered separately.

In three of the five possible scenarios, the generator is an LQG; in one scenario, the generator is an SQG; and in one scenario, the generator is a VSQG.

As the table indicates, in the first three scenarios, the generator is an LQG if it generates any of the following in a calendar month: More than 1 kilogram of acute hazardous waste, 1,000 kilograms or more of non-acute hazardous waste, or more than 100 kilograms of residues from the cleanup of a spill of acute hazardous waste. This is true regardless of the amount of waste generated in the other categories. This fact is made clear in the final regulatory definition of ''LQG'' by stating that a generator is an LQG if it generates ''any'' of the types of hazardous waste in the amounts listed and by using of the word ''or'' between (1), (2), and (3).

As an LQG, the generator must comply with the independent requirements for LQGs (specified in § 262.10) and the conditions for exemption for LQGs (specified in § 262.17), as well as any applicable conditions for exemption for SAAs at § 262.15.

In the fourth scenario, the generator is an SQG if, in a calendar month, it generates greater than 100 kilograms and less than 1,000 kilograms of non-acute hazardous waste and also 1 kilogram or less of acute hazardous waste and 100 kilograms or less of residues from the cleanup of a spill of acute hazardous waste.[16] The final regulatory text expresses this scenario by using the word ''and'' between (1), (2), and (3) in the definition of SQG.

As an SQG, the generator must comply with the independent requirements for SQGs (specified in § 262.10) and the conditions for the exemption for SQGs (specified in § 262.16), as well as any applicable conditions for exemption for SAAs at § 262.15.

Finally, in the fifth scenario, if a generator generates 1 kilogram or less of acute hazardous waste and 100 kilograms or less of non-acute hazardous waste and 100 kilograms or less of residue from the cleanup of a spill of acute hazardous waste, then the generator is a VSQG for that calendar month. The regulatory text expresses this scenario by using the word ''and'' between (1), (2), and (3) in the definition.

As a VSQG, the generator must comply with the independent requirements for VSQGs (specified in § 262.10) and the conditions for exemption for VSQGs (specified in § 262.14).

3. What changed since proposal?

EPA is finalizing the definitions for the generator categories as proposed and has not made revisions to how it expects generators to determine their generator category when they generate acute and non-acute hazardous waste.

4. Major Comments

Some commenters who opposed EPA's proposal that a generator should manage all its waste under the same generator category argued this would be a change to how they are currently operating and that it is burdensome to operate a whole generator site as an LQG because of the existence of LQG levels of acute hazardous waste.

EPA recognizes commenters' concerns about disruption to, and burdens on, current operations. However, EPA has determined that if the definitions of the generator categories are going to depend on the amounts of hazardous waste generated, it does not, in the end, make practical sense to have a generator that is operating in more than one category. EPA notes that some comments stated that there will be a difference for those generators that have been managing acute hazardous waste in a separate area and only having a RCRA contingency plan for that area, but believes that those generators are LQGs and should be following the independent requirements and conditions for exemption for LQGs for all waste areas. Again, many states and EPA Regions commented that they are already interpreting the regulations in this way so EPA does not anticipate that these changes will have a major effect in program implementation. In fact, these revisions are making the regulations consistent with how most programs are operating currently.

Effect of the Reorganization: This section is not affected by the reorganization.

C. Definition of Central Accumulation Area (40 CFR 260.10)

1. Introduction

In the proposal at 80 FR 57927, the Agency discussed defining the term ''central accumulation area'' (CAA) in § 260.10. LQGs may accumulate hazardous waste on site without a permit or complying with the interim status standards for up to 90 days, provided they comply with the conditions of § 262.17 and SQGs may do the same for up to 180 days, provided they comply with the conditions of § 262.16.[17] Over the years, stakeholders have used different terms to refer to these on-site generator accumulation areas, including ''generator accumulation areas,'' ''less-than-90-day areas,'' and ''less-than-180-day areas.'' In December 2008, EPA promulgated a definition of ''central accumulation area'' in subpart K of part 262 to refer to these types of areas.[18] EPA codified the term ''central accumulation area'' for the sake of convenience to distinguish these types of accumulation areas from satellite accumulation areas and laboratories, which are both subject to different regulations than central accumulation areas are in that rule. At the time, EPA promulgated the term in

[16] Amount of hazardous waste accumulated on site at any given time can also impact what regulations the SQG must comply with.

[17] SQGs can also accumulate hazardous waste for up to 270 days if they ship the hazardous waste greater than 200 miles.

[18] ''Academic Labs Rule''; 73 FR 72912, December 1, 2008.

§ 262.200 and indicated the definition only applied to part 262 subpart K. Since then, the term has become more widely used and therefore EPA proposed to define the term ''central accumulation area'' in § 260.10 to allow its use when referring to all generator accumulation areas, including those that are not operating under part 262 subpart K.

2. What is EPA finalizing?

EPA is finalizing the definition of ''central accumulation area'' to mean any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either § 262.16 (for small quantity generators) or § 262.17 (for large quantity generators).[19] The definition also states that a CAA at an eligible academic entity that chooses to be subject to part 262 subpart K must also comply with § 262.211 when accumulating unwanted material and/or hazardous waste.

EPA emphasizes again that we are defining the term ''central accumulation area'' only as a matter of convenience. It is helpful for both the regulated community and the implementers to use a common term when referring to locations where generators accumulate hazardous waste other than satellite accumulation areas. Furthermore, the term is helpful for EPA to use when writing regulations, preamble, and guidance. The addition of the term does not establish any new regulatory standards or burden on generators.

EPA also wants to emphasize that generators may continue to have more than one CAA on site, as long as all CAAs meet the conditions for accumulation of hazardous waste. We are making this clear in the definition by stating that a ''central accumulation area'' means *any* on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either § 262.16 or § 262.17.

Further, the use of the word ''central'' does not denote a physical location or indicate that the generator must establish the CAA in a location that is centrally located within the site. The term ''central'' is used in the sense that many generators consolidate or *centralize* their hazardous waste from multiple satellite accumulation areas at a CAA prior to shipment off site. The CAA can be in any location at the generator site as long as it meets the conditions for the accumulation of hazardous waste.

As a result of making this change for all of part 262, we are also removing the definition of ''central accumulation area'' from part 262 subpart K.

3. What changed since proposal?

EPA is finalizing the definition for ''central accumulation area'' as proposed.

4. Major Comments

EPA received comments on the proposed revisions that expressed concern that the word ''central'' might be misconstrued to mean a generator might be limited to maintaining just one CAA or that the CAA might have to be in the center of the generator's property. Commenters suggested other terms, such as ''generator accumulation area'' or ''hazardous waste accumulation area.'' Although these terms would likely work equally well in many respects, ''central accumulation area'' is already commonly understood by many stakeholders. It has been in use for many years and has been in the regulations since the promulgation of the Academic Labs Rule. EPA has addressed the commenters concerns about the word ''central'' in the previous discussion and does not see a compelling reason to promulgate a term different than the one proposed.

Effect of the Reorganization: This section is affected by the reorganization. The definition of ''central accumulation area'' references other regulatory citations that are part of the reorganization. The reorganization is discussed in section VI of this preamble.

VIII. Detailed Discussion of Revisions to 40 CFR Part 261—Requiring Biennial Reporting for Owners or Operators of Facilities That Recycle Hazardous Waste Without Storing It (40 CFR 261.6(c)(2))

A. Introduction

As part of this rulemaking, EPA proposed to modify 40 CFR 261.6(c)(2) and require owners or operators of facilities that recycle hazardous waste without storing the wastes, or facilities that receive and partially reclaim hazardous wastes prior to producing a commodity-like material as described at § 260.31, to comply with the biennial reporting requirements at 40 CFR 265.75. This modification was primarily a clarification of the existing rules because the Agency was concerned, based on an analysis of biennial reports, that not all of these type facilities were completing a biennial report when they should have been doing so. Recycling facilities and partial reclamation facilities receiving manifested hazardous waste by a hazardous waste transporter are similar to permitted TSDFs that also must complete a biennial report. Without biennial report information, the Agency and states may have an incomplete picture of which facilities recycle hazardous waste and the quantities of regulated hazardous wastes that are recycled, impeding EPA and the states' ability to provide adequate oversight for those facilities.

The Agency believes that only a few recycling facilities will be affected by this change. Additionally, considering that most facilities already have sophisticated information systems to manage and track incoming shipments of hazardous waste, we believe the burden imposed on such facilities should be minimal if they are affected by this change.

B. What is EPA finalizing?

The Agency is finalizing the proposal at § 261.6(c)(2). Owners or operators of facilities that receive and partially reclaim hazardous wastes into a commodity like material, or recycle regulated hazardous waste (*i.e.,* hazardous secondary materials not excluded from the definition of solid waste, or hazardous waste not exempt other recycling regulations) without storing it prior to recycling must comply with the biennial reporting requirements at 40 CFR 265.75. However, based on a few comments, the Agency wishes to make clear that this provision is only applicable to owners and operators of facilities that receive regulated hazardous waste from off site and/or do not store incoming hazardous waste prior to recycling. LQGs that generate and recycle their own regulated hazardous wastes continue to be regulated under § 261.6(b).

In an effort to ensure the universe of facilities affected by this new provision is aware of their obligation to complete and submit a biennial report, the Agency will highlight these changes in the Biennial Report Instructions and Forms and describe what facilities must do to complete and submit a report. Similarly, the Agency, as part of its outreach efforts for this new rule, will educate facilities about this new reporting requirement where appropriate.

C. Major Comments

Most commenters supported this provision but a few commenters questioned the utility of this provision. As stated previously, the Agency is

[19] This definition includes citations to the newly promulgated sections of part 262 that are as part of the reorganization of the generator regulations. The predecessors to the small quantity generator regulations are at § 262.34(d) through (f) and the predecessors to large quantity generator regulations are at § 262.34(a). For a full discussion of the reorganization, see section VI of the preamble.

aware of situations through the years where a partial reclamation facility or a recycling facility that does not store prior to recycling (and hence may not have a need for a RCRA storage permit) failed to complete and submit a required Biennial Report because they were receiving regulated hazardous waste. Without this information, the Agency and states have an incomplete understanding of hazardous waste recycling activities occurring nationally. This provision is meant to make such facilities aware of their biennial reporting obligations. In addition, such recycling facilities cannot accept regulated hazardous waste from generating facilities without the recycling facilities having a RCRA identification number.

IX. Detailed Discussion of Revisions to 40 CFR part 262—Standards Applicable to Generators of Hazardous Waste

A. Addition of Terms Used in this Part and Changes to Purpose, Scope, and Applicability (40 CFR 262.1 and 262.10)

As previously discussed, one of the objectives of this rulemaking is to revise the hazardous waste generator regulations to make them more user-friendly and easily understood by both the regulated community and federal and state regulators. The hazardous waste generator regulations have long been located primarily in three different parts of the CFR (40 CFR parts 261, 262, and 265), making it sometimes difficult to determine what components of the regulations apply to different categories of hazardous waste generators.

The reorganization is addressing some of these problems by reducing the need to refer to separate parts of the regulations through consolidation of the generator regulations into part 262 and by organizing the regulations based on a generator's category so generators can more easily determine which regulations apply to them. As described in section VI, EPA is finalizing three new sections in part 262 subpart A to set forth the conditions for exemption for each of the categories of generators that accumulate waste on site and one new section to set forth the conditions for exemption for SAAs. These new sections are § 262.14 for VSQGs, § 262.15 for SAAs, § 262.16 for SQGs, and § 262.17 for exemption for LQGs.

In concert with the reorganization of the generator conditions for exemption for on-site accumulation of hazardous waste, EPA is adding regulatory language to more clearly explain how the regulations work for generators and to lay out which provisions apply to each of the different categories of generators. EPA is making additional changes to otherwise clarify the framework of the hazardous waste generator program, including the addition of § 262.1 and the revisions to § 262.10. EPA is also adding an explicit prohibition on sending hazardous waste to a facility that is not authorized to accept it and is removing outdated and unnecessary provisions.

Note that the changes to the regulatory text for § 262.10 in this action take into account the revisions being made as a part of the ''Hazardous Waste Export-Import Revisions'' Final Rule (Docket ID EPA–HQ–RCRA–2015–0147; FRL–9947–74–OLEM), including replacing the reference to § 262.12 in paragraph (d) with a reference to § 262.18 and referring to subpart H of part 262 for provisions on imports and exports of hazardous waste instead of to subparts E and F, which are being removed and reserved.

1. Regulatory Framework for Independent Requirements and Conditional Exemptions for Generators (Sections 262.1, 262.10(a), and 262.10(g))

a. *Introduction.* In developing the proposed rule, EPA determined that the RCRA regulations could be clarified regarding the distinction between the two types of generator requirements: (1) Those requirements that any generator generating hazardous waste must meet, which EPA is calling ''independent requirements,'' and (2) those conditional requirements that a generator who also accumulates waste must meet only if it wants the benefits of an exemption from RCRA storage facility permitting (or interim status) requirements, which EPA is calling ''conditions for exemption.'' In order to make the regulations clearer regarding this distinction, EPA proposed to include definitions for these types of provisions in a new section of the regulations, to list which regulations for generators are independent requirements and which are conditions, and to clarify the regulatory difference between those types of requirements with regards to enforcement. These changes were proposed in a new § 262.1 and in revisions to the existing § 262.10(a) and (g).

b. *What is EPA finalizing?* EPA is finalizing the proposal to clearly define and reflect in the regulations the distinction between independent requirements and conditions for exemption that has existed, less explicitly, in the RCRA generator regulations since their initial implementation over 30 years ago. Because some commenters expressed continuing confusion over the distinction, a more extended discussion here will help to address and further clarify the meanings of the terms.

The difference between independent requirements and conditions for exemption lies in the nature of each type of provision and in the consequences that may result if each is not met. An ''independent requirement'' in part 262 is the common type of regulatory requirement one usually thinks of, equivalent to a law that can be broken: It is the statement of a duty that must be met, or else a violation of RCRA or the regulations has occurred that is subject to a penalty. In other words, in the context of 40 CFR part 262, an ''independent requirement'' is an unconditional requirement or demand that is imposed upon the generator and with which the generator must comply. Because the sole purpose of the independent requirement is to achieve or prohibit the stated behavior, event, or standard, the only potential legal consequence to the generator from failing to meet an independent requirement, is some form of enforcement action for violating that particular requirement (*e.g.,* a notice of violation, civil or criminal penalties, or injunctive relief under section 3008 of RCRA).

Most important to the distinction between an ''independent requirement'' and a ''condition for exemption'' in part 262 is the fact that an independent requirement does not provide a mechanism for the generator to avoid having to comply with other requirements, such as the storage facility regulations in parts 264, 265 and 270.

Also important to note is that the ''independent requirements'' of part 262 are not legally tied to the accumulation of hazardous waste. These part 262 independent requirements are applicable and enforceable, and must be met, by a generator of hazardous waste, whether or not the generator actually accumulates hazardous waste on site. In that sense, they are ''independent'' of the conditions for exemption from storage facility regulation, which are only applicable to generators who also accumulate hazardous waste. The independent requirements of part 262 are therefore enforceable whether or not the generator has obtained, or is attempting to obtain, an exemption from the storage facility permit (or interim status) and operations requirements by meeting the conditions for that exemption in §§ 262.14, 262.15, 262.16, or 262.17.

An example of such an ''independent requirement'' is § 262.30, the pre-transport waste packaging requirement. This requirement is an unconditional demand, and failure to meet this requirement is subject to penalty or injunctive relief for violating § 262.30. The requirement applies without regard to whether the generator accumulates waste on site; and it applies and is enforceable regardless of whether the generator has an exemption from storage facility permit and operations regulations.

A condition for exemption, on the other hand, is a requirement that is contingent in nature: It is only necessary to meet the condition if the generator is using it to obtain an optional exemption from other requirements. A condition for exemption is not the common type of regulatory requirement that absolutely demands compliance under threat of penalty for violation of that requirement. Meeting a condition for exemption is required only if the generator wants an exemption, and then is ''required'' only in the sense that it is a necessary step to take in order to successfully obtain that optional exemption.

The primary legal consequence of *not* complying with the condition for exemption is that the generator who accumulates waste on site can be charged with operating a non-exempt storage facility (unless it is meeting the conditions for exemption of a larger generator category). A generator operating a storage facility without any exemption is subject to, and potentially in violation of, many storage permit and operations requirements in parts 124, 264 through 268, and 270.

As an example, § 262.17 provides the conditions for the LQG exemption from storage facility regulation by stating that the LQG may accumulate hazardous waste on site without a permit or interim status, and without complying with storage facility operating requirements, provided it meets the conditions stated in that paragraph. The stated conditions for exemption in § 262.17 are the necessary steps the LQG can take to obtain the exemption, if it chooses to do so.

The distinction between part 262 independent requirements and part 262 conditions for exemption is also important because violation of an independent requirement (as discussed previously in this section), such as an SQG failing to obtain an EPA identification number, can result in a notice of violation and enforcement action for that particular independent requirement only. In contrast, noncompliance with a condition for exemption, such as an LQG accumulating hazardous waste for more than 90 days may result in an entity losing its storage facility exemptions and becoming the operator of a non-exempt storage facility subject to the applicable requirements for storage facilities in parts 124, 264 through 268, and 270.

The first part of the revisions EPA is finalizing contains the definitions for ''independent requirement'' and ''condition of exemption,'' so that the meaning of the terms will be clear as we have described them here. We use these terms throughout this preamble and the final regulations to distinguish between these two types of provisions for generators in part 262.

EPA is also finalizing the changes to § 262.10(a) with some revisions. Section 262.10(a) addresses the purpose, scope, and applicability of the hazardous waste generator regulations and contains both a list of which independent requirements apply to each generator category and also references to the later sections at which generators can find the full list of conditions for the applicable generator exemption. At the same time, § 262.10(a) distinguishes which generator provisions are independent requirements and which are conditions for a generator exemption.

The language in § 262.10(a) also continues to explain the significance of the conditional exemption from storage facility permit, interim status, and operating requirements by stating specifically that if the conditions for exemption (those requirements in § 262.14, 262.15, 262.16, or 262.17) are not met, then the generator will be subject to the permitting or interim facility provisions in parts 124, 264 through 268, 270, and section 3010 of RCRA.

The reaction to the proposed changes was mixed among the states. Many states agreed that the explanations of conditions for exemption from permitting for generators accurately describes how the generator regulations have operated all along and stated that including this explanation in a straightforward way in the regulations would be a benefit and would make the RCRA program more transparent to the regulated community. Some states, however, expressed concern that the new regulations would limit their flexibility in how they enforce the RCRA regulations within their states and were opposed to the changes for that reason.

Comments from industry stakeholders expressed great concern that the language EPA proposed represented a major shift in the Agency's enforcement paradigm to a draconian system of enforcement that would lead to an excessive number of violations and penalties. EPA disagrees with this comments and did not intend to create any sort of shift in EPA's enforcement actions. In response to these comments on the proposal, EPA has revised the final language to be clearer and to further explain the regulations.

In this final rule, EPA reiterates that the distinction between independent requirements for all generators and conditions for exemption from the storage facility regulations that are available to generators who are accumulating hazardous waste on site has always existed in the RCRA program. It has been the Agency's longstanding position that generators that do not comply with a condition of a generator exemption fail to qualify for the exemption and (if they have not qualified for a larger generator exemption) they would be considered an operator of a non-exempt storage facility, in addition to being a generator. The changes to § 262.10 in this rule do not constitute a substantive change to this long-standing position.

Thus, these revisions to the regulations make this distinction more clear to all generators by listing the independent requirements and conditions for exemption applicable to all hazardous waste generators based on their generator category. The reason for this change is to reduce confusion for the regulated community in the context of compliance and any enforcement actions.

Additionally, EPA is revising another part of § 262.10 in its effort to make the framework of the regulations more clear. Historically § 262.10(g) has stated that a generator is subject to the compliance requirements and penalties prescribed in section 3008 of [RCRA] if it does not comply with the requirements of part 262. However, this paragraph did not previously explain the distinction between the potential penalties for violating part 262 independent requirements and the consequences of not complying with the conditions for a generator exemption that are not subject to direct penalties. As a result, confusion has persisted over the legal consequences of failure to comply with the conditions for exemption and this confusion is reflected in the comments to our proposed rule.

Therefore, EPA is revising § 262.10(g) to make the legal framework clear to the regulated community. Section 262.10(g)(1) establishes that violation of an independent requirement, such as the hazardous waste determination

requirement of § 262.11 or the EPA ID number requirement of § 262.18 is subject to penalty and injunctive relief under section 3008 of RCRA. However, § 262.10(g)(2) establishes, as explained throughout this portion of the preamble, that noncompliance with a condition for exemption is not subject to penalty and injunctive relief under section 3008 of RCRA as a violation of part 262. Rather, noncompliance with a condition for exemption by a generator accumulating waste on site results in the generator losing the storage facility exemption from parts 124, 264 through 268, and 270. Without an exemption, the generator is subject to the requirements of those parts of the storage facility regulations, the violation of which is subject to penalty and injunctive relief under section 3008 of RCRA.

As a whole, EPA believes that these three sets of revisions—the new definitions in § 262.1 and the revisions to § 262.10(a) and (g)—will clarify EPA's longstanding position on how the RCRA generator program works and how the two types of requirements—independent requirements and conditions for exemption—interact and apply. As stated previously, EPA does not consider these revisions to the regulatory language as a change to the RCRA generator program because the regulations that were previously in § 262.34 (now in §§ 262.14–17) and the provisions for VSQGs that were in § 261.5 [20] were always conditions for exemption from storage facility permit, interim status, and operating requirements and have always worked in the same way as we are explaining in this rule.

As explained in the preamble to the proposal, the clarifications regarding the distinction between independent generator requirements, and the conditions for exemption from storage facility regulations for generators that accumulate hazardous waste on site, do not alter the way the generator regulatory scheme has operated over the last 30 years. Similarly, the clarifications regarding the enforcement consequences of independent requirement violations and non-compliance with conditions for exemption do not signal a change from how most enforcement actions have been pursued when a generator has been found in noncompliance with a condition for exemption.

For violations of independent generator requirements, federal and state regulatory agencies continue to retain full enforcement discretion authority to determine whether an enforcement action is warranted and if so, what enforcement tools, including notices of violation, civil and criminal complaints, penalties and injunctive relief, are appropriate to address any detected violations.

Likewise, regulatory agencies retain the same discretion and authority regarding bringing various types of enforcement actions that they have always exercised in situations where non-compliance with conditions for exemptions have been detected. The clarifications in this rule do not mandate that regulatory agencies pursue enforcement actions where they previously would have exercised enforcement discretion in forgoing such actions. In addition, this final rule does not mandate charging and penalization of every violation of regulatory requirements that legally may result when a generator loses its exemption from the storage permit and operations requirements, when, for example, such action would be disproportionate to the seriousness of the generator's violations. EPA and states have always had, and continue to have, enforcement discretion to bring charges and seek penalties that accurately reflect the seriousness of the violations and their potential for harm.

In addition, we do note that when implementing the regulations, enforcement agencies can elect to cite violations based on the failure to obtain a permit in part 270; or on a specific requirement in the storage facility operations regulations in parts 264 and 265 that is a companion to the out-of-compliance condition found in part 262; or both; and/or other violations found in the operations regulations that are applicable to the generator as a result of the non-compliance.

c. What changed since proposal? In the definitions in § 262.1, EPA made some changes to the language of the definition of ''condition for exemption'' to clarify the wording, to complete the list of sections in which conditions for exemption are found, and to correct the list of parts of 40 CFR from which generators can be exempted. EPA removed part 268 from that list. Although part 268 focuses on the technical requirements for land disposal, some parts of it apply to generators, notably parts of § 268.7 and § 268.9. EPA did not want to cause confusion by stating generators would be exempt from part 268 provisions, because those particular part 268 provisions are designed specifically for generators and do apply.

EPA has also made a few changes to the language in § 262.10(a) since the proposal. Some commenters on the proposed rule suggested that we include a list of the independent requirements applicable to VSQGs in § 262.10(a)(1) to make the regulations parallel for VSQGs, SQGs, and LQGs. VSQGs have very few independent requirements, but a VSQG does have to make a waste determination and determine its generator category. EPA agrees with this comment and, therefore, we have inserted a new § 262.10(a)(1)(i) for VSQGs and listed these two independent requirements there.

In addition to that change, we also revised the language in § 262.10(a)(2) to clarify the language and to correct the list of parts that would be applicable to generators that fail to meet the conditions for exemption by deleting part 263 for transporters of hazardous waste and adding the permit requirements in part 270. EPA realized the proposed language was not consistent and, in some places, included references that would not be accurate.

EPA also made changes to the revisions in § 262.10(g) in response to comments that this language was confusing and too ''legalistic.'' It is important to EPA that the regulated community understand the concepts we are describing. Therefore, in § 262.10(g)(1), EPA revised the language to make it clear that the provision is focused on the independent requirements for generators that, by definition, appear in part 262 of the regulations and not requirements in other parts.

EPA also made changes to § 262.10(g)(2), which addresses noncompliance with conditions for exemption. Several comments stated that the language here was confusing. To address this concern, EPA revised the language in an attempt to clarify it for the average generator. The language now explains what might happen in the case of noncompliance in a more narrative fashion, stating what the consequences are of not qualifying for the exemption from the permitting regulations, as EPA has already described in this preamble. Finally, EPA revised the list of parts that apply to a generator that does not qualify for the exemption from the storage facility regulations, in order to be consistent with other places in the rule.

Effect of the Reorganization: Sections 262.1 and 262.10(g) are not affected by the reorganization. Section 262.10(a) is affected by the reorganization—the section now describes the structure of much of part 262. The reorganization is discussed in section VI of this preamble.

[20] Previously referred to as ''conditionally exempt small quantity generators.''

2. Generators Shall Not Transport to a Non-Designated Facility

a. Introduction. As the Agency has stated numerous times in the development and implementation of the RCRA hazardous waste program, a fundamental aspect of the program is the responsibility placed on the generator of hazardous waste to ensure its hazardous waste is properly managed from cradle to grave. Numerous existing regulatory provisions are designed to ensure that generators send their hazardous waste only to authorized TSDFs or other authorized facilities. See for example, §§ 262.18(c),[21] 262.20(b), 262.40(a). However, from experience with implementing the program, the Agency has found situations where a generator failed to send its hazardous waste to a facility authorized to receive that waste, thus creating both regulatory and potential hazardous waste mismanagement problems. The Agency believes that a statement expressly prohibiting a generator from sending hazardous waste to a facility not authorized to accept it is necessary to ensure that generators understand they have this obligation. Therefore, the Agency proposed adding such a new independent requirement at § 262.10(a)(3).

b. What is EPA finalizing? EPA is finalizing this provision as proposed and is promulgating § 262.10(a)(3), which clearly and explicitly states that a generator cannot offer or otherwise cause its waste to be sent to a facility that is not authorized to accept it.

This provision is being added to the regulatory framework and not replacing §§ 262.18(c), 262.20(b), 262.40(a), as those provisions are aimed at other aspects of the generator program (for example, ensuring manifests are properly completed).

EPA received general support from most of the commenters on this provision, with one commenter stating that the provision was unnecessary. EPA believes that the provision is necessary, as it is a cornerstone of the generator program and should be explicitly stated in the regulations to ensure that all generators are aware of it.

Effect of the Reorganization: This section is not affected by the reorganization.

3. Deletion of § 262.10(c)

a. Introduction. EPA proposed deleting and reserving § 262.10(c) of the hazardous waste regulations because it is outdated, confusing and unnecessary. The provision describes the requirements for a generator who treats, stores, or disposes of hazardous waste on site and includes a list of provisions these generators must comply with.

When § 262.10(c) was initially promulgated on February 26, 1980, the hazardous waste generator regulations distinguished between the generators that sent hazardous waste to be managed off site and those that managed their hazardous waste on site. Generators that sent hazardous waste off site could manage it for 90 days in an accumulation area, but generators that managed hazardous waste on site were expected to manage it under their permits or under interim status regulations. The purpose of § 262.10(c) was to provide the list of requirements that generators managing hazardous waste were required to follow in addition to those permits or interim status requirements.

This distinction meant that the two types of generators had very different standards for the areas where newly generated hazardous waste was managed. Significantly, generators sending hazardous waste off site could easily make physical changes to their accumulation areas, whereas a similar generator managing hazardous waste on site under a permit had to go through the permit modification process to make the same kind of changes. EPA effectively eliminated the distinctions by revising these regulations (45 FR 76624, November 19, 1980 and 47 FR 1248, January 11, 1982). The final rule promulgated in January 11, 1982, made a change to § 262.10(c) that added the generator accumulation provisions at § 262.34 to the list of provisions that apply to a generator that treats, stores, or disposes of hazardous waste on site. Currently, the Agency does not make this distinction between generators that send waste for treatment off site and those that manage waste on site. This revision is therefore outdated and, thus, should be deleted and reserved.

b. What is EPA finalizing? EPA received general support from most commenters who addressed this issue and is finalizing the deletion of the paragraph. Section 262.10(c) will be reserved to avoid reusing that specific paragraph.

Effect of the Reorganization: This deletion is not affected by the reorganization.

4. Deletion of Reference to Laboratory XL Project Regulations (40 CFR 262.10(j) and Part 262 Subpart J)

The Laboratory XL Project was created for Boston College, the University of Massachusetts, and the University of Vermont, and was finalized in the **Federal Register** on September 28, 1999 (64 FR 53292). Originally, the program was to expire on September 30, 2003. But on June 21, 2006, EPA extended the program and the new expiration date was changed to April 15, 2009 (71 FR 35550). Since the program has now expired, EPA is deleting paragraph (j) from § 262.10, as well as part 262 subpart J and reserving them.

Effect of the Reorganization: This deletion is not affected by the reorganization.

B. Waste Determinations (40 CFR 262.11)

1. Introduction

Under RCRA, generators are the first critical link in ensuring safe management of hazardous waste. They are the cradle in the cradle-to-grave RCRA system. The first and most important step in the regulations is for generators of solid waste (as defined at § 261.2) to determine whether their waste is also a hazardous waste by using § 262.11. If a generator fails to identify a hazardous waste as hazardous, it will not start the waste down the hazardous waste management path and the critical gateway to the RCRA Subtitle C safe management system will be missed. Such mismanagement of hazardous waste may result in damage to human health and/or the environment.

Thus, the success of the hazardous waste regulatory program depends, to a great extent, on generators making accurate hazardous waste determinations. However, as described in the proposal, EPA has observed through various efforts that generators struggle with this crucial first step with the estimated rates of non-compliance ranging from 20 to 30 percent.[22] With an estimated generator universe in the hundreds of thousands, the potential for the mismanagement of hazardous waste and the impact on public health and the environment is significant. Therefore, given the importance of this regulatory provision, the Agency proposed several changes to the waste determination regulations at § 262.11 in an effort to clarify them, and thereby foster

[21] Section 262.18(c) has been moved as part of the reorganization from § 262.12(c).

[22] Hazardous Waste Determination Program Evaluation, IEc, April 2013. *http://www.epa.gov/evaluate/pdf/waste/haz-waste-determination.pdf*; and Summary of Waste Determination Meetings with VT and NH State Officials on September 27–28, 2010; and ''10 Most Common Hazardous Waste (RCRA) Violations in Georgia: 40 CFR 262.11 ''Hazardous Waste Determination,'' Georgia Department of Natural Resources *https://epd.georgia.gov/sites/epd.georgia.gov/files/related_files/site_page/guidehwdet.pdf*. For more citations, see the proposed Generator Improvements Rule, page 57936–57937, September 25, 2015.

improved compliance by generators. These proposed changes were intended primarily to codify Agency interpretations that have been developed and implemented over the last 35 years in **Federal Register** notices, policy, letters, and other guidance.

Specifically, the proposed rule included revisions to the § 262.11 regulations that would (1) clarify that hazardous waste determinations must be accurate; (2) confirm that a generator's waste must be classified at its point of generation and, for wastes potentially exhibiting a hazardous characteristic, at any time during the course of its management when the properties of the wastes may change in such a way as to change the hazardous waste determination; (3) revise the language on how to make a determination for listed hazardous waste in § 262.11 to explain more fully how generators can make this kind of determination using generator knowledge; (4) explain more completely in the regulations at § 262.11 how a generator should evaluate its waste to determine whether the waste may exhibit one of the hazardous characteristics; (5) move the independent recordkeeping and retention requirements for hazardous waste determinations currently found at § 262.40(c) into § 262.11 to integrate this provision more directly into the hazardous waste determination regulations; (6) revise the hazardous waste determination recordkeeping regulations to require that SQGs and LQGs maintain records of any test results, waste analyses, or other determinations made in accordance with § 262.11 for at least three years, including waste determinations where a solid waste (as defined in § 261.2) is found not to be a RCRA hazardous waste (as defined in § 261.3); (7) revise the hazardous waste determination regulations by copying § 262.40(d) into § 262.11 to address situations where an enforcement action has been initiated and the period of record retention (*e.g.,* three years from when the record was generated) must be extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator, and (8) require generators identify all applicable EPA hazardous waste numbers (EPA hazardous waste codes) in subparts C and D of part 261 if the solid waste is determined to be a hazardous waste.

The Agency also requested comment regarding how best to emphasize the importance of accurate hazardous waste determinations and the length of time records must be maintained. Finally, EPA also asked for comment on the utility of developing an electronic decision making tool for hazardous waste determinations.

2. What is EPA finalizing?

The Agency is finalizing the following changes to § 262.11:

(1) Requiring that a solid and hazardous waste determination must be accurate, and expanding on why this determination is important; *i.e.,* to ensure the proper management of the waste within the RCRA framework;

(2) Requiring that a hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors such that its waste classification may have changed;

(3) Incorporating regulatory language that elaborates on how to make a hazardous waste determination for listed and characteristic hazardous waste;

(4) Referencing the applicable RCRA regulations for identifying possible exclusions or exemptions for the hazardous waste at in § 262.11(e).

(5) Moving the independent recordkeeping and retention requirements for hazardous waste determinations currently found at § 262.40(c) into § 262.11(f), with clarifications on what records must be kept; and

(6) Requiring SQGs and LQGs to identify the applicable RCRA waste codes for the hazardous waste they have generated, but clarifying that such identification must occur no later than immediately prior to shipping hazardous waste off site to a RCRA permitted treatment, storage and disposal facility in accordance with the requirements of § 262.32.

The Agency is not finalizing the proposed requirement that SQGs and LQGs maintain records of their non-hazardous waste determinations. Nor is the EPA finalizing a requirement for SQGs and LQGs to maintain records of their hazardous waste determinations until the generator closes its site.

Finally, EPA requested feedback regarding the feasibility and effectiveness of developing electronic decision-making tools for hazardous waste determinations and whether such tools would be a helpful to generators. Based on comments, the Agency is not finalizing any provision related to electronic decision-making tools for hazardous waste determinations but will continue to explore feasibility in the future. The Agency took comment on a number of electronic tools and reporting options and has organized our discussions of all of these options in section XIII of this preamble. See this section for a more in-depth discussion regarding electronic waste determination decision tools and other electronic options.

a. Solid and hazardous waste determinations must be accurate. The Agency is finalizing the proposed requirement for generators to make accurate hazardous waste determinations. However, we are also modifying the proposed regulatory text in response to comments to provide a rationale for this change by stating that the accurate determination is in order to ensure wastes are properly managed under RCRA. Accurate hazardous waste determinations are necessary to ensure the proper management of waste within the RCRA framework; in doing so, environmental protection will be enhanced and greater generator accountability fostered.

EPA believes that waste determinations are of utmost importance and warrant this emphasis regarding accuracy. As one commenter stated, ''Accurate waste determinations are required to ensure that each waste stream generated by a company is properly managed. Additionally, accurate waste determinations protect workers by making the company and the worker(s) aware of the dangers of the waste(s) being managed. Further, accurate waste determinations will ultimately lead to an accurate generator status determination.'' [23]

Some commenters argued that addition of the term ''accurate'' to the regulation would be superfluous, as the Agency's intent that hazardous waste determinations be accurate is self-evident, and that adding this term may even imply that other aspects of the RCRA program need not be accurately implemented. The Agency's intent is that all parts of the RCRA regulatory program be implemented in the manner required by the regulations. In adding the term ''accurate'' to the waste determination requirement of § 262.11, the Agency intends to emphasize the importance of this step in the waste management process. Inaccurate hazardous waste determinations will lead to violation of other RCRA regulatory requirements and mismanagement of the waste, which may result in damage to human health or the environment.

[23] Comment by individual consumer. Docket number: EPA–HQ–RCRA–2012–0121–0160

Another reason for including the language explaining a generator must make an accurate waste determination to ensure the wastes are properly managed is to clarify the applicability of § 262.11 in instances in which generators choose to manage their non-hazardous wastes as hazardous wastes. Even if the waste may not be hazardous, ''over managing'' the waste is acceptable and meets the requirements in § 262.11 because the generator has made a determination intended to ensure, beyond a doubt, proper and protective management of the waste within the RCRA regulatory program. The practice of over-managing non-hazardous waste as hazardous waste has been in existence for years and EPA's final language in § 262.11 continues to allow this practice.

In addition to concerns about the regulatory status of over-classified wastes, commenters also expressed concerns about generators using the best available information and still making an inaccurate determination because of the errors and omissions of others. Generators are, and always have been, ultimately responsible for making accurate hazardous waste determinations. Hiring a third party contractor, waste broker, or consultant, or reliance on information provided by suppliers does not transfer this responsibility to those third parties. While the Agency understands that reliance on third parties may sometimes result in an inaccurate waste determination, the responsibility remains with the generator. It would be prudent for the generators to practice due diligence and establish processes and procedures that ask questions of their suppliers and waste management companies to understand why their materials are hazardous or not.

One commenter mentioned that the term 'accurate' also does not provide any guidance about how intensive or deep a generator's research must be to meet the intended standard. This commenter goes on to discuss that a five-minute review of a Safety Data Sheet (SDS) and product brochure may well be 'accurate' but much too superficial to ensure the generator has considered all potentially hazardous attributes of the waste. The Agency disagrees with this commenter. Waste determinations are site specific and each generator must evaluate the amount of time and effort needed to make an accurate waste determination. In some cases, a review of an SDS may suffice because the identification of the constituents and their concentration ranges may make it clear whether the chemical is or is not a hazardous waste upon disposal. Conversely, the Agency can see a number of situations where a generator must conduct analysis and testing to meet this requirement. Regardless of the effort invested in making a hazardous waste determination, the Agency's intent is that the *results* of the determination be accurate and bring about the proper management of the waste under the RCRA regulatory framework.

b. A hazardous waste determination must be made at the point of generation before any dilution, mixing, or other alteration of the waste occurs. As described in the proposed rule, the Agency's policy and position from the beginning of the RCRA program has been that a waste determination must be made at the point of generation (*i.e.,* the point at which the material first becomes a solid waste under RCRA; See, for example, 55 FR 11830, March 29, 1990). This includes both the time and place the waste was first generated. By requiring that the hazardous waste determination be made at the point of generation in § 262.11(a), the final regulation clarifies that the determination cannot be made downstream in the process, where other materials could be mixed with the waste or where the waste may have changed its physical or chemical characteristics. A generator's hazardous waste determination at the initial point of generation is critical to ensure proper management of the waste not only by the generator, but also by transporters and TSDFs who rely on the generator's determination to allow them to safely manage the waste and provide appropriate treatment and disposal. This proposed revision to § 262.11 is not a substantive change to the program; preambles to a number of previous rules explain that EPA has always maintained that hazardous waste determinations must be made at the initial point of generation.[24] The Agency is finalizing this requirement as proposed.

Many commenters expressed concern with EPA's proposed requirement that hazardous waste determinations must be made at the point of generation. For many generators, the Agency believes making a hazardous waste determination on new wastes should be an infrequent evaluation. An analysis of 2013 biennial report data identified 46 percent of LQGs generated between one and five waste streams. Similarly, this same analysis found that overall LQGs generated a median of 6 hazardous waste streams and a mean of 13 hazardous waste streams.[25] Many of these generators continue to generate the same wastes over long time periods, and absent changes in the waste, the generator may continue to rely on an initial determination of the waste's RCRA status (particularly for listed hazardous wastes). Of course, should a generator in this scenario change either its production feedstocks or production process, or know of any other factors that may result in changes to the waste's origin or properties, the generator may have a new waste requiring a new waste determination.

Based on EPA's 2013 Hazardous Waste Determination Program Evaluation [26] and stakeholder discussions, the Agency has determined that most generators make a hazardous waste determination by using knowledge of their processes, including feedstocks and possible side reactions, and other materials used at the facility to evaluate whether waste is hazardous or not. In order to properly classify and manage waste, generators must make a hazardous waste determination when the waste is first generated. Most generators should have sufficient knowledge of their waste to determine whether the waste is hazardous and why it is hazardous *i.e.,* whether the waste meets one of the listing descriptions in subpart D of part 261 [27] or whether the waste may exhibit one or more hazardous waste characteristics described in subpart C of part 261, and to manage the hazardous waste according to its hazards, under RCRA. When generator knowledge is inconclusive or uncertain, testing may be appropriate.

We have and continue to recognize that situations will occur where a generator is not able to make an accurate waste determination based on knowledge alone, and the generator will need to send a representative sample of the waste to be tested. However, as the EPA has stated in the past, the generator must manage the waste as hazardous waste until the results of the test are received, and continue to manage it as

[24] See 45 FR 33095–96, May 19, 1980 and 55 FR 11830, March 29, 1990.

[25] See ''Regulatory Impact Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule.'' A copy of the analysis is available in the docket for this action.

[26] Hazardous Waste Determination Program Evaluation, IEc, April 2013. *http://www.epa.gov/evaluate/pdf/waste/haz-waste-determination.pdf.*

[27] **Note:** If the waste is listed, a generator may file a delisting petition under 40 CFR 260.20 and 260.22 to EPA or the authorized state to demonstrate that the waste from this particular site or operation is not a hazardous waste.

hazardous waste if the hazardous waste determination is confirmed by the test.[28]

The Agency is also aware that many generators, such as academic and industrial laboratories, generate new or different waste streams frequently, and that making hazardous waste determinations for multiple waste streams is more difficult than when a generator has a small number of waste streams that seldom vary. However, EPA stresses that in the laboratory setting, it may be even more important to make accurate hazardous waste determinations at the point of generation, so that emergency scenarios involving mixing of incompatible wastes or other dangerous situations can be avoided and lab worker safety maintained. Whether a generator generates one new waste daily or annually, the process for making a hazardous waste determination is still the same. Through knowledge of the process or materials, and/or through testing, all generators must make a hazardous waste determination at the point of generation. The Agency would expect generators producing new wastes frequently to establish efficient processes to make those waste determinations, particularly to the extent they can use knowledge of the materials or feedstocks in the waste determination process.

Both the retail and laboratory sectors raised concerns about the undue waste determination burden from the large numbers of potentially hazardous wastes that might be generated at their sites. EPA realizes that both of these sectors operate differently from the traditional industrial hazardous waste generators. In fact, to address laboratory sector concerns, EPA developed an optional set of alternative standards in 40 CFR part 262 subpart K, entitled, ''Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities.'' This rule was designed to account for the manner in which academic laboratories operate. In addition, a few years ago, the EPA began a review of how RCRA hazardous waste regulations apply to the retail sector in order to better understand retailers' challenges in complying with RCRA regulation. These efforts are on-going.

A few commenters disagreed with the proposal to add language clarifying that waste determinations must be made at the ''point of generation,'' arguing that the Agency has issued waste determinations in the past contradicting this policy. The Agency disagrees with this commenter. EPA has been consistent in its position that a waste determination must be made at the point of generation, unless for some unforeseen and rare circumstance, the determination must be made in a subsequent location. Without clarifying in the regulation that a waste determination must be made at the point of generation, the RCRA ''cradle to grave'' system could be easily circumvented, with generators and handlers able to delay the waste determination process until a convenient time and place, including by a subsequent handler who knows little about the waste.

However, in response to comments, the Agency is stating that existing guidance and memoranda addressing specific situations relating to the point of generation are not superseded by this final rule. Specific examples of such situations are discussed in the Agency's Response to Comment document found in the docket to this rule.

As part of finalizing § 262.11(a), the Agency is also finalizing the language that explicitly clarifies the waste determination policies identified and discussed in 1980 (45 FR 33095–96, May 19, 1980); *i.e.,* that the point of generation is identified as the point at which the material is first identified as a solid waste under RCRA, before any dilution, mixing, or other alteration of the waste occurs. Further, RCRA solid and hazardous waste must be reevaluated at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste, such that the RCRA classification may have changed. As discussed in the proposal rule at 80 FR 57938, and in referring to characteristic hazardous wastes, the Agency stated:

> This implies that a generator's waste characterization obligations may continue beyond the determination made at the initial point of generation. In the case of a non-hazardous waste that may, at some point in the course of its management, exhibit a hazardous waste characteristic, there is an ongoing responsibility to monitor and reassess its regulatory status if changes occur that may cause the waste to become hazardous. Thus, the generator must monitor the waste for potential changes if there is reason to believe that the waste may physically or chemically change during management in a way that might cause the waste, or a portion of the waste, to become hazardous.

Many commenters were concerned that in practice, this provision would require them to constantly re-evaluate their wastes. However, the Agency stands by and is not changing this long-standing position. Generators have a responsibility to understand the properties of their waste, not only to make an accurate determination, but also to manage the waste properly. In many instances, the properties of the waste most likely will not change. But in other situations, exposure to the elements, or the very nature of the chemicals in the waste may cause its properties to change. Generators have a responsibility as part of the waste determination and waste management processes to be aware of those situations.[29] In such situations, generators should also notify any subsequent waste handlers to monitor for changes in waste properties. The Agency emphasizes that a generator needs to understand what type of waste it has generated, why it is or is not hazardous at the point of generation, and proceed accordingly in managing and monitoring its waste. If a generator is aware that its waste tends to have the potential to change over time, the generator may wish to establish processes to determine whether the nature of its waste has changed and make a new hazardous waste determination.

c. Use of generator knowledge and testing in making a hazardous waste determination. At § 262.11(c) and at § 262.11(d)(2), the Agency, in its proposed rule, elaborated on the existing regulatory text associated with the use of generator knowledge to determine whether wastes are either listed hazardous wastes and/or characteristically hazardous waste, respectively. As part of this proposed change, the Agency provided examples of the types of knowledge and information deemed acceptable that generators may use. The types of information identified in § 262.11(c) and § 262.11(d)(2) that generators could use as acceptable knowledge in determining if their wastes are listed wastes, or characteristically hazardous, were not all inclusive, or limited to those examples. However, this may not have been clear in the proposal. The Agency, therefore, is finalizing § 262.11(c) and now § 262.11(d)(1) with slight changes to clarify that the examples identified in the regulatory text are not limited to those kinds of information.[30]

[28] See letter from Lowrance to Axtell, April 21, 1989, RCRA Online 11424.

[29] See for example, discussion at 80 FR 57939 and 55 FR 39410, September 27, 1990.

[30] **Note:** As stated below, the Agency reversed § 262.11(d)(1) and (d)(2) in the final rule, with paragraph (d)(1) emphasizing the types of knowledge a generator could use in making a hazardous waste determination and paragraph (d)(2) addressing test methods.

Similarly, in the proposal at § 262.11(d)(1), the Agency elaborated on the test methods generators may use to determine whether their wastes are hazardous. Included were test methods set forth in subpart C of part 261 or an equivalent method approved by the Administrator under § 260.21. The Agency, in its proposal, also stated under § 262.11(d)(2) that where a test method is specified in the regulation, the results of the regulatory test, when properly performed, are ''definitive'' for determining the regulatory status of the waste.

The Agency received numerous comments on this latter provision, with commenters expressing concerns that by stating a regulatory test, when properly performed, is ''definitive'' in determining a waste's regulatory status, EPA was also implying that use of generator knowledge was not definitive and less trustworthy as a means to make a hazardous waste determination. Several commenters went so far as to suggest the Agency, for all practical purposes, was eliminating the ability to use process knowledge for waste determinations and was requiring actual testing.

These commenters misinterpreted the proposed change. The Agency reaffirms that generators may use knowledge of their processes and of the materials used in the process, among other types of information (as described in the proposal preamble), to make a hazardous waste determination. In fact, generators can only use knowledge of their process and knowledge of the materials used in the production process to determine whether their waste meets any of the F-, K-, P- and U-waste listings.

Further, in determining whether wastes may exhibit a hazardous characteristic, EPA expects that most generators will use generator knowledge to make waste determinations, and this is appropriate provided that such knowledge results in an accurate determination. Where generator knowledge is inconclusive or uncertain, testing using the test methods described in part 261 subpart C, or equivalent methods approved by the Agency in § 260.21, will resolve any uncertainty. The results of such testing, when properly performed, are definitive because these tests are part of the regulatory definition for those parts of the hazardous characteristics that include them. The Agency is reversing the order of the proposed § 262.11(d)(1) and (d)(2) in the final regulations to clarify the roles of knowledge and testing in making hazardous waste determinations.

One commenter mentioned that while EPA has adopted the terminology ''acceptable knowledge'' in the rule from its waste analysis guidance, we have not identified what is unacceptable knowledge and we may be adding confusion to the process. While the Agency believes the term ''acceptable knowledge'' is clear, and has used it in discussing this topic in older **Federal Register** notices, and also included examples of those types of information that may assist a generator in making an accurate hazardous waste determination in the proposal preamble, the Agency also stated above that the examples provided do not comprise an inclusive list, but rather are examples. As to what the Agency would view as ''unacceptable,'' guessing is not acceptable. The Agency also views using resources that do not contain information about the process that produced the waste or the chemicals in the waste as unacceptable. It is also unacceptable for generators to simply assume their waste is non-hazardous until told otherwise by the relevant regulatory agency. In using the phrase ''acceptable knowledge'', the Agency intends that knowledge-based determinations be based on relevant and reliable (*i.e.,* verifiable) information from any source that indicates, to a greater or lesser degree, that the waste is either hazardous or non-hazardous under part 261 subpart C and D regulations, and that such information is organized or presented in a logical way that illustrates how it supports the generator's conclusions. Such determinations are inherently done on a case-by-case basis. In some cases, this may be clear and straightforward and in others more complex or uncertain, depending on the waste and the availability of reliable and relevant information. Similarly, the Agency cannot *a priori* determine how much information is ''enough'', as this too is case-specific. As discussed previously, the Agency's intent is that hazardous waste determinations, regardless of their basis, be accurate and result in appropriate management of the waste under RCRA.[31]

One commenter also suggested that the word ''applicable'' be inserted before ''methods'' in proposed § 262.11(d)(1) to read: ''The person must test the waste according to the *applicable* methods set forth in Subpart C of § Part 261 or according to an equivalent method approved by the administrator under § 260.21 and in accordance with the following . . . (emphasis added)''. The commenter argued that by adding the word ''applicable,'' this rule will make clear, for example, that if a waste is being evaluated for the toxicity characteristic, a Method 1311 test should be used, as opposed to one of the test methods that must be used to evaluate whether a waste is ignitable. The Agency agrees with this clarification and has modified the regulatory text accordingly.

d. Possible exclusions and restrictions for the waste at § 262.11(e). The Agency is moving the language that was proposed at § 262.11(g) to § 262.11(e) in the final rule. This language states that if the waste is determined to be hazardous, the generator must refer to the applicable RCRA regulations of this chapter to determine whether other possible exclusions or restrictions apply to the management of the specific waste. The Agency believes, in retrospect, that this paragraph belongs more appropriately immediately after the generator has determined whether it has generated either a listed and/or characteristically hazardous waste. As a result of this change, subsequent paragraphs in this section shift in numbering as well.

e. Recordkeeping Requirements at § 262.11(f). The Agency is finalizing, with clarifications, a number of revisions to the waste determination recordkeeping requirements proposed at § 262.11(e), but being finalized at § 262.11(f). First, we are finalizing the move of the waste determination recordkeeping requirements previously found in § 262.40(c), into § 262.11, in order to highlight the recordkeeping requirement for hazardous waste determinations. The Agency is also providing a reference in § 262.40(c) to the new regulatory location of the hazardous waste determination recordkeeping requirement in § 262.11(f) instead of deleting and reserving § 262.40(c). EPA is finalizing this change as a conforming change with the reorganization to prevent generators that are looking for recordkeeping requirements in § 262.40 to miss the other recordkeeping requirement now located in § 262.11.

Second, we are finalizing the proposed expanded language to better articulate the types of waste determination information that must be maintained as records of hazardous waste determinations made using

[31] In using knowledge of a waste to make a hazardous waste determination, the Agency would also offer the advice that generators review and account for information they may identify that may tend to refute their conclusions. A conclusion that considers and honestly weighs adverse information is much more likely to be accepted by the Agency than is a conclusion based on data carefully selected to support the conclusion and which ignores contrary information that may be more convincing.

generator knowledge and/or testing. This language includes a list of specific types of records that might be used when making a waste determination by either method. To further clarify, the Agency is incorporating into the final rule language the term ''other determinations,'' which was previously in the text in § 262.40(c). This term captures the concept that records must be kept for hazardous waste determinations made by any method.

While the Agency is aware that some states interpret the words ''other determinations'' in the existing § 262.40(c) recordkeeping requirement to include non-hazardous waste determinations, as discussed in the proposed rule, EPA has not held, and continues to not hold, the same interpretation. By adding this language back into the final hazardous waste determination recordkeeping regulatory section rather than deleting it, as proposed, it is possible that those states will maintain their more stringent interpretation.

As discussed in more detail later on, EPA is not finalizing the requirement that generators maintain records of their non-hazardous waste determinations. However, the Agency will continue to recommend that generators document their non-hazardous waste determinations as a best management practice, particularly in situations where wastes contain known hazardous chemical attributes that could be mistaken for a hazardous waste.

Third, the Agency is finalizing the time period as proposed: Waste determination records must be maintained for at least three years. EPA asked for comment on extending the time period to the life of the facility and commenters were practically unanimous in opposing the extension, responding with various reasons why extending this time period is not practical, including the existence of a statute of limitations after which no enforcement actions can be brought against a generator, and the fact that once a production process changes and a particular waste is no longer generated, those records are not needed for the life of the facility.

EPA proposed to change when the three-year clock would start for this recordkeeping requirement to the date last generated. However, we are reverting to the original § 262.40(c) language that states that three years is measured from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. The few comments on this proposed change referred to previously existing regulatory language as if the commenters did not realize we had proposed a change. The Agency has reconsidered this issue and concludes that generators will have an easier time maintaining records of when their waste was sent for disposal rather than generated. Moreover, maintaining the status quo in the original regulations eliminates the need for generators to change operating procedures.

Fourth, the Agency is deleting the sentence regarding the co-mingling of wastes proposed at § 262.11(e). With the Agency addressing the mixing of solid with hazardous wastes by generators at § 262.13(f), this statement in § 262.11 is not needed.

Fifth, a few commenters suggested that types of information not be limited to those cited in the proposed rule at § 262.11(e). The Agency believes that the language in § 262.11(e) is very broad intentionally to capture any type of information used to support a hazardous waste determination. Thus, we believe that the examples provided are not all-inclusive and this is already implicit in the regulatory text and we have not made a change.

Finally, the Agency is reaffirming in preamble that inspectors have the existing authority to require a generator to perform a waste determination during an inspection to support their finding that the waste of concern is not a hazardous waste if no documentation exists.

f. SQGs and LQGs must identify the RCRA waste codes associated with the hazardous waste. The Agency is finalizing at § 262.11(g), the requirement proposed at § 262.11(f) that all applicable EPA hazardous waste numbers (EPA hazardous waste codes) be identified, but with two clarifications: (1) This requirement only applies to SQGs and LQGs; and (2) the codes do not need to be marked on the container until the hazardous waste is being prepared for shipment off site (*i.e.* pre-transport requirements). However, SQGs and LQGs may have waste management practices in place and choose to identify the RCRA waste codes sooner than prior to shipment.

EPA is limiting this requirement in the final rule to SQGs and LQGs because VSQGs have no requirement to label or mark their hazardous waste. Without this labeling or marking requirement, the Agency believes it is unnecessary for the VSQG to identify all applicable hazardous waste codes.

Currently, there is no direct or explicit regulatory linkage between the hazardous waste identification requirements of § 262.11 and hazardous waste manifesting requirements of subpart B of part 262 where RCRA waste codes must be identified. From stakeholder discussions, the EPA understands that some states interpret the hazardous waste determination process to include identifying the waste codes. We view this requirement to simply provide the connection between what wastes are in the container and what is on the hazardous waste manifest document. The Agency believes this linkage is important to program integrity and received support from commenters.

These commenters mentioned that the proposed identification of RCRA waste codes on containers at the time of the pre-transport requirements at § 262.32 provides another level of hazard communication for regulatory inspectors and emergency responders. They also suggested that this requirement decreases overall burden for generators, transporters and TSDFs because there will be fewer instances when a generator has failed to identify its hazardous waste, and therefore fewer cases where a designated facility needs to identify the hazardous waste or send the wastes back to the generator for proper identification. Similarly, this additional marking information also provides for quicker and more confident acceptance screening at the receiving facility.

Commenters opposing this requirement raised concerns about the increase in burden and potential conflicts with DOT requirements, such as with 49 CFR 172.401. EPA disagrees that this is an increase in burden. Generators have always had to identify hazardous waste codes for the manifest and many states already require waste codes on containers. Without EPA hazardous waste codes, TSDFs may not be able to treat the waste to meet LDR requirements. In terms of potential DOT conflicts, EPA's pre-shipment marking requirements in § 262.32 (where we are finalizing the marking of hazardous waste codes on containers) are designed to be in compliance with 49 CFR 172.304 and these regulations reference that the marking must be in compliance with the DOT regulations.

Other commenters raised the concern that adding waste codes to containers managed on site does not improve a generator's ability to properly manage that waste. EPA agrees with these comments that generators treating, storing, or disposing their hazardous waste on site do not need to identify the hazardous waste codes because they should have sufficient information already about their waste to ensure they meet the proper LDR requirements.

Finally, as discussed in more detail in the marking and labeling section IX.E, EPA is finalizing the requirement in

§ 262.32 to add the waste codes to containers with the clarification that in lieu of marking their containers with EPA waste codes, generators may use a nationally recognized electronic systems such as bar coding (common industry practice) that includes the EPA waste codes. Also, EPA reaffirms that it is not changing the manifest waste code procedures. See the marking and labeling section IX.E for additional discussion.

g. Non-hazardous waste determination documentation. The Agency is not finalizing the proposed recordkeeping requirement that generators maintain documentation of their non-hazardous waste determinations. The objective of this proposed change was to foster a change in generator behavior related to their waste determination processes and procedures. By requiring such documentation, generators would need to further consider why the solid waste was not a hazardous waste and provide a rationale in writing.

Numerous organizations voiced disapproval of the Agency's proposal to require SQGs and LQGs to document their non-hazardous waste determinations. Reasons included, but were not limited to, the following themes:

(1) The Agency has no legal authority to require such documentation because the Subtitle C regulations do not regulate non-hazardous wastes;

(2) There is no compelling reason to require such documentation because generators have a very strong incentive to ensure they have accurately classified their wastes, given that failure to do so can result in significant penalties for the illegal management of hazardous waste;

(3) The Agency failed to account for generators that generate numerous waste streams every day, such as the retail sector and academic and industrial laboratories; and

(4) The rule would create so much regulatory uncertainty that the only way to protect themselves against non-compliance would be to document every waste stream generated.

Counterbalancing these arguments were comments from other organizations supportive of the non-hazardous waste determination recordkeeping requirement with the following themes:

(1) Accurate waste determinations are difficult for regulators to verify if records are not kept, particularly for unknown waste that reasonably may display the attributes of a hazardous waste but for which there is no written evaluation showing it as non-hazardous;

(2) Unknown wastes must be assumed to be hazardous and managed accordingly unless and until evaluated to be otherwise;

(3) Recordkeeping costs are overstated. Businesses spend time and effort identifying and purchasing certain materials based on their characteristics so they should already have information about the nature of these materials;

(4) Lack of documentation of waste determinations leads to confusion when knowledge is lost during staff turnover and must be re-created by the replacement staff; and

(5) Most generators already keep this information as part of best practices.

The Agency concludes that many of these arguments, both in favor of and against the proposal, have some measure of validity. However, the Agency strongly recommends that as a best management practice, generators document their non-hazardous waste determinations, particularly in situations where the waste may display the attributes of a hazardous waste and where staff turnover may cause a worker to question the contents of a container. Most importantly, when situations warrant, inspectors have the authority to ask that a hazardous waste determination be performed by the generator in the absence of any documentation and the attributes of the waste suggest a potential problem.

Several commenters questioned the Agency's authority to require such documentation of non-hazardous waste determinations because the Subtitle C regulations do not regulate non-hazardous wastes. The commenters are incorrect. The Agency has the authority under sections 3007 and 2002 of RCRA to require such records be kept, but instead has chosen not to finalize our use of such authority in this case and rather follow an alternative approach.

Specifically, RCRA section 3007 allows us to gather information about any material when we have reason to believe that it may be a solid waste and possibly a hazardous waste within the meaning of RCRA section 1004(5). A generator will not know definitively whether a waste that has potential to be hazardous is hazardous or non-hazardous unless it identifies the waste and documents that identification, even if the waste turns out to be non-hazardous. Moreover, RCRA section 2002 also gives EPA authority to issue regulations necessary to carry out the purposes of RCRA. The intent of the proposed requirement to document non-hazardous waste determinations is to provide basic information to EPA about the potentially hazardous nature of the waste that is generated (even if it is ultimately determined to be non-hazardous) in order to ensure its proper management, enable regulatory agencies to monitor compliance adequately and to ensure appropriate environmental protection.

Several commenters also questioned the need for such documentation because generators have a very strong incentive to ensure they have accurately classified their wastes, given that failure to do so can result in significant penalties for the illegal management of hazardous waste. The Agency does not disagree with this argument, but in reality, not all generators are motivated to comply, given the high rate of non-compliance with making accurate hazardous waste determinations.

Other commenters, particularly in the retail and academic and industrial laboratory sectors, stated that the Agency failed to account for organizations with numerous waste streams generated every day when proposing documentation of non-hazardous waste determinations. The Agency was aware of and did identify several sectors (including these) in the proposal where this requirement had the potential to be more challenging, given the high number of waste streams generated. Also, the Agency sought comment on how best to address this potential burden. However, the Agency is not finalizing this provision.

A few commenters also stated that most generators already keep this information because their state requires it or because they realize the importance of systematically evaluating the waste streams they generate to ensure they are managing it properly. As stated previously, the Agency supports this non-hazardous waste determination recordkeeping practice by industry and recommends it as a best management practice.

The Agency did receive a number of comments supporting the proposal to require SQGs and LQGs to document their non-hazardous waste determinations. This support bolsters the Agency's conclusion that more work is needed to ensure generators make accurate hazardous waste determinations. At this time, in lieu of requiring such documentation, the Agency is considering initiating a dialogue with industry and states to identify the root causes of this problem and identify potential solutions. Such solutions may include establishing best management processes and practices, along with the possible development of generic decision tools or other technical assistance information that can assist generators with the process of

evaluating whether the solid waste they have generated is a hazardous waste.

C. Determining Generator Category (40 CFR 262.13)

A generator must correctly count the quantity of hazardous waste that it generates in order to determine its generator category. During the development of the proposed rule, EPA determined that the extent of the counting requirements in the generator regulations at the time consisted of lists in § 261.5(c)–(d) and (h)–(j) of what materials must and must not be included when counting waste. These regulations did not address other counting considerations. EPA therefore proposed a new § 262.13 to describe how a generator determines its generator category, containing the previously existing language in § 261.5(c)–(d) as well as some specific steps to calculate an amount that includes the correct amounts of hazardous waste.

Elsewhere in the proposed rule, EPA proposed regulatory language for each of the categories of generators describing how the rules regarding mixing from § 261.5(h)–(j) would impact their generator categories and how to count mixtures of hazardous waste and solid waste. EPA is consolidating the discussion of counting hazardous waste from all these areas of the proposed rule into § 262.13 for the final rule in order to make these requirements easily understandable by the regulated community and thus improve compliance and consistency.

1. Counting Hazardous Waste

a. Introduction. The purpose of proposed § 262.13 was to lay out the framework for making a generator category determination in paragraph (a) and to stress that the generator's category can change from month to month. The proposed regulation set forth procedures to determine whether a generator is a VSQG, an SQG, or an LQG for a particular month, as defined in § 260.10. As EPA discussed in the proposed rule, the regulations in § 262.13 do not constitute a new requirement for generators, but in the regulations up to this point, the counting requirements have not been presented in a clear and succinct manner.

b. What is EPA finalizing? EPA is finalizing a new § 262.13 to address how to make a generator category determination. It includes the language discussed in this section on counting as well as the mixing requirements discussed later in this chapter of the preamble. The addition of the definitions of generator categories to § 260.10 and this paragraph on how to make a generator category determination provide specific instructions on this matter for the regulated community and thereby improve compliance with the generator regulations.

The introductory language of § 262.13 states that a generator must determine its generator category and that the category is based on the amount of hazardous waste that is generated in a calendar month. This requirement for a generator category to be based on a monthly generation amount is derived from the RCRA statute and is critical to the framework of the generator regulations.[32] The regulations also state that a generator's category can change from month to month. Although many generators change categories several times a year, depending on various factors such as inputs, demand, processing volume, and production, EPA knows many generators choose to operate as LQGs all the time to simplify their regulatory compliance. EPA encourages this practice, but notes in the regulations that actual generator category can change month to month.

In addition, EPA notes that a VSQG or an SQG that generates more hazardous waste in a particular calendar month than allowed in its generator category must make a determination that it now meets the higher generator category (if it is not covered by the episodic generation provisions discussed in section X of this preamble).

Paragraph (a) of § 262.13 presents basic procedures for counting hazardous waste generated in the calendar month, subtracting or excluding anything that is exempt and using the difference to determine the generator category. Paragraph (b) of § 262.13 specifically addresses the situation in which a generator generates any combination of non-acute hazardous waste, acute hazardous waste, and the residues from the cleanup of a spill of acute hazardous waste. This paragraph presents a series of steps for a generator to follow when determining its generator category to ensure it selects the appropriate category for the total amount and types of hazardous waste generated.

Sections 262.13(c) and (d) are existing provisions that EPA is moving from § 261.5(c) and (d) of the existing regulations with a few small wording changes to reinforce that category determinations are made monthly and do not otherwise represent a change in the generator regulations.

Section 262.13(e) completes the main process of counting by stating that based on the generator category that is determined under the steps laid out in the section, the generator should determine which of the sets of generator provisions apply to it.

c. What changed since proposal? EPA made several changes to § 262.13(a)–(e) in response to the comments received on the proposed rule. First, several commenters pointed out that this section tailors its procedures for generators that generator acute and non-acute hazardous waste in the same month, but does not directly address generators that generator only acute hazardous waste or non-acute hazardous waste. EPA agrees with this comment and, therefore, converted the proposed paragraph (a) to introductory language for the section and made a new § 262.13(a) that addresses those generators that generate only acute or non-acute hazardous waste. This section includes a simplified version of the same procedures in paragraph (b) for those without both types of hazardous waste.

Commenters also noted that although EPA included a Table 1 to § 262.13 in the regulations, the table was not referenced in the regulations. EPA therefore added references to Table 1 in the regulatory text in paragraphs (a) and (b). Also, in Table 1 in this section, we are deleting the first column of numbers that denoted which generation scenario was being represented by each row. This column was potentially useful in the preamble discussion, but served no purpose in the regulations and has been removed.

In addition, several commenters stated that although a generator's category is based on the amount of hazardous waste it generates in a calendar month, every generator need not make an exact category determination every month. The commenters argued that many generators have a very accurate sense of what category they are month-to-month because their processes generate consistent amounts of hazardous waste over time. Only those generators with generation amounts near the limit would have to count regularly to make the category determination. These commenters stated that many generators with categories that fluctuate from month-to-month choose to operate as LQGs full time and would, therefore, not need to count every month to determine generator category.

EPA agrees with the commenters and therefore has made revisions to the introductory language for the section to state that a generator is required to determine its generator category. The language continues to stress that a category is based on monthly generation

[32] RCRA 3001(d).

and may change from month to month, but generators are not required to follow the included steps every month. EPA notes, however, that an LQG must keep track of its amounts of hazardous waste for the purpose of completing the Biennial Report, when applicable.

Finally, EPA added the language in § 262.13(e) upon determining that although the purpose of the section is to lead the generator through counting its hazardous waste for the purpose of determining the correct generator category, the proposed regulations did not include the final step in the process.

Effect of the Reorganization: This section is partially affected by the reorganization. Some of the language in § 262.13 on what materials to count when determining generator category moved from previous § 261.5, but much of this regulation is new text. Section VI of this preamble discusses the reorganization.

2. Mixtures of Non-Hazardous Waste and Hazardous Waste

a. *Introduction.* In an effort to explain how mixtures of non-hazardous waste (solid waste) and hazardous waste affect generator category determinations, the Agency proposed a series of modifications in §§ 262.14, 262.16 and 262.17 for VSQGs, SQGs and LQGs, respectively. The proposed rule also discussed how SQGs and LQGs are subject to the mixture rules in § 261.3. As explained in the preamble to the proposed rule on page 57928, this clarification was also designed to clarify the language that was found at §§ 261.5(h) and (i) which addressed the mixing of hazardous waste and non-hazardous waste by a VSQG and the implications to its generator category if the mixture is determined to be a hazardous waste. The language specifically addressed how the regulations apply when VSQG hazardous waste is mixed with non-hazardous solid waste and the resulting combination exceeds the VSQG quantity limits.

b. *What is EPA finalizing?* The Agency is finalizing the regulations applicable to generators mixing hazardous waste with solid waste as follows:

1. Moving the proposed relevant provisions of §§ 262.14(b), 262.16(d) and 262.17(f) applicable to mixtures of hazardous waste and solid waste to § 262.13(f). The act of mixing a solid waste and a hazardous waste is not the same as a generator accumulating hazardous waste, nor is the act of mixing in any way related to the conditions for exemption from permitting. The purpose of moving the requirements for mixtures to § 262.13 is to make generators aware of the regulations applicable to mixtures of hazardous waste and solid waste, and to accurately explain how the mixing of a hazardous waste with a solid waste may affect a generator's category determination for the calendar month.

2. Clarifying that a VSQG mixing hazardous waste with solid waste can remain subject to § 262.14, even though the mixture may exceed the VSQG quantity limits (either 100 kg per month generated or 1,000 kg accumulated on site at any one time) unless the mixture exhibits one or more of the characteristics of a hazardous waste. If the resultant mixture exhibits a hazardous waste characteristic, the VSQG must add the quantity from the resulting mixture with any other regulated hazardous waste generated in the calendar month and determine whether the total quantity generated exceeds the generator calendar month quantity identified in the definition of generator categories found in 40 CFR 260.10.

3. For both SQGs and LQGs:

a. Reemphasizing that both the hazardous waste portion of the resulting mixture and other amounts of hazardous waste generated in a calendar month must be counted towards a generator's category determination.

b. Making SQGs and LQGs aware of the § 268.3(a) prohibition of impermissible dilution of a hazardous waste with a solid waste to decharacterize the hazardous waste. The regulation at 40 CFR 268.3(a) states, ''. . . no generator, transporter, handler, or owner or operator of a treatment, storage, or disposal facility shall in any way dilute a restricted waste or the residual from treatment of a restricted waste as a *substitute for adequate treatment to achieve compliance* (emphasis added) with Subpart D of this part . . .'' In particular, if a solid waste is mixed with a characteristic hazardous waste, the solid waste must provide a useful and effective contribution to de-characterizing the hazardous waste (*i.e.* possess a unique property to remove the hazardous characteristic from the hazardous waste instead of merely diluting it).

c. Stating that SQGs and LQGs are subject to the regulations applicable to mixtures found in § 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i).

d. Stating that SQGs or LQGs that mix a characteristic hazardous waste with a solid waste to remove any hazardous characteristics are subject to the treatment standards found at § 268.40, as well as the ''impermissible dilution'' requirements in § 268.3.[33]

4. For all generators, reminding them they must make a hazardous waste determination at § 262.11 when mixing a hazardous waste with a solid waste.

c. What changed since proposal? As discussed previously, the Agency made a significant number of clarifying changes in the final rule for this provision based on review and evaluation of comments. These include the following: Moving the relevant proposed provisions of §§ 262.14, 262.16 and 262.17 applicable to mixtures of hazardous waste and solid waste to § 262.13 (f); stating that SQGs and LQGs are subject to the mixture rule found in §§ 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i); stating that SQGs and LQGs must comply with § 268.3(a), which prohibit's impermissible dilution to avoid regulation; for all generators, stating that both the hazardous waste portion generated from mixing and the hazardous waste generated in a calendar month must be counted for establishing the generator category for that month; and stating that all generators must make a hazardous waste determination for their mixed waste.

d. Major comments. Many commenters supported the proposed changes to include the application of the mixture rules in a generator's regulatory category determination. Others, however, requested greater clarity and specificity regarding these regulatory provisions. They asked for an explanation of the parameters allowed when mixing a solid waste and a hazardous waste. They also asked for clarification about when an SQG or LQG that mixes a characteristic hazardous waste with a solid waste and generates a mixture that no longer exhibits the hazardous characteristic must also meet the treatment standards found at § 268.40, and a clarification that a hazardous waste determination is also required for wastes resulting from mixing of solid waste and hazardous waste. EPA made adjustments to § 262.13(f) in response to these comments where appropriate.

One commenter pointed out that the applicable regulations for mixtures are unrelated to the conditions for an exemption from operating without a permit and therefore, the requirements applicable to mixtures do not belong under §§ 262.14, 262.16, and 262.17. The Agency agrees these are valid

[33] Also see EPA document, Land Disposal Restrictions: Summary of Requirements, U.S. EPA Office of Solid Waste and Emergency Response and Office of Enforcement and Compliance Assurance, EPA–530–R–01–007, Revised August 2001.

comments and has incorporated these changes as already described.

Effect of the Reorganization: This section is affected by the reorganization. The mixing provisions for VSQGs that are now found in § 262.13 were previously located in § 261.5(i) and (h). The reorganization is discussed in section VI of this preamble.

D. Very Small Quantity Generator Conditions for Exemption (40 CFR 262.14)

The regulations for VSQGs have moved, with some changes, from their previous location in § 261.5 to § 262.14 as part of the reorganization of the generator regulations. Although there are some changes to these regulations, they were mainly relocated from one part to the other. Please see section VI of this preamble for a discussion of the reorganization and for an overview of the new § 262.14.

E. Marking and Labeling and Hazardous Waste Numbers (40 CFR 262.15(a)(5), 262.16(b)(6), 262.17(a)(5), 262.32(b)–(d), 263.12(b) and 268.50(a)(2)(i)

This section discusses the final rules associated with the marking and labeling of hazardous waste accumulated on site by SQGs and LQGs in containers and tanks. This section also addresses the marking and labeling requirements for (1) hazardous waste transporters that store containers of hazardous waste at transfer facilities (see 40 CFR 263.12) and (2) TSDFs that store containers of hazardous waste under the storage prohibition of the land disposal restriction requirements at 40 CFR 268.50(a)(2)(i). Lastly, in this section, we discuss the application of EPA hazardous waste codes to containers prior to shipment off site to a designated facility.

The regulatory changes EPA proposed to the marking and labeling for waste accumulation units are designed to enhance three critical areas: Risk communication, emergency preparedness and prevention, and the accuracy of hazardous waste determinations. Although labeling may appear to be an inconsequential ''paperwork'' exercise, it is, in fact, vitally important to ensuring that waste is identified and managed properly. Without proper labeling, hazardous waste may be mismanaged as non-hazardous waste, or as the wrong type of hazardous waste, which could cause harm to human health and the environment. As one commenter stated, ''The department appreciates the opportunity to revisit this important topic, as we believe [it] is of critical importance in both the prevention of releases and in ensuring that, in the event of a release, the response to the incident is appropriate for the materials being stored.'' [34] Accordingly, EPA proposed to strengthen the marking and labeling for containers and tanks throughout the cradle to grave management chain, including for SAAs, SQGs, LQGs, VSQGs that send their hazardous waste to LQGs under the same control, episodic generators, transfer facilities, and TSDFs. The Agency proposed consistent changes for marking and labeling throughout the regulations, and many of the comments we received on the topic marking and labeling are relevant throughout, so the primary discussion of those changes will be in this section. In certain instances, specific aspects of the marking and labeling requirements are addressed in other sections of this preamble, such as with VSQGs that send their hazardous waste to LQGs under the same control, episodic generators, and SQGs and LQGs that accumulate on drip pads and in containment buildings.

1. Marking and Labeling for SQGs and LQGs With Containers in SAAs (40 CFR 262.15(a)(5))

a. Introduction. The previous regulations for SAAs in § 262.34(c)(1)(ii) required an SQG or LQG to mark its SAA containers ''either with the words 'Hazardous Waste' *or* with other words that identify the contents of the containers'' [emphasis added]. The Agency proposed two modifications to strengthen the labeling and marking regulations for containers accumulating hazardous waste in SAAs. First, EPA proposed to change the ''or'' to an ''and'' and thus require that generators mark containers in the SAA with both the words ''Hazardous Waste'' and ''other words to identify the contents of the container.'' Although the words ''Hazardous Waste'' are important to convey that the container contains a waste, as opposed to a product, and that a hazardous waste determination has been made for the contents, it does not convey more practical information regarding the contents of the container that workers must be familiar with for purposes of on-site handling.

Second, while the words ''Hazardous Waste'' on containers provide some measure of information regarding the contents, this information fails to describe the specific hazards of the contents and what risk these wastes could pose to human health and the environment. EPA believes it is important that employees, transporters, downstream handlers, emergency personnel, and EPA and state inspectors know as much as possible about the potential hazards of the contents in containers being accumulated, transported, and managed, whether on site and/or off site, so that the hazardous wastes are managed in an environmentally sound manner. Therefore, EPA proposed that SQGs and LQGs must indicate the hazards of the contents of the containers while giving them flexibility in how to comply with this new provision. That is, we proposed that generators could indicate the hazards of the contents of the container using any of several established methods, including, but not limited to an EPA hazardous waste characteristic(s) (ignitable, corrosive, reactive or toxic); a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200; a chemical hazard label consistent with NFPA code 704; or a hazard pictogram consistent with the United Nations' Global Harmonized System (GHS). We also proposed that generators could also use any other marking or labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers.

These proposed changes were designed to alert workers, emergency responders, and others to the potential hazards posed by the contents of a container. Identifying the hazard increases awareness to workers and others who might come into contact with the hazardous waste container and reduces potential risks to human health and the environment from container mismanagement. EPA reasoned that the pre-transport requirements of part 262 subpart C already require hazardous waste generators to comply with the DOT labeling/marking requirements of 49 CFR part 172. By requiring generators to include information on container labels while *on site,* the Agency proposed that generators perform a task that is already required when preparing the container prior to transporting the hazardous waste *off site* for subsequent waste management. Because, in most cases the hazardous waste will be shipped off site and thus be subject to DOT regulations, we proposed that SQGs and LQGs could use the DOT hazard class labels to comply with the new labeling and marking regulation for containers in SAAs. However, we proposed several alternatives to using DOT hazard labels (as noted previously)

[34] Missouri Department of Natural Resources, EPA–HQ–RCRA–2012–0121–0223.

from which generators could choose to indicate the hazards of the container.

In summary, EPA proposed to modify the marking and labeling regulations for SAAs to require SQGs and LQGs to mark containers with the following: (1) The words ''Hazardous Waste''; (2) other words that identify the contents of the containers (examples which may include, but are not limited to the name of the chemical(s), such as ''acetone'' or ''methylene dichloride,'' or the type or class of chemical, such as ''organic solvents'' or ''halogenated organic solvents'' or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D); and (3) an indication of the hazards of the contents of the container. Examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200; a chemical hazard label consistent with the NFPA code 704; or a hazard pictogram consistent with the United Nations' GHS. EPA also proposed that SQGs and LQGs could use any other marking and labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers. EPA did not propose to change the existing requirement for when the SAA maximum accumulation volumes are exceeded, to ''mark the container holding the excess accumulation of hazardous waste with the date the excess amount began accumulating'' (40 CFR 262.34(c)(2)).

b. What is EPA finalizing for the marking and labeling of containers in SAAs? The final regulations for marking and labeling of containers in SAAs require SQGs and LQGs to mark containers with the following: (1) The words ''Hazardous Waste''; and (2) an indication of the hazards of the contents of the container including, but not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the NFPA code 704).

c. What changed since proposal? The Agency received a large number of comments regarding the marking and labeling changes throughout the proposed rule. In response to comments, we have simplified the proposed marking and labeling for containers in SAAs by eliminating the requirement that SQGs and LQGs mark their containers with words that identify the contents of their containers. Commenters argued, and EPA agrees, that a requirement to identify the contents of a container could be subject to much interpretation and problems with implementation and compliance could emerge. One commenter suggested that EPA's regulations should not interfere with a practice that is often already done as a best management practice.[35] Another commenter suggested that we allow generators to choose between identifying the contents of the container and identifying the hazards of the contents.[36] EPA considered this option, but concluded the potential for interpretation and implementation problems would remain for those generators that chose the option of identifying the contents of the container and, therefore, decided against this approach. Nevertheless, while the Agency is not finalizing the requirement that generators identify the contents of their containers, we not only encourage, but would expect, that generators would identify the contents of hazardous waste in their containers considering both the operational and potential downstream regulatory problems that would likely emerge if the contents were not identified. As one commenter noted, ''it is a best management practice for generators to know the nature of the wastes they generate and accumulate, as well as for emergency responders to know the nature of the wastes they may encounter.'' [37] One other minor change is that we removed the mention of the United Nations Globally Harmonized System (GHS) as a means of identifying the hazards of the contents of the container. Now that OSHA has aligned its regulations with the GHS, it is no longer necessary to identify the GHS separately.

d. Major comments. While some commenters supported our proposed marking/labeling regulations, many other commenters objected to the burden imposed by the additional marking/labeling requirements. Commenters questioned the benefits and the practicality of the proposed requirements, although one commenter noted it had similar marking and labeling procedures in place for over twenty years and they worked very well.[38] Several commenters, particularly emergency responders, expressed a preference for identifying the hazards of the contents over identifying the contents in the container. In large part, this expressed preference helped EPA decide to retain the requirement to identify the hazards of the contents and eliminate the requirement to identify the contents of the container.

Some commenters had the misperception that we are requiring the use of DOT hazard class labels on containers during on-site accumulation. In actuality, the Agency is providing flexibility to generators in how they identify the hazards of the hazardous waste in the container, and using DOT hazard communication such as hazard class labels (or placards, if appropriate) is one option for complying with this requirement. In fact, one commenter supported EPA's approach of ''giving generators options to accomplish this strengthened communication.'' [39] However, as a matter of practicality, it would benefit many generators to consider the use of DOT hazard communication, since such a method would not only satisfy EPA's requirement, but it may also satisfy DOT requirements when the wastes are shipped off site to a RCRA-designated facility, such as an interim status or permitted TSDF. It is important to note that if generators choose to identify the hazards of the contents of their containers using the DOT, OSHA or NFPA labeling methods, those methods must be used appropriately. Furthermore, if a method other than DOT hazard communication is used while the waste is accumulating on site, when the waste is shipped off site, generators and transporters must ensure that those markings and labels are located away from and do not obscure DOT marking and labeling.[40]

A number of commenters also had the misperception that the requirement for identifying the hazards of the contents is duplicative with OSHA requirements and/or DOT requirements. On the contrary, EPA notes that the marking

[35] Colorado Department of Public Health and Environment (CDPHE), EPA–HQ–RCRA–2012–0121–0085.

[36] Department of Energy, EPA–HQ–RCRA–2012–0121–0123.

[37] Savannah River Site, EPA–HQ–RCRA–2012–0121–0092.

[38] Savannah River Site, EPA–HQ–RCRA–2012–0121–0092.

[39] Institute of Makers of Explosives, EPA–HQ–RCRA–2012–0121–0126.

[40] See 49 CFR 172.304(a)(4) which requires DOT markings to be ''located away from any other marking (such as advertising) that could substantially reduce its effectiveness. Also see 49 CFR 172.406(f) which states that a ''label must be clearly visible and may not be obscured by markings or attachments.

and labeling of containers is not duplicative of other regulations: OSHA Hazard Communication does not apply to hazardous waste (See 29 CFR 1900.1200(b)(6)(i)) and DOT requirements only apply during transportation. In fact, under the RCRA rules being finalized in this rulemaking, the Agency believes it is closing a loophole for hazard communication for hazardous wastes accumulated on site.

On a separate but related matter, one commenter reminded EPA that OSHA has new regulations for hazard communication that align with the GHS system and that the regulated community needs to adjust to these before RCRA changes are adopted.[41] OSHA's transition to the GHS regulations have been phased in over time, with June 1, 2016, as the final phase-in date. These RCRA final regulations will not be effective in most states until the authorized state adopts the revised regulations, and therefore, most generators will have ample time to plan for these RCRA marking and labeling changes before they become effective. Furthermore, generators may choose to use the OSHA/GHS system for identifying the hazards of the contents of their containers and thereby reduce the burden of learning additional marking/labeling mechanisms. It is important to note, however, that EPA is requiring only that the hazards of the contents are identified. And although generators may use the OSHA/GHS system to comply with this provision, we are not requiring full OSHA/GHS compliant marking and labeling for hazardous wastes. For our purposes, an OSHA/GHS hazard statement or pictogram would be sufficient.

Finally, commenters asked EPA to clarify several aspects of the container marking and labeling requirements. First, one commenter asked us to specify that the labeling should occur at the initial point of generation.[42] We concur with this commenter that the marking and labeling requirements apply at the point of generation of the hazardous waste which is both the time and place where the hazardous waste is initially generated. Second, in keeping with existing EPA guidance, generators would be able to continue to mark outer/secondary containers, such as labpacks, color-coded bins, etc. with the words ''Hazardous Waste'' and the hazards of the hazardous waste instead of marking a small container (*e.g.,* tubes, vials, etc.) that is placed inside the secondary container.[43] Alternatively, as one commenter suggested, generators using small containers may attach a tag to a container to comply with the marking and labeling requirements.[44] Third, if a hazardous waste is in a container that already has the appropriate marking and labeling (*e.g.,* the hazardous waste is an unused commercial chemical product that is in its original container with an intact label), the existing marking and labeling would be sufficient. The generator would not need to duplicate the marking and labeling, assuming the original label contains the information necessary to comply with the marking and labeling requirements.

2. Marking and Labeling for SQGs and LQGs With Containers in CAAs (40 CFR 262.16(b)(6) and 262.17(a)(5))

a. Introduction. The previous LQG and SQG regulations in § 262.34(a)(3) and § 262.34(d)(4), respectively, required each container to be labeled or marked clearly with the words, ''Hazardous Waste.'' The Agency proposed two modifications to strengthen the labeling and marking for SQGs and LQGs accumulating hazardous waste in containers. In order to provide continuity and consistency, these changes were similar to those proposed for containers in satellite accumulation areas (see section IX.E.1.) First, the Agency proposed that SQGs and LQGs accumulating hazardous waste in containers mark them with the words ''Hazardous Waste.'' Second, EPA proposed that SQGs and LQGs mark or label their containers in CAAs with ''other words that identify the contents of the containers.'' Third, we proposed that SQGs and LQGs mark and label their containers with an indication of the hazards of the contents. EPA stated that this approach would establish consistency between the marking and labeling practices of hazardous wastes accumulated in containers in SAAs and CAAs, and thereby allowing some degree of business efficiency as containers are moved from SAAs into CAAs. We did not propose to change the existing provision that requires SQGs and LQGs to mark clearly and visibly the date accumulation began on each container and make that marking visible for inspection.

b. What is EPA finalizing? The Agency is finalizing the following marking and labeling provisions for SQGs and LQGs accumulating hazardous wastes in containers located in CAAs. SQGs and LQGs accumulating hazardous waste in containers must mark their containers with the words ''Hazardous Waste.'' SQGs and LQGs also must mark and label their containers with an indication of the hazards of the contents of the containers. Examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the NFPA code 704. Also, as discussed in section IX.E.7, SQGs and LQGs are required to mark their containers with the applicable EPA hazardous waste number(s) prior to shipping their containers off site to a RCRA-permitted TSDF.

The marking and labeling requirements for containers in CAAs are consistent and identical to the marking and labeling requirements for hazardous wastes accumulated in containers located in SAAs. For the reasons cited under the SAA discussion (*i.e.,* simplifying requirements, avoiding implementation problems, responding to commenter concerns), EPA is finalizing the same marking and labeling requirements for hazardous wastes accumulated in containers located in CAAs and SAAs. The only difference is that SQGs and LQGs must mark or label containers in SAAs with the date that maximum volumes (or mass) are exceeded, while SQGs and LQGs must mark or label containers in CAAs with the date the hazardous waste first began accumulating. Both of these dating requirements are existing requirements that remain unaffected by this final rule.

c. What changed since proposal? For the same reasons discussed under section IX.E.1, the Agency is not finalizing the requirement for SQGs and LQGs with CAAs to mark or label their containers with ''other words that identify the contents of the container.''

3. Marking and Labeling for SQGs and LQGs With Tanks in CAAs (40 CFR 262.16(b)(6)(ii) and 262.17(a)(5)(ii))

a. Introduction. The Agency also proposed a number of changes to improve the marking and labeling of hazardous wastes accumulated in tanks by both SQGs and LQGs at § 262.16(b)(6)(ii) and § 262.17(a)(5)(ii),

[41] Tennessee Chamber of Commerce & Industry, EPA–HQ–RCRA–2012–0121–0225.

[42] Tennessee Department of Environment and Conservation, EPA–HQ–RCRA–2012–0121–0116.

[43] See Robert Springer, Director of Office of Solid Waste to RCRA Directors, Regions 1–10, Frequently Asked Questions About Satellite Accumulation Areas, March 17, 2004.

[44] Carl Severn, EPA–HQ–RCRA–2012–0121–0079.

respectively. Specifically, the Agency proposed that SQGs and LQGs: (1) Mark or label their tanks with the words ''Hazardous Waste''; (2) use inventory logs, monitoring equipment, or records to identify the contents of the tank and its associated hazards; (3) use inventory logs, monitoring equipment or records to identify the date each period of accumulation begins; and (4) keep inventory logs or records with the above information in close proximity to the tank.

b. What is EPA finalizing? EPA is finalizing the following marking and labeling requirements for SQGs and LQGs accumulating hazardous waste in tanks: (1) While hazardous wastes are being accumulated on site, SQGs and LQGs must mark their tanks with the words ''Hazardous Waste''; (2) consistent with the revised requirements for the marking and labeling of containers, SQGs and LQGs must mark or label their tanks with an indication of the hazards of the contents. Examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the NFPA code 704); (3) use inventory logs, monitoring equipment, or other records to demonstrate that hazardous waste has been emptied within 180 days for SQGs (or 90 days for LQGs) of first entering the tank if using a batch process, or in the case of a tank with a continuous flow process, demonstrate that estimated volumes of hazardous waste entering the tank daily exit the tank within 180 days for SQGs (or 90 days for LQGs) of first entering; and (4) keep inventory logs or records with the above information on site and readily available for inspections.

c. What changed since proposal? Three changes were made between the proposed rule and the final rule. First, consistent with the changes to container marking and labeling, SQGs and LQGs are not required to identify the contents of their tanks, although we strongly recommend generators maintain records identifying the contents of the tanks as a best management practice. Second, we have modified where inventory logs or records for tanks must be kept. We had proposed that the information must be in close proximity to the tank. Commenters indicated that having records in close proximity may not always be practical or even desirable. For instance, some hazardous waste accumulation tanks are outside and having records in close proximity would mean that the records would be exposed to the elements. In response to comments, we have modified the regulations so that the records must be kept on site and readily available for inspections. Ideally these records will be in close proximity to where hazardous waste is being accumulated in the tank, or if not practical (*i.e.,* exposure to weather, physically infeasible, etc.) in a control room, or other central location at the facility.

Third, the Agency changed the dating requirement for tanks at SQGs and LQGs so that instead of using logs, monitoring equipment or records to identify when the 180- or 90-day accumulation period begins, generators must use logs, monitoring equipment or other records to demonstrate that hazardous waste is either emptied or removed from the tank within 180 or 90 days, with the final regulations now addressing both batch and continuous flow processes. While the Agency discussed both types of processes in the preamble to the proposed rule, the regulatory text in the proposed rule failed to address continuous flow processes. SQGs and LQGs with batch process tanks must demonstrate that their tanks are emptied every 180 or 90 days, respectively. However, the Agency recognizes that when hazardous waste is accumulated in tanks with continuous flow processes it may not be possible for SQGs and LQGs to demonstrate that a tank is emptied every 180 or 90 days, respectively, from when the hazardous waste first entered the tank. Therefore, generators with tanks with a continuous flow process have flexibility in how to demonstrate that hazardous waste has been turned over (as opposed to emptied) in a tank. For a continuous flow process, this demonstration involves a generator identifying the estimated daily input or inflow of hazardous wastes into the tank, the estimated outflow from the tank, and the capacity of the tank to estimate how many days the hazardous waste will reside in the tank before exiting.

As an example, if a tank with a continuous flow process has a capacity of 10,000 gallons, an inflow of hazardous wastes of 1,000 gallons per day and an outflow estimated at 500 gallons per day, then the expected residence time of the hazardous waste in the tank would be 20 days. The residence time would be calculated by first subtracting the daily outflow from the daily inflow (1,000 − 500 = 500). Then the tank capacity would be divided by the difference between the outflow and the inflow (10,000/500 = 20). The resulting residence time is 20 days.

d. Major comments. Commenters were supportive of the proposed changes for marking and labeling of tanks with the words ''Hazardous Waste'' and maintaining records that prove the amount of time hazardous waste remained in the tank did not exceed either 90 or 180 days for LQGs and SQGs, respectively. One commenter mentioned, and EPA agrees, that the markings must be visible and legible to a person observing the tank. Another commenter supported the options we proposed for indicating the hazards of tanks, noting that it will help generators be able to choose the method that work best for their facility. Several commenters were supportive of the flexibility provided to generators to prove the amount of time hazardous waste remained in the tank (*e.g.,* inventory logs, monitoring equipment, or records). EPA notes that generators may use paper or electronic records, provided they are on site and readily available for inspection. Several commenters expressed concern that EPA did not explicitly discuss tanks with continuous flow processes in the proposed regulatory text (though they are discussed in the preamble to the proposed rule). As discussed previously, the Agency has revised the regulatory text of the final rule to explicitly address these comments.

4. Marking and Labeling for SQGs and LQGs With Drip Pads and Containment Buildings

In the proposed rule, the Agency proposed marking and labeling requirements for generators accumulating hazardous waste on drip pads and in containment buildings. Upon review of comments and further evaluation, the Agency now believes the marking and labeling provisions for these type of units belongs more appropriately under the discussion of the waste accumulation regulations for these types of units. Therefore, for further discussion, the Agency directs the reader to section IX.G.—Accumulation of Hazardous Waste by SQGs and LQGs on Drip Pads and in Containment Buildings.

5. Marking and Labeling for Transfer Facilities (40 CFR 263.12(b))

a. Introduction. The Agency proposed to change the marking and labeling requirements for transporters handling hazardous waste in containers at transfer facilities, found at § 263.12(b), to be consistent with the proposed

changes for marking and labeling for containers for SQGs, for LQGs, and in SAAs. More specifically, EPA proposed that transporters storing hazardous wastes in containers at transfer facilities mark the containers with the following: (1) The words ''Hazardous Waste''; (2) other words that identify the contents of the containers, with examples that may include, but are not limited, the name of the chemical(s), or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; and (3) an indication of the hazards of the contents of the container. In addition to these proposed changes, EPA also proposed to require that containers of hazardous waste at transfer facilities be labeled with the applicable EPA hazardous waste number(s) (EPA hazardous waste codes), which would help the TSDF receiving the hazardous waste comply with the LDR regulations in 40 CFR part 268.

The Agency proposed these modifications to ensure hazardous wastes are appropriately labeled and marked throughout its cradle-to-grave management, including transportation to a RCRA-permitted or interim status TSDF or to another transfer facility. Similarly, this additional information on the container would alert workers and other handlers to the contents of the container and the potential hazards of the materials therein.

In proposing these changes, the Agency believed that, in almost all cases, containers received by the transfer facility would already be marked and labeled by the generator, and therefore, any additional burden on the transfer facility would be minimal. However, in the preamble to the proposed rule, the Agency identified other situations where a transporter would be required to initiate the marking and labeling of a container; *e.g.,* when the transporter consolidates two containers with the same hazardous waste into a new container or when it is able to combine and consolidate two different hazardous wastes that are compatible with each other and are able to be subsequently managed consistently in compliance with the applicable regulations in parts 264, 265, 267, 268 and 270 of this chapter.

b. What is EPA finalizing? The Agency is requiring that transporters must mark or label containers with the words ''Hazardous Waste'' when they consolidate the contents of two or more containers with the same hazardous waste into a new container, or when the transporter consolidates hazardous wastes that are compatible with each other. As discussed in section IX.E.7, when such consolidation occurs, the transporter will also be required to mark or label the container with the applicable RCRA waste codes, in compliance with § 262.32(b) or (c).

c. What changed since proposal? First, consistent with the marking and labeling requirements being finalized in several sections of this rule, transporters are not required to mark or label the container with its contents. However, the Agency expects that transporters, as well as generators, will identify the contents of the container as a best management practice. Second, as discussed elsewhere, in cases where a transporter must mark its containers with the applicable EPA hazardous waste codes, they will have flexibility in how they comply. Third, because containers at transfer facilities are, by definition, in transport, DOT marking and labeling apply to them. As a result, we have removed the proposed requirement to identify the hazards of the container, since it would be duplicative of (and possibly even contradictory to) the DOT requirements. Fourth, consistent with the pre-transport requirements for SQGs and LQGs in § 262.32, the Agency is clarifying that the marking and labeling applies to transporters using containers of 119 gallons or less (*i.e.,* what DOT refers to as non-bulk packaging).

d. Major comments. Comments both supported and opposed this provision. Critical comments questioned the need for this provision because generators are responsible for the marking and labeling of containers that subsequently arrive at transfer facilities. Similarly, more than one commenter questioned the need for transporters to mark containers with the applicable EPA hazardous waste codes and discussed the problems requiring this information would cause to the waste management industry since they have well-established waste profile systems that accomplish that function. One commenter also was critical of the manner in which the regulatory text was written whereby the Agency made it the responsibility of the transporter to ensure all marking and labeling information is correct. Another commenter pointed out that as per DOT regulations, rail cars used to accumulate and transport hazardous waste and other bulk shipments do not have to be labeled ''Hazardous Waste'' in transit. As discussed in an earlier section, the Agency took these comments into account when finalizing this rule.

6. Marking and Labeling for TSDFs With Containers and Tanks (40 CFR 268.50(a)(2)(i))

a. Introduction. As part of its effort to improve risk communication with respect to the management of hazardous waste, the Agency also proposed changing the regulations for marking and labeling containers at TSDFs in § 268.50(a)(2)(i)—consistent with the proposed marking and labeling changes for SAAs, SQGs, LQGs, and for transfer facilities. More specifically, EPA proposed that TSDFs storing hazardous wastes in containers mark their containers with the following: (1) The words ''Hazardous Waste''; (2) other words that identify the contents of the containers, with examples that may include, but are not limited, the name of the chemical(s), or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; and (3) an indication of the hazards of the contents of the container. The Agency also proposed that containers must be labeled with the applicable EPA hazardous waste number(s) (EPA hazardous waste codes), which help the TSDF comply with the applicable land disposal restriction (LDR) regulations. The LDR regulations list many of the treatment standards based on the hazardous waste code. In the proposal, the Agency left unchanged the pre-existing provisions of § 268.50(a)(2)(i), which require TSDFs to clearly mark each container to identify its contents and the date each period of accumulation begins.

b. What is EPA finalizing? The Agency is finalizing the requirement for TSDFs to mark or label containers of hazardous waste with the words ''Hazardous Waste,'' an indication of the hazards of the contents, and the applicable EPA hazardous waste numbers (waste codes) consistent with § 262.32(b)–(d). As with transfer facilities, EPA expects almost all incoming containers received by a TSDF will already have the appropriate marking and labeling information and, therefore, that a TSDF will usually only need to mark or label a container themselves when receiving shipments from facilities that are neither SQGs nor LQGs. As an example, TSDFs may receive hazardous wastes directly from VSQGs. Under the federal program, VSQGs are not required to mark and label their containers ''Hazardous Wastes'' and identify the hazards associated with the wastes in the container. In this situation, the TSDF must mark or label the container with the words ''Hazardous Waste,'' the

applicable hazardous waste codes, and identify the hazards of the container. Additionally, consistent with the pre-existing regulations at § 268.50(a)(2)(i), a TSDF must also continue to mark or label each container of hazardous waste to identify the contents of the container and the date each period of accumulation begins, regardless of whether the TSDF receives the containers from a VSQG, SQG, LQG, or transfer facility. The Agency is also reiterating that if a TSDF generates its own hazardous waste, it must follow the applicable RCRA generator regulations in part 262, including the marking and labeling provisions for containers and tanks.

c. What changed since proposal? The Agency revised the marking and labeling requirements pertaining to identifying the hazards of the container, consistent with changes in other parts of this rule (*i.e.,* the SAAs, SQGs, LQGs, and transfer facilities marking and labeling requirements).

d. Major comments. The Agency received few comments concerning this provision of the rule. Some commenters supported the proposed changes while other commenters stated that these changes were unnecessary. As discussed previously, the Agency believes it has responded to commenters who expressed concerns by clarifying the applicability of this provision.

7. Hazardous Waste Numbers (Waste Codes) (40 CFR 262.32(b) and (c))

a. Introduction. The Agency proposed § 262.32(c) to require SQGs and LQGs to mark their containers with the applicable EPA hazardous waste number (RCRA hazardous waste code) prior to transporting their hazardous waste off site to a designated RCRA facility for subsequent management. EPA proposed this revision so that TSDFs can readily identify the contents of hazardous waste containers they are receiving from generators and effectively treat the wastes to meet LDRs. As stated in the preamble to the proposed rule, the Agency believes most generators, or their designated waste handlers, already mark their containers with the applicable EPA hazardous waste numbers prior to transporting their hazardous waste off site. As part of this discussion, the Agency stated that by marking containers with EPA hazardous waste numbers, the overall burden would be decreased because the TSDF would avoid the need to identify the hazardous waste or send the waste back to the generator for proper identification.

b. What is EPA finalizing? The Agency is finalizing the pre-transport marking requirements at § 262.32 by modifying § 262.32(b) to include the EPA hazardous waste number or code as part of the marking requirements for containers, and also adding § 262.32(c) to allow generators, transporters and TSDFs, in lieu of § 262.32(b), to use a nationally recognized electronic system, such as a bar-coding system that is part of a waste management industry's waste profiling system, to identify the applicable EPA hazardous waste numbers. A waste profiling system typically consists of bar codes, scanners, and an associated computer system. Waste management industry commenters indicated that they use bar code electronic systems, similar to commercial transport companies, to profile hazardous waste. Information often includes a description of the hazardous waste in terms of physical state, common name, hazard codes, LDR treatment standards, and DOT description.[45] Some of these electronic systems also include the EPA hazardous waste numbers. This approach also allows for the development of future technologies to accomplish the same function as the bar-coding system. The Agency is providing this flexibility because while there is considerable movement by generators and the waste management industry in adopting the use of electronic systems that contain detailed waste profiling information, it is neither universal nor mandatory. EPA is requiring that SQGs and LQGs include EPA hazardous waste codes, either by marking their containers or through electronic means, to inform the receiving TSDF of the container's contents in order to ensure hazardous wastes are managed to meet the applicable LDR treatment standards.

For lab packs, which typically contain many different wastes, we are providing an exception to the requirement to include EPA hazardous waste numbers if the lab packs will be incinerated. Specifically, lab packs that will be treated using the alternative treatment standard of incineration, as allowed by § 268.42(c), do not have to be marked or labeled with the EPA hazardous waste numbers. However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), the EPA hazardous waste number must be marked or labeled with the EPA hazardous waste numbers (or use electronic means may be used). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal.

c. What changed from proposal? In response to comments, the Agency is providing needed flexibility in complying with this requirement to account for alternative ways of marking containers with EPA hazardous waste codes. By doing so, the Agency is accommodating existing processes used by many generators and the waste management industry. Also in response to comment, we are providing an exception for lab packs that will be incinerated.

d. Major comments. Several commenters pointed out that while many generators still mark their containers with the applicable EPA hazardous waste codes, the industry trend is for generators to rely on their waste handlers who have developed sophisticated computerized systems that use detailed waste profiling procedures with bar codes and scanners (similar to package shipping and other national logistics companies). They use these systems to accurately identify individual drum contents and some include the EPA hazardous waste numbers. As stated by one commenter, TSDFs commonly prepare labels and shipping papers for their generator customers, and as part of this service, also utilize a waste profiling process that fully describes the waste in terms of physical state, common name, hazard codes, LDR applicability, and DOT description.[46] This commenter argues that to not allow this industry-wide service to continue would only cause confusion to a well-established process. EPA agrees and has modified the requirement accordingly.

F. Revisions to Satellite Accumulation Area (SAA) Regulations for SQGs and LQGs (262.15)

Hazardous waste generators are allowed, though not required, to use SAAs, provided that the generators meet the conditions for their use. SAAs are designed to assist generators who generate and accumulate small amounts of hazardous waste in different areas of their facilities. Alternatively, SQGs and LQGs may choose to accumulate hazardous waste only in CAAs rather than in SAAs. If an SQG or LQG does choose to accumulate hazardous waste in an SAA, the generator may accumulate a limited amount of

[45] See comments from Veolia ES Technical Solutions LLC, EPA–HQ–RCRA–2012–0121–0181; Environmental Technology Council, EPA–HQ–RCRA–2012–0121–0134; Waste Management, EPA–HQ–RCRA–2012–0121–0159

[46] Environmental Technology Council, EPA–HQ–RCRA–2012–0121–0134.

hazardous waste within each SAA. Once that threshold is reached, the SQG or LQG must transfer the hazardous waste to a CAA. Alternatively, a generator may accumulate hazardous waste within an SAA and never move the waste to a CAA once the threshold is reached, but instead, ship the waste directly off site to a RCRA designated facility (*e.g.,* a TSDF).

The Agency proposed six changes to the regulations for SAAs, now found at § 262.15. These six proposed regulatory changes and the final regulatory changes are individually discussed here in detail. In addition to these six proposed regulatory changes, EPA discussed two additional issues in the preamble to the proposed rule: (1) Our intention to rescind a guidance memo regarding the accumulation of reactive (D003) hazardous waste at locations away from the point of generation and (2) examples to help generators better understand the term ''under the control of the operator,'' which is used in the SAA regulations. These proposed changes were in response to stakeholder requests for additional clarification, additional flexibility or increased environmental protection that have been expressed through the years in various interactions, including the 2004 Generator Initiative,[47] with the regulated community, as well as state and regional regulators.

The Agency is finalizing these six proposed regulatory changes, with minor modifications, along with three additional minor changes. These nine regulatory changes are all summarized individually here, and six of the changes are discussed in further detail later on. First, SQGs and LQGs that accumulate hazardous waste in SAAs will now be required to comply with the special requirements for incompatible wastes found at § 265.177 (with minor revisions). Second, we are providing regulatory flexibility by providing limited exceptions to the regulation requiring generators to keep containers closed at all times (with minor revisions). Third, when maximum volumes are reached in SAAs, we are clarifying that generators will have three consecutive calendar days to remove the hazardous waste from the SAA or come into compliance with the CAA regulations. Fourth, we are providing additional flexibility to allow generators that accumulate acute hazardous waste in SAAs to choose between using a maximum accumulation volume (1 quart for liquids) or maximum accumulation weight (1 kg or 2.2 lbs for solids). Fifth, we are clarifying the regulations for situations when the maximum volume (or weight) is exceeded in an SAA. Sixth, containers used in SAAs will be subject to the strengthened marking and labeling standards (note these marking and labeling changes are the same as those for containers in CAAs and were discussed previously in section IX.E. of the preamble to this final rule). The seventh change being made to SAA regulations pertains to the applicability of preparedness, prevention and emergency procedures. The eighth change is a minor wording change in response to a comment from the Association of State and Territorial Solid Waste Management Officials (ASTSWMO).[48] They recommend, and we agree, that under § 262.15(a)(1), the regulatory language should have the word ''immediately'' added to state explicitly that if a container in an SAA is leaking, the generator must *immediately* transfer the hazardous waste to a container in good condition that does not leak (emphasis added). Similarly, a generator has the option to transfer a damaged or leaking container to a CAA, also immediately, and we have added language to clarify that the CAA must be operated in compliance with the CAA regulations. Therefore, § 262.15(a)(1) now states that if a container holding hazardous waste is not in good condition, or if it begins to leak, the generator must immediately transfer the hazardous waste from this container to a container that is in good condition and does not leak, or immediately transfer and manage the waste in a central accumulation area operated in compliance with § 262.16(b) or § 262.17(a). The ninth change is rewording of § 262.15(a) to be consistent with changes made to the SQG and LQG regulations to make it clear that an SQG or LQG can choose to operate an SAA and that the SAA is not required to comply with the SQG regulations of § 262.16(b) or LQG regulations of § 262.17(a), and is not required to have a permit or interim status, and is not required to comply with parts 124, 264 through 267, and 270, provided the generator complies with the conditions of exemption for an SAA.

With regard to the non-regulatory actions pertaining to SAAs that were discussed in the proposed rule, we are moving forward to rescind the January 13, 1988 memo that allowed a storage shed outside of a building where a reactive hazardous waste (D003) is initially generated to be considered an SAA.[49] Finally, we will further discuss in the preamble what is meant by ''under the control of the operator,'' a term that is used in the SAA regulations. These two non-regulatory actions are discussed individually in detail later.

1. Requiring SQGs and LQGs To Comply With the Special Requirements for Incompatible Wastes for Containers Accumulating Hazardous Wastes in SAAs (40 CFR 262.15(a)(3))

We *proposed* that SQGs and LQGs accumulating hazardous waste in SAAs must comply with the special requirements for incompatible wastes found at § 265.177. The regulations at § 265.177 include three requirements (1) incompatibles must not be placed in the same container unless § 265.17 (b)[50] is complied with, (2) hazardous waste must not be placed in an unwashed container that previously held an incompatible unless § 265.17 (b) is complied with and (3) a container holding an incompatible must be separated from the other material by means of a dike, berm, wall, or other device. The Agency believes that in developing the regulations for SAAs in 1984, it inadvertently failed to account for SQGs and LQGs that might accumulate incompatible wastes. Most commenters were supportive of requiring SQGs and LQGs that accumulate hazardous waste in SAAs to comply with the special requirements for incompatible wastes found at § 265.177, including a few states that said they already have corrected this oversight in their state regulations. However, some commenters argued it was unnecessary to add it to the regulations because it is in a generator's best interest to keep incompatibles separate and therefore they already comply with this best management practice at their SAAs. The Agency is encouraged to hear from commenters that they believe generators already routinely segregate their incompatibles. Nevertheless, for additional clarity and to ensure generators that are not following these best management practices adopt them, the Agency is finalizing the requirement that SQGs

[47] In 2004, EPA held a series of public meetings to solicit input from stakeholders about the generator regulations.

[48] Association of State and Territorial Solid Waste Management Officials (ASTSWMO), EPA–HQ–RCRA–2012–0121–0217.

[49] Letter from Marcia E. Williams, Director of EPA's Office of Solid Waste, to Michael E. Young, Atlantic Research Corporation, January 13, 1988, RCRA Online 11317.

[50] Section 265.17(b), which is entitled General requirements for ignitable, reactive, or incompatible wastes is in part 265 subpart B, the General Facility Standards that apply to interim status TSDFs. Section 265.17(b) also applies to SQGs and LQGs that accumulate ignitable, reactive, or incompatible wastes in CAAs.

and LQGs accumulating hazardous waste in SAAs comply with the part 265 subpart I container management standards for incompatible hazardous wastes at § 265.177. We agree with the commenter who ''view[s] this as a codification of an existing safe practice.'' [51]

Several commenters objected to the third requirement of § 265.177 in that they felt it unnecessary and impracticable to require that a container holding an incompatible hazardous waste in an SAA be separated from the other material by means of a dike, berm, wall, or other device. This proposed regulatory language was taken directly from the language in § 265.177, which applies to interim status TSDFs, as well as CAAs at SQGs and LQGs. The commenters argue that a dike, berm or wall would not be feasible in the confines of an SAA, which is only allowed to accumulate a maximum of 55 gallons of hazardous waste. The Agency agrees that most SAAs would not accommodate a dike, berm or wall. Although, the proposed regulatory language also allows for ''other device[s],'' to keep incompatibles segregated, the Agency has decided to replace the regulatory language ''by means of a dike, berm, wall or other device'' with the phrase ''by any practical means'' in order to address commenters' concerns. One commenter provided an example of what they do to avoid potential comingling of incompatible wastes in their CAA—they ''. . . segregate incompatible wastes onto separate pallets in the 90-day accumulation area. Pallets holding incompatible wastes are separated by at least one pallet width (*i.e.,* the ''pallet footprint'') in all directions. For example, a pallet of oxidizers and a pallet of flammables cannot be placed next to, above, or below each other.'' [52] Another commenter suggested that drip trays, or secondary containers would be more appropriate means to segregate incompatibles accumulating in SAAs.[53] The Agency believes that either of these practices constitute ''any practical means,'' and are allowed by the SAA regulations for separating incompatibles in SAAs.

EPA is making one additional minor revision to this section of the SAA regulations. We are removing the reference to piles, open tanks and surface impoundments. Containers are the only type of waste accumulation units allowed in SAAs. As previously noted, these regulations were copied from the interim status TSDF regulations, where these additional waste accumulation units are allowed. At the time of proposal, the Agency inadvertently overlooked this and is therefore making conforming changes as part of this rulemaking.

2. Limited Exceptions To Keeping Containers Closed at all Times in SAAs (40 CFR 262.15(a)(4))

The previous regulations for generators accumulating hazardous waste in SAAs required containers accumulating hazardous waste to be kept closed, except when it is necessary to add or remove waste (§ 262.34(c)(1)(i), which referenced the container regulations for interim status TSDFs in § 265.173(a)). We proposed to modify this provision for SAAs, now found at § 262.15, in order to allow containers of hazardous waste in SAAs to remain open under limited circumstances. These changes pertain only to containers accumulating hazardous waste in SAAs; it will not affect the requirements for container management at CAAs or interim status TSDFs. Specifically, we proposed that containers of hazardous waste in SAAs may be open when it is necessary either for the operation of equipment to which the SAA container is attached or to prevent dangerous situations, such as the build-up of extreme pressure or heat, because closing a container can be more dangerous than keeping it open temporarily in those situations. Stakeholders had identified situations where keeping SAA containers closed can interfere with the operation of equipment when the container is attached directly to the equipment via piping or tubing. Stakeholders had also identified situations in which closing a container can be more dangerous than keeping it open temporarily; for example, when the hazardous waste is very hot. Therefore, EPA proposed to modify the regulations to allow containers to be vented in such situations. In 2008, the Agency finalized these limited exceptions to the closed container requirement as part of the Academic Laboratories rule (subpart K) and thought they would benefit other generators as well.

Nearly all commenters supported this proposed change. However, some state commenters were concerned the regulatory language was not sufficiently clear that this exception to requiring closed containers was intended for temporary situations only. In the preamble to the proposed rule, we indicated that the requirement to keep the container closed applies when the danger passes (*e.g.,* the contents cool), and when the equipment is not in operation. However, these commenters thought the regulatory text should include language to make our intent clear. In response to these concerns, EPA is finalizing this provision, as proposed, with a minor addition. The regulatory language has been modified so that a container holding hazardous waste must be closed at all times during accumulation, except when adding, removing, or consolidating waste, or when *temporary* venting of a container is necessary (1) for the proper operation of equipment, or (2) to prevent dangerous situations, such as build-up of extreme pressure (emphasis added). EPA stresses it does not intend to create a loophole to the closed container requirement or to allow intentional evaporation of hazardous waste. Rather, the intent of the flexibility is to address the limited cases in which ''strict adherence to the ''container closure'' requirements could substantially increase a risk of a hazardous waste incident rather than decrease it.'' [54] As with the proposed rule, the flexibility for containers to remain open in specific situations applies only to containers in SAAs because that is where hazardous waste initially accumulates. At this time, we are not extending this flexibility to containers accumulating in CAAs.

3. Clarify What Is Meant by ''Three Days'' (40 CFR 262.15(a)(6)(i))

The previous SAA regulations at § 262.34(c)(2) stated that a generator who accumulates either hazardous waste or acutely hazardous waste must, with respect to that amount of excess waste, comply ''within three days'' with paragraph (a) of that section or other applicable provisions of the chapter. Over the years, the Agency was frequently asked what was meant by ''three days.'' As a result, the Agency proposed to amend the regulations to replace the term ''three days'' with ''three calendar days,'' as opposed to ''three business days'' or ''three working days.'' The Agency already clarified this term in a 2004 memo,[55] which was based on preamble discussions from the

[51] University of Nebraska-Lincoln (UNL), comment number EPA–HQ–RCRA–2012–0121–0121.

[52] Stericycle, comment number EPA–HQ–RCRA–2012–0121–0127.

[53] Pacific Northwest National Laboratory, comment number EPA–HQ–RCRA–2012–0121–0078.

[54] Minnesota Pollution Control Agency, EPA–HQ–RCRA–2012–0121–0232.

[55] Memorandum from Robert Springer, Director or EPA's Office of Solid Waste, to RCRA Regional Directors, ''Frequently Asked Questions About Satellite Accumulation Areas,'' March 17, 2004, RCRA Online 14703.

proposed and final SAA regulations.[56] As stated in the memo, ''Originally, the Agency had proposed to use 72 hours as the time limit but realized that determining when 72 hours had elapsed would have required placing both the date *and* time of day on containers. In the final rule the Agency switched to using three days so that generators only need to date containers that hold the excess of 55 gallons of non-acute hazardous waste (or 1 quart of acute hazardous waste).'' The Agency was simply proposing to codify long-standing, existing policy on the issue of what ''three days'' meant, as it is used in the SAA regulations.

Comments on this issue were mixed, with some commenters supporting the codification of the policy, while others preferred that we allow the term ''three days'' to mean ''three business days'' or ''three working days.'' Still others suggested that we take this opportunity to lengthen the time frame to 5, 7, or even 10 days. Although many commenters argued that we should allow ''three working days,'' one commenter conceded that, ''due to differences in business schedules, this becomes difficult to define in a rule.'' [57] For example, some companies shut down completely for lengthy periods around the holidays or during seasonal slowdowns. As a result, if we relied on ''three working days,'' it would create an uneven and unfair implementation of this SAA provision. Further, it's easy to imagine a raft of implementation questions that would ensue about the definition of a ''working day.'' Therefore, the Agency is finalizing this provision, as proposed, with one minor revision. While in the preamble to the proposed rule we used the term ''three consecutive calendar days,'' in the proposed regulatory language, we used ''three calendar days.'' To promote the most clarity, in the final rule, we will use ''three consecutive calendar days.''

4. Providing a Maximum Weight for the Accumulations of Acute Hazardous Waste in Containers at SAAs (40 CFR 262.15(a))

The SAA regulations impose maximum volumes of hazardous waste that may be accumulated in an SAA without a permit, or interim status, or complying with the central accumulation area standards for SQGs or LQGs. For non-acute hazardous waste, the maximum volume is 55 gallons. For acute hazardous waste, the maximum volume has been, until this rulemaking, 1 quart. When the SAA regulations were finalized in 1984, EPA explained that 55 gallons was selected for non-acute hazardous waste in part because it is the size of the most commonly used accumulation container.[58] EPA also explained in that final SAA rule that 1 quart was chosen for acute hazardous waste because it is the volumetric equivalent of 1 kilogram of acute hazardous waste used elsewhere in the regulations [59] and that commenters expressed opposition to using a weight measure. Since then, however, stakeholders have indicated that the 1-quart volume maximum is not a practical way to measure the accumulation of some wastes, particularly non-liquid acute hazardous wastes. Therefore, we proposed to add a weight measurement [60] to the SAA regulations for the maximum accumulation of acute hazardous wastes. Specifically, we proposed that 1 quart or 1 kilogram (2.2 pounds) of acute hazardous waste may be accumulated in an SAA. We proposed that generators that accumulate acute hazardous waste in SAAs would have the choice of whether to use 1 quart or 1 kilogram, but they would be required to identify which metric they choose. We did not propose to add a similar weight equivalent to the 55-gallon threshold for non-acute hazardous waste because stakeholders had not expressed a similar need; however, we did request comment on whether it would be useful to have a maximum weight for the accumulation of non-acute hazardous waste in SAAs.

Although some commenters did not see the need for the additional flexibility for the accumulation of acute hazardous waste in SAAs, most commenters supported the change, with a minor revision. Specifically, commenters suggested that, instead of allowing a generator to choose which unit to use, we should specify in the regulations that the 1 quart maximum for acute hazardous waste in an SAA should apply to liquids and the 1 kg maximum for acute hazardous waste in an SAA should apply to solids. We agree with these commenters and we are revising the final regulatory language for SAAs so that acute hazardous wastes that are liquids have a maximum volume of 1 quart, and acute hazardous wastes that are solids have a maximum mass of 1 kg (or 2.2 lbs). The maximum thresholds for acute hazardous wastes are not intended to be additive, so in cases where a generator has both liquid and solid acute hazardous waste accumulating in an SAA, the 1 kg or 2.2 lb limit will be applied.

In contrast, for non-acute hazardous waste, commenters indicated that the existing volumetric accumulation limit of 55 gallons for SAAs is sufficient and that it is not necessary to add a mass equivalent. Therefore, for non-acute hazardous waste, 55 gallons will remain the only unit for measuring maximum accumulation limits in SAAs. EPA continues to rely on its existing interpretation that at an SAA where more than one type of waste is accumulated, the *total* allowable accumulation is 55 gallons of hazardous waste—not 55 gallons per waste stream.[61]

One commenter asked for clarification about whether the weight of the packaging (such as fully dispensed vials that once held P-listed pharmaceuticals) would have to be included in determining the maximum mass or volume of an acute hazardous waste in an SAA. In a February 17, 2016, memo, EPA clarified that the container (*e.g.,* packaging) does not need to be included when calculating the maximum accumulation volume of acute hazardous waste in an SAA.[62] This would also be the case when calculating the maximum accumulation weight (mass) of acute hazardous waste in an SAA.

5. Modifying the Language for When the Maximum Volume or Weight Is Exceeded in an SAA (40 CFR 262.15(a)(6))

Previously, the regulation at § 262.34(c)(2) stated that, when the maximum volumes are exceeded in an SAA, a generator ''must, with respect to that amount of excess waste, comply within three days with paragraph (a) of this section or other applicable provisions of this chapter.'' The Agency proposed to reword this regulation in order to more clearly state the generator's options for managing the materials that exceed the limit. The

[56] Proposed rule: January 3, 1983 48 FR 118; Final rule: December 20, 1984; 49 FR 49569.

[57] The Boeing Company, EPA–HQ–RCRA–2012–0121–0133.

[58] December 20, 1984; 49 FR 49569–70.

[59] Though this is only a rough equivalent, as 1 quart is an English unit and 1 kg is a metric unit. Further, as one commenter noted, whether 1 quart (or liter) is equivalent to 1 kg depends on the density of the waste (Iowa State University, EPA–HQ–RCRA–2012–0121–0099).

[60] As one commenter pointed out, 1 kg is more accurately a measurement of mass, not weight (Minnesota Pollution Control Agency, EPA–HQ–RCRA–2012–0121–0232).

[61] Memorandum from Robert Springer, Director or EPA's Office of Solid Waste, to RCRA Regional Directors, ''Frequently Asked Questions About Satellite Accumulation Areas,'' March 17, 2004, RCRA Online 14703.

[62] Letter from Barnes Johnson, Director of EPA's Office of Resource Conservation and Recovery, to Charlotte A. Smith, PharmEcology Services, February 17, 2016, RCRA Online 14875.

proposed regulatory text stated that a generator who accumulates either non-acute hazardous waste or acute hazardous waste listed in § 261.31 or § 261.33(e) in excess of the amounts listed in paragraph (a)(1) of this section at or near any point of generation must remove the excess from the satellite accumulation area within three calendar days either to (1) a central accumulation area, (2) an on-site interim status or permitted treatment, storage, or disposal facility, or (3) an off-site designated facility. The proposed regulatory text also stated that during the three-calendar-day period, the generator must continue to comply with paragraphs (a)(1)(i) through (iv) of this section and must mark the container(s) holding the excess accumulation of hazardous waste with the date the excess amount began accumulating. The Agency did not view this as a substantive change to the SAA regulations.

We are finalizing this change, with two minor changes to address commenters' concerns. First, commenters pointed out that the proposed rewording of this section of the SAA regulations expands a generator's options for where the excess hazardous waste can be sent when the maximum volumes (or mass) are reached, but it removed the option that had originally existed to convert the SAA to a CAA and manage the hazardous waste in place. At the time of proposal, the Agency did not anticipate that generators would choose to convert SAAs into CAAs. However, one commenter pointed out that some generators do not have a CAA to move the waste to and therefore must manage the SAA as an CAA when volumes (or mass) are exceeded. In response to comments, in the final rule the Agency has amended the regulatory text to retain the option to allow generators to convert an SAA to a CAA when maximum volumes (or mass) are exceeded. Second, in this section of the SAA regulations, as well as other sections of the SAA regulations, where we mention CAAs, we have inserted the citation for the CAA regulations.

Other comments on this section of the SAA regulations were related to the phrasing of the previous SAA regulations that we did not propose to change. Specifically, the Connecticut Department of Energy and Environmental Protection (CT DEEP) ''believes that the revised language should not focus on the ''excess waste,'' but on the waste that was accumulated before the excess amount was generated. That is, the rule should require that the waste that was in storage before the generation of the ''excess waste'' be removed from the area, not just the ''excess waste.'' This would prevent situations in which only the ''excess waste'' is removed time and time again, leaving the remaining waste behind indefinitely.'' [63] EPA agrees with CT DEEP and, during the development of the proposed rule, we sought to revise this aspect of the SAA regulations. We also agree with CT DEEP that ''In reality, what happens in most cases is that the generator removes the older waste, and continues to accumulate the most-recently generated waste. For example, if a generator has a 55-gallon drum in an SAA and that drum becomes full, the generator might begin accumulating newly generated waste in a second 55-gallon drum.'' Unfortunately, during the development of the proposed rule, EPA's attempts to convey this idea through regulatory changes were unsuccessful and therefore were not included in the proposed rule. Nevertheless, we endorse CT DEEP's description as a best management practice for removing hazardous waste from an SAA. One alternative suggested by Wisconsin Department of Natural Resources (WDNR) is to ''clarify that a full 55-gallon drum must be moved from the satellite accumulation area. As the proposed rule reads now, a full 55-gallon drum may be under the satellite accumulation requirements indefinitely because 40 CFR 262.15(a)(6) refers to excess amounts . . . If a satellite accumulation drum is at capacity it should be moved into the central accumulation area.'' [64] Again, the Agency agrees that a full 55-gallon drum should be moved to a CAA. During the development of the proposed rule, we considered rewording this section of the proposed regulations as the WDNR suggested but we declined to use this construct in the proposal out of concern that generators would be able to easily circumvent our intent by not completely filling a container before beginning to fill another container.

6. Preparedness, Prevention, and Emergency Procedures for SQGs and LQGs

EPA is adding paragraphs (a)(7) and (a)(8) to the SAA regulations in § 262.15 to clarify that the preparedness, prevention, and emergency procedures for SQGs and LQGs that are found in § 262.16(b)(8) and part 262 subpart M, respectively, extend to any SAAs on site, as well as CAAs. These specific changes to the SAA regulatory text were not proposed, although we did request comment, but are being added in the final rule in response to comments we received on the proposed addition of part 262 subpart M, which is discussed more thoroughly in section XI of this preamble.

7. Rescinding a Memo Regarding Accumulating Reactive Hazardous Waste Away From the Point of Generation

In a memo dated January 13, 1988, EPA wrote that a storage shed that is outside of a building where a reactive hazardous waste (D003) is initially generated could be considered an SAA.[65] According to the company's incoming letter to EPA, the Atlantic Research Corporation (ARC) ''manufactures solid rocket propellant. In it's [sic] operations, ARC generates waste chemicals which are accumulated in containers located in storage sheds outside of the buildings generating the materials. The waste chemicals are accumulated outside of the buildings for safety reasons due to the explosive nature of the work conducted.'' [66]

There were no proposed regulatory changes associated with this action; however, in the preamble to the proposed rule, EPA gave notice that it was proposing to revoke this interpretation. EPA agreed with ARC that in some instances it is safer to accumulate hazardous waste away from the initial point of generation, such as hazardous wastes that are explosive. However, in the preamble to the proposed rule, EPA reasoned that, because SAAs are subject to less stringent conditions than CAAs, it is not appropriate for such dangerous hazardous wastes to be stored in SAAs. Rather, EPA stated that if a generator accumulates hazardous waste that is so dangerous it needs to be accumulated away from the point of generation, it should be accumulated under the more rigorous accumulation standards for central accumulation areas.

We received more than a dozen comments on this action. Several commenters supported the action to rescind the memo. Others, such as Pacific Northwest National Laboratory (PNNL), Utility Solid Waste Activities Group (USWAG) and Institute of Makers of Explosives (IME) supported it, but suggested that additional clarity was

[63] Comment number EPA–HQ–RCRA–2012–0121–0178.

[64] Comment number EPA–HQ–RCRA–2012–0121–0206.

[65] Letter from Marcia E. Williams, Director of EPA's Office of Solid Waste, to Michael E. Young, Atlantic Research Corporation, January 13, 1988, RCRA Online 11317.

[66] Ibid.

needed.[67] We intend to rescind the memo, as proposed, while addressing commenters' concerns. First, not only do SAAs have fewer regulations and safeguards associated with them than CAAs, but the regulations require that they must be ''at or near the point of generation.'' EPA would not consider a shed outside a building where the waste is initially generated to be ''at or near the point of generation.'' Nevertheless, as this term is not particularly specific, implementing regulatory agencies will retain authority in determining what they consider ''at or near the point of generation.''

Both PNNL and USWAG were concerned that EPA was implying that all reactive hazardous wastes (D003) were required to be accumulated away from the initial area of generation and, therefore, could not be accumulated in SAAs. Additionally, PNNL was concerned that there might be a ''Catch-22 where EPA does not allow remote accumulation and OSHA or the International Fire Code does not allow them to be accumulated at the point of generation.'' This was not our intent. Our intent was that if, for safety reasons, which may be driven by fire codes or OSHA regulations, a reactive hazardous waste (or other hazardous waste, for that matter) needs to be accumulated away from the initial area of generation, then that accumulation area should be considered a CAA, not an SAA. EPA is not prohibiting remote accumulation; rather, we are clarifying that it is more appropriate to regulate the remote accumulation area as a CAA than an SAA. Likewise, EPA did not intend to suggest that all storage sheds would necessarily be CAAs. For example, a storage shed that is located ''at or near the point of generation'' could be considered an SAA.

In its comments IME said it ''would have no objection to rescinding this memorandum so long as the agency allows accumulated SAA waste to be temporarily moved from the initial point of generation for purposes of complying with the regulations of other federal agencies. For example, a number of IME member companies collect hazardous waste in containers at SAAs. Regulations administered by the Bureau of Alcohol, Tobacco, Firearms and Explosives (''ATF'') require that these containers be moved to a magazine at the end of a shift . . . The containers are returned to the SAA at the start of the subsequent shift.'' [68] EPA's SAA and CAA regulations do not prohibit generators from moving hazardous waste from the SAA's initial point of generation to a CAA (*e.g.* magazine) and back again to the SAA for further accumulation.

8. Examples of the Meaning of ''Under the Control of the Operator''

The previous SAA regulation at § 262.34(c)(1) used the term ' ''under the control of the operator,'' as do the revised SAA regulations being finalized at § 262.15(a). EPA has not defined this term in the regulations, has not discussed it in preamble and discussed it only minimally in guidance letters.[69] However, over the years, the Agency has received inquiries about what constitutes ''under the control of the operator.'' In an effort to assist generators to better understand this term and to foster improved compliance with the SAA provisions, the Agency provided examples in the preamble to the proposed rule. For example, EPA stated that it would consider waste to be ''under the control of the operator'' if the operator controlled access to an area, building, or room in which the SAA is located, such as with entry by access card, key or lock box. Another example EPA provided was if the operator accumulates waste in a locked cabinet and controlled access to the key, even if the cabinet is stored inside a room to which access is not controlled.

Commenters were concerned that EPA is imposing new requirements on SAAs. To the contrary, the Agency requested comment on this issue in the hope of developing a list of best management practices that regulators and the regulated community could rely on to fulfill this existing requirement. The Agency deliberately did not propose any regulatory text to define the term ''under the control of the operator.''

A number of commenters provided helpful examples of what they believe constitutes ''under the control of the operator'' as it pertains to the SAA regulations. For example, the Oklahoma Department of Environmental Quality ''believes that the term ''Under the control of the operator'' has a much broader meaning than those examples in the proposed rules; *e.g.* a situation where the operator is regularly within view of the SAA during the course of their job, or a situation where the operator is expected to be able to observe any individuals that may enter or exit the SAA.'' [70] One state commenting as part of the Association of State and Territorial Solid Waste Management Officials (ASTSWMO) ''believes as a general rule the SAAs in a manufacturing plant are not in locked cabinets or in locked rooms. They are generally in centralized locations along the assembly lines so all the employees, in several shifts, have access to them. SAA closest to the assembly line employees would be under their control and be at or near the point of generation. This state does not believe the regulated community would agree to buying several locked cabinets and placing them on the plant floor. It would be very inconvenient for the employees to run and look for the person with the keys to unlock the cabinet every time they need to place waste in the SAA. The sites have controlled access so the entire building would be under control of the operator.'' [71] The District of Columbia (DC) Department of Energy and Environment suggests that '' 'under control of the operator' would not include situations where the waste cannot be seen unless the area is equipped with 24 hour video surveillance or 24 hour sensor surveillance. DC also suggests adding criteria such as: the area must be monitored daily by trained personnel and access to the area must be limited to prevent access by untrained personnel or visitors.'' [72]

In addition, one commenter referenced an EPA memo that discussed the term ''under control of the operator.'' [73] EPA states: ''The condition that wastes accumulated under the satellite provision 'be under control of the operator of the process generating the waste' is met provided the generator demonstrates that the personnel responsible for generating/or accumulating the waste have adequate control over the temporary storage of these wastes. The EPA recognizes that for many wastes, the person who first generates the waste may not be the same person responsible for the accumulation of all of these wastes; rather, another worker may have responsibility of overseeing the temporary storage of wastes.'' The Agency then states that ''the goal is that this temporary accumulation is performed responsibly and safely, with adequate oversight and control.'' On a related matter, commenters asked EPA to clarify whether an ''operator'' must be a single

[67] Comments EPA–HQ–RCRA–2012–0121–0078, EPA–HQ–RCRA–2012–0121–0093 and EPA–HQ–RCRA–2012–0121–0126, respectively.

[68] Comment EPA–HQ–RCRA–2012–0121–0126.

[69] Letter from Sylvia K. Lowrance, Director of the Office of Solid Waste to Mr. D.B. Redington, February 23, 1993, RCRA Online 11728.

[70] Comment Number EPA–HQ–RCRA–2012–0121–0182.

[71] Comment Number EPA–HQ–RCRA–2012–0121–0217.

[72] Comment Number EPA–HQ–RCRA–2012–0121–0248.

[73] Letter from Sylvia K. Lowrance, Director of the Office of Solid Waste to Mr. D.B. Redington, February 23, 1993, RCRA Online 11728.

individual. The Agency believes that there can be more than one operator per SAA over time. For example, as employees change shifts over the course of a day, the role of the operator can be transferred from one employee to another. Likewise, the Agency believes that there can also be more than one operator per SAA at the same time. For example, multiple operators may be running laboratory equipment in the same room and share hazardous waste containers located in a single SAA.[74] However, the term operator does refer to an individual or individuals responsible for the equipment or processes generating the hazardous waste and does not refer to a company or entity as a whole.

The examples discussed in the preamble to the proposed rule and final rule are not an all-inclusive or exhaustive list of practices that may be used to meet the requirement that hazardous waste in an SAA must be ''under the control of the operator.'' Implementing regulatory agencies may consider these examples or alternatives to meet the intent of the term, which is to ensure that someone familiar with the operations generating the hazardous waste is aware of and able to attend to the operations, if needed, while also providing some measure of controlled access.

G. Accumulation of Hazardous Waste by SQGs and LQGs on Drip Pads and in Containment Buildings

As part of its reorganization efforts to improve the user-friendliness of the hazardous waste generator regulations, the Agency proposed to consolidate the waste accumulation provisions for tanks, drip pads and containment buildings into one section. The Agency also proposed to include specific provisions for SQGs that may accumulate hazardous waste on drip pads and in containment buildings at § 262.16 (b)(4) and (5), respectively. Previously, the regulatory provisions for LQGs referred to drip pads and containment buildings, but these accumulation units were not specifically identified in the SQG provisions. Therefore, if an SQG desired to accumulate hazardous waste in these type units, they could only do so by complying with the more stringent LQG regulations. In the proposed rule, the Agency attempted to provide clarity by adding the regulations applicable to LQG drip pads and containment buildings (previously found at § 262.34 (a)(1)(iii) and (iv)) to provisions for SQGs accumulating hazardous waste in these units.

With respect to the marking and labeling provisions for hazardous waste accumulated on drip pads and in containment buildings, the Agency proposed that SQGs and LQGs mark or label its waste accumulation units with the words ''Hazardous Waste'' in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, etc. We also proposed that SQGs and LQGs use inventory logs, monitoring equipment, or records to: Identify the contents of the drip pad and containment building and its associated hazards; to identify the date upon which each period of accumulation begins; and keep inventory logs or records with the above information in close proximity to the drip pad and containment building.

1. Drip Pads

a. What is EPA finalizing? The Agency is finalizing the regulations associated with the accumulation of hazardous waste on drip pads for SQGs and LQGs § 262.16(b)(4) and § 262.17(a)(3), respectively. This provision was previously found at § 262.34(a)(1)(iii) for LQGs only. This provision states that a generator with drip pads must comply with subpart W of 40 CFR part 265, and, consistent with existing regulations, must remove all hazardous wastes from the drip pad and associated collection system at least once every 90 days. Similarly, at closure, SQGs and LQGs must comply with § 265.445(a) and (b), but not (c). Once the hazardous wastes are removed from a drip pad, LQGs would have up to 90 days and SQGs up to 180 days to accumulate the hazardous wastes without a permit or interim status. SQGs and LQGs would also have to maintain the following records at the facility by use of inventory logs, monitoring equipment, or any other effective means: Records that describe the procedures that will be followed to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and records that document each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.

These records would need to be kept on site and readily available for inspections. Ideally these records would be in close proximity to where hazardous waste is being accumulated after removal from the drip pad, such as in a control room, or other central location at the facility.

In addition, consistent with guidance previously issued by the Agency for wood treaters, that if hazardous waste is placed in a satellite accumulation area, the waste can remain there until the drum is full. Once the drum is full, it must be dated and moved to the hazardous waste storage area. Thereafter, the 90 or 180 day accumulation clock for LQGs and SQGs, respectively, begins.[75]

Additionally, consistent with this same guidance for wood preservers, EPA is clarifying in this final rule that VSQGs may accumulate hazardous waste on drip pads as long as they also comply with the technical standards of 40 CFR part 265 subpart W to ensure the drip pads are operated in an environmentally safe and responsible manner.[76]

b. *What changed since proposal?* In the process of trying to consolidate the waste accumulating provisions for tanks, drip pads and containment buildings in the proposed rule, the Agency failed to properly take notice that drip pads are very different in operation than tanks and containment buildings. The unique nature of drip pads was addressed through several earlier rulemakings. For example, on December 6, 1990, EPA promulgated several new hazardous waste listings specific to the wood preserving industry, along with unit-specific hazardous waste standards for drip pads ('subpart W') and corresponding generator accumulation provisions for persons generating hazardous waste and managing the waste on drip pads (55 FR 50450). As part of that rulemaking, EPA established a standard by which generators must remove all hazardous wastes from their drip pad at least once every 90 days, while still allowing for additional time to accumulate the hazardous waste (*e.g.,* in tanks or containers) depending on their generator status. This latter issue was clarified in subsequent guidance, but is being further clarified in this final rule. Therefore, for both LQGs and SQGs, hazardous wastes must be removed from the drip pad and associated collection system at least once every 90 days, and the Agency is retaining the regulatory text previously found at § 262.34 (a)(1)(iii). By incorporating this provision, the Agency will also address the requirements that generators

[74] Memorandum from Robert Springer, Director or EPA's Office of Solid Waste, to RCRA Regional Directors, ''Frequently Asked Questions About Satellite Accumulation Areas,'' March 17, 2004, RCRA Online 14703.

[75] *See* U.S. Environmental Protection Agency, *Wood Preserving Resource Conservation and Recovery Act Compliance Guide: A Guide to Federal Environmental Regulation,* EPA–305–B–96–001, at section 5–17 (June 1996).

[76] Ibid., 5–8

describe the procedures to demonstrate that all wastes have been removed from the drip pad and associated collection system at least once every 90 days.

The Agency is not finalizing the provision that would require SQGs and LQGs to mark drip pads with the words ''Hazardous Waste'' in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, etc. As stated by one commenter, labeling the entire drip pad with the words ''Hazardous Waste'' is inaccurate because not all of the materials on the drip pad are hazardous waste, such as the poles and lumber being treated on the drip pad. Finally, the drums stored on the drip pad or drum storage area that contain hazardous waste and the drum storage area would already be labeled with those words. Similarly, identifying the hazards of wastes is inappropriate because drip pads contain both wastes and components of treated wood operations.

Similarly, we have modified where inventory logs or records for drip pads must be kept. We had proposed that the information must be in close proximity to the drip pad. Commenters indicated that having records in close proximity may not always be practical or even desirable. In response to comments, we have modified the regulations so that the records must be kept on site and readily available for inspections.

c. *Major Comments.* Commenters primarily focused on explaining how drip pad operations work and identifying the mistake the Agency inadvertently made in consolidating the waste accumulation regulations for all types of units. Commenters also requested that the Agency change the waste accumulation time for SQGs from 90 days to 180 days for wastes removed from the drip pad to be consistent with other waste accumulation unit time limits. This comment is also consistent with Agency guidance issued for drip pads.[77] One commenter identified a number of problems associated with the marking and labeling of hazardous wastes on drip pads, including generators marking drip pads with the words ''Hazardous Waste'' in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, etc, and identifying the hazards of wastes as being inappropriate. As discussed previously, the Agency has responded to these comments.

[77] Ibid, section 5–17.

2. Containment Buildings

a. *What is EPA finalizing?* The Agency is finalizing the regulations that were proposed in § 262.16 (b)(5) and § 262.17 (a)(4) for hazardous wastes accumulated in containment buildings by both SQGs and LQGs, respectively.[78] This provision states that an SQG or LQG accumulating hazardous waste in a containment building must comply with subpart DD of 40 CFR part 265, place its professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101 in the generator's files prior to operation of the unit, and maintain the following records by use of inventory logs, monitoring equipment, records, or any other effective means: (1) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the site showing that they are consistent with respecting the 90 day limit, and documentation that the procedures are complied with; or (2) documentation that the unit is emptied at least once every 90 days. The Agency is also stating that these records must be readily available upon request from the implementing agency. These recordkeeping provisions were found under the marking and labeling provisions for containment buildings in the proposed rule.

The Agency is also requiring SQGs and LQGs accumulating hazardous waste in containment buildings to label their containment building with the words ''Hazardous Waste'' located in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers or other persons on site and also provide an indication of the hazards of the waste using one of several methods described under § 262.16(b)(6)(i)(B) and (b)(6)(ii)(B)—Labeling of containers and tanks.

b. What changed from proposal? Similar to the changes made for drip pads, the Agency moved the marking and labeling provisions to the waste accumulation section because these provisions more appropriately address how generators will meet the 90 day waste accumulation time limit. The Agency is also adding a provision to clarify that the records used to demonstrate that hazardous wastes have been removed within 90 days must be readily available upon request from the implementing agency.

[78] This regulatory text was originally found at § 262.34(a)(1)(iv).

c. *Major comments.* There were very few comments about this provision. One commenter did not support the provision allowing SQGs to accumulate hazardous waste in containment buildings because these are complicated units requiring a fairly high level of knowledge and expertise to properly construct and operate. While the Agency agrees with this commenter conceptually, we have no basis to prohibit such an operation, such as damage cases from generators accumulating hazardous wastes in such units. Another commenter sought clarification to differentiate between containment buildings and manufacturing process buildings. As described at subpart DD of part 265, containment buildings are specially designed and constructed buildings that address the waste accumulation of hazardous wastes. Manufacturing process buildings may or may not have similar design specifications, but if they are not generating or accumulating hazardous wastes, they need not comply with subpart DD requirements. Also, the Agency maintained the 90 day accumulation time period for any SQGs accumulating hazardous wastes in containment buildings consistent with what was proposed.

H. Special Requirements for Ignitable and Reactive Wastes for LQGs (40 CFR 262.17(a)(1)(vi))

Some generators, especially as those located in urban environments, have expressed their concern regarding the LQG provision requiring generators to place containers holding ignitable or reactive waste 15 meters (50 feet) from the site's property line. In some cases, it may not be physically possible to meet this standard, particularly if the width of the site is 100 feet or less or when the generator's operations have expanded such that it no longer has the ability to accumulate ignitable or reactive waste at least 15 meters (50 feet) from the site's property line. Insurance companies and local fire departments often assist hazardous waste generators in minimizing their environmental hazards and liabilities, but site dimensions may sometimes physically prevent a generator from complying with this condition.

The Agency proposed to allow LQGs to apply for a site-specific waiver from their local fire department if they are unable to meet the 15 meter ignitable and reactive hazardous waste accumulation property line condition. This proposed change would require LQGs to obtain a written approval from a local fire department and keep the written approval in their records.

Additional details are discussed in section XI of the preamble of the proposed rule (80 FR 57979).

1. What is EPA finalizing?

The Agency is finalizing the proposed regulation with a minor modification. The final regulation allows an LQG to apply for a site-specific waiver from the authority having jurisdiction (AHJ) over the fire code if the LQG is unable to meet the 15 meter ignitable and reactive hazardous waste accumulation property line condition. If an LQG wants this waiver, they are required to obtain a written approved waiver from the AHJ who has the ability to determine a safe and practical location for the facility to store ignitable or reactive waste that is within 15 meters (50 feet) of the facility's property line. LQGs are then required to keep the written approval in their records.

2. What changed since proposal?

EPA originally proposed that the facility contact their local fire department for the site-specific approval. While several commenters agreed that most fire departments are well qualified to approve this waiver, some commenters indicated that there may be some confusion as to who can approve this waiver. For example, some areas may require a designated official to interpret and enforce the fire code rather than the local fire department. In this case, the designated official will grant the approval. The Agency did not intend to restrict the ability of those who can grant this approval to only local fire departments. However, the Agency did intend that the entity or individual granting this approval has detailed knowledge of the fire code, has the ability to evaluate the site conditions to determine a safe and practical place for storing ignitable and reactive wastes, and is authorized by the state or local government to enforce the fire code.

To address these comments, the Agency changed the terminology from the ''fire department'' to the ''authority having jurisdiction (AHJ)'' over the fire code within the facility's state or locality. An AHJ may or may not be the fire marshal, fire chief, building official, or another official as designated by the state or local government. AHJ is a term developed by the National Fire Protection Association (NFPA) and has been adopted by several state and local governments. Considering the wide use of the term ''AHJ'' in various fire codes, the Agency believes the more general term will ensure that regardless of who has the authority (local/state), the generator will be able to apply for the site-specific waiver. Furthermore, the Agency believes that the AHJ is well qualified at finding the most appropriate place to accumulate this waste and to determine that there is a sufficient level of protection for the facility and the surrounding community prior to issuing this approval.

We requested comment on whether EPA should set conditions for the waiver, but determined from the commenters that the decision should be made on a site-specific basis dependent on the characteristics of the generator, the physical make-up of the site, and the surrounding area. EPA expects the AHJ to be sufficiently qualified to make a site-specific determination for the waiver and consider relevant factors when making that decision, such as the length of time the hazardous waste can be accumulated, the amount of hazardous waste that can be accumulated, and any physical or technical controls. The AHJ should also consider any potential off-site conditions, such as the proximity to populated public areas (schools, hospitals, or playgrounds), off-site sources of ignition, and the proximity to an adjacent property's storage area of ignitable or reactive waste.

3. Major Comments

A few commenters recommended that EPA directly allow deference to locally applicable fire codes rather than requiring the generator to obtain an approval. EPA proposed a rule in 1984 that is similar to the commenters' recommendation. It would have amended the buffer zone requirements and adopted NFPA fire codes but the rule was never finalized.[79] However, the 1984 proposal shows that adopting the fire code appears to be more complicated than the commenters realize due to the differences in terms and definitions. Furthermore, fire codes differ from locality to locality and some rural areas have no fire code or fire department. While EPA agrees that this recommendation would be easier to implement for the generator since it removes the approval process, at this time, the Agency cannot defer to local fire codes because the complexity involved may increase confusion and in some cases it may present a danger for the community or for the facility itself. However, the Agency may reevaluate this topic in future rulemakings.

The Agency took comment on whether owners and operators of permitted and interim TSDFs should also be able to apply for this approval. While several commenters agreed that TSDFs should be included, EPA determined that TSDFs already go through an existing permit process, including public notice and comment, to determine site-specific conditions that include identifying locations for accumulating hazardous waste.[80] Considering that parts of the permit process may be bypassed if owners/operators of TSDFs were allowed to apply for this waiver, EPA concludes that it is not appropriate to include TSDFs in this waiver.

Effect of the Reorganization: This section is affected by the reorganization. The special requirements for ignitable and reactive waste were found at 40 CFR 265.176.

I. LQG Closure Regulations (40 CFR 262.17(a)(8))

In an effort to improve the clarity and understanding of the closure regulations for LQGs, as well as to strengthen M. he closure regulations to improve environmental protection, the Agency proposed three changes to the closure provisions for LQGs previously found at § 262.34(a)(1)(iv)(B).

First, EPA proposed to consolidate the closure regulations for LQGs accumulating hazardous waste at § 262.17(a)(8). EPA believed the organization of the closure regulations previously found at § 262.34(a)(1)(iv)(B) (which referred to various closure requirements in part 265) was confusing and difficult to follow. The proposed consolidation included both the facility-wide general performance requirements found at §§ 265.111 and 265.114 for hazardous wastes accumulated in containers, tanks, drip pads, and containment buildings, and the unit-specific requirements found at § 265.197 for tanks, § 265.445 for drip pads and § 265.1102 for containment buildings.

Second, EPA proposed to strengthen the closure regulations for LQGs accumulating hazardous waste in containers in central accumulation areas that plan to stop hazardous waste accumulation by requiring them to meet the same type of closure regulations that apply to tanks, drip pads and containment buildings, including those situations where a generator is not able to demonstrate that its hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products can be practicably removed or decontaminated (*i.e.,* cannot ''clean close''). The Agency demonstrated the need for closure requirements to apply to LQGs accumulating hazardous waste in containers as discussed in detail in the

[79] 49 FR 23290, June 5, 1984.

[80] 40 CFR part 270.

preamble to the proposed rule at 80 FR 57955 and provided in the docket a list of Superfund damage cases to the environment caused by generators who accumulated hazardous wastes in containers and abandoned these facilities.

Third, EPA proposed to require an LQG to notify EPA or the authorized state using EPA Form 8700–12 at least 30 days prior to closing the generator's facility or when the generator closes a unit accumulating hazardous waste. Additionally, EPA proposed that an LQG notify EPA or its authorized state within 90 days after closing the facility or the unit accumulating the hazardous waste. This notification would state the LQG had clean closed or failed to clean close and therefore, must close as a landfill.

1. What is EPA finalizing?

Based on review and evaluation of comments, the Agency is finalizing the following provisions associated with the closure regulations for LQGs. First, we are consolidating the closure regulations at § 262.17(a)(8). These regulations consist of two components: Closure of a waste accumulation unit, such as a tank system and container accumulation area, and closure of a generator's facility.

When closing a waste accumulation unit at § 262.17(a)(8), a generator may either elect to place a notice in its operating record that identifies the unit they are closing and not conduct the formal closure performance standards of § 262.17(a)(8)(iii) in the case of a container, tank or containment accumulation unit, or § 262.17(a)(8)(iv) in the case of a drip pad unit, until the facility closes, or they can formally perform the closure provisions in § 262.17(a)(8)(ii)(B) through § 262.17(a)(8)(iv) including clean closure performance standards and notification to EPA that the facility has closed that accumulation unit within 90 days of closing the unit.

When closing the facility, the generator would be required to meet the notification standards of § 262.17(a)(8)(ii) and performance standards of § 262.17(a)(8)(iii) for container, tank and containment building units, and § 262.17(a)(8) (iv) for drip pad units. The performance standards of § 262.17(a)(8)(iii) include four paragraphs. The first two paragraphs incorporate the closure performance requirements at §§ 265.111 and 265.114 when an LQG's waste accumulation unit or facility closes. The third paragraph addresses what must be done with any hazardous wastes generated as a result of an LQG clean closing its waste accumulation areas. The fourth paragraph addresses the situation when an LQG that has accumulated hazardous waste in a container, tank or containment building waste accumulation area cannot meet the closure performance standards or clean close (*i.e.,* situations where contaminated soils and wastes cannot be practicably removed or decontaminated).

In addition, LQGs with drip pads must continue to comply with the unit-specific closure performance standards found at § 265.445(a) and (b)[81] and the general closure requirements now found at § 262.17(a)(8)(iii)(A)(*1*) and (*3*). In the proposed rule, the Agency consolidated drip pad closure requirements with tanks and containment buildings and in the process, incorrectly modified the closure requirements. In this final rule, § 262.17(a)(8)(iv) has been added to specifically address the closure requirements for drip pads and correct the modification.

As mentioned previously, LQGs need to notify EPA or their authorized state using the Site ID form (EPA Form 8700–12) when they are closing their facility. Specifically, LQGs must notify EPA or the authorized state using the Site ID form (EPA Form 8700–12) at least 30 days prior to closing their facility, and also notify EPA or the authorized state within 90 days after closing the facility. This second notification using form 8700–12 would state that the LQG has either met the closure performance standards of § 262.17(a)(8)(iii) or failed to meet such standards, in which case they must notify that they are closing as a landfill. In the case of LQGs with drip pads, they would either notify using form 8700–12 they had met the closure performance standards of § 265.445(a), or if they failed to meet those standards, notify that they must close in comply with the requirements of § 265.445(b). In response to comments, the Agency is allowing LQGs to request additional time to clean close at § 262.17(a)(8)(ii)(C). However, the LQG must notify EPA using form 8700–12 or its authorized state within 75 days after closing their site to request an extension and provide an explanation as to why the additional time is required.

Third, the Agency is clarifying that closure requirements do not apply to satellite accumulation areas at § 262.17(a)(8)(v). While the Agency did not receive any specific comments on the scope of closure requirements, we are clarifying that the closure requirements do not apply to satellite accumulation areas.

2. What changed since proposal?

The Agency simplified and clarified the closure process. First, EPA is providing LQGs a choice for when they close a hazardous waste accumulation unit (*i.e.,* CAA, tank, containment building, drip pad): (1) Put a notice in the operating record stating they closed the accumulation unit, or (2) follow the closure procedures in § 262.17(a)(8)(ii)–(iv). The Agency is making this change in the final rule based on information from commenters who described normal operating situations where accumulation units close and reopen, or are relocated to another part of the site. The Agency did not want the accumulation unit closure provisions to interfere with facility operations and the generation and accumulation of hazardous wastes, especially as the Agency is aware of situations where hazardous wastes are placed in containers that are mobile storage devices. However, when closing their overall facility, generators must ensure all remaining hazardous wastes they have generated and accumulated are removed from their facility and clean close per § 262.17(a)(8)(iii) (*i.e.,* minimize the need for further maintenance by controlling, minimizing, or eliminating the post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere to the extent necessary to protect human health and the environment).

Second, rather than have LQGs notify EPA or an authorized state every time they close a waste accumulation unit, they must now notify only when they are closing their facility. The Agency received many comments that providing a notification every time a waste accumulation unit is closing, particularly for container waste accumulation units, is impractical. Commenters noted that opening, closing and reopening waste accumulation units, even temporarily, occurs periodically and the Agency does not want to interfere with the operations of the facility.

Third, in finalizing the closure performance standards § 262.17(a)(8)(iii), the Agency has reverted back to the existing regulatory text previously found at § 265.197(a) for closure of tanks and § 265.1102(a) for closure of containment buildings for purposes of consistency, and because one of the primary purposes of this

[81] See Generator Closure Requirements, RCRA/Superfund Hotline Monthly Report, December 1998, EPA530–R–98–005.

section is to consolidate the closure regulations found in different parts of the program.

Finally, the Agency separated the closure performance requirements for drip pads because they are different than those of containers, tanks and containment buildings.

3. Major Comments

Many commenters supported the consolidation of closure requirements to make them more user-friendly and easier to comply with. Many commenters did not support EPA's proposal to require notification every time a waste accumulation area was closing and requiring LQGs to clean close every time a waste accumulation area closed. In both cases, commenters stated the proposed changes were inefficient, impractical and/or unnecessary. One commenter, representing several generator organizations, did not believe closure standards should be identified as conditions for exemption. However, EPA notes that closure standards are a condition for exemption under the existing RCRA program. See section IX.A for a more detailed discussion of the distinction between conditions for exemption and independent requirements. This commenter also recommended that the concept proposed in § 262.17(a)(8)(ii)(A)(*1*) that closure should be undertaken ''to the extent necessary to protect human health and the environment,'' should be moved up to the introductory paragraph since this is an important risk-based concept applicable to all of the requirements in § 262.17(a)(8)(ii)(A), not just to subparagraph (*1*). The Agency believes the regulations being finalized already take into account a risk-based concept because ''minimizing the need for further maintenance by controlling, minimizing, or eliminating, to the extent necessary to protect human health and the environment'' is a risk-based standard. Hence, we have not finalized this change.

This same commenter expressed serious concerns that this proposal was a major departure from existing regulations regarding the clean closure of container central accumulation areas and specifically, the requirement that if the facility could not clean close, then the generator must close as a landfill with all the associated requirements (*e.g.,* installing groundwater monitoring wells upgradient and downgradient from the container area; installing monitoring wells for 30 years or longer during a post-closure care groundwater monitoring program, etc.)

The Agency agrees that this is a new provision. However, as discussed in the proposal (80 FR 57955), many Superfund removal actions over the years have resulted from generators who failed to clean close their hazardous waste container accumulation areas. The EPA believes that facilities accumulating hazardous wastes in containers should have to close as a landfill if they cannot clean close like all other LQGs accumulating hazardous waste. The inability to clean close would indicate major environmental problems have occurred at the generator's facility. If so, the responsibility falls on the generator to address the potential contamination just as a generator would address any problems that resulted from its accumulated hazardous wastes in tanks, drip pads, or containment buildings. Whether a generator would actually have to meet all the requirements of closing as a landfill would be a site-specific decision, made in conjunction with EPA or the authorized state., Generally, if a LQG has been managing its hazardous waste in accordance with the LQG provisions including proper accumulation standards and spill clean-up, then clean closure will consist of removing the containers from the accumulation area. EPA anticipates this will be the case in most situations for container central accumulation areas. The Agency has determined that clean closure requirements should apply equally to all hazardous waste accumulation areas.

Finally, one commenter pointed out that the proposal to consolidate the closure standards for drip pads with tanks and containment buildings would modify existing drip pad closure requirements. The Agency acknowledges this was an inadvertent mistake and has reverted back to the existing subpart W requirements of part 265. However, for purposes of consolidation and consistency, LQGs that accumulate hazardous waste on drip pads and that are closing their facility must still comply with the notification and waste management provisions found at § 262.17(a)(8)(ii) and (a)(8)(iii)(A)(*3*), as well as 40 CFR part 265 subpart W.

Effect of the Reorganization: This section is affected by the reorganization. The closure requirements were previously found in § 262.34(a)(1)(iv)(B). The reorganization is discussed in section VI of the preamble.

J. Documentation of Inspections of Waste Accumulation Units

As part of the of the proposed Hazardous Waste Generator Improvements rule, the Agency at 80 FR 57952–53 requested comment on requiring generators to document the results of their container, tank and drip pad inspections. More specifically, the Agency requested comment on whether to require the following: (1) Both SQGs and LQGs document the results of their required ''at least weekly'' container inspections; (2) SQGs accumulating hazardous waste in tank systems document the results of their tank inspections; and (3) both SQGs and LQGs accumulating hazardous waste on drip pads document the results of their drip pad inspections.

The Agency requested comment on modifying these provisions to require documentation of inspections for these waste accumulation units to emphasize the importance of these inspections in preventing releases into the environment and to provide a measure of accountability that a generator's inspection of its containers, tanks or drip pads actually took place when required. Currently, the only way an inspector can determine whether the required inspections actually occurred is to inspect a generator site at the same time that the inspection is supposed to occur, or conduct an inspection within one week of the first inspection—assuming the inspector knew when the first inspection actually occurred. Both situations have low probabilities of occurring.

As part of the proposed rule, the Agency noted that many states already require generators accumulating hazardous waste in waste accumulation units to maintain records of their inspections. Many of these states provide templates for generators to use to assist them in recording the results of their inspections. Similarly, EPA stated the burden imposed upon generators to record the results of its inspections would not be significant, particularly if generators use a template to document the results of inspections.

The Agency also stated that documenting the results of these inspections is an important best management practice for generators to use not only to prevent any releases, but also to identify situations, such as damaged containers, tanks or drip pads that could lead to a potential release to the environment.

1. What is EPA finalizing?

The Agency is not moving forward at this time to require SQGs and LQGs to

document those situations identified earlier where documentation of inspections is currently not required. At this time, the Agency believes further analysis and evaluation is required before a final decision can be made. However, as already noted, the Agency believes this is a best management practice that serves to protect generators from possible releases and cleanup and which also bolsters the preventive aspects of the RCRA program. EPA encourages generators to examine the feasibility of adopting this practice as part of their standard operating procedures.

2. Major Comments

Commenters were mixed on the need to require SQGs and LQGs to document the results of their inspections associated with containers, tanks and drip pads. Among the reasons commenters cited for supporting documentation of inspections included: Such a process acts as a reminder to ensure there are no problems; the requirement is not unduly burdensome; companies are already in the habit of preparing and maintaining these types of records; the records are useful in tracking containers within the accumulation areas and corrective actions needed and taken, and in documenting that no releases occurred within the unit; and documentation will result in greater protection against hazardous waste releases into the environment.

Commenters who opposed this requirement stated that adding additional recordkeeping requirements shifts the focus away from actual storage practices to secondary recordkeeping practices; there is not sufficient justification for imposing this requirement; there is no added benefit because accumulation units in poor condition have obviously not been regularly inspected; and the Agency would be better served by increasing outreach to small generators to increase awareness of the inspection requirement.

K. Allowing VSQGs To Send Hazardous Waste to LQGs Under the Control of the Same Person (40 CFR 262.14(a)(5)(viii) and 262.17(f))

EPA is finalizing the proposed provision to allow VSQGs to send their hazardous waste to an LQG that is under the control of the same person, as defined at § 260.10, provided both the VSQG and LQG comply with specified conditions.

1. Introduction

Before the revisions in this rulemaking, under the regulations at § 261.5(f)(3) for acute hazardous waste, and § 261.5(g)(3) for non-acute hazardous waste, a VSQG was allowed to either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, which included RCRA-permitted hazardous waste facilities, interim status hazardous waste facilities, municipal solid waste facilities, non-municipal non-hazardous waste facilities, recycling facilities, and universal waste handlers. The previous VSQG regulations did not allow a generator to send its hazardous waste off site to another generator unless the receiving generator had a storage permit or was otherwise one of the types of facilities cited previously. Thus, persons looking to reduce their overall environmental liability across multiple facilities were prohibited from managing their VSQG hazardous waste at one or more of their LQG facilities without first obtaining a permit or complying with the interim status standards.

EPA determined that providing the option for VSQGs to send their hazardous waste to an LQG that is under the control of the same person will improve the management of that hazardous waste for the following reasons. First, LQGs are subject to more stringent management conditions compared to VSQGs, such as accumulation time, labeling, training, emergency planning, and containment standards. In addition, LQGs may only transport (using a hazardous waste manifest) hazardous waste to RCRA-permitted or interim status hazardous waste TSDFs, which in turn, are subject to more stringent management standards than the municipal or non-municipal solid waste facilities that VSQGs are allowed to use. Therefore, allowing hazardous waste generated by a VSQG to be sent to an LQG under the control of the same person will improve overall tracking, oversight and management of the hazardous waste and enable more effective environmental protection.

Furthermore, a company, because of economies of scale, may reduce its overall waste management costs, as well as its potential financial liabilities for hazardous waste it generates at VSQG facilities, as it would be handled under the more comprehensive LQG and TSDF regulatory programs. Consolidation by an LQG of hazardous waste generated by several VSQGs under its control may also increase potential opportunities for hazardous waste recycling by the LQG.

In addition, whereas LQGs have up to 90 days to accumulate hazardous waste in compliance with all the LQG conditions for exemption without having to obtain a RCRA storage permit or comply with all the other standards otherwise applicable, VSQGs may accumulate up to 1,000 kilograms of non-acute hazardous waste or up to 1 kilogram of acute hazardous waste or up to 100 kilograms of residues from the cleanup of a spill of acute hazardous waste without any time constraint. Even though the amount of hazardous waste allowed on site by VSQGs at any one time is limited, the longer that hazardous waste is accumulated on site, the greater the risk of adverse impacts to human health and the environment. Allowing VSQGs to send their hazardous waste to an LQG under the control of the same person will likely reduce the overall time that the VSQG accumulates hazardous waste on site, which would further reduce the potential risk to human health and the environment.

Finally, this new provision will give companies flexibility in allocating labor and resources required to manage the company's total quantity of hazardous waste generated, as the company is now allowed to consolidate its hazardous waste from VSQG facilities at its LQG facilities.

EPA has received requests over the years from industry to amend the regulations to allow VSQGs to send their hazardous waste to LQGs for consolidation. Many of the commenters, including state agencies, the generator industry, and the waste management industry, supported adding this option to the regulations. Commenters expressed their support for consolidation, stating that it will ease the financial and administrative burden for VSQGs and encourage responsible waste management, treatment, and disposal. Specifically, some commenters stated that consolidation at an LQG would ensure greater safety and environmental protection because LQG staff are generally more knowledgeable than those at a VSQG. In addition, the Minnesota Pollution Control Agency confirmed with direct observation that allowing a VSQG to send its hazardous waste to another site where proper and safe management is available at a reasonable financial and management price, such as is provided by a VSQG collection site, does consistently reduce the average time that VSQGs accumulate waste on site, reducing on-site health and safety risks and also lowering the potential for both accidental releases

and the temptation for improper disposal of larger amounts.[82]

Adding the consolidation option in the regulations will enable generators to employ greater control over the management of their hazardous waste, thereby resulting in improved efficiency and reduced liability for the generator. Commenters noted numerous examples where VSQGs and LQGs under the same ownership may take advantage of the new consolidation provision. For example, Army National Guard and Reserve units that may be VSQGs can send their hazardous waste to an active Army base that is an LQG. The same situation applies to Air Force, Navy, and Marine Corps reserve units as well. Additionally, many universities commented that they supported this provision. Often, individual laboratory buildings qualify as VSQGs. Allowing different laboratory buildings within a university or industrial environment that are VSQGs to send their hazardous waste to another university or industrial entity that is an LQG under the same control will provide both economic and environmental benefits. Furthermore, utilities, retailers, and remote oil and gas production facilities also represent examples of industrial sectors that indicated they expect to benefit from the intra-company transfer of hazardous waste from VSQGs to LQGs.

2. What is EPA finalizing?

The Agency is finalizing the provision that allows a VSQG to send its hazardous waste to an LQG that is under the control of the same person, provided specified conditions are met.

a. *Scope.* EPA is finalizing its proposal to amend the regulations under the previous regulatory framework at § 261.5(f)(3) and (g)(3) to allow VSQGs to send hazardous waste to an LQG under the control of the same person. ''Person'' is defined in § 260.10 to mean an individual, trust, firm, joint stock company, federal agency, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state or any interstate body. For the purposes of this section, ''control'' means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate as generators on behalf of a different person shall not be deemed to ''control'' such generators. EPA notes that these are the same key terms used in the exclusion from the definition of solid waste for hazardous secondary materials that are generated and legitimately reclaimed under the control of the generator (40 CFR 261.4(a)(23)), which was promulgated on October 30, 2008, (73 FR 64668) and revised on January 13, 2015 (80 FR 57918). Consistent with the October 30, 2008, final rule, companies within the same corporate structure would be considered ''under the control of the same person'' if they meet the definition of same ''person'' and ''control'' as outlined above.

Limiting transfers to facilities under control of the same person is appropriate because it ensures common control is maintained over both facilities and takes advantage of strong liability incentives to ensure the hazardous waste is safely managed. Additionally, if a VSQG sends hazardous waste to an LQG under the control of the same person, the LQG is likely to be more familiar with the type of hazardous waste generated by the VSQG. Furthermore, questions regarding liability and responsibility for such hazardous waste are clearer than is the case with facilities from unrelated companies. The majority of commenters, including most of the states, supported limiting the VSQG consolidation option to facilities under the control of the same person at this time for similar reasons.

EPA is also finalizing the proposed requirements for certain labeling and marking standards for VSQG waste being transferred to LQGs under the control of the same person under this provision. Note that aside from these conditions, the same standards for management of VSQG waste apply to materials going to an LQG under this provision as to other VSQG waste, including the exemption from the requirement to ship using a hazardous waste manifest. However, DOT shipping requirements do still apply as appropriate.

b. Conditions for Exemption

Condition for Exemption for VSQGs

As part of this provision, VSQGs are required to meet the following conditions for exemption, found at § 262.14(a)(5)(viii).

Under control of the same person. As described previously, the VSQG and the LQG must be under control of the same person, according to the definition in § 260.10.

Labeling and marking of containers. The Agency is requiring that a VSQG transferring waste to an LQG under the control of the same person label its containers with (1) the words ''Hazardous waste'' and (2) an indication of the hazards of the contents of the container (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association (NFPA) code 704). This condition is also consistent with the revisions for labeling and marking of containers found in 40 CFR parts 262, 263, and 268 and discussed in section IX.E.1 of this preamble.

Conditions for Exemption for LQGs

EPA is finalizing the following conditions for exemption for LQGs receiving hazardous waste from VSQGs under the control of the same person, all found at § 262.17(f).

Notification. LQGs receiving hazardous waste from VSQGs under the control of the same person must submit a notification to EPA or their authorized state using EPA Form 8700–12 (*i.e.,* the Site Identification (Site ID) form) at least 30 days prior to receiving the first shipment of hazardous waste from the VSQG. LQGs are required to identify on the Site ID form the name(s), site address(es), and contact information for the VSQG(s) that will be transferring hazardous waste to the LQG. LQGs are also required to submit an updated Site ID form within 30 days should the name or site address for the VSQG change. Since the process to update the Site ID form to reflect this final rule will not be completed by the time some facilities are required to notify, EPA will create an interim procedure for submitting notifications for the regulated community to aid their compliance efforts with the new consolidation provision and publish it on the EPA Web site.

Notification in this instance serves to inform the regulatory authorities of which LQGs are receiving hazardous waste from which VSQGs under the control of the same person. The Agency has determined notification is necessary in order to communicate to inspectors the origin of the hazardous waste received by the LQG and to ensure the received shipment is managed in compliance with the conditions of the provision. EPA also believes notification by the LQG, rather than notification by the VSQG, is more efficient and less

[82] Minnesota Pollution Control Agency (MPCA), Comment Number: EPA–HQ–RCRA–2012–0121–0232.

burdensome, because LQGs are already required to submit Site ID forms as part of obtaining a RCRA Identification Number and as part of the biennial reporting process. Additionally, it is more efficient for one LQG to notify on behalf of numerous VSQGs.

EPA has recently made available an electronic interface for states and the regulated community to use to submit Site ID forms electronically, which will further reduce burden on LQGs. Facilities should check with their states regarding whether and when their state will use EPA's electronic submittal process.

Recordkeeping. LQGs are required to maintain records for three years from the date the hazardous waste was received from the VSQG with the following information:

—The name, site address, and contact information for each VSQG; and
—A description of each waste shipment received from the VSQG, including the quantity and the date the hazardous waste was received.

Recordkeeping is necessary to ensure the VSQG and LQGs operating under the consolidation provision are meeting the conditions of the provision, including that the VSQG and LQG are under control of the same person. Records can also be used to ensure that the hazardous waste from the VSQG is managed according to the other conditions for exemption of this provision, such as the requirement that LQGs are receiving shipments of hazardous waste from VSQGs in quantities commensurate with the VSQG's generator category. This recordkeeping condition can be fulfilled through routine business records, such as a bill of lading, and will not present an undue burden to the LQG. Additionally, the LQG can then use this information to report the hazardous waste from the VSQG on its biennial report forms.

Labeling and marking of containers. The Agency is requiring that LQGs comply with the same labeling and marking conditions for exemption under § 262.17(a)(5), including the date accumulation started (*i.e.,* the date the hazardous waste was received from the VSQG). (Note: These are the same standards that VSQGs must comply with in labeling and marking containers that they send to LQGs, as discussed previously, with the exception of the accumulation start date.) If the LQG is consolidating incoming hazardous waste from a VSQG with either its own hazardous waste or with hazardous waste from another VSQG, the LQG must mark each container with the earliest date any hazardous waste in the container was accumulated on site. This will prevent an LQG from starting the accumulation clock over again, which could lead to an endless loop of accumulation.

Because the LQG must manage the hazardous waste it receives from VSQGs according to the LQG regulations, EPA has determined the same labeling and marking requirements should apply to both its own hazardous waste and hazardous waste received from a VSQG. EPA believes that it is important that employees, transporters, downstream handlers, emergency personnel, EPA, and the states know as much as possible about the potential hazards of the contents in containers that LQGs accumulate, transport, and manage.

Waste management. Under the finalized consolidation provision, an LQG is required to manage all incoming hazardous waste from a VSQG in compliance with the regulations applicable to its LQG generator category. In other words, there will be no difference in how the hazardous waste from a VSQG is managed relative to the management of the LQG's own hazardous waste, although hazardous waste from a VSQG is not eligible for management under the satellite accumulation regulations (§ 262.15) (That is, VSQG waste must be placed in a central accumulation area or immediately shipped off site from the LQG.)

Biennial Reporting. An LQG must also report the hazardous waste it receives from VSQGs on its biennial report, as required under § 262.41. EPA will include a new source code in the biennial report instructions that LQGs will use to identify the hazardous waste received from a VSQG (to differentiate from hazardous waste the LQG generates on site). Generators are required to report hazardous waste they receive from VSQGs by type of hazardous waste. In other words, if an LQG receives the same type of hazardous waste from multiple VSQGs, it only need report the total quantity of that hazardous waste received from all VSQGs. This will enable states and EPA to better understand the additional volumes and types of hazardous wastes managed at an LQG, which will assist in prioritizing compliance assistance.

c. No maximum limit of hazardous waste LQGs receive from VSQGs. Because LQGs currently have no maximum limit on the amount of hazardous waste they can accumulate, and because the regulations that are applicable to LQGs are protective, the Agency has determined there is no need to establish a maximum limit on the amount or types of hazardous waste that an LQG can receive from VSQGs. In fact, we believe the more hazardous waste that is shipped to LQGs, the greater potential for better management, since these hazardous wastes will be managed under the more comprehensive hazardous waste regulations, as opposed to potentially being sent to non-hazardous waste disposal facilities. In addition, the LQG will need to move the VSQG waste off site in a timely manner since the 90-day accumulation limit for the exemption from permitting will still apply.

d. Enforcement. The conditions in this final rule that allow VSQGs to send their hazardous waste to an LQG under the control of the same person are necessary to ensure protection of human health and the environment. Failure to meet one or more of the conditions could lead to potential mismanagement of the hazardous waste, potentially resulting in a release of hazardous waste or hazardous waste constituents to the environment. Persons taking advantage of the consolidation provision who fail to meet one or more of the conditions for exemption would lose their exemption from a permit, interim status, and operating requirements and be subject to an enforcement action under RCRA section 3008 for violations of the applicable requirements in part 264 through 268, 270, and the notification requirements of section 3010 of RCRA. EPA and authorized states also have the authority to cease specific transfers of hazardous waste from VSQGs to an LQG in the context of an enforcement action. EPA also notes that failure on the part of the LQG to meet one of the conditions for exemption would not mean that the VSQG is subject to a permit, interim status, and operating requirements, provided that the VSQG met its conditions for exemption and vice versa.

e. Interstate shipments. Under RCRA, authorized state programs may be more stringent than the federal program and thus states may choose not to adopt the finalized consolidation provision allowing VSQGs to send their hazardous waste to an LQG under the control of the same person. In the case of interstate shipments where a VSQG wants to transfer its waste to an LQG located in a different state than the VSQG, the VSQG must ensure that both states have adopted the provision (including the exemption from the requirement to ship using a hazardous waste manifest). Additionally, if a VSQG wants to transit its waste through states that have not adopted the consolidation provision, EPA recommends that generators contact any transit states through which

the hazardous waste will be shipped to ascertain their policy about such shipments.

2. What changed since proposal?

a. Labeling and Marking of Containers. EPA proposed that the VSQG would label its containers with the words ''Very small quantity generator hazardous waste.'' However, several commenters stated that having two ''systems'' of labeling was confusing and discussed other ways to distinguish the VSQG waste from the LQG's own waste when it is consolidated. Specifically, the records that an LQG are required to keep should be sufficient to distinguish VSQG waste from the LQG's own waste. In addition, there will likely be situations where an LQG supplies the labels to the VSQG, so using one common label is reasonable. EPA has determined that using a different label would not improve management of the hazardous waste at either generator. Therefore, EPA has decided that labeling the VSQG's waste to be consolidated with the words ''Hazardous Waste'' (along with the other labeling requirements) are sufficient under the consolidation provision.

In addition, we are not requiring the following marking and labeling: (1) Other words that identify the contents of the containers and (2) the applicable hazardous waste number(s) (EPA hazardous waste code). First, we are not requiring ''the contents'' of the container to be consistent with the finalized marking and labeling requirements for all generators as discussed in section IX.E.1. In addition, we are not requiring the applicable hazardous waste number(s) be included on the label because we have determined that it is not necessary at this point in the management of the VSQG waste. Due to the fact that LQGs do not need to add the hazardous waste codes until the waste is ready to be shipped off site to a designated RCRA facility for subsequent management, we determined that was also the best option for the VSQG waste being consolidated at an LQG. Therefore, the VSQG waste only needs to be labeled with the words ''Hazardous Waste'' and an indication of the hazards of the contents when it is sent for consolidation at an LQG under the same control. Once at the LQG, the date the accumulation starts (*i.e.,* the date the hazardous waste was received from the VSQG) must be added to the label. Of course, if the VSQG wants to include words that identify the contents of the containers and/or the applicable EPA hazardous waste number(s) (hazardous waste codes), that is encouraged as discussed in the general marking and labeling provisions in this preamble (section IX.E.1). Due to the fact that the VSQG and the LQG are under the control of the same person, EPA assumes that the two parties will consult and determine the most appropriate labeling for the safe management of their hazardous waste that meets the minimum requirements laid out in the regulations.

b. LQG notification. EPA proposed that LQGs notify using an updated Site ID form 8700–12 within 30 days of a change in the site name, site address, or contact information for a VSQG sending their hazardous waste for consolidation at the LQG. Several commenters recommended only requiring notification of changes to the site name and/or address of the VSQG. EPA agrees that if the site name and address remains the same, it is not necessary for the LQG to notify again simply because the contact information for the VSQG changes. Due to the fact that the VSQG consolidation provision is limited to facilities under the control of the same person, the LQG would likely have knowledge of any change in contact information and could provide that to the implementing agencies if necessary.

3. Major Comments

a. Expanding scope of the provision. EPA also requested comment on whether to establish a process that would allow a generator (whether VSQG or LQG) to request approval from its EPA Regional Administrator or the authorized state to transfer hazardous waste from VSQGs to LQGs that are not under the control of the same person. Additionally, the Agency also requested comment on a variation that would allow LQGs to consolidate VSQG hazardous waste from VSQGs that are not under the control of the same person by submitting a request for approval. The difference under this variation was that after 60 days, the generator could start consolidating regardless of whether it had heard back from the implementing agency.

After consideration of the comments received, EPA has decided not to finalize an inter-company consolidation provision at this time. There was not enough support in the public comments and significant implementation issues were identified. It is likely that additional safeguards would need to be put in place to allow VSQG consolidation at an LQG that is not under the control of the same person. After a sufficient number of states adopt the intra-company consolidation provision, the Agency plans to evaluate how the consolidation option is working. EPA will then consider possible expansion of the provision in the future, including whether to allow VSQG consolidation at SQGs under the same control and/or LQGs under the control of a different person.

b. Effect on existing state programs. EPA received comments from the retail sector suggesting that, under the existing RCRA regulations, VSQG hazardous waste can be consolidated at any intermediate location, as long as the VSQG ensures ultimate delivery to an acceptable facility listed under the regulations. However, EPA does not agree with that characterization of the existing regulations and has expressed that in writing as far back as 1987.[83] As explained in the guidance, a VSQG must either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site facility listed in previous § 261.5(f)(3) and now found at § 262.14(a)(4).

In addition, other commenters noted that certain states already operate consolidation programs that go beyond what EPA is finalizing in this document. For example, Minnesota operates a VSQG collection program (VSQGCP) where non-affiliated LQGs apply and are individually reviewed and approved by the state to receive hazardous waste from any VSQG at their discretion. Currently, Minnesota has approved 31 such VSQGCPs, providing relatively convenient safe disposal for VSQGs across the state.[84] The Utility Solid Waste Activities Group also expressed their concern that EPA has not acknowledged many state practices that facilitate the removal of small hazardous waste streams from remote, unmanned locations.[85]

It is not EPA's intention to interfere with existing state consolidation programs. If a state has authorized a facility to manage hazardous waste or has permitted, licensed, or registered a facility to manage municipal solid waste or non-municipal, non-hazardous waste, EPA would consider that to be a facility allowed to receive VSQG waste under § 262.14(a)(5). In addition, EPA notes that states can be more stringent and thus, can adopt the VSQG consolidation provision finalized in this rule and add other requirements as they deem necessary and allowable under state law.

[83] See RCRA Hotline Monthly Report Question, April, 1987, RCRA Online 12894.

[84] Minnesota Pollution Control Agency (MPCA), Comment Number: EPA–HQ–RCRA–2012–0121–0232.

[85] The Utility Solid Waste Activities Group, Comment Number: EPA–HQ–RCRA–2012–0121–0093.

Effect of the Reorganization: This section is affected by the reorganization. The reorganization of the generator regulations moved the conditions for VSQGs from § 261.5 to § 262.14 and the conditions for LQGs from § 262.34 to § 262.17. The reorganization is discussed in section VI of this preamble.

L. EPA Identification Numbers and Re-notification for SQGs and LQGs (40 CFR 262.18)

Under existing RCRA regulations, SQGs and LQGs are required to notify EPA using form 8700–12 (Site ID form) in order to obtain an EPA identification number. The Site ID form contains such information as the name and address of the generator, the industrial sector in which it belongs (*i.e.,* NAICS code), name of a facility contact, what type of waste activities take place at the facility, etc. Without such an identification number, a generator cannot treat, store, dispose of, or transport its hazardous waste. Subsequent to obtaining an EPA ID, there is no federal regulation requiring SQGs or LQGs to re-notify EPA to update their site information or confirm the information remains accurate. However, LQGs do update their site information every two years as part of the biennial report, as the Site ID form is part of the biennial report submission.

The lack of a re-notification requirement, especially for SQGs at the federal level, greatly impairs EPA's and the states' ability to use the information for compliance monitoring and programmatic purposes. This is because a one-time notification provides no assurance that the information collected in EPA's and the states' databases over time will accurately reflect which facilities are generating hazardous waste.

To address these issues, the Agency proposed several changes to the RCRA SQG and LQG site-identification and re-notification processes. First, we proposed to add an independent requirement for LQGs that reflects existing processes by which LQGs already submit Site ID forms as part of the biennial reporting process. Second, we proposed that SQGs must re-notify EPA using the Site ID form prior to February 1 of each even-numbered year, similar to the biennial report with the SQG re-notifications occurring one month prior. EPA took comment on alternative time frames for SQG re-notification such as every four years, alternate cycles from the biennial report, and rolling re-notifications. Finally, EPA took comment on whether a better approach would be for EPA to require an SQG or LQG to re-notify only in the event of a change to certain information, such as change in ownership or generator category.

1. What is EPA finalizing?

The Agency is finalizing the requirement for SQGs to re-notify EPA (or an authorized state program) beginning in 2021 and every four years thereafter using EPA Form 8700–12. While still several years away, states must become authorized for this provision. In the meantime, the Agency will work with the states and the regulated community to develop the necessary software and instructions to effectively implement this new requirement. This re-notification requirement will also occur in years in which federal biennial reporting is not required. This form must be submitted by September 1st of each year in which re-notifications are required.

In addition, EPA is finalizing in § 262.18(d)(2) the formalization of LQGs re-notifying using EPA Form 8700–12, the RCRA Site Identification form, as part of the LQG's biennial report required under § 262.41.

Note that the changes to the regulatory text for § 262.18 in this action take into account the revisions being made as a part of the ''Hazardous Waste Export-Import Revisions'' Final Rule (Docket ID EPA–HQ–RCRA–2015–0147; FRL–9947–74–OLEM), including the reference in § 262.18(e) for recognized traders.

2. What changed since proposal?

The Agency, in response to comments, increased the interval for SQG re-notifying from every two years to every four years. A number of commenters responded to our requests for alternative timing for SQG notification. Significantly, we heard from a number of states as well as the RCRAInfo Expert Group (a group of EPA and state RCRAInfo data experts), that keeping the SQG notifications on the same cycle as the biennial report is too burdensome and not practical given the large volume of data they receive for the biennial report. These commenters suggested that we reduce the frequency of SQG notifications from two years to every four years and stagger it from the timing of the biennial report. The EPA agrees with these experts and, as described previously, is finalizing the SQG re-notification requirement with these changes as recommended.

There was varied support from commenters on alterative timing for SQG notification. Some commenters supported keeping the timing to every two years both on the biennial report cycle and off. EPA agrees there is general awareness in the generator population of when the biennial report is due, which could make it easier for SQGs to comply with this new requirement. Also, the Agency understands that for companies or facilities that may have multiple sites that are LQGs and SQGs, it may be difficult to keep track of one schedule for LQGs and the biennial report and another for the SQG re-notification. However, the Agency decided to defer to the comments regarding how keeping SQG re-notification timing on the same cycle as the biennial report would overwhelm state and EPA workload capacity to keep up with the data submissions. In order for the data to be usable and the collection effort worthwhile, the Agency must be able to ensure it is entered into our system correctly and we believe the four year cycle alternating with the biennial report will best address capacity issues.

Both state and industry commenters pointed out that many states already require annual re-notification by LQGs and some for SQGs as well. Most asked that EPA clarify that this collected state data can be used to satisfy the federal SQG re-notification requirement. We are clarifying that as long as the more frequently state-collected data is transferred into the national RCRA information management system or RCRAInfo by the state on the timetable EPA is finalizing in this rulemaking for SQG re-notification, these existing state regulations would meet the requirement.

Two concepts were raised by commenters that EPA intends to investigate for possible changes to the Site ID form in the future. First, commenters asked for the ability to check a box certifying that their site ID information had not changed rather than have to fill out the entire Site ID form each time they re-notify. By increasing the time interval for SQG re-notification to every four years, EPA believes there will be reduced burden, but understands this option would increase efficiency for the regulated community and implementers. We intend to work with our national data experts to explore a possible form change to accommodate this idea. Second, commenters asked for a check box or another mechanism to inactivate a RCRA Site ID number. EPA intended for the SQG re-notification process to provide a mechanism for EPA and the states to deactivate RCRA identification numbers when no activity occurred for long periods of time. The Agency intends to work with our state partners in exploring whether the Site ID form or data system changes can be made, or

guidance issued, to allow this action to occur.

Some in industry questioned the need for such information. Commenters suggested that alternative information collection mechanisms already exist, such as using the Biennial Report submission for LQGs and manifest data. First, the existing one-time notification for SQGs provides no assurance that the information collected by EPA and many states, over time, will accurately reflect which facilities are generating hazardous waste and whether they still are SQGs. EPA agrees that the Biennial Report required by LQGs does provide a mechanism by which LQGs regularly re-notify, and we are simply codifying that process in this final rule. While TSDFs report hazardous waste received by SQGs in their Waste Received (WR) form, they do not identify the generator category of the facility they are receiving waste from, only the RCRA identification number. From experience, the Agency has found there is no guarantee that cross walking the RCRA identification number of a facility reported in the WR form with the information found in an existing RCRA Site Identification form will guarantee that the regulatory category of the generator is correct. Therefore, the Agency believes periodic re-notification is required.

With respect to using manifest data, currently manifest data is owned by the states and not required to be sent EPA. This is changing with the e-Manifest system under development, in that the e-manifest data will be available to EPA and the states. However, as the system is being designed, specifications do not include a generator category data element, nor is including this data element possible without a regulatory change. However, the Agency will continue to investigate the feasibility of using e-Manifest data to identify active SQGs and LQGs.

A number of commenters supported the idea that SQG re-notification be required when a specified event occurs. Technically, generators already have this capability. The existing instructions for completing EPA Form 8700–12 include the statement, ''You must use this form to submit a subsequent notification if your site already has an EPA Identification Number *and you wish to change information* (*e.g.,* generator status, new site contact person, new owner, new mailing address, new regulated waste activity, etc.).'' [86]

While the Agency took comment on this option, we believe that having EPA and states conduct a census re-notification process every four years is a more cost effective process guaranteeing a greater response rate than requiring a self-initiation process on the part of generators (*i.e.,* from past experience, EPA and the states have had to remind many generators they failed to re-notify). In fact, the Minnesota Pollution Control Agency comments strongly cautioned EPA to not adopt this approach and to learn from Minnesota's negative experience requiring re-notification when events occur. EPA and the states also have experience regarding how to implement a census re-notification process via the Biennial Reporting process for LQGs that they can apply to the new SQG re-notification process.

The retail sector also requested that the Agency limit the periodic re-notification requirement for their stores, and provide a streamlined process for large retail chains (*e.g.,* allowing a consolidated update that identifies only key changes).[87] The Agency understands the retailers' concerns, which are among the reasons we are not finalizing re-notification based on specified events. EPA continues to explore the various approaches to the retail sector as they, similar to laboratories, tend to operate very differently than typical hazardous waste generators and face unique issues with the RCRA regulations.

Finally, EPA is clarifying that when an SQG or LQG changes location, it is required to notify EPA because a new RCRA identification number will be needed as these numbers are tied to a physical site. EPA and the states will work with the generator to inactivate the previous RCRA identification number held by the generator while also assigning a new RCRA Identification number. Also, while not required, EPA recommends that generators who change ownership re-notify and alert EPA or their state that a new owner is responsible for the management of hazardous waste at the facility.

Overall, this provision of the final rule provides a balanced approach between the re-notification needs of EPA, the states, and SQGs. We will work with all parties to ensure its effective implementation.

Effect of Reorganization: This section is affected by the reorganization. The reorganization of the generator regulations moved the requirements for EPA identification numbers from § 262.12 to § 262.18. The reorganization is discussed in section VI of this preamble.

M. Provision Prohibiting Generators From Disposing of Liquids in Landfills (40 CFR 262.14(b) and 262.35)

RCRA section 3004(c) prohibits the disposal of bulk or non-containerized liquid hazardous waste or free liquids contained in hazardous waste in any landfill. This prohibition is necessary because the disposal of liquids in landfills can be a significant source of leachate generation. Restricting the introduction of liquids into landfills would minimize the leachate generation potential of landfills and reduce the risk of liner failure and subsequent contamination of the ground water.[88] The Agency codified this prohibition for municipal solid waste landfills (MSWLFs) at § 258.28, and at § 264.314 and § 265.314 for permitted and interim status hazardous waste landfills. This prohibition is not a new provision and has been in place for almost 25 years. However, the Agency believes it is important to emphasize that the responsibility for complying with this statutory provision resides not only with municipal and hazardous waste haulers and landfill operators, but also with hazardous waste generators. Additional information can be found in the preamble of the proposed rule (80 FR 57971).

1. What is EPA finalizing?

The Agency is finalizing the proposed regulatory language prohibiting hazardous waste generators from disposing of liquid hazardous wastes in landfills. The final regulatory language is located at § 262.14(b) for VSQGs and at § 262.35 for SQGs and LQGs. As explained in the proposal, EPA is clarifying existing language to emphasize that hazardous waste generators are also responsible for complying with this provision. Also, the Agency is adding references to § 264.314 and § 265.314 in the SQG and LQG regulation (§ 262.35). Liquid waste disposed in a hazardous waste landfill must meet the additional requirements in § 264.314 and § 265.314, notably the requirement that the sorbents be nonbiodegradable. EPA is adding these references to § 262.35 in response to comments about sorbed hazardous waste liquids and to clarify the requirements that must be met prior to disposal in a hazardous waste landfill.

[86] See 2015 Biennial Report Instructions, page 11–12 at *https://www.epa.gov/sites/production/files/2015-11/documents/2015_hwr_instructions_forms.pdf.*

[87] See Comments of the Retail Associations in Response to EPA's proposal, Docket ID NO. EPA–HQ–RCRA–2012–0121, December 23, 2015.

[88] October 9, 1991, 56 FR 51055.

2. Major Comments

Several commenters expressed concern that the proposed regulatory language would cause confusion and force generators to alter their current practices for disposal of liquids. This was not the intent of this proposed regulation; EPA simply wanted to make generators more aware of this prohibition. Because the statutory prohibition was codified in the TSDF regulations and not in the generator regulations, some generators may have been unaware of the prohibition against the disposal of liquids in landfills. EPA disagrees with the commenter's suggestion to alter the proposed regulatory language for generators. EPA concludes that the proposed regulatory language prohibiting liquids in landfills is appropriate because the language was adopted directly from the statute and the same language is found in other parts of the regulations which applies to generators. It would be confusing to have slightly varying versions of this prohibition for each generator category and TSDFs.

A few commenters had concerns over the phrase ''whether or not sorbents have been added'' in the proposed regulatory text. The Agency is clarifying that this phrase does not restrict the use of sorbents as treatment prior to disposing in a landfill. If sorbents have been used but free liquids are still present, then the waste is prohibited from disposal in all landfills. However, if there are no free liquids as defined in § 260.10 after the use of sorbents, then the waste may be disposed in the correct corresponding landfill.

EPA would like to clarify how current practices that remove free liquids prior to disposal in a landfill will not be altered by this proposed regulatory language, although commenters believed otherwise. These current practices will not be altered by this regulation and most generators should be able to continue operating as they have prior to this rule unless their waste contains free liquids when disposed in landfills. If there are free liquids, they are already out of compliance with the current requirements even before this rule takes effect. Methods that remove or solidify free liquids, such as mixing in sorbents until no free liquids are present, must continue to be utilized by all generators prior to disposal in any landfill. However, sorbed hazardous waste liquids by an SQG and LQG must meet additional criteria specified in § 264.314 and § 265.314 prior to disposal in a hazardous waste landfill.[89] [90] For example, one criterion, as some commenters pointed out, is that the sorbent must be non-biodegradable if disposed in a hazardous waste landfill. In instances where biodegradable sorbents are used, such as prior to incineration or energy recovery, then SQGs and LQGs must ensure that these wastes are not disposed in a hazardous waste landfill. VSQGs are not required to follow the additional criteria in § 264.314 and § 265.314 if they are disposing their waste in a MSWLF, but they must still ensure that their waste contains no free liquids prior to disposal in any landfill.

Some generators commented that they have agreements where a TSDF is stabilizing all or some of their liquid hazardous waste. These generators are concerned that this regulation will end these agreements. EPA would like to clarify that this practice is not restricted by this regulation and generators may continue to ship their liquid waste to TSDFs for stabilization.

Effect of the Reorganization: This section is not affected by the reorganization. Regulatory language regarding the prohibition of liquids in landfills was duplicated from § 258.28, and at § 264.314 and § 265.314.

N. Clarification of Biennial Reporting Requirements (40 CFR 262.41, 264.75 and 265.75)

The Agency proposed changes to biennial reporting requirements at § 262.41, § 264.75 and § 265.75. For purposes of convenience and efficiency, a discussion of proposed changes being finalized in this rulemaking are consolidated here.

The biennial report provides EPA and the states with important information from all LQGs and RCRA treatment, storage and disposal facilities associated with hazardous waste generation and management. For LQGs, this information includes, for each hazardous waste generated, the quantity generated and the hazardous waste composition, as well as how and where this waste is managed. For TSDFs, this information includes hazardous wastes received from not only LQGs but also SQGs and VSQGs. This information is used to support various EPA and state program management and compliance monitoring functions.

The regulations associated with biennial reporting by both generators and TSDFs have been in existence for approximately thirty years with very little change over this time period. From experience through years of implementing this program, the Agency identified areas where clarifications and changes to these regulations could improve both program efficiency and effectiveness. The Agency proposed such changes as part of this rulemaking. A discussion of the proposed changes being finalized follows.

EPA proposed to modify the biennial reporting regulations for generators found at 40 CFR 262.41 in order to make the regulations consistent with Agency guidance, including its biennial report instructions and forms. More specifically, the Agency proposed the following revisions: (1) Only LQGs need to submit biennial reports; (2) LQGs must report all of the hazardous waste they generate for the entire reporting year, not just the month(s) the generator was an LQG; (3) LQGs completing a biennial report must report all hazardous wastes they generated in the reporting year, regardless of whether they transferred the waste off site during the reporting year; and (4) a reference to the biennial report form (EPA Form 8700–13) at § 262.41 rather than the list of specific data elements in currently at that citation.

Additionally, EPA proposed to modify the title of part 262 subpart D from ''Recordkeeping and Reporting'' to ''Recordkeeping and Reporting Applicable to Small and Large Quantity Generators'' in order to highlight which entities need to comply with this subpart.

With respect to permitted and interim status TSDFs at § 264.75 and § 265.75, EPA proposed to modify the regulations at §§ 264.75 and 265.75 to eliminate the list of specific data elements and to require the completion and submission of all data elements in the biennial report form (EPA Form 8700–13).

1. Standards Applicable for LQGs (40 CFR 262.41)

a. What is EPA finalizing for LQGs? First, only LQGs need to complete and submit biennial reports. The previous regulatory text was unclear as to which generators had to submit a biennial report. Previous regulatory text also did not include the word ''complete'' which now has been added. However, the Agency is modifying the regulatory text per a comment to clarify that information is to be reported for every odd-numbered year and that the actual Biennial Report must be completed and submitted using EPA Form 8700–13 A/B to the Regional Administrator by March 1 of the following even-

[89] November 18, 1992, 57 FR 54452.

[90] RCRA Online 11798, November 17, 1993.

numbered year.[91] The states may have more frequent or additional data reporting requirements over and above EPA's and may use a different, but equivalent, form to collect federal data and satisfy their own program data reporting needs.

Second, LQGs must report all of the hazardous waste they generate for the entire reporting year, not just the month(s) the generator was an LQG. Almost all states require their LQGs to perform this function already since the Biennial Report instructions require such reporting. This change simply creates consistency between the instruction and regulations. This change also provides EPA and the states with a much more reliable estimate of hazardous waste generated annually. As stated in the preamble to the proposed rule, LQGs should have this information available through their hazardous waste manifests and other counting processes.

Third, rather than citing specific data elements to be reported in § 262.41, as proposed, the Agency is simply referencing the Biennial Report form (EPA Form 8700–13 A/B) at § 262.41(a) and (b) in this final rule. Through the years, the Agency has modified what data elements it was collecting in the biennial report through changes in biennial report instructions but not updating the regulations. Therefore this change formalizes this process. Several commenters had concerns about this process as discussed in this section.

The Agency is also not finalizing a commenter's suggestion that an LQG be allowed to report a solid waste that was generated at the end of a reporting year, but which was not determined to be hazardous until the beginning of the next, or non-reporting, year. With the Agency maintaining the existing regulatory framework for what must be reported (*i.e.,* hazardous waste generated and also sent off site in the reporting year, this situation no longer matters.

b. What changed since proposal? In the proposed rule, the Agency modified the regulatory text at § 262.41(a) to require all LQGs to complete and submit a biennial report for all hazardous wastes generated in the reporting year. This change altered what hazardous waste has to be reported, particularly for LQGs that manage their waste off site. Under the previous biennial reporting regulations, an LQG had to report all hazardous wastes both generated and shipped off site to a TSDF within the United States. Not included were hazardous wastes generated in the reporting year but not yet shipped off site because LQGs have up to 90 days to accumulate hazardous wastes prior to either managing the material on site or shipping it off site to a TSDF. Hence, the possibility existed that EPA and the states were not obtaining a reliable estimate of how much hazardous wastes was generated annually by LQGs.

Several commenters were concerned that such a change would dramatically alter the existing processes and procedures long established by LQGs, and by TSDFs who support LQGs in completing the Biennial Report. Others pointed out that EPA was obtaining a reliable estimate of hazardous wastes generated by LQGs, although not necessarily in a clear cut manner. A closer examination of existing biennial reporting instructions revealed that the amount reported included: (1) Hazardous waste generated and accumulated on site and subsequently managed on site or shipped off site in the reporting year; or (2) hazardous waste generated and accumulated on site in the reporting year but not managed on site or shipped off site until the following year; or (3) hazardous waste generated and accumulated on site prior to the reporting year but either managed on site or shipped off site in the reporting year. In other words, an estimate of hazardous waste generated by LQGs is already being captured and reported for a 12 month period, but not necessarily only in the reporting year.

Based on these comments, EPA is not finalizing the proposed § 262.41(a) changes and will instead revert back to the previous language found in § 262.41(a).

c. Major comments.. Many of the comments submitted by individuals and organizations concerned these issues. However, a number of commenters expressed concern regarding the Agency's process of involving the public in making changes to the Biennial Report forms now that the regulatory language will cite the form and no longer identify the required data to be submitted. Specifically, commenters mistakenly believed that EPA may impose additional substantive reporting requirements by simply changing the form, rather than through a rulemaking to change § 262.41. However, the Agency has been following the Administrative Procedures Act (APA) and will continue to do so. Commenters may not have been aware but changes to EPA Form 8700–13A/B are subject to the Paperwork Reduction Act (PRA), which requires an amendment to the Information Collection Request (ICR), which is approved by the Office of Management and Budget (OMB). Before amending the ICR, EPA publishes a notice in the **Federal Register** informing the public that the ICR is to be amended, and takes comment on the draft form, which is available in the docket. Moreover, there is a follow-up notice in the **Federal Register** informing the public when the ICR amendment has been submitted to OMB for approval. In the future, in order to ensure more transparency, the Agency also will post a copy of the draft form along with a discussion of any proposed changes, including the need for such changes, as part of the **Federal Register** notice. As part of this process, the Agency also will inform stakeholders of this **Federal Register** notice on the RCRAInfo Web page at *https://rcrainfo.epa.gov/rcrainfoweb/*.

One state commenter also disagreed that LQGs had to submit hazardous waste generation information for the months they were either an SQG or VSQG. The Agency believes generators should not find it difficult to submit this information because they will have maintained hazardous waste manifest records which identify the quantity of hazardous waste generated over a particular time period. Likewise, if the generator is an SQG or VSQG for eleven months of the year they may be able to take advantage of the new episodic event regulations being finalized at § 262.230. As already discussed, almost all states already require this information as part of their biennial reporting requirements, and it has long been included in the BR instructions.

Another commenter mentioned that it may be difficult for generators to determine in a precise way the amounts of waste that were generated at the beginning and end of each reporting year, particularly for wastes that are generated in small amounts at a time or that are initially stored in satellite accumulation areas, since they typically do not keep the records necessary to produce this information—especially by the time the reports are due, which could be a year or more after the fact. Generators are responsible for calculating the amount of hazardous waste they generate monthly to determine their generator category. Therefore, generators should have the requisite processes in place to accomplish this function.

One state expressed concerns that any changes to EPA Form 8700–13 A/B would also involve changes to the Biennial Report instructions and forms, as well as the RCRAInfo database, and wanted to ensure state input in this process. The Agency wants to assure all stakeholders that we will work with our

[91] See comments from the staff of the Hazardous Waste Section in the Hawaii Department of Health, Docket No. EPA–HQ–RCRA–2012–0121–0082.

state partners in developing any changes to Biennial Report forms and instructions, as well as any changes to the RCRAInfo database, through established processes and procedures.

Note that the changes to the regulatory text for § 262.41 in this action take into account the revisions being made as a part of the ''Hazardous Waste Export-Import Revisions'' Final Rule (Docket ID EPA–HQ–RCRA–2015–0147; FRL–9947–74–OLEM), including changing the reference to ''§ 262.56'' that used to be in § 262.41(b) to a reference to ''§ 262.83(g)'' in § 262.41(c).

2. Standards Applicable for TSDFs (40 CFR 264.75 and 265.75)

a. What is EPA finalizing? The Agency is also finalizing the provision that requires permitted and interim status TSDFs at § 264.75 and § 265.75, respectively to complete and submit EPA Form 8700–13 A/B to the Regional Administrator by March 1 of each even numbered year for facility activities during the previous calendar year. This change is similar to those proposed for LQGs at § 262.41.

b. Major comments. Comments received were very similar to those discussed under § 262.41 where concern was expressed with the process EPA would use to notify stakeholders that changes to EPA Form 8700–13 A/B were being proposed. Commenters were concerned that EPA might impose substantive reporting requirements merely by reference to a form that can be changed at the Agency's whim which would violate the notice and comment provisions of the APA. As previously described, the Agency will ensure that it follows a transparent process with respect to any proposed changes and that stakeholders will continue to have an opportunity to comment on any proposed form or reporting element changes.

Effect of the Reorganization: This provision is not affected by the reorganization of the generator regulations.

O. Extending Time Limit for Accumulation Under Alternative Requirements for Laboratories Owned by Eligible Academic Entities (40 CFR part 262 Subpart K)

Under 40 CFR part 262 subpart K, eligible academic entities have the choice of operating their laboratories under the alternative subpart K standards instead of the satellite accumulation area regulations at 40 CFR 262.15. When subpart K was initially promulgated, if the eligible academic entity chose to operate its laboratories under subpart K, the entity had to remove the unwanted material from each laboratory under the following two timetables: (1) every 6 months; or (2) within 10 calendar days, if the laboratory accumulates more than 55 gallons of unwanted material or 1 quart of reactive acutely hazardous unwanted material.

Operating under the SAA regulations, an eligible academic entity has no time limit for accumulation. Therefore, for smaller eligible academic entities that do not accumulate 55 gallons in a laboratory, subpart K's six-month accumulation time limit can mean a shorter, more stringent, accumulation time than they have under the satellite accumulation area regulations. Eligible academic entities have cited this shorter accumulation time as a disincentive for opting into the alternative standards in subpart K. The Agency, therefore, proposed to increase the accumulation time limit in an eligible academic entity's laboratory to 12 months.

1. What is EPA finalizing?

We are finalizing the increased accumulation time limit, as proposed. Therefore, laboratories at eligible academic entities that have opted into subpart K will be required to remove the unwanted material from each laboratory under the following timetables: (1) Every 12 months; or (2) within 10 calendar days, if the laboratory accumulates more than 55 gallons of unwanted material or 1 quart of reactive acutely hazardous unwanted material. EPA proposed a number of other changes to subpart K, but they were all conforming changes, meaning they were necessary to make the terminology and citations consistent with the new generator regulations (*e.g.,* changing the term ''conditionally exempt small quantity generator'' to ''very small quantity generator''). These conforming changes will also be finalized as proposed.

2. Major Comments

Although we received approximately 60 comments from academic institutions, very few commented on this specific proposed change. All that did comment on this proposed change, were in favor of the longer accumulation time.

The remainder of the comments received from academic institutions were outside the scope of the narrow and specific change that we proposed to subpart K. Although we are not legally obligated to respond to comments outside the scope of the proposal, in this case we are choosing to respond to certain comments in order for EPA to better explain the existing subpart K regulations and some common misunderstandings about them.

Many academic institutions indicated that they are not able to opt into subpart K because they are in states that have not adopted subpart K. Since subpart K was finalized in 2008, EPA has made an effort to track which states have adopted the rule. At this point, subpart K is effective in approximately 22 states.[92] Additional states have told EPA they are in the process of adoption. Some of the states that have not adopted subpart K have told EPA it is because the colleges and universities in their state have not expressed an interest in opting into the rule, so they didn't see the need to go through the process of adopting and becoming authorized for this regulation. Few, if any, states have expressed an outright opposition to adopting subpart K. EPA strongly encourages the states that have not adopted subpart K to do so; however, we do not have the authority to mandate or compel them to adopt this rule, as it was not deemed more stringent than the standard generator regulations.

Another common theme from the commenters was that subpart K, which was designed for laboratory operations, should apply across the academic institution, and not just to laboratories. Commenters argue that opting into subpart K obligates the institution to operate under more than one set of RCRA regulations at the same institution. However, EPA maintains that academic institutions most likely have been operating under more than one set of RCRA regulations for some time, including used oil regulations for the maintenance of their motor vehicle fleets, and universal waste for their fluorescent bulbs. Furthermore, EPA's engagement with academia over the past 25 years has always been limited to the management of hazardous waste from laboratories. This includes the Laboratories eXcellence and Leadership program (XL Project), as well as the pilot project led by the Howard Hughes Medical Institute (HHMI) to develop and implement a performance-based approach to the management of laboratory waste at ten colleges and universities. These efforts regarding hazardous waste were targeted at laboratories because of the way in which hazardous wastes are generated in laboratories: There are a large number of waste streams that vary over time and the wastes are often generated by students, who lack the training and accountability of a professional

[92] *http://www.epa.gov/hwgenerators/where-managing-hazardous-waste-academic-laboratories-rule-effect.*

workforce. For that reason, at no point in developing subpart K did EPA ever indicate it was considering a hazardous waste regulation that would apply to the entire academic institution.

Finally, in its comments, the Campus Safety Health and Environmental Management Association (CSHEMA) offered to lead a dialogue with EPA about how to make subpart K more useful to the academic sector.[93] EPA spent considerable time and resources addressing the needs of the academic community when it developed subpart K. EPA believes that before we enter into additional dialogue on this regulation, more states need to adopt it and more colleges and universities need to opt into it so that data on the rule and its effects are available.

Effect of the Reorganization: This section is not affected by the reorganization.

P. Deletion of Performance Track and Project XL Regulations

EPA launched the National Environmental Performance Track in 2000 to provide regulatory and administrative benefits to Performance Track members. Performance Track was a public-private partnership that encouraged continuous environmental improvement through use of environmental management systems, community outreach, and measurable results. In order to provide regulatory benefits to members, EPA made changes to the RCRA hazardous waste regulations, among others, that specifically referenced members of Performance Track.

EPA terminated the Performance Track program in 2009. Therefore, EPA is removing obsolete references to Performance Track in the RCRA hazardous waste regulations as a part of this rulemaking. In some cases, a whole paragraph of regulation will be removed and in other instances we will remove just the part of the paragraph that references Performance Track. The deleted paragraphs will be reserved to reduce the possibility of confusion by replacing them with other regulations. The following references are being removed:

- § 260.10: definition of Performance Track member facility;
- § 262.34(j), (k), and (l): regulations for accumulation of hazardous waste by LQGs in Performance Track;
- § 262.211(c): two parenthetical references to § 262.34 (j) and (k) in the regulations for academic labs in subpart K of part 262;
- §§ 264.15(b)(4) and 265.15(b)(4): references to the requirements for inspection of areas of the facility subject to spills in §§ 264.15(b)(5) and 265.15(b)(5), respectively;
- §§ 264.15(b)(5) and 265.15(b)(5): requirements for Performance Track member facilities that reduce inspection frequency for areas subject to spills;
- §§ 264.174 and 265.174: references to Performance Track requirements for inspections of areas where containers are stored;
- §§ 264.195(e), 265.195(d), and 265.201(e): requirements for Performance Track member facilities for inspections of tank systems;
- §§ 264.1101(c)(4) and 265.1101(c)(4): requirements for Performance Track member facilities for reduced inspections of containment buildings;
- § 270.42(l): procedures for permit modifications for Performance Track member facilities; and
- Appendix 1 to § 270.42—Classification of Permit Modification, Section O.1: Indication that a permit modification for reduced inspections for a Performance Track member facility is a Class 1 permit modification.

These provisions were added to the regulations in the National Environmental Performance Track Program final rule, dated April 22, 2004 (69 FR 21737), the Resource Conservation and Recovery Act Burden Reduction Initiative final rule, dated April 4, 2006 (71 FR 16862), and the Academic Laboratories final rule, dated December 1, 2008 (73 FR 72912).

EPA is also removing references to Project XL programs that have been discontinued. These include the New York State Public Utilities Project XL program at subpart I of 40 CFR part 262 and the Laboratories Project XL program at subpart J of 40 CFR part 262. The New York State Public Utilities Project XL piloted a program to allow public utilities located in New York State to consolidate at central collection facilities hazardous wastes generated at remote locations. The Laboratory XL Project was created for Boston College, the University of Massachusetts, and the University of Vermont, and was finalized in the **Federal Register** on September 28, 1999 (64 FR 53292). The Laboratories Project XL piloted an alternate hazardous waste management system for college and university laboratories. Originally, the program was to expire on September 30, 2003. On June 21, 2006, EPA extended the program to April 15, 2009 (71 FR 35550). Now that the program has now expired, EPA is removing paragraph (j) from § 262.10, as well as part 262 subpart J. We have also removed and reserved the reference at § 262.10(j) to the University Laboratories Project XL.

Effect of the Reorganization: This section is not affected by the reorganization.

X. Addition to 40 CFR Part 262 for Generators That Temporarily Change Generator Category as a Result of an Episodic Event

A. Introduction

EPA is finalizing the revisions to the generator regulations that allow a VSQG or an SQG to maintain its existing generator category if, as a result of a planned or unplanned episodic event, the generator would generate a quantity of hazardous waste in a calendar month sufficient to cause the facility to move into a more stringent generator category (*i.e.,* VSQG to either an SQG or an LQG; or an SQG to an LQG). This revision allows a VSQG or an SQG to generate additional quantities of hazardous waste—exceeding its normal generator category limits temporarily—and still maintain its existing generator category, provided it complies with the specified conditions. Because these events are considered to be temporary and episodic in nature, the hazardous waste generator may only use this provision once every calendar year, unless there is a second event for which the generator receives approval from EPA to manage as an additional episodic event.[94]

Under the RCRA regulatory framework for hazardous waste generators, a generator's category is determined by the quantity of hazardous waste it generates in a calendar month. As described in the proposed rulemaking at 80 FR 57972, at issue is when the generator generates an additional quantity of hazardous waste in a calendar month as a result of an episodic event—planned or unplanned—only to revert back to its normal waste generation quantities in the following month. For example, one such event would be if a VSQG plans a short-term demolition project that generates an additional 500 kilograms of hazardous waste in the calendar month, resulting in the VSQG becoming an SQG for that calendar month. However, once the demolition project has been completed, the generator's waste generation drops such that it again qualifies as a VSQG. Other examples of planned episodic events include tank cleanouts, short-term construction projects, short-term site remediation,

[93] EPA–HQ–RCRA–2012–0121–0158.

[94] Note that when a state begins implementing this provision as part of its authorized RCRA program, all petitions and approvals are managed by the authorized state rather than EPA.

equipment maintenance during plant shutdowns, and removal of excess chemical inventories. Unplanned episodic events, which EPA expects would be less frequent, include production process upsets, product recalls, accidental spills, or ''acts of nature,'' such as a tornado, hurricane, or flood.

EPA has determined that requiring a VSQG to comply with the additional SQG or LQG regulations or an SQG to comply with the LQG regulations for the month its hazardous waste exceeded the quantity limits based on an episodic event (planned or unplanned) is unnecessary to protect human health and the environment. Instead, the Agency is finalizing the more practical approach laid out in the proposed rule to ease compliance for episodic generators and still protect human health and the environment, with some minor changes. By complying with the specified conditions, the generator would be able to maintain its current generator category and would not be required to comply with the more stringent site-wide regulations applicable to the higher generator category. EPA currently estimates that approximately 1,270 to 2,540 generators may take advantage of this provision once it is adopted by the authorized states.[95]

B. What is EPA finalizing?

Under the final rule, a VSQG or an SQG generating an increased quantity of hazardous waste because of an episodic event that results in a temporary change in a generator's category would be able to maintain its existing generator category, provided specified conditions are met. EPA has determined that these conditions will be sufficient to ensure these additional hazardous wastes are managed in an environmentally sound manner. Like the general framework of the regulations for generators, should a VSQG fail to meet the specified conditions, it loses the VSQG exemption and becomes the operator of a non-exempt storage facility unless it also immediately complies with all of the conditions for exemption for an SQG or LQG. If an SQG fails to meet any specified condition for exemption, it loses its exemption and becomes the operator of a non-exempt storage facility unless it immediately complies with all of the conditions for an exemption for an LQG.

For both VSQGs and SQGs taking advantage of this provision, the following conditions must be met: (1) Episodic events are limited to one per calendar year; (2) the generator must notify EPA at least 30 calendar days prior to initiating a planned episodic event or within 72 hours after an unplanned episodic event; the generator must identify the start and end dates of the episodic event, which may be no more than 60 days apart, as well as other information about the event; and identify a facility contact and/or emergency coordinator with 24-hour telephone access to discuss notification submittal or respond to an emergency related to the episodic event; (3) the generator must obtain an EPA ID number (VSQGs); (4) the generator must comply with specified hazardous waste management conditions as the waste is accumulated on site; (5) the generator must use a hazardous waste manifest and hazardous waste transporter to ship the waste generated by the episodic event to a RCRA-designated facility within 60 calendar days from the start of the episodic event; and (6) the generator must complete and maintain specified records.

EPA is also finalizing a petition process at § 262.233 to allow hazardous waste generators to request from EPA one additional episodic event within the same calendar year to cover the possibility that a generator could face an unplanned episodic event in the same year it is conducting a planned event. The regulations for episodic generators are found in a new part 262 subpart L, §§ 262.230–262.233.

1. Number of Episodic Events per Calendar Year

Under the episodic generator provisions in subpart L, a VSQG or an SQG may exceed its generator category limits only once per calendar year without affecting its generator category, with the opportunity to petition EPA for a second event. EPA has several reasons for this restriction. First, if a VSQG or SQG exceeds its generator category limits more frequently than once per calendar year, EPA is concerned that these generators are more likely to be routinely generating greater amounts of hazardous waste and thus it is more appropriate for the generator to comply with the regulations applicable to the higher generator category, at least for the months they exceed the quantity limits for their generator category.

Second, EPA believes most hazardous waste generators experience an episodic event infrequently, such as once every few years, and these events are typically planned maintenance projects. Third, the Agency is not limiting an episodic event to a single project within the generator's facility. In fact, a generator could start and complete multiple projects (*e.g.,* a small demolition project, a tank cleanout, and removal of excess chemicals) at different dates within the 60-day time limit, so long as all projects are completed within the 60-day start and end dates identified on the notification form. Under that scenario, all hazardous waste generated would be considered part of the same episodic event.

2. Notification

A VSQG or an SQG must notify EPA no later than 30 days prior to initiating a planned episodic event using EPA Form 8700–12 (Site ID form). Subsequent to the publication of this final rule, EPA will be revising form 8700–12 to account for the new rule provisions, but in the meantime, we will issue guidance on how to use the form in its current state to make this notification. The hazardous waste generator must identify the dates the episodic event will begin and end—a time frame not to exceed 60 calendar days—as well as describe the reason for the event and the types and estimated quantities of hazardous wastes that would be generated during the event.

For a generator's first event in a calendar year, the episodic event begins on the date identified on its form 8700–12. The date identified on the notification form as the start date for the episodic event is assumed to be the date of the release or the date the generator initiates physical action in generating and accumulating the hazardous waste. Whether such action actually occurs on that date or after by the generator will have no impact in changing the end date of the episodic event identified on the notification form. The end date must be no later than 60 calendar days from the date identified on the notification form as the start date of the episodic event.

If the generator does not know the exact day the event will end at the time of notification, it can notify using an end date that is 60 calendar days from the start of the event as long as it ensures that all hazardous waste from the episodic event is shipped off site by that date.

Should an unplanned event occur, the generator must notify EPA within 72 hours via phone or email, and subsequently submit EPA Form 8700–12 (Site ID form) with the same information laid out above for a planned event. In the case of spills of hazardous materials, a 72-hour time frame for reporting the spill to the authorities is common and allows the facility some time to evaluate

[95] See the docket for the Regulatory Impact Assessment of the Potential costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule.

the situation before requesting the episodic event. A facility would have to wait for EPA to respond to the petition for a second event, but this should not impact the initial steps that the generator has to take to appropriately manage the hazardous waste since those standards still apply.

3. EPA ID Number

A VSQG generating and accumulating quantities of hazardous waste using the episodic event provisions to manage hazardous waste must obtain an EPA ID number using EPA Form 8700–12 if one has not previously been assigned. A generator cannot initiate a hazardous waste shipment to a RCRA-designated facility without an EPA ID number. (SQGs are already required to obtain an EPA ID number.)

4. Waste Management Standards

a. *Accumulation standards for VSQGs.* Under the standard generator regulations, a VSQG must not accumulate more than 1,000 kilograms of non-acute hazardous waste at any one time, but otherwise does not have any on-site waste management standards when accumulating hazardous waste, primarily because the quantities generated every month are so small. However, EPA is finalizing that a VSQG generating episodic hazardous waste that would otherwise cause the VSQG to exceed its generator category limit for the calendar month must comply with the following accumulation standards for containers and tanks that manage the episodic wastes. EPA believes these standards are necessary because the quantity of hazardous waste that is accumulated during this episodic period requires standards for safe management in order to adequately protect human health and the environment.

When accumulating hazardous waste in containers, the VSQG would be required to mark or label its containers with the following: (1) The words ''Episodic Hazardous Waste'' and (2) an indication of the hazards of the contents of the container—examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic). In the case of hazardous wastes ultimately treated and disposed of off site, the generator could use hazard communication consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding), use a hazard statement or pictogram consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200, or use a chemical hazard label consistent with the NFPA code 704. These marking standards are the same as those for LQGs and SQGs accumulating hazardous wastes in containers in the course of normal business operations and are necessary to protect human health and the environment. In addition to these, the VSQG must mark the date that the episodic event began clearly on each container.

For tanks, the VSQG must mark or label the tank containing hazardous waste accumulated during the event with the words ''Episodic Hazardous Waste'' and would be required to use inventory logs, monitoring equipment, or other records to identify the associated hazards and to identify the date that the episodic event began. The records containing this information must be on site and available for inspection.

In addition, the generator must manage the hazardous waste in a manner that minimizes the possibility of an accident or release. Management standards are critical to ensure the hazardous waste does not pose a risk to human health and the environment. A VSQG may use best management practices to comply with this condition. In practice, this includes managing the hazardous waste in containers that are in good condition and chemically compatible with any hazardous waste accumulated therein and keeping the containers closed except to add or remove waste. Complying with the standards in part 265 subpart I would satisfy this condition.

If a VSQG is managing episodic hazardous waste in tanks, the following standards must be followed: (1) Having procedures in place to prevent overflow (*e.g.,* the tank is equipped with a means to stop inflow with a system such as a waste feed cutoff system or bypass system to a standby tank when hazardous waste is continuously fed into the tank); (2) inspecting the tank(s) at least once each operating day during the episodic event to ensure all applicable discharge control equipment, such as waste feed cutoff systems, bypass systems, and drainage systems, are in good working order and (3) using appropriate controls and practices to prevent spills and overflows from tank or secondary containment systems including, at a minimum, spill prevention controls (*e.g.,* check valves, dry disconnect couplings); overfill prevention controls (*e.g.,* level sensing devices, high level alarms, automatic feed cutoff, or bypass to a standby tank); and maintenance of sufficient freeboard in uncovered tanks to prevent overtopping by wave or wind action or by precipitation. For tank management, such practices are necessary to prevent the release of the hazardous waste or hazardous constituents to air, soil, or water, which could threaten human health and the environment.

As mentioned already, an emergency coordinator (in compliance with § 262.16(b)(9)(i)) must be identified for the duration of the episodic event on the notification form. An emergency coordinator is needed because the VSQG will be generating greater amounts of hazardous waste than normal and, should an accident occur, the emergency coordinator would need to be prepared to handle the situation.

Under the management standards for VSQGs, the generator may not treat hazardous waste generated on site, except in an on-site elementary neutralization unit.[96] After considering the comments on treatment by VSQGs managing hazardous waste under an episodic event, EPA has determined that the same standards should apply and VSQGs may not treat hazardous waste on site under an episodic event. Although VSQGs must meet some additional waste management requirements for an episodic event, the provisions allowing treatment by SQGs and LQGs in containers and tanks were based on those containers meeting the more extensive standards that containers and tanks at TSDFs must meet in subparts I and J of parts 264 and 265.[97] These same standards still apply to SQGs and LQGs, though they have been copied into part 262 as a part of the reorganization in this final rule. However, under the episodic generation provisions, VSQGs holding an episodic event do not have to meet these same standards for waste management—they must meet a performance standard instead. EPA believes that the performance standard is appropriate for accumulating that waste on site for 60 days or less until it is sent off site for treatment or disposal, but is not appropriate for treatment on site by the VSQG. Several commenters argued that VSQGs are sophisticated facilities with the capability to safely treat, but EPA must design the regulations to be protective and not based solely on the

[96] Elementary neutralization units, as defined in § 260.10, are exempt from RCRA treatment, storage, and disposal standards and permitting requirements. The elementary neutralization unit exclusion does not preclude a VSQG from treating waste in the exempt unit as long as the generator meets the criteria outlined in §§ 264.1(g)(6), 265.1(c)(10), and 270.1(c)(2)(v). Specifically, the elementary neutralization unit must meet the definition of a container, tank, tank system, transport vehicle, or vessel, and must be used for neutralizing wastes that are hazardous only because of the corrosivity characteristic. RCRA Hotline Q & A, February 1996, RCRA Online 13778.

[97] 51 FR 10168, March 24, 1986.

most sophisticated actors. If a sophisticated VSQG wants to perform generator treatment, it can choose to operate as an SQG and meet the standards that apply to that category.

b. *Manifest use by VSQGs and management at a RCRA-designated facility.* When holding an episodic event and operating under the provisions of subpart L, VSQGs must manifest the hazardous waste generated from the episodic event and send it to a RCRA-designated facility. Generally, VSQGs are not required to manifest their hazardous waste to a RCRA-designated facility, but can ship them without a manifest to one of eight types of facilities listed in § 262.14(a)(5). However, because the VSQG will be generating quantities of hazardous waste that exceed its normal generator category thresholds, the Agency has determined that the use of a hazardous waste manifest and the shipment of the hazardous waste to a RCRA-designated facility is most protective of human health and the environment.

However, the condition to manifest the hazardous waste and send it off site to a RCRA-designated facility only applies to the hazardous waste generated as a result of the episodic event. The condition does not apply to other hazardous waste generated at the same time as, but separately from, the episodic event. However, if the VSQG desires to ship all hazardous waste generated and accumulated on site to a RCRA-designated facility at once, for economic or logistical reasons, then it can be sent off site together. This applies whether the hazardous waste was generated as a result of the episodic event, independent of the episodic event, or prior to the event.

c. *Accumulation standards for SQGs.* For containers and tanks, EPA is finalizing accumulation standards as conditions for managing waste under the episodic generation provisions. When accumulating hazardous waste generated as a result of an episodic event in containers, the SQG must mark its containers with the following: (1) The words ''Episodic Hazardous Waste''; (2) an indication of the hazards of the contents of the container—examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic), hazard communication consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding), a hazard statement or pictogram consistent with the OSHA Hazard Communication Standard at 29 CFR 1910.1200, or a chemical hazard label consistent with the NFPA code 704. These standards are the same as those for SQGs accumulating hazardous wastes in containers in the course of normal business operations and are necessary to protect human health and the environment. In addition to these standards, the SQG is required to mark the date that the episodic event began clearly on each container.

For tanks, the SQG must mark or label the tank containing hazardous waste accumulated during the event with the words ''Episodic Hazardous Waste'' and is required to use inventory logs, monitoring equipment, or other records to identify the hazards of the contents and to identify the date that the episodic event began and ended. The generator must have records containing this information on site and available for inspection.

EPA is also finalizing its proposal that SQGs may not take advantage of the episodic generation provision for wastes accumulated on drip pads or in containment buildings. EPA has determined that it is most appropriate that hazardous waste that is being accumulated and managed on drip pads and in containment buildings be managed under the specific requirements in part 265 subpart W and subpart DD for those units. If a generator experiences an episodic event in an area of the facility that is separate from its accumulation in these units, it can use subpart L for those hazardous wastes.

In addition, the SQG must comply with all the conditions of the exemption in § 262.16—for example, the waste accumulation, waste management, employee training, and emergency preparedness and prevention conditions.

d. *Manifest use by SQGs.* SQGs must manifest the hazardous waste generated from an episodic event and send it to a RCRA-designated facility, unless the waste is managed on site. The Agency has determined that the use of a hazardous waste manifest and shipment of the hazardous waste to a RCRA-designated facility is necessary to protect human health and the environment. Note that, unlike VSQGs, the use of the hazardous waste manifest applies not only to the wastes generated from the episodic event, but to all other hazardous wastes the SQG generates.

5. Duration of the Episodic Event

VSQGs and SQGs have 60 calendar days to initiate and complete an episodic event, which includes generation, accumulation, and management (*e.g.,* recycling, treatment and disposal—either on site, such as waste neutralization in a container, or off site at a RCRA-designated facility) of all hazardous waste resulting from the episodic event. After considering the comments on the proposal to allow 45 days, the Agency has determined 60 days is a more appropriate time limit and is sufficient time for a generator to complete the episodic event, arrange for treatment or disposal, and complete management of the hazardous waste.

In the case of planned events, EPA believes that in most cases, hazardous waste is likely to be characterized before the event begins and any contracts required for waste removal and disposal can also be arranged before the event. However, in the case of an unplanned event, waste may have to be characterized and contracts for disposal bid and negotiated. In order to maintain a parallel structure for planned and unplanned episodic events, EPA is finalizing a 60-day time frame. In the case of a planned event, the 60 days start on the first day of any activities affiliated with the event and in the case of a storm or spill, the 60 days start on the day of the storm. All hazardous waste generated from the episodic event must be removed, transported by hazardous waste transporter with a hazardous waste manifest, and sent to a RCRA-designated facility by the end date of the event, no more than 60 days from its start. In addition, the Agency sees no reason to preclude a generator from taking advantage of this provision to also dispose of other hazardous wastes generated during the time of the episodic event.

EPA has determined that events requiring more than 60 days to complete are not episodic generation of hazardous waste and the generator should be operating in a higher generator category to accumulate and manage that hazardous waste.

As a result of this longer time frame, EPA is not finalizing the proposed provision regarding a petition for an extension to an episodic event.

6. Recordkeeping

Generators must keep the following information in their records: (1) Beginning and end dates of the episodic event; (2) a description of the episodic event; (3) a description of the types and quantities of hazardous wastes generated during the episodic event; (4) a description of how the hazardous waste was managed, as well as the name of the RCRA-designated facility that received the hazardous waste; (5) name(s) of hazardous waste transporters, as appropriate; and (6) an approval letter from EPA, if the generator successfully petitioned to conduct an additional episodic event during the calendar year.

The information required to be maintained in items (1) through (3) above is the same information that must be identified on the generator's notification to EPA about the episodic event. Maintaining records of the name of the RCRA-designated facility that received the waste and the ultimate management of that waste as well as the name of any hazardous waste transporters fulfills the RCRA requirement for the generator to be responsible for its hazardous waste from cradle to grave. In addition, a record of any approval letters from EPA for a second event are critical for generators to be able to show that they were in compliance with subpart L when conducting that second episodic event.

These records must be maintained on site by the generator for three years from the completion date of each episodic event. The recordkeeping condition is critical to enable effective and credible oversight. We also have determined that the required items represent the minimum information necessary to determine that any hazardous waste generated during the episodic event is managed properly.

7. Petition To Request One Additional Episodic Event

While the Agency believes that most generators will experience an episodic event infrequently, we also recognize that there may be situations, often unexpected, where a hazardous waste generator may have more than one episodic event within a calendar year, such as an unexpected product recall, a major spill, or an act of nature. Therefore, the Agency is finalizing a provision to allow VSQGs and SQGs to petition EPA for permission to manage one additional planned or unplanned episodic event per year without impacting the hazardous waste generator category (provided that they do not have two of the same type of event within the same calendar year).

EPA proposed that VSQGs and SQGs could petition EPA for permission regarding an additional episodic event per year, either planned or unplanned. However, in response to some of the comments received on the proposed rule from the states that implement the RCRA program, EPA has determined that it is most appropriate to allow only one event of each type per year and to require the generator to petition EPA for the second event and be approved. That is, if a generator holds a planned event early in the year, it can petition the EPA Regional Administrator for an unplanned event later in the year if needed.[98]

In parallel fashion, if the generator has an unplanned event early in the year, it can still petition EPA to hold a planned event later in the year. In both cases, EPA must approve the petition for a second event. EPA wants to allow for the case of a second event, in cases where the generator is legitimately having episodic events, but has determined that not allowing a generator to hold two planned events in a year ensures that the provision is being used for true cases of episodic generation and not as a way for generators to regularly avoid managing hazardous waste at higher generator categories. Similarly, EPA has determined that not allowing the generator to hold two unplanned events in one year will ensure that the episodic generation provision is not used in a way that creates an incentive for irresponsible management of hazardous waste.

Because a petition for a second event distinguishes between an unplanned event and a planned event, EPA is adding definitions of planned episodic event and unplanned episodic event to the regulations in subpart L. A planned episodic event is an episodic event that the generator planned and prepared for, including regular maintenance, tank cleanouts, short-term projects, and removal of excess chemical inventory. An unplanned episodic event is an episodic event that the generator did not plan nor expect to occur, including, but not limited to, production process upsets, product recalls, accidental spills, or ''acts of nature,'' such as a tornado, hurricane, or flood. Some of these events are more sudden than others, but they would all be unanticipated by the generator. EPA is not including excess inventory in the definition of an unplanned event because a case of excess inventory is, more than the others, a result of decisions made by the generator in the regular course of business and is not, therefore, an unplanned episodic event.

Consistent with the notification requirements, the generator must petition EPA for the second event. For a planned event, the generator must submit a petition for a second event and indicate that this is a petition for a second event. For an unplanned event, the petition must be in the form of a notification to EPA within 72 hours of the start of the event by phone, email, or fax and subsequent submittal of a complete petition with the relevant information for the event.

The petition must include (1) the reason why an additional episodic event is needed and the nature of the episodic event; (2) the estimated amount of hazardous waste to be managed from the event; (3) how the hazardous waste is to be managed; (4) the estimated length of time needed to complete management of the hazardous waste generated from the episodic event—not to exceed 60 days; and (5) information regarding previous episodic event(s) managed by the generator and how it complied with the conditions. EPA would then evaluate this and other site-specific information to determine whether a generator should be allowed to complete the episodic event under the alternative standards.

In the case of a planned second episodic event, a generator may not manage the hazardous waste from the event under the episodic generation conditions in subpart L until it has approval from the implementing agency for that second event. There is no mandatory time frame for submitting a petition for a second planned event, but the generator should allow enough time for the implementing agency to review the petition so that they can begin the event on time.

EPA has determined that in the case of a petition for an unplanned second event, the generator may manage hazardous waste for the additional unplanned episodic event under the episodic event standards until written approval by EPA has been received. SQGs requesting a second event will be managing the hazardous waste under the same technical standards in § 262.16 in both situations. It would be impractical for a VSQG requesting a second episodic event to meet § 262.16 accumulation standards while waiting for approval to no longer have to meet them. Therefore, the VSQGs would be required to meet the performance standards outlined in § 262.232(a)(4)(iii). These subpart L accumulation standards for VSQGs are designed to minimize the possibility of a fire, explosion, or release and containers and tanks must be in good condition and compatible with the hazardous waste they contain.

If EPA approves the petition for a second event, the generator must retain the written approval in its records for three years from the date the episodic event ended. If EPA rejects a generator's petition for a second event, the generator must then start managing the hazardous waste from the episodic event and all other hazardous waste at its facility under the standards for the

[98] Authorized states will develop their own procedures for petitions under this provision.

applicable more stringent generator category.

EPA is not promulgating criteria for evaluating petitions for a second unplanned episodic event, but recommends that the implementing agency base its decision on factors including the validity of the proposed episodic event, the generator's enforcement history and evidence of the generator's ability to responsibly manage the waste.

8. Tracking and Accounting for Hazardous Waste Generation and Accumulation as a Result of an Episodic Event Along With Normal Production Operations

In practice, a VSQG or SQG taking advantage of this rule must track and monitor the start and end dates of the episodic event in conjunction with the date the calendar month ends to ensure compliance with all RCRA regulatory provisions associated with hazardous waste generation and management.

The following example demonstrates how this provision of the rule will work. A VSQG could have a number of facility operations (*e.g.,* tank cleanouts, disposal of off-spec products it cannot sell or reclaim, and/or repair work involving the removal of lead paint chips) that would result in a temporary change in its regulatory category. The VSQG decides to notify EPA two months prior (as well as identifying a point of contact and emergency coordinator) that it will initiate the planned episodic event on July 20 and take advantage of the full 60 days allowed to conduct the event and, therefore, end on September 17. Beginning on July 20, the generator must comply with all of the conditions of subpart L to maintain its exemption as a VSQG. Under this example, if the generator complies with subpart L, it can generate more than 1,000 kilograms of hazardous waste as a result of the events it identified in the identification until September 17.

On or before September 17, the generator must remove and dispose of all the hazardous wastes it generated over the course of the previous 60 days from the episodic event. Provided the generator meets that deadline, that waste does not count when determining the generator's category.

In this example, the generator could choose to also dispose of waste generated from its normal operations in the same shipment. However, in this case, any waste generated from production or events that were not identified in the notification to EPA about the episodic event (or in the petition for a second event) must be counted for the purposes of determining the generator's category for any months impacted by the episodic event. Specifically as an example, the quantity of hazardous waste the VSQG generates outside the episodic event from September 1 through September 17 would be added the amount of hazardous waste generated for the remainder of September (starting on September 18 until the end of the month) to determine the generator's category for that month.

The same approach applies to the accumulation limit for hazardous waste at a VSQG. If the VSQG exceeds 1,000 kg of hazardous waste on site as a part of its episodic event, that waste can be managed under the provisions of subpart L until September 17. If, however, the hazardous waste has not been shipped off site by September 18, the generator must manage the waste as LQG waste. In addition, the generator would be in violation of the conditions of the episodic generation provision.

In summary, if a generator's waste is to be considered part of the episodic event and not be counted toward monthly generator category, then the waste must be part of the episodic event identified in the generator's notification. EPA has determined that this will prevent generators from using the time frame of an episodic event as a free-for-all for generation of all types of waste, regardless of whether it is identified in the notification of the event. EPA has revised this interpretation of how the episodic generation provision will work from the preamble discussion in the proposed rule in reaction to concerns from commenters that the episodic generation provision would provide excessive relief from the hazardous waste regulations for generators.

C. What changed since proposal?

EPA is finalizing the episodic generation provisions in subpart L mostly as they were proposed on September 25, 2015, but with several important revisions: (1) Lengthening the time allowed for an episodic event from 45 days to 60 days and removing the option for a petition to extend an event; (2) revising the situations in which a generator can petition for a second event to ensure that a generator holds no more than one planned and one unplanned episodic event in a calendar year; (3) revising the notification requirements for unplanned events to allow 72 hours for notification; and (4) revising the labeling requirements to remain parallel with the labeling requirements for all generators being revised in the final rule (see section IX.E for more details on marking and labeling revisions).

1. Allowing 60 Days To Complete an Episodic Event

Most of the comments EPA received on the episodic generation provision in the proposal revolved around how long each episodic event could be and the number of events allowed per year. EPA's goal is to find a balance between a time frame that would be useful and workable for industry and not making episodic generation a loophole for generators to use to circumvent the regulations by holding episodic events over a large part of the year. The first part of achieving this balance is determining how long an event should be.

EPA proposed a 45-day limit for an episodic event with an option to petition for a 30-day extension, for a potential total of 75 days. EPA proposed 45 days because it believed that 45 days allowed enough time for an event to be initiated and completed and for the waste to be removed. The petition option was meant to account for any unexpected problems that the generator might have with transporting the waste off site. EPA did not want to extend the episodic event for so long that it might represent a large portion of the year. EPA determined that if the episodic event provision were too expansive, it would be more likely to allow generators that are more permanently generating in a higher category to try to use the provision as a way to avoid those requirements.

However, many commenters on this aspect of the provision argued that the 45-day limit was too restrictive and one stated that the limit ''undermines the benefits to operators of the episodic event rule.'' [99] However, it should be noted that there was also some support for the 45-day time frame in the comments, as well as at least one commenter who argued that 45 days is too long for an episodic event because most truly episodic events are very short-term spikes.[100]

One of the main reasons that commenters argued that 45 days is too restrictive a time period for episodic events was the time needed for waste disposal contracts to be competitively bid and the time needed for generators to classify waste and prepare and schedule shipments. Other commenters also pointed out that events themselves may take place over several weeks and that some remote facilities may have special circumstances that require longer time frames to resolve. Other

[99] Alyeska Pipeline Service, EPA–HQ–RCRA–2012–0121–0088

[100] Minnesota Pollution Control Agency, EPA–HQ–RCRA–2012–0121–0232

commenters argued that some events may be special projects or demolition or remediation projects that would take longer than 45 days.

Many commenters suggested a 90-day time frame, to match up with the requirements for large quantity generators, and some suggested a 60-day time frame. Other commenters suggested time frames as long as 180 days.

EPA was persuaded by the commenters who stated that a longer time frame was appropriate for an episodic event, particularly because of the arguments surrounding the planning needed to remove waste from the generator site in the case of an unplanned event. For planned events, it should be a matter of course for the generator to have characterized waste as hazardous or not and made arrangements for shipment off site in advance. However, in the case of an unplanned event, the generator might not know if the material that must be disposed qualifies as a hazardous waste and may not have a waste hauler available for a pick up. If the generator has to competitively bid for the service, as some of the commenters on the rule argued that they must, the process of getting the waste off site will take longer.

However, EPA was not persuaded by the commenters who argued that some events themselves will take longer than the time allowed, such as long-term demolition or remediation projects. Rather, these bigger long-term projects do not appear to be the kind of event that EPA would consider an ''episodic'' event and warrant the facility shifting into the larger waste category for the duration of the increased waste generation to properly manage the site and the hazardous waste itself.

Therefore, EPA is finalizing a longer time frame than proposed to account for some of the challenges in managing waste from an unplanned episodic event. EPA has determined that 60 days is an effective balance between allowing time for the generators to use the provision without making the time frame so long that it becomes something generators can abuse. A 90-day time frame, suggested by many of the commenters, struck EPA as being excessively long, as it would mean that a generator could consider the waste being generated during a full quarter of the year as waste from an episodic event. Shortening the event time and allowing a full 90 days of accumulation time also went counter to the Agency's goal of encouraging these generators that are generating above their normal category to arrange for the shipment of the waste to a RCRA-designated facility as soon as possible.

As part of our decision to lengthen the time frame for an episodic event, EPA also determined that a petition for a 30-day extension to an episodic event is no longer necessary. The longer time frame of 60 days should mean that extensions are not necessary in many cases. In addition, EPA received comments from the authorized states that they are concerned about the potential volume of petitions they might receive from the proposed episodic generation provisions and eliminating the option to petition for an extension is responsive to their concerns about the effect of the new provision on their resources. Accordingly, if a generator operating under the episodic generator conditions finds itself at the end of the 60-day time period and is unable to remove the waste from its site before the deadline, its generator category will change to SQG or LQG once the deadline has passed and the hazardous waste must be managed under the appropriate generator standards.

2. Petition for a Second Event

EPA proposed that a generator could petition EPA for a second episodic event, planned or unplanned. The proposal was based on the idea that in some cases a generator may want to hold a second event, but EPA did not want to simply allow two episodic events per year for all generators without a petition because of the potential abuse of the provision by generators that are not truly generating higher volumes of waste episodically, but should be operating in the larger generator category. EPA also wanted the petition to operate as a check that an implementing agency could use if it thought that a generator might be abusing the provisions.

The comments EPA received on this aspect of the proposal argued for a wide variety of options. Some commenters suggested that two events per year should be allowed, some suggested allowing a petition for a third, and one commenter supported allowing up to three episodic events in a year provided the generator has a standing agreement with a facility to accept the waste. However, several of the states supported limiting the episodic generation provision to one event per calendar year with no possibility for a second event while others argued that the proposed one event and a petition was appropriate. One state also suggested that the implementing agency should examine the causes of each event at each generator and determine if the episodic event could be held.

After considering the comments, EPA has determined that it is appropriate to allow a facility to petition for a second event in a calendar year, but only if the generator is only holding one planned and one unplanned event in that calendar year. For instance, if the generator has already held a planned episodic event in a year, a planned second 60-day event in the course of the year could indicate that the generator should be operating at a higher generator category. However, a generator that is truly a VSQG or SQG could have an occasion where it has performed a clean out or system shut down already during the year and then an act of nature or other truly unplanned event occurs. EPA would not expect this to be a regular occurrence for generators and will depend on the implementing agencies operating the RCRA programs to take note and act accordingly if a generator is regularly requesting a second episodic event.

At the same time, a generator may be planning to conduct an episodic event such as a tank clean out or maintenance project late in the year when it gets struck with a hurricane that can be managed as an unplanned episodic event for hazardous waste. In this case, the generator can hold an episodic event to respond to the storm and then petition EPA for a second event for the cleanout, while explaining that it needs the second event because of the occurrence of the storm earlier in the year.

EPA also believes that limiting the type of event that a generator can petition for will reduce the numbers of petitions submitted as a part of this provision, which is responsive to some of the comments received by states concerned about increased workload.

3. Notification

EPA proposed notification requirements for episodic events to ensure that the authorized state or EPA is informed of when a generator is holding an event that would otherwise cause that generator to be operating in a higher generator category. The proposed requirement was that in the case of a planned event, the generator must notify EPA no later than 30 days before the event begins. For notification in the case of an unplanned event, EPA proposed that the generator notify within 24 hours or as soon as possible by phone or email and then follow up with a full notification using EPA Form 8700–12 (the Site ID form).

Many of the comments on the notification provision singled out the notification for an unplanned episodic event as difficult to meet. Most of these

commenters stated that 24 hours is an insufficient time frame and did not mention EPA's addition of the phrase ''or as soon as possible'' in the proposal. Commenters noted that in the case of an unplanned event, the generator may not know if the waste is hazardous or if there is enough hazardous waste to make an episodic event necessary. Commenters suggested alternative approaches that included allowing longer time frames for notification, including 72 hours, 7 days or 30 days or simply ''as soon as possible.'' Another suggested approach was to require notification 24 hours after a waste determination was made. EPA also heard that having a specific time frame in which the notification must be made is critical for making the requirement enforceable by the states.

EPA understands that in the case of an unplanned episodic event, a generator will have competing priorities, particularly if a spill has occurred. However, the notification requirement for the episodic generation provision is critical in maintaining the appropriate levels of oversight for the generators taking advantage of this provision. EPA determined that it would not be appropriate to base the time frame for notification on when a waste determination is made, as that would not be parallel to any other area of the generator program and would be difficult to enforce. In addition, EPA found that the suggestions for the notification time limit to be lengthened to 7 or 30 days would result in excessive delays between the start of an episodic event and notification to EPA, compromising the ability to provide adequate oversight.

EPA has determined that it is reasonable, however, to adjust the time frame for initial notification to EPA of an unplanned episodic event by phone, email, or fax within 72 hours from when the event begins. EPA believes that this adjustment provides the generator with some additional time in case there is a necessary delay in contacting EPA due to emergency conditions, but does think that a timely notification to the Agency is important in the case of unplanned events at the generator to ensure proper oversight. A 72-hour limit ensures that timely notification.

If a generator finds that it notifies of an event and then it turns out that the material in question is not hazardous waste or does not in fact top the limit for the generator's category, the generator can work with EPA by explaining that the event was not necessary after all. Under the previous regulations, that generator would have to manage the excess generated material as hazardous waste until it is determined not to be, which would have included a notification of a higher generator category, so the requirement being finalized is not an additional burden.

4. VSQGs Notifying Local Fire Department

EPA proposed that a VSQG would be required to notify its local fire department that it was taking advantage of an episodic event. The notice would need to include the start and end dates and identify the types and quantities of hazardous wastes that would be generated. EPA stated that the purpose of the notification was to inform regulatory authorities of the facility's activities in order to enable adequate compliance monitoring of the facility with the conditions of the alternative standards.

EPA did not receive support in the public comments for this proposal. The commenters stated that the notification requirement was excessive and would be an unnecessary burden to both the VSQGs and to the fire departments that would have received the notifications. Commenters on this provision included both industry stakeholders and state agencies. Therefore, EPA is not finalizing this notification requirement as part of subpart L.

5. Labeling

EPA proposed a labeling requirement as part of episodic generation that paralleled the labeling and marking being proposed throughout the generator program. The proposed requirement was for episodic generators to label their waste as ''episodic hazardous waste,'' to label the container with the contents of the container and the hazards of the contents and to mark the start date of the episodic event as well. The requirements for tanks would have allowed the relevant information about the contents, hazards, and episodic event to be recorded in a log book instead of on the container.

In this final rule, EPA has revised the marking and labeling requirements throughout the generator program to remove the requirement that the contents of the container or tank be noted. The provision focuses instead on the hazards of the contents, as that requirement tracks more directly to the needs of responders in an emergency. EPA does expect that many facilities already label containers with the contents and will continue to do so to ensure that the correct information is available for manifesting when it comes time to ship the materials off site or for proper treatment on site.

The marking and labeling requirements in subpart L for episodic generation have likewise been revised to remain parallel with the requirements in the other parts of the generator program. (See section IX.E for a complete discussion of the marking and labeling revisions.)

6. Management of Other Hazardous Waste Generated During Episodic Event

In EPA's proposal, the preamble included an interpretation of the proposed provision for episodic generation that discussed allowing a generator to include hazardous waste that was generated outside an episodic event to be managed with the hazardous waste from the episodic event. This interpretation included both physical management of the waste and shipment off site, as well as not counting that other hazardous waste toward the generator's category.

Some of the comments that EPA received from the states on this episodic generation provision argued that it would provide excessive relief from the generator regulations and, therefore, that it would not be appropriate to allow this relief. As discussed elsewhere, EPA carefully considered what parts of this proposal could be revised to ensure that the episodic generation provisions are used just for the management of waste that is episodically generated and not be used to allow a generator to avoid managing waste in a larger generator category that it is operating in more regularly. EPA identified this discussion as an area where the interpretation of the final provision should be revised to clearly state that only the waste from the identified episodic event is exempt from being counted toward a generator's category. EPA has therefore revised this discussion for this final preamble.

D. Major Comments

1. Labeling Waste as ''Episodic Hazardous Waste''

EPA received several comments stating that the proposed requirement to label hazardous waste from an episodic event as ''episodic hazardous waste'' rather than ''hazardous waste'' is an unneeded distinction. The commenters stated that it would be a burden to get and use a label that is different than the standard ''hazardous waste'' label.

EPA disagrees with the commenters on the usefulness of the ''episodic hazardous waste'' label. EPA is retaining this requirement because it will be important for generators holding episodic events to be able to distinguish hazardous wastes generated during those events from other hazardous

wastes generated on site. Although both types of hazardous waste can be managed and shipped off site together, if convenient, hazardous waste that was generated before the episodic event began retains its original time frame for being treated or shipped off site whereas hazardous waste from an episodic event must be treated or shipped off site within the 60-day period for the event.

If there is no distinction on the labels for hazardous waste from an episodic event, it would be difficult for a generator or an inspector to be able to determine which hazardous waste is a part of the episodic event with the 60-day limit and which hazardous waste has an alternate schedule for treatment and shipment. EPA does note, however, that the generator does not have to use a specific ''episodic hazardous waste'' label that would have to be purchased separately and, if practicable, can simply add the word ''episodic'' to the labeling with a self-designed label or with a large permanent marker.

2. Notification of Episodic Events

EPA also received several comments that notification of episodic events to EPA is an unneeded burden to the generators and will decrease the likelihood of generators using this provision.

EPA disagrees that there is little to be gained from notification and, instead, has determined that it is critical to the enforceability of this provision and for the states to oversee the hazardous waste activity under their authority. Without a notification requirement for episodic waste, a generator could potentially operate as if under an episodic event at all times, changing the starting date, so that during any given inspection, it appears as though there is an episodic event on site. EPA does not expect that many generators would manage hazardous waste in this way, but the regulations must include checks and balances to prevent such abuse and the notification requirement is one way to allow the implementing agencies to follow up in person if such action is warranted.

3. VSQGs Exceeding Generation Limit During Normal Operations

EPA received some comments stating that a VSQG that does not discover until the end of the month that it has exceeded its threshold for generation of hazardous waste as a VSQG would have difficulty complying with the episodic generation provision because of the notification requirements.

EPA would not consider the situation described by the commenters to be a case of an episodic event because the VSQG in this case is exceeding its generation limit in the course of normal operations. An episodic event is an activity that does not occur within normal operations that causes the generator to exceed its normal limit.

XI. Detailed Discussion of Preparedness, Prevention, and Emergency Procedures Provisions for SQGs (40 CFR 262.16) and LQGs (40 CFR 262.17 and 40 CFR part 262 Subpart M)

A. Introduction

EPA is finalizing a number of proposed modifications to the conditions for exemption for both SQGs and LQGs regarding preparedness, prevention and emergency procedures, as described in the proposed rulemaking (80 FR 57972). Proposed conditions for SQGs were found at § 262.16(b)(8)–(9) and for LQGs at § 262.17(a)(6)–(7), which reference part 262 subpart M. The preamble to the proposed rulemaking discussed in detail the rationale for making several revisions to existing regulations, as well as specifically taking comment on certain proposed revisions and on other potential changes that were not reflected in revisions to existing regulations.

In discussing these modifications in the proposed rule, EPA provided examples of catastrophic chemical accidents in the United States to highlight the need for continued improvement in a number of areas related to chemical facility safety. EPA also noted that, to address these concerns, the President issued Executive Order 13650—Improving Chemical Facility Safety and Security (EO) on August 1, 2013, which directed the EPA and other federal agencies to identify ways to improve operational coordination with state, local, tribal, and territorial partners; enhance federal agency coordination and information sharing; modernize policies, regulations, and standards to enhance safety and security in chemical facilities; and work with stakeholders to identify best practices to reduce safety and security risks in the production and storage of potentially harmful chemicals. EPA explained that several of these modifications are aligned with EO-related efforts in that they will facilitate collection and analysis of chemical information from local facilities, as well as development of local emergency response plans to mitigate or prevent a devastating chemical disaster. EPA further explained that these modifications will also update the regulations to make them compatible with the current infrastructure of emergency planning and response, as well as provide a more usable contingency plan to emergency responders en route to a time-sensitive emergency at a facility that generates hazardous waste. Proposed or potential modifications, as well as key comments received on each, are discussed in this section in terms of the extent to which they are being incorporated into this final rulemaking.

B. What is EPA finalizing as proposed?

1. Changes to Contingency Plan Regulations for Large Quantity Generators: Eliminating Employee Personal Information in Contingency Plans

The condition for exemption for LQGs at § 262.17(a)(6)–(7) references 40 CFR part 262 subpart M, which includes requirements associated with contingency plan content at § 262.261. EPA proposed to modify the language to allow an LQG the flexibility to eliminate unnecessary employee personal information in the contingency plan in order to protect those individuals' privacy while still providing necessary information to address emergencies. Specifically, while retaining the name of persons qualified to act as emergency coordinators, the Agency proposed to remove references to addresses and changed the reference to home and office telephone numbers to ''emergency telephone number.'' EPA also proposed to add language stating that, in situations where the generator site has an emergency coordinator continuously on duty because it operates 24 hours per day and every day of the year, the plan may list the staffed position (*e.g.,* operations manager, shift coordinator, shift operations supervisor, or some other similar position) as well as an emergency telephone number that can be guaranteed to be answered at all times. The Agency requested comment on this proposed modification.

The majority of commenters supported EPA's proposal to remove addresses and home phone numbers for personnel and to allow listing of staffed positions. A few commenters suggested extending this provision to cover SQGs, even though they are not required to have contingency plans, and TSDFs. EPA has decided it is appropriate at this time to focus on changes for LQGs only because they pose the greatest concern in matters of emergency preparedness; consequently, the Agency is finalizing § 262.261(d) as proposed. Although EPA is not extending these requirements to other generator categories or to TSDFs, the Agency would encourage facilities

to adopt these changes as a best management practice.

2. Technical Changes Applicable to Both Small Quantity Generators and Large Quantity Generators

EPA proposed clarifications and modifications to preparedness and prevention procedures dealing with the location of required equipment and access to communications or alarm systems based on 30 years of experience with these rules, feedback from stakeholders as part of the Agency's November 2004 Hazardous Waste Generator Regulatory Program Evaluation (Docket ID No. RCRA–2003–0014), and other discussions with stakeholders. These revisions are discussed below.

a. Proposed technical changes to introductory paragraph on required equipment. EPA noted that existing regulations are unclear regarding whether the required emergency response equipment must be placed in those areas of operation where hazardous waste is generated and accumulated or other parts of the facility where hazardous waste is not generated or accumulated. The Agency added that it may not always be appropriate or safe to store equipment in the actual waste generation or accumulation area—even though the requirement itself applies only to the generation and accumulation (and treatment, as appropriate) of hazardous waste. Therefore, the generator should have the flexibility to store this equipment in other areas of the facility in situations where it is infeasible or inappropriate for safety reasons to have the equipment located immediately next to hazardous waste generation and accumulation areas. EPA proposed to clarify that, while the equipment provision applies to only those areas where hazardous waste is either being generated or accumulated, the generator may determine the most appropriate locations within its facility to locate equipment necessary to prepare for and respond to emergencies. EPA requested comment on this proposal.

Commenters generally supported EPA's proposed clarification as it provides flexibility in determining the most appropriate locations of emergency response equipment, although several commenters suggested various changes/clarifications related to the location and accessibility of emergency equipment. EPA does not believe these other changes/clarifications are necessary and is finalizing § 262.16(b)(8)(ii) and § 262.252 as proposed.

b. The meaning of ''immediate access.'' Preparedness and prevention provisions include the condition that, whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, *unless* such a device is not required. At issue is whether the phrase ''immediate access'' is clearly understood or whether additional clarity is necessary. EPA proposed to modify this language to include the parenthetical ''(*e.g.,* direct or unimpeded access)'' after the phrase ''immediate access.'' EPA requested comment on the usefulness of modifying this language.

The majority of commenters supported this modification, although one commenter expressed concern regarding what would constitute immediate or unimpeded access. Another commenter requested clarification as to whether access to a cell phone satisfies the requirement for immediate access to an alarm or communication device. EPA believes that, although cell phones are a useful means of communication, they should not be relied upon solely to satisfy this requirement. The Agency is therefore finalizing § 262.16(b)(8)(iv) and § 262.254 as proposed.

3. Technical Changes Applicable to Small Quantity Generators

Based on experience and feedback received from the regulatory community and other stakeholders, EPA proposed revisions that address two of the four provisions regarding emergency procedures for those areas where SQG hazardous waste is generated and accumulated. These revisions are as follows.

a. Require certain information be posted ''next to the telephone.'' In the proposed rule, EPA explained that existing regulations were unclear where required information (*i.e.,* name/telephone number of the emergency coordinator, the location of fire extinguishers, spill control material, fire alarms and, as necessary, telephone number of the fire department) should be posted in the facility. The Agency stated that a facility may have many operations and components that have no relationship with the generation and accumulation of hazardous waste. EPA noted that stakeholders have recommended deletion of this particular provision because, in this age of near-universal 911 availability, it is not important from a regulatory standpoint to have emergency telephone numbers, including the number (and name) of the emergency coordinator, and have also asserted that locations of the equipment in question should be conveyed to relevant employees and displayed in a worker break area rather than the facility office. EPA disagreed with eliminating this provision since making such information readily available is important for workers and others so that they would know what to do and where to go in the case of an emergency. However, the Agency nevertheless believed the regulation should be modified, adding that it is unclear whether the telephone number for the emergency coordinator refers to a home or business phone. With cell phones and other means of instant communication now prevalent, EPA proposed to modify this language to state that the SQG must post the name and emergency telephone number of the emergency coordinator next to telephones or in areas directly involved in the generation and accumulation of hazardous waste. EPA requested comment on this proposed change.

Commenters generally expressed support for this proposed change, although certain commenters questioned the posting of emergency information where hazardous waste is generated or accumulated. Some commenters requested the option of keeping emergency information on cell phones, while another commenter cautioned that cell phone reliability could be compromised during a widespread emergency. EPA understands that cell phone use may be compromised but also realizes that cell phones are widely used and that the inability to use cell phones for communication purposes would not prevent an employee from accessing stored information, such as land line telephone numbers (*e.g.,* home or business phone). The Agency is finalizing § 262.16(b)(9)(ii) as proposed in order to accord flexibility in complying with this SQG requirement.

b. Allow containment and cleanup to be conducted by a contractor. EPA's understanding was that most SQGs would hire a spill cleanup contractor to perform containment and cleanup of hazardous waste in the event of a spill rather than train employees to perform the response. Although EPA agreed that allowing an SQG to hire a contractor trained to address hazardous waste spills would be appropriate, the Agency indicated that regulations in place arguably do not provide this flexibility. EPA proposed to modify this language to allow containment and cleanup to either be conducted either by the SQG or by a contractor on behalf of the SQG. EPA requested comment on this

proposed change, including whether any unintended consequences could arise from providing SQGs with this flexibility.

Nearly all of the commenters supported EPA's proposed modification, although some commenters opined that existing language already allows for contractors to perform this work. Other commenters mentioned that the generator is ultimately responsible for ensuring proper response and cleanup and a few suggested adding language clarifying contractor liability in performing cleanups. EPA is finalizing § 262.16(b)(9)(iv)(B) as proposed.

C. What is EPA finalizing with changes to proposed rule language?

1. Areas Subject to Preparedness, Contingency Planning, and Emergency Procedures Regulations

EPA stated in the proposal that current preparedness and emergency procedures regulations do not clearly state whether they are applicable to the entire facility or only to areas where hazardous waste is generated and accumulated on site or where allowable treatment may occur in accumulation units (*i.e.,* in containers and tanks per EPA guidance) and when transported off site for subsequent treatment, storage, and disposal. Therefore, EPA proposed that regulations for preparedness and prevention and for contingency planning and emergency procedures apply only to those areas where hazardous waste is generated and accumulated and, where applicable, to those areas where allowable treatment may occur in accumulation units. For this reason, EPA proposed to explicitly state that the RCRA preparedness and emergency procedures regulations are limited strictly to these areas.

EPA acknowledged that previous Agency guidance indicated RCRA preparedness and emergency procedures regulations, including development of contingency plans by LQGs, would only apply to 90-day accumulation units, otherwise known as CAAs. In this guidance, the Agency states that, when developing a contingency plan, LQGs would only need to include those 90-day accumulation units involved in the on-site management of hazardous waste.[101] At that time, Agency expressed a desire to limit the applicability of these regulations only to these areas because several other statutes already address the development and implementation of contingency plans associated with other areas of a generator facility, such as the storage of chemical materials and substances other than hazardous wastes. The Agency also noted that considerable overlap exists in the requirements in the various statutes and, since 1997, the federal government has encouraged facilities to develop integrated contingency plans. Examples include EO 13650 and the Agency's aforementioned One Plan guidance.

EPA proposed that subpart M apply only to those areas of an LQG where hazardous waste is generated and accumulated on site in accordance with the conditions in § 262.17. This proposal included a parallel change for the emergency procedures regulations for SQGs in § 262.16.

Although the primary objective of these changes was to ensure that preparedness and planning regulations under RCRA did not apply to the entire facility, EPA received several comments on whether SAAs and points of generation should or should not be included. Comments were roughly split on whether areas besides CAAs, such as SAAs and points of generation, should be included within the scope of preparedness and planning regulations. Notwithstanding existing guidance, EPA continues to believe there are benefits to addressing areas besides CAAs. Throughout a facility, there may be many points of generation and associated SAAs from which hazardous wastes are routinely moved to CAAs; therefore, the potential for spills exists during the accumulation and management process. For this reason, EPA has determined it is appropriate to address these additional areas, consistent with the objectives of EO 13650, in order to ensure protection of human health and the environment, as part of preparedness and planning regulations.

With respect to allowable treatment, EPA believes that locations of such treatment would be covered as part of the overall accumulation and management process within a facility. Although EPA has not specifically defined allowable treatment in the regulations, the Agency has determined at this time to continue to address allowable treatment at generator facilities within the framework of existing guidance.[102]

EPA is, therefore, finalizing regulations making it clear that points of generation and SAAs, in addition to CAAs, fall within the scope of regulations for preparedness and planning in § 262.16(b)(8) for SQGs and 40 CFR part 262 subpart M for LQGs. This includes adding clarifying language in § 262.15(a)(7) and (8) regarding the conditions for exemption for both SQGs and LQGs that specifically relate to SAAs.

2. Making and Documenting Arrangements With the Local Emergency Planning Committees

EPA noted in the proposal that RCRA generator regulations, which were finalized in 1980, have not been updated to reflect significant changes to the national, state and local infrastructure for emergency planning and response, one of which was passage of the Emergency Planning and Community Right-To-Know Act (EPCRA) in 1986. The Agency also discussed EPCRA in terms of emergency planning and notification requirements, as related to preparedness, prevention and emergency procedures established by hazardous waste management regulations. This included the roles and responsibilities of Local Emergency Planning Committees (LEPCs) under EPCRA. EPA explained that facilities covered under EPCRA are required to report chemical information to LEPCs, as well as other entities, and that LEPCs are required to prepare a comprehensive emergency response plan. Facilities covered by EPCRA planning provisions are required to cooperate in emergency plan preparation and designate a facility emergency coordinator to participate in this process.

For this reason, EPA proposed revisions to require that SQGs and LQGs must first attempt to enter into arrangements with their LEPCs. EPA also proposed regulatory text that describes procedures for how a facility that is not able to make arrangements with the LEPC would make such arrangements with the fire department and other local emergency services. The Agency requested comment on its proposal to require an SQG or LQG to enter into arrangements with its LEPC unless there is no LEPC, the LEPC does not respond, or the LEPC determines that it is not the appropriate organization to make arrangements with, in which case the SQG or LQG

[101] Memorandum from Matt Hale, Director of EPA's Office of Solid Waste, to RCRA Division Directors, November 7, 2006, RCRA Online 14758.

[102] On March 24, 1986, EPA finalized regulations applicable to generators of between 100 kg and 1000 kg of hazardous waste in a calendar month (51 FR 10146) in which the Agency indicated that these generators could treat such waste in accumulation tanks or containers without a permit provided that treatment conformed to established management standards for tanks and containers. An example of subsequent guidance regarding allowable treatment at both SQGs and LQGs is a memorandum from Elizabeth Cotsworth, Director of EPA's Office of Solid Waste, to RCRA Senior Policy Advisors, August 16, 2002, RCRA Online 14618.

would enter into an arrangement with its local emergency responders.

Due to the fact that some SQGs and LQGs may already coordinate with their LEPCs annually as part of their EPCRA requirements, EPA opined that it would be unnecessary to include time frames for updating in this rule. The Agency, nevertheless, requested comments on whether the regulations should mandate how frequently a generator must communicate with its LEPC or local fire department if it has not otherwise communicated with them.

EPA also proposed to modify existing regulations to state that the generator shall maintain records documenting the arrangements with the LEPC or, if appropriate, with the local fire department, as well as any other organization necessary to respond to an emergency. The Agency asked for comment on this proposed change to documentation, in particular, whether local ordinances already require generators to have documentation of arrangements with local emergency response organizations.

Finally, the Agency asked for comment on the feasibility of providing a waiver from requiring either an SQG or LQG to enter into arrangements with an LEPC or, if appropriate, other local authorities when they have 24-hour on-site emergency response capabilities, and particularly under what circumstances a waiver would be granted.

The majority of commenters indicated that local emergency responders, as opposed to LEPCs, should serve as the initial point-of-contact for LQGs, citing concerns about an emphasis on LEPCs, which usually are not involved in actual responses to emergencies. Regarding the extent to which SQGs and LQGs should document efforts to enter into arrangements with local authorities/first responders, some commenters stated the generator cannot be held responsible for making arrangements with a party over which it has no control and noted that a mandated arrangement differs greatly from being required only to make an ''attempt.'' There were also questions on what would constitute appropriate documentation. Although there was some opinion to the contrary, the majority of commenters believed that large facilities with internal emergency response capability should be given a waiver or allowed to seek a waiver from entering into arrangements with local authorities.

Based on the comments received, EPA is not finalizing the proposed references to LEPCs as the primary contact identified at § 262.16(b)(8)(vi) and § 262.256 for SQGs and LQGs, respectively. EPA is also not finalizing proposed language indicating that generators must make arrangements with local responders and is clarifying that generators must simply attempt to make arrangements with local responders and document either the attempts or, if successful, the final arrangements. Some commenters provided feedback in terms of what constitutes sufficient ''documentation'' that best efforts were made to enter into arrangements. In considering these comments, EPA is revising the proposed language at §§ 262.16(b)(8)(vi)(B) and 262.256(b) to remove the term ''certified letter'' in recognition of the fact that there are various means of confirming that arrangements actively exist, or were sought but not obtained, including, but by no means limited to, a certified letter, fax and electronic mail. Additionally, based on these comments, EPA is revising proposed language to insert the phrase ''in the operating record,'' which would include the contingency plan, to provide additional flexibility regarding where such documentation can be retained. Finally, during implementation of the final rule, as part of coordinating with stakeholders and conducting associated outreach activities, EPA intends to address the issue of what constitutes reasonable efforts or sufficient attempts by SQGs and LQGs to make and document arrangements with local authorities.

With respect to large facilities possessing internal emergency response capability, EPA is adding language at §§ 262.16(b)(8)(vi)(C) and § 262.256(c) that allows these facilities to obtain a waiver from the authority having jurisdiction (AHJ) over the fire code within the facility's state or locality in terms of entering into arrangements with local authorities provided the waiver is documented in the operating record. As previously stated in the final rule preamble, an AHJ may or may not be the fire marshal, fire chief, building official, or another official as designated by the state or local government. EPA believes that, practically speaking, the AHJ would be in the best position to evaluate whether a particular facility, in fact, possesses 24-hour response capabilities. This is consistent with the Agency's rationale when discussing waivers from the 15 meter property line condition in the case of ignitable or reactive hazardous waste accumulation. The Agency is similarly allowing flexibility regarding how the generator documents that a waiver has been obtained.

3. Changes to Contingency Plan Regulations for Large Quantity Generators: Submitting a Contingency Plan Executive Summary to Emergency Management Authorities

In the preamble to the proposed rule, EPA noted that RCRA regulations on contingency planning and emergency procedures address the purpose of the contingency plan, what it must contain, who receives copies, how to amend the contingency plan, and responsibilities of the facility's emergency coordinator and emergency procedures. The Agency also noted that the owner or operator of the facility can develop one contingency plan that meets all the regulatory standards for the various statutory and regulatory provisions associated with contingency planning, which were specifically identified in the proposed rule preamble. In doing this, the Agency recommended that generators base their contingency plan on the National Response Team's Integrated Contingency Plan Guidance One Plan (June 5, 1996: 61 FR 28642).

EPA's discussions with emergency management professionals indicated that the length of the facility contingency plans may prevent first responders from being able to fully review these documents when responding to an emergency and what first responders really need is readily available information describing what they will immediately confront upon arrival at the scene. EPA recognized that, once the incident is under control, first responders will be able to review the contingency plan to determine whether longer-term responses are necessary. However, the Agency also indicated that a shorter document, such as an executive summary of the contingency plan, would allow a more effective initial response to an incident at a facility.

Based on a review of information required as part of a RCRA contingency plan, as well as information required by the local fire department, EPA identified certain components that would be useful in an executive summary. In particular, EPA proposed to require that the following information be included in an executive summary to assist emergency responders in the event of an incident: (1) The types/names of hazardous wastes in layman's terms and the associated hazard associated with each waste present at any one time (*e.g.,* toxic paint wastes, spent ignitable solvent, corrosive acid); (2) the estimated maximum amount of each waste that may be present at any one time; (3) the identification of any hazardous wastes where exposure

would require a unique or special treatment by medical or hospital staff; (4) a map of the site showing where hazardous wastes are generated and accumulated and routes for accessing these wastes; (5) a street map of the facility in relation to surrounding businesses, schools, and residential areas to understand how best to get to the facility and also evacuate citizens and workers; (6) the locations of water supply (*e.g.,* fire hydrant and its flow rate, drafting locations); (7) the identification of on-site notification systems (*e.g.,* a fire alarm that rings off site, smoke alarms); and (8) the name of the emergency coordinator and 24/7 emergency telephone number.

Because of the usefulness of a shorter document for emergency responders, EPA proposed to require that a new LQG, as of the effective date of the rule, submit an executive summary of its contingency plan, in addition to the full contingency plan, to the emergency management authorities; in particular, LEPCs. Although EPA believed the eight elements previously discussed should be included as part of an executive summary, the Agency asked for comment on the appropriateness of this information.

Roughly twice as many commenters supported the requirement for an executive summary for LQGs than opposed it, arguing that EPA's proposal to require a contingency plan executive summary would improve the ability of emergency response teams to respond to an incident at an LQG's facility. These commenters generally favored including at least some of the eight elements as part of contingency plan executive summary, although some commenters stated a preference for excluding certain elements or suggested others for inclusion. Other commenters suggested a document format, such as a table of contents or index that allows the reader to quickly access needed information. Some commenters disagreed with making submission of the executive summary a mandatory requirement, while others advocated flexibility in terms of content and submission. One commenter requested clarification as to the meaning of ''new LQG.'' Commenters who objected to this proposal believed that it was unnecessarily prescriptive and duplicative.

The Agency subsequently decided to modify language at § 262.262(b)(8) to account for situations where an emergency coordinator is continuously on duty in order to ensure consistency with final regulatory text at § 262.261(d). Otherwise, the Agency believes these elements provide key information for use in the event of an emergency, which will be beneficial to workers and the public in general. EPA is also requiring new LQGs (*i.e.,* facilities that become LQGs after the effective date of this regulation) to develop and submit an executive summary of their contingency plan to emergency authorities in addition to a full contingency plan. As EPA expressed in the proposal and states again in this final rule, developing the executive summary during the initial writing of the contingency plan will not be a significant extra step. As discussed subsequently, EPA is finalizing changes regarding the name of this document (*i.e.,* changing from ''executive summary'' to ''quick reference guide'') and clarifying how existing LQGs are covered by this requirement. Additionally, as noted elsewhere in this preamble, EPA is not finalizing proposed references to LEPCs in terms of making arrangements with local authorities at § 262.16(b)(8)(vi) and § 262.256 for SQGs and LQGs, respectively, or submitting a quick reference guide to local emergency responders at § 262.262(a) for LQGs.

4. Technical Changes on Personnel Training Applicable to Large Quantity Generators

EPA has acknowledged that, since promulgation of personnel training regulations in the 1980s, use of computerized training has become a common practice for generators to teach their workers about the management of hazardous waste. Due to the fact that many generators already use this method for training workers, a modification that reflects use of online computer training would simply bring the hazardous waste personnel training regulations up to date with existing industry practices. Therefore, EPA proposed to also allow a generator to use online computer training, in addition to classroom instruction and on-the-job training, to complete the personnel training requirements. EPA requested comment on this proposed modification.

The vast majority of commenters supported EPA's proposal to clarify that online training is acceptable to meet hazardous waste generator training requirements. However, some commenters suggested replacing the word ''online'' with ''computer-based'' or ''electronic training'' or identifying additional training options. EPA has considered these comments and is modifying proposed § 262.17(a)(7)(i)(A) by inserting language that takes into account computer-based and/or electronic training options.

5. Executive Summary Submission for Existing Large Quantity Generators

As previously stated, EPA believes that a shorter document, such as an executive summary of the contingency plan, which will be referred to as a quick reference guide, will allow more effective response to an incident at a facility. EPA is requiring new LQGs, in addition to a full contingency plan, to develop and submit an executive summary of their contingency plan to local emergency responders identified at § 262.262(a). With respect to existing LQGs, which have already developed and submitted a contingency plan to local emergency responders, EPA proposed not to require these facilities to develop an executive summary because of the additional burden. However, the Agency recommend that existing LQGs may want to submit an executive summary when conducting a periodic update on their contingency plans to ensure that the emergency responders have the appropriate information on hand in the event of an emergency. EPA took comment on whether existing LQGs that have already provided a full contingency plan should also be required to submit an executive summary to the LEPC or, if appropriate, the fire department or other emergency responders.

Comments received indicated a very strong preference for requiring an existing LQGs to submit an executive summary. However, certain commenters suggested that submission should occur when existing LQGs update their contingency plans to reflect, for example, personnel changes, facility updates, waste relocations, emergency equipment upgrades, and other operational or physical alterations. Other commenters suggested that submission occur after a specified period of time has elapsed.

In the final rule, EPA is clarifying in new language at § 262.262(b) regarding existing and new LQGs with respect to preparation and submission of a quick reference guide. EPA is also adding new language at § 262.262(c) to require that all LQGs update their quick reference guides, if necessary, whenever the contingency plan is amended. EPA does not consider that the changes to the final regulations in this rule would automatically require amendments to an existing LQG's contingency plan under the requirements in § 262.263(a).

In response to certain comments, EPA is also replacing the term ''executive summary'' with the term ''quick reference guide'' in order to more closely mirror the intended purpose of this document. The Agency believes this

wording better conveys the fact that this document should be prepared in a format enabling first responders to quickly access key information in the event of an emergency. Lastly, as previously stated, EPA is not finalizing references to LEPCs as the primary contact identified at § 262.16(b)(8)(vi) and § 262.256 for SQGs and LQGs, respectively. Instead, LQGs are directed to submit the quick reference guide to local emergency responders identified at § 262.262(a).

6. Other Changes

EPA proposed to replace the word ''facility'' in these regulations regarding emergency preparedness and prevention with the word ''site'' because ''facility'' is defined in § 260.10 as specific to TSDFs. Certain commenters discussed EPA's proposal. One commenter noted that ''site'' is too general and could be misinterpreted, while another commenter noted that, although the term ''facility'' has a defined meaning in RCRA, ''site'' does not. As a result of these comments, EPA has reconsidered its proposal and decided not to change existing regulations; consequently, the Agency is replacing the word ''site'' where it appeared in this context in the proposal with the word ''facility'' throughout final rule language. EPA has concluded that use of the word ''facility'' in these regulations would also be more consistent with the word ''facility,'' which is used and defined in EPCRA emergency planning and notification regulations at 40 CFR part 355, as well as in Spill Prevention, Control and Countermeasures (SPCC) plan regulations at 40 CFR part 112.

EPA also proposed incorporating a minor revision associated with a ''comment'' in existing regulatory text into the final rule at § 262.264 because the **Federal Register** style no longer permits this kind of comment in new regulations. One commenter noted that certain text in the comment in question, ''Applicable responsibilities for the emergency coordinator vary, depending on factors such as type and variety of waste(s) handled by the facility, and type and complexity of the facility'' was not incorporated and suggested that this regulatory text be retained to give some flexibility to those who must perform certain emergency response duties. EPA will incorporate the suggested text into § 262.264.

D. What is EPA not including in the final rule?

EPA asked for comment on certain potential revisions to existing regulations that the Agency has subsequently decided not to address as part of this final rule. Each is discussed in turn as follows.

1. Changes to Contingency Plan Regulations for LQGs: Including Alternative Evacuation Routes in the Contingency Plan

EPA identified a potential issue regarding whether a contingency plan must contain information about alternative evacuation routes or whether a different approach for addressing alternative evacuation routes would be more effective. This issue resulted from stakeholder discussions regarding the Agency's November 2004 Hazardous Waste Generator Regulatory Program Evaluation (Docket ID No. RCRA–2003–0014). EPA received a comment stating that it does not make sense to include in the contingency plan hundreds of possible evacuation routes that may be present at a facility, depending on its configuration, along with a suggestion that, although regulations should be modified to require that evacuation routes be posted and drills be conducted, regulations should not require the routes to be in the contingency plan.

EPA indicated that, although the Agency did not believe regulations require all potential evacuation routes be identified, emergency responders may need this type of information in order to determine the most efficient and timely approach to reach the facility. Therefore, EPA requested comment on the necessity of modifying the condition on alternative evacuation routes in a contingency plan. EPA also asked for comment on whether requirements to post evacuation routes and hold annual evacuation training/drills would be an effective substitute to maintaining alternative evacuation routes in the contingency plan and whether regulations should discuss shelter-in-place as part of the contingency plan.

Slightly more commenters disagreed than agreed with requiring alternate evacuation routes in contingency plans. Some commenters noted that, while alternative evacuation routes should be considered, they may not exist or may not be practical in certain instances. Another commenter believed that the decision to require alternative evacuation routes should rest with the LEPC. Commenters also offered suggestions such as requiring identification of employee muster locations or including a map with possible exists marked, with another commenter stating that including evacuation routes only in the contingency plan is not useful. EPA did not receive many comments regarding either posting evacuation routes and holding annual evacuation training/drills or discussing shelter-in-place, although the comments received indicated support for these approaches.

EPA understands that it may not always be possible to identify alternate evaluation routes and likewise realizes that immediate evacuation may not always be advisable due to the nature of the emergency. Nevertheless, the Agency believes that, in the majority of instances, evacuation will be the selected course of action and that it will be possible to identify an alternate evacuation route. EPA also believes comments on the proposed rule regarding this issue should be considered by facilities when developing or amending contingency plans. This would include posting evacuation routes, as well as muster and shelter-in-place locations, within the facility (and/or making such information available on cell phones) and conducting periodic training/drills. These efforts would be undertaken, as necessary, in consultation with local emergency responders. Due to the varying types/varieties of wastes handled by facilities and differing physical settings in which facilities are located, however, the regulations should allow flexibility on the part of the LQG. Therefore, EPA is not making any changes to § 262.261(f), as proposed.

2. Changes to Contingency Plan Regulations for LQGs: A Potential Electronic RCRA Contingency Planning Application

EPA requested comment on whether contingency plans should be submitted electronically to emergency responders to enhance their ability to respond safely and effectively to an emergency at an LQG, including what EPA's role should be in electronic submittals. In making this request, EPA noted that the Agency currently makes numerous electronic databases and tools available for helping first responders with emergency management. A specific example cited was a suite of software applications (Computer-Aided Management of Emergency Operations), which is used to assist with data management requirements under EPCRA. EPA asked whether an additional tool to manage contingency plans under RCRA would be a useful addition to this software suite and whether it would assist LEPCs by integrating the contingency plan with their existing data on facilities, thereby making the information available to the first responders in the most usable way. EPA also inquired as to the feasibility/effectiveness of private sector parties or

non-profit or governmental entities in developing software that LQGs could use to provide important information to emergency responders during an emergency.

The majority of comments received supported electronic submission of contingency plans to emergency responders, including five commenters who suggested incorporating submissions of contingency plan information into existing software applications—two of who preferred this to direct submission of the plan—consistent with EPCRA requirements. Some commenters cautioned against making electronic submission mandatory and a few others indicated that electronic submission of a contingency plan would preclude the need for submission of an executive summary. Commenters opposed to this approach cited reasons such as unnecessary burden and potential lack of availability during a power outage. Few comments directly addressed the question of software development, beyond mentioning existing software applications, although limited feedback did not indicate support for this additional effort.

Proposed regulations did not specify the format in which the contingency plan must be provided nor did they discuss software applications. EPA strongly encourages LQGs to work with first responders to determine whether electronic submission of contingency plans, including incorporating contingency plan information into existing software applications, is an acceptable approach either in lieu of or in addition to a hard copy submission. However, EPA believes regulations must be sufficiently flexible to allow these decisions to be made on a facility-by-facility basis; therefore, the Agency is not making any changes to proposed regulations at § 262.262(a) regarding transmission of the contingency plan.

3. Additional Information for Contingency Plan Executive Summary

EPA took comment on certain aspects of the contingency plan executive summary, which the Agency is renaming as a quick reference guide, related to element #1. This element discusses the types/names of hazardous wastes in layman's terms and the associated hazard associated with each waste present at any one time. EPA asked whether providing information regarding identification of hazardous waste is sufficient for ensuring that first responders will be able to identify the appropriate actions to take during emergency responses. EPA also asked whether referencing material in the North American Emergency Response Guide, where appropriate, would be useful (*i.e.,* likely reduce the time it takes to get the necessary information for managing the situation) to first responders and whether generators can easily access this information to add to their contingency plans. EPA received few comments related to element #1, although limited comments received seemed to indicate support for including additional information. Given the relative lack of comments received and to avoid being overly prescriptive, EPA will not make it a requirement to include this additional information. The Agency is not making any changes to what was proposed at § 262.262(b)(1).

EPA also took comment regarding whether element #3 of the contingency plan executive summary, which discusses identification of any hazardous wastes where exposure would require a unique or special treatment by medical or hospital staff, should also include a requirement that the generator provide medical-related information for exposure to hazardous wastes requiring special treatment; specifically, whether this information is readily available to the generator for inclusion in the executive summary of the contingency plan and whether first responders would find this additional information useful for responses. EPA received few comments related to element #3; as such, there was no meaningful basis for justifying any additional regulatory changes. Although EPA would encourage the generator, in consultation with first responders, to include medical-related information associated with exposure to certain hazardous wastes, the Agency is not making any changes to what was proposed at § 262.262(b)(3).

4. Contingency Plan Executive Summary for SQGs

Another aspect of the contingency plan executive summary on which EPA took comment involved whether an SQG should be required to develop an executive summary of a contingency plan. In posing this question, EPA noted that the major differences between the preparedness, prevention, and emergency procedures regulations applicable to SQGs and those applicable to LQGs are the development and implementation of a contingency plan and more rigorous responsibilities for the LQG emergency coordinator.

Although SQGs are not required to develop contingency plans under RCRA, EPA noted that many SQGs may already have developed contingency plans to comply with other statutory and regulatory requirements and that many of the elements of an executive summary may already be available. For these reasons, EPA thought that the requirement for SQGs to provide an executive summary of a contingency plan to first responders could provide information that is critical during emergencies with little extra effort being expended by the SQGs.

Although a few commenters supported creation of an executive summary for SQGs, the majority did not. Reasons provided included the fact that a contingency plan is not required under RCRA and the belief that this decision should be made by individual states, as well as the potential for unnecessary burden and possibly duplication of effort. Other commenters, while seeming not to support creation of an executive summary, nonetheless suggested that EPA specify information that would be included in the case of SQGs.

As previously noted, SQGs may have already developed emergency plans to comply with other statutory and regulatory requirements, such as SPCC or EPCRA. Moreover, under existing RCRA regulations, SQGs are required to attempt to make arrangements, as appropriate, with local authorities regarding the types of wastes handled at their facilities. Therefore, it is possible that these facilities have incorporated information regarding hazardous waste management into these emergency plans. EPA also recognizes that there exist a large number of SQGs operating under RCRA, as compared to LQGs. For instance, as noted elsewhere in this rulemaking, EPA estimates the number of SQGs to range from approximately 49,900 to 64,300 while the number of LQGs is estimated to be approximately 20,800.[103] EPA is not making any changes to existing regulations. However, given the prevalence of SQGs and the associated potential for adverse impacts to human health and the environment, the Agency strongly encourages these facilities, as a best management practice, to develop a quick reference guide (*i.e.,* new term for the document referred to as an ''executive summary'' in the proposed rule) and share this information with local emergency responders.

5. Revisions to Applicability of Personnel Training

EPA asked for comment on whether the regulations should specifically identify positions at LQGs for which

[103] See ''Regulatory Impact Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule.'' A copy of the analysis is available in the docket for this action.

hazardous waste training would be required and for which a written job description is necessary, as well as what those job duties should be. Although current EPA guidance excludes staff working in SAAs from the training requirements, the Agency expressed a belief that such personnel have a similar need to know the risks associated with hazardous wastes as personnel working in central accumulation areas. Therefore, EPA also asked for comment on whether personnel involved in handling or managing hazardous wastes in SAAs should be required to undergo hazardous waste training.

EPA noted that, besides the statement indicating that personnel must be able to respond effectively to emergencies by familiarizing them with emergency procedures, emergency equipment, and emergency systems, existing regulations are not specific about which personnel at an LQG must complete the hazardous waste training. At issue is the scope of these training standards, the applicability of the training provision to employees who are not assigned to work in the CAAs (*e.g.,* personnel working at SAAs), and whether to require training and a written job description for specific types of employees working in areas of hazardous waste management related to central accumulation areas.

With the assistance of staff from certain states (*e.g.,* Connecticut, New York and Vermont), EPA previously identified the following areas of hazardous waste management for which personnel training and a written job description should be required: (1) Completes and/or signs the hazardous waste manifest; (2) manages hazardous waste in areas where hazardous wastes are accumulated; (3) maintains hazardous waste inventory; (4) conducts daily or weekly inspections of areas where hazardous wastes are accumulated and (5) plans or responds to emergencies that involve hazardous wastes. EPA believed this clarification would have the benefit of assisting LQGs in determining more readily the scope of their hazardous waste training program. Nevertheless, in the proposal, the Agency requested feedback on this issue and others before making a final decision.

Commenters were generally evenly divided on whether or not the regulations should specifically identify positions at LQGs where hazardous waste training and a written job description is necessary. Supporters who agreed with the areas of hazardous waste management identified by EPA also identified additional job functions, including those not directly involved in handling hazardous waste that effectively expanded the areas of waste management, while others believed training should apply to employees who are handling hazardous waste on a daily basis. Commenters who did not support specifying positions and including written job descriptions expressed concern that proposed revisions could, in practice, have the opposite of the intended beneficial effect envisioned by the Agency. Certain commenters also stated that LQGs would be in the best position to identify employee training needs, while others recommended removing the requirement for written job descriptions as they believe such information does not benefit the facility or inspectors.

Comments were roughly split on whether EPA should require hazardous waste training for personnel who work at SAAs. Taking into account the differing opinions of commenters, the existence of EPA guidance on this point and the desire to maintain flexibility, the Agency has decided not to revise § 262.17(a)(7) to identify areas of hazardous waste management for which personnel training and a written job description are required or to specifically require training for staff at SAAs. However, EPA would encourage all generators to take appropriate steps to ensure that all employees who work at areas where hazardous waste is accumulated, including at SAAs, or are otherwise involved in hazardous waste management receive sufficient training to ensure that they are familiar with proper handling and emergency procedures.

6. Revising Frequency of Communication With Emergency Response Agencies

During discussions related to making and documenting arrangements with the LEPCs, EPA noted that existing regulations do not specify how frequently hazardous waste generators must make arrangements with local authorities. Considering that some SQGs and LQGs may already coordinate with their LEPCs annually as part of their EPCRA requirements, EPA opined that it would not be necessary to include time frames as part of this rule. The Agency, nevertheless, requested comments on whether the regulations should mandate how frequently a generator must communicate with its LEPC or local fire department if it has not otherwise communicated with them.

With the exception of one commenter who suggested that arrangements should be updated annually, at a minimum, and more frequently if modification is needed based on changes such as the type/amount of waste generated, comments received did not indicate support for revising existing regulations to specify time frames. These commenters felt that the provisions necessary for LQGs to communicate with local emergency response personnel are already in place or that communication should only occur in the event that the facility has a major change in its operations. Another commenter indicated that mandating how frequently a generator must communicate with its LEPC or local fire department would only work if corresponding changes were also made to EPCRA requirements. EPA agrees with the majority of commenters and continues to believe that it is unnecessary to mandate how frequently a generator should communicate with its emergency response agency. Therefore, the Agency is not making any changes to what was proposed at § 262.16(b)(8)(vi) for SQGs or to § 262.256 for LQGs.

7. Applying Emergency Planning and Procedures Revisions to Parts 264 and 265

Although revisions to emergency planning and procedure regulations pertain only to generators (language in an expanded 40 CFR part 262), many of these provisions were taken from part 265 with only slight revisions. Therefore, EPA asked whether it would be appropriate/helpful if proposed revisions to part 262 were also be made in the applicable paragraphs of parts 264 (permitted facilities) and/or 265 (facilities operating under interim status) to ensure consistency or whether the regulations should remain unchanged despite the result that generators and TSDFs would be left with some regulations that are very similar but not exactly the same.

Although the majority of those who commented supported making changes to TSDF regulations, EPA is not making changes as part of this rulemaking because the Agency believes that emergency planning and procedure requirements at TSDFs can best be addressed on a facility-specific basis through the permitting process.

XII. Technical Corrections and Conforming Changes to 40 CFR Parts 257, 258, 260 Through 265, 270, 273, and 279

The proposed rule included 23 technical corrections and conforming changes to various paragraphs in parts of 257, 258, 260 through 265, 270, 273, and 279 discussed at 80 FR 57984. These changes eliminate the regulatory text for discontinued programs, identify areas where conforming changes are

necessary, update existing regulatory text to account for new programs, improve the readability of certain paragraphs, and correct typographical errors. As an example, we proposed to revise § 260.3, which currently reads, ''As used in parts 260 through 265 and 268 of this chapter.'' However, this text fails to account for additional parts of the regulations that were promulgated after 1986, such as parts 266, 267, and 270 through 273. Therefore, the Agency proposed to revise this paragraph to correct this oversight to read, ''As used in parts 260 through 273 of this chapter.''

A. What is EPA finalizing?

The Agency is finalizing 20 of the 23 proposed technical corrections. The three proposed technical corrections not being finalized in this action are also discussed. In addition, EPA is finalizing conforming changes throughout the text to account for the reorganization and the changes in defined terms. Also note that EPA is making a conforming change to § 266.80(a) in this action to take into account the revisions being made as a part of the ''Hazardous Waste Export-Import Revisions'' Final Rule (Docket ID EPA–HQ–RCRA–2015–0147; FRL–9947–74–OLEM).

The technical corrections the Agency is finalizing are:

(1) Revise § 260.3, which previously read, ''As used in parts 260 through 265 and 268 of this chapter'' to currently read ''As used in parts 260 through 273 of this chapter'' to account for additional parts of the regulations that were promulgated after 1986, such as parts 266, 267, and 270 through 273.

(2) Modify the definitions of ''Treatability Study,'' ''Universal Waste Handler,'' ''Universal Waste Transporter'' in § 260.10 to only capitalize the first word (*e.g.,* ''Universal'') in order to match the formatting in the rest of this section.

(3) Remove the closed parenthesis after ''(*e.g.,*)'' from § 261.1(c)(6).

(4) Improve the readability of § 261.4(a)(7), which previously read, ''Spent sulfuric acid used to produce virgin sulfuric acid, unless it is accumulated speculatively as defined in § 261.1(c) of this chapter'' to currently read ''Spent sulfuric acid used to produce virgin sulfuric acid provided it is not accumulated speculatively as defined in § 261.1(c) of this chapter.''

(5) Make conforming changes to citations that reference § 261.5 to reflect the reorganization of these regulations. The citations where references to § 261.5 are revised include all the following: §§ 262.10(b), 262.10(l)(2), 262.201(b), 262.204(a), 262.210(b)(3), 262.210(d)(2), 262.211(e)(3), 262.213(a)(2), 262.213(a)(3), 262.213(b)(2), 262.216(b), 264.1(g)(1), 268.1(e)(1), 270.1(c)(2)(iii), and 279.10(b)(3). In § 261.33(e) and (f), EPA is removing the references to §§ 261.5(e) and 261.5(a) and (g), respectively, because the quantity limits for hazardous wastes are contained in EPA's definitions for very small quantity generator, small quantity generator, and large quantity generator. (Note: The comments at the end of § 261.33(e) and (f) remain.)

(6) Replace the word ''waste'' with ''water'' in previous § 261.5(e)(2), which read, ''A total of 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water . . . .'' Prior to 1985, the word ''waste'' was ''water'' and the Agency was not able to determine why this change occurred so we are reverting back to the original regulatory language. (In the reorganization, this language is moved to § 260.10 and is contained in the definitions of large quantity generator, small quantity generator and very small quantity generator.)

(7) Revise § 261.420 to clarify that the requirement in § 261.411(c) that all employees be familiar with proper waste handling and emergency procedures relevant to their responsibilities applies to facilities that generate or accumulate more than 6,000 kg of hazardous materials as well as to facilities that generate or accumulate less than that amount.

(8) Remove Notes 1 and 2 from § 262.10. Note 1 previously stated that the provisions of § 262.34 are applicable to the on-site accumulation of hazardous waste by generators. Therefore, the provisions of § 262.34 only apply to owners or operators who are shipping hazardous waste which they generated at that facility. Note 2 previously stated that a generator who treats, stores, or disposes of hazardous waste on site must comply with the applicable standards and permit requirements set forth in 40 CFR parts 264, 265, 266, 268, and 270. These notes are no longer necessary because the Agency replaced § 262.34 with a new reorganization of the regulations that address Note 1 and in § 262.10 that address Note 2.

(9) Remove the extra period in the last line of the paragraph at § 262.10(l).

(10) Made conforming changes to sections that reference § 262.34 to reflect EPA's move of these regulations. The citations where references to § 262.34 are revised include the following: §§ 262.10(l)(1), 262.201(a), 262.201(a), 262.216(a), 264.1(g)(3), 264.71(c), 264.1030(b)(2), 264.1050(b)(2), 265.1(c)(7), 265.71(c), 265.1030(b)(2) and (b)(3), 268.7(a)(5) and 270.1(c)(2)(i).

(11) Correct the statutory citation at § 262.43 that referred to sections 2002(a) and 3002(6) of the Act. The reference to 3002(6) should be to 3002(a)(6). Additionally, the word ''he'' was removed in order to be gender neutral.

(12) Make two conforming changes to the definition of ''central accumulation area'' previously found in § 262.200 in subpart K. We moved this definition from this location to § 260.10 with the following revisions. First, because of the reorganization of the regulations in 40 CFR part 262, we changed the references to the applicable regulations for the central accumulation areas that are used in the definition of central accumulation area in § 262.200. For LQGs, the reference to § 262.34(a) has been changed to § 262.17 and for SQGs, the reference to § 262.34(d) through (f) has been changed to § 262.16.

Second, we removed the reference to Performance Track in the definition of ''central accumulation area'' in § 262.200 of subpart K because the Performance Track program was terminated (74 FR 22741; May 14, 2009). Both of these conforming changes are reflected in the definition of ''central accumulation area'' that has been added in § 260.10.

(13) Make conforming changes to citations that previously used the term ''conditionally exempt small quantity generator'' to reflect EPA's change to the term ''very small quantity generator.'' The citations where ''conditionally exempt small quantity generator'' was replaced with ''very small quantity generator'' include: §§ 262.200, 262.201(b), 262.202(b), 262.203(a), 262.203(b)(2), 262.204(a), 262.209(b), 262.210(d)(2), 262.213(a)(3), 268.1(e)(1), 270.1(c)(2)(iii), 273.8, 273.8(a)(2), 273.81(b), and 279.10(b)(3). EPA also made this conforming change in 40 CFR parts 257 and 258 as well. Although EPA had not explicitly specified these parts as affected citations in the proposal, EPA had explained clearly in the preamble to the proposal that we would need to replace the term ''CESQG'' with the new term ''VSQG'' throughout the entire EPA regulations.

(14) Improve the readability of § 264.170, which previously read, ''The regulations in this subpart apply to owners and operators of all hazardous waste facilities that store containers of hazardous waste . . . .'' The Agency revised this language to currently read, ''The regulations in this subpart apply to owners and operators of all hazardous waste facilities that store hazardous waste in containers . . . .''

(15) Improve the readability of the first sentence in § 264.191(a), which previously read, ''For each existing tank system . . . the owner or operator must determine that the tank system is not leaking or is unfit for use.'' The Agency revised this language to currently read, ''For each existing tank system . . . the owner or operator must determine that the tank system is not leaking or is fit for use.''

(16) Make conforming changes to and improve the readability of § 265.1(c)(7), which previously read, ''A generator accumulating waste on-site in compliance with § 262.34 of this chapter, except to the extent the requirements are included in § 262.34 of this chapter.'' The Agency revised this sentence to currently read, ''A generator accumulating waste on site in compliance with applicable conditions for exemption in § 262.14 though § 262.17 and subparts K and L of part 262, except to the extent the requirements of this part are included in those section and subparts.'' The new references to the conditions for exemption in 262.14 and 262.15, and subparts K and L provide the locations of the existing conditions for exemption from part 265 for VSQGs, satellite accumulation, and academic entities; and the new conditions for exemption for episodic generation.

(17) Correct the list of **Federal Register** notices in § 265.54 to be consistent with the list of references in § 264.54. The reference to 53 FR 37935, September 28, 1988, was missing from § 265.54.

(18) Make a conforming change that removed and reserved § 265.201 (Special requirements for generators of between 100 and 1,000 kg/mo that accumulate hazardous waste in tanks). EPA moved this section to § 262.16.

(19) Add a missing reference to 40 CFR part 268 in § 270.1(a)(3), which previously read, ''The RCRA permit program . . . in 40 CFR parts 264, 266, and 267'' to read, ''The RCRA permit program . . . in 40 CFR parts 264, 266, 267, and 268. ''

B. What changed since proposal?

The Agency is not finalizing three technical corrections. First, we are not finalizing the conforming change to remove and reserve § 262.40(c) that was proposed to be moved to § 262.11. One commenter pointed out that other parts of the regulations reference § 262.40(c). In addition, the title of § 262.40 is Recordkeeping and it is located in subpart D, titled ''Recordkeeping and Reporting.'' EPA has determined that it is appropriate to retain a reference to this recordkeeping requirement for generators in this section. Therefore, we are including a reference from § 262.40(c) to the recordkeeping requirement in § 262.11(f) as part of this final rule.

Second, the Agency is not finalizing the two proposed technical corrections that would have added § 265.445, applicable to drip pads, to § 265.111(c) and § 265.114, respectively. As pointed out by one commenter, this change is not necessary because and § 262.17 already references § 265.445 as part of LQGs having to comply with part 265 subpart W drip pad regulations.

C. Major Comments

Except for the comments associated with the proposed changes to § 262.40(c), § 265.111(c) and § 265.114, as well as two commenters pointing out the inadvertent mistakes at § 261.33(e) and (f), commenters were either in support of the proposed technical corrections or had no comments associated with these changes.

XIII. Electronic Tools To Streamline Hazardous Waste Reporting and Recordkeeping Requirements

This section summarizes the comments the Agency received regarding the feasibility of using electronic tools to support increases in RCRA program efficiency and effectiveness. More specifically, in the proposed rule, the Agency requested comment on the use of electronic tools in three program areas. In section VIII.B.9 of the proposed rule (80 FR 57946), the Agency requested comment on the feasibility of developing an electronic decision tool to assist generators in making accurate hazardous waste determinations. As part of that discussion, the Agency requested comment on the feasibility of the private sector developing electronic application software (apps) and whether there is a market for such an app and what EPA could do to facilitate software development. In section VIII.H.3 of the proposed rule (80 FR 57961), the Agency requested comment on the feasibility of developing an electronic application containing information from the executive summaries (now referred to as a ''quick reference guide'') of contingency plans that emergency responders could use in responding to an emergency. Also, in section XV (80 FR 57985), the Agency explored with stakeholders the feasibility of using electronic tools to streamline hazardous waste reporting and recordkeeping requirements.

In broad terms, and as discussed in preamble to the proposed rule, the use of electronic tools may be able to help hazardous waste generators improve and maintain compliance with the RCRA regulations, thereby reducing violations and increasing environmental benefits. Similarly, the use of electronic tools may reduce the costs to EPA, the states and regulated community for records required to be kept on file, or documents required to be reported that currently are submitted on paper.

From an efficiency standpoint, when information is submitted to EPA or the states on paper, this requires government staff or contractors to manually enter the data into federal and state data systems. These processes can be time-consuming, leading sometimes to important information going unnoticed, potential errors introduced through manual data entry requiring time-consuming correction processes by both regulated entities and the government. As an example, when the Toxics Release inventory switched from paper reporting to e-reporting, costs of managing the data went down by 99 percent and accuracy of submissions also was increased. Better use of information technology may be an important step to improving program efficiency, and as a result, program effectiveness as well. However, at this time, the Agency is not finalizing any electronic tools, but will continue to evaluate the comments received and explore the feasibility in the future.

A. Waste Determination Tools

Many commenters expressed concerns about the feasibility of developing a waste determination decision tool. Three related areas of concern frequently stood out in their comments. First, developing a decision tool with some measure of reliability would involve a complex undertaking. To be effective and helpful, the decision tool would need to account of all of the different factors associated with generating a waste, including industrial sectors, materials of production, chemical processes, and more. Incorporating these many factors into a reliable decision tool may not be feasible. Second, because of the complexity and time involved, development costs would be expensive, and, as several commenters mentioned, costs to maintain the decision tool would be expensive as well. As expressed by at least one commenter, if there were a viable market for such a tool, the private sector would have stepped in by now and developed it. Hence, the viability of such a tool being developed by the private sector seems remote. Third, if a tool was developed, and if a generator used the tool as the basis of its waste determination and it

was found to be wrong, a difficult question over liability may arise. More than one commenter stated that developing a decision tool with 100 percent accuracy was impossible.

However, others did see merit in such a tool, if carefully scoped out and developed. More than one commenter suggested that EPA consider developing a decision tool that focused on common or ''simple'' waste streams that could help VSQGs and SQGs in making waste determinations.

In line with this thought, one commenter recommended that the decision tool include 'filtering' questions such as ''Does the waste vary per batch? Is the waste associated with a particular type of manufacturing? Do you know what is in the waste?'' Depending on the answers, the generator could proceed or stop since the decision tool would not be useful. One commenter went even further by describing an analytical approach by having the tool first determine if the waste is listed or characteristically hazardous, and then determine if it is eligible for one of the exemptions identified in the regulations. By performing the determination this way, the generator would be aware that the waste could potentially be hazardous if it is managed in a way that does not qualify it for an exemption. This commenter also suggested that the tool should provide the user with some sort of output that documents the characterization process, including the generator's answers to the key questions that produced the end result. That way inspectors and others attempting to verify the determination would be able to clearly see the basis for it. Finally, more than one commenter suggested EPA focus on the generic process of making a hazardous waste determination rather than a waste-specific approach.

B. Emergency Response Executive Summary App

Interestingly, most commenters did not respond directly to the request for comment concerning the viability of developing an emergency response executive summary app. For those commenters that did respond, comments received were mixed with some favoring development and others opposed either because such tools already exist or are under development, or because they do not see the need. For example, one commenter mentioned that their fire departments were already using CAMEO (Computer-Aided Management of Emergency Operations) in such a way that some form of integration between the existing CAMEO interface and the RCRA contingency planning information would make the most practical sense.

However, several commenters did see the need for electronic submittal of contingency plans to make them more accessible and useful, although one commenter pointed out that electronic submittal could prove problematic during an emergency when power and communications may be lost or disrupted.

C. Recordkeeping and Reporting Tools

Commenters were generally supportive of EPA pursuing the development of electronic recordkeeping and reporting tools to improve compliance, but in some cases, not mandating their use. One commenter, a state, supports the use of electronic tools for managing and reporting environmental data, an example being the submittal of groundwater monitoring data by municipal solid waste landfill facilities. Conversely, another state commenter did not support the development of electronic tools that require additional submittals by the regulated community, such as submittal of training or inspection records. Another state commenter encouraged the use of any electronic tools (''e-tools'') for notices or reporting required by regulations that would result in a reduction of manual data entry by states.

D. Analysis of Comments

A review and analysis of comments regarding the feasibility of using electronic tools to support increases in RCRA program efficiency and effectiveness suggest commenters generally support use of electronic tools that reduce costs, have wide applicability, and improve program effectiveness. Where those criteria cannot be met, support usually was not forthcoming. Hence, many of the commenters did not see the cost-effectiveness of developing a waste determination decision tool unless properly scoped out to address common or simple wastes where the costs of development could be manageable—also realizing that using any potential tool developed would be a guide to assist generators in making a waste determination and not a definitive decision tool that guaranteed an accurate answer.

As many know, the Agency has already developed an electronic tool to enter site identification information on EPA Form 8700–12 as well as biennial report information on EPA Form 8700–13 A/B. Similarly, the Agency is in the process of developing e-Manifest to increase the efficiency and effectiveness of hazardous waste shipments. Based on comments, the Agency will continue to review existing RCRA reporting and recordkeeping regulatory requirements to identify cost-effective areas of opportunity to either use electronic tools or allow for submittal of information, such as RCRA contingency plans.

XIV. Enforceability

Persons that generate hazardous waste must comply with all the applicable independent requirements of the RCRA hazardous waste regulations, unless they obtain a conditional exemption from those requirements, provided by § 262.14, or by § 262.15, 262.16, or 262.17, or by § 262.70. Each generator category's independent requirements are listed in § 262.10 of this final rule. If a person violates independent requirements, EPA may bring an enforcement action under section 3008 of RCRA for violations of the independent requirements. Where a generator does not comply with conditions for an exemption and is therefore no longer exempt, the enforcement action will allege violations of those requirements for hazardous waste storage facilities from which the generator was attempting to remain exempt. States may choose to enforce against violations of state hazardous waste requirements under state authorities.

As with any violation, EPA and authorized states have numerous enforcement mechanisms available that range in severity. These include notices of violation, orders for compliance, orders for operations to cease, or assessment of penalties as appropriate. In addition, EPA and authorized states have flexibility in applying these mechanisms to the various responsible parties as appropriate to the specific circumstances. This rule does not affect the availability of any of these mechanisms, or EPA's or states' choice as to which type of enforcement approach to pursue against violators. The rule does distinguish between independent requirements and conditions from exemption in the generator regulations: It makes clear that a generator's violation of a condition of exemption results in the generator losing that exemption, resulting in a violation of the hazardous waste storage requirement from which the generator was seeking an exemption.

XV. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA-related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.[104] RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

[104] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

B. Effect on State Authorization of Final Rule

This document finalizes regulations that amend certain sections of the hazardous waste generator regulations in 40 CFR parts 260 through 265, 268, 270, 273, and 279. These regulations were promulgated under the authority of sections 2002, 3001, 3002, 3003, 3004, 3007, and 3010 of RCRA). These changes are promulgated under non-HSWA authority.

Thus, the standards will be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs.

Several of the revisions to the hazardous waste generator regulations are more stringent than those promulgated earlier. These include the following: (1) Requiring SQGs, LQGs and transfer facilities to better define the risks of hazardous wastes accumulated in tanks, containers, drip pads, and containment buildings, as well as when hazardous waste is accumulated in satellite accumulation areas (section IX.E. of this preamble); (2) requiring LQGs to notify EPA or their authorized state when they plan to close their facilities (section IX.I of this preamble); (3) requiring SQGs to re-notify every four years (section IX.L of this preamble); (4) requiring LQGs to submit a biennial report that identifies all of the hazardous wastes generated in the calendar year, not just for the months the facility was an LQG (sections IX.N of this preamble); (5) requiring LQGs updating their contingency plans to prepare a quick reference guide for their contingency plans to assist responders in an emergency (section XI of this preamble); and (6) requiring facilities that recycle hazardous waste without storing the waste to prepare and submit a Biennial Report. Therefore, states that have adopted the base RCRA program will be required to modify their hazardous waste programs to incorporate equivalent provisions if these standards are finalized.

On the other hand, three of the final revisions are less stringent than the current hazardous waste regulations. These revisions include the following: (1) Allowing VSQGs to voluntarily send hazardous waste to LQGs under the control of the same person (section IX.K of this preamble); (2) allowing LQGs to apply for a waiver from their local fire department to accumulate ignitable and reactive wastes within the 50 foot facility boundary (section IX.H of this preamble); and (3) allowing VSQGs and SQGs to voluntarily maintain their existing regulatory status if they have an episodic event that generates additional amounts of hazardous waste which would have resulted in them moving into a higher generator category for a short period of time, so long as they comply with specified conditions (section X of this preamble). Thus, authorized states may, but are not required to, adopt these changes.

This final rule also includes several revisions that are neither more nor less stringent, such as (1) reorganizing the hazardous waste generator regulations to make them more user-friendly (section VI of this preamble); (2) defining central accumulation area and the generator categories (section VII of this preamble); (3) mixing a non-hazardous waste with a hazardous waste (section IX.C of this preamble); (4) repeating the prohibition for generators from sending hazardous liquids to landfills (section IX.M of this preamble); (5) replacing the list of specific data elements with a requirement to complete and submit all data elements required in the Biennial Report form (section IX.N of this preamble); (6) deleting the performance track and laboratories XL regulations (section IX.P of this preamble); and (7) technical corrections and conforming changes to various parts of the RCRA regulations (section XII of this preamble). Thus, authorized states may, but are not required to, adopt these changes.

XVI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. This action is a ''significant regulatory action'' in that it may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Any changes made in response to OMB recommendations have been documented in the docket.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This

analysis is contained in EPA's Regulatory Impact Analysis (RIA) document titled ''Regulatory Impact Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Hazardous Waste Generator Improvements Rule.'' A copy of the analysis is available in the docket for this action and the analysis is briefly summarized here.

EPA estimates the future annualized cost to industry to comply with the requirements of this action at between $5.9 and $13.3 million at 7% discount rate. Similarly, the annualized cost savings or benefits for facilities opting to take advantage of two voluntary programs in the rule (*e.g.,* consolidation of VSQG waste by large quantity generators under the same ownership, and generators who would not be required to change generator status as a result of an episodic event) in combination with the less stringent requirements for SQGs accumulating waste on drip pads or in containment buildings is between $8.3 and $14.4 million at 7% discount rate. This results in a net annualized benefit for the whole rule of $2.4 million for the low-end estimate and $1.1 million for the high-end estimate at a 7% discount rate.

B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2513.02. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

This rule is necessary for EPA and authorized states to oversee the generation and management of hazardous waste. EPA is promulgating the establishment of these information collection requirements under the authority of RCRA Subtitle C. Several provisions in this rule will require respondents to either submit information to EPA or their authorized state, or maintain records at their facility. For example, generators will have to notify EPA or their authorized state they plan to take advantage of two voluntary provisions that will provide greater flexibility in how they manage they hazardous waste (*i.e.,* VSQG consolidation of their hazardous waste by a LQG under control of the same person or company; and episodic generation of hazardous waste resulting in a temporary change in regulatory status).

Similarly, SQGs will have to re-notify EPA or their authorized state every four years that they have not changed their regulatory category to support effective inspections and program management activities. New LQGs and LQGs that have to update their emergency response plan will be required to develop and submit a quick reference guide of their emergency response plan to their local emergency responders or, as appropriate, the Local Emergency Planning Committee to effectively assist these parties in responding to an emergency.

EPA and state agencies will use the collected information to ensure that hazardous wastes are managed in a cost-effective manner that minimizes risks to human health and the environment. Local emergency response organizations will also use the collected information to prepare contingency plans to reduce risks to emergency responders and bystanders. EPA does not expect confidentiality to be an issue in generators either providing information to EPA or an authorized state or in maintaining the necessary records required by the rule. The statutory authority to collect this information is found at RCRA 3002 (42 U.S.C. 6922) and RCRA 3003 (42 U.S.C. 6923).

Respondents/affected entities: Private sector and state and local authorities.

Respondent's obligation to respond: Mandatory.

Estimated number of respondents: 167,346.

Frequency of response: On occasion, annually, and biennially depending on the requirement.

Total estimated burden: 260,366 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $14,184,000 (per year), includes $2,526,000 in annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule.

The small entities directly regulated by this final rule include entities that generate hazardous waste across various industries, including, but not limited to, pesticide end-users and application services; industrial chemical manufacturers; wood preservation; pharmaceutical and other chemical and chemical product manufacturers; dry cleaners and industrial launderers; funeral services and crematories; photography; textile manufacturing; vehicle maintenance; metal manufacturing; construction; printing; professional cleaning services; hospitals; and wholesale paints and chemicals. The RIA estimated that the compliance costs of the final rule represent less than 1 percent of average annual revenues for small entities in the affected universe. The RIA used the Economic Census and Census of Agriculture data to calculate the average annual revenues of small entities in the affected universe. The average annualized costs of the rule are estimated to be between $112 and $209 on a per facility basis for small entities in the affected universe (using a 7 percent discount rate). At most, the RIA estimates the costs of the final rule represent between 0.08 and 0.15 percent of annual revenues for small entities in the affected universe. Therefore, we have concluded that this action is not expected to have a significant impact to a substantial number of small entities.

D. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of $100 million as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The RIA estimates that the state, local, and tribal government share of future average annualized direct costs for the final rule requirements to range between $0.2 million and $0.4 million per year (using a 7 percent discount rate). Thus, this final rule is not subject to the requirements of sections 202 or 205 of UMRA.

This final rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The rulemaking finalizes clarifications and

modifications to the hazardous waste generator regulations, which impacts only those entities that generate hazardous waste. Small governments would only be subject to the changes in the final rule if they generated hazardous waste subject to the RCRA hazardous waste requirements.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the final changes to the hazardous waste regulations would not impose any direct costs on tribal governments.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this action.

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The Agency does not believe that this action presents risks to the public. In fact, there are several components to this final rule that modify the existing hazardous waste generator regulations to enhance environmental protection in the local community, which includes protection of children. Examples include (1) requiring LQGs and SQGs to provide more detailed marking and labeling information for containers, tanks, drip pads, and containment buildings accumulating hazardous wastes; (2) requiring LQGs to notify EPA or an authorized state when they plan to close either a hazardous waste accumulation unit or their site; (3) requiring LQGs and SQGs to re-notify EPA or the authorized state on a periodic basis of their hazardous waste generator activities; and (4) improving emergency preparedness and response regulations on the part of SQGs and LQGs.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This final rule does not involve the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environment effects on minority, low-income and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The final rule aims to improve human health and environmental protection in a variety of ways. For example, there are several components to this final rule that modify the existing hazardous waste generator regulations to assist generators in understanding and facilitating improved compliance with the hazardous waste regulations. Examples include clarifying regulations regarding the mixing of non-hazardous waste with a hazardous waste by a generator, and better explaining the process by which generators determine under what level of regulation that they must manage their hazardous waste (*i.e.,* determining if they are VSQG, SQG, or LQG). Additionally, EPA is reorganizing the hazardous waste generator rules to make them more user-friendly and therefore assist generators in understanding their responsibilities in managing the hazardous waste they generate safely.

Still other components of this final rule enhance protection of the local community, and therefore foster improved human health and environmental protection, including for minority and low-income populations. These components include, for example, (1) requiring LQGs and SQGs to provide more comprehensive marking and labeling information for containers, tanks, drip pads, and containment buildings accumulating hazardous wastes; (2) requiring LQGs to notify EPA or an authorized state when they plan to close either a hazardous waste unit or their site; (3) requiring LQGs and SQGs to re-notify EPA or the authorized state on a periodic basis of their hazardous waste generator activities; and (4) improving emergency preparedness and response regulations on the part of SQGs and LQGs.

Furthermore, EPA is allowing VSQGs to ship their hazardous waste to an LQG under the control of the same person. As described in section IX.K of the preamble, this may increase environmental protection in the local community because hazardous waste generated by VSQGs would be subject to more stringent requirements upon receipt by the LQG, including ultimate management by a RCRA permitted TSDF (as opposed to being managed possibly in a municipal solid waste landfill). Although this change could result in an increase in traffic for certain communities, EPA believes the increase would not be significant given that VSQGs currently may send their hazardous waste to a number of destinations, including municipal and non-municipal solid waste management facilities.

Last, EPA is finalizing alternative standards for VSQGs and SQGs that would allow these entities to maintain their generator category if they generate hazardous waste during an episodic event. Although these generators will be allowed to temporarily manage a greater amount of hazardous waste than their current generator category allows, EPA is finalizing conditions under which the hazardous waste generated from an episodic event must be managed in order to maintain protection of human health and the environment. Therefore, EPA does not anticipate disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations from these alternative standards.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United

States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 257

Environmental protection, Waste treatment and disposal.

40 CFR Part 258

Environmental protection, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Incorporation by reference, Reporting and recordkeeping requirements.

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 263

Environmental protection, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Incorporation by reference, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 267

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

40 CFR Part 279

Environmental protection, Petroleum, Recycling, Reporting and recordkeeping requirements.

Dated: October 28, 2016.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 257—CRITERIA FOR CLASSIFICATION OF SOLID WASTE DISPOSAL FACILITIES AND PRACTICES

■ 1. The authority citation for part 257 continues to read as follows:

Authority: 42 U.S.C. 6907(a)(3), 6912(a)(1), 6944(a), and 6949a(c); 33 U.S.C. 1345(d) and (e).

■ 2. Section 257.1 is amended by revising paragraph (a) introductory text to read as follows:

§ 257.1 Scope and purpose.

(a) Unless otherwise provided, the criteria in §§ 257.1 through 257.4 are adopted for determining which solid waste disposal facilities and practices pose a reasonable probability of adverse effects on health or the environment under sections 1008(a)(3) and 4004(a) of the Resource Conservation and Recovery Act (The Act). Unless otherwise provided, the criteria in §§ 257.5 through 257.30 are adopted for purposes of ensuring that non-municipal non-hazardous waste disposal units that receive very small quantity generator (VSQG) waste do not present risks to human health and the environment taking into account the practicable capability of such units in accordance with section 4010(c) of the Act. Unless otherwise provided, the criteria in §§ 257.50 through 257.107 are adopted for determining which CCR landfills and CCR surface impoundments pose a reasonable probability of adverse effects on health or the environment under sections 1008(a)(3) and 4004(a) of the Act.

* * * * *

■ 3. Section 257.2 is amended by revising the definition for *Construction and demolition (C&D) landfill* to read as follows:

§ 257.2 Definitions.

* * * * *

Construction and demolition (C&D) landfill means a solid waste disposal facility subject to the requirements of subparts A or B of this part that receives construction and demolition waste and does not receive hazardous waste (defined in § 261.3 of this chapter) or industrial solid waste (defined in § 258.2 of this chapter). Only a C&D landfill that meets the requirements of subpart B of this part may receive very small quantity generator waste (defined in § 260.10 of this chapter). A C&D landfill typically receives any one or more of the following types of solid wastes: Roadwork material, excavated material, demolition waste, construction/renovation waste, and site clearance waste.

* * * * *

■ 4. Part 257 is amended by revising the heading for Subpart B to read as follows:

Subpart B—Disposal Standards for the Receipt of Very Small Quantity Generator (VSQG) Wastes at Non-Municipal Non-Hazardous Waste Disposal Units

■ 5. Section 257.5 is amended by revising its section heading; paragraph (a); and the paragraph (b) definitions of ''Existing unit'' and ''New unit'' to read as follows:

§ 257.5 Disposal standards for owners/operators of non-municipal non-hazardous waste disposal units that receive Very Small Quantity Generator (VSQG) waste.

(a) *Applicability.* (1) The requirements in this section apply to owners/operators of any non-municipal non-hazardous waste disposal unit that receives VSQG hazardous waste, as defined in 40 CFR 260.10. Non-

municipal non-hazardous waste disposal units that meet the requirements of this section may receive VSQG wastes. Any owner/operator of a non-municipal non-hazardous waste disposal unit that receives VSQG hazardous waste continues to be subject to the requirements in §§ 257.3–2, 257.3–3, 257.3–5, 257.3–6, 257.3–7, and 257.3–8(a), (b), and (d).

(2) Any non-municipal non-hazardous waste disposal unit that is receiving VSQG hazardous waste as of January 1, 1998, must be in compliance with the requirements in §§ 257.7 through 257.13 and § 257.30 by January 1, 1998, and the requirements in §§ 257.21 through 257.28 by July 1, 1998.

(3) Any non-municipal non-hazardous waste disposal unit that does not meet the requirements in this section may not receive VSQG wastes.

(4) Any non-municipal non-hazardous waste disposal unit that is not receiving VSQG Hazardous waste as of January 1, 1998, continues to be subject to the requirements in §§ 257.1 through 257.4.

(5) Any non-municipal non-hazardous waste disposal unit that first receives VSQG hazardous waste after January 1, 1998, must be in compliance with §§ 257.7 through 257.30 prior to the receipt of VSQG hazardous waste.

(b) * * *

Existing unit means any non-municipal non-hazardous waste disposal unit that is receiving VSQG hazardous waste as of January 1, 1998.

* * * * *

New unit means any non-municipal non-hazardous waste disposal unit that has not received VSQG hazardous waste prior to January 1, 1998.

* * * * *

§ 257.13 [Amended]

■ 6. Amend § 257.13 by removing the text ''CESQG'' and adding the text ''VSQG'' in its place.

■ 7. Section 257.21 is amended by revising paragraph (h) introductory text to read as follows:

§ 257.21 Applicability.

* * * * *

(h) Directors of approved States can use the flexibility in paragraph (i) of this section for any non-municipal non-hazardous waste disposal unit that receives VSQG waste, if the non-municipal non-hazardous waste disposal unit:

* * * * *

PART 258—CRITERIA FOR MUNICIPAL SOLID WASTE LANDFILLS

■ 8. The authority citation for part 258 continues to read as follows:

Authority: 33 U.S.C. 1345(d) and (e); 42 U.S.C. 6902(a), 6907, 6912(a), 6944, 6945(c) and 6949a(c), 6981(a).

■ 9. Section 258.2 is amended by revising the definitions for ''Construction and demolition (C&D) landfill'' and ''Municipal solid waste landfill (MSWLF)'' to read as follows:

§ 258.2 Definitions.

* * * * *

Construction and demolition (C&D) landfill means a solid waste disposal facility subject to the requirements in part 257, subparts A or B of this chapter that receives construction and demolition waste and does not receive hazardous waste (defined in § 261.3 of this chapter) or industrial solid waste (defined in this section). Only a C&D landfill that meets the requirements of 40 CFR part 257, subpart B may receive very small quantity generator waste (defined in § 260.10 of this chapter). A C&D landfill typically receives any one or more of the following types of solid wastes: Roadwork material, excavated material, demolition waste, construction/renovation waste, and site clearance waste.

* * * * *

Municipal solid waste landfill (MSWLF) unit means a discrete area of land or an excavation that receives household waste, and that is not a land application unit, surface impoundment, injection well, or waste pile, as those terms are defined under § 257.2 of this chapter. A MSWLF unit also may receive other types of RCRA Subtitle D wastes, such as commercial solid waste, nonhazardous sludge, very small quantity generator waste and industrial solid waste. Such a landfill may be publicly or privately owned. A MSWLF unit may be a new MSWLF unit, an existing MSWLF unit or a lateral expansion. A construction and demolition landfill that receives residential lead-based paint waste and does not receive any other household waste is not a MSWLF unit.

* * * * *

■ 10. Section 258.20 is amended by revising paragraph (b) to read as follows:

§ 258.20 Procedures for excluding the receipt of hazardous waste.

* * * * *

(b) For purposes of this section, *regulated hazardous waste* means a solid waste that is a hazardous waste, as defined in 40 CFR 261.3, that is not excluded from regulation as a hazardous waste under 40 CFR 261.4(b) or was not generated by a very small quantity generator as defined in § 260.10 of this chapter.

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 11. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

■ 12. Section 260.3 is amended by revising the introductory text to read as follows:

§ 260.3 Use of number and gender.

As used in parts 260 through 273 of this chapter:

* * * * *

■ 13. Amend § 260.10 by:

■ a. Adding in alphabetical order the definitions of ''Acute hazardous waste'', ''Central accumulation area'', ''Large quantity generator'', and ''Non-acute hazardous waste'';

■ b. Removing the definition for ''Performance Track member facility'';

■ c. Revising the definition of ''Small quantity generator'';

■ d. Revising the heading of the definition ''Treatability Study'' to read ''Treatability study'';

■ e. Revising the heading of the definition ''Universal Waste Handler'' to read ''Universal waste handler'';

■ f. Revising the heading of the definition ''Universal Waste Transporter'' to read ''Universal waste transporter''; and

■ g. Adding in alphabetical order the definition of ''Very small quantity generator''.

The revisions and additions read as follows:

§ 260.10 Definitions.

* * * * *

Acute hazardous waste means hazardous wastes that meet the listing criteria in § 261.11(a)(2) and therefore are either listed in § 261.31 of this chapter with the assigned hazard code of (H) or are listed in § 261.33(e) of this chapter.

* * * * *

Central accumulation area means any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either § 262.16 (for small quantity generators) or § 262.17 of this chapter (for large quantity generators). A central accumulation area at an eligible academic entity that chooses to operate under 40 CFR part 262 subpart K is also subject to § 262.211 when accumulating unwanted material and/or hazardous waste.

* * * * *

Large quantity generator is a generator who generates any of the following amounts in a calendar month:

(1) Greater than or equal to 1,000 kilograms (2200 lbs) of non-acute hazardous waste; or

(2) Greater than 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter; or

(3) Greater than 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter.

* * * * *

Non-acute hazardous waste means all hazardous wastes that are not acute hazardous waste, as defined in this section.

* * * * *

Small quantity generator is a generator who generates the following amounts in a calendar month:

(1) Greater than 100 kilograms (220 lbs) but less than 1,000 kilograms (2200 lbs) of non-acute hazardous waste; and

(2) Less than or equal to 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter; and

(3) Less than or equal to 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter.

* * * * *

Very small quantity generator is a generator who generates less than or equal to the following amounts in a calendar month:

(1) 100 kilograms (220 lbs) of non-acute hazardous waste; and

(2) 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter; and

(3) 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter.

* * * * *

■ 14. Section 260.11 is amended by revising the section heading and paragraph (d)(1) to read as follows:

§ 260.11 Incorporation by reference.

* * * * *

(d) * * *

(1) ''Flammable and Combustible Liquids Code'' (NFPA 30), 1977 or 1981, IBR approved for §§ 262.16(b), 264.198(b), 265.198(b), 267.202(b).

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 15. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

■ 16. Section 261.1 is amended by revising paragraphs (a)(1) and (c)(6) to read as follows:

§ 261.1 Purpose and scope.

(a) * * *

(1) Subpart A defines the terms ''solid waste'' and ''hazardous waste'', identifies those wastes which are excluded from regulation under parts 262 through 266, 268 and 270 of this chapter and establishes special management requirements for hazardous waste produced by very small quantity generators and hazardous waste which is recycled.

* * * * *

(c) * * *

(6) ''Scrap metal'' is bits and pieces of metal parts (*e.g.,* bars, turnings, rods, sheets, wire) or metal pieces that may be combined together with bolts or soldering (*e.g.,* radiators, scrap automobiles, railroad box cars), which when worn or superfluous can be recycled.

* * * * *

■ 17. Section 261.4 is amended by revising paragraph (a)(7) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(7) Spent sulfuric acid used to produce virgin sulfuric acid provided it is not accumulated speculatively as defined in § 261.1(c) of this chapter.

* * * * *

§ 261.5 [Removed and reserved]

■ 18. Remove and reserve § 261.5.

■ 19. Section 261.6 is amended by adding paragraph (c)(2)(iv) to read as follows:

§ 261.6 Requirements for recyclable materials.

* * * * *

(c) * * *

(2) * * *

(iv) Section 265.75 of this chapter (biennial reporting requirements).

* * * * *

■ 20. Section 261.33 is amended by revising paragraphs (e) introductory text and (f) introductory text to read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(e) The commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates referred to in paragraphs (a) through (d) of this section, are identified as acute hazardous wastes (H).

* * * * *

(f) The commercial chemical products, manufacturing chemical intermediates, or off-specification commercial chemical products referred to in paragraphs (a) through (d) of this section, are identified as toxic wastes (T) unless otherwise designated.

* * * * *

■ 21. Section 261.420 is amended by adding paragraph (g) to read as follows:

§ 261.420 Contingency planning and emergency procedures for facilities generating or accumulating more than 6000 kg of hazardous secondary material.

* * * * *

(g) *Personnel training.* All employees must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 22. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

Subpart A—General

■ 23. Section 262.1 is added to subpart A to read as follows:

§ 262.1 Terms used in this part.

As used in this part:

Condition for exemption means any requirement in §§ 262.14, 262.15, 262.16, 262.17, 262.70, or subpart K or subpart L of this part that states an event, action, or standard that must occur or be met in order to obtain an exemption from any applicable requirement in parts 124, 264 through 268, and 270 of this chapter, or from any requirement for notification under section 3010 of RCRA.

Independent requirement means a requirement of part 262 that states an event, action, or standard that must occur or be met; and that applies without relation to, or irrespective of, the purpose of obtaining a conditional

exemption from storage facility permit, interim status, and operating requirements under §§ 262.14, 262.15, 262.16, 262.17, or subpart K or subpart L of this part.

■ 24. Section 262.10 is amended by:

■ a. Revising paragraphs (a) and (b);

■ b. Removing and reserving paragraph (c);

■ c. Revising paragraph (d);

■ d. Revising paragraph (g);

■ e. Removing and reserving paragraph (j); and

■ f. Revising paragraph (l).

The revisions read as follows:

§ 262.10 Purpose, scope, and applicability.

(a) The regulations in this part establish standards for generators of hazardous waste as defined by 40 CFR 260.10.

(1) A person who generates a hazardous waste as defined by 40 CFR part 261 is subject to all the applicable independent requirements in the subparts and sections listed below:

(i) *Independent requirements of a very small quantity generator.* (A) Section 262.11(a) through (d) Hazardous waste determination and recordkeeping; and

(B) Section 262.13 Generator category determination.

(ii) *Independent requirements of a small quantity generator.* (A) Section 262.11 Hazardous waste determination and recordkeeping;

(B) Section 262.13 Generator category determination;

(C) Section 262.18 EPA identification numbers and re-notification for small quantity generators and large quantity generators;

(D) Part 262 subpart B—Manifest requirements applicable to small and large quantity generators;

(E) Part 262 subpart C—Pre-transport requirements applicable to small and large quantity generators;

(F) Section 262.40 Recordkeeping;

(G) Section 262.44 Recordkeeping for small quantity generators; and

(H) Part 262 subpart H—Transboundary movements of hazardous waste for recovery or disposal.

(iii) *Independent requirements of a large quantity generator.* (A) Section 262.11 Hazardous waste determination and recordkeeping;

(B) Section 262.13 Generator category determination;

(C) Section 262.18 EPA identification numbers and re-notification for small quantity generators and large quantity generators;

(D) Part 262 subpart B—Manifest requirements applicable to small and large quantity generators;

(E) Part 262 subpart C—Pre-transport requirements applicable to small and large quantity generators;

(F) Part 262 subpart D—Recordkeeping and reporting applicable to small and large quantity generators, except § 262.44; and

(G) Part 262 subpart H—Transboundary movements of hazardous waste for recovery or disposal.

(2) A generator that accumulates hazardous waste on site is a person that stores hazardous waste; such generator is subject to the applicable requirements of parts 124, 264 through 267, and 270 of this chapter and section 3010 of RCRA, unless it is one of the following:

(i) A very small quantity generator that meets the conditions for exemption in § 262.14;

(ii) A small quantity generator that meets the conditions for exemption in §§ 262.15 and 262.16; or

(iii) A large quantity generator that meets the conditions for exemption in §§ 262.15 and 262.17.

(3) A generator shall not transport, offer its hazardous waste for transport, or otherwise cause its hazardous waste to be sent to a facility that is not a designated facility, as defined in § 260.10 of this chapter, or not otherwise authorized to receive the generator's hazardous waste.

(b) *Determining generator category.* A generator must use § 262.13 to determine which provisions of this part are applicable to the generator based on the quantity of hazardous waste generated per calendar month.

* * * * *

(d) Any person who exports or imports hazardous wastes must comply with § 262.18 and subpart H of this part.

* * * * *

(g)(1) A generator's violation of an independent requirement is subject to penalty and injunctive relief under section 3008 of RCRA.

(2) A generator's noncompliance with a condition for exemption in this part is not subject to penalty or injunctive relief under section 3008 of RCRA as a violation of a 40 CFR part 262 condition for exemption. Noncompliance by any generator with an applicable condition for exemption from storage permit and operations requirements means that the facility is a storage facility operating without an exemption from the permit, interim status, and operations requirements in 40 CFR parts 124, 264 through 267, and 270 of this chapter, and the notification requirements of section 3010 of RCRA. Without an exemption, any violations of such storage requirements are subject to penalty and injunctive relief under section 3008 of RCRA.

* * * * *

(l) The laboratories owned by an eligible academic entity that chooses to be subject to the requirements of subpart K of this part are not subject to (for purposes of this paragraph, the terms ''laboratory'' and ''eligible academic entity'' shall have the meaning as defined in § 262.200):

(1) The independent requirements of § 262.11 or the regulations in § 262.15 for large quantity generators and small quantity generators, except as provided in subpart K, and

(2) The conditions of § 262.14, for very small quantity generators, except as provided in subpart K.

* * * * *

■ 25. Revise § 262.11 to read as follows:

§ 262.11 Hazardous waste determination and recordkeeping.

A person who generates a solid waste, as defined in 40 CFR 261.2, must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to applicable RCRA regulations. A hazardous waste determination is made using the following steps:

(a) The hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste such that the RCRA classification of the waste may change.

(b) A person must determine whether the solid waste is excluded from regulation under 40 CFR 261.4.

(c) If the waste is not excluded under 40 CFR 261.4, the person must then use knowledge of the waste to determine whether the waste meets any of the listing descriptions under subpart D of 40 CFR part 261. Acceptable knowledge that may be used in making an accurate determination as to whether the waste is listed may include waste origin, composition, the process producing the waste, feedstock, and other reliable and relevant information. If the waste is listed, the person may file a delisting petition under 40 CFR 260.20 and 260.22 to demonstrate to the Administrator that the waste from this particular site or operation is not a hazardous waste.

(d) The person then must also determine whether the waste exhibits one or more hazardous characteristics as

identified in subpart C of 40 CFR part 261 by following the procedures in paragraph (d)(1) or (2) of this section, or a combination of both.

(1) The person must apply knowledge of the hazard characteristic of the waste in light of the materials or the processes used to generate the waste. Acceptable knowledge may include process knowledge (*e.g.,* information about chemical feedstocks and other inputs to the production process); knowledge of products, by-products, and intermediates produced by the manufacturing process; chemical or physical characterization of wastes; information on the chemical and physical properties of the chemicals used or produced by the process or otherwise contained in the waste; testing that illustrates the properties of the waste; or other reliable and relevant information about the properties of the waste or its constituents. A test other than a test method set forth in subpart C of 40 CFR part 261, or an equivalent test method approved by the Administrator under 40 CFR 260.21, may be used as part of a person's knowledge to determine whether a solid waste exhibits a characteristic of hazardous waste. However, such tests do not, by themselves, provide definitive results. Persons testing their waste must obtain a representative sample of the waste for the testing, as defined at 40 CFR 260.10.

(2) When available knowledge is inadequate to make an accurate determination, the person must test the waste according to the applicable methods set forth in subpart C of 40 CFR part 261 or according to an equivalent method approved by the Administrator under 40 CFR 260.21 and in accordance with the following:

(i) Persons testing their waste must obtain a representative sample of the waste for the testing, as defined at 40 CFR 260.10.

(ii) Where a test method is specified in subpart C of 40 CFR part 261, the results of the regulatory test, when properly performed, are definitive for determining the regulatory status of the waste.

(e) If the waste is determined to be hazardous, the generator must refer to parts 261, 264, 265, 266, 267, 268, and 273 of this chapter for other possible exclusions or restrictions pertaining to management of the specific waste.

(f) *Recordkeeping for small and large quantity generators.* A small or large quantity generator must maintain records supporting its hazardous waste determinations, including records that identify whether a solid waste is a hazardous waste, as defined by 40 CFR 261.3. Records must be maintained for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. These records must comprise the generator's knowledge of the waste and support the generator's determination, as described at paragraphs (c) and (d) of this section. The records must include, but are not limited to, the following types of information: The results of any tests, sampling, waste analyses, or other determinations made in accordance with this section; records documenting the tests, sampling, and analytical methods used to demonstrate the validity and relevance of such tests; records consulted in order to determine the process by which the waste was generated, the composition of the waste, and the properties of the waste; and records which explain the knowledge basis for the generator's determination, as described at paragraph (d)(1) of this section. The periods of record retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

(g) *Identifying hazardous waste numbers for small and large quantity generators.* If the waste is determined to be hazardous, small quantity generators and large quantity generators must identify all applicable EPA hazardous waste numbers (EPA hazardous waste codes) in subparts C and D of part 261 of this chapter. Prior to shipping the waste off site, the generator also must mark its containers with all applicable EPA hazardous waste numbers (EPA hazardous waste codes) according to § 262.32.

§ 262.12 [Removed and reserved]

■ 26. Remove and reserve § 262.12.

■ 27. Subpart A of part 262 is amended by adding §§ 262.13 through 262.18 to read as follows:

Subpart A—General

* * * * *

Sec.

* * * * *

§ 262.13 Generator category determination.

A generator must determine its generator category. A generator's category is based on the amount of hazardous waste generated each month and may change from month to month. This section sets forth procedures to determine whether a generator is a very small quantity generator, a small quantity generator, or a large quantity generator for a particular month, as defined in § 260.10 of this chapter.

(a) *Generators of either acute hazardous waste or non-acute hazardous waste.* A generator who either generates acute hazardous waste or non-acute hazardous waste in a calendar month shall determine its generator category for that month by doing the following:

(1) Counting the total amount of hazardous waste generated in the calendar month;

(2) Subtracting from the total any amounts of waste exempt from counting as described in paragraphs (c) and (d) of this section; and

(3) Determining the resulting generator category for the hazardous waste generated using Table 1 of this section.

(b) *Generators of both acute and non-acute hazardous wastes.* A generator who generates both acute hazardous waste and non-acute hazardous waste in the same calendar month shall determine its generator category for that month by doing the following:

(1) Counting separately the total amount of acute hazardous waste and the total amount of non-acute hazardous waste generated in the calendar month;

(2) Subtracting from each total any amounts of waste exempt from counting as described in paragraphs (c) and (d) of this section;

(3) Determining separately the resulting generator categories for the quantities of acute and non-acute hazardous waste generated using Table 1 of this section; and

(4) Comparing the resulting generator categories from paragraph (b)(3) of this section and applying the more stringent generator category to the accumulation and management of both non-acute hazardous waste and acute hazardous waste generated for that month.

TABLE 1 TO § 262.13—GENERATOR CATEGORIES BASED ON QUANTITY OF WASTE GENERATED IN A CALENDAR MONTH

Quantity of acute hazardous waste generated in a calendar month	Quantity of non-acute hazardous waste generated in a calendar month	Quantity of residues from a clean-up of acute hazardous waste generated in a calendar month	Generator category
> 1 kg	Any amount	Any amount	Large quantity generator.
Any amount	≥ 1,000 kg	Any amount	Large quantity generator.
Any amount	Any amount	> 100 kg	Large quantity generator.
≤ 1 kg	> 100 kg and < 1,000 kg	≤ 100 kg	Small quantity generator.
≤ 1 kg	≤ 100 kg	≤ 100 kg	Very small quantity generator.

(c) When making the monthly quantity-based determinations required by this part, the generator must include all hazardous waste that it generates, except hazardous waste that:

(1) Is exempt from regulation under 40 CFR 261.4(c) through (f), 261.6(a)(3), 261.7(a)(1), or 261.8;

(2) Is managed immediately upon generation only in on-site elementary neutralization units, wastewater treatment units, or totally enclosed treatment facilities as defined in 40 CFR 260.10;

(3) Is recycled, without prior storage or accumulation, only in an on-site process subject to regulation under 40 CFR 261.6(c)(2);

(4) Is used oil managed under the requirements of 40 CFR 261.6(a)(4) and 40 CFR part 279;

(5) Is spent lead-acid batteries managed under the requirements of 40 CFR part 266 subpart G;

(6) Is universal waste managed under 40 CFR 261.9 and 40 CFR part 273;

(7) Is a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261 subpart D or exhibiting one or more characteristics in 40 CFR part 261 subpart C) that is generated solely as a result of a laboratory clean-out conducted at an eligible academic entity pursuant to § 262.213. For purposes of this provision, the term eligible academic entity shall have the meaning as defined in § 262.200; or

(8) Is managed as part of an episodic event in compliance with the conditions of subpart L of this part.

(d) In determining the quantity of hazardous waste generated in a calendar month, a generator need not include:

(1) Hazardous waste when it is removed from on-site accumulation, so long as the hazardous waste was previously counted once;

(2) Hazardous waste generated by on-site treatment (including reclamation) of the generator's hazardous waste, so long as the hazardous waste that is treated was previously counted once; and

(3) Hazardous waste spent materials that are generated, reclaimed, and subsequently reused on site, so long as such spent materials have been previously counted once.

(e) Based on the generator category as determined under this section, the generator must meet the applicable independent requirements listed in § 262.10. A generator's category also determines which of the provisions of §§ 262.14, 262.15, 262.16 or 262.17 must be met to obtain an exemption from the storage facility permit, interim status, and operating requirements when accumulating hazardous waste.

(f) *Mixing hazardous wastes with solid wastes*—(1) *Very small quantity generator wastes.* (i) Hazardous wastes generated by a very small quantity generator may be mixed with solid wastes. Very small quantity generators may mix a portion or all of its hazardous waste with solid waste and remain subject to § 262.14 even though the resultant mixture exceeds the quantity limits identified in the definition of very small quantity generator at § 260.10 of this chapter, unless the mixture exhibits one or more of the characteristics of hazardous waste identified in part 261 subpart C of this chapter.

(ii) If the resulting mixture exhibits a characteristic of hazardous waste, this resultant mixture is a newly-generated hazardous waste. The very small quantity generator must count both the resultant mixture amount plus the other hazardous waste generated in the calendar month to determine whether the total quantity exceeds the very small quantity generator calendar month quantity limits identified in the definition of generator categories found in § 260.10 of this chapter. If so, to remain exempt from the permitting, interim status, and operating standards, the very small quantity generator must meet the conditions for exemption applicable to either a small quantity generator or a large quantity generator. The very small quantity generator must also comply with the applicable independent requirements for either a small quantity generator or a large quantity generator.

(iii) If a very small quantity generator's wastes are mixed with used oil, the mixture is subject to 40 CFR part 279. Any material produced from such a mixture by processing, blending, or other treatment is also regulated under 40 CFR part 279.

(2) *Small quantity generator and large quantity generator wastes.* (i) Hazardous wastes generated by a small quantity generator or large quantity generator may be mixed with solid waste. These mixtures are subject to the following: the mixture rule in §§ 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i); the prohibition of dilution rule at § 268.3(a); the land disposal restriction requirements of § 268.40 if a characteristic hazardous waste is mixed with a solid waste so that it no longer exhibits the hazardous characteristic; and the hazardous waste determination requirement at § 262.11.

(ii) If the resulting mixture is found to be a hazardous waste, this resultant mixture is a newly-generated hazardous waste. A small quantity generator must count both the resultant mixture amount plus the other hazardous waste generated in the calendar month to determine whether the total quantity exceeds the small quantity generator calendar monthly quantity limits identified in the definition of generator categories found in § 260.10 of this chapter. If so, to remain exempt from the permitting, interim status, and operating standards, the small quantity generator must meet the conditions for exemption applicable to a large quantity generator. The small quantity generator must also comply with the applicable independent requirements for a large quantity generator.

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) Provided that the very small quantity generator meets all the conditions for exemption listed in this section, hazardous waste generated by the very small quantity generator is not subject to the requirements of parts 124, 262 (except §§ 262.10–262.14) through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA and the very small quantity generator may accumulate hazardous waste on site without

complying with such requirements. The conditions for exemption are as follows:

(1) In a calendar month the very small quantity generator generates less than or equal to the amounts specified in the definition of ''very small quantity generator'' in § 260.10 of this chapter;

(2) The very small quantity generator complies with § 262.11(a) through (d);

(3) If the very small quantity generator accumulates at any time greater than 1 kilogram (2.2 lbs) of acute hazardous waste or 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in §§ 261.31 or 261.33(e) of this chapter, all quantities of that acute hazardous waste are subject to the following additional conditions for exemption:

(i) Such waste is held on site for no more than 90 days beginning on the date when the accumulated wastes exceed the amounts provided above; and

(ii) The conditions for exemption in § 262.17(a) through (g).

(4) If the very small quantity generator accumulates at any time 1,000 kilograms (2,200 lbs) or greater of non-acute hazardous waste, all quantities of that hazardous waste are subject to the following additional conditions for exemption:

(i) Such waste is held on site for no more than 180 days, or 270 days, if applicable, beginning on the date when the accumulated waste exceed the amounts provided above;

(ii) The quantity of waste accumulated on site never exceeds 6,000 kilograms (13,200 lbs); and

(iii) The conditions for exemption in § 262.16(b)(2) through (f).

(5) A very small quantity generator that accumulates hazardous waste in amounts less than or equal to the limits in paragraphs (a)(3) and (4) of this section must either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under part 270 of this chapter;

(ii) In interim status under parts 265 and 270 of this chapter;

(iii) Authorized to manage hazardous waste by a state with a hazardous waste management program approved under part 271 of this chapter;

(iv) Permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill is subject to part 258 of this chapter;

(v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit, is subject to the requirements in §§ 257.5 through 257.30 of this chapter;

(vi) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;

(vii) For universal waste managed under part 273 of this chapter, a universal waste handler or destination facility subject to the requirements of part 273 of this chapter;

(viii) A large quantity generator under the control of the same person as the very small quantity generator, provided the following conditions are met:

(A) The very small quantity generator and the large quantity generator are under the control of the same person as defined in § 260.10 of this chapter. ''Control,'' for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to ''control'' such generators.

(B) The very small quantity generator marks its container(s) of hazardous waste with:

(*1*) The words ''Hazardous Waste'' and

(*2*) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

(b) The placement of bulk or non-containerized liquid hazardous waste or hazardous waste containing free liquids (whether or not sorbents have been added) in any landfill is prohibited.

(c) A very small quantity generator experiencing an episodic event may generate and accumulate hazardous waste in accordance with subpart L of this part in lieu of §§ 262.15, 262.16, and 262.17.

§ 262.15 Satellite accumulation area regulations for small and large quantity generators.

(a) A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or either one quart of liquid acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter or 1 kg (2.2 lbs) of solid acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste, without a permit or interim status and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, provided that all of the conditions for exemption in this section are met. A generator may comply with the conditions for exemption in this section instead of complying with the conditions for exemption in § 262.16(b) or § 262.17(a), except as required in § 262.15(a)(7) and (8). The conditions for exemption for satellite accumulation are:

(1) If a container holding hazardous waste is not in good condition, or if it begins to leak, the generator must immediately transfer the hazardous waste from this container to a container that is in good condition and does not leak, or immediately transfer and manage the waste in a central accumulation area operated in compliance with § 262.16(b) or § 262.17(a).

(2) The generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be accumulated, so that the ability of the container to contain the waste is not impaired.

(3) Special standards for incompatible wastes.

(i) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(ii) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(iii) A container holding a hazardous waste that is incompatible with any waste or other materials accumulated nearby in other containers must be separated from the other materials or protected from them by any practical means.

(4) A container holding hazardous waste must be closed at all times during accumulation, except:

(i) When adding, removing, or consolidating waste; or

(ii) When temporary venting of a container is necessary

(A) For the proper operation of equipment, or

(B) To prevent dangerous situations, such as build-up of extreme pressure.

(5) A generator must mark or label its container with the following:

(i) The words ''Hazardous Waste'' and

(ii) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

(6) A generator who accumulates either acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter or non-acute hazardous waste in excess of the amounts listed in paragraph (a) of this section at or near any point of generation must do the following:

(i) Comply within three consecutive calendar days with the applicable central accumulation area regulations in § 262.16(b) or § 262.17(a), or

(ii) Remove the excess from the satellite accumulation area within three consecutive calendar days to either:

(A) A central accumulation area operated in accordance with the applicable regulations in § 262.16(b) or § 262.17(a);

(B) An on-site interim status or permitted treatment, storage, or disposal facility, or

(C) An off-site designated facility; and

(iii) During the three-consecutive-calendar-day period the generator must continue to comply with paragraphs (a)(1) through (5) of this section. The generator must mark or label the container(s) holding the excess accumulation of hazardous waste with the date the excess amount began accumulating.

(7) All satellite accumulation areas operated by a small quantity generator must meet the preparedness and prevention regulations of § 262.16(b)(8) and emergency procedures at § 262.16(b)(9).

(8) All satellite accumulation areas operated by a large quantity generator must meet the Preparedness, Prevention and Emergency Procedures in subpart M of this part.

(b) [Reserved]

§ 262.16 Conditions for exemption for a small quantity generator that accumulates hazardous waste.

A small quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA, provided that all the conditions for exemption listed in this section are met:

(a) *Generation.* The generator generates in a calendar month no more than the amounts specified in the definition of ''small quantity generator'' in § 260.10 of this chapter.

(b) *Accumulation.* The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (d) and (e) of this section. The following accumulation conditions also apply:

(1) *Accumulation limit.* The quantity of hazardous waste accumulated on site never exceeds 6,000 kilograms (13,200 pounds);

(2) *Accumulation of hazardous waste in containers*—(i) *Condition of containers.* If a container holding hazardous waste is not in good condition, or if it begins to leak, the small quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of this section.

(ii) *Compatibility of waste with container.* The small quantity generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be accumulated, so that the ability of the container to contain the waste is not impaired.

(iii) *Management of containers.* (A) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste.

(B) A container holding hazardous waste must not be opened, handled, or accumulated in a manner that may rupture the container or cause it to leak.

(iv) *Inspections.* At least weekly, the small quantity generator must inspect central accumulation areas. The small quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (b)(2)(i) of this section for remedial action required if deterioration or leaks are detected.

(v) *Special conditions for accumulation of incompatible wastes.* (A) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(B) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(C) A container accumulating hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(3) *Accumulation of hazardous waste in tanks.*

(i) [Reserved]

(ii) A small quantity generator of hazardous waste must comply with the following general operating conditions:

(A) Treatment or accumulation of hazardous waste in tanks must comply with § 265.17(b) of this chapter.

(B) Hazardous wastes or treatment reagents must not be placed in a tank if they could cause the tank or its inner liner to rupture, leak, corrode, or otherwise fail before the end of its intended life.

(C) Uncovered tanks must be operated to ensure at least 60 centimeters (2 feet) of freeboard, unless the tank is equipped with a containment structure (*e.g.,* dike or trench), a drainage control system, or a diversion structure (*e.g.,* standby tank) with a capacity that equals or exceeds the volume of the top 60 centimeters (2 feet) of the tank.

(D) Where hazardous waste is continuously fed into a tank, the tank must be equipped with a means to stop this inflow (*e.g.,* waste feed cutoff system or by-pass system to a stand-by tank).

(iii) Except as noted in paragraph (b)(3)(iv) of this section, a small quantity generator that accumulates hazardous waste in tanks must inspect, where present:

(A) Discharge control equipment (*e.g.,* waste feed cutoff systems, by-pass systems, and drainage systems) at least once each operating day, to ensure that it is in good working order;

(B) Data gathered from monitoring equipment (*e.g.,* pressure and

temperature gauges) at least once each operating day to ensure that the tank is being operated according to its design;

(C) The level of waste in the tank at least once each operating day to ensure compliance with paragraph (b)(3)(ii)(C) of this section;

(D) The construction materials of the tank at least weekly to detect corrosion or leaking of fixtures or seams; and

(E) The construction materials of, and the area immediately surrounding, discharge confinement structures (*e.g.,* dikes) at least weekly to detect erosion or obvious signs of leakage (*e.g.,* wet spots or dead vegetation). The generator must remedy any deterioration or malfunction of equipment or structures which the inspection reveals on a schedule which ensures that the problem does not lead to an environmental or human health hazard. Where a hazard is imminent or has already occurred, remedial action must be taken immediately.

(iv) A small quantity generator accumulating hazardous waste in tanks or tank systems that have full secondary containment and that either use leak detection equipment to alert personnel to leaks, or implement established workplace practices to ensure leaks are promptly identified, must inspect at least weekly, where applicable, the areas identified in paragraphs (b)(3)(iii)(A) through (E) of this section. Use of the alternate inspection schedule must be documented in the generator's operating record. This documentation must include a description of the established workplace practices at the generator.

(v) [Reserved]

(vi) A small quantity generator accumulating hazardous waste in tanks must, upon closure of the facility, remove all hazardous waste from tanks, discharge control equipment, and discharge confinement structures. At closure, as throughout the operating period, unless the small quantity generator can demonstrate, in accordance with § 261.3(c) or (d) of this chapter, that any solid waste removed from its tank is not a hazardous waste, then it must manage such waste in accordance with all applicable provisions of parts 262, 263, 265 and 268 of this chapter.

(vii) A small quantity generator must comply with the following special conditions for accumulation of ignitable or reactive waste:

(A) Ignitable or reactive waste must not be placed in a tank, unless:

(*1*) The waste is treated, rendered, or mixed before or immediately after placement in a tank so that the resulting waste, mixture, or dissolution of material no longer meets the definition of ignitable or reactive waste under § 261.21 or § 261.23 of this chapter and § 265.17(b) of this chapter is complied with; or

(*2*) The waste is accumulated or treated in such a way that it is protected from any material or conditions that may cause the waste to ignite or react; or

(*3*) The tank is used solely for emergencies.

(B) A small quantity generator which treats or accumulates ignitable or reactive waste in covered tanks must comply with the buffer zone requirements for tanks contained in Tables 2–1 through 2–6 of the National Fire Protection Association's ''Flammable and Combustible Liquids Code'' (1977 or 1981) (incorporated by reference, see § 260.11).

(C) A small quantity generator must comply with the following special conditions for incompatible wastes:

(*1*) Incompatible wastes, or incompatible wastes and materials, (see part 265 appendix V for examples) must not be placed in the same tank, unless § 265.17(b) of this chapter is complied with.

(*2*) Hazardous waste must not be placed in an unwashed tank that previously held an incompatible waste or material, unless § 265.17(b) of this chapter is complied with.

(4) *Accumulation of hazardous waste on drip pads.* If the waste is placed on drip pads, the small quantity generator must comply with the following:

(i) Subpart W of 40 CFR part 265 (except § 265.445 (c));

(ii) The small quantity generator must remove all wastes from the drip pad at least once every 90 days. Any hazardous wastes that are removed from the drip pad at least once every 90 days are then subject to the 180-day accumulation limit in paragraph (b) of this section and § 262.15 if hazardous wastes are being managed in satellite accumulation areas prior to being moved to the central accumulation area; and

(iii) The small quantity generator must maintain on site at the facility the following records readily available for inspection:

(A) A written description of procedures that are followed to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and

(B) Documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.

(5) *Accumulation of hazardous waste in containment buildings.* If the waste is placed in containment buildings, the small quantity generator must comply with of 40 CFR part 265 subpart DD. The generator must label its containment buildings with the words ''Hazardous Waste'' in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, or other persons on site and also in a conspicuous place provide an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).The generator must also maintain:

(i) The professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101. This certification must be in the generator's files prior to operation of the unit; and

(ii) The following records by use of inventory logs, monitoring equipment, or any other effective means:

(A) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the facility showing that the generator is consistent with maintaining the 90 day limit, and documentation that the procedures are complied with; or

(B) Documentation that the unit is emptied at least once every 90 days.

(C) Inventory logs or records with the above information must be maintained on site and readily available for inspection.

(6) *Labeling and marking of containers and tanks—.* (i) *Containers.* A small quantity generator must mark or label its containers with the following:

(A) The words ''Hazardous Waste'';

(B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard

Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and

(C) The date upon which each period of accumulation begins clearly visible for inspection on each container.

(ii) *Tanks.* A small quantity generator accumulating hazardous waste in tanks must do the following:

(A) Mark or label its tanks with the words ''Hazardous Waste'';

(B) Mark or label its tanks with an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(C) Use inventory logs, monitoring equipment, or other records to demonstrate that hazardous waste has been emptied within 180 days of first entering the tank if using a batch process, or in the case of a tank with a continuous flow process, demonstrate that estimated volumes of hazardous waste entering the tank daily exit the tank within 180 days of first entering; and

(D) Keep inventory logs or records with the above information on site and readily available for inspection.

(7) *Land disposal restrictions.* A small quantity generator must comply with all the applicable requirements under 40 CFR part 268.

(8) *Preparedness and prevention*—(i) *Maintenance and operation of facility.* A small quantity generator must maintain and operate its facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

(ii) *Required equipment.* All areas where hazardous waste is either generated or accumulated must be equipped with the items in paragraphs (b)(8)(ii)(A) through (D) of this section (*unless* none of the hazards posed by waste handled at the facility could require a particular kind of equipment specified below or the actual waste generation or accumulation area does not lend itself for safety reasons to have a particular kind of equipment specified below). A small quantity generator may determine the most appropriate locations to locate equipment necessary to prepare for and respond to emergencies.

(A) An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to facility personnel;

(B) A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or State or local emergency response teams;

(C) Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment, and decontamination equipment; and

(D) Water at adequate volume and pressure to supply water hose streams, or foam producing equipment, or automatic sprinklers, or water spray systems.

(iii) *Testing and maintenance of equipment.* All communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment, where required, must be tested and maintained as necessary to assure its proper operation in time of emergency.

(iv) *Access to communications or alarm system.* (A) Whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access (*e.g.,* direct or unimpeded access) to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, *unless* such a device is not required under paragraph (a)(8)(ii) of this section.

(B) In the event there is just one employee on the premises while the facility is operating, the employee must have immediate access (*e.g.,* direct or unimpeded access) to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, *unless* such a device is not required under paragraph (a)(8)(ii) of this section.

(v) *Required aisle space.* The small quantity generator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

(vi) *Arrangements with local authorities.* (A) The small quantity generator must attempt to make arrangements with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals, taking into account the types and quantities of hazardous wastes handled at the facility. Arrangements may be made with the Local Emergency Planning Committee, if it is determined to be the appropriate organization with which to make arrangements.

(*1*) A small quantity generator attempting to make arrangements with its local fire department must determine the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals.

(*2*) As part of this coordination, the small quantity generator shall attempt to make arrangements, as necessary, to familiarize the above organizations with the layout of the facility, the properties of hazardous waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes as well as the types of injuries or illnesses that could result from fires, explosions, or releases at the facility.

(*3*) Where more than one police or fire department might respond to an emergency, the small quantity generator shall attempt to make arrangements designating primary emergency authority to a specific fire or police department, and arrangements with any others to provide support to the primary emergency authority.

(B) A small quantity generator shall maintain records documenting the arrangements with the local fire department as well as any other organization necessary to respond to an emergency. This documentation must include documentation in the operating record that either confirms such arrangements actively exist or, in cases where no arrangements exist, confirms that attempts to make such arrangements were made.

(C) A facility possessing 24-hour response capabilities may seek a waiver from the authority having jurisdiction (AHJ) over the fire code within the facility's state or locality as far as needing to make arrangements with the local fire department as well as any other organization necessary to respond to an emergency, provided that the waiver is documented in the operating record.

(9) *Emergency procedures.* The small quantity generator complies with the following conditions for those areas of the generator facility where hazardous waste is generated and accumulated:

(i) At all times there must be at least one employee either on the premises or on call (*i.e.,* available to respond to an emergency by reaching the facility within a short period of time) with the responsibility for coordinating all emergency response measures specified in paragraph (b)(9)(iv) of this section. This employee is the emergency coordinator.

(ii) The small quantity generator must post the following information next to telephones or in areas directly involved in the generation and accumulation of hazardous waste:

(A) The name and emergency telephone number of the emergency coordinator;

(B) Location of fire extinguishers and spill control material, and, if present, fire alarm; and

(C) The telephone number of the fire department, unless the facility has a direct alarm.

(iii) The small quantity generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies;

(iv) The emergency coordinator or his designee must respond to any emergencies that arise. The applicable responses are as follows:

(A) In the event of a fire, call the fire department or attempt to extinguish it using a fire extinguisher;

(B) In the event of a spill, the small quantity generator is responsible for containing the flow of hazardous waste to the extent possible, and as soon as is practicable, cleaning up the hazardous waste and any contaminated materials or soil. Such containment and cleanup can be conducted either by the small quantity generator or by a contractor on behalf of the small quantity generator;

(C) In the event of a fire, explosion, or other release that could threaten human health outside the facility or when the small quantity generator has knowledge that a spill has reached surface water, the small quantity generator must immediately notify the National Response Center (using their 24-hour toll free number 800/424–8802). The report must include the following information:

(*1*) The name, address, and U.S. EPA identification number of the small quantity generator;

(*2*) Date, time, and type of incident (*e.g.,* spill or fire);

(*3*) Quantity and type of hazardous waste involved in the incident;

(*4*) Extent of injuries, if any; and

(*5*) Estimated quantity and disposition of recovered materials, if any.

(c) *Transporting over 200 miles.* A small quantity generator who must transport its waste, or offer its waste for transportation, over a distance of 200 miles or more for off-site treatment, storage or disposal may accumulate hazardous waste on site for 270 days or less without a permit or without having interim status provided that the generator complies with the conditions of paragraph (b) of this section.

(d) *Accumulation time limit extension.* A small quantity generator who accumulates hazardous waste for more than 180 days (or for more than 270 days if it must transport its waste, or offer its waste for transportation, over a distance of 200 miles or more) is subject to the requirements of 40 CFR parts 264, 265, 267, 268, and 270 of this chapter unless it has been granted an extension to the 180-day (or 270-day if applicable) period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 180 days (or 270 days if applicable) due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(e) *Rejected load.* A small quantity generator who sends a shipment of hazardous waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned waste on site in accordance with paragraphs (a)–(d) of this section. Upon receipt of the returned shipment, the generator must:

(1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or

(2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.

(f) A small quantity generator experiencing an episodic event may accumulate hazardous waste in accordance with subpart L of this part in lieu of § 262.17.

§ 262.17 Conditions for exemption for a large quantity generator that accumulates hazardous waste.

A large quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with the requirements of parts 124, 264 through 267, and 270 of this chapter, or the notification requirements of section 3010 of RCRA, provided that all of the following conditions for exemption are met:

(a) *Accumulation.* A large quantity generator accumulates hazardous waste on site for no more than 90 days, unless in compliance with the accumulation time limit extension or F006 accumulation conditions for exemption in paragraphs (b) through (e) of this section. The following accumulation conditions also apply:

(1) *Accumulation of hazardous waste in containers.* If the hazardous waste is placed in containers, the large quantity generator must comply with the following:

(i) *Air emission standards.* The applicable requirements of subparts AA, BB, and CC of 40 CFR part 265;

(ii) *Condition of containers.* If a container holding hazardous waste is not in good condition, or if it begins to leak, the large quantity generator must immediately transfer the hazardous waste from this container to a container that is in good condition, or immediately manage the waste in some other way that complies with the conditions for exemption of this section;

(iii) *Compatibility of waste with container.* The large quantity generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be stored, so that the ability of the container to contain the waste is not impaired;

(iv) *Management of containers.* (A) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste.

(B) A container holding hazardous waste must not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

(v) *Inspections.* At least weekly, the large quantity generator must inspect central accumulation areas. The large quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(1)(ii) of this section for remedial action required if deterioration or leaks are detected.

(vi) *Special conditions for accumulation of ignitable and reactive wastes.* (A) Containers holding ignitable or reactive waste must be located at least 15 meters (50 feet) from the facility's property line unless a written approval is obtained from the authority having jurisdiction over the local fire code allowing hazardous waste accumulation to occur within this

restricted area. A record of the written approval must be maintained as long as ignitable or reactive hazardous waste is accumulated in this area.

(B) The large quantity generator must take precautions to prevent accidental ignition or reaction of ignitable or reactive waste. This waste must be separated and protected from sources of ignition or reaction including but not limited to the following: Open flames, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, or mechanical), spontaneous ignition (*e.g.,* from heat-producing chemical reactions), and radiant heat. While ignitable or reactive waste is being handled, the large quantity generator must confine smoking and open flame to specially designated locations. ''No Smoking'' signs must be conspicuously placed wherever there is a hazard from ignitable or reactive waste.

(vii) *Special conditions for accumulation of incompatible wastes.* (A) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(B) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(C) A container holding a hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(2) *Accumulation of hazardous waste in tanks.* If the waste is placed in tanks, the large quantity generator must comply with the applicable requirements of subparts J, except § 265.197(c) of Closure and post-closure care and § 265.200—Waste analysis and trial tests, as well as the applicable requirements of AA, BB, and CC of 40 CFR part 265.

(3) *Accumulation of hazardous waste on drip pads.* If the hazardous waste is placed on drip pads, the large quantity generator must comply with the following:

(i) Subpart W of 40 CFR part 265;

(ii) The large quantity generator must remove all wastes from the drip pad at least once every 90 days. Any hazardous wastes that are removed from the drip pad are then subject to the 90-day accumulation limit in paragraph (a) of this section and § 262.15, if the hazardous wastes are being managed in satellite accumulation areas prior to being moved to a central accumulation area; and

(iii) The large quantity generator must maintain on site at the facility the following records readily available for inspection:

(A) A written description of procedures that are followed to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and

(B) Documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.

(4) *Accumulation of hazardous waste in containment buildings.* If the waste is placed in containment buildings, the large quantity generator must comply with of 40 CFR part 265 subpart DD. The generator must label its containment building with the words ''Hazardous Waste'' in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, or other persons on site, and also in a conspicuous place provide an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704). The generator must also maintain:

(i) The professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101. This certification must be in the generator's files prior to operation of the unit; and

(ii) The following records by use of inventory logs, monitoring equipment, or any other effective means:

(A) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the facility showing that the generator is consistent with respecting the 90 day limit, and documentation that the procedures are complied with; or

(B) Documentation that the unit is emptied at least once every 90 days.

(C) Inventory logs or records with the above information must be maintained on site and readily available for inspection.

(5) *Labeling and marking of containers and tanks*—(i) *Containers.* A large quantity generator must mark or label its containers with the following:

(A) The words ''Hazardous Waste'';

(B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and

(C) The date upon which each period of accumulation begins clearly visible for inspection on each container.

(ii) *Tanks.* A large quantity generator accumulating hazardous waste in tanks must do the following:

(A) Mark or label its tanks with the words ''Hazardous Waste'';

(B) Mark or label its tanks with an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(C) Use inventory logs, monitoring equipment or other records to demonstrate that hazardous waste has been emptied within 90 days of first entering the tank if using a batch process, or in the case of a tank with a continuous flow process, demonstrate that estimated volumes of hazardous waste entering the tank daily exit the tank within 90 days of first entering; and

(D) Keep inventory logs or records with the above information on site and readily available for inspection.

(6) *Emergency procedures.* The large quantity generator complies with the standards in subpart M of this part, Preparedness, Prevention and

Emergency Procedures for Large Quantity Generators.

(7) *Personnel training.* (i)(A*)* Facility personnel must successfully complete a program of classroom instruction, online training (*e.g.,* computer-based or electronic), or on-the-job training that teaches them to perform their duties in a way that ensures compliance with this part. The large quantity generator must ensure that this program includes all the elements described in the document required under paragraph (a)(7)(iv) of this section.

(B) This program must be directed by a person trained in hazardous waste management procedures, and must include instruction which teaches facility personnel hazardous waste management procedures (including contingency plan implementation) relevant to the positions in which they are employed.

(C) At a minimum, the training program must be designed to ensure that facility personnel are able to respond effectively to emergencies by familiarizing them with emergency procedures, emergency equipment, and emergency systems, including where applicable:

(*1*) Procedures for using, inspecting, repairing, and replacing facility emergency and monitoring equipment;

(*2*) Key parameters for automatic waste feed cut-off systems;

(*3*) Communications or alarm systems;

(*4*) Response to fires or explosions;

(*5*) Response to ground-water contamination incidents; and

(*6*) Shutdown of operations.

(D) For facility employees that receive emergency response training pursuant to Occupational Safety and Health Administration regulations 29 CFR 1910.120(p)(8) and 1910.120(q), the large quantity generator is not required to provide separate emergency response training pursuant to this section, provided that the overall facility training meets all the conditions of exemption in this section.

(ii) Facility personnel must successfully complete the program required in paragraph (a)(7)(i) of this section within six months after the date of their employment or assignment to the facility, or to a new position at the facility, whichever is later. Employees must not work in unsupervised positions until they have completed the training standards of paragraph (a)(7)(i) of this section.

(iii) Facility personnel must take part in an annual review of the initial training required in paragraph (a)(7)(i) of this section.

(iv) The large quantity generator must maintain the following documents and records at the facility:

(A) The job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job;

(B) A written job description for each position listed under paragraph (a)(7)(iv)(A) of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of facility personnel assigned to each position;

(C) A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed under paragraph (a)(7)(iv)(A) of this section;

(D) Records that document that the training or job experience, required under paragraphs (a)(7)(i), (ii), and (iii) of this section, has been given to, and completed by, facility personnel.

(v) Training records on current personnel must be kept until closure of the facility. Training records on former employees must be kept for at least three years from the date the employee last worked at the facility. Personnel training records may accompany personnel transferred within the same company.

(8) *Closure.* A large quantity generator accumulating hazardous wastes in containers, tanks, drip pads, and containment buildings, prior to closing a unit at the facility, or prior to closing the facility, must meet the following conditions:

(i) *Notification for closure of a waste accumulation unit.* A large quantity generator must perform one of the following when closing a waste accumulation unit:

(A) Place a notice in the operating record within 30 days after closure identifying the location of the unit within the facility; or

(B) Meet the closure performance standards of paragraph (a)(8)(iii) of this section for container, tank, and containment building waste accumulation units or paragraph (a)(8)(iv) of this section for drip pads and notify EPA following the procedures in paragraph (a)(8)(ii)(B) of this section for the waste accumulation unit. If the waste accumulation unit is subsequently reopened, the generator may remove the notice from the operating record.

(ii) *Notification for closure of the facility.* (A) Notify EPA using form 8700–12 no later than 30 days prior to closing the facility.

(B) Notify EPA using form 8700–12 within 90 days after closing the facility that it has complied with the closure performance standards of paragraph (a)(8)(iii) or (iv) of this section. If the facility cannot meet the closure performance standards of paragraph (a)(8)(iii) or (iv) of this section, notify EPA using form 8700–12 that it will close as a landfill under § 265.310 of this chapter in the case of a container, tank or containment building unit(s), or for a facility with drip pads, notify using form 8700–12 that it will close under the standards of § 265.445(b).

(C) A large quantity generator may request additional time to clean close, but it must notify EPA using form 8700–12 within 75 days after the date provided in paragraph (a)(8)(ii)(A) of this section to request an extension and provide an explanation as to why the additional time is required.

(iii) *Closure performance standards for container, tank systems, and containment building waste accumulation units.* (A) At closure, the generator must close the waste accumulation unit or facility in a manner that:

(1) Minimizes the need for further maintenance by controlling, minimizing, or eliminating, to the extent necessary to protect human health and the environment, the post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere,

(2) Removes or decontaminates all contaminated equipment, structures and soil and any remaining hazardous waste residues from waste accumulation units including containment system components (pads, liners, etc.), contaminated soils and subsoils, bases, and structures and equipment contaminated with waste, unless § 261.3(d) of this chapter applies.

(3) Any hazardous waste generated in the process of closing either the generator's facility or unit(s) accumulating hazardous waste must be managed in accordance with all applicable standards of parts 262, 263, 265 and 268 of this chapter, including removing any hazardous waste contained in these units within 90 days of generating it and managing these wastes in a RCRA Subtitle C hazardous waste permitted treatment, storage and disposal facility or interim status facility.

(4) If the generator demonstrates that any contaminated soils and wastes cannot be practicably removed or

decontaminated as required in paragraph (a)(8)(ii)(A)(*2*) of this section, then the waste accumulation unit is considered to be a landfill and the generator must close the waste accumulation unit and perform post-closure care in accordance with the closure and post-closure care requirements that apply to landfills (§ 265.310 of this chapter). In addition, for the purposes of closure, post-closure, and financial responsibility, such a waste accumulation unit is then considered to be a landfill, and the generator must meet all of the requirements for landfills specified in subparts G and H of part 265 of this chapter.

(iv) *Closure performance standards for drip pad waste accumulation units.* At closure, the generator must comply with the closure requirements of paragraphs (a)(8)(ii) and (a)(8)(iii)(A)(*1*) and (*3*) of this section, and § 265.445(a) and (b) of this chapter.

(v) The closure requirements of paragraph (a)(8) of this section do not apply to satellite accumulation areas.

(9) *Land disposal restrictions.* The large quantity generator complies with all applicable requirements under 40 CFR part 268.

(b) *Accumulation time limit extension.* A large quantity generator who accumulates hazardous waste for more than 90 days is subject to the requirements of 40 CFR parts 124, 264 through 268, and part 270 of this chapter, and the notification requirements of section 3010 of RCRA, unless it has been granted an extension to the 90-day period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 90 days due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(c) *Accumulation of F006.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, may accumulate F006 waste on site for more than 90 days, but not more than 180 days without being subject to parts 124, 264 through 267 and 270 of this chapter, and the notification requirements of section 3010 of RCRA, provided that it complies with all of the following additional conditions for exemption:

(1) The large quantity generator has implemented pollution prevention practices that reduce the amount of any hazardous substances, pollutants, or contaminants entering F006 or otherwise released to the environment prior to its recycling;

(2) The F006 waste is legitimately recycled through metals recovery;

(3) No more than 20,000 kilograms of F006 waste is accumulated on site at any one time; and

(4) The F006 waste is managed in accordance with the following:

(i)(A) If the F006 waste is placed in containers, the large quantity generator must comply with the applicable conditions for exemption in paragraph (a)(1) of this section; and/or

(B) If the F006 is placed in tanks, the large quantity generator must comply with the applicable conditions for exemption of paragraph (a)(2) of this section; and/or

(C) If the F006 is placed in containment buildings, the large quantity generator must comply with subpart DD of 40 CFR part 265, and has placed its professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101 in the facility's files prior to operation of the unit. The large quantity generator must maintain the following records:

(*1*) A written description of procedures to ensure that the F006 waste remains in the unit for no more than 180 days, a written description of the waste generation and management practices for the facility showing that they are consistent with the 180-day limit, and documentation that the large quantity generator is complying with the procedures; or

(*2*) Documentation that the unit is emptied at least once every 180 days.

(ii) The large quantity generator is exempt from all the requirements in subparts G and H of 40 CFR part 265, except for those referenced in paragraph (a)(8) of this section.

(iii) The date upon which each period of accumulation begins is clearly marked and must be clearly visible for inspection on each container;

(iv) While being accumulated on site, each container and tank is labeled or marked clearly with:

(A) The words ''Hazardous Waste''; and

(B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704).

(v) The large quantity generator complies with the requirements in paragraphs(a)(6) and (7) of this section.

(d) *F006 transported over 200 miles.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, and who must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more for off-site metals recovery, may accumulate F006 waste on site for more than 90 days, but not more than 270 days without being subject to parts 124, 264 through 267, 270, and the notification requirements of section 3010 of RCRA, if the large quantity generator complies with all of the conditions for exemption of paragraphs (c)(1) through (4) of this section.

(e) *F006 accumulation time extension.* A large quantity generator accumulating F006 in accordance with paragraphs (c) and (d) of this section who accumulates F006 waste on site for more than 180 days (or for more than 270 days if the generator must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more), or who accumulates more than 20,000 kilograms of F006 waste on site is an operator of a storage facility and is subject to the requirements of 40 CFR parts 124, 264, 265, 267, and 270 of this chapter, and the notification requirements of section 3010 of RCRA, unless the generator has been granted an extension to the 180-day (or 270-day if applicable) period or an exception to the 20,000 kilogram accumulation limit. Such extensions and exceptions may be granted by EPA if F006 waste must remain on site for longer than 180 days (or 270 days if applicable) or if more than 20,000 kilograms of F006 waste must remain on site due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days or an exception to the accumulation limit may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(f) *Consolidation of hazardous waste received from very small quantity generators.* Large quantity generators may accumulate on site hazardous waste received from very small quantity generators under control of the same person (as defined in § 260.10 of this chapter), without a storage permit or interim status and without complying with the requirements of parts 124, 264 through 268, and 270 of this chapter, and the notification requirements of

section 3010 of RCRA, provided that they comply with the following conditions. ''Control,'' for the purposes of this section, means the power to direct the policies of the generator, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator facilities on behalf of a different person shall not be deemed to ''control'' such generators.

(1) The large quantity generator notifies EPA at least thirty (30) days prior to receiving the first shipment from a very small quantity generator(s) using EPA Form 8700–12; and

(i) Identifies on the form the name(s) and site address(es) for the very small quantity generator(s) as well as the name and business telephone number for a contact person for the very small quantity generator(s); and

(ii) Submits an updated Site ID form (EPA Form 8700–12) within 30 days after a change in the name or site address for the very small quantity generator.

(2) The large quantity generator maintains records of shipments for three years from the date the hazardous waste was received from the very small quantity generator. These records must identify the name, site address, and contact information for the very small quantity generator and include a description of the hazardous waste received, including the quantity and the date the waste was received.

(3) The large quantity generator complies with the independent requirements identified in § 262.10(a)(1)(iii) and the conditions for exemption in this section for all hazardous waste received from a very small quantity generator. For purposes of the labeling and marking regulations in paragraph (a)(5) of this section, the large quantity generator must label the container or unit with the date accumulation started (*i.e.,* the date the hazardous waste was received from the very small quantity generator). If the large quantity generator is consolidating incoming hazardous waste from a very small quantity generator with either its own hazardous waste or with hazardous waste from other very small quantity generators, the large quantity generator must label each container or unit with the earliest date any hazardous waste in the container was accumulated on site.

(g) *Rejected load.* A large quantity generator who sends a shipment of hazardous waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned waste on site in accordance with paragraphs (a) and (b) of this section. Upon receipt of the returned shipment, the generator must:

(1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or

(2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.

§ 262.18 EPA identification numbers and re-notification for small quantity generators and large quantity generators.

(a) A generator must not treat, store, dispose of, transport, or offer for transportation, hazardous waste without having received an EPA identification number from the Administrator.

(b) A generator who has not received an EPA identification number must obtain one by applying to the Administrator using EPA Form 8700–12. Upon receiving the request the Administrator will assign an EPA identification number to the generator.

(c) A generator must not offer its hazardous waste to transporters or to treatment, storage, or disposal facilities that have not received an EPA identification number.

(d) *Re-notification.* (1) A small quantity generator must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700–12. This re-notification must be submitted by September 1st of each year in which re-notifications are required.

(2) A large quantity generator must re-notify EPA by March 1 of each even-numbered year thereafter using EPA Form 8700–12. A large quantity generator may submit this re-notification as part of its Biennial Report required under § 262.41.

(e) A recognized trader must not arrange for import or export of hazardous waste without having received an EPA identification number from the Administrator.

■ 28. Revise the heading for subpart B to read as follows:

Subpart B—Manifest Requirements Applicable to Small and Large Quantity Generators

■ 29. Revise the heading for subpart C to read as follows:

Subpart C—Pre-Transport Requirements Applicable to Small and Large Quantity Generators

■ 30. Section 262.32 is amended by revising paragraph (b) and adding paragraphs (c) and (d) to read as follows:

§ 262.32 Marking.

* * * * *

(b) Before transporting hazardous waste or offering hazardous waste for transportation off site, a generator must mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

(1) HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

(2) Generator's Name and Address _____.

(3) Generator's EPA Identification Number _____.

(4) Manifest Tracking Number _____.

(5) EPA Hazardous Waste Number(s) _____.

(c) A generator may use a nationally recognized electronic system, such as bar coding, to identify the EPA Hazardous Waste Number(s), as required by paragraph (b)(5) or paragraph (d).

(d) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable.

§ 262.34 [Removed and reserved]

■ 31. Remove and reserve § 262.34.

■ 32. Add § 262.35 to subpart C read as follows:

§ 262.35 Liquids in landfills prohibition.

The placement of bulk or non-containerized liquid hazardous waste or hazardous waste containing free liquids (whether or not sorbents have been added) in any landfill is prohibited. Prior to disposal in a hazardous waste landfill, liquids must meet additional requirements as specified in §§ 264.314 and 265.314.

■ 33. Revise the heading for subpart D to read as follows:

Subpart D—Recordkeeping and Reporting Applicable to Small and Large Quantity Generators

■ 34. Section 262.40 is amended by revising paragraph (c) to read as follows:

§ 262.40 Recordkeeping.

* * * * *

(c) See § 262.11(f) for recordkeeping requirements for documenting hazardous waste determinations.

* * * * *

■ 35. Section 262.41 is revised to read as follows:

§ 262.41 Biennial report for large quantity generators.

(a) A generator who is a large quantity generator for at least one month of an odd-numbered year (reporting year) who ships any hazardous waste off-site to a treatment, storage or disposal facility within the United States must complete and submit EPA Form 8700–13 A/B to the Regional Administrator by March 1 of the following even-numbered year and must cover generator activities during the previous year.

(b) Any generator who is a large quantity generator for at least one month of an odd-numbered year (reporting year) who treats, stores, or disposes of hazardous waste on site must complete and submit EPA Form 8700–13 A/B to the Regional Administrator by March 1 of the following even-numbered year covering those wastes in accordance with the provisions of 40 CFR parts 264, 265, 266, 267 and 270. This requirement also applies to large quantity generators that receive hazardous waste from very small quantity generators pursuant to § 262.17(f).

(c) Exports of hazardous waste to foreign countries are not required to be reported on the Biennial Report form. A separate annual report requirement is set forth at § 262.83(g) for hazardous waste exporters.

■ 36. Section 262.43 is revised to read as follows:

§ 262.43 Additional reporting.

The Administrator, as deemed necessary under sections 2002(a) and 3002(a)(6) of the Act, may require generators to furnish additional reports concerning the quantities and disposition of wastes identified or listed in 40 CFR part 261.

■ 37. Section 262.44 is amended by revising the section heading and the introductory text to read as follows:

§ 262.44 Recordkeeping for small quantity generators.

A small quantity generator is subject only to the following independent requirements in this subpart:

* * * * *

Subparts I and J [Removed and Reserved]

■ 38. Remove and reserve subparts I and J.

Subpart K—Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

■ 39. Section 262.200 is amended by removing the definition of ''Central accumulation area'' and revising the definition of ''Trained professional'' to read as follows:

§ 262.200 Definitions for this subpart.

* * * * *

Trained professional means a person who has completed the applicable RCRA training requirements of § 262.17 for large quantity generators, or is knowledgeable about normal operations and emergencies in accordance with § 262.16 for small quantity generators and very small quantity generators. A trained professional may be an employee of the eligible academic entity or may be a contractor or vendor who meets the requisite training requirements.

* * * * *

■ 40. Section 262.201 is revised to read as follows:

§ 262.201 Applicability of this subpart.

(a) *Large quantity generators and small quantity generators.* This subpart provides alternative requirements to the requirements in §§ 262.11 and 262.15 for the hazardous waste determination and accumulation of hazardous waste in laboratories owned by eligible academic entities that choose to be subject to this subpart, provided that they complete the notification requirements of § 262.203.

(b) *Very small quantity generators.* This subpart provides alternative requirements to the conditional exemption in § 262.14 for the accumulation of hazardous waste in laboratories owned by eligible academic entities that choose to be subject to this subpart, provided that they complete the notification requirements of § 262.203.

■ 41. Section 262.202 is revised to read as follows:

§ 262.202 This subpart is optional.

(a) *Large quantity generators and small quantity generators.* Eligible academic entities have the option of complying with this subpart with respect to its laboratories, as an alternative to complying with the requirements of §§ 262.11 and 262.15.

(b) *Very small quantity generators.* Eligible academic entities have the option of complying with this subpart with respect to laboratories, as an alternative to complying with the conditional exemption of § 262.14.

■ 42. Section 262.203 is amended by revising paragraphs (a) and (b)(2) to read as follows:

§ 262.203 How an eligible academic entity indicates it will be subject to the requirements of this subpart.

(a) An eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12), that it is electing to be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity under the same EPA identification number. An eligible academic entity that is a very small quantity generator and does not have an EPA identification number must notify that it is electing to be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity that are on site, as defined by § 260.10 of this chapter. An eligible academic entity must submit a separate notification (Site Identification Form) for each EPA identification number (or site, for very small quantity generators) that is electing to be subject to the requirements of this subpart, and must submit the Site Identification Form before it begins operating under this subpart.

(b) * * *

(2) Site EPA identification number (except for very small quantity generators).

* * * * *

■ 43. Section 262.204 is amended by revising paragraph (a) to read as follows:

§ 262.204 How an eligible academic entity indicates it will withdraw from the requirements of this subpart.

(a) An eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12), that it is electing to no longer be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity under the same EPA identification number and that it will comply with the requirements of §§ 262.11 and 262.15 for small quantity generators and large quantity generators. An eligible academic entity that is a very small quantity generator and does not have an EPA identification number must notify that it is withdrawing from the requirements of this subpart for all the laboratories owned by the eligible academic entity that are on site and that it will comply with the conditional exemption in § 262.14. An eligible academic entity must submit a separate notification (Site Identification Form) for each EPA identification number (or site, for very small quantity generators) that is withdrawing from the requirements of this subpart and must

submit the Site Identification Form before it begins operating under the standards in §§ 262.11 and 262.15 for small quantity generators and large quantity generators or § 262.14 for very small quantity generators.

* * * * *

§ 262.206 [Amended]

■ 44. Amend § 262.206 in paragraph (b)(3)(iii) by removing the period at the end of the sentence and adding a colon in its place.

■ 45. Section 262.207 is amended by revising paragraph (d)(2) to read as follows:

§ 262.207 Training.

* * * * *

(d) * * *

(2) Make the hazardous waste determination, pursuant to § 262.11(a) through (d), for unwanted material.

■ 46. Section 262.208 is amended by revising paragraphs (a)(1) and (2), and (d)(2) to read as follows:

§ 262.208 Removing containers of unwanted material from the laboratory.

(a) * * *

(1) Remove all containers of unwanted material from each laboratory on a regular interval, not to exceed 12 months; or

(2) Remove containers of unwanted material from each laboratory within 12 months of each container's accumulation start date.

* * * * *

(d) * * *

(2) If a laboratory accumulates more than 1 quart of liquid reactive acutely hazardous unwanted material or more than 1 kg (2.2 pounds) of solid reactive acutely hazardous unwanted material before the regularly scheduled removal, then the eligible academic entity must ensure that all containers of reactive acutely hazardous unwanted material:

(i) Are marked on the label that is associated with the container (or on the label that is affixed or attached to the container, if that is preferred) with the date that 1 quart or 1 kg is exceeded; and

(ii) Are removed from the laboratory within 10 calendar days of the date that 1 quart or 1 kg was exceeded, or at the next regularly scheduled removal, whichever comes first.

■ 47. Section 262.209 is amended by revising paragraph (b) to read as follows:

§ 262.209 Where and when to make the hazardous waste determination and where to send containers of unwanted material upon removal from the laboratory.

* * * * *

(b) *Very small quantity generators.* An eligible academic entity must ensure that a trained professional makes a hazardous waste determination, pursuant to § 262.11(a) through (d), for unwanted material in the laboratory before the unwanted material is removed from the laboratory, in accordance with § 262.210.

■ 48. Section 262.210 is amended by revising paragraphs (a), (b)(3), and (d)(2) to read as follows:

§ 262.210 Making the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory.

* * * * *

(a) A trained professional must make the hazardous waste determination, pursuant to § 262.11(a) through (d), before the unwanted material is removed from the laboratory.

(b) * * *

(3) Count the hazardous waste toward the eligible academic entity's generator category, pursuant to § 262.13, in the calendar month that the hazardous waste determination was made.

* * * * *

(d) * * *

(2) Very small quantity generators must ensure it is taken directly from the laboratory(ies) to any of the types of facilities listed in § 262.14.

* * * * *

■ 49. Section 262.211 is amended by revising paragraphs (c), (d), and (e)(3) to read as follows:

§ 262.211 Making the hazardous waste determination at an on-site central accumulation area.

* * * * *

(c) The unwanted material becomes subject to the generator accumulation regulations of § 262.16 for small quantity generators or § 262.17 for large quantity generators as soon as it arrives in the central accumulation area, except for the ''hazardous waste'' labeling conditions of § 262.16(b)(6) and § 262.17(a)(5).

(d) A trained professional must determine, pursuant to § 262.11(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials' arrival at the on-site central accumulation area.

(e) * * *

(3) Count the hazardous waste toward the eligible academic entity's generator category, pursuant to § 262.13 in the calendar month that the hazardous waste determination was made, and

* * * * *

■ 50. Section 262.212 is amended by revising paragraph (d) to read as follows:

§ 262.212 Making the hazardous waste determination at an on-site interim status or permitted treatment, storage, or disposal facility.

* * * * *

(d) A trained professional must determine, pursuant to § 262.11(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials' arrival at an on-site interim status or permitted treatment, storage, or disposal facility.

* * * * *

■ 51. Section 262.213 is amended by revising paragraphs (a)(1), (2) and (3) and (b)(2) to read as follows:

§ 262.213 Laboratory clean-outs.

(a) * * *

(1) If the volume of unwanted material in the laboratory exceeds 55 gallons (or 1 quart of liquid reactive acutely hazardous unwanted material or 1 kg of solid reactive acutely hazardous unwanted material), the eligible academic entity is not required to remove all unwanted materials from the laboratory within 10 calendar days of exceeding 55 gallons (or 1 quart of liquid reactive acutely hazardous unwanted material or 1 kg or solid reactive acutely hazardous unwanted material), as required by § 262.208. Instead, the eligible academic entity must remove all unwanted materials from the laboratory within 30 calendar days from the start of the laboratory clean-out; and

(2) For the purposes of on-site accumulation, an eligible academic entity is not required to count a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261, subpart D or exhibiting one or more characteristics in 40 CFR part 261, subpart C) generated solely during the laboratory clean-out toward its hazardous waste generator category, pursuant to § 262.13. An unwanted material that is generated prior to the beginning of the laboratory clean-out and is still in the laboratory at the time the laboratory clean-out commences must be counted toward hazardous waste generator category, pursuant to § 262.13, if it is determined to be hazardous waste; and

(3) For the purposes of off-site management, an eligible academic entity must count all its hazardous waste, regardless of whether the hazardous waste was counted toward generator category under paragraph (a)(2) of this section, and if it generates more than 1 kg/month of acute hazardous waste or more than 100 kg/month of non-acute hazardous waste (*i.e.,* the very small quantity generator limits as defined in § 260.10 of this

chapter), the hazardous waste is subject to all applicable hazardous waste regulations when it is transported off site; and

* * * * *

(b) * * *

(2) The requirement to count all hazardous waste, including unused hazardous waste, generated during the laboratory clean-out toward its hazardous waste generator category, pursuant to § 262.13.

■ 52. Section 262.214 is amended by revising paragraph (b)(5) to read as follows:

§ 262.214 Laboratory management plan.

* * * * *

(b) * * *

(5) Describe its intended best practices for making hazardous waste determinations, including specifying the duties of the individuals involved in the process (see the required standards at § 262.11(a) through (d) and §§ 262.209 through 262.212).

* * * * *

■ 53. Section 262.216 is amended by revising paragraphs (a) and (b) to read as follows:

§ 262.216 Non-laboratory hazardous waste generated at an eligible academic entity.

* * * * *

(a) Remains subject to the generator requirements of §§ 262.11 and 262.15 for large quantity generators and small quantity generators (if the hazardous waste is managed in a satellite accumulation area), and all other applicable generator requirements of 40 CFR part 262, with respect to that hazardous waste; or

(b) Remains subject to the conditional exemption of § 262.14 for very small quantity generators, with respect to that hazardous waste.

■ 54. Subpart L is added to read as follows:

Subpart L— Alternative Standards for Episodic Generation

Sec.

Subpart L—Alternative Standards for Episodic Generation

§ 262.230 Applicability.

This subpart is applicable to very small quantity generators and small quantity generators as defined in § 260.10 of this chapter.

§ 262.231 Definitions for this subpart.

Episodic event means an activity or activities, either planned or unplanned, that does not normally occur during generator operations, resulting in an increase in the generation of hazardous wastes that exceeds the calendar month quantity limits for the generator's usual category.

Planned episodic event means an episodic event that the generator planned and prepared for, including regular maintenance, tank cleanouts, short-term projects, and removal of excess chemical inventory

Unplanned episodic event means an episodic event that the generator did not plan or reasonably did not expect to occur, including production process upsets, product recalls, accidental spills, or ''acts of nature,'' such as tornado, hurricane, or flood.

§ 262.232 Conditions for a generator managing hazardous waste from an episodic event.

(a) *Very small quantity generator.* A very small quantity generator may maintain its existing generator category for hazardous waste generated during an episodic event provided that the generator complies with the following conditions:

(1) The very small quantity generator is limited to one episodic event per calendar year, unless a petition is granted under § 262.233;

(2) *Notification.* The very small quantity generator must notify EPA no later than thirty (30) calendar days prior to initiating a planned episodic event using EPA Form 8700–12. In the event of an unplanned episodic event, the generator must notify EPA within 72 hours of the unplanned event via phone, email, or fax and subsequently submit EPA Form 8700–12. The generator shall include the start date and end date of the episodic event, the reason(s) for the event, types and estimated quantities of hazardous waste expected to be generated as a result of the episodic event, and shall identify a facility contact and emergency coordinator with 24-hour telephone access to discuss the notification submittal or respond to an emergency in compliance with § 262.16(b)(9)(i);

(3) *EPA ID Number.* The very small quantity generator must have an EPA identification number or obtain an EPA identification number using EPA Form 8700–12;

(4) *Accumulation.* A very small quantity generator is prohibited from accumulating hazardous waste generated from an episodic event on drip pads and in containment buildings. When accumulating hazardous waste in containers and tanks the following conditions apply:

(i) *Containers.* A very small quantity generator accumulating in containers must mark or label its containers with the following:

(A) The words ''Episodic Hazardous Waste'';

(B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and

(C) The date upon which the episodic event began, clearly visible for inspection on each container.

(ii) *Tanks.* A very small quantity generator accumulating episodic hazardous waste in tanks must do the following:

(A) Mark or label the tank with the words ''Episodic Hazardous Waste'';

(B) Mark or label its tanks with an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(C) Use inventory logs, monitoring equipment or other records to identify the date upon which each episodic event begins; and

(D) Keep inventory logs or records with the above information on site and readily available for inspection.

(iii) Hazardous waste must be managed in a manner that minimizes the possibility of a fire, explosion, or release of hazardous waste or hazardous waste constituents to the air, soil, or water;

(A) Containers must be in good condition and compatible with the hazardous waste being accumulated therein. Containers must be kept closed except to add or remove waste; and.

(B) Tanks must be in good condition and compatible with the hazardous waste accumulated therein. Tanks must have procedures in place to prevent the overflow (*e.g.,* be equipped with a means to stop inflow with systems such as a waste feed cutoff system or bypass system to a standby tank when hazardous waste is continuously fed into the tank). Tanks must be inspected at least once each operating day to ensure all applicable discharge control equipment, such as waste feed cutoff systems, bypass systems, and drainage systems are in good working order and to ensure the tank is operated according to its design by reviewing the data gathered from monitoring equipment such as pressure and temperature gauges from the inspection.

(5) The very small quantity generator must comply with the hazardous waste manifest provisions of subpart B of this part when it sends its episodic event hazardous waste off site to a designated facility, as defined in § 260.10 of this chapter.

(6) The very small quantity generator has up to sixty (60) calendar days from the start of the episodic event to manifest and send its hazardous waste generated from the episodic event to a designated facility, as defined in § 260.10 of this chapter.

(7) Very small quantity generators must maintain the following records for three (3) years from the end date of the episodic event:

(i) Beginning and end dates of the episodic event;

(ii) A description of the episodic event;

(iii) A description of the types and quantities of hazardous wastes generated during the event;

(iv) A description of how the hazardous waste was managed as well as the name of the RCRA-designated facility that received the hazardous waste;

(v) Name(s) of hazardous waste transporters; and

(vi) An approval letter from EPA if the generator petitioned to conduct one additional episodic event per calendar year.

(b) *Small quantity generators.* A small quantity generator may maintain its existing generator category during an episodic event provided that the generator complies with the following conditions:

(1) The small quantity generator is limited to one episodic event per calendar year unless a petition is granted under § 262.233;

(2) *Notification.* The small quantity generator must notify EPA no later than thirty (30) calendar days prior to initiating a planned episodic event using EPA Form 8700–12. In the event of an unplanned episodic event, the small quantity generator must notify EPA within 72 hours of the unplanned event via phone, email, or fax, and subsequently submit EPA Form 8700–12. The small quantity generator shall include the start date and end date of the episodic event and the reason(s) for the event, types and estimated quantities of hazardous wastes expected to be generated as a result of the episodic event, and identify a facility contact and emergency coordinator with 24-hour telephone access to discuss the notification submittal or respond to emergency;

(3) *EPA ID Number.* The small quantity generator must have an EPA identification number or obtain an EPA identification number using EPA Form 8700–12; and

(4) *Accumulation by small quantity generators.* A small quantity generator is prohibited from accumulating hazardous wastes generated from an episodic event waste on drip pads and in containment buildings. When accumulating hazardous waste generated from an episodic event in containers and tanks, the following conditions apply:

(i) *Containers.* A small quantity generator accumulating episodic hazardous waste in containers must meet the standards at § 262.16(b)(2) of this chapter and must mark or label its containers with the following:

(A) The words ''Episodic Hazardous Waste'';

(B) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and

(C) The date upon which the episodic event began, clearly visible for inspection on each container.

(ii) *Tanks.* A small quantity generator accumulating episodic hazardous waste in tanks must meet the standards at § 262.16(b)(3) and must do the following:

(A) Mark or label its tank with the words ''Episodic Hazardous Waste'';

(B) Mark or label its tanks with an indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704);

(C) Use inventory logs, monitoring equipment or other records to identify the date upon which each period of accumulation begins and ends; and

(D) Keep inventory logs or records with the above information on site and available for inspection.

(5) The small quantity generator must treat hazardous waste generated from an episodic event on site or manifest and ship such hazardous waste off site to a designated facility (as defined by § 260.10 of this chapter) within sixty (60) calendar days from the start of the episodic event.

(6) The small quantity generator must maintain the following records for three (3) years from the end date of the episodic event:

(i) Beginning and end dates of the episodic event;

(ii) A description of the episodic event;

(iii) A description of the types and quantities of hazardous wastes generated during the event;

(iv) A description of how the hazardous waste was managed as well as the name of the designated facility (as defined by § 260.10 of this chapter) that received the hazardous waste;

(v) Name(s) of hazardous waste transporters; and

(vi) An approval letter from EPA if the generator petitioned to conduct one additional episodic event per calendar year.

§ 262.233 Petition to manage one additional episodic event per calendar year.

(a) A generator may petition the Regional Administrator for a second episodic event in a calendar year without impacting its generator category under the following conditions:

(1) If a very small quantity generator or small quantity generator has already held a planned episodic event in a calendar year, the generator may petition EPA for an additional unplanned episodic event in that calendar year within 72 hours of the unplanned event.

(2) If a very small quantity generator or small quantity generator has already

held an unplanned episodic event in a calendar year, the generator may petition EPA for an additional planned episodic event in that calendar year.

(b) The petition must include the following:

(1) The reason(s) why an additional episodic event is needed and the nature of the episodic event;

(2) The estimated amount of hazardous waste to be managed from the event;

(3) How the hazardous waste is to be managed;

(4) The estimated length of time needed to complete management of the hazardous waste generated from the episodic event—not to exceed sixty (60) days; and

(5) Information regarding the previous episodic event managed by the generator, including the nature of the event, whether it was a planned or unplanned event, and how the generator complied with the conditions.

(c) The petition must be made to the Regional Administrator in writing, either on paper or electronically.

(d) The generator must retain written approval in its records for three (3) years from the date the episodic event ended.

■ 55. Subpart M is added to read as follows:

Subpart M—Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators

Sec.

Subpart M—Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators

§ 262.250 Applicability.

The regulations of this subpart apply to those areas of a large quantity generator where hazardous waste is generated or accumulated on site.

§ 262.251 Maintenance and operation of facility.

A large quantity generator must maintain and operate its facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

§ 262.252 Required equipment.

All areas deemed applicable by § 262.250 must be equipped with the items in paragraphs (a) through (d) of this section (unless none of the hazards posed by waste handled at the facility could require a particular kind of equipment specified below or the actual hazardous waste generation or accumulation area does not lend itself for safety reasons to have a particular kind of equipment specified below). A large quantity generator may determine the most appropriate locations within its facility to locate equipment necessary to prepare for and respond to emergencies:

(a) An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to facility personnel;

(b) A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or state or local emergency response teams;

(c) Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment, and decontamination equipment; and

(d) Water at adequate volume and pressure to supply water hose streams, or foam producing equipment, or automatic sprinklers, or water spray systems.

§ 262.253 Testing and maintenance of equipment.

All communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment, where required, must be tested and maintained as necessary to assure its proper operation in time of emergency.

§ 262.254 Access to communications or alarm system.

(a) Whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access (*e.g.,* direct or unimpeded access) to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, *unless* such a device is not required under § 262.252.

(b) In the event there is just one employee on the premises while the facility is operating, the employee must have immediate access (*e.g.,* direct or unimpeded access) to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, *unless* such a device is not required under § 262.252.

§ 262.255 Required aisle space.

The large quantity generator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.

§ 262.256 Arrangements with local authorities.

(a) The large quantity generator must attempt to make arrangements with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers, and local hospitals, taking into account the types and quantities of hazardous wastes handled at the facility. Arrangements may be made with the Local Emergency Planning Committee, if it is determined to be the appropriate organization with which to make arrangements.

(1) A large quantity generator attempting to make arrangements with its local fire department must determine the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals.

(2) As part of this coordination, the large quantity generator shall attempt to make arrangements, as necessary, to familiarize the above organizations with the layout of the facility, the properties of the hazardous waste handled at the facility and associated hazards, places where personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes as well as the types of injuries or illnesses which could result from fires, explosions, or releases at the facility.

(3) Where more than one police or fire department might respond to an emergency, the large quantity generator shall attempt to make arrangements designating primary emergency authority to a specific fire or police department, and arrangements with any others to provide support to the primary emergency authority.

(b) The large quantity generator shall maintain records documenting the arrangements with the local fire department as well as any other organization necessary to respond to an emergency. This documentation must include documentation in the operating record that either confirms such arrangements actively exist or, in cases where no arrangements exist, confirms that attempts to make such arrangements were made.

(c) A facility possessing 24-hour response capabilities may seek a waiver from the authority having jurisdiction (AHJ) over the fire code within the facility's state or locality as far as needing to make arrangements with the local fire department as well as any other organization necessary to respond to an emergency, provided that the waiver is documented in the operating record.

§ 262.260 Purpose and implementation of contingency plan.

(a) A large quantity generator must have a contingency plan for the facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water.

(b) The provisions of the plan must be carried out immediately whenever there is a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.

§ 262.261 Content of contingency plan.

(a) The contingency plan must describe the actions facility personnel must take to comply with §§ 262.260 and 262.265 in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the facility.

(b) If the generator has already prepared a Spill Prevention, Control, and Countermeasures (SPCC) Plan in accordance with part 112 of this chapter, or some other emergency or contingency plan, it need only amend that plan to incorporate hazardous waste management provisions that are sufficient to comply with the standards of this part. The generator may develop one contingency plan that meets all regulatory standards. EPA recommends that the plan be based on the National Response Team's Integrated Contingency Plan Guidance (''One Plan'').

(c) The plan must describe arrangements agreed to with the local police department, fire department, other emergency response teams, emergency response contractors, equipment suppliers, local hospitals or, if applicable, the Local Emergency Planning Committee, pursuant to § 262.256.

(d) The plan must list names and emergency telephone numbers of all persons qualified to act as emergency coordinator (see § 262.264), and this list must be kept up to date. Where more than one person is listed, one must be named as primary emergency coordinator and others must be listed in the order in which they will assume responsibility as alternates. In situations where the generator facility has an emergency coordinator continuously on duty because it operates 24 hours per day, every day of the year, the plan may list the staffed position (*e.g.,* operations manager, shift coordinator, shift operations supervisor) as well as an emergency telephone number that can be guaranteed to be answered at all times.

(e) The plan must include a list of all emergency equipment at the facility (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.

(f) The plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

§ 262.262 Copies of contingency plan.

A copy of the contingency plan and all revisions to the plan must be maintained at the large quantity generator and—

(a) The large quantity generator must submit a copy of the contingency plan and all revisions to all local emergency responders (*i.e.,* police departments, fire departments, hospitals and State and local emergency response teams that may be called upon to provide emergency services). This document may also be submitted to the Local Emergency Planning Committee, as appropriate.

(b) A large quantity generator that first becomes subject to these provisions after May 30, 2017 or a large quantity generator that is otherwise amending its contingency plan must at that time submit a quick reference guide of the contingency plan to the local emergency responders identified at paragraph (a) of this section or, as appropriate, the Local Emergency Planning Committee. The quick reference guide must include the following elements:

(1) The types/names of hazardous wastes in layman's terms and the associated hazard associated with each hazardous waste present at any one time (*e.g.,* toxic paint wastes, spent ignitable solvent, corrosive acid);

(2) The estimated maximum amount of each hazardous waste that may be present at any one time;

(3) The identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff;

(4) A map of the facility showing where hazardous wastes are generated, accumulated and treated and routes for accessing these wastes;

(5) A street map of the facility in relation to surrounding businesses, schools and residential areas to understand how best to get to the facility and also evacuate citizens and workers;

(6) The locations of water supply (*e.g.,* fire hydrant and its flow rate);

(7) The identification of on-site notification systems (*e.g.,* a fire alarm that rings off site, smoke alarms); and

(8) The name of the emergency coordinator(s) and 7/24-hour emergency telephone number(s) or, in the case of a facility where an emergency coordinator is continuously on duty, the emergency telephone number for the emergency coordinator.

(c) Generators must update, if necessary, their quick reference guides, whenever the contingency plan is amended and submit these documents to the local emergency responders identified at paragraph (a) of this section or, as appropriate, the Local Emergency Planning Committee.

§ 262.263 Amendment of contingency plan.

The contingency plan must be reviewed, and immediately amended, if necessary, whenever:

(a) Applicable regulations are revised;

(b) The plan fails in an emergency;

(c) The generator facility changes—in its design, construction, operation, maintenance, or other circumstances—in a way that materially increases the potential for fires, explosions, or releases of hazardous waste or hazardous waste constituents, or changes the response necessary in an emergency;

(d) The list of emergency coordinators changes; or

(e) The list of emergency equipment changes.

§ 262.264 Emergency coordinator.

At all times, there must be at least one employee either on the generator's premises or on call (*i.e.,* available to respond to an emergency by reaching the facility within a short period of time) with the responsibility for coordinating all emergency response measures and implementing the necessary emergency procedures outlined in § 262.265. Although responsibilities may vary depending on factors such as type and variety of hazardous waste(s) handled by the facility, as well as type and complexity of the facility, this emergency coordinator must be thoroughly familiar with all aspects of the generator's contingency plan, all operations and activities at the facility, the location and characteristics of hazardous waste handled, the location of all records within the facility, and the facility's layout. In addition, this person must have the authority to commit the resources needed to carry out the contingency plan.

§ 262.265 Emergency procedures.

(a) Whenever there is an imminent or actual emergency situation, the emergency coordinator (or his designee when the emergency coordinator is on call) must immediately:

(1) Activate internal facility alarms or communication systems, where applicable, to notify all facility personnel; and

(2) Notify appropriate state or local agencies with designated response roles if their help is needed.

(b) Whenever there is a release, fire, or explosion, the emergency coordinator must immediately identify the character, exact source, amount, and areal extent of any released materials. The emergency coordinator may do this by observation or review of the facility records or manifests and, if necessary, by chemical analysis.

(c) Concurrently, the emergency coordinator must assess possible hazards to human health or the environment that may result from the release, fire, or explosion. This assessment must consider both direct and indirect effects of the release, fire, or explosion (*e.g.,* the effects of any toxic, irritating, or asphyxiating gases that are generated, or the effects of any hazardous surface water run-offs from water or chemical agents used to control fire and heat-induced explosions).

(d) If the emergency coordinator determines that the facility has had a release, fire, or explosion which could threaten human health, or the environment, outside the facility, the emergency coordinator must report the findings as follows:

(1) If the assessment indicates that evacuation of local areas may be advisable, the emergency coordinator must immediately notify appropriate local authorities. The emergency coordinator must be available to help appropriate officials decide whether local areas should be evacuated; and

(2) The emergency coordinator must immediately notify either the government official designated as the on-scene coordinator for that geographical area, or the National Response Center (using their 24-hour toll free number 800/424–8802). The report must include:

(i) Name and telephone number of reporter;

(ii) Name and address of the generator;

(iii) Time and type of incident (*e.g.,* release, fire);

(iv) Name and quantity of material(s) involved, to the extent known;

(v) The extent of injuries, if any; and

(vi) The possible hazards to human health, or the environment, outside the facility.

(e) During an emergency, the emergency coordinator must take all reasonable measures necessary to ensure that fires, explosions, and releases do not occur, recur, or spread to other hazardous waste at the generator's facility. These measures must include, where applicable, stopping processes and operations, collecting and containing released hazardous waste, and removing or isolating containers.

(f) If the generator stops operations in response to a fire, explosion or release, the emergency coordinator must monitor for leaks, pressure buildup, gas generation, or ruptures in valves, pipes, or other equipment, wherever this is appropriate.

(g) Immediately after an emergency, the emergency coordinator must provide for treating, storing, or disposing of recovered waste, contaminated soil or surface water, or any other material that results from a release, fire, or explosion at the facility. Unless the generator can demonstrate, in accordance with § 261.3(c) or (d) of this chapter, that the recovered material is not a hazardous waste, then it is a newly generated hazardous waste that must be managed in accordance with all the applicable requirements and conditions for exemption in parts 262, 263, and 265 of this chapter.

(h) The emergency coordinator must ensure that, in the affected area(s) of the facility:

(1) No hazardous waste that may be incompatible with the released material is treated, stored, or disposed of until cleanup procedures are completed; and

(2) All emergency equipment listed in the contingency plan is cleaned and fit for its intended use before operations are resumed.

(i) The generator must note in the operating record the time, date, and details of any incident that requires implementing the contingency plan. Within 15 days after the incident, the generator must submit a written report on the incident to the Regional Administrator. The report must include:

(1) Name, address, and telephone number of the generator;

(2) Date, time, and type of incident (*e.g.,* fire, explosion);

(3) Name and quantity of material(s) involved;

(4) The extent of injuries, if any;

(5) An assessment of actual or potential hazards to human health or the environment, where this is applicable; and

(6) Estimated quantity and disposition of recovered material that resulted from the incident.

PART 263—STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

■ 56. The authority citation for part 263 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

■ 57. Section 263.12 is revised to read as follows:

§ 263.12 Transfer facility requirements.

(a) A transporter who stores manifested shipments of hazardous waste in containers meeting the independent requirements of § 262.30 of this chapter at a transfer facility for a period of ten (10) days or less is not subject to regulation under parts 264, 265, 267, 268, and 270 of this chapter with respect to the storage of those wastes.

(b) When consolidating the contents of two or more containers with the same hazardous waste into a new container, or when combining and consolidating two different hazardous wastes that are compatible with each other, the transporter must mark its containers of 119 gallons or less with the following information:

(1) The words ''Hazardous Waste'' and

(2) The applicable EPA hazardous waste number(s) (EPA hazardous waste

codes) in subparts C and D of part 261 of this chapter, or in compliance with § 262.32(c).

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 58. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

■ 59. Section 264.1 is amended by revising paragraphs (g)(1) and (3) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(1) The owner or operator of a facility permitted, licensed, or registered by a state to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under this part by § 262.14 of this chapter;

* * * * *

(3) A generator accumulating waste on site in compliance with §§ 262.14, 262.15, 262.16, or 262.17 of this chapter.

* * * * *

■ 60. Section 264.15 is amended by revising paragraph (b)(4) and removing the comment to paragraph (b)(4) to read as follows:

§ 264.15 General inspection requirements.

* * * * *

(b) * * *

(4) The frequency of inspection may vary for the items on the schedule. However, the frequency should be based on the rate of deterioration of the equipment and the probability of an environmental or human health incident if the deterioration, malfunction, or operator error goes undetected between inspections. Areas subject to spills, such as loading and unloading areas, must be inspected daily when in use. At a minimum, the inspection schedule must include the items and frequencies called for in §§ 264.174, 264.193, 264.195, 264.226, 264.254, 264.278, 264.303, 264.347, 264.602, 264.1033, 264.1052, 264.1053, 264.1058, and 264.1083 through 264.1089, where applicable. Part 270 of this chapter requires the inspection schedule to be submitted with part B of the permit application. EPA will evaluate the schedule along with the rest of the application to ensure that it adequately protects human health and the environment. As part of this review, EPA may modify or amend the schedule as may be necessary.

* * * * *

■ 61. Section 264.71 is amended by revising paragraph (c) and removing the comment to paragraph (c) to read as follows:

§ 264.71 Use of manifest system.

* * * * *

(c) Whenever a shipment of hazardous waste is initiated from a facility, the owner or operator of that facility must comply with the requirements of part 262 of this chapter. The provisions of §§ 262.15, 262.16, and 262.17 of this chapter are applicable to the on-site accumulation of hazardous wastes by generators. Therefore, the provisions of §§ 262.15, 262.16, and 262.17 of this chapter only apply to owners or operators who are shipping hazardous waste which they generated at that facility or operating as a large quantity generator consolidating hazardous waste from very small quantity generators under § 262.17(f).

* * * * *

■ 62. Section 264.75 is revised to read as follows:

§ 264.75 Biennial report.

The owner or operator must complete and submit EPA Form 8700–13 A/B to the Regional Administrator by March 1 of the following even numbered year and must cover activities during the previous year.

■ 63. Section 264.170 is revised to read as follows:

§ 264.170 Applicability.

The regulations in this subpart apply to owners and operators of all hazardous waste facilities that store hazardous waste in containers, except as § 264.1 provides otherwise.

[*Comment:* Under § 261.7 and § 261.33(c) of this chapter, if a hazardous waste is emptied from a container the residue remaining in the container is not considered a hazardous waste if the container is ''empty'' as defined in § 261.7. In that event, management of the container is exempt from the requirements of this subpart.]

■ 64. Section 264.174 is revised to read as follows:

§ 264.174 Inspections.

At least weekly, the owner or operator must inspect areas where containers are stored. The owner or operator must look for leaking containers and for deterioration of containers and the containment system cause by corrosion or other factors. See §§ 264.15(c) and 264.171 for remedial action required if deterioration or leaks are detected.

■ 65. Section 264.191 is amended by revising paragraph (a) to read as follows:

§ 264.191 Assessment of existing tank system's integrity.

(a) For each existing tank system that does not have secondary containment meeting the requirements of § 264.193, the owner or operator must determine that the tank system is not leaking or is fit for use. Except as provided in paragraph (c) of this section, the owner or operator must obtain and keep on file at the facility a written assessment reviewed and certified by a qualified Professional Engineer, in accordance with § 270.11(d) of this chapter, that attests to the tank system's integrity by January 12, 1988.

* * * * *

§ 264.195 [Amended]

■ 66. Section 264.195 is amended by removing and reserving paragraph (e).

■ 67. Section 264.1030 is amended by revising paragraph (b)(2) to read as follows:

§ 264.1030 Applicability.

* * * * *

(b) * * *

(2) A unit (including a hazardous waste recycling unit) that is not exempt from permitting under the provisions of 40 CFR 262.17 (*i.e.,* a hazardous waste recycling unit that is not a 90-day tank or container) and that is located at a hazardous waste management facility otherwise subject to the permitting requirements of 40 CFR part 270; or

* * * * *

■ 68. Section 264.1050 is amended by revising paragraph (b)(3) to read as follows:

§ 264.1050 Applicability.

* * * * *

(b) * * *

(3) A unit that is exempt from permitting under the provisions of 40 CFR 262.17 (*i.e.,* a ''90-day'' tank or container) and is not a recycling unit under the provisions of 40 CFR 261.6.

* * * * *

■ 69. Section 264.1101 is amended by revising paragraph (c)(4) to read as follows:

§ 264.1101 Design and operating standards.

* * * * *

(c) * * *

(4) Inspect and record in the facility operating record, at least once every seven days, data gathered from monitoring and leak detection equipment as well as the containment building and the area immediately surrounding the containment building

to detect signs of releases of hazardous waste.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 70. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937.

■ 71. Section 265.1 is amended by revising paragraphs (c)(5) and (7) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(5) The owner or operator of a facility permitted, licensed, or registered by a State to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under this part by § 262.14 of this chapter;

* * * * *

(7) A generator accumulating waste on site in compliance with applicable conditions for exemption in §§ 262.14 through 262.17 and subparts K and L of part 262 of this chapter, except to the extent the requirements of this part are included in those sections and subparts;

* * * * *

■ 72. Section 265.15 is amended by revising paragraph (b)(4) and removing paragraph (b)(5).

The revision reads as follows:

§ 265.15 General inspection requirements.

* * * * *

(b) * * *

(4) The frequency of inspection may vary for the items on the schedule. However, the frequency should be based on the rate of deterioration of the equipment and the probability of an environmental or human health incident if the deterioration, malfunction, or operator error goes undetected between inspections. Areas subject to spills, such as loading and unloading areas, must be inspected daily when in use. At a minimum, the inspection schedule must include the items and frequencies called for in §§ 265.174, 265.193, 265.195, 265.226, 265.260, 265.278, 265.304, 265.347, 265.377, 265.403, 265.1033, 265.1052, 265.1053, 265.1058, and 265.1084 through 265.1090, where applicable.

* * * * *

■ 73. Section 265.71 is amended by revising paragraph (c) to read as follows:

§ 265.71 Use of manifest system.

* * * * *

(c) Whenever a shipment of hazardous waste is initiated from a facility, the owner or operator of that facility must comply with the requirements of part 262 of this chapter. The provisions of §§ 262.15, 262.16, and 262.17 of this chapter are applicable to the on-site accumulation of hazardous wastes by generators. Therefore, the provisions of §§ 262.15, 262.16, and 262.17 only apply to owners or operators who are shipping hazardous waste which they generated at that facility or operating as a large quantity generator consolidating hazardous waste from very small quantity generators under § 262.17(f).

* * * * *

■ 74. Section 265.75 is revised to read as follows:

§ 265.75 Biennial report.

The owner or operator must complete and submit EPA Form 8700–13 A/B to the Regional Administrator by March 1 of the following even numbered year and must cover activities during the previous year.

■ 75. Section 265.174 is revised to read as follows:

§ 265.174 Inspections.

At least weekly, the owner or operator must inspect areas where containers are stored. The owner or operator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See § 265.171 for remedial action required if deterioration or leaks are detected.

§ 265.195 [Amended]

■ 76. Section 265.195 is amended by removing and reserving paragraph (d).

§ 265.201 [Removed and reserved]

■ 77. Remove and reserve § 265.201.

■ 78. Section 265.1030 is amended by revising paragraphs (b)(2) and (3) to read as follows:

§ 265.1030 Applicability.

* * * * *

(b) * * *

(2) A unit (including a hazardous waste recycling unit) that is not exempt from permitting under the provisions of 40 CFR 262.17 (*i.e.,* a hazardous waste recycling unit that is not a 90-day tank or container) and that is located at a hazardous waste management facility otherwise subject to the permitting requirements of 40 CFR part 270, or

(3) A unit that is exempt from permitting under the provisions of 40 CFR 262.17 (*i.e.,* a ''90-day'' tank or container) and is not a recycling unit under the requirements of 40 CFR 261.6.

* * * * *

§ 265.1050 [Amended]

■ 79. Amend § 265.1050 by removing the text ''40 CFR 262.34(a)'' wherever it appears and adding in its place the text ''40 CFR 262.17''.

■ 80. Section 265.1101 is amended by revising paragraph (c)(4) to read as follows:

§ 265.1101 Design and operating standards.

* * * * *

(c) * * *

(4) Inspect and record in the facility's operating record at least once every seven days data gathered from monitoring and leak detection equipment as well as the containment building and the area immediately surrounding the containment building to detect signs of releases of hazardous waste.

* * * * *

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILTIES

■ 81. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

§ 266.80 [Amended]

■ 82. Amend § 266.80(a) by removing the text ''§ 262.12'' and adding the text ''§ 262.18'' in its place, seven times.

§ 266.255 [Amended]

■ 83. Amend § 266.255(a) by removing the text ''40 CFR 262.34'' and adding the text ''40 CFR 262.16 or 262.17'' in its place.

PART 267—STANDARDS FOR OWNERS AND OPERATORS OF FACILITIES OPERATING UNDER A STANDARDIZED PERMIT

■ 84. The authority citation for part 267 continues to read as follows:

Authority: 42 U.S.C. 6902, 6912(a), 6924–6926, and 6930.

§ 267.71 [Amended]

■ 85. Amend § 267.71(c) by removing the text ''§ 262.34'' wherever it appears and adding in its place the text ''§ 262.16 or 262.17''.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 86. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 87. Section 268.1 is amended by revising paragraph (e)(1) to read as follows:

§ 268.1 Purpose, scope, and applicability.

* * * * *

(e) * * *

(1) Waste generated by very small quantity generators, as defined in § 260.10 of this chapter;

* * * * *

■ 88. Section 268.7 is amended by revising paragraph (a)(5) introductory paragraph to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, treaters, and disposal facilities.

(a) * * *

(5) If a generator is managing and treating prohibited waste or contaminated soil in tanks, containers, or containment buildings regulated under 40 CFR 262.15, 262.16, and 262.17 to meet applicable LDR treatment standards found at § 268.40, the generator must develop and follow a written waste analysis plan which describes the procedures they will carry out to comply with the treatment standards. (Generators treating hazardous debris under the alternative treatment standards of Table 1 to § 268.45, however, are not subject to these waste analysis requirements.) The plan must be kept on site in the generator's records, and the following requirements must be met:

* * * * *

■ 89. Section 268.50 is amended by revising paragraph (a)(1) and (a)(2)(i) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(1) A generator stores such wastes in tanks, containers, or containment buildings on-site solely for the purpose of the accumulation of such quantities of hazardous waste as necessary to facilitate proper recovery, treatment, or disposal and the generator complies with the requirements in §§ 262.16 and 262.17 and parts 264 and 265 of this chapter.

(2) * * *

(i) Each container is clearly marked to identify its contents and with:

(A) The words ''Hazardous Waste'';

(B) The applicable EPA hazardous waste number(s) (EPA hazardous waste codes) in subparts C and D of part 261 of this chapter; or use a nationally recognized electronic system, such as bar coding, to identify the EPA hazardous waste number(s);

(C) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.,* ignitable, corrosive, reactive, toxic); hazard communication consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling) or subpart F (placarding); a hazard statement or pictogram consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1910.1200; or a chemical hazard label consistent with the National Fire Protection Association code 704); and

(D) The date each period of accumulation begins.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 90. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 91. Section 270.1 is amended by revising paragraphs (a)(3), (c)(2) introductory text, (c)(2)(i), and (c)(2)(iii) to read as follows:

§ 270.1 Purpose and scope of these regulations.

(a) * * *

(3) *Technical regulations.* The RCRA permit program has separate additional regulations that contain technical requirements. These separate regulations are used by permit issuing authorities to determine what requirements must be placed in permits if they are issued. These separate regulations are located in 40 CFR parts 264, 266, 267, and 268.

* * * * *

(c) * * *

(2) *Specific exclusions and exemptions.* The following persons are among those who are not required to obtain a RCRA permit:

(i) Generators who accumulate hazardous waste on site in compliance with all of the conditions for exemption provided in 40 CFR 262.14, 262.15, 262.16, and 262.17.

* * * * *

(iii) Persons who own or operate facilities solely for the treatment, storage, or disposal of hazardous waste excluded from regulations under this part by 40 CFR 261.4 or 262.14 (very small quantity generator exemption).

* * * * *

§ 270.42 [Amended]

■ 92. Section 270.42 is amended by removing and reserving paragraph (l) and the entries under O.1. in the table of appendix I to § 270.42.

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

■ 93. The authority citation for part 271 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), and 6926.

§ 271.10 [Amended]

■ 94. Amend § 271.10(c) by removing the text '' 262.34'' and adding in its place the text ''262.16 or 262.17''.

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 95. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 96. Section 273.8 is amended by revising the section heading and paragraph (a)(2) to read as follows:

§ 273.8 Applicability—household and very small quantity generator waste.

(a) * * *

(2) Very small quantity generator wastes that are exempt under § 262.14 of this chapter and are also of the same type as the universal wastes defined at § 273.9.

* * * * *

■ 97. Section 273.81 is amended by revising paragraph (b) to read as follows:

§ 273.81 Factors for petitions to include other wastes under 40 CFR part 273.

* * * * *

(b) The waste or category of waste is not exclusive to a specific industry or group of industries, is commonly generated by a wide variety of types of establishments (including, for example, households, retail and commercial businesses, office complexes, very small quantity generators, small businesses, government organizations, as well as large industrial facilities);

* * * * *

PART 279—STANDARDS FOR THE MANAGEMENT OF USED OIL

■ 98. The authority citation for part 279 continues to read as follows:

Authority: Sections 1006, 2002(a), 3001 through 3007, 3010, 3014, and 7004 of the Solid Waste Disposal Act, as amended (42 U.S.C. 6905, 6912(a), 6921 through 6927, 6930, 6934, and 6974); and sections 101(37) and 144(c) of CERCLA (42 U.S.C. 9601(37) and 9614(c)).

■ 99. Section 279.10 is amended by revising paragraph (b)(3) to read as follows:

§ 279.10 Applicability.

* * * * *

(b) * * *

(3) *Very small quantity generator hazardous waste.* Mixtures of used oil and very small quantity generator hazardous waste regulated under § 262.14 of this chapter are subject to regulation as used oil under this part.

* * * * *

[FR Doc. 2016–27429 Filed 11–25–16; 8:45 am]

BILLING CODE 6560–50–P

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[FR Doc. 2017–27805 Filed 12–22–17; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, and 262

[EPA–HQ–OLEM–2016–0492; FRL–9971–49–OLEM]

RIN 2050–AG90

Confidentiality Determinations for Hazardous Waste Export and Import Documents

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is amending existing regulations regarding the export and import of hazardous wastes from and into the United States. Specifically, this rule applies a confidentiality determination such that no person can assert confidential business information (CBI) claims for documents related to the export, import, and transit of hazardous waste and export of excluded cathode ray tubes (CRTs). EPA is making these changes to apply a consistent approach in addressing confidentiality claims for export and import documentation. The rule will result in cost-savings and greater efficiency for EPA and the regulated community as well as facilitate transparency with respect to the documents that are within the scope of this rulemaking. However, EPA is not finalizing the proposed internet posting requirement in the proposed rule.

DATES: The final rule is effective on June 26, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2016–0492. All documents in the docket are listed at *https://www.regulations.gov*. Docket materials are also available in hard copy at the EPA Docket Center Reading Room. Please see *https://www.epa.gov/dockets/epa-docket-center-reading-room* or call (202) 566–1744 for more information on the Docket Center Reading Room.

FOR FURTHER INFORMATION CONTACT: Lia Yohannes, Office of Resource Conservation and Recovery; telephone number: (703) 308–8413; email: *yohannes.lia@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What is the Agency's authority for taking this action?

EPA's authority to promulgate this rule is found in sections 1002, 2002(a), 3001–3004, and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), and as amended by the Hazardous and Solid Waste Amendments, 42 U.S.C. 6901 *et seq.,* 6912, 6921–6924, and 6938.

B. Does this action apply to me?

The application of confidentiality determinations to RCRA export, import, and transit documents in this action generally affects three (3) groups: (1) All persons who export or import (or arrange for the export or import of) of hazardous waste for recycling or disposal, including those hazardous wastes subject to the alternate management standards for (a) universal waste for recycling or disposal, (b) spent lead-acid batteries (SLABs) being shipped for reclamation, (c) industrial ethyl alcohol being shipped for reclamation, (d) hazardous waste samples of more than 25 kilograms being shipped for waste characterization or treatability studies, and (e) hazardous recyclable materials being shipped for precious metal recovery; (2) all recycling and disposal facilities who receive imports of such hazardous wastes for recycling or disposal; and (3) all persons who export (or arrange for the export of) conditionally excluded cathode ray tubes (CRTs) being shipped for recycling.

Potentially affected entities may include, but are not limited to:

NAICS code	NAICS description
211	Oil and Gas Extraction.
324	Petroleum and Coal Products Manufacturing.
325	Chemical Manufacturing.
326	Plastics and Rubber Products Manufacturing.
327	Nonmetallic Mineral Product Manufacturing.
331	Primary Metal Manufacturing.
332	Fabricated Metal Product Manufacturing.
333	Machinery Manufacturing.
334	Computer and Electronic Product Manufacturing.
335	Electrical Equipment, Appliance, and Component Manufacturing.
336	Transportation Equipment Manufacturing.
339	Miscellaneous Manufacturing.
423	Merchant Wholesalers, Durable Goods.
424	Merchant Wholesalers, Nondurable Goods.
522	Credit Intermediation and Related Activities.
525	Funds, Trusts, and Other Financial Vehicles.
531	Real Estate.
541	Professional, Scientific, and Technical Services.
561	Administrative and Support Services.
562	Waste Management and Remediation Services.
721	Accommodation.
813	Religious, Grantmaking, Civic, Professional, and Similar Organizations.
211	Oil and Gas Extraction.
324	Petroleum and Coal Products Manufacturing.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. If you have questions regarding the applicability of this rule to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

II. Background

On November 28, 2016, EPA proposed revisions to the current RCRA regulations governing imports and exports of hazardous waste and certain other materials in parts 260, 262, 264, 265, and 267 in order to strengthen public accessibility and transparency of import and export-related documentation to better monitor proper compliance with EPA's hazardous waste regulations and help ensure that hazardous waste shipments are properly received and disposed (81 FR 85459). The internet Posting of and Confidentiality Determinations for Hazardous Waste Export and Import Documents Proposed Rule was a companion action to EPA's Hazardous

Waste Export-Import Revisions Final Rule (''Revisions Final Rule'') published on November 28, 2016 (81 FR 85696), which was one of the Agency's priority actions under its plan for periodic retrospective reviews of existing regulations, as required by Executive Order 13563. Under the Revisions Final Rule, export notices for hazardous waste and excluded CRTs exported for recycling are currently required to be submitted electronically to EPA using EPA's Waste Import Export Tracking System (WIETS) as of December 31, 2016. Export annual reports for hazardous waste and excluded CRTs exported for recycling will be required to be submitted electronically to EPA using WIETS on March 1, 2019. Other import and export documents for hazardous waste and excluded CRTs exported for recycling are transitioning from paper submittal to electronic submittal, and will be required to be submitted electronically to EPA using WIETS on a future compliance date to be announced in a future, separate **Federal Register** notice.

The proposed rulemaking for this final action consisted of two parts. First, EPA proposed requiring exporters and receiving facilities of hazardous waste from foreign sources to post *confirmation of receipt* and *confirmation of recovery or disposal* documents on publicly accessible websites when such documents are required for individual export and import shipments of hazardous wastes. EPA proposed that the documents be publicly accessible on company websites by the first of March of each year and that the websites include all of the confirmations of receipt and confirmations of recovery or disposal received by the exporter or sent out by the receiving facility related to exports or imports of hazardous waste made during the previous calendar year. Each document was to be made available for a period of at least three years following the date on which each document was first posted to the website. The proposed internet posting requirement was planned to be effective during the interim period prior to the electronic import-export reporting compliance date when electronic submittal to EPA of confirmations of receipt and confirmations of recovery or disposal for hazardous waste shipments will be required in EPA's WIETS system per the Revisions Final Rule. The second part of the proposed rule consisted of applying confidentiality determinations such that no person could assert CBI claims for individual documents and compiled data for required documents related to the export, import, and transit of hazardous waste and export of conditionally excluded cathode ray tubes (CRTs).

III. Detailed Discussion of the Final Rule

A. Summary of the Final Rule

This section provides an overview of this final rule and describes the way in which it differs from the proposal. With this action, EPA finalizes the application of confidentiality determinations such that no CBI claims may be asserted by any person with respect to any of the following documents related to the export, import, and transit of hazardous waste and export of excluded CRTs:

(1) Documents related to the export of Resource Conservation and Recovery Act (RCRA) hazardous waste under 40 CFR part 262, subpart H, including but not limited to the notifications of intent to export, contracts submitted in response to requests for supplemental information from countries of import or transit, RCRA manifests, annual reports, EPA acknowledgements of consent, any subsequent communication withdrawing a prior consent or objection, responses that neither consent nor object, exception reports, transit notifications, and renotifications;

(2) Documents related to the import of hazardous waste, under 40 CFR part 262, subpart H, including but not limited to contracts and notifications of intent to import hazardous waste into the U.S. from foreign countries or U.S. importers;

(3) Documents related to the confirmation of receipt and confirmation of recovery or disposal of hazardous waste exports and imports, under 40 CFR part 262, subpart H;

(4) Documents related to the transit of hazardous waste, under 40 CFR part 262, subpart H, including notifications from U.S. exporters of intent to transit through foreign countries, or notifications from foreign countries of intent to transit through the U.S.;

(5) Documents related to the export of cathode ray tubes (CRTs), under 40 CFR part 261, subpart E, including but not limited to notifications of intent to export CRTs;

(6) Documents related to the export and import of non-crushed spent lead acid batteries (SLABs) with intact casings, under 40 CFR part 266 subpart G, including but not limited to notifications of intent to export SLABs;

(7) Submissions from transporters under 40 CFR part 263, or from treatment, storage or disposal facilities under 40 CFR parts 264 and 265, related to exports or imports of hazardous waste, including but not limited to receiving facility notices of the need to arrange alternate management or return of an import shipment under 40 CFR 264.12(a) and 265.12(a); and

(8) Documents related to the export and import of RCRA universal waste under 40 CFR part 273, subparts B, C, D, and F.

(9) Documents required under 40 CFR 262, subparts E, F, and H and submitted in accordance with consents issued prior to December 31, 2016.

Unless otherwise required by Federal law, EPA is not considering the documents described in items (1) through (9) in this preamble to be final until March 1 of the year after which the shipments occur.

These changes will be reflected in revisions to 40 CFR part 260, as proposed, and in conforming revisions to 40 CFR parts 261 and 262.

EPA is not finalizing the proposed internet posting requirement of *confirmation of receipt* and *confirmation of recovery or disposal* documents where they would have been required for individual export and import shipments of hazardous wastes. As required under the recordkeeping requirements for exports and imports of hazardous waste under 40 CFR part 262, subpart H, exporters and receiving facilities of hazardous waste from foreign sources are required to retain paper copies of such confirmations such that copies are available for viewing and production if requested by any EPA or authorized state inspector. Once electronic submittals of the confirmation documents are required after the electronic import-export reporting compliance date that EPA will establish in a separate **Federal Register** notice, electronically submitted confirmations can be retained in EPA's Waste Import Export Tracking System (WIETS), or its successor system, such that copies are available for viewing and production if requested by any EPA or authorized state inspector.

B. Summary of Public Comments

The Agency received seven unique comments in response to its November 28, 2016 proposed rule. Of the seven comments, two were submitted anonymously, two were submitted from individual companies, one was submitted by a trade association representing hazardous waste treatment, recycling and disposal companies, one was submitted by a coalition representing generators of hazardous waste, and one was submitted by a trade association representing fuel and petrochemical manufacturers.

With respect to the proposed internet posting requirement, two anonymous commenters expressed their support, stating that it would improve transparency and environmental awareness of the potential environmental and health risks associated with exposure to hazardous waste, and potentially lead to reduced generation and improved management of hazardous waste. The remaining five commenters from industry expressed concern with the proposed internet posting requirement. These commenters stated that EPA underestimated the costs associated with posting information on company websites and were apprehensive about the burden of complying with a temporary requirement that would be in place for an unspecified amount of time. Two commenters suggested that the lag in time between when the confirmations of receipt and confirmations of recovery or disposal are required to be sent and when the documents would be posted on company websites would cause confusion and an incorrect perception by the general public of mismanagement. Two commenters also suggested that requiring industry to submit export and import documentation to EPA, rather than post on individual company websites, would provide better consistency to the regulated community and ensure greater compliance with export and import regulations. Finally, one commenter suggested that EPA develop its own website to post the documents to improve public access to the information. (See Section ''II.C. Changes to the Proposed Rule'' of this preamble for EPA's rationale for not finalizing the proposed internet posting requirement.)

EPA received only one comment on the proposed confidentiality determination. The commenter expressed concerns about the application of a confidentiality determination to aggregate data related to exports and imports of hazardous waste. EPA considers aggregate data to be a list of consolidated information about shipments organized by company. According to the commenter, the application of a confidentiality determination to aggregate data poses different concerns from those raised by application of confidentiality determinations to individual documents. The commenter was specifically concerned about the potential for competitive harm from public release of customer lists and issues related to national security if aggregate data about shipments were available to individuals with the intent to do harm. Because of the substantial effort required to compile a customer list from individual export and import documents, the commenter did not have similar concerns with respect to the release of individual hazardous waste export and import documents. (See response to comments document and Section ''II.D. Rationale for Final Rule'' of this preamble for details on EPA's response to these comments.)

C. Changes to the Proposed Rule

After considering all the submitted comments, EPA is finalizing, as proposed, the application of confidentiality determinations to documents related to the export, import and transit of hazardous waste and export of excluded CRTs. We provide our rationale in the following section. EPA is not finalizing the proposed internet posting requirement that exporters and receiving facilities of hazardous waste from foreign sources upload confirmations of receipt and confirmations of recovery or disposal on their websites. This internet posting requirement was intended to be in effect on a temporary basis while EPA develops its Waste Import Export Tracking System (WIETS) to be able to receive electronic submittals of the documents. Recognizing that the internet posting requirement would be superseded when exporters and receiving facilities are required to submit confirmations electronically, EPA has decided to avoid the potential confusion as described by some commenters, that may result from requiring internet posting of documents on a temporary basis on company websites and from the time lag between the receipt and posting of confirmations of receipt and confirmations of recovery or disposal.

D. Rationale for the Final Rule

This final rule applies confidentiality determinations such that EPA will no longer accept future CBI claims for individual documents and/or aggregate data related to the export, import, and transit of hazardous waste and export of excluded CRTs. EPA is making these changes to apply a consistent approach in addressing confidentiality claims for export and import documentation which will result in cost-savings and greater efficiency for EPA and the regulated community. Moreover, as described in the proposed rulemaking, EPA will no longer publish the annual **Federal Register** notice requesting comment from third party affected businesses (other than original submitters), as defined in 40 CFR 2.201(d), on their need to assert confidentiality claims for documents submitted to EPA related to hazardous waste exports and imports as well as data compiled from such documents, prior to EPA considering such documents releasable upon public request. The **Federal Register** notice covers documents related to the export, import and transit of RCRA hazardous waste, including those hazardous wastes managed under the special management standards in 40 CFR part 266 (*e.g.,* spent lead acid batteries) and 40 CFR part 273 (*e.g.,* universal waste batteries, universal waste mercury lamps), and related to the export of CRTs under 40 CFR part 261, made during the previous calendar year. The annual **Federal Register** notices have not addressed CBI claims likely to be made by the original submitters, since RCRA regulations at 40 CFR 260.2(b) already address the CBI requirements for original submitters.

Our rationale for applying confidentiality determinations to these documents is summarized in the following paragraphs.

As discussed in the proposed rulemaking, application of confidentiality determinations is consistent with the non-CBI treatment of hazardous waste manifests at the Federal and state level. Manifests contain similar information as that required by the documents related to the export, import and transit of hazardous waste and export of conditionally excluded CRTs within the scope of this action. On February 7, 2014, EPA published the Hazardous Waste Management System; Modification of the Hazardous Waste Manifest System; Electronic Manifests final rule (79 FR 7518) which made a categorical determination for individual RCRA hazardous waste manifest records and aggregate data. In that action, EPA concluded that information contained in individual manifested records and aggregate data are essentially public information and therefore is not eligible under Federal law for treatment as CBI. The effect of this decision was that EPA made a categorical determination that it will not accept any CBI claims that might be asserted in connection with processing, using, or retaining individual paper or electronic manifests or aggregate data (see 40 CFR 260.2(c)(1)). The decision in that action is consistent with how manifests are treated in many states that have policies that do not recognize CBI claims for manifests as individual documents or as aggregate data. Because the information contained in RCRA hazardous waste manifests is largely similar to the information contained in hazardous waste export and import documents,

such as information about the waste being shipped (waste codes, type, quantity) and contact information for the generator, transporter, and destination or receiving facility, EPA concludes that application of confidentiality determinations in this action is consistent with the categorical determination that electronic manifests are not CBI.

Furthermore, EPA believes that any CBI claim that might be asserted with respect to the hazardous waste documents within the scope of this action would be extremely difficult to sustain under the substantive CBI criteria set forth in the Agency's CBI regulations (40 CFR part 2, subpart B). For example, to make a CBI claim, a business must satisfactorily show that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures. The documents related to the export, import, and transit of hazardous waste and export of excluded CRTs submitted to EPA are also shared with several commercial entities while they are being processed and used. As a result, a business concerned with protecting its commercial information would find it exceedingly difficult to protect its records from disclosure by all the other persons who come into contact with the documents.

Moreover, to substantiate a CBI claim, a business must also show that the information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding). Since the documents are shared with several commercial entities throughout the chain of custody of a hazardous waste shipment, they are easily accessible to other parties without the business's explicit consent.

For these reasons, EPA believes that any CBI claim that might be asserted with respect to hazardous waste export and import documents would be difficult to sustain under the substantive CBI criteria (40 CFR part 2, subpart B).

EPA has also established precedent in determining that the information contained in certain hazardous waste export documents is not entitled to confidential treatment. To date, our records indicate that EPA has received four assertions of confidentiality for documents within the scope of this action and for which EPA has made a CBI determination: One from Horizon Environment, Inc. in 2004, two from Johnson Controls Battery Group, Inc. in 2010 and 2011, and one from Waste Technologies Industries in 1994. In three of the four cases, the Agency determined that the information claimed as confidential was not entitled to confidential treatment.

In the confidentiality claims presented by Horizon Environment, Inc. and Johnson Controls Battery Group, Inc., both companies asserted confidentiality for certain hazardous waste export documents that were responsive to Freedom of Information Act (FOIA) requests to EPA. The FOIA, 5 U.S.C. 552(a), section 3007(b) of RCRA, and EPA regulations implementing the FOIA and RCRA section 3007(b) generally mandate the disclosure to the public of information and records in the possession of government agencies. However, there are nine categories of information that may be exempt from disclosure, and one such category of information (Exemption 4) is for ''trade secrets and commercial information obtained from a person and privileged or confidential'' (see 5 U.S.C. 552(b)(4)). Under these statutes and regulations, ''business information'' means information which pertains to the interests of a business, was acquired or developed by the business, and which is possessed by EPA in a recorded form (see 40 CFR 2.201(c)). Such business information may be claimed by an ''affected business'' to be entitled to treatment as CBI if the business information is a ''trade secret'' or other type of proprietary information which produces business or competitive advantages for the business, such that the business has a legally protected right to limit the use of the information or its disclosure to others. See § 2.201(e).

In order for information to meet the requirements of Exemption 4, EPA must find that the information is either (1) a trade secret; or (2) commercial or financial information obtained from a person and privileged or confidential (commonly referred to as ''Confidential Business Information'' (CBI)). Horizon Environment's claims related to export notices, and Johnson Controls Battery Group's claims related to annual reports. Both companies claimed the information to be confidential, but did not claim that the information was privileged. Information that is required to be submitted to the Government is confidential if its ''disclosure would be likely either (1) to impair the Government' s ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.''' Critical Mass, 975 F.2d at 878 (quoting *National Parks and Conservation Association* v. *Morton,* 498 F.2d 765, 770 (DC Cir. 1974)) (footnote omitted). In these cases, the Agency had the authority to require the submission of the information and exercised it. Therefore, EPA concluded that the information was a required submission and was not voluntary.

EPA also found that the information the companies claimed as confidential did not meet EPA's CBI criteria. As set forth in EPA's regulations at 40 CFR 2.208, required business information is entitled to confidential treatment if: The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position. After careful consideration of the arguments submitted by both companies, EPA concluded that neither claim explained specifically how disclosure of the information in the submissions would likely cause substantial competitive harm to the companies, and therefore did not support the claim of competitive harm. Accordingly, EPA concluded that release of this was not likely to cause substantial harm to the companies' competitive positions.

As a result of these analyses, EPA found that the information the companies claimed as confidential was not within the scope of Exemption 4 of the FOIA.

For the fourth confidentiality claim submitted by Waste Technologies Industries in 1994, EPA determined that the identities and addresses of the foreign generators listed in its import notification letters were entitled to confidential treatment under EPA's criteria (40 CFR 2.208). Since that time, EPA promulgated the Electronic Manifest final rule in which it was determined that manifests and the data contained therein are not CBI (79 FR 7518). Because the contact information of foreign generators is a required data element on manifests, this information is no longer treated as confidential. EPA found the record pertaining to this case after the proposed rule was published.

Based on EPA's analysis and decision in three of the four confidentiality claims asserted by companies for their hazardous waste export notices and annual reports, EPA expects to similarly conclude that these and the other documents within the scope of this rulemaking are not entitled to confidential treatment. As for the fourth decision in the Waste Technologies Industries' claim, EPA's more recent determination that manifests are no longer CBI supersedes the decision to withhold the information as confidential in 1994.

Finally, EPA has never received a claim of confidentiality from a third-party business with respect to hazardous waste export and import documentation. As described previously, EPA issues a **Federal Register** notice each year requesting comment from affected businesses (other than original submitters), as defined in 40 CFR 2.201(d), on their need to assert confidentiality claims for documents submitted to EPA related to hazardous waste exports and imports as well as data compiled from such documents, prior to EPA considering such documents releasable upon public request. To date, EPA has never received a comment from any business not an original submitter as a result of the annual **Federal Register** notice.

EPA received one comment in response to our request for input about applying confidentiality determinations to individual documents and aggregate data related to hazardous waste export and import shipments. In its comment, a trade association for the hazardous waste treatment industry expressed concern about the ability of competitors to gain an unfair advantage from access to aggregate export and import data. The commenter also indicated that access to aggregate data could pose national security concerns if sensitive shipment information were available to parties with malicious intent. The commenter stated that aggregate shipment data are a more efficient means to gain access to customer lists and export and import patterns compared to individual documents, which would require significant cost and labor to compile. However, as stated previously, at the Federal level and in many states, CBI claims are not accepted with respect to individual or aggregate manifest data. The main difference between the manifest and the export and import documents is that the manifest provides information on domestic management of hazardous waste shipments, while the export and import documents provide information related to both the domestic and the international part of those shipments. Because the information contained in hazardous waste export and import documents is so similar to that contained in manifests, EPA believes that it is appropriate to treat the domestic and international shipping documents the same.

Nonetheless, while EPA is not accepting CBI claims for either individual documents or aggregate data related to exports and imports, EPA recognizes that the information in its possession may not be ready for general release to the public because it is not yet ''final.'' As with manifests, hazardous waste exporters, importers, receiving facilities and brokers acting on their behalf need sufficient time to address discrepancies or exceptions related to hazardous waste shipments and to verify and correct data recorded on their documents. Until such time as these corrections can be made and data can be verified and finalized, the data in these documents, just as in manifests, will be considered ''in process.'' To that end, unless otherwise required by Federal law, EPA is not considering such documents to be final until March 1 of the year after which the shipments occur. EPA believes this timeframe is responsive to the concerns about competitive harm and national security risk with respect to access to aggregate data. EPA believes that this relatively long timeframe also makes it more likely that the shipment will have been received and the waste recovered or disposed by the time the documents are considered final.

Furthermore, in response to the national security concerns raised by commenters on the proposed rule and on the e-manifest user fee proposed rule (81 FR 49072, July 26, 2016), EPA has consulted with the Department of Homeland Security (DHS) to determine whether public access to certain shipment information in the e-Manifest system poses a significant chemical security risk and if so, the action the Agency should take to mitigate that risk. Because the export and import data are similar to the data collected on manifests, EPA will apply mitigating measures to manage export and import data in a manner consistent with those implemented by the e-Manifest system.

III. Costs and Benefits of the Final Rule

A. Cost Impacts

The Agency conducted an economic assessment for the proposed rule to this action which evaluated costs, cost savings, benefits, and other impacts, such as environmental justice, children's health, unfunded mandates, regulatory takings, and small entity impacts. The costs incurred by the regulated community under the proposed rule were associated with the proposed internet posting requirement only. Because EPA is not finalizing the proposed internet posting requirement, there are no costs associated with this action and the economic assessment conducted for the proposed rule no longer applies. Rather, the final rule reduces burden and results in cost-savings.

B. Benefits

There are a number of qualitative benefits associated with this final rule. By providing a consistent approach to addressing confidentiality claims with respect to the documents within the scope of this rulemaking, this action will result in cost-savings and greater efficiency to both the regulated community and EPA. The Agency will not incur the costs associated with developing and publishing the annual **Federal Register** notice requesting comment from affected businesses (other than original submitters), as defined in 40 CFR 2.201(d), on their need to assert confidentiality claims for documents submitted to EPA related to hazardous waste exports and imports. Industry cost-savings result from the avoided costs associated with reading and responding to the **Federal Register** notice. Furthermore, this action will achieve greater transparency by excluding export and import documents from CBI claims.

IV. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer their own hazardous waste programs in lieu of the Federal program within the State. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271. Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent Federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new Federal requirements did not take effect in an authorized State until the State adopted the Federal requirements as State law.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. EPA is directed by

the statute to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA related provisions as State law to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their programs only when EPA enacts Federal requirements that are more stringent or broader in scope than existing Federal requirements. RCRA section 3009 allows the States to impose standards more stringent than those in the Federal program (see also 40 CFR 271.1). Therefore, authorized States may, but are not required to, adopt Federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous Federal regulations.

B. Effect on State Authorization

Because of the Federal government's special role in matters of foreign policy, EPA does not authorize States to administer Federal import/export functions in any section of the RCRA hazardous waste regulations. This approach of having Federal, rather than State, administering of the import/export functions promotes national coordination, uniformity and the expeditious transmission of information between the United States and foreign countries.

Although States do not receive authorization to administer the Federal government's import/export functions in 40 CFR part 262, subpart H, or the import/export relation functions in any other section of the RCRA hazardous waste regulations, State programs are still required to adopt the provisions in this rule to maintain their equivalency with the Federal program (see 40 CFR 271.10(e)).

This final rule contains amendments to 40 CFR 260.2 such that no claim of business confidentiality may be asserted by any person with respect to information from cathode ray tube export documents prepared, used and submitted under §§ 261.39(a)(5) and 261.41(a) and hazardous waste export, import, and transit documents prepared, used and submitted under §§ 262.82, 262.83, 262.84, 263.20, 264.12, 264.71, 265.12, 265.71, and 267.71.

The States that have previously adopted 40 CFR part 262, subparts E, F and H, 40 CFR part 263, 40 CFR part 264, 40 CFR part 265, and any other import/export related regulations, and that will be adopting the revisions in the Hazardous Waste Export-Import Revisions Final Rule (81 FR 85696) must adopt the revisions to those provisions in this final rule. But only States that have previously adopted the optional CRT conditional exclusion in 40 CFR 261.39 are required to adopt the revisions related to that exclusion in this final rule.

When a State adopts the import/export provisions in this rule, they must not replace Federal or international references or terms with State references or terms.

The provisions of this rule will take effect in all States on the effective date of the rule, since these export and import requirements will be administered by the Federal government as a foreign policy matter, and will not be administered by States.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This final rule is a non-significant regulatory action because it does not have a significant economic impact nor does it raise novel legal or policy issues. The Office of Management and Budget (OMB) waived review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. This final rule provides burden reduction by providing a consistent approach to addressing confidentiality claims with respect to the documents within the scope of this rulemaking. As a result, this action will result in cost-savings and greater efficiency for industry and EPA. EPA will no longer expend resources to publish an annual **Federal Register** notice related to confidential business information and industry will avoid the costs and burden associated with reading and responding to the annual **Federal Register** notice.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because it does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

EPA certifies that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. The small entities subject to the requirements of this action are hazardous waste exporters, importers, receiving facilities and brokers acting on their behalf. There are no costs associated with this action; rather, the final rule results in cost-savings. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. Thus, it is not subject to Sections 202, 203, and 205 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

F. Executive Order 13132: Federalism

This action does not have federalism implications because the state and local governments do not administer the export and import requirements under RCRA. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. No exporters, importers or transporters affected by this action are known to be owned by Tribal governments or located within or adjacent to Tribal lands. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994), because this action only applies a confidentiality determination such that no person can assert confidential business information (CBI) claims for documents related to the export, import, and transit of hazardous waste and export of excluded cathode ray tubes (CRTs).

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 260

Environmental protection, Cathode ray tubes (CRTs), Confidential business information, Exports, Hazardous waste, Imports, Reporting and recordkeeping requirements.

40 CFR Part 261

Environmental protection, Cathode ray tubes (CRTs), Confidential business information, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Confidential business information, Exports, Hazardous waste, Imports, Reporting and recordkeeping requirements.

Dated: December 11, 2017.

E. Scott Pruitt,

Administrator.

For the reasons stated in the preamble, EPA amends 40 CFR parts 260, 261, and 262 as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

■ 2. Amend § 260.2 by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 260.2 Availability of information; confidentiality of information.

* * * * *

(b) Except as provided under paragraphs (c) and (d) of this section, any person who submits information to EPA in accordance with parts 260 through 266 and 268 of this chapter may assert a claim of business confidentiality covering part or all of that information by following the procedures set forth in § 2.203(b) of this chapter. Information covered by such a claim will be disclosed by EPA only to the extent, and by means of the procedures, set forth in part 2, subpart B, of this chapter.

* * * * *

(d)(1) After June 26, 2018, no claim of business confidentiality may be asserted by any person with respect to information contained in cathode ray tube export documents prepared, used and submitted under §§ 261.39(a)(5) and 261.41(a) of this chapter, and with respect to information contained in hazardous waste export, import, and transit documents prepared, used and submitted under §§ 262.82, 262.83, 262.84, 263.20, 264.12, 264.71, 265.12, 265.71, and 267.71 of this chapter, whether submitted electronically into EPA's Waste Import Export Tracking System or in paper format.

(2) EPA will make any cathode ray tube export documents prepared, used and submitted under §§ 261.39(a)(5) and 261.41(a) of this chapter, and any hazardous waste export, import, and transit documents prepared, used and submitted under §§ 262.82, 262.83, 262.84, 263.20, 264.12, 264.71, 265.12, 265.71, and 267.71 of this chapter available to the public under this section when these electronic or paper documents are considered by EPA to be final documents. These submitted electronic and paper documents related to hazardous waste exports, imports and transits and cathode ray tube exports are considered by EPA to be final documents on March 1 of the calendar year after the related cathode ray tube exports or hazardous waste exports, imports, or transits occur.

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 3. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 4. Amend § 261.39 by revising paragraph (a)(5)(iv) to read as follows:

§ 261.39 Conditional Exclusion for Used, Broken Cathode Ray Tubes (CRTs) and Processed CRT Glass Undergoing Recycling.

* * * * *

(a) * * *

(5) * * *

(iv) EPA will provide a complete notification to the receiving country and any transit countries. A notification is complete when EPA receives a notification which EPA determines satisfies the requirements of paragraph (a)(5)(i) of this section.

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C 6906, 6912, 6922–6925, 6937, and 6938.

■ 6. Amend § 262.83 by revising paragraphs (b)(5) and (f)(9) to read as follows:

§ 262.83 Exports of hazardous waste.

* * * * *

(b) * * *

(5) For cases where the proposed country of import and recovery or disposal operations are not covered under an international agreement to which both the United States and the country of import are parties, EPA will coordinate with the Department of State to provide the complete notification to country of import and any countries of transit. In all other cases, EPA will provide the notification directly to the country of import and any countries of transit. A notification is complete when EPA receives a notification which EPA determines satisfies the requirements of paragraphs (b)(1)(i) through (xiii) of this section.

* * * * *

(f) * * *

(9) Upon request by EPA, U.S. exporters, importers, or recovery facilities must submit to EPA copies of

contracts, chain of contracts, or equivalent arrangements (when the movement occurs between parties controlled by the same corporate or legal entity).

* * * * *

■ 7. Amend § 262.84 by revising paragraphs (b)(4) and (f)(8) to read as follows:

§ 262.84 Imports of hazardous waste.

* * * * *

(b) * * *

(4) A notification is complete when EPA determines the notification satisfies the requirements of paragraphs (b)(1)(i) through (xiii) of this section.

* * * * *

(f) * * *

(8) Upon request by EPA, importers or disposal or recovery facilities must submit to EPA copies of contracts, chain of contracts, or equivalent arrangements (when the movement occurs between parties controlled by the same corporate or legal entity).

* * * * *

[FR Doc. 2017–27525 Filed 12–22–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1987–0002; FRL–9972–38–Region 3]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the C&D Recycling Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) Region III is publishing a direct final Notice of Deletion of the C&D Recycling Superfund Site (Site), located in Foster Township, Pennsylvania, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the Commonwealth of Pennsylvania (Commonwealth), through the Pennsylvania Department of Environmental Protection (PADEP), because EPA has determined that all appropriate response actions under CERCLA have been completed. However, this deletion does not preclude EPA from taking future actions at the Site under Superfund.

DATES: This direct final deletion is effective February 26, 2018 unless EPA receives adverse comments by January 25, 2018. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–SFUND–1987–0002 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Gregory Voigt, Remedial Project Manager, U.S. Environmental Protection Agency, Region III, Mail Code 3HS21, 1650 Arch Street, Philadelphia, PA 19013, (215) 814–5737, email: *voigt.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA Region III is publishing this direct final Notice of Deletion of the C&D Recycling Superfund Site, from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR part 300, which is the Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in § 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed remedial actions if future conditions warrant such actions.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Site and demonstrates how it meets the deletion criteria. Section V discusses EPA's action to delete the Site from the NPL unless adverse comments are received during the public comment period.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the state, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to deletion of the Site:

(1) EPA consulted with the Commonwealth prior to developing this direct final Notice of Deletion and the Notice of Intent to Delete co-published

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 262, 263, 264, 265, and 271

[EPA–HQ–OLEM–2016–0177; FRL–9965–27–OLEM]

RIN 2050–AG80

Hazardous Waste Management System; User Fees for the Electronic Hazardous Waste Manifest System and Amendments to Manifest Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is establishing by this regulation the methodology the Agency will use to determine and revise the user fees applicable to the electronic and paper manifests to be submitted to the national electronic manifest system (e-Manifest system) that EPA is developing under the Hazardous Waste Electronic Manifest Establishment Act. After the e-Manifest system's implementation date, certain users of the hazardous waste manifest will be required to pay a prescribed fee for each electronic and paper manifest they use and submit to the national system so that EPA can recover the costs of developing and operating the national e-Manifest system. This final rule also announces the date when EPA expects the system to be operational and available to users. EPA will begin accepting manifest submissions and collecting the corresponding manifest submission fees on this date.

In addition, this action announces final decisions and regulations relating to several non-fee related matters that were included in the proposed rule. This includes modifying the existing regulations to: allow changes to the transporters designated on a manifest while the shipment is en route; describe how data corrections may be made to existing manifest records in the system; and amend the previous e-Manifest regulation (the One Year Rule) to allow the use, in certain instances, of a mixed paper and electronic manifest to track a hazardous waste shipment.

DATES: This final rule is effective on June 30, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OLEM–2016–0177. All documents in this docket are listed in the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically at *www.regulations.gov* or in hard copy at the EPA Docket Center Reading Room. Please see *https://www.epa.gov/dockets/epa-docket-center-reading-room* or call (202) 566–1744 for more information on the Docket Center Reading Room.

FOR FURTHER INFORMATION CONTACT: Richard LaShier, Office of Resource Conservation and Recovery, (703) 308–8796, *lashier.rich@epa.gov,* or Bryan Groce, Office of Resource Conservation and Recovery, (703) 308–8750, *groce.bryan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This rule affects those entities required to use the hazardous waste manifest, a regulated universe that includes approximately 80,000 federally regulated entities, and an equal or greater number of entities handling state-only regulated wastes in at least 45 industries and is expected to result in a net cost savings for them amounting to $66 million per year, when discounted at 7% and annualized over 6 years. Further information on the economic effects of this action can be found in section IV of this preamble. These industries are involved in generating, transporting, and receiving several million tons annually of wastes that are hazardous under Subtitle C of the Resource Conservation and Recovery Act (RCRA), or, are regulated by states and also are subject to tracking with the RCRA hazardous waste manifest. EPA estimates that these entities currently use between three and five million hazardous waste manifests (EPA Form 8700–22) and continuation sheets (EPA Form 8700–22A) to track RCRA hazardous and state-only regulated wastes from generation sites to off-site receiving facilities. The affected entities include hazardous waste generators, hazardous waste transporters, and owners or operators of treatment, storage, and disposal facilities (TSDFs), as well as the corresponding entities that handle state-only regulated wastes subject to tracking with the RCRA manifest.

However, the user fee obligations that are the primary focus of this final rule will mostly affect a subset of these regulated entities, particularly, the several hundred commercial RCRA TSDFs and the corresponding receiving facilities for state-only regulated wastes under RCRA manifests. As explained in section III.A. of this preamble, this final rule focuses the payment and collection of e-Manifest related user fees on these several hundred commercial TSDFs and state-only waste receiving facilities because EPA concludes that this is the most effective and efficient means for collecting user fees via the e-Manifest system. The final rule action includes a tentative fee schedule for the initial two years of system operations, based on the most current projections of program costs available to the Agency at the time of development of this final rule action. EPA will update the tentative fee schedule with a final fee schedule for the initial two years of system operations when we obtain more complete program cost data, and we will publish the final fee schedule to the e-Manifest program's website 90 days prior to the system launch. The affected entities and categories include, but are not necessarily limited to:

NAICS description	NAICS code	Examples of potentially affected entities
Transportation and Warehousing	48–49	Transportation of hazardous waste.
Waste Management and Remediation Services	562	Facilities that manage hazardous waste.

This table provides a guide for readers regarding the entities that will be regulated by this action. The table lists the types of entities that EPA is aware to be involved in the activities affected by the RCRA manifest and regulated by this action. Other types of entities not listed in this table also could be regulated by this final rule. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in title 40 of the CFR parts 260, 262, 263, 264, and 265. If you have questions regarding the applicability of this action to a particular entity, consult the persons listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the Agency taking?

The Agency is publishing its final rule action announcing requirements that establish the methodology and process that EPA will use to determine and revise the e-Manifest user fees that EPA has determined to be necessary to recover the costs of developing and operating the national e-Manifest system. These include the costs of processing data from both electronic and paper manifests that will be submitted to the national e-Manifest system after the system's implementation date. The Agency also is announcing final decisions on several non-fee related proposals that affect the use of the manifest and manifest data quality, including changes to designated transporters during transportation, a process for manifest data corrections, and the circumstances under which EPA will allow a ''hybrid'' or mixed paper/electronic manifest to be used to track a specific shipment.

C. What is the Agency's authority for taking this action?

The authority to issue this rule is found in sections 1002, 2002(a), 3001–3004, and 3017 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), and as amended by the Hazardous and Solid Waste Amendments, 42 U.S.C. 6901, 6906 *et. seq.,* 6912, 6921–6925, 6937, and 6938, and as further amended by the Hazardous Waste Electronic Manifest Establishment Act, Public Law 112–195, section 6939g.

D. Effective Date

This final rule will be effective on June 30, 2018, the date on which EPA plans to launch and begin the operation of the e-Manifest system. This is the date when EPA will implement all e-Manifest Act regulations, including the requirements of this final rule, and the requirements of the One Year Rule that EPA issued on February 7, 2014. This final rule is being published with an accelerated effective date to coincide with the launch of the e-Manifest system on June 30, 2018. On that date, EPA will begin collecting fees to recover the costs of developing and operating the system.

Under 40 CFR 3.2(a)(2), electronic reporting of documents required under title 40 of the Code of Federal Regulations (CFR) may occur after EPA has first published a document in the **Federal Register** announcing that EPA is prepared to receive, in electronic form, documents required or permitted by the identified part or subpart of title 40. By this final rule action, EPA is announcing that it is prepared to receive electronic hazardous waste manifests, as well as certain paper manifest copies that continue in use after the e-Manifest system's implementation date, through the national e-Manifest system. The electronic manifests will be accepted by e-Manifest as the electronic document substitutes for the paper manifest and continuation sheet forms (EPA Forms 8700–22 and 8700–22A) that are described in 40 CFR part 262, subpart B (hazardous waste generators), 40 CFR part 263, subpart B (hazardous waste transporters), and subpart E of 40 CFR parts 264 and 265 (owners and operators of hazardous waste treatment, storage, and disposal facilities). The implementation and compliance date on which EPA plans to begin receiving these electronic manifest and related paper manifest copies is June 30, 2018. This is the date that EPA expects to begin e-Manifest system operations, and begin both the collection of manifests and the collection of user fees for manifest submissions required under this final rule. EPA is also clarifying that the June 30, 2018, implementation date for e-Manifest is limited to the collection of domestic hazardous waste manifests and domestic shipments of state-only regulated waste subject under state law to the RCRA manifest. EPA will not begin the collection of export manifests described in subpart H of 40 CFR part 262 on the June 30, 2018, e-Manifest system implementation date. EPA will announce the implementation and compliance date for the electronic submission of export manifests in a separate notice to be issued in the future, when EPA is ready to collect those documents electronically and assess the appropriate fee for their processing. Until that occurs, export manifests should continue to be completed as paper documents.

II. Background

EPA published a detailed background discussion providing context for the e-Manifest User Fee rulemaking in the proposed rulemaking action. *See* 81 FR 49072 at 49074–76 (July 26, 2016). EPA incorporates that detailed background discussion into this document for purposes of this final rule, and refers readers to that proposed rulemaking rather than reprinting all of it in this final rule document. For this action, EPA will summarize key points from the earlier background discussion:

- In 2012, Congress enacted the Hazardous Waste Electronic Manifest Establishment Act (e-Manifest Act). The e-Manifest Act required EPA to establish a national electronic manifest system, the development of which would be initially funded by annual appropriations, and ultimately funded by user fees, which would both offset the system's development costs, as well as the costs of operating, maintaining, and upgrading the system.
- The e-Manifest Act further required EPA to develop implementing regulations for electronic manifesting within one year of enactment, and to establish a nine-member System Advisory Board to make recommendations to EPA on the performance of the system.
- Section 2(c) of the e-Manifest Act conferred broad discretion to EPA to impose on users of the system ''such reasonable service fees as the Administrator determines to be necessary'' to pay all system related costs, including the costs of processing data from any paper manifests that continue to be used after the system implementation date, as the e-Manifest Act allows users the option to continue to use paper manifests. This is the principal source of statutory authority for this action and its user fee methodology.
- Section 2(d) of the e-Manifest Act authorized the establishment of a special System Fund in the U.S. Treasury for the deposit of e-Manifest user fees. Funds deposited in the System Fund may be spent by EPA for system related costs to the extent provided in annual appropriations acts, but such funds can only be spent on e-Manifest related costs.
- EPA issued its first implementing regulation on electronic manifesting on February 7, 2014 (79 FR 7518–7563). This regulation, referred to as the ''One Year Rule'' because of the e-Manifest Act's mandate to publish the regulation within one year of enactment, established the legal and policy framework for the use of electronic manifests, and prescribed the conditions under which electronic manifests are the full legal equivalent of paper manifest forms for all RCRA purposes. The One Year Rule also codified key scope and consistency provisions included in the e-Manifest Act. The One Year Rule did not address e-Manifest user fees, instead deferring regulatory action on user fees until this separate e-Manifest User Fee rulemaking.
- EPA relied extensively on two Federal guidance documents on user fee design to develop its e-Manifest User Fee methodology: (1) OMB Circular A–25, a memorandum to Executive Departments and agencies addressing ''user charges,'' and (2) user fee design guidance found in the United States Government Accountability Office

(GAO) Report No. GAO–08–386SP, *Federal User Fees, A Design Guide,* (May 2008).

• The OMB Circular A–25 guidance was relied upon substantially for the following principles used in formulating the final rule user fee methodology: (1) The imposition of user fees on those recipients of the special benefits from federal activities, but not recipients of incidental benefits; (2) the requirement that user fees should accomplish full cost recovery; (3) the explanation of the various types of direct and indirect costs that can be recovered by user fees; (4) the general policy that user fees be instituted through the promulgation of regulations; and (5) the policy that user fees be reviewed biennially, to provide assurance that fees are adjusted to reflect changes in program costs.

• The GAO Federal User Fees Design guide also was heavily relied upon in developing the rationale for this final rule user fee methodology, particularly with respect to: (1) Collecting fees so as to strike an appropriate balance between ensuring compliance with fees and minimizing administrative costs; (2) the manner of reviewing and updating user fees so they remain aligned with actual program costs and activities, and are adjusted for changes in program costs; and (3) balancing several key outcomes involved in fee design, including: the economic efficiency of the program's user fees; the equity of the fee system in ensuring that beneficiaries pay their fair share while not disregarding their ability to pay; the adequacy of resulting revenues to pay all known program costs and to keep pace with inflation and other changes to program cost; and the administrative burden of the fees, including the balancing of the fee compliance costs with the costs of their collection and enforcement.

III. Detailed Discussion of the Final Rule

A. Which users of manifests and manifest data will be charged user fees?

1. Background

In addressing this issue in the proposed rulemaking, EPA acknowledged that there were two distinct classes of users who might become involved with the e-Manifest system. First, there are the regulated community members, *e.g.,* the hazardous waste generators, transporters, and receiving facilities (*e.g.,* RCRA TSDFs) who are required to use the manifest in connection with tracking a hazardous waste shipment in which they are involved and are named as one of the handlers on the manifest. Second, there are the data consumers, *e.g.,* members of the public or state and local governments that might wish to access e-Manifest in order to obtain information about wastes and shipments of interest to them in their capacity as a data consumer, but not as a member of the regulated community. Since the beginning of the planning for e-Manifest, EPA has indicated that it considered public access and transparency important functions of an e-Manifest system. EPA has planned to develop a public facing module in e-Manifest to provide such data access, with certain restrictions on that access. However, the interest in public access to data is a secondary interest, and it is clear that the regulatory community users are the primary community of interest served by e-Manifest, and that they obtain the primary services and benefits from the system.

In the notice of proposed rulemaking, EPA proposed that the primary beneficiaries of e-Manifest—the regulatory community users within the definition of ''user'' in the e-Manifest Act—would at a threshold level be the community of users potentially subject to user fee obligations. Thus, for this initial level of fee eligibility, EPA proposed to limit the imposition of user fees to the members of the regulatory community that must use the RCRA manifest, as a matter of regulatory compliance under federal or state law, for tracking the off-site shipments of hazardous waste or state-only regulated waste between generation sites and the facilities where such wastes are received for management. EPA did not propose to impose fees on the community of data consumers, *i.e.,* members of the general public, accessing the system only to obtain data about wastes and waste shipments of interest to them. In the proposed rule, we explained that excluding the public from user fee payments was consistent with OMB Circular A–25 policy to not charge incidental beneficiaries of a service a user fee. We also explained that this proposal was motivated by the desire to avoid the large administrative burden of establishing payment accounts for all those members of the public who might access the system, and of processing payments for such a large and potentially diverse community. EPA believes that the costs of providing data access to the public would be fairly modest relative to the cost of servicing the regulatory community. The funding result under the proposed rule would thus have the costs of providing the public with access to data funded as an incremental increase in the fees charged to the regulated users.

As a second proposal on the scope of fee obligations, EPA proposed to further restrict the payment of e-Manifest fees to the approximately 400 RCRA receiving facilities (TSDFs) that receive waste from off-site, as well as the corresponding receiving facilities of state-only regulated wastes tracked under RCRA manifests under state law. EPA explained in the notice of proposed rulemaking (NPR), that it considered the submission of the final, signed manifest to the e-Manifest system by the receiving facility designated on the manifest to be the primary ''billable event'' in the e-Manifest system that would give rise to a user fee obligation. The effect of this second aspect of the proposal would be to limit fee obligations and payments to the receiving facilities on manifests, and to generally exclude the other regulatory community ''users'' from fee payment obligations. This aspect of the proposed rule was premised on the goal of simplifying the fee system, and avoiding the potentially large administrative burden of establishing payment accounts and collecting fee payments from 100,000 or more generators or other regulated users. It was assumed that the receiving facilities assessed these fees could choose to pass these fees through to the generator customers as a part of their service agreement, thus balancing the equities and burdens of the fee system without EPA's further intervention.

2. Comment Analysis

On the issue of public access and its funding, we received numerous comments from state agencies supporting the exclusion of states and the general public from the requirement to pay fees, and supporting the imposition of e-Manifest fees on the regulated users of the system. However, there were several comments from hazardous waste TSDFs and their trade organizations objecting to the proposed rule's approach to funding public access through an incremental increase in these facilities' fees. These TSDF commenters argued that the e-Manifest Act's definition of ''user'' was intended to limit system access to the regulated community and not afford access to the public. The TSDF commenters suggested that EPA should be responsible for funding public access through another means or another EPA appropriation, perhaps treating public access requests through the Freedom of Information Act or FOIA. As a final matter, several of these TSDF commenters also questioned EPA's assumption that the cost of public access would be modest.

On the issue of the proposed ''billable event,'' all commenters supported the proposal limiting fee obligations to the receiving facilities designated on the manifest, and classifying the submission of the final copy of the manifest signed by the receiving facility as the primary billable event in the system. The states, generators, and receiving facilities that commented on the proposed rule all supported EPA's rationale that the balancing of administrative efficiency and simplifying the fee payment system justified limiting the fee obligations to the manifest's receiving facilities. To make their support of this proposal clearer, several of these commenters suggested that EPA remove from the existing part 262 (generator) and part 263 (transporter) regulations all vestiges of regulatory language from the first e-Manifest rule suggesting EPA might impose user fees on generators and transporters. Several commenters also suggested that EPA should be consistent in drafting the final rule, and avoid using the terms TSDF, receiving facility, and designated facility interchangeably in the regulatory language, as these terms do not have the same scope of coverage.

Finally, in connection with the proposed rule's discussion of the public access issue and the proposed rule's focus on receiving facilities for the rule's fee obligations, EPA received several additional comments raising significant issues for the Agency to consider.

A RCRA receiving facility and the Department of Defense submitted comments raising the concern that unfettered public access to e-Manifest might enable data mining from the system by those with malevolent intent. These comments raised a concern that those conducting data mining for illicit purposes could discern information about particular wastes involving chemicals of concern, or about the sites managing them, or patterns in the movement of wastes that could be weaponized or otherwise vulnerable if diverted. One commenter suggested there should be a homeland security basis for excluding public access to such information, and identified the homeland security list of chemicals of interest in 6 CFR part 27, appendix A, as a resource that might be helpful in excluding hazardous waste and manifest data potentially posing a Homeland Security risk. The Department of Defense also raised a concern that generator site information and the aggregate waste information gleaned from e-Manifest could in some instances constitute classified information.

In addition, EPA received several helpful comments that pointed out some weaknesses or challenges that will arise from the proposed rule approach and its focus on the final manifest submissions by receiving facilities as the billable event that will trigger fee obligations. As one example of such a challenge, several industry and state agency commenters noted that there may be significant numbers of receiving facilities, particularly those facilities receiving state-only regulated wastes, which lack RCRA permits and lack EPA Identification Numbers. Examples cited in the comments were facilities managing industrial wastes, used oil, wastes regulated as special wastes by the states, or conditionally exempt small quantity generator (CESQG) [1] wastes regulated more stringently by states and subject to manifests under state law. If EPA is intending to track the billable manifests from receiving facilities by keying on the EPA Identification Number of the receiving facility, EPA will need to issue unique identification numbers to these facilities or otherwise address how these receiving facilities and their manifests will be tracked uniquely and billed for services in e-Manifest.

Other helpful comments received in response to the proposed billable event were several industry and state agency comments noting that there were two other types of waste shipment transactions with manifests that did not lend themselves to the proposed approach of billing the receiving facility for the manifest. The two transaction types cited as posing particular challenges were: (1) Rejected wastes returned under manifests to generators, as the ''receiving facility'' for such return shipments are generators and not the conventional permitted facilities (*e.g.,* RCRA TSDFs); and (2) hazardous wastes exported from the U.S., as the manifests for exported hazardous wastes are not received by a domestic receiving facility, but are instead received by foreign consignees that are beyond the jurisdiction of the U.S. to compel a final manifest submission and fee payment. These commenters questioned how EPA would address these transactions in the final rule.

3. Final Rule Decisions

a. How will public access to data be funded?

In this final rule, EPA is sustaining the proposed rule's position that public access is an incidental benefit of the system, and that the regulatory community users obtain the primary and major benefits of e-Manifest services. Since members of the public are at best incidental beneficiaries, EPA has decided not to charge members of the public a fee for access to manifest data from the public facing module of e-Manifest. This decision is consistent with the policy announced in OMB Circular A–25, which generally excludes incidental beneficiaries of services from service charges, and instead requires the primary beneficiaries to cover these costs. Therefore, as we proposed in the July 2016 NPR, the regulatory community users—the primary beneficiaries of e-Manifest—will fund the costs of public access through an incremental increase in their user fees. EPA concludes that this policy best effectuates the program's transparency goal with respect to manifest data, and avoids discouraging the public's access by the imposition of a fee on such access. EPA remains convinced that the incremental increase in users' fees to fund public access will be modest. This further focuses cost recovery and collections on the several hundred receiving facilities, thereby avoiding the complexity and administrative burden of attempting fee collections from members of the public.

b. Which regulatory community users will pay fees?

Second, for this final rule, EPA has decided to sustain the proposed rule's approach of focusing the fee payment obligations of the regulatory community users on only the receiving facilities named on manifests. The final rule therefore refines the user fee obligation by excluding generators, transporters, and entities other than receiving facilities designated on manifests from the rule's user fee requirements. The commenters on the proposed rule expressed unanimous support for this proposal, and EPA concludes that it is much more practical and efficient administratively to focus fee collections and payments in the system on the several hundred hazardous waste and state-only regulated waste receiving facilities, and to define the ''billable event'' giving rise to a fee obligation in the system as the submission of the final manifest copy signed by these receiving facilities.

EPA is further clarifying that with respect to the continued use of paper manifests, the preferred means of submission to the system by receiving facilities is a data file (*e.g.,* JAVA Script Object Notation (JSON) file) presenting the data from these paper manifests. Such data file submissions will eliminate much of the manual

[1] Conditionally exempt small quantity generators are now known as Very Small Quantity Generators.

processing of these manifests, including opening and sorting mail, and the very labor intensive process of manually keying data from paper manifests into the data system. Receiving facilities may submit their data files from completed, ink signed paper manifests either individually or as a batch submission. Whether submitted individually or in a batch upload, the receiving facility must also submit an image file of each manifest that is included in the data file upload. At the time of submission of the individual or batch file upload, a responsible representative of the receiving facility must make a CROMERR compliant certification that to the representative's knowledge and belief, the data and images submitted are accurate and complete, and that the facility acknowledges that it is obligated to pay the appropriate per manifest fee for all the manifests included in the submission. These data file upload requirements are spelled out in §§ 264.1311(c) and 265.1311(c) in this final rule.

c. How will the rule address homeland security risks?

The Agency acknowledges the several public comments raising the concern that unfettered public access to manifest data might enable those with malevolent intent to obtain data from e-Manifest that might pose a homeland security risk. EPA believes that the homeland security risk posed by public access to e-Manifest is minimal for the majority of manifested hazardous waste shipments, because few hazardous wastes are likely to be found in forms and circumstances that would make them attractive to terrorists, and because public access to data through e-Manifest will in all cases be delayed for a period of 90 days after receipt of hazardous wastes at the receiving facility designated on the manifest. However, commenters indicated that the 90-day delay in public access might not mitigate all such security risks, since even with delayed access to manifest data, a terrorist with system access could perhaps discern shipment patterns for particular chemical wastes of concern and the generators and facilities handling them. Thus, commenters suggested that EPA take a more proactive position to guard against homeland security risks posed by data disclosures from e-Manifest. In particular, as a means to identify RCRA hazardous waste shipments that might pose a security risk, the commenters suggested that EPA utilize the Department of Homeland Security's (DHS's) Chemicals of Interest, a screening tool for chemical security risks that DHS has published in appendix A to its 6 CFR part 27 regulations pertaining to the security of the nation's chemical facilities.

EPA consulted with the DHS to determine if the information that will be publicly accessible from e-Manifest poses a significant chemical security risk, and if so, the action the Agency should take to mitigate that risk. DHS concluded that there was a plausible chemical security risk posed by unrestricted public access to data in e-Manifest, and the agencies collaborated on a strategy to mitigate that risk.

EPA believes that the appendix A Chemicals of Interest list and screening tool can be applied to the hazardous wastes and facilities covered by DHS's chemical security regulations to aid EPA in identifying a solution to the security concerns raised by commenters. Rather than duplicating the efforts of DHS in this area, or perhaps developing a conflicting approach, EPA is relying upon the expertise of DHS, the DHS chemical security regulations, and the DHS Chemicals of Interest (COI) appendix to flag those manifested waste shipments and the data that should be withheld from public disclosure by e-Manifest to avoid the release of information that could plausibly be used to harm the homeland.

First, it is significant that DHS has previously determined that the security risks addressed in its 6 CFR part 27 regulations are only potentially presented by a narrow subset of RCRA solid and hazardous wastes. In promulgating the appendix A COI list in November 2007, DHS determined that most RCRA solid and hazardous wastes would not be found in forms or circumstances that would make them attractive to terrorists, with the result that most RCRA wastes are excluded from the COI screening process for chemical security risks. See 72 FR 65397 at 65398 (November 20, 2007). However, DHS concluded that a subset of RCRA hazardous wastes—the so-called ''P-List'' and ''U-List'' wastes consisting of the discarded commercial chemical products and related wastes identified in 40 CFR 261.33—should be subject to screening as COI for chemical security risks. DHS concluded that only these P-List and U-List wastes are covered by the 6 CFR part 27 screening process for COI, because the discarded commercial chemical products, off-specification species, and other such wastes were likely to be just as attractive to terrorists as the chemical products themselves. Id. Thus, our consideration of homeland security risks potentially posed by public access to manifest data should, in the first instance, be limited to a consideration of those manifests for the P-List and U-List wastes with chemical names that also appear on the list of COI in the appendix A to the DHS's 6 CFR part 27 regulation.

Under the DHS chemical security regulations, the COI appendix is used as an initial screening tool for identifying high risk chemical facilities. The COI appendix identifies for each listed chemical substance a Screening Threshold Quantity (STQ) and minimum concentration that apply to each of several modes of vulnerability (release, theft, sabotage) and the related security issues (toxic, flammable, or explosive releases; theft enabling use of chemical weapons or weapons of mass effect; sabotage, etc.). The purpose of the COI list and the STQs published for the relevant security issues is to screen for those chemicals that if released, stolen, diverted, and/or contaminated, have the potential to create significant human life and/or health consequences.

Moreover, the presence of a COI at a facility at quantities exceeding the STQ is not itself a trigger for whether that facility is a ''high risk'' or ''covered facility'' within the meaning of the part 27 DHS chemical security regulations. Rather, the presence of a COI chemical at or above the STQ is the threshold for determining when a facility must be evaluated further by DHS for the chemical security risks at that facility. Exceeding an STQ triggers the requirement for the facility to submit to DHS a Top-Screen document. Only after DHS has gathered additional information through the Top Screen will DHS make a determination whether the facility handling that COI chemical is a ''high risk'' facility and must comply with the substantive requirements of the part 27 regulations. These requirements include the preparation and submission to DHS of a Security Vulnerability Assessment and a Site Security Plan.

While EPA would ideally have the information available to withhold from public disclosure the manifest associated only with ''high risk'' facilities, the Agency is not in a position to determine whether particular facilities associated with P-List and U-List wastes that are COI are high risk for chemical security issues. However, in order to be protective respecting any plausible chemical security risk at facilities with manifested hazardous wastes, the Agency will apply the COI list screening tool broadly to prevent access to information on chemical wastes by those who might have an intent to harm the homeland.

Therefore, in this final rule, EPA is clarifying that the e-Manifest system will withhold from public access

specific data from those manifests related to chemical facilities that handle P-List and U-List wastes that are also included on the appendix A COI list. For manifests that include such chemical wastes, the e-Manifest system will withhold from disclosure to the public-facing module of e-Manifest the following data items: The chemical waste name and specific P- or U-List waste code, the quantity of such wastes included in the shipment, and the date of the shipment. The shipping description for these chemical wastes will instead bear the generic information ''P-List or U-List waste'' in the public facing e-Manifest system. After consultation with DHS, the two agencies have concluded that these measures will be effective to prevent a terrorist from obtaining information on which facilities might possess or manage hazardous wastes that are COI at quantities of concern, as well as prevent such a person from ascertaining information about shipment dates and patterns of shipments involving these chemical wastes of interest.

While the withholding of this limited data from a limited subset of manifests may appear at odds with the Agency's transparency goals for e-Manifest, EPA believes that the mitigation strategy described here represents a reasonable accommodation with homeland security interests, and is a prudent response to the concerns raised by commenters and DHS officials.

d. How will the rule address state regulated facilities lacking EPA Identification Numbers?

EPA acknowledges the comments identifying the problem posed by tracking and collecting payments from state regulated receiving facilities that currently lack EPA identification numbers. The e-Manifest system will be programmed to track manifest activity and bill facilities for their activities with reference to the identification number of the receiving facility listed on each manifest. Therefore, prior to or at the time of system implementation, EPA will need to identify a means by which such facilities can obtain unique identifiers that they can list on their manifests in the EPA identification number field.

As part of the e-Manifest system development, EPA is including a so-called ''non-handler IDs'' initiative aimed at ensuring that each site has its own unique ID to use with its electronic manifests. Further, this initiative is aimed at ensuring that each receiving facility entered in e-Manifest will have a unique identity for tracking and billing purposes. Sites that are listed in Item 8 of manifests as designated or receiving facilities must obtain a handler ID from their state or EPA and be listed in the RCRAInfo data system. These efforts will require considerable outreach and cooperation between EPA, the states regulating these facilities, and the receiving facilities to maximize the inclusion of these sites in the system and ensure the proper billing of their shipments.

e. How will the rule address out-of-state shipments of non-RCRA wastes?

The e-Manifest Act extends the scope of the e-Manifest program to wastes subject to manifest tracking under federal RCRA or under state law. Some state programs regulate more wastes than EPA regulates federally under its Subtitle C regulations, and these additional non-RCRA wastes are often referred to as state-only regulated wastes or as ''broader in scope'' wastes to indicate the more extensive coverage of the state programs. These state-only regulated, non-RCRA wastes can present manifest implementation and tracking challenges when shipments involving these wastes cross state lines. While any non-RCRA waste subject to a manifest under state law in the destination state should be accompanied by a manifest in the destination state and thus would be required by this final rule to be submitted by the receiving facility to the e-Manifest system, the compliance situation is not as straightforward for other out-of-state shipment scenarios. In particular, the manifest requirements may be less clear for waste shipments that originate in a state with more extensive or ''broader in scope'' coverage and that are then shipped out-of-state to a destination facility in a state where the waste is not regulated as hazardous and does not require a manifest under the law of the destination state. Prior to e-Manifest, EPA was not significantly involved in the collection of manifests, and the question of supplying manifest copies to states was governed exclusively by state law. EPA is aware from discussions with state regulators that it was at times problematic for the origination states to collect manifest copies from out-of-state receiving facilities, and that it was often difficult to ensure compliance with copy return requirements from facilities beyond the territorial jurisdiction of the origination state.

Under the e-Manifest Act, however, any such jurisdictional barrier has been eliminated by the Congress. In section 2(h) of the Act, Congress prescribed a self-implementing provision that speaks directly to the obligation of receiving facilities to close out and return manifests to the e-Manifest system, if the waste being shipped for management is subject to a manifest in either the origination state or the destination state. This provision of the Act provides that if either state's law requires that the waste is tracked through a hazardous waste manifest, then the designated facility, regardless of location, shall complete the facility portion of the manifest, sign and date (*i.e.* complete the facility certification), and submit the manifest to the system.

Thus, under the Act, for shipments that cross state lines, a designated or receiving facility that receives waste shipments accompanied by a manifest, and that manifest is required for the tracking the waste shipment by either the law of the origination or destination state, then the receiving facility must attend to that manifest, must close it out by completing the facility portion and signing and dating the facility certification on the manifest, and must submit the signed, final copy of that manifest to the e-Manifest system for processing. These requirements apply to receiving facilities under federal law even if the law of the destination state would not require a manifest for the wastes involved, and would not require the facility to take any action with respect to the manifest required by the origination state. States that desire the return copies of these manifests can therefore rely upon this federal provision that ensures consistency in the tracking of these shipments to their completion, and they will not be as dependent on attempts to extend their state laws in an extraterritorial fashion to out-of-state entities. Receiving facilities can know that their supplying one final copy to the e-Manifest system will satisfy any and all requirements for return copies to tracking states, wherever they may be situated.

While the provisions of section 2(h) of the e-Manifest Act are self-implementing, EPA is including an explanation of this statutory provision in this final rule so that regulated entities will receive ample notice of its requirements. EPA is including this summary of section 2(h) under this preamble topic, because the effect of this statutory provision is to classify the out-of-state waste shipments subject to manifest tracking in either the origination state or destination state as a mandatory type of manifest submission to e-Manifest, and thus another type of ''billable event'' within the meaning of this final rule. In other words, receiving facilities subject to this statutory provision affecting interstate waste shipments must submit the final manifest copies to e-Manifest, and pay

the fee required by this final rule, based upon the type of submission.

The Agency is codifying the exact terms of section 2(h) of the Act at 40 CFR 260.4. EPA has chosen to codify the statutory provision in the general applicability subpart of part 260, because we expect that many of the state-regulated facilities that will be affected by the copy submission requirement of section 2(h) are not RCRA-permitted TSDFs, and thus it would not be appropriate to include the codified text of section 2(h) of the Act in the part 264 or part 265 regulations that prescribe the unit location and management standards for RCRA TSDFs. Part 260 is reserved for regulatory provisions of general applicability, so EPA has chosen to codify the manifest copy return requirement affecting interstate waste shipments at new § 260.4.

f. How will the rule address hazardous waste exports and return shipments of rejected hazardous wastes?

The commenters who identified these two atypical shipment types raised valid points that the proposed rule approach of billing the receiving facilities upon submission of the final signed manifest did not lend itself well to the processing of hazardous waste export manifests and manifests for rejected hazardous wastes that are being shipped as returns to the generators of those wastes.

With respect to hazardous waste export shipments, EPA is not including the tracking of export manifests described in subpart H of 40 CFR part 262 in the initial phase of e-Manifest system implementation. As EPA is not accepting the submission of export manifests to the system at this time, the Agency also is not requiring the payment of a fee in connection with export manifests. EPA's system planning and development efforts to date have been focused on the domestic manifest, as the domestic shipments are the dominant use case for the hazardous waste manifest.[2] Moreover, EPA has not yet determined who in the export shipment chain of custody (*i.e.,* primary exporter vs. transporter moving waste from U.S. or other entity) is best suited for making the submission of the export manifest to the system and paying the requisite processing fee; nor have we provided notice-and-comment opportunities for the exporters or other handlers involved with these shipments. Therefore, these determinations on export manifest submissions and the payment of e-Manifest fees for export manifests must await a future rulemaking connected with the planning for the next phase of e-Manifest implementation. EPA plans to consult the Advisory Board on future e-Manifest system enhancements and expansions, and the future inclusion of export manifests is a topic that the Advisory Board can help us address in our regular meetings with the Board. Until then, current arrangements for handling export manifests and tracking information on exports in other Agency tracking systems will continue.

With respect to rejected hazardous waste shipments, EPA has addressed commenters' concerns in this final rule. With rejections, there are generally two possible outcomes: (1) The rejected wastes are re-shipped under a manifest that forwards the rejected wastes from the rejecting facility to an alternate receiving facility (typically, another RCRA TSDF) for management, or (2) the rejected wastes are re-shipped under a manifest from the rejecting facility as a return shipment back to the original generator of the waste.

The first outcome discussed previously—the forwarding of rejected wastes to an alternate facility—is not unlike the conventional manifested shipment of a waste to a permitted facility for management. The key difference is that the rejected waste shipment originates with the rejecting facility rather than the generator. Otherwise, forwarded rejections are tracked through off-site transportation to another receiving facility (typically another permitted TSDF), which completes the tracking of the shipment by signing the manifest to certify to the receipt of the wastes at the designated facility. Since forwarding rejected wastes to an alternate facility is tracked on the manifest like conventional waste shipments to a receiving facility, EPA can treat them like conventional shipments insofar as the submission of the final copy to the system and the payment of the fee. Therefore, for rejected wastes that are forwarded to an alternate facility for management, the alternate facility that signs the manifest to certify the receipt of wastes must submit that final, signed copy to the system and pay the applicable per manifest fee for that submission.

The unique circumstances surrounding the tracking of return shipments requires a different treatment in this final rule. For return shipments to generators, the rejecting facility is typically listed as the generator on the return manifest, while the original generator of the waste receiving its waste as a return is shown as the designated or receiving facility. EPA's billable event approach of charging the receiving facility of conventional shipments is premised on efficiency and avoiding the inclusion of hazardous waste generators in the e-Manifest payments system. It would conflict with this policy objective if the return shipments were then to implicate generators in the fee payment system, because they appear to be the receivers of return shipments. Therefore, in the final rule, EPA is announcing a different outcome applicable only to the return shipment scenario. For return shipments to generators, the rejecting facility is responsible for the payment of the fee for the return manifest, and the billable event for this fee obligation is the rejecting facility's submission of the original manifest signed by the facility to indicate the rejection and the submission of a copy of the return shipment manifest that will accompany the return shipment to the generator. Each rejection resulting in a return shipment must therefore include the submission by the rejecting facility of the original manifest signed by the rejecting facility and a copy of the return shipment manifest. Thus, the rejecting facility is paying the fee for the processing of the return manifest when it submits the return manifest, as the return manifest and its processing fee will not be collected by the system from the generator.[3] By handling return shipments in this manner, the fee payments required in the system can be confined to the intended class of conventional, permitted receiving facilities. While it may seem irregular to charge the rejecting facility the e-Manifest fee for return shipments of rejected wastes, a chargeback by the facility to its generator customer is an option to balance the equities of the resulting fees. EPA concludes that this decision allocates the fees for rejected wastes most fairly, as the rejecting facility is charged the fee only in the exceptional circumstances of return shipments to a generator, while the alternate receiving facility will pay the fees for the more conventional scenario of wastes being re-shipped and forwarded to another receiving facility for management. Therefore, §§ 264.1311(a)(3) and 265.1311(a)(3) of the final rule will include among the manifest transactions that are subject to

[2] EPA estimates that there are 3 to 5 million domestic manifests produced each year for tracking waste shipments within the U.S., whereas the export trade produces only about 23,000 manifests annually.

[3] EPA notes that in those cases of a facility partially rejecting wastes on the original manifest, with a return of rejected wastes to a generator, the rejecting facility will be charged both the processing fee for the original manifests for processing data on the wastes received, as well as the fee for the return manifest to the generator.

fees the submission by receiving facilities of manifests indicating a rejected waste and a return shipment to the generator of that waste.

g. What other changes are being made in response to comments?

EPA accepts the comments asking for the removal of all vestiges in the existing regulations that suggest EPA could impose e-Manifest fees on generators under part 262 regulations or on transporters under part 263 regulations. These provisions were added during the promulgation of the One Year Rule, which codified quite generally the authority conferred under the e-Manifest Act to impose reasonable fees on all classes of manifest ''users,'' a term which included hazardous waste generators, transporters, and owners or operators of facilities receiving wastes under manifests for management. Thus, EPA included in the One Year Rule provisions in parts 260, 262, 263, 264/265, and 271 so that the codified authority to impose user fees could reach all the possible users of the manifest. In the proposed User Fee Rule, 81 FR 49071, July 26, 2016, EPA stated that if the proposed rule's approach to charging only receiving facilities user fees were to be adopted in the final rule, EPA intended to eliminate from parts 262 and 263 those provisions that would appear to extend user fee authority to generators and transporters. (81 FR 49072 at 49078). Based on the supportive comments in the docket, and the Agency's continued belief that restricting fee collections to receiving facilities is sound policy, EPA is finalizing this policy and thus removing all references in parts 262 and 263 to user fee obligations for generators and transporters of hazardous waste. The result is the removal from the regulations of existing §§ 262.24(g) and 263.20(a)(8) addressing the imposition of user fees on generators and transporters, respectively.

EPA also is accepting the comment noting that EPA had used the terms TSDF, designated facility, and receiving facility interchangeably in the proposed rulemaking, even though those terms do not have the same scope of coverage. The term TSDF connotes a facility having a RCRA treatment, storage, or disposal permit (or interim status), a class of facilities that is narrower than the scope intended by the e-Manifest Act. The commenter is correct in pointing out that the e-Manifest Act intends broader coverage than RCRA TSDFs, since it is clear that many receiving facilities of state-only regulated wastes lack RCRA permits, and yet are facilities that could receive manifested wastes under state law and thus be included in the coverage of the e-Manifest Act and the e-Manifest system. The commenter also is correct that EPA should rely on a term that expresses the intended scope of the e-Manifest Act, and use that term consistently in the final rule. In response, EPA is clarifying in this final rule that ''receiving facility'' is the term with the proper breadth that will capture all facilities regulated by the final User Fee Rule. The final rule will therefore focus on receiving facilities, and not TSDF or designated facility, as both of the latter terms are defined by current federal regulations more narrowly to include only the RCRA permitted facilities. The term receiving facility is sufficiently broad to include every type of federally regulated or state regulated facility that could receive a hazardous or state-only regulated waste covered by the e-Manifest Act.

Consistent with the broad scope of coverage intended by the e-Manifest Act, the Agency is adding new authority in 40 CFR 260.5 to cover the receiving facilities of state-only regulated wastes that are not RCRA TSDFs. Under the final rule's § 260.5, facilities receiving state-only regulated wastes must comply with the requirements of § 264.71 on use of the manifest, the requirements of § 264.72 on manifest discrepancies, and the requirements of subpart FF of part 264 addressing the fee determination methodology, fee payment methods, fee dispute procedures, and other fee requirements. EPA is subjecting the state-only regulated waste receiving facilities to these requirements under § 260.5 so as to clarify the applicability of e-Manifest Act requirements to these state regulated facilities that are not RCRA TSDFs subject to part 264 or part 265.

EPA is also revising the manifest printing specification by adding a § 262.21(f)(8) that will require all printed manifests and continuation sheets to bear a prominent notice to these facilities in the bottom margin of the designated facility copy. This notice will refer the facilities to the manifest instructions that explain their requirements to complete and sign all manifests so received, to submit these manifests to the e-Manifest system, and to pay to EPA the appropriate fee for the processing of these manifests.

B. What other transactions will be subject to user fees?

1. Background

In the discussion earlier on the billable event in e-Manifest, EPA clarified that the primary transaction in e-Manifest that will give rise to a user fee obligation is the submission by the receiving facility of the final copy of the manifest signed by the receiving facility to certify to the receipt of the wastes or to any discrepancies related to the shipment.[4] However, in the proposed rule, EPA proposed several additional types of manifest-related transactions that might warrant a fee, and solicited comment on others that might warrant a fee because of the complexity of some transactions (*e.g.,* rejections, split loads, consolidations), or to deter activities that might incur large labor costs, such as a paper manifest premium or a charge for help desk encounters. EPA explained in the proposed rule that the several complex transactions did not warrant any premium fees, because these transactions—rejected waste shipments, consolidated shipments, or split shipments—tend to require additional manifests to be completed and submitted, so the fees related to the additional manifests would be collected as a matter of course without any premium fees. For help desk encounters, EPA concluded that a per encounter fee would discourage users from seeking assistance, and that it was more appropriate to aggregate help desk costs and recover these as operations and maintenance costs of the system to be shared by all manifests.

In footnote 16 at 81 FR 49088 July 26, 2016, proposed rulemaking, EPA stated that it intended to impose a per page transactional fee for manifest continuation sheets. EPA believed the per page continuation sheet fee was justified, as these continuation sheets were separate forms styled similarly to manifest forms, and with many of the same data elements. Particularly when submitted as paper forms for processing, these continuation sheets could require the same sorts of manual processing steps and quality assurance/quality control measures as paper forms. Therefore, EPA stated in the proposed rule footnote that each page of a continuation sheet would generate the same fee as an individual manifest form.

Also, in the preamble section of the proposed rule addressing possible fee premiums, EPA proposed a distinct transactional fee for sorting and returning certain types of extraneous documents that handlers might submit to the paper processing center with their manifests, and for correction submissions sent to the system by receiving facilities to enter corrections

[4] As noted in section III.A.3.e in this preamble, another billable transaction for receiving facilities is the submission of a manifest showing in Item 18a a return shipment to a generator, where a fee is charged for the return manifest.

in the data-base of existing manifest records. See 81 FR 49072 at 49088, July 26, 2016. EPA proposed the extraneous document fee, because EPA had learned from several state agency partners that such extraneous documents were frequently encountered by states with tracking programs, and their sorting and return, if required, would incur considerable manual processing steps and resulting labor costs. It was believed that a premium fee charged for extraneous documents might deter these submissions and recover their related costs to the system.

EPA proposed the corrections submission fee, because the proposed corrections process included in the proposed rulemaking action would require a certified submission by TSDFs to effectuate a change to previously entered manifest records. The proposed rule included a fairly structured submission requirement that would have required the receiving facility submitter to identify the data elements being corrected, to list both the data item as previously entered and as corrected, and then to certify that the data as corrected are complete and accurate. Such submissions would result in system-related costs being incurred, and it was believed that a corrections fee might induce facilities to improve the data quality of their initial submissions so as to avoid the costs of later correction submissions.

2. Comment Analysis

EPA received many comments in response to the proposal regarding which transactions might warrant additional fees. Numerous industry and state commenters agreed that continuation sheets should not be charged a separate or per page fee. These commenters contend that most continuation sheets simply add additional waste streams or an additional transporter to the original manifest. Since continuation sheets carry the same tracking number as the original manifest to which they are appended, the commenters believed that only one fee should be charged for the original manifest and any continuation sheets attached to it.

EPA received many comments from industry and state commenters contesting the proposed fee for sorting and returning stray or extraneous documents. Nearly all of these comments suggested that EPA should not be spending time and resources sorting extraneous documents and attempting to return them to senders, but should simply discard them. Commenters suggested that discarding the stray documents with no additional effort expended on them would not necessitate a separate fee. Several such commenters did question what the term ''extraneous'' meant in connection with non-manifest documents submitted to the system. For example, commenters asked if polychlorinated biphenyl (PCB) continuation sheets and land disposal restriction (LDR) certifications would be treated as extraneous, even though other EPA regulations may require them to be attached to manifest forms.

Commenters generally agreed with EPA's assessment that help desk encounters should not be charged separate per encounter fees. These commenters agreed with EPA's statement in the proposed rulemaking that the help desk costs should be aggregated and shared by all manifests as operations and maintenance costs. Similarly, commenters agreed with EPA's assessment that a premium fee for paper manifest use was not warranted at this time, as the differential fee approach in the proposed rule would already assess higher fees for paper manifest submissions, because of their higher processing and labor costs. Commenters said that the differential fee proposal already created the appropriate incentives against the continued use of paper manifests without an additional premium fee.

Many industry commenters and several state agency commenters submitted comments objecting to the proposed data correction fee, although a few commenters stated they would support a corrections fee focused on paper manifest submissions only. The commenters objecting to the proposed corrections fee, particularly RCRA TSDFs and their trade associations, argued that a separate fee levied on correction submissions would deter corrections being made, and would result in disincentives for data quality in the system. These commenters suggested that the system should encourage, not discourage, data corrections from the user community.

3. Final Rule Decisions

EPA accepts the numerous comments objecting to a separate transactional fee for manifest continuation sheets. EPA is persuaded that most continuation sheets add minimal additional data to a manifest, typically several additional waste streams or an additional transporter, and that processing these additional data items will not incur significant costs to the system. Also, as these continuation sheets will be tracked by the same manifest tracking number displayed on the original manifest, it will not be practical to track and invoice users separately for continuation sheets. Any marginal costs that result in the aggregate from the processing of continuation sheets will be added to the system's operating and maintenance costs. Thus, the policy of charging a per sheet fee for continuation sheets, as suggested in the proposed rulemaking, 81 FR 49072 at 49088, footnote 16, July 26, 2016, will not be adopted in the final rule.

EPA also accepts the numerous comments criticizing the proposal to charge a separate transactional fee for sorting and returning extraneous documents submitted to the system's processing center with paper forms. Commenters all expressed alarm that EPA would spend time and resources sorting and returning extraneous documents, and EPA accepts the commenters' reasoning that the proper outcome should be to simply discard, and not return, any such stray or extraneous items that are not in fact manifest related. Thus, under the final rule, there will be no fee assessed for processing extraneous documents, and any nominal costs from sorting and discarding these documents will be added to the system's operating and maintenance costs. Thus, in this final rule, EPA is not finalizing proposed § 264.1311(b)(1) or § 265.1311(b)(1), which would have assessed fees for the processing of extraneous documents submitted with paper manifests to EPA's paper processing center.

In relation to this issue, EPA will treat all documents that are not manifest related, *i.e.,* a hazardous waste manifest form or a manifest continuation sheet, as extraneous and discard them under this rule's policy. PCB continuation sheets will be considered manifest related, as they are required to be attached to PCB manifests under federal law and contain specific details related to tracking specific PCB waste items that are being shipped off-site. However, EPA is not planning to process LDR certifications at the e-Manifest processing center, and any plans to process LDR-related documents in e-Manifest will await a later phase of system implementation. Such LDR certifications are currently intended to be delivered to the RCRA receiving facility the first time LDR-restricted wastes are shipped to a particular facility for management. Therefore, these LDR certifications should remain at these facilities and be kept among these facilities' records, and not submitted with manifests to the e-Manifest system. Until such time as EPA decides to process LDR-related documents in e-Manifest, EPA will discard any LDR certifications that are received by the system under this rule's

policy of discarding extraneous documents.

EPA also is accepting the comments objecting to the proposed rule's fee for data correction submissions. EPA is persuaded that a fee for such corrections might have the unintended effect of discouraging corrections and data quality. Moreover, as the great majority of correction submissions will be made electronically, their processing should entail nominal system costs, which EPA can include among the system's operation and maintenance costs to be shared by all manifests. Therefore, the final rule action does not finalize proposed §§ 264.1311(b)(2) and 265.1311(b)(2), which would have assessed fees for manifest data correction submissions by facilities. Other changes to the proposed data corrections process are discussed in section III.F of this preamble.

Finally, the Agency acknowledges the general support in the comments for EPA's proposed rule rationale for not charging any additional transaction based fee for help desk encounters nor charging an additional premium fee for the use of paper manifests. EPA concluded in the proposed rule that the cost of help desk support should be aggregated and funded as an operating and maintenance costs shared by all manifests. EPA further explained that the proposed differential fee approach (see section III.C of this preamble) already included appropriate fee disincentives to discourage paper manifest use, without a premium fee being necessary or appropriate at this time. As commenters agreed with both of these proposals, and EPA believes both are backed by sound policy, EPA is affirming in this final rule that no transactional fee will be charged for help desk encounters. In addition, no premium fee (beyond the higher differential fee under the rule's fee formula) will be charged for the continued use of paper manifests.

C. What formula and methodology will be used to determine user fees?

1. Background

In the July 26, 2016, notice of proposed rulemaking, EPA proposed what it described as a ''differential fee formula.'' The proposed formula differentiated among the several types of electronic and paper-based manifests that would be submitted to the system for processing. The most significant feature distinguishing the processing of these different manifest types under the proposed fee formula was the marginal labor cost of processing the data from these manifests into the system. EPA developed an economic model to project the marginal labor costs for processing the several manifest types allowed to be submitted to the system. Paper manifests mailed to the system for sorting and manual data key entry would entail the greatest marginal labor costs to process. Paper manifests submitted as image files (*e.g.,* Adobe Portable Document (PDF) files) would have marginally lower costs than mailed forms, but would still require manual data key entry steps. Paper manifests submitted as data files (*e.g.,* JSON file with an image file attachment) would require even less manual effort to process. The lowest cost manifests to process would be the fully electronic manifests that originate in the system and are transmitted electronically with no manual intervention at all. The result of the proposed differential fee formula is thus a continuum of manifest fees, with fully electronic manifests involving the lowest costs and fees, with somewhat higher fees for paper manifests submitted as JSON or data files, with moderately higher costs for the paper manifests submitted as image files, and with the highest fees imposed on paper manifests mailed to the system.

The key purpose of the fee formula is to determine the per-manifest fee to be charged manifest users. In simplest terms, the formula allocates all the system-related costs over all the manifests in use to arrive at a per manifest fee. In the July 26, 2016, proposal, EPA explained the nature of the several system-related cost categories that would be included in fee determinations with the proposed formula. See 81 FR 49072 at 49079. The major cost categories identified in the proposal were System Setup Costs, Operations and Maintenance Costs, and Indirect costs.

The proposed rulemaking discussion of the differential fee formula broke down the system-related costs into two key sub-categories, System Procurement Costs and EPA Program Costs. These sub-categories are helpful to distinguish the information technology (IT) system acquisition and contracting costs from the other EPA Program Costs that the Agency would incur in planning, developing, operating, and managing the e-Manifest program, including the program's IT system and regulatory components. The EPA Program costs extend as well to the costs of conducting outreach, as well as establishing and operating the e-Manifest Advisory Board.

In the fee formula methodology proposed by the Agency, the System Setup Costs are simply the System Procurement Costs and EPA Program Costs incurred by EPA *before* the e-Manifest system's operational date, whereas the Operations and Maintenance Costs consist of the System Procurement Costs and EPA Program Costs incurred *after* the operational date of the system. Because the e-Manifest Act requires that EPA reduce the user fees upon the recovery of all the system development costs, the proposed rule methodology would accomplish this by simply dropping the System Development Costs from the formula after five years, as EPA proposed an amortization period of five years for the recovery of the system development costs. 81 FR 49079, July 6, 2016. However, it is possible that the cost recovery period could extend beyond the five years, should, for example EPA find that actual O&M costs exceed estimates. EPA will closely track the actual progress in the recovery of system start-up costs, and will notify users accordingly when the reduced fees will take effect.

In developing the proposed rulemaking, EPA considered three distinct fee models or options, which were discussed in detail in the proposed rule preamble. See 81 FR 49081–49083, July 26, 2016. All three options focused on the marginal labor cost of processing each manifest as the primary cost item contributing to the calculated fee, and to this marginal cost was added the result of dividing the System Setup and Operations and Maintenance by the numbers of manifests, with allowance also for amortizing the System Setup Costs over five years. The three fee models or options varied by how extensively the models tracked costs and manifest numbers by manifest type, and by how rigorously the models attempted to allocate the substantial paper manifest processing costs to only the paper manifests, rather than sharing these costs equally with the electronic manifests. Thus, the Agency considered a very simple ''Average Cost Fee Option'' that shared all costs equally among all manifests, paper or electronic, to arrive at an average marginal labor cost and the same average fee for all manifest types. A second or intermediate option was discussed as the Marginal Cost Differentiated Fee Option, which focused on the marginal labor cost of processing each manifest type (fully electronic, paper by mail, paper by image file, or paper by JSON file) as the key contributing cost item, but which allocated all other system setup and non-labor operating costs equally across all manifests. The third and most detailed option was the Highly

Differentiated Fee Option, which also focused on the marginal labor cost of processing each manifest by type, but was more particular in tracking operation and maintenance costs and manifest numbers by their type, and in allocating the non-labor costs of operating the paper manifest processing center to only the paper manifests rather than having all manifest types share in these costs.

In the July 26, 2016, proposed rulemaking, EPA proposed a combination of the second, Marginal Cost Differentiated Fee option and the third option, the Highly Differentiated Fee option. See 81 FR at 49083. Under the proposed fee model, EPA would initially implement the second, Marginal Cost Differentiated Fee Option, but would shift to the third or Highly Differentiated Fee Option if the Agency were to find that electronic manifest usage had not reached the programmatic goal of 75% after four years. EPA rationalized the proposal on the basis that it represented a useful compromise between promoting electronic manifest use, while also recognizing that there likely would be a transition from paper manifest use, to JSON data uploads from facility's paper manifests, and finally to fully electronic manifests and submissions. The intermediate step in the transition—receiving facility uploads of JSON data files generated from their paper manifests—would produce benefits and cost savings for industry and the Agency's national data system. Thus, EPA believed that the combination of the two fee models, with the pivot to the more aggressive fee model if necessary after a four-year period, would facilitate this transition and not have the potentially undesirable effect of penalizing paper manifest usage initially. EPA had previously espoused the 75% usage rate goal in our economic analyses for e-Manifest to project program savings and benefits, and we believe that the 75% adoption rate within four years for electronic manifests is a useful benchmark for measuring the success of the program and for incentivizing the transition to electronic manifests through this User Fee rule.

2. Comment Analysis

There was general agreement among both industry and state commenters in support of the proposed rule's differential fee formula and its approach keyed to the marginal labor cost of processing the various manifest types into the national data system. The majority of these commenters indicated that the proposed formula was well explained, and that it provided a generally sound justification for the variability of fees among the different manifest types, that is, fully electronic manifests, and paper manifest submissions delivered by mail, by image file upload, and by JSON data file upload. These commenters also were satisfied that the proposed formula and the explanation in the proposal of the formula's cost categories and their sources were adequate to explain how the fees would be determined. Only one industry commenter expressed a dissenting view, and suggested that EPA had not substantiated the cost factors and resulting fees. This commenter expressed alarm at the level of fees published in the preamble's table showing the illustrative fees under the proposed formula, while another commenter criticized the table of illustrative fees for the range of possible fees it presented, and suggested that EPA should have been able to pin down the costs and resulting fees more closely by now.

In addition, there was general support in the industry and state comments for the proposed rule including the fee pivot feature, so that fees for paper manifests would become more aggressive if electronic manifest usage goals were not met. However, commenters representing several large RCRA TSDFs, and their trade association, objected to the final rule codifying the 75% electronic usage goal in four years as the trigger for the pivot to the more aggressive fee formula. In the view of these commenters, the 75% in four years electronic usage goal was arbitrary and should not be locked into a regulation. Rather, these commenters would prefer that EPA refer the matter of when and under what conditions to raise fees to the e-Manifest Advisory Board for its recommendation.

Few comments were received on the proposed five-year amortization period for the recovery of system development costs and their payback to the Treasury. One state agency commenter expressed support for the five-year amortization period as reasonable, but emphasized that amortized costs that accumulate in the System Fund must not be treated as a surplus, as the e-Manifest Act places limits on surplus accumulations in the System Fund. Another state commenter suggested the amortization period should be set at six years, for consistency with the Fee Rule's general reliance on a two-year cycle for publishing and revising fees.

3. Final Rule Decisions

For this final rule, EPA is sustaining its proposed approach to the differential fee formula. The final rule provides that EPA will initially implement the Marginal Cost Differentiated Fee model, and then shift to the Highly Differentiated Fee model, if electronic manifest usage has not reached a 75% adoption rate after four years of system implementation. However, EPA will evaluate the circumstances of the electronic manifest adoption rate as we reach the four-year anniversary date for the e-Manifest system. At that time, EPA will publish a document indicating whether the 75% adoption rate has been realized and any facts or circumstances that might explain why the goal was met or not met. At the time EPA publishes this action, the Agency will either state that the fee pivot will go into effect on a date determined by EPA under the conditions of the final rule's fee pivot provisions, or, EPA will determine then to refer the matter of the adoption rate and fee impacts to the Advisory Board and seek the Board's recommendations on the issue. In this manner, EPA can still implement the more aggressive fee formula pivot under the terms of this final rule, rather than having to wait on the Advisory Board's advice and possibly another rulemaking. EPA believes that the more aggressive or Highly Differentiated Fee formula is an appropriate means of ensuring that paper manifests ultimately bear their full costs, and this is an important principle of user fee design. EPA only proposed the intermediate fee model to facilitate a transition to electronic manifests, and the Agency concludes that four years is a reasonable period of time to promote such a transition. Rather than an arbitrary pivot condition, the inclusion of the 75% adoption rate condition with the four-year transition period actually moderates the transition period condition. EPA could have required the pivot to the more aggressive formula with certainty after four years, without regard to the electronic usage rate. As moderated by the usage rate condition, if the 75% adoption rate is realized, the transition to the more aggressive fees after four years is in effect canceled and the intermediate model's fees would remain in effect. In addition, EPA notes that the fee increases resulting under the more aggressive fee formula are not prohibitive, *e.g.,* about $2 more for a mailed paper submission and only a few cents difference per manifest for a JSON data upload from a paper form. EPA is not persuaded by comments suggesting that the proposed rule's fee pivot is unreasonable or arbitrary under the proposed conditions. Indeed, were the conditions not codified in the final rule, the decision to increase the paper

manifest fees even moderately would involve the substantial delay of referring the issue to the Advisory Board, waiting on their report, and then having to initiate new notice and comment rulemaking to implement the change. The decision to raise fees under particular conditions is a decision that only the Agency, not an Advisory Board, can make. Therefore, EPA is issuing the final rule to include a transition to the Highly Differentiated Fee model after four years, if electronic manifest usage has not reached 75% by that time. However, we will decide at that time through a separate action whether the fee model pivot will go into effect by the terms of the final rule, or if we find there are extenuating circumstances such that it would be helpful first to seek the advice of the Board. In either case, EPA will announce its decision to either allow the fee pivot to go into effect, or to consult on the matter with the Advisory Board.

EPA also is finalizing the rule with the proposed five-year amortization period for the recovery of system development costs. EPA received one comment supporting the proposed period as reasonable, and only one other comment suggesting the amortization period be extended to six years to align better with the proposal's two-year fee revision cycles. For the final rule, EPA is retaining the proposed five-year amortization period, and concludes that five years reasonably balances the Government's desire to promptly recover the system's development monies, while moderating the effect of the development costs insofar as keeping the resulting user fees at reasonable levels. By concluding the amortization period after the fifth year, the fee revision schedule that EPA publishes for the two-year cycle covering the fifth and sixth years will more palpably show the users the effect of the recovery of start-up costs in reducing the scheduled fees for the sixth year relative to the fifth year.

D. What indirect costs are considered by EPA in user fee determinations?

In the 81 FR 49072, July 26, 2016, proposed rulemaking, EPA explained that the e-Manifest system related costs fall into three main categories: (1) System Setup costs, (2) Operations and Maintenance costs, and (3) Indirect costs. The nature and source of System Setup costs and the Operations and Maintenance costs are explained above in the discussion of the Fee Formula and how these costs are factored into the determination of fees. However, indirect costs also are factored into the Fee Formula calculation of user fees, and EPA believes this third major category of system-related costs merits more explanation.

Indirect costs are the intramural and extramural costs that are incurred by EPA in operating the system, but that are not captured in the EPA Program cost and marginal labor cost sub-categories that EPA tracks as direct costs in determining overall costs and resulting fees. The indirect costs are part of full cost recovery, because of their necessary supporting or enabling nature in executing the program. (81 FR 49072 at 49080, July 26, 2016). Indirect costs typically include such items as physical overhead, maintenance, utilities, and rents on land, buildings, or equipment. In e-Manifest, these indirect costs also include the cost of participation by administrative EPA offices outside of the Office of Resource Conservation and Recovery (ORCR), the lead office at EPA for implementing the e-Manifest program, and the participation of upper management level personnel from the EPA offices that provide support to all aspects of the e-Manifest program. *Id.*

Indirect costs tend to be disparate and more difficult to track closely than other cost categories, because they are typically incurred as part of the normal flow of work involving many offices across the Agency, and cannot be attributed directly to the particular activities they support. Also, the level of participation by different offices, and the level of indirect costs incurred by them, changes over the course of the program's implementation. Thus, as we explained in the proposed rule, indirect costs require a different method of tracking and accounting than the other categories of e-Manifest costs. *Id.*

EPA accounts for indirect costs in its user fee determinations by developing an indirect cost rate, and factoring that rate times the base fees determined from the direct cost categories in the fee formula. Typically, agency-wide indirect cost rates are determined for EPA user fee programs by EPA's Office of the Controller, using an indirect cost methodology that this office has developed to meet the Federal Accounting Standards Advisory Board's Statement of Federal Financial Accounting Standards No. 4: Managerial Cost Accounting Standards and Concepts. EPA's Office of the Controller annually publishes an indirect cost rate for each of the Regional Offices and for each of the Assistant Administrator-level offices within EPA Headquarters. Thus, there is an Interagency Agreement (IA) indirect cost rate issued each fiscal year for the Office of Land and Emergency Management (OLEM). The Fiscal Year 2015 IA indirect cost rate for OLEM, which we discussed in the proposed rulemaking preamble and used for purposes of the proposed rule's table of illustrative e-Manifest fees at 81 FR 49085 of the proposed rule, was 19.74%. *Id.* at 81 FR 49080, footnote 11.

In the 81 FR 49072, July 26, 2016, proposed rulemaking, EPA stated that it intended to develop a customized indirect cost rate that we believed would capture the indirect costs of the e-Manifest program at a greater level of specificity than the IA indirect cost rate for OLEM. EPA received no public comments on the issue of indirect costs. Nor did the Agency receive any comments on its statements in the proposal regarding its intent to develop a new custom indirect cost rate for e-Manifest.

EPA is announcing in this final rule the custom indirect cost rate for e-Manifest, which was based on EPA's existing indirect cost methodology, and taking into account with more particularity other appropriate indirect costs attributable to the ORCR program office that were not captured by the previously used IA rate alone.

Using the new custom indirect cost rate methodology for e-Manifest, the indirect cost rate for e-Manifest in fiscal year 2018 is 33.22%.[5] This indirect cost rate for e-Manifest will be calculated and reissued each fiscal year. Thus, when the Fee Formula is run to determine e-Manifest user fees, the applicable indirect cost rate will be factored times the base fees calculated from the direct cost categories in the fee formula to arrive at the total user fees.

E. What process and factors will be used to revise e-Manifest fees?

1. Background

In the 81 FR 49072, July 26, 2016, proposed rulemaking, EPA proposed both a process and several fee adjusters that the Agency was considering to address the so-called ''fee trajectory'' concern. Fee trajectory provides a means to ensure that the program's user fees remain aligned with any changes to program costs. Changes to program costs could arise, for example, from increased labor costs for EPA's internal staffing or for its contractors, from increases in the

[5] The custom indirect cost rate includes those indirect costs incurred by EPA in operating and managing the e-Manifest program. This custom rate also includes EPA Headquarters general and administrative expenses, including OLEM's Immediate Office and the ORCR's administrative office, which are not captured as part of the EPA Program costs that EPA tracks as direct costs in determining the program's overall costs and resulting fees. All costs are captured in the Agency's financial system.

costs of licensing software or other system components, as well as from inflation. In addition, since the calculation of e-Manifest fees is highly dependent on accurate information about program costs and the numbers of manifests in use, the e-Manifest user fees need to be reevaluated regularly to ensure that the fees are based on the most recent cost and manifest usage data.

To address fee trajectory, EPA proposed a fee revision process under which the fee formula would be re-run with the latest program cost and manifest usage numbers at two-year intervals. EPA based this proposal on the perceived advantages of providing more stability to users under a two-year fee schedule, as well as the advantage to EPA of avoiding the administrative burden of constantly updating and publishing fee revisions annually. Moreover, we believed that a two-year fee refresh cycle was consistent with OMB's Circular A–25 user fee guidance, which requires agencies of the executive branch to conduct biennial reviews of its user fees, including any adjustments to the fees charged. See 81 FR 49072 at 49086, July 26, 2016.

In addition, since EPA would retain the formula and merely refresh the fee schedules to reflect the most recent program cost and manifest numbers, the refresh and publication of the revised fee schedules under the proposal would be conducted informally. That is, EPA would not conduct notice-and-comment rulemaking with each fee schedule revision cycle, but would instead publish the revised fee schedule to users through the e-Manifest program's website, and publish the fee schedules in this manner 90 days prior to the effective date of the new fee schedule.

To enable a more durable fee methodology and avoid the need for frequent regulatory amendments, EPA included several fee adjusters in the proposed rule. The point of these adjusters was to keep the calculated fees current with any anticipated program cost changes, and avoid having to revise the formula and methodology by new regulations. If the fee formula with the proposed adjusters could keep the e-Manifest fees aligned with program cost changes, then EPA could retain the fee formula over an extended period of time, simply by refreshing the fees at two-year intervals with the latest budget and manifest numbers, and applying the regulation's adjusters. This is what EPA intended by a durable fee methodology.

EPA proposed several such adjusters. First, we proposed an inflation adjustment factor predicated on the Consumer Price Index, for all items not seasonally adjusted, or CPI–U. EPA believed the CPI–U was a sufficiently representative inflationary index, and we proposed to use that index to adjust e-Manifest fees between the first year and second year of each two-year fee revision cycle.

Second, EPA proposed a revenue recapture adjuster to deal with revenue losses that might result to the program from imprecise estimates of manifest numbers used to determine fees in the fee formula. The fees calculated under the fee formula, and therefore the revenue to be collected from e-Manifest user fees, are highly sensitive to the numbers of manifests actually in use each year. Over time, as EPA obtains data from the system showing precisely how many manifests are submitted to the national system, the program should be less vulnerable to losses from imprecise estimates. But particularly in the initial years of implementation, when our fee formula will work off of estimates of manifest usage developed from economic analyses rather than actual experience, imprecise estimates of manifest numbers are an area of revenue vulnerability. Therefore, EPA included the revenue recapture adjuster so that we could compare our estimated manifest usage numbers for each fee cycle with the numbers actually submitted, and then recapture the revenues lost from inaccuracies in the subsequent fee cycle. In this manner, the fee methodology would become self-correcting for any such revenue losses.

Third, EPA proposed a third adjuster that we referred to as the uncollectable fee adjuster. Like the above revenue recapture adjuster, this proposed adjuster also sought to recover revenue losses from the previous two-year cycle. This adjuster, however, was focused on revenue losses that arose from fees that proved to be uncollectable after being billed to facilities. Thus, the effect of this proposed adjuster was to track how much revenue the program lost from unpaid and uncollectable fees billed to facilities, and then recover those revenues in the next fee cycle by increasing user fees sufficiently to recoup those losses. All the proposed adjusters were aimed at accomplishing full cost recovery, and providing a means for the fee system to be durable and self-correcting, where possible.

2. Comment Analysis

The majority of industry and state agency commenters supported the proposal to refresh fee schedules at two-year intervals, with informal publication of the revised fees to the program's website 90 days in advance of their effective date. Several commenters objected to certain aspects of the proposed informal fee revision process. An industry trade association objected to the 90-day lead time for new fee schedules as too short, and suggested a 180-day lead time was more appropriate, especially if there were large (>10%) fee increases. Two industry commenters objected to EPA making any fee changes without conducting a rulemaking, while a state agency commenter asserted that new fee schedules should be developed annually.

Other commenters requested clarification of points raised in the proposal. One comment asked the Agency to clarify if it was the intent of the proposed rule that fees would be identical for both years of a fee cycle, or, would they change between years. Another commenter requested clarification about the effective date of fee revisions, and whether a fee would be charged based on the date of initiation of a manifest, or on the date of receipt at the receiving facility.

For the proposed fee adjusters, there was general agreement among both industry and state agency commenters in support of the inflation adjuster based on the CPI–U as the measure of the inflationary impact. However, a minority of commenters stated that an inflation adjuster did not seem necessary, if user fees were to be refreshed as frequently as every two years. There also was support expressed by several commenters for the proposed adjuster to recover losses from imprecise manifest usage estimates. There were strong and general objections expressed by both industry and state agency commenters to the proposed uncollectable manifest fee adjuster. Nearly all these commenters expressed the view that it was unfair to charge responsible users who were paying their fees on time additional amounts to compensate for non-paying users. However, one generator did submit a comment in support of the uncollectable fee adjuster.

3. Final Rule Decisions

For the final rule, EPA is affirming the proposed fee revision process to be conducted at two-year cycles by refreshing the fee formula with the most recent e-Manifest program cost numbers and manifest usage numbers. We also affirm that the process will be conducted informally rather than through notice-and-comment rulemaking, as long as the Agency is using the same fee setting methodology promulgated in this rule. Thus, the final rule will provide that the new fee schedules developed every two years

from re-running the fee formula will be published to users via the e-Manifest program's website, at least 90 days prior to their effective date. While the Agency appreciates that an annual fee revision process would be even more responsive to program cost and manifest number changes than the final rule's two-year cycle, the Agency is persuaded that any such advantage is overwhelmed by the additional administrative burden to EPA in conducting a nearly constant, annual fee refresh process. Also, we believe there are advantages to users in having access to a stable fee schedule of two years' duration, rather than having to anticipate and react to a more frequent fee revision process.

In finalizing the rule with this informal fee revision process, EPA rejects the comments suggesting that all fee revisions require a new rulemaking. While we acknowledge that OMB Circular A–25 requires agencies to promulgate user fees by regulation, EPA concludes that this requirement is met by developing this Fee Rule announcing our durable fee methodology through the regulatory process. By developing our durable fee methodology through rulemaking, EPA is providing the user community with notice and opportunity to comment on the information and process EPA will rely on in setting e-Manifest user fees, including those factors that will be used to adjust fees to align them with changes in program costs. EPA is aware that other fee programs follow similar processes in determining and revising their fees. EPA believes the durable fee methodology and informal fee refresh process announced in this rule meets all applicable legal requirements and OMB Circular A–25 policy. Otherwise, the result would be a prohibitively burdensome administrative process were EPA to constantly develop regulations for every fee revision. In addition, while EPA understands the desire to have more lead time to understand and budget for user fee revisions, EPA concludes that a 90-day lead time should be workable, as it will enable EPA to base the new fees on the latest cost and manifest usage trends, while still affording users reasonable time to plan for the revised fees. Also, by refreshing the fees at two year intervals, it would seem unlikely that fee changes will be so significant between cycles that facilities will need six months or more to prepare for their implementation.

Based on the public comments and the necessity of full cost recovery and stable revenues, EPA is finalizing the rule to include the inflation adjuster based on the CPI–U, and the revenue recovery adjuster for revenue losses from imprecise manifest usage estimates. The inflation adjuster will operate to adjust fees between the first and second year of a fee cycle, so it is likely that fees will not be identical for both years of a cycle, but differ somewhat to reflect the inflation adjustment. The revenue recovery adjuster for imprecise manifest numbers will operate between fee cycles, to adjust fees in the new cycle to account for revenue losses during the previous cycle. Since the billable event for e-Manifest fees is the submission of the final manifest by the receiving facility, the fee charged will be determined based on the date of submission by the receiving facility, and not the date of initiation by a generator.

Finally, EPA is not including the proposed uncollectable manifest fee adjuster in §§ 264.1313(c) and 265.1313(c) of the final rule. While such an adjuster might help to stabilize program revenues in the event of significant non-payment incidents, EPA is persuaded by comments objecting to the fairness of charging responsible users for the revenue losses occasioned by delinquent payers. In addition, EPA believes that non-payment episodes will be infrequent, and should be resolved or moderated through the dispute process provided in the rule, or through the deterrent effect of the rule's sanctions for non-payment.

F. What process will be used for manifest data corrections?

1. Background

In the 81 FR 49072, July 26, 2016, proposed rulemaking, EPA proposed a process by which receiving facilities only could submit a certified corrections submission electronically in order to make corrections in the data system to existing manifest records. (81 FR 49072 at 49098). The facilities could make these corrections by accessing the web-based e-Manifest application directly, or, by uploading a correction submission (*e.g.,* a JSON file) affecting one or a batch of manifest records. Every correction submission by a facility would require a Cross-Media Electronic Reporting Rule (CROMERR)-compliant signature certifying that the data as corrected are true, accurate and complete. *Id.* The proposed rule's correction submission would clearly identify the Manifest Tracking Number of the affected manifest(s), the items on the manifest being altered, and set out both the data previously entered and the data as corrected. *Id.*

The proposed data correction provisions also included a fairly detailed process by which corrections would be initiated and reviewed by interested persons, *i.e.,* other handlers included on the affected manifest, and state regulators. Critical to this proposed process was the requirement that all data corrections were to be completed within 90 days of receipt of the manifested wastes, so that the corrections process would be completed by the date that manifest data could be disclosed by the system to the public under existing regulations. The proposed rule discussed one process under which the data correction was initiated by the receiving facility and another process under which another interested person (other waste handler or state) initiated a correction by providing the facility with notice of a data error. In either case, the proposed rule provided comment windows for interested persons to respond to the facility's data correction, and the correction process had to be completed by the facility no later than 90 days post-receipt for the waste shipment. *Id.* at 49099. Finally, EPA proposed that a fee would be collected for all data correction submissions from receiving facilities. *Id.*

2. Comment Analysis

EPA received a variety of comments both supporting and objecting to the proposed data corrections process. A trade association of large receiving facilities and several members of the industry supported the major features of the proposed corrections process, including the proposal that only receiving facilities could submit data changes to the system, and the proposed requirement to submit all corrections electronically. These industry members also supported the batch certification process whereby one electronic signature would suffice to certify to a batch of data record changes.

Among members of the waste industry, there were several comments that dissented to the proposal that only receiving facilities could enter data changes in the system. The dissenting commenters questioned why generators, transporters, or state agency representatives could not also make these changes, and one objected to the idea that the proposed rule seemed to portray receiving facilities as owners of manifest data, when generators should be playing this role. Other industry commenters and a state agency observed that not all facilities would be able to submit their corrections electronically, and that the rule should provide appropriate exceptions.

EPA received many comments from industry and state agencies objecting to

the proposed 90-day window for making data corrections. These commenters provided examples of several situations where errors and the need for corrections would not become apparent until after the 90-day window had passed, such as errors discovered after containers placed in storage were opened, during an audit, or while preparing an annual or biennial report. All these commenters urged EPA to reconsider this 90-day window, and allow data corrections to occur at any time they are needed.

Many industry commenters also objected to the proposed fee for data correction submissions. Theses commenters asserted that a fee charged for corrections would operate as a disincentive to correcting data errors, and denigrate data quality in the system.

The remaining comments on this topic were concerned with the clarity of the proposed corrections process, and they suggested several ideas for clarifying and improving the process. Within these comments were suggestions that the final rule:

- Clarify the interested parties who can participate in the corrections process,
- Clarify how receiving facilities will notify off-line generators of errors, discrepancies, or proposed corrections, and how off-line generators will notify facilities of data errors,
- Clarify how generators will be alerted to proposed corrections and how they will be able to validate or dispute such corrections,
- Clarify which states will receive notices of proposed corrections,
- Clarify the data validation rules and standards that will be followed for paper manifests, and the expectations for QA/QC and resource implications for states, and
- Clarify how the original and corrected versions of the manifest will be retained in the system.

In addition, at the initial e-Manifest Advisory Board meeting conducted on January 10–12, 2017, Advisory Board members discussed the proposed rule's corrections process and offered suggestions to EPA representatives. Several Board members suggested there should not be detailed regulatory provisions or a prescriptive process for data corrections. Instead, the Advisory Board members suggested a minimal role for a regulation, and an open process by which any waste handler named on a manifest could at any time make a data correction. All interested parties should be made aware of another's proposed data change, and the last change made in the system would stand until corrected.

3. Final Rule Decisions

For the final rule, EPA is accepting the many comments that objected to the 90-day post-receipt window for making corrections, as well as the numerous comments objecting to the collection of a fee for correction submissions. EPA is persuaded by the comments that both of these proposals could have the deleterious effect of discouraging data quality.[6] Further, EPA agrees that all interested persons (*e.g.,* waste handlers named on manifests) should have the ability to submit a data correction, whenever a data error in an existing record becomes apparent.

EPA also is accepting the suggestion of e-Manifest Advisory Board members that the e-Manifest data corrections process should be an open process governed by minimal regulatory provisions, and without regulatory limits on who, when, or how many changes are made to manifest data records. Therefore, the final rule provisions on data corrections are much simpler than the proposed approach, and specify only that any interested person (*e.g.,* waste handler named on the manifest) may make a data correction submission at any time. Data correction submissions must be made electronically, with electronic notice to other interested persons shown on the manifest. The correction submission may relate to an individual record or to an identified batch of records, and must be accompanied by a CROMERR-compliant certification that to the person's knowledge and belief, the data as corrected will cause the affected data records to be true, accurate, and complete.

EPA emphasizes that under the final rule, the initiation of data corrections is not limited to receiving facilities, so the proposed rule approach under which only receiving facilities could submit corrections (at their own initiative or in response to a notice of error from an interested party) is not being finalized in the regulation. Instead, the final rule will simply state that any interested person (*e.g.,* waste handler shown on a manifest) may submit a data correction submission at any time, by submitting a single record or batch correction electronically to the system; by making the required CROMERR-compliant certification to that person's knowledge and belief, the data records as corrected are true, accurate, and complete; and by giving electronic notice to the other interested persons shown on the manifest. Consistent with the proposed rule, the correction submission must indicate the record being corrected by its Manifest Tracking Number, must identify the Item Number of the manifest data fields affected by the correction, and for each data field corrected, must show the previously entered data and the data as corrected. The final rule corrections process is therefore an open and cumulative process under which any interested person may submit a correction affecting the data from the original manifest record, or affecting the data from previous corrections submitted by others. There is no limit to the number of corrections that may be entered, and the last submitted correction is presumed valid and accurate unless corrected by a subsequent data correction.

Those persons making data corrections must provide electronic notice of the changes to other interested persons shown on the manifest. The notice to interested persons must be provided by email or by another system-generated electronic notice.

With respect to data corrections from off-line generators, and notices of corrections to these off-line generators, all generators must provide an email address where they may be contacted, so that they may participate in the data corrections process and receive correction related notices. While a generator may receive notices of data corrections by email, a generator must have system access credentials and must enter electronically any data corrections relating to electronic or paper manifests in the system, and must provide the required certification of any data corrections so entered.

Finally, EPA is clarifying that it is not the intent of the data corrections process to produce amended or revised manifests, but rather to produce changes only to the data records from manifests that reside in the national data system. The role of the manifest is to serve as a tracking document during the transportation of off-site shipments of hazardous waste and state only regulated wastes. The function of the manifest is complete at the time the receiving facility signs the manifest to indicate the receipt of the waste (or a discrepancy), and the signed copy showing the data at the time of receipt is distributed to the other interested persons. The data from completed,

[6] EPA notes that the proposed 90-day window on submitting data corrections was premised in part on the desire to produce final, corrected manifest data in the system prior to the data becoming publicly available by virtue of the One Year Rule's policy that manifest data shall be made publicly available 90 days after receipt of a shipment at the receiving facility. The result of the decision, in this final rule, to remove the proposed 90-day corrections window is that in some instances, the data disclosed to the public after 90 days may not be final data and may be subject to subsequent corrections.

original manifests become the first representation of the manifest data records in the data system, but these data records are subject to revision through the final rule's corrections process, as well as through the discrepancy reporting process. The resulting data corrections will be made only to the data records in the national data repository, but will not result in the original, completed manifests being revised and redistributed. The system will retain the final manifest copy signed by the receiving facility as the copy of record of the completed manifest, and all subsequent corrections will be entered in the data system records, with an auditable trail of the corrections made and who made them retained in the system.

G. How does the final rule address fee sanctions?

1. Background

EPA proposed several tiers of fee sanctions in the User Fee proposed rule that would be included in the e-Manifest fee program to induce manifest users to pay their fee obligations promptly. EPA explained in the proposal that these sanctions are necessary because the e-Manifest fee program would become vulnerable to revenue instability if significant numbers of invoiced payments were not paid promptly. Such instability would quickly put at risk the Agency's ability to operate the e-Manifest system on a self-sustaining basis and to meet its financial obligations in running the national system. For the purpose of ensuring timely payment of e-Manifest user fees, EPA proposed sanctions that would increase in their severity based on the degree and duration of the delinquency. See 81 FR 49072 at 49094, July 26, 2016.

Specifically, EPA proposed a first tier sanction based on a financial penalty under 31 U.S.C. 3717(a)(1), a provision of the federal claims collection statutes that imposes an interest charge at the Current Value of Funds Rate or CVFR on those persons who are delinquent in paying claims owed to the federal government. EPA considers a fee payment to be delinquent and subject to this interest charge if payment is not received by the due date specified on an invoice, which for e-Manifest fees, would be 30 days from the date of the invoice. Thus, for e-Manifest users, payments received later than 30 days from the date of the invoice would be subject to this initial interest charge measured at the currently prescribed CVFR rate.

If the first tier interest charge at the CVFR rate were not effective in causing a delinquent fee payer to make the outstanding payment, then the proposed rule's fee sanctions would assess a second tier 6% financial penalty charge for e-Manifest user fee debts that are more than 90 days past due, that is, user fee debts that are not paid by the date 120 days from the date of the invoice. Like the initial interest charge at the CVFR rate, this additional 6% financial penalty also is based on the federal claims collection statutes. 31 U.S.C. 3717(e).

As a third tier of proposed fee payment sanctions, EPA proposed that receiving facilities would become eligible for inclusion in a list of delinquent fee payors when the period of their delinquency extended to 120 days or greater. Finally, the proposal also explained that if any manifests remained incomplete because of owed fees, then the receiving facility could be in violation for failure to fully complete a manifest per proposed § 264.1315(d) and/or § 265.1315(d), and EPA could enforce this violation under RCRA section 3008.

In addition to these several proposed sanctions, EPA requested comment on additional sanctions (*i.e.,* denial of manifest services and the withdrawal or suspension of authority to operate (*i.e.,* RCRA ID numbers or permits). See 81 FR at 49094, July 26, 2016. EPA's intention was to develop a credible mix of available sanctions that could be scaled to the degree of the offense caused by the delinquency or non-payment, with the expectation that this framework would minimize or avoid delinquent payments.

2. Comment Analysis

Industry and state comments on the proposed rule generally supported the financial sanctions, as well as the civil enforcement sanction for ''egregious'' cases, but several industry stakeholders expressed concern with the proposed definition of ''incomplete'' manifests. These commenters stated that the proposed definition could be construed to negatively impact generators, who are more generally responsible for completing RCRA manifests. Other commenters showed little support for the publicity sanction or denial of services as a sanction. These commenters indicated that a publicity sanction would not likely be effective in influencing payment behavior and would be unprecedented in existing EPA fee programs. Other comments opposing the denial of services sanction indicated such a sanction would be too severe, as it would tend to penalize generators too much in their efforts to obtain waste services, and would likely cause a backlog of manifests in the EPA data system. Another commenter suggested that denial of services to facilities and their customers could cause constrictions in waste management and perhaps cause frustrated generators to mismanage their wastes.

3. Final Rule Decisions

After careful consideration, EPA is accepting the numerous comments that generally supported the tiered sanction approach and that provided particular support for the proposed financial sanctions under the federal claims collection statutes and the availability of RCRA civil enforcement orders to enforce non-payment of fees. Thus, EPA is finalizing these proposed sanctions at 40 CFR 264.1315 and 265.1315 with slight modification in the rule. Specifically, the final rule adopts the proposed sanctions detailed in paragraphs (a) and (b) at §§ 264.1315 and 265.1315 for financial interest and penalty charges without change. EPA, however, is persuaded by the adverse comments to the proposed publicity or delinquent payors list sanction and therefore is not adopting this proposed sanction in the final rule.

EPA also accepts the commenters' opposition to the ''incomplete manifest'' terminology in proposed paragraph (d) of §§ 264.1315 and 265.1315. EPA intended to define a regulatory violation applicable only to the receiving facilities that have not ''completed'' their manifest transactions by submitting their manifests to the system and paying fees for the manifest services they have obtained from the system. The proposed violation was not intended to cause confusion relating to what is meant by the requirement for generators to initiate and complete manifests to track their off-site waste shipments. EPA, therefore, has amended the proposed ''incomplete manifest'' terminology in the rule to keep manifest completion distinct from the financial context intended in the proposed rule. To avoid any confusion with the concept of manifest completion, EPA is denoting a manifest for which fees remain unpaid by the receiving facility as an ''unperfected'' manifest. The final rule amends the proposed paragraph (d) at §§ 264.1315 and 265.1315 by assigning it as new paragraph (c) and clarifying that a manifest is not fully perfected until it is both submitted to the system and all fees for those manifests have been paid by the receiving facility submitting it. Thus, the RCRA civil enforcement sanction

included in this final rule would apply only to the receiving facilities that are involved with unperfected manifests by not submitting them to the system or by not paying the applicable fee for their processing. This civil enforcement sanction would have no applicability to the activities of generators in their use of the manifest. The designation of a manifest as ''unperfected'' for purposes of payment by a receiving facility in no way impacts the validity of a manifest supplied by a generator for tracking its waste during its transportation off-site to a facility.

Finally, EPA also accepts the numerous commenters that objected to the additional sanctions (*i.e.,* denial of manifest services and the withdrawal or suspension of authority to operate) discussed in the proposal. Therefore, EPA is not promulgating these sanctions as part of this rule. EPA concludes that the several financial and civil enforcement sanctions adopted in the final rule create a credible mix of available sanctions that increase in their severity based on the degree and duration of the delinquency.

H. How does the final rule address user fee disputes?

1. Background

In the User Fee proposed rule, EPA acknowledged that over the course of invoicing users for their fee obligations, errors may occasionally be made and thus may give rise to disputes concerning the amount of a user fee payment that is due in response to an invoice. EPA explained in the proposed rule that the Agency is not proposing a formal dispute resolution process governed by explicit and detailed regulatory provisions and processes. Rather, EPA intends to address e-Manifest fee disputes through a more informal process that EPA concludes will be sufficient and less burdensome than a formal process, while scaled more appropriately to the nature of such disputes. EPA requested comment on an informal fee dispute process under which users who believe their invoice is in error (statement incorrect on numbers or types of manifests billed, or a mathematical or other error) could first seek resolution via the system's billing representatives by making a claim identifying the nature and amount of the error. If not satisfied by the handling of their claim at this initial level, the claimant could appeal to the Office Director (OD) of EPA's Office of Resource Conservation and Recovery (ORCR), whose decision on the claim would be final and not subject to further Agency review. See 81 FR 49093, July 26, 2016.

2. Comment Analysis

Industry commenters generally supported the proposed informal process, but one industry commenter had reservations about the fairness of the proposed appeals process. This commenter suggested that the ORCR OD would not be as unbiased as an independent third party and suggested that the OD's decision be subject to the Alternative Dispute Resolution program administered by the EPA's Office of General Counsel. See 65 FR 81858, December 27, 2000. Another commenter underscored the need for EPA to establish accessible customer support for timely resolutions. One state commenter, however, opposed the proposed informal process, and suggested that EPA should instead adopt a formal dispute resolution process that affords due process and creates perhaps a stronger record for fee dispute decisions.

3. Final Rule Decisions

After analyzing the comments to the proposed informal process, EPA is promulgating the proposed informal process in the final rule. EPA acknowledges the industry commenter's apprehension about the fairness of the appeal process under the informal process, but the Agency does not accept the industry comment favoring an appeal of the OD's decision to an independent third party decision maker under an Alternative Dispute Resolution (ADR) process. EPA opposes this suggestion for a couple of reasons. Although the ADR process offers conciliation, facilitation, arbitration, mediation, fact-finding, mini-trials, and other services to claimants, EPA's December 2000 **Federal Register** publication announcing the ADR processes at EPA (65 FR 81858) suggests that ADR was intended for matters far more substantial and potentially controversial (*e.g.,* adjudications, rulemaking, policy development, administrative and civil enforcement actions, permit issuance, contract award protests, workplace grievances, and litigious matters where a more substantial fact-finding and record development are necessary) than for the fairly simple fee disputes we anticipate in e-Manifest. Second, EPA understands that the use of the Agency's ADR process would be very time consuming and involve much greater costs than an informal process. The Agency believes the informal process scales well to the relative simplicity expected of fee disputes, and will result in more timely and less burdensome resolution of e-Manifest program fee disputes. EPA intends to respond to billing disputes within ten days of receipt of a claim under the informal dispute process. Finally, the Agency also concludes that the ORCR Office Director is sufficiently unbiased on such fee dispute matters to afford fairness to these informal proceedings.

EPA also rejects the state agency comment recommending that EPA establish a formal dispute process. EPA concludes that the adjudicatory processes typically associated with formal dispute resolution are not well matched with the simplistic nature of the e-Manifest fee disputes. In addition, evidentiary proceedings typically are the most time consuming and resource intensive processes that could be selected.

As stated in the proposed rule and adopted under this action, EPA will post on the e-Manifest website a phone number and an email address where users may contact the system's billing representatives with any questions they may have about the accuracy of a monthly user fee invoice. Whether a fee dispute claim is asserted over the phone, or by email, EPA expects the facility to provide sufficient information to support its claim that an invoice is in error. At a minimum, EPA expects that fee dispute claimants will provide the following information to the system's billing representatives:

- The claimant's name, the facility where the claimant is employed, the EPA Identification Number of the affected facility, the date and/or other information to identify the particular invoice that is the subject of the dispute, and a phone number or email address where the claimant can be contacted;
- Sufficient supporting information or calculations to identify the nature and amount of the fee dispute, including:

—Whether the error results from the types of manifests submitted being inaccurately described in the invoice,
—Whether the error results from the number of manifests submitted being inaccurately described in the invoice,
—Whether the error results from a mathematical error made in calculating the amount of the invoice, or
—Other information described by the claimant that explains why the invoiced amount is in error and what the fee amount invoiced should be if corrected.

EPA's system billing representatives will endeavor to respond to all such billing disputes within ten days of

receipt of a claim. In their response, the system's billing representative will indicate whether the claim is accepted or rejected, and if accepted, the response will indicate the amount of any fee adjustment that will be refunded or credited to the facility. If the claimant is not satisfied with the response of the EPA system's billing representative, the claimant may appeal its claim within ten days to the Office Director for the Office of Resource Conservation and Recovery.

EPA further emphasizes that the assertion of a fee dispute claim through this informal process does not excuse the requirement to make timely electronic payments of the invoiced fee amounts. Fee adjustments will be handled as refunds or credits of amounts paid, and the existence of a claim does not justify withholding payment of invoiced fees.

Finally, EPA is clarifying that once a claim has been addressed by the Agency under this informal dispute resolution and appeal process, the resolution that is reached after appeal to the Office Director concludes the matter and is non-reviewable by any other Agency official or in any other Agency proceeding.

I. Conforming Changes to the Paper Manifest Printing Specifications

In March 2005, EPA announced the Manifest Registry system that described procedural mechanisms and offered federal printing specifications at § 262.21(f) to ensure that printers approved by EPA used unique tracking numbers on each manifest, and to reduce the possibility of printing many variations of manifest forms. As part of the printing specifications, EPA also required approved printers to indicate on the bottom, right margin of the form the distribution scheme so that the form would be distributed as follows:

Page 1 (top copy): ''Designated facility to consignment state'' (if required);
Page 2: ''Designated facility to generator state'' (if required);
Page 3: ''Designated facility to generator'';
Page 4: ''Designated facility copy'';
Page 5: ''Transporter copy''; and
Page 6 (bottom copy): ''Generator's initial copy.''

However, the e-Manifest regulations and the plans to begin e-Manifest system operations on June 30, 2018, have necessitated a conforming change to the current manifest copy distribution scheme. Currently, the manifest form printing specification requires that the top copy (Page 1) of the six-copy set of forms be sent by the designated facility to the consignment or destination state, if required by that state. However, on February 7, 2014, EPA announced in its e-Manifest ''One Year Rule'' that when the e-Manifest system becomes operational, designated facilities must send the top copy (Page 1) of the six-copy paper form to the e-Manifest system for purposes of data entry and processing. See 79 FR 7518 at 7548. EPA is codifying in this final rule the regulatory decision EPA announced (but did not codify) in the February 7, 2014 issuance of the One Year Rule.

Since the states with manifest collection and tracking programs have continued to collect manifest copies during the planning and development of e-Manifest, EPA chose to defer the collection of the top copy by e-Manifest until the e-Manifest system was ready for operations. With the announcement in the final rule that e-Manifest system operations will commence on June 30, 2018, it is necessary to implement with this final rule action this change to the copy submission requirement, as well as the conforming change to the printing specifications for manifest printers.

Therefore, the final rule modifies the printing specification requirements at § 262.21(f)(5) and (f)(6)(i) to align with the new manifest submission requirement for receiving facilities announced in the One Year Rule. Thus, by June 30, 2018, approved printers must make available to users a printed five-copy form that indicates that the top copy of the manifest must be submitted by designated or receiving facilities to EPA's e-Manifest system. Manifest users must begin using the new 5-copy manifest form with this revised copy distribution notation on June 30, 2018. Specifically, the copies of the form must be distributed as follows:

Page 1 (top copy): ''Designated facility to EPA's e-Manifest system'';
Page 2: ''Designated facility to generator'';
Page 3: ''Designated facility copy'';
Page 4: ''Transporter copy''; and,
Page 5 (bottom copy): ''Generator's initial copy.''

This change to the manifest form printing specification will bring the manifest forms that will be used on or after June 30, 2018, into alignment with the paper manifest submission requirements that will be in effect on that date. Beginning on June 30, 2018, the top copy of any paper manifests that continue in use must be sent to the e-Manifest system, rather than being sent by the receiving facility directly to the consignment or destination state. In addition, the new five-copy form eliminates the copy, previously denoted as ''Page 2: Designated facility to generator state,'' since the submission of the top copy to the system by the receiving facility will itself enable both destination states and generator states to receive their copies from the system. This is the copy that EPA will use for data entry purposes. As the central hub for manifest collection, EPA will share these data with interested states, but receiving facility copies will not be sent directly to either consignment or generator states on or after June 30, 2018. Therefore, one copy of the current six-copy form set is being eliminated in the final rule, and the new manifest printing specifications will require only a five-copy form to be printed and used beginning on June 30, 2018.[7]

EPA emphasizes that the requirement that receiving facility copies of paper manifests be submitted to the e-Manifest system rather than directly to states is promulgated under the authority of the e-Manifest Act. As such, the requirement for facilities to submit manifest copies to e-Manifest in lieu of direct submission of these copies to the states must be implemented consistently in all states starting on the system launch date of June 30, 2018. As the Agency explained in the One Year Rule, requirements under state law that are less stringent than or inconsistent with requirements issued by EPA under the e-Manifest Act are superseded by the e-Manifest Act requirements when these requirements become effective on the system launch date. See 79 FR 7554, February 7, 2014. This principle is also codified in this final rule in 40 CFR 271.3(b)(4), which explains the superseding effect of e-Manifest Act requirements on less stringent or inconsistent requirements contained in state law and authorized programs. Finally, in § 271.12(i), addressing manifest program requirements that must be included in authorized state programs, EPA is adding a new paragraph (i)(2) that will require state manifest programs to include a specific requirement for owners or operators of hazardous waste management facilities to submit a signed copy of the manifest to EPA's e-Manifest system in lieu of sending a copy directly to origination or destination states.

The final rule also revises the printing specification at § 262.21(f)(7) to comport with the aforementioned changes to the manifest form and continuation sheet. The uniform manifest instructions for completing the generator's copy, the transporter's copy, and the designated facility's copy of the manifest and continuation sheet must now appear on

[7] The changes to copy distribution requirements in the final rule affect the receiving facility copies. The e-Manifest system will not collect generator copies of paper manifests, and states that still wish to collect paper copies directly from generators may continue to do so under state law.

the back of copies five, four, and three, respectively.

J. Requirement That Facilities Submit Paper Manifest Data Digitally

1. Background

In the User Fee proposed rule, EPA did not propose but requested comment on an approach under which receiving facilities would be prohibited from submitting paper manifests by mail to EPA. Instead, receiving facilities would be expected to submit manifest-related data to EPA by electronic means only, that is, by uploading image files to EPA, or by uploading a data file (*e.g.,* JSON file) of manifest data accompanied by an image file. Although EPA explicitly stated in the e-Manifest Final rule that the e-Manifest Act and the regulations adopted by the final rule allow manifest users to continue to use paper in the field to track their waste shipments, EPA explained in the User Fee proposed rule that the Agency was considering restricting receiving facilities to digital submission of their paper manifests for a couple of reasons.

First, EPA acknowledged in the proposed rulemaking (81 FR 49074, July 26, 2016) that the proposed differential fee approach should itself discourage facilities from submitting large numbers of manifests by mail but conceded that it would be difficult for the Agency to project with confidence how many paper manifests will be mailed to the Agency in the initial years of e-Manifest operations. Consequently, the processing of mailed forms could involve significant personnel and contractor costs for opening and screening mail, for data key entry, document archiving, and for QA activities related to resolving data quality issues. Second, EPA believes paper processing costs could dominate the O&M costs in the early years of operation, and if mail submissions occur in unexpectedly large numbers, EPA may need to increase fees or consume more of its annual spending authority than anticipated to process mailed manifests. For these reasons, EPA requested specific comments on the merits of an approach that would restrict receiving facilities to submitting their paper manifest data to the Agency by digital methods only, and not by mailing hard copies to the EPA system.

2. Comment Analysis

Industry commenters to the User Fee Proposal generally supported limiting receiving facilities' paper submissions of paper manifest related data to digital format only (*i.e.,* scanned images or data file with scanned image uploads) and not by mailing paper hardcopies to EPA. However, several commenters who supported the digital submission restriction suggested EPA impose a several-year transition period before instituting the paper submission ban. Other commenters supporting the paper submission ban suggested EPA provide an exception to the ban should unforeseen circumstances, such as unanticipated burdens, data security issues, access issues for responders, and compliance issues when the system is down or data are lost, occur.

Some state commenters presented mixed comments on the merits of a mailed paper submission ban. One state commenter supported the paper copy submission ban, noting that paper infrastructure costs are great, and the ban would help to reduce uncertainty in fee formula's marginal cost calculations. Another state commenter opposed an outright ban and argued that there could be substantial burden and cost for some facilities to change platforms. The commenter suggested that especially for those facilities not owned by nationwide companies, the costs to them of converting to digital only submissions could be prohibitive in the initial years. The commenter suggested EPA implement a phase-out deadline of several years for the mailed paper copy submissions. Finally, one state commenter objected to the ban of postal mail submissions and argued that EPA has overestimated the sophistication of some industry members, especially those receiving facilities that are not RCRA permitted facilities.

3. Final Rule Decision on Facility Submissions of Paper Manifests

After careful consideration of the comments to the User Fee Proposed Rule, EPA has decided not to implement an outright paper submission ban. Instead, EPA will initially allow both digital and mailed manifest submissions from receiving facilities to the system, but will schedule a phase-out of paper mail submissions after three years of system operations. EPA made this determination for a few reasons. First, while EPA acknowledges its decision could result in the Agency receiving more paper forms in the initial years of operation, EPA is persuaded by a few commenters' arguments that an out-right ban on day one of system launch may cause financial hardship to certain facilities that currently do not have the technological capacity to digitally submit paper manifest related data to EPA. Second, EPA concludes that a phase-out approach on a paper submission ban best accommodates the uncertainty over how many and what types of facilities might be burdened by the paper submission ban. EPA has consulted primarily with a trade association (the Environmental Technology Council) that is comprised of larger receiving facilities, so at this time the Agency does not know whether mid-size or smaller receiving facilities would be similarly inclined to submit data files and scanned images of manifests to EPA and avoid mailing paper forms to EPA for processing. EPA, however, believes a phase-out scheduled after three years of system operations provides fairness and flexibility to those facilities that need time to adjust to electronic manifests and acquire and develop digital capability.

Finally, this approach is consistent with the e-Manifest Act's terms allowing the continued use of paper and authorizing EPA to issue requirements to facilitate transition to electronic manifests. Thus, the adoption of phase-out approach scheduled after three years in the final rule best accommodates the Agency's objective of minimizing mailed paper submissions with our legal authority that allows the continued use of paper manifests while requiring EPA to issue regulations to facilitate the transition to electronic manifests.

EPA notes that the aforementioned phase-out of manifest hardcopies applies only to the backend of the manifest workflow (*i.e.,* manifest submissions to the EPA system). Hazardous waste generators who currently initiate their waste shipments using the paper manifest and continuation sheet (EPA Forms 8700–22 and 8700–22A, respectively) and want the flexibility to continue to use those forms once the e-Manifest system becomes available for use, will for now be afforded the flexibility to continue to use the manifest form and continuation sheet once the phase-out period begins.[8] If a receiving facility's customer prefers to use the paper manifest and continuation sheet after the phase-out period, then the receiving facility will be expected to transfer the manifest data from those paper hardcopies to digital format prior to submitting that data to the EPA system.

[8] In section IV of this preamble, however, EPA signals that it is the Agency's goal to curtail as far as possible the use of paper manifests and migrate to a fully electronic manifest within five years of the start of system implementation. EPA will collect information from the system on manifest usage, monitor this information, and consult with the e-Manifest Advisory Board in several years on how best to accomplish this goal.

K. How does final rule address user fee payment methods?

1. Background

The User Fee proposal included two distinct options for comment: (1) A monthly invoicing option, and (2) an advance, fixed payment option. EPA proposed the monthly invoicing option as its preferred option. Under this option, the Agency would bill each receiving facility monthly for its actual manifest activity engaged in during the previous month. The receiving facilities would receive an electronic invoice displaying their manifest activity during the prior month, and each facility would be directed to Treasury's *Pay.gov* website to submit their electronic payments. Once directed to *Pay.gov*, the payor could make their payment using one of the electronic payment methods supported by *Pay.gov*. These methods include credit cards, debit cards, and Automated Clearing House (ACH) debits from commercial bank accounts. EPA met with the Environmental Technology Council and its RCRA TSDF members prior to publication of the proposed rule, and learned that this trade association and its members preferred the monthly invoice option to the advance fixed payment option.

In the July 26, 2016, proposed rulemaking, EPA requested public comment on the advance, fixed payment option. With this option, EPA explained that receiving facility users would make a monthly fixed amount payment on the first of each month. The monthly payment amount would be determined using an estimate of expected manifest usage for the year, based on manifest usage during the prior year. The prior year's manifest use numbers would be totaled by manifest type and divided by 12 to arrive at the estimates of monthly manifest usage. The monthly manifest fee would be calculated by applying the fee schedule amounts to the monthly manifest usage estimates. Once so determined, the monthly fee amount to be paid to EPA would remain fixed for the entire year, and this fixed amount would be debited from the receiving facility's commercial bank account by an Automated Clearing House (ACH) debit on the first of each month. The fixed payment feature was included so that this payment option would be consistent with the standards of *Pay.gov* for recurring periodic payments.

EPA explained in the proposed rulemaking that the Agency believes advance payment is advantageous, from an administrative perspective, because such payments would allow for the collection of fees in advance of manifest services, which is administratively efficient on the front-end of the collection process. Such an approach also could provide a more stable revenue stream to cover system costs throughout the year, because of the nearly automatic, scheduled nature of the payments. This feature of the advanced payment option also could generate revenue more promptly for the initial year of system operations. However, the receiving facilities that the Agency consulted expressed some skepticism about this payment option, as an estimated payment would not be as accurate as payments invoiced from actual usage. These facility representatives advised that there can be significant variability from year-to-year in manifest usage, so the estimated payments collected through the advance payment approach may diverge significantly from the payments that would be owed based on actual usage.

To address this issue, EPA explained in the proposed rule that it would send one invoice to receiving facilities at the end of each year to reconcile the amounts paid based on manifest use estimates with the actual amounts owed as calculated from actual manifest usage data. Thus, this option would involve a reduced volume of invoicing compared to monthly invoicing, with resulting lower administrative costs to the Agency. Moreover, the revenue stability risk posed by the two-month lag inherent in monthly invoicing would be ameliorated by this alternative, with its automatic payments each month. Stakeholders stated that there would likely be resistance to automatic, estimated payments, unless EPA identified clear incentives for this option.

More recently, EPA convened the e-Manifest Advisory Board in January 2017 and sought guidance on how to address comments received on the advance, fixed payment approaches detailed in the proposed rule. During the Advisory Board meeting, the EPA stated that the Agency anticipates that the e-Manifest system will be operational in June 2018, assuming that the Agency receives adequate funding in fiscal years 2017 and 2018. At that time, EPA will transition to a fee collection system, and the majority of appropriated funds for e-Manifest in fiscal year 2018 will be used for operating and maintaining a paper processing center and IT help desk. While EPA expects to recover these costs through fees, EPA acknowledged at the Advisory Board meeting that a cash flow issue could arise as the system transitions from the developmental to fully operational stage and underscored that the advance monthly invoicing option could mitigate the potential cash flow problems during the initial years of system launch if the funds appropriated for operations were inadequate.

2. Comment Analysis

Comments received on the proposal and recommendations presented by the E-Manifest System Advisory Board in January 2017 generally supported the monthly invoicing option, while most comments opposed the advance payment approach. Industry and several state commenters generally supported the monthly invoicing and indicated that paying for actual usage on a monthly basis was the more precise option, and was more consistent with common commercial practice. Industry commenters argued further that it would be difficult to develop accurate manifest use projections needed for an advance option and stated pre-paying in advance could result in substantial under or over payments requiring later reconciliation, which could adversely impact system financial stability. One state commenter affirmed this sentiment and questioned how EPA would prevent advance payers from greatly underestimating usage for the year, and then owing huge balances at the end of the year. One industry commenter suggested the monthly invoicing is the most logical approach and will work well with the TSDF's process of invoicing their customers (manifest generators) for the associated manifest fees following acceptance of the waste shipments. Although most commenters supported monthly invoicing, a few stated 30 days is insufficient to pay invoices and suggested 45 or 60 days is a more realistic time frame. Finally, one commenter suggested EPA utilize the advance payment approach as a sanction for those who are chronically late with their fee payments.

While most commenters supported monthly invoicing, a few commenters supported advance, fixed payments. One state commenter supported the advance payment option because it is the least burdensome to the Agency to administer and most stable for the system. This commenter, however, suggested EPA create capacity to invoice a small number of smaller TSDFs or the non-permitted state-regulated facilities. Another commenter suggested that EPA retain advance payments as an option, because it could gain greater participation after TSDFs have a few years of experience with the e-Manifest system.

3. Final Rule Decisions

EPA is persuaded by the comments supporting the monthly invoice

proposal and the recommendation of the e-Manifest Advisory Board to promulgate the proposed payment method whereby e-Manifest user fees will be paid by facilities in response to a monthly invoice that summarizes manifest activity for the prior month. EPA, however, does not accept the suggested preference to allow TSDFs up to 60 days to pay invoices. The monthly invoicing option by its nature introduces a lag of perhaps two months between the time manifest services are used and the time when payments are received. This delay is unavoidable, as the invoice would be sent after a month of usage has occurred, and the TSDF would then be expected to make their payment on the invoice's due date of 30 days post-receipt of the invoice. Extending the proposed time frame from 30 days to 60 days would further increase the lag time from two to three months. EPA is concerned the additional lag time could further undermine EPA's ability to pay promptly its system related expenses, and exacerbate the revenue instability risks posed during the initial year of operations. Therefore, e-Manifest fees must be paid by facilities by 30 days from receipt of an invoice, and payments not paid by this date will be treated as delinquent by the Agency.

Specifically, the rule promulgates the monthly invoice approach per the proposed regulation at 40 CFR 264.1314(c) and 265.1314(c). Receiving facilities will be required to pay all fees owed in response to an electronic invoice or bill within 30 days of the date of the invoice or bill. E-Manifest fees will be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, facilities will visit *www.pay.gov,* and follow the instructions posted to the e-Manifest program's website on how to make e-Manifest electronic fee payments.

Automatic debits to your business account may be blocked by the bank. This security feature is called an ACH Debit Block, ACH Positive Pay, or ACH Fraud Prevention Filters. ACH Debit Block works by having an allowed list of ACH Company IDs. The list enables allowable automatic debits. If the ACH Company ID accompanying a request for an automatic debit is not on the allowed list, the payment is rejected. It is returned with an ACH Return Reason Code of R29—Corporate Customer Advises Not Authorized. You must contact your bank to add the U.S. EPA to your list for allowed debit payments.

L. Transporter Changes on the Manifest While En Route to the Designated Facility

1. Background

The User Fee proposed rule proposed to modify the current regulations regarding transporter changes to shipment routing information on the manifest during transportation. The Agency proposed on July 26, 2016, to amend paragraphs (a) and (b) of 40 CFR 263.21 so that changes to shipment routing on the manifest can be made: (1) To address an emergency; or (2) to accommodate transportation convenience or safety, *e.g.,* to allow more efficient transport from a transfer facility or enable the substitution of a transporter that is the sub-contractor of the designated transporter. In addition, the proposal indicated that a change in transporter designation on the manifest could be effectuated by: (1) A consultation with the generator and generator approval of the change; or (2) a contractual provision authorizing the transporter to make such a change on behalf of the generator. See 81 FR 49072 at 49104.

EPA explained in the proposed rule that the aforementioned modifications to the regulation were needed for a several reasons. First, the amendments to the regulation are necessary to align them more closely with the current industry practice of allowing transporter changes to shipment routing on the manifest, as the transporters and brokers often have more expertise than some generators in arranging the logistics and routing of hazardous waste shipments. The proposed rule also recognized that many hazardous waste generators, particularly small quantity generators, are willing to delegate the responsibility of arranging waste shipments to their brokers and transporters. Current manifest regulations limit waste shipment delivery options to only the facilities or transporters designated on the generator's manifest, unless an emergency condition prevents delivery to the designated facility or the next transporter. Thus, under existing regulations, any changes to the routing plan, including changes to transporters designated on the manifest, require generator consultation and approval.

Second, industry stakeholders have argued for years against the Agency's notion that the generator should bear the sole responsibility for designating the routing of its waste on the manifest and must be consulted explicitly on any proposed changes to named transporters during transportation. Industry transporters contend that transporter changes to the initial routing of hazardous waste shipments are often necessary to accommodate transportation convenience or safety (*e.g.,* to allow more efficient transport from a transfer facility or enable the substitution of a transporter that is the sub-contractor of the designated transporter). Further, industry stakeholders have stated that a limited agency authority granted to transporters in the service contracts with their generator customers should allow them to act ''on behalf of'' and change the routing for the generator without specific consultation with the generator on each change (81 FR 49096, July 26, 2016).

Finally, EPA consulted with our authorized states on this issue, and the Agency has concluded that the states generally have not actively pursued enforcement actions against transporters who have made these types of transporter changes to the manifest under the existing regulation. Amending the regulation as proposed would make the language of the transporter regulations consistent with industry practices.

2. Comment Analysis

Comments received to the User Fee proposed rule generally supported the proposed changes to paragraphs (a) and (b) of 40 CFR 263.21, but a few raised questions about the details of implementation. One industry commenter supported the proposed changes, but suggested EPA clarify what statement needs to be entered on the manifest to ''describe the contractual authorization'' given a transporter to act as generator's agent. Another industry commenter in support of the proposal, suggested that EPA allot space, other than Item 14, on the manifest so that the contract information can be recorded.

State commenters generally supported the proposal, but raised questions about the details of implementation. One state commenter suggested that EPA add a definition of ''agency authority'' and require legible changes. Another state commenter inquired how an inspector will know which generators have such contracts, and asked if the generator or transporter will be responsible for keeping the records of such contracts. The commenter also asked whether the contract authorization details would be recorded in Item 14 or in a separate data element on the manifest form.

A few commenters, however, did not support the proposed changes for various reasons. One commenter argued that re-routing is already a common industry practice that does not require rule change for support. Other commenters opposed listing contract

arrangements on the manifest and argued that the receipt of manifest copies displaying the routing changes was adequate. One commenter representing the generator sector opposed the proposal and raised concern that the proposal may affect the generator's liability or responsibility for compliance with the generator requirements of RCRA Subtitle C.

3. Final Rule Decision

After careful consideration of all comments on this issue, EPA is promulgating in the final rule the proposed changes to paragraphs (a) and (b) of 40 CFR 263.21 virtually unchanged. Specifically, EPA is promulgating proposed paragraph (a) and proposed § 263.21(b)(1), (2), and (4) without change. EPA, however, is promulgating the proposed § 263.21(b)(3) in the final rule with slight modification. EPA accepts the commenter's suggestion that the Agency clarify the statement needed to be recorded in Item 14 of the manifest to characterize the contract authority given to a transporter to act as a generator's agent. Therefore, EPA is modifying the proposed § 263.21(b)(3)(ii) so that transporters or brokers who intend to oversee and control the routing of the shipments on behalf of the generator must enter the following statement in Item 14 of the manifest: ''*Contract retained by generator confers agency authority on initial transporter to add or substitute additional transporters on generator's behalf.*''

In addition, EPA concludes that this standard statement should meet state concerns and enforcement needs. The statement provides explicit direction to generators who have granted agency authority to transporters to maintain a copy of the contract. Second, the statement adequately articulates the limited agency authority granted to the transporter service company by the generator. Thus, the states could pursue enforcement actions against generators for failure to produce the contract upon request as well as enforce actions against transporter service companies for failure to comply with the statement recorded in Item 14.

The Agency acknowledges one commenter's assertion that Item 14 is overused, but does not accept the suggestion for recording the contract details in a separate line item on the manifest. The Agency believes the contract authority language detailed in new § 263.21(b)(3)(ii) is brief and should not inhibit the generator's ability to legibly record other manifest information about the shipment in the restricted space. However, EPA acknowledges that the commenters' suggestion is worthy of further consideration for e-Manifest and may pursue such a separate data field within the electronic system as it continues its development of the e-Manifest system.

The Agency disagrees with the commenter that the aforementioned changes to 40 CFR part 263 do not require a rule change for support. The adoption of these regulatory changes in this final rule is a shift in EPA's longstanding policy that the generator must control the routing of his or her hazardous waste shipment, and that changes to routing must occur with generator consultation and approval, and are appropriate in cases of emergencies. The adoption of the 1980 final manifest regulation and the prior policy were based on prominent pre-RCRA incidents in which transporters and brokers had diverted hazardous waste shipments to unauthorized sites involving ''roadside'' or ''midnight'' dumping. Thus, previous policy underscored the intention of the 1980 regulation that the generator should bear primary responsibility for designating the routing of its waste on the manifest and for ensuring delivery of its waste to proper waste management facilities. The new regulatory policy extends the process for effecting changes beyond consultations to include an agency contract to make these changes on behalf of the generator. The new policy also extends the conditions permitting such changes beyond emergencies to include transporter convenience and safety. EPA concludes that a regulatory change is necessary to avoid any confusion about what transporter changes are permissible, under what circumstances they are permissible, and how these changes should be effected. The rule change should also protect industry members from any enforcement actions that could result from regulators enforcing the stricter policy of generator control suggested by the current regulation. The adoption of the final rule will help to maintain a consistent national policy on the manifest, particularly as the Agency continues its efforts to establish the e-Manifest system. Industry practice, regulatory policy, and state enforcement policies will now be better aligned, and EPA can develop technical requirements for the e-Manifest system that are consistent with this policy.

The adoption of the amendments to 40 CFR 263.21 recognize two distinct classes of transporters involved in changes to shipment routing on the manifest. First, § 263.21(b)(2) applies to those transporters that lack contractual (agency) authority to act on behalf of the generator in making any transporter substitutions or additions. For such transporters, this final rule will continue the existing requirement to consult with the generator and obtain the generator's explicit approval of the proposed changes in the shipment's routing. The final rule authorizes changes in circumstances of an emergency, as well as for purposes of transporter efficiency, convenience, and safety.

Second, § 263.21(b)(3) applies to those transporters that have contractual authority to act as the agent of the generator with respect to adding or substituting other transporters while hazardous waste is in transport. The transporter making such changes must record the aforementioned statement regarding its contractual authorization in Item 14 of each manifest for which such a change is made. In addition, § 263.21(b)(4) clarifies that any such grant of authority by a generator to a transporter to act on the generator's behalf in making changes to transporter designations does not affect the generator's liability or responsibility for compliance with the generator requirements of RCRA Subtitle C. The final rule provides that transporters acting under agency authority on behalf of the generator may add or substitute another transporter in circumstances of an emergency, as well as for purposes of transporter efficiency, convenience, and safety.

Finally, the existing provisions of § 263.21(a)(1), (2), and (4), addressing the conditions and process by which a generator must, under an emergency situation, be consulted on and approve any change to the designated facility, the alternate designated facility, or the place outside the United States designated by the generator for delivery of export shipments, are not altered by the adopted regulatory changes.

The Agency notes that the revisions adopted in this final rule only authorize limited agency authority to the transporter service company to make changes to the designated transporters on the manifest, on behalf of the generator, while the generator's shipment is en route to the designated receiving facility. They do not authorize any broader agency authority to a transporter to act ''on behalf of'' generators with respect to other generator responsibilities. For example, a transporter cannot assume broad agency authority to substitute a different designated facility or alternate facility, or, for exports, the receiving facility outside the U.S. designated by the generator, without consulting the generator. Nor could a transporter

assume the responsibility to maintain a generator's manifest records and submit Exception Reports or resolve discrepancies on behalf of the generator. These are control and oversight functions that must remain with the generator.

In addition, as explained in the proposed rulemaking (81 FR 49096, July 26, 2016), this regulatory change with respect to manifest changes during transport does not grant transporters (acting as agents for generators) the authority to correct the waste description data (*e.g.,* quantities, types, shipping names, waste codes) entered on the manifest. If such changes are necessary, then the transporter must consult with the generator and revise the manifest according to the generator's instructions.

Finally, the amendments do not affect EPA's adoption of the Department of Transportation's Hazardous Materials rules and policies in the March 2005 Manifest Revisions rule pertaining to ''offerors'' and pre-transportation functions for hazardous waste shipments. The offeror authority does not apply to activities that occur during transport. Therefore, a generator's transport contractor can act on behalf of the generator in its capacity as offeror for pre-transport functions, and under this action, the generator's transport contractor could modify the manifest on behalf of the generator during transportation, but only to modify the transporter designations pursuant to authority granted by the generator in its contract for this purpose.

M. Mixed Paper and Electronic Manifest Transactions

1. Background

In EPA's One Year Rule, the Agency determined not to allow mixed paper and electronic manifest transactions. This decision was codified in 40 CFR 262.24(c), which addresses restrictions on the use of electronic manifests. See 79 FR 7518 at 7549 (February 7, 2014). The final regulation at § 262.24(c) states that a hazardous waste generator may prepare an electronic manifest for tracking waste shipments ''only if it is known at the time the manifest is originated that all waste handlers named on the manifest participate in the electronic manifest system.'' In the User Fee Proposed Rule, EPA raised the specific issue of allowing mixed paper and electronic manifests in the limited circumstances of completing and signing the generator's initial copy of the manifest. EPA explained in the proposed Fee Rule that a policy banning all mixed manifests, without exception, could be too restrictive and might rule out needed implementation flexibility at generator sites where a phase-in of electronic manifesting could be particularly helpful. 81 FR 49072 at 49099.

Therefore, EPA proposed for public comment an approach at § 262.24(c)(1) that would relax the mixed (also referred to as hybrid) manifest ban in limited circumstances. EPA proposed to allow generators to choose to complete and sign a paper manifest in the conventional manner, to obtain the ink signature of the initial transporter at the time the transporter acknowledges its receipt of the hazardous wastes for transportation off-site, and to retain this ink-signed paper copy among its records as the initial generator copy of the manifest. For the generator, the manifest would operate exactly as the current paper system. However, the initial transporter and subsequent handlers would execute the same manifest electronically, presumably on portable devices, and all handlers subsequent to the generator would sign the electronic manifest with their electronic signatures. The final copy signed electronically by the receiving facility would be submitted to the system and retained as the copy of record of the shipment, while the initial generator copy would remain as a paper copy at the generator site.

2. Comment Analysis

Industry comments from the Environmental Technology Council (ETC) and its waste receiving facility members generally supported the proposed hybrid option, noting that there would be significant challenges for both generators and transporters in adopting electronic manifesting. The ETC and members supported the flexibility in the proposed hybrid, and suggested that the proposed mixed manifest approach could be part of the solution to the larger implementation challenge of integrating all waste handlers into e-Manifest. The comments further suggested that the hybrid might help to avoid a situation where EPA might ''flip a switch'' and attempt to implement e-Manifest for all waste handlers all at once.

Emphasizing the need for a broader solution, the ETC and its members responded to the proposal with comments advocating a more comprehensive phased implementation of the electronic manifest system, involving three phases. Under Phase I, the paper manifest process would continue as under current rules, but receiving facilities would convert their paper manifest data to CROMERR certified electronic data files for upload to EPA's national data system. Under Phase II, EPA would place its emphasis on preparing generators for e-Manifest implementation, conducting outreach on generator administrative requirements, and enabling generators with system access to receive their final signed manifest copies electronically through the system. Finally, in Phase III, EPA would adopt full implementation of electronic manifests by generators, transporters, and receiving facilities. The ETC comments suggested that this phased approach could progress in an orderly manner, with about six months between the several phases. Commenters supporting this phased approach further suggested that the collection of full user fees be deferred until Phase III. These commenters suggested that EPA only impose a ''nominal fee'' in Phase II, measured only by the costs of EPA receiving the uploaded data, thereby reducing any ''sticker shock'' that would be faced by users when initially confronted with the new system's user fees.

One industry commenter expressed frustration with the lack of real progress in developing e-Manifest, and suggested that the effort should end with the Phase I approach described earlier, or, wait for the Department of Transportation to proceed with electronic shipping papers for Phase II. Another, commenter remarked that it was not clear how the hybrid manifest option would affect EPA's stated goal in the fee pivot discussion of reaching 75% electronic manifest usage in four years. The commenter asked whether the ''hybrid'' manifests would count toward EPA's 75% electronic use goal that determines if the fees will pivot.

Other industry and state commenters objected to EPA's hybrid or mixed manifest proposal, stating that it possibly would produce severed manifests with conflicting paper and electronic versions that would remain disconnected in the system. Several commenters noted as well that the hybrid proposal was incomplete in not describing fully how waste receipt confirmations, exception reporting, and other downstream processes will be conducted if only the generator has the paper form. These commenters argued that regulations hold the generator responsible for what is on the manifest, but if the receiving facility later changes the electronic version, the generator may not be made aware. These commenters questioned how generators could remain liable for manifest data that ultimately appears on an electronic version that they may not see.

More recently, EPA convened the first e-Manifest Advisory Board meeting in January 2017. At this meeting, EPA presented on the proposed hybrid option and the aforementioned phased implementation approach presented in industry comments. The Advisory Board members generally supported a phased approach that would initially continue the paper manifest process through the transportation and delivery of hazardous waste shipments, and then allow the receiving facilities to upload electronically the certified data from their paper manifests to the system. However, in response to suggestions from generator members of the Board, this discussion concluded with the suggestion that the receiving facility should also upload a scanned image of the final, signed paper manifest to the EPA system with the data file.

3. Final Rule Decisions

After careful consideration of the comments received on the proposed rule, EPA has elected to promulgate in the final rule the mixed manifest proposal announced in the proposed rule. Therefore, this action modifies § 262.24 by adding paragraph (c)(1) as proposed. Under this regulation as amended, generators who wish to initially track their shipments by paper will complete and sign a paper manifest in the conventional manner and obtain the ink signature of the initial transporter at the time the transporter acknowledges its receipt of the hazardous wastes for transportation off-site. Generators will retain this ink-signed paper copy among their records as the initial generator copy of the manifest. The initial transporter and subsequent handlers will complete the remainder of the manifest copies electronically. The final copy signed electronically by the receiving facility will be submitted to the system and retained as the copy of record of the shipment, and distributed to waste handlers and interested states via the system. The initial generator copy will remain as a paper copy (or stored image) at the generator site, and will be available there for inspection.

EPA also sees substantial merit in the receiving facilities' several comments urging EPA to implement e-Manifest under a phased approach. Some confusion has arisen surrounding the hybrid manifest concept, as it has been used to describe both the mixed manifest regulatory change that EPA proposed in the July 26, 2016 proposed rule, as well as to describe the industry's recommended phased system approach. However, while the hybrid and phased approaches are complementary, and both involve some combination of paper and electronic processing, they do differ in important respects.

The mixed manifest approach finalized by EPA in the rule is by its nature an electronic manifest, with a narrow exception allowing the generator only to sign and retain a paper copy.[9] However, this manifest will originate in the e-Manifest system as an electronic manifest, it will be assigned a unique manifest tracking number by the system; all subsequent tracking of the waste shipment and all manifest signatures executed during its transportation and delivery will be conducted electronically through the system. The creation of a paper manifest copy from the system generated manifest is merely an accommodation to the generator, while all other aspects of the transaction and shipment tracking are through an electronic manifest. Thus, manifests prepared and executed in this manner will be regarded and processed as electronic manifests, and will be subject to the fees for electronic manifests. To further clarify the status of these hybrid or mixed manifests as electronic manifests, the final rule also provides that the §§ 264.1310 and 265.1310 definitions of electronic manifest submissions include the mixed or hybrid manifests authorized in the final rule at § 262.24(c)(1).

The industry recommended phased approach, particularly during phases I and II, is not per se an electronic manifest. A closer evaluation of the phased approach discloses that during at least the first and second phases, it is expected that the paper manifest will continue to be used during the actual tracking of the waste shipment through its transportation and until delivery of the waste to the receiving facility. Because the tracking of waste transportation and delivery to the facility is conducted with paper manifests, and all manifest signatures are collected as conventional ink or by hand signatures, these are by their nature paper manifest transactions, rather than electronic manifests. However, there is an electronic transaction conducted in the e-Manifest system by the receiving facility post-receipt, and this consists of the upload of the manifest data derived from the received paper manifests to the e-Manifest system for processing. This latter, electronic transaction is executed as an electronic data file and image file upload to the system, with a CROMERR compliant certification by the facility owner or operator. As this is a transfer of data from paper manifests, not electronic manifests, the manifests processed in this manner would be charged the scheduled fee for paper manifests submitted as a data file with an image file attachment.

EPA agrees that there are advantages to the phased approach to implementation suggested in the industry comments. First, EPA agrees that the suggested Phase I is a useful way to commence e-Manifest operations, as it will enable EPA to establish for the first time a national data-base system containing all manifest data from all sources, and allow the collection of fee revenues (based on paper manifest processing fees) so as to fund the system's development and operating costs in a self-sustaining manner. This system also will be available on Day 1 for fully electronic manifesting by those able to do so.

Second, the Agency also agrees that industry's suggested Phase II, involving significant generator outreach and the electronic transmittal of final manifest copies to participating generators, has considerable merit to it. In fact, the regulations EPA developed in the One Year Rule already support the industry phased approach. In the One Year Rule, the Agency provided that paper manifests could continue to be used in waste tracking, and that receiving facilities could submit the data from such paper manifests to the system as a data file in JSON or similar data exchange language, with the inclusion of the paper manifest image file.[10] Thus, all the regulatory authority needed to support Phases I and II of industry's phased approach was promulgated by EPA previously in the One Year Rule, and the final rule clarifies the fee that will be assessed for these transactions. EPA also emphasizes that to support this effort, it is currently conducting outreach to encourage user/stakeholder engagement and participation to enhance e-Manifest participation once the system becomes available for use. As

[9] The initial transporter would sign this copy by hand as well, enabling the generator to retain its initial copy signed by the transporter to acknowledge receipt of the waste. The initial transporter also would sign this manifest electronically in the system, and all subsequent tracking and signatures would be conducted electronically through e-Manifest.

[10] While the discussion by Advisory Board Members in January 2017 recommended that an image file be included as an additional element in the phased implementation approach, EPA notes that the inclusion of the image file was already required by EPA regulation as a necessary component of a data file upload from paper manifest records. The image file upload, however, is not a part of the mixed electronic/paper manifest process, as the receiving facility submission is an electronic manifest that will be processed without any manual image uploads.

part of this effort, EPA's intention is to offer open forums prior to system launch that promote the opportunity for stakeholders to participate in user testing and to continue Advisory Board meetings during the progression of the e-Manifest system launch.

Nevertheless, there are aspects of the commenters' phased approach that concern EPA. While there is considerable detail on the objectives for suggested Phases I and II, which continue the use of paper manifests, the comments provide little detail on how the regulated community would move from Phases I and II to a fully electronic manifest in Phase III, and how that would be accomplished in six months. Without more detail, the industry's phased approach appears to lack incentives for facilities and other handlers to adopt fully electronic manifesting and finally transition to the desired paperless manifest. Therefore, while we believe the commenters' phased approach presents a useful starting point for setting up and operating an initial fee-worthy e-Manifest system and data-base, we will need to explore carefully with stakeholders what additional steps and phases will be necessary to establish a credible path to a widely adopted electronic manifest.

EPA is finalizing the mixed manifest regulation with this action, because we believe it could be a useful component in the phased strategy suggested by the industry commenters. The mixed manifest or hybrid manifest enables an electronic manifest to be initiated in the system and executed electronically through the transportation and delivery phases of a waste shipment, allowing only the generator to retain a paper copy signed with conventional ink signatures. EPA developed this regulation on account of perceived challenges for generators to participate in a fully electronic workflow, so the mixed manifest could permit more of these waste shipments to originate and conclude electronically, by accommodating the generator with a paper copy for its files only. Admittedly, the hybrid approach will only become useful as part of the phased implementation strategy when there are receiving facilities working in concert with transporters (their own or independent) that are willing to install portable devices on their transport vehicles and take the electronic manifest out into the field to the generators. These are important links that must be put in place for electronic manifesting to achieve widespread adoption, and it will be a focus of our discussions in the near term with the user community and the e-Manifest Advisory Board.

EPA is not persuaded by comments suggesting EPA retain the mixed manifest ban announced in the One Year Rule. EPA acknowledges that the mixed manifest approach promulgated in the final rule may present some of the same difficulties that caused EPA to reject a mixed manifest approach in the One Year Rule. In particular, there is in fact some complexity that arises from allowing a paper copy to remain at the generator site, severed from the electronic version that continues in play with subsequent handlers. The severed nature of the manifest presents issues for generators in monitoring the progress of their shipments, and it results in the generator copy being available for inspection only at the generator's site, and not through the system. This problem is amplified if the electronic version undergoes editing and markup while the shipment continues to the receiving facility. However, given the substantial challenges faced at generator sites in the initial implementation of e-Manifest, EPA continues to believe there could be merit to this hybrid option, as it will enable many of the desired efficiencies and burden reductions of electronic manifesting to occur beyond the generator site. Any drawbacks posed by the presence of mixed manifests should be surpassed by the advantages and efficiencies of executing and transmitting more manifests electronically, particularly as an interim solution prior to the adoption and widespread use of fully electronic manifests by generators.

While the severed manifest issues are not insignificant, there are workarounds available. EPA expects that all generators will be afforded access to the e-Manifest system, whether or not they choose to participate in executing manifests electronically. Generators will soon be able to obtain access credentials and will then be able to view the final copies of manifests that will be distributed by the system. So, any changes made to mixed electronic manifests by subsequent handlers should be apparent to the generator when they view the final manifest copy from the system. Generators viewing their final manifest copies distributed by the system will thus be able to participate in the corrections process, respond to discrepancies, and note any exceptions, as they would if receiving a paper manifest through the mail. EPA does not believe it is placing great demands on generators insofar as expecting them to obtain access credentials and monitor their manifest activity in the system. While this will initially involve generators having to compare their initial paper manifest copies with a later delivered electronic file accessed in the system, any complexity in this result should only persist during the time that the user community is transitioning from paper to electronic manifesting. Electronic based transactions are becoming the norm in all walks of life, and the manifest user community must be prepared for the transition to electronic tracking of hazardous waste shipments with e-Manifest.

With respect to other comments submitted on the phased implementation of e-Manifest, EPA cannot accept the commenters' suggestion to only accept a nominal fee initially through Phase II, and defer full payment of manifest transactional fees until Phase III. As explained in Section III.C of this preamble, the final fee methodology and fee schedule prescribed in this rule must cover all system related costs for all of EPA's activities related to developing and operating e-Manifest, including costs to process paper manifests that continue in use. Our differential fee methodology is based on workload models that project the labor and other costs of processing each type of manifest. The fees also include a component to recover our system development costs, which the fee methodology is amortizing over a five-year period. Any effort at manipulating the fees to defer their full impact until later phases would only mean that the fees would be enhanced later to recover any deferred revenues, which would possibly cause the fees to seem excessive to some users when so adjusted. In addition, this suggestion would likely further aggravate revenue stability issues for EPA during the initial years of operation, when ensuring a stable revenue stream may be most essential.

EPA rejects the industry commenter's suggestion that e-Manifest efforts conclude with the Phase I solution (paper manifests with only a data upload from the receiving facility), or that our implementation efforts on e-Manifest await progress by DOT on its electronic shipping paper initiative. The Congress has mandated in the e-Manifest Act that EPA develop a national tracking system for hazardous waste shipments, and that we coordinate with DOT on this effort. While EPA is very interested in the progress of DOT's electronic shipping paper pilots, that effort is not conceived at this time as a national system approach such as that mandated for e-Manifest, so there are only so many

synergies that can be exploited between these efforts. The Agency will continue to consult with DOT as we develop and implement the e-Manifest system.

Finally, concluding the e-Manifest effort with the industry suggested Phase I system is not an acceptable outcome to the Agency. Phase I as the end point would essentially leave the paper manifest system in place indefinitely. The e-Manifest Act mandate for an electronic manifest system was not motivated solely by the desire to develop a national data-base of waste shipment data. The Act also contemplated that the national e-Manifest system would produce paperwork burden reductions by migrating to a paperless manifest. The significant cost and burden reductions identified with the e-Manifest project will only be realized when paper manifests are minimized and ultimately eliminated.

While the Agency appreciates the suggestion of industry commenters that the execution of their suggested phased approach can be accomplished in a little more than a year's time, we believe that the migration to widespread use of electronic manifests will likely take several years to accomplish. In short, the phased approach presented by commenters is commendable, but EPA would be very concerned if progress on electronic manifesting were to stall at Phase I or Phase II, and paper manifesting with a back-office data upload from facilities was the end product of the effort. Progress toward the fully electronic manifest must be maintained and monitored.

Therefore, EPA is announcing that it intends to monitor the progress toward electronic manifest adoption and report this progress annually to stakeholders and to the e-Manifest Advisory Board. In section III.J. of this preamble, EPA signaled that beginning June 30, 2021, it will not accept mailed paper manifests from facilities for processing in e-Manifest. It is further EPA's intent that the use of paper manifests, and the submission of data from paper manifests, whether by image files or data file uploads, be curtailed by June 30, 2023, that is, after five years of system implementation.

After three years of system implementation, EPA will collect information from the system on the trends reported on paper and electronic manifest usage, and present this information to the e-Manifest Advisory Board. We will examine these data closely to determine if mailed paper manifest submissions have been eliminated; if we are on track to meet the 75% electronic manifest usage goal by year four (which affects this rule's possible fee pivot); and if we are seeing meaningful progress toward the widespread adoption of electronic manifesting. If the Agency should find that meaningful progress is lacking, we will seek the Board's advice on what combination of incentives or restrictions (*e.g.,* a regulatory ban of paper manifest use after 2023), or other measures should be implemented to accomplish the program's goal of realizing all the efficiencies and benefits of an electronic manifest system. We will also examine the trends in relation to the use of the hybrid or mixed manifest approach by generators, and seek the advice of the Advisory Board on whether it is aiding or hindering the adoption of electronic manifesting, and whether it should perhaps be phased out as well.

N. Removal of Part 262 Appendix From the Code of Federal Regulations

Since the adoption of the Uniform Manifest in 1984, EPA has published the Uniform Manifest (EPA Form 8700–22), the Manifest Continuation Sheet (EPA Form 8700–22A), and the corresponding instructions for completing each of these forms in a distinct appendix published at the end of 40 CFR part 262. This means that any change to the forms required costly and time-consuming rulemaking. This practice has continued for more than 30 years, despite the fact that the Agency must also comply with the regulations implementing the Paperwork Reduction Act (PRA) at 5 CFR part 1320. Specifically, pursuant to the PRA, the Agency must receive approval from the Office of Management and Budget (OMB) for any substantive or material change it seeks to make to the two forms (OMB control number 2050–0039). As part of these requirements, among other things, the Agency must include as part of its request for OMB clearance, evidence that it informed and provided reasonable notice to the public of changes it seeks to make to the forms as well as an estimate of the burden resulting from the changes, provided the public with an opportunity to comment on the changes, and an explanation of how the Agency addressed those comments. In fact, even if the Agency does not seek to make any changes to the forms, it must seek approval from OMB for continued use of the forms every three years.

While the codification of these forms and their instructions in an appendix to part 262 may have been a useful means of publishing the details of the manifest forms and their use to the regulated community in the 1980's when there was no internet, EPA believes that this codification no longer serves that purpose. This conclusion follows from the impending availability of these forms and their instructions on the Agency's internet domain. Codification of these forms in part 262 is also duplicative with the management of the manifest's information collection requirements under the PRA. The manifest and continuation sheet forms displayed in the current appendix only display one sample copy of the multi-copy manifest and continuation sheet forms. These codified versions are sample displays only and cannot be used in commerce at all, and users who need a manifest must obtain them from the registered printers EPA has approved to distribute valid manifests commercially. With the implementation of e-Manifest, EPA has designated an internet domain—*www.epa.gov/e-Manifest*—where it will publish and make available to users the currently required manifest forms and instructions, serving the same purpose as the codification in the appendix in the CFR. EPA will be able to publish, make available to the public, and maintain the manifest forms and instructions much more efficiently and effectively through this means on the internet domain than by continuing to codify them in an appendix in the CFR. Moreover, the internet domain also provides a convenient location at which EPA can inform the public of any changes it seeks to make to the forms and provide the public with instructions on how they can submit comments. Any issues that the public might have concerning the paperwork compliance burdens posed by the manifest forms and their instructions can continue to be addressed in the Information Collection Request (ICR) process set out in the PRA.

EPA did not propose the removal of the manifest forms and instructions from the part 262 appendix as part of the July 26, 2016 proposed user fee rule. The proposed user fee rule was focused fundamentally on the user fee methodology and policy and several pending non-fee issues related to the use of manifests. As the final rule was being developed, EPA recognized the need to make several minor, conforming changes to the manifest forms and instructions to implement several of the new requirements under the e-Manifest Act. The development of these conforming changes to the forms and instructions accentuated for EPA the need to move away from the archaic practice of continuing to publish the forms and instruction in the CFR rather than publishing them to the public more

effectively on the program's internet domain. In addition, as EPA shifts its attention in the future to integrating the manifest with the reporting of waste receipts for the RCRA biennial report, there will be many advantages to EPA and the public in having the integration of these two collections addressed through the PRA process rather than a separate rulemaking focused only on the manifest forms in the CFR appendix.

The Agency is including this action in this final rule, without notice and comment, pursuant to section 553(b)(3)(A) of the Administrative Procedure Act (APA). Section 553(b)(3)(A) of the APA exempts notice and comment proceedings for ''interpretive rule, general statements of policy, or rules of agency organization, procedure, or practice.'' The decision to publish the manifest forms and instructions though EPA's internet domain, and to address public comments on form changes and their burden through the PRA processes rather than through a separate rulemaking on the part 262 appendix, is primarily a matter of how EPA organizes its forms and their procedures and practices. Moreover, the PRA provides another adequate process by which the public can be informed of manifest form changes and provide comment on them. For emphasis, we note that no other form required for RCRA Subtitle C compliance purposes (*e.g.,* the Site ID Form, the biennial report's waste generation or waste receipt forms) are codified in the CFR. Removing the manifest forms and instructions from the part 262 appendix will enable EPA to organize, manage, and maintain the manifest forms in the same sensible and efficient manner as the other Subtitle C form requirements.

Therefore, EPA is including in this final rule two minor regulatory amendments to effectuate this action. First, EPA is amending § 262.20(a)(1) to remove the current language that specifies that generators must prepare manifests ''according to the instructions included in the appendix to this part.'' The language in quotations above will be removed, and the language that remains will simply require the generators to prepare a manifest, and will continue to cite the EPA Forms 8700–22 and 8700–22A that identify the hazardous waste manifest and continuation sheet, as well as the OMB control number 2050–0039 by which OMB manages the information collection requirements for the manifest forms. Second, EPA is including an amendment to part 262 to remove the current manifest forms-related appendix from part 262.

IV. The Projected Economic Impacts of the Electronic Manifest

A. Introduction

EPA estimated the costs and benefits of the final rule in a Regulatory Impact Analysis (RIA), which is available in the docket for this action. The RIA estimates costs and costs savings attributable to electronic manifests. Cost savings are presented against estimated baseline costs of the existing RCRA hazardous waste paper manifest system. The RIA also qualitatively describes un-monetized benefits of electronic manifests.

B. Count of RCRA Hazardous Waste Manifests

The RIA estimates paper manifest system baseline costs and electronic manifest costs savings at the per-manifest level. Per-manifest costs and cost savings are then scaled up to arrive at national estimates of paper manifest costs and electronic manifest cost savings. Because costs and cost savings are estimated at the per-manifest level, the count of manifests used drives costs and cost savings estimates in the RIA analysis.

Because all RCRA manifests will be processed centrally by EPA, the RIA estimated the entire scope of manifest usage. While the federal RCRA manifest (EPA forms 8700–22 and 8700–22A) has been the sole manifest accompanying shipments of hazardous waste since the 2005 Uniform Hazardous Waste Manifest form rule, the manifest has two applications. The first is to accompany shipments of hazardous wastes listed in the federal RCRA regulations. The second is to accompany shipments of state-only regulated wastes listed in various state RCRA regulations. A total count of manifests which include both federal and state applications was estimated in the RIA. EPA estimated an average annual count of hazardous waste manifests used by extrapolating from data on the generation of hazardous waste, data on the number of shippers of hazardous waste, and by making assumptions about the likely shipping frequency of hazardous and state-only regulated wastes. EPA corroborated this estimate through consultations with companies that print and sell copies of the hazardous waste manifest. The average annual count of hazardous waste manifests used is estimated to be 3.2 million

C. Baseline Cost of the Paper Manifest System

EPA estimated baseline costs for all aspects of the existing paper manifest system which will be affected by electronic manifests. EPA estimated six categories of costs accruing to: Industrial users of paper manifests, state governments that collect paper manifests, and EPA. The six categories of costs are:

- Paper manifest costs accruing to industry for federal manifests,
- Paper manifest costs accruing to industry for state manifests,
- EPA burden to process paper manifests,
- State government burden to process paper manifests,
- Industry burden to comply with hazardous waste Biennial Report requirements, and
- State government burden to comply with hazardous waste Biennial Report requirements.

In total, discounting at 7% over six years, the annualized baseline costs of the paper manifest system are estimated to be $238 million.

D. Costs Savings and Other Benefits of Electronic Manifests

EPA estimated both monetized cost savings and other, non-monetized, benefits of electronic manifests. Cost savings are the difference between the pre-rule cost of manifesting and the post-rule cost of manifesting. They are estimated to accrue to both industrial and state government users of electronic manifests. Over the six-year period of analysis modeled in the RIA, the annualized post-rule costs of manifesting were estimated to be $172 million when discounting at 7%. Since the pre-rule cost of manifesting is estimated to be $238 million, annualized cost savings from electronic manifests are estimated to be $66 million.

EPA expects that electronic manifests will enhance many stakeholders' ability to track and extract data on waste shipments by storing and distributing these data in a central, accessible location. EPA has identified six stakeholder groups that may benefit from better access to manifest shipping data:

- Members of industry that use the manifest for tracking waste shipments should know the status of their shipments faster than under the current paper based system. They should also benefit from the increased legibility of electronic manifest records compared to current paper manifests.
- Federal and state government RCRA enforcement officials, who use manifest data in the course of their investigations of RCRA compliance should benefit from the centralized storage of manifest data and the greater accessibility of these data under e-Manifest.

• Emergency responders should benefit from increased access to data on the generation, shipment, and storage of hazardous wastes in the event that a spill or other accident involving hazardous waste occurs.

• Research institutions from academia to industry may find novel uses for manifest data.

• Communities near RCRA facilities will have better information on the generation, shipment, treatment, storage, and disposal of hazardous waste near their communities.

EPA has not attempted to quantify the value of this benefit.

SUMMARY OF ESTIMATED COSTS AND COST SAVINGS

[Annualized and discounted at 7% over six years]

Pre-rule costs ($ million)	Post-rule costs ($ million)	Cost savings ($ million)
238	172	66

V. State Implementation

A. Applicability of Rules in Authorized States—General Principles

Under section 3006 of RCRA, EPA may authorize qualified states to administer their own hazardous waste programs in lieu of the federal program within the state. Following authorization, EPA retains enforcement authority under section 3008, 3013, and 7003 of RCRA, although authorized states have primary enforcement responsibility. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to the enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA) and of the Hazardous Waste Electronic Manifest Establishment Act, a state with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that state. The federal requirements no longer applied in the authorized state, and EPA could not issue permits for any facilities in that state, since only the state was authorized to administer the program and issue RCRA permits. When new, more stringent federal requirements were promulgated, a state with final RCRA authorization was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized state until the state adopted the federal requirements as state law.

In contrast, with the adoption of RCRA section 3006(g), which was added by HSWA, new requirements and prohibitions imposed under the HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. EPA is directed by section 3006(g) to implement HSWA-based requirements and prohibitions in authorized states until the state is granted authorization to do so. While states must still adopt HSWA related provisions as state law to retain final authorization, EPA implements the HSWA provisions in authorized states until the states are authorized to do so.

The e-Manifest Act contains similar authority to HSWA with respect to federal and state implementation responsibilities in RCRA authorized states. Section 2(g)(3) of the e-Manifest Act, entitled Administration, provides that EPA shall carry out regulations promulgated under the Act in each state unless the state program is fully authorized to carry out such regulations in lieu of EPA. Also, section 2(g)(2) of the Act provides that any regulation promulgated by EPA under the e-Manifest Act shall take effect in each state (under federal authority) on the same effective date that EPA specifies in its promulgating regulation. The result is that regulations promulgated by EPA under the e-Manifest Act, like HSWA-based regulations, are implemented and enforced by EPA until the states are authorized to carry them out.

Authorized states generally are required to modify their programs when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements. However, as EPA explained previously when adopting manifest form revisions to fully standardize the RCRA manifest, the hazardous waste manifest is treated differently. Rather, EPA requires strict consistency in the manifest requirements, so that any EPA changes to federal manifest requirements that are authorizable to states must be implemented consistently in the states, regardless whether the change might be considered more stringent or broader in scope than existing requirements. See 70 FR 10776 at 10810 (March 4, 2005). This is so, whether the manifest program change is based on base RCRA or on e-Manifest Act authority.

B. Legal Authority for This Rule's Regulatory Changes and Implications

Only one of the authorizable [11] regulatory changes included in this final rule is based on the so-called base RCRA or 1976 RCRA statutory authority.[12] This regulatory provision is the § 263.21(b) regulation addressing en route changes to transporters. This is not a user fee related provision, but a more general change in the requirements governing the use of the hazardous waste manifest by hazardous waste transporters. Because this provision is promulgated under RCRA base program authority, this regulatory change will not become effective in authorized states until the regulatory change is adopted under state law and EPA authorizes the state program modification. States must adopt this regulatory change in their authorized programs to maintain manifest program consistency. In unauthorized states, this regulation will become effective on the effective date of this final rule, which is June 30, 2018.

Most of the remaining regulatory changes promulgated in this final rule are issued under the authority of the e-Manifest Act. These provisions will be implemented and enforced by EPA in all states consistently on the effective date of this final rule. States must adopt the authorizable e-Manifest Act-based provisions of this final rule in order to enforce them under state law, and to maintain manifest program consistency. However, EPA will continue to implement and enforce these provisions until such time as the state modifies its authorized program to adopt these provisions and receives authorization from EPA for the program modification.

C. Authorizable e-Manifest Act Provisions

The authorizable provisions promulgated under e-Manifest Act authority are set out in the following table listing the regulatory section of 40 CFR that is affected and the subject of the regulation. These particular provisions listed below can be administered and enforced by states after they are authorized for these provisions.

[11] EPA uses the term authorizable to distinguish those provisions of the final rule that can be administered and enforced by a state as a part of its authorized RCRA program from those provisions, such as determining and collecting e-Manifest user fees, that can be administered and enforced only by EPA.

[12] The final rule's changes to the manifest form printing specifications at § 262.21(f)(5) through (7) are also issued under base RCRA authority. However, as the manifest printing specifications are not authorizable, the changes to the printing specification will be effective federally on the final rule's effective date, and are not affected by state program modifications.

Regulation	Subject
§ 260.4	Copy submission requirements for interstate shipments.
§ 260.5	Applicability of e-Manifest system and fees to facilities receiving state-only regulated wastes.
§ 262.24(c)(1)	Use of mixed paper/electronic manifests.
§ 262.24(h)	Generators and post-receipt data corrections.
§ 263.20(a)(9)	Transporters and post-receipt data corrections.
§ 264.71(a)(2)(v), § 265.71(a)(2)(v)	Receiving facilities' required paper manifest submissions to system.
§ 264.71(j), § 265.71(j)	Imposition of user fees on receiving facilities for their manifest submissions.
§ 264.71(l), § 265.71(l)	Receiving facilities and post-receipt data corrections.

D. Provisions of the Final Rule That Are Not Authorizable

There are some provisions in this final rule that can be administered and enforced only by EPA, and not by authorized states. The first group of non-authorizable requirements included in this final rule are § 262.21(f)(5), (6), and (7). These provisions together announce the revised printing specification for the five-copy paper manifest and continuation sheet paper forms, the revised copy distribution requirements to be printed on each copy of the form, and the revised specification for printing the appropriate manifest instructions on the back of the form copies. These printing specifications apply to registered manifest printers and are administered solely by EPA. State programs are not required to take any action respecting these regulatory changes to the printing specifications, and they will take effect in all states on the effective date of this final rule.

The second group of non-authorizable requirements in this final rule consists of the fee methodology and related fee implementation provisions set forth in subpart FF of 40 CFR parts 264 and 265. These requirements include definitions relevant to the program's fee calculations (§ 264.1311, § 265.1311), the user fee calculation methodology (§ 264.1312, § 265.1312), the user fee revisions and publication process (§ 264.1313, § 265.1313), how to make user fee payments (§ 264.1314, § 265.1314), sanctions for delinquent payments (§ 264.1315, § 265.1315), and the informal fee dispute process (§ 264.1316, § 265.1316). These user fee provisions in subpart FF are promulgated under the authority of the e-Manifest Act, and will be implemented and enforced by EPA on the effective date of this final rule and perpetually thereafter. The user fee provisions of subpart FF describe the methods and processes that EPA alone will use in setting fees to recover its program costs, and in administering and enforcing the user fee requirements. Therefore, states cannot be authorized to implement or enforce any of the subpart FF provisions.

Although states cannot receive authorization to administer or enforce the federal government's e-Manifest program user fees, authorized state programs must still include the content of or references to the subpart FF requirements. This is necessary to ensure that members of their regulated communities will be on notice of their responsibilities to pay user fees to the EPA e-Manifest system when they utilize the system. Authorized state programs must either adopt or reference appropriately the user fee requirements of this final rule.[13] However, when a state adopts the user fee provisions of this rule, the state must not replace federal or EPA references with state references or terms that would suggest the collection or implementation of these user fees by the state. Alternatively, an authorized state may reference the subpart FF fee provisions appropriately by simply adopting state law counterparts to §§ 264.71(j) and 265.71(j) that include all the detailed citations to the subpart FF provisions as set out in the §§ 264.71(j) and 265.71(j) provisions of this final rule.

E. Non-Fee Related Provisions of the Final Rule

In addition to the § 263.21(b) provision discussed above addressing transporter changes en route, two other non-fee related provisions are included in this final rule that the states will be required to adopt as components of their authorized programs. These provisions include: (1) The amendments to §§ 264.71(l) and 265.71(l), addressing post-receipt manifest data corrections in the e-Manifest data system; and (2) the amendment at § 262.24(c)(1), allowing a mixed paper and electronic manifest to be used by certain generators. Each of these non-fee related amendments must be adopted by authorized state programs to maintain consistency with the federal RCRA program. Moreover, because all three of these provisions address the use of the RCRA hazardous waste manifest or the national e-Manifest system to be established under the e-Manifest Act, these provisions must be adopted uniformly and fully consistently with the promulgated federal requirements. Because these provisions are based on e-Manifest Act authority, they will be implemented and enforced by EPA in all states on the effective date of this final rule, and will be implemented by EPA until the states obtain RCRA authorization for these program modifications.

This final rule also includes two conforming changes to 40 CFR 271.12, addressing the requirements for hazardous waste management facilities that must be included in authorized state programs to maintain consistency with the federal program. The first change at § 271.12(k) clarifies that authorized state programs must include requirements for hazardous waste management facilities and facilities receiving state regulated wastes under manifests to pay user fees to EPA to recover all costs related to the development and operation of an electronic hazardous waste manifest system (e-Manifest system). The second such change at § 271.12(i)(2) clarifies that authorized programs must include a requirement that designated or receiving facilities submit a signed copy of each paper manifest (or the data from paper manifests) to the EPA's e-Manifest system, in lieu of sending signed copies directly to either the origination or destination states. The latter modification is necessary to effectuate the intent of Congress that under the e-Manifest Act, the e-Manifest system will operate as a national, one-stop reporting hub for manifests and data. When e-Manifest is operational, EPA expects that the states with such tracking

[13] EPA believes it is important that states adopt or reference EPA's subpart FF user fee provisions in their state programs, so that all receiving facilities in the states are on notice of their obligations to submit their final manifest copies to the system and to pay user fees to EPA for the processing of their manifests. EPA has added § 260.5 to provide federal notice of these e-Manifest Act responsibilities to the facilities that receive state-only regulated wastes that are tracked with a RCRA manifest per state law. However, the adoption by the states of appropriate state program revisions alerting such facilities that receive state-only regulated wastes to these e-Manifest Act requirements should greatly enhance the notice afforded these receiving facilities and their rate of compliance.

programs will obtain their manifest copies and data from e-Manifest, rather than requiring regulated entities to mail their manifests to these states.[14]

Also, several of these states with manifest tracking programs assess their own fees to offset the costs of administering their state manifest tracking programs, or they may assess waste generation or management fees to support state programs, based on manifest data in their state tracking systems. It is likely that many of these state manifest tracking programs and related fees may continue to operate for the foreseeable future. EPA emphasizes that the federal user fees that are the subject of this regulation are solely to offset EPA's costs in developing and operating the e-Manifest system. It is not the purpose of this regulation to suspend, reduce, or otherwise impact the existing state fees that support states' manifest tracking programs or the fees levied by state programs on waste generation or management. EPA is not now in a position to predict what, if any, impact this federal user fee regulation may have on any such state fee collection programs.

VI. Estimated Fee Schedule for Initial Operation Period

EPA has developed an illustrative estimate of the program's initial user fees based on the best system use, system cost, and program budget projections available at the time of this rule's publication. These estimates are for user fees in the first year of system operation. They are driven by assumptions about the magnitude and distribution of manifest types that the system will receive. These assumptions are explained in detail in Chapter 5 of the RIA that accompanies this rulemaking. These fees also incorporate estimates of costs of setting up and hosting the system, and the costs of running the paper processing center. At the time of this rule's publication EPA does not have a final budget for the program in Fiscal Year 2018, nor does EPA have all the contracts in place for setting up and hosting the system, and for running the paper processing center. For this reason, the following table of fee estimates should be interpreted as rough approximations of the final fees. EPA will publish a final two-year schedule of user fees on the e-Manifest website, at *www.epa.gov/e-Manifest,* when more information about the e-Manifest budget and contracts awards becomes available.

The fee estimates presented in the following table are per-manifest fees for each manifest submission type. They are derived from the proposed rule's Option 2, Marginal Cost Differentiated Fee methodology, which in this final rule, EPA will rely on for setting fee levels for at least the initial four years of program implementation.

YEAR 1 MARGINAL COST MANIFEST FEES BY MANIFEST TYPE

[2017$]

Manifest submission type		Year 1 fee
Paper Manifest Types	Mailed Paper	$20.00
	Image Uploads	13.00
	Data File Uploads	7.00
Electronic Manifests (includes hybrid)	Electronic	4.00

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it may raise novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket for this action. The EPA prepared a regulatory impact analysis of the potential costs and benefits associated with this action, which is available in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 0801.22. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This implementation of e-Manifest and this Fee Rule will impose new information collection requirements on the regulated community, although we expect that the net effect will be to significantly reduce the paperwork burden relative to the paper manifest system. Although the primary effect of the e-Manifest implementation will be to replace current paper-based information requirements with electronic-based requirements to submit or retain the same shipment information, there could be minor additions or changes to the information collection requirements, such as information that may be provided to establish user accounts and fee payment accounts, information submitted for identity management, as well as waste profile or other information that may be useful for the creation and submission of electronic manifests. Additionally, EPA did not update the information collection burden associated with the regulatory changes to the manifest system announced in the ''One Year Rule.'' While EPA acknowledged that the adoption of e-Manifest will change the manner in which information will be collected and transmitted, the system was not currently available and consequently the ''One Year Rule'' did

[14] One exception we note is that EPA will not collect in e-Manifest generator or transporter copies of any paper manifests that continue in use after e-Manifest is operational. States that wish to continue to obtain these paper generator or transporter copies will need to continue to require their direct submission to the states.

not change the information collected by the hazardous waste manifest, nor the scope of the wastes that are now subject to manifesting. EPA indicated that it would update the information collection burden estimates in this user fee rule, which are as follows:

Respondents/affected entities: Private waste handlers.

Respondent's obligation to respond: Mandatory (RCRA 3002(a)(5)).

Estimated number of respondents: 203,927.

Frequency of response: Monthly (for paper copies), On occasion.

Total estimated burden: 2,608,292 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $128,661,312, includes $38,784,093 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Analysis (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant adverse-economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule.

The small entities directly regulated by this final rule include entities that receive shipments of hazardous waste across various industries, including, but not limited to, NAICS 562211 Hazardous Waste Treatment and Disposal; NAICS 562920 Materials Recovery Facilities; NAICS 331410 Nonferrous Metal (except Aluminum) Smelting and Refining; NAICS 331492 Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum); NAICS 523910 Miscellaneous Intermediation; and NAICS 562219 Other Nonhazardous Waste Treatment and Disposal. The RIA considers as potentially small any firm within the affected universe that cannot be positively identified as not small according to SBA's size standards.

The Regulatory Impact Analysis (RIA) conducted for this rulemaking found that the e-Manifest rule would reduce the compliance burden associated with manifesting shipments of hazardous waste. The RIA estimates that in the initial six years after the e-Manifest system is operational, annualized savings from manifest related burden reduction would equal approximately $66 million per year when discounted at 7%. The RIA estimates that these savings would accrue to firms of all sizes, including 70 potentially small firms, that adopt electronic manifests as well as to firms that adopt one of the two paper manifest submission options other than postal mail submissions. The RIA concludes the e-Manifest rule will not have a significant adverse economic impact on a substantial number of small entities.

As a precaution, the RIA also estimates the impacts of the e-Manifest rule under the unlikely hypothetical scenario in which small firms do not adopt e-Manifest but instead continue to submit paper manifests via postal mail. As a consequence, these firms might not realize any savings from the e-Manifest rule but could instead face increasing costs from e-Manifest fees. The small entities examined in this worst case analysis consist of 70 potentially small firms located within the relevant industries. Potential costs for these firms are estimated by multiplying the cost of a paper manifest submission fee by the number of manifests a firm is estimated to submit within a year. The number of manifests a firm is estimated to submit is based on the amount of hazardous waste they receive. For each firm, the cost of fees is then compared to estimated revenues. Even under these unlikely and highly conservative assumptions, the RIA finds that the rule will not have a significant adverse economic impact on a substantial number of small entities, which the RIA considers as revenue impacts of greater than 1% per year for 20% or more of small entities. The RIA, in particular Section 7.2, describes in greater depth how EPA assembled a universe of small entities, how EPA estimated the hypothetical impacts of the e-Manifest rule under these conservative assumptions, and the criteria EPA used in this instance to determine significant adverse economic impacts on a substantial number of small entities. The RIA is available in the docket for this rulemaking.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not impose any new requirements on tribal officials nor will it impose substantial direct compliance costs on them. This action will not create a mandate for tribal governments, *i.e.,* there are no authorized tribal programs that will require revision and reauthorization on account of the e-Manifest system and regulatory program requirements. Nor do we believe that the e-Manifest system and this Fee Rule will impose any enforceable duties on these entities. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action requires the payment of user fees from certain members of the hazardous waste management industry for their use of an electronic manifest

system, which will not have a significant effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA concludes that this action does not have potential disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not affect what facilities, materials, or activities are subject to RCRA. Thus, this action does not affect the level of protection provided to human health or the environment. When implemented, the e-Manifest system could improve access for minority, low-income or indigenous populations and communities to information on waste movements to, from, or through neighborhoods where these populations live and work. Thus, the system could only have beneficial effects on such populations and communities.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 260

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 263

Environmental protection, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Hazardous waste, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Fees.

40 CFR Part 265

Environmental protection, Hazardous waste, Packaging and containers, Reporting and recordkeeping requirements, Fees.

40 CFR Part 271

Environmental protection, Administrative practice and procedure Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements.

Dated: December 20, 2017.

E. Scott Pruitt,

Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR parts 260, 262, 263, 264 and 265, and 271 as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, 6939g, and 6974.

■ 2. Add §§ 260.4 and 260.5 to subpart A to read as follows:

§ 260.4 Manifest copy submission requirements for certain interstate waste shipments.

(a) In any case in which the state in which waste is generated, or the state in which waste will be transported to a designated facility, requires that the waste be regulated as a hazardous waste or otherwise be tracked through a hazardous waste manifest, the designated facility that receives the waste shall, regardless of the state in which the facility is located:

(1) Complete the facility portion of the applicable manifest;

(2) Sign and date the facility certification;

(3) Submit to the e-Manifest system a final copy of the manifest for data processing purposes; and

(4) Pay the appropriate per manifest fee to EPA for each manifest submitted to the e-Manifest system, subject to the fee determination methodology, payment methods, dispute procedures, sanctions, and other fee requirements specified in subpart FF of part 264 of this chapter.

§ 260.5 Applicability of electronic manifest system and user fee requirements to facilities receiving state-only regulated waste shipments.

(a) For purposes of this section, ''state-only regulated waste'' means:

(1) A non-RCRA waste that a state regulates more broadly under its state regulatory program, or

(2) A RCRA hazardous waste that is federally exempt from manifest requirements, but not exempt from manifest requirements under state law.

(b) In any case in which a state requires a RCRA manifest to be used under state law to track the shipment and transportation of a state-only regulated waste to a receiving facility, the facility receiving such a waste shipment for management shall:

(1) Comply with the provisions of §§ 264.71 (use of the manifest) and 264.72 (manifest discrepancies) of this chapter; and

(2) Pay the appropriate per manifest fee to EPA for each manifest submitted to the e-Manifest system, subject to the fee determination methodology, payment methods, dispute procedures, sanctions, and other fee requirements specified in subpart FF of part 264 of this chapter.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 3. The authority citation for part 262 is revised to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938 and 6939g.

■ 4. Section 262.20 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 262.20 General requirements.

(a)(1) A generator that transports, or offers for transport a hazardous waste for offsite treatment, storage, or disposal, or a treatment, storage, or disposal facility that offers for transport a rejected hazardous waste load, must prepare a Manifest (OMB Control number 2050–0039) on EPA Form 8700–22, and, if necessary, EPA Form 8700–22A.

(2) The revised manifest form and procedures in 40 CFR 260.10, 261.7, 262.20, 262.21, 262.27, 262.32, 262.34, 262.54, and 262.60, shall not apply until September 5, 2006. The manifest form and procedures in 40 CFR 260.10, 261.7, 262.20, 262.21, 262.32, 262.34, 262.54, and 262.60, contained in the 40 CFR, parts 260 to 265, edition revised as of July 1, 2004, shall be applicable until September 5, 2006.

* * * * *

■ 5. Section 262.21 is amended by revising paragraphs (f)(5) and (6) and (f)(7) and adding paragraph (f)(8) to read as follows:

§ 262.21 Manifest tracking numbers, manifest printing, and obtaining manifests.

* * * * *

(f) * * *

(5) The manifest and continuation sheet must be printed as five-copy forms. Copy-to-copy registration must be exact within 1/32nd of an inch. Handwritten and typed impressions on the form must be legible on all five copies. Copies must be bound together by one or more common stubs that reasonably ensure that they will not become detached inadvertently during normal use.

(6) Each copy of the manifest and continuation sheet must indicate how the copy must be distributed, as follows:

(i) Page 1 (top copy): ''Designated facility to EPA's e-Manifest system'';

(ii) Page 2: ''Designated facility to generator'';

(iii) Page 3: ''Designated facility copy'';

(iv) Page 4: ''Transporter copy''; and

(v) Page 5 (bottom copy): ''Generator's initial copy.''

(7) The instructions for the manifest form (EPA Form 8700–22) and the manifest continuation sheet (EPA Form 8700–22A) shall be printed in accordance with the content that is currently approved under OMB Control Number 2050–0039 and published to the e-Manifest program's website. The instructions must appear legibly on the back of the copies of the manifest and continuation sheet as provided in this paragraph (f). The instructions must not be visible through the front of the copies when photocopied or faxed.

(i) Manifest Form 8700–22.

(A) The ''Instructions for Generators'' on Copy 5;

(B) The ''Instructions for International Shipment Block'' and ''Instructions for Transporters'' on Copy 4; and

(C) The ''Instructions for Treatment, Storage, and Disposal Facilities'' on Copy 3.

(ii) Manifest Form 8700–22A.

(A) The ''Instructions for Generators'' on Copy 5;

(B) The ''Instructions for Transporters'' on Copy 4; and

(C) The ''Instructions for Treatment, Storage, and Disposal Facilities'' on Copy 3.

(8) The designated facility copy of each manifest and continuation sheet must include in the bottom margin the following warning in prominent font: ''If you received this manifest, you have responsibilities under the e-Manifest Act. See instructions on reverse side.''

* * * * *

■ 6. Section 262.24 is amended by:

■ a. Revising paragraphs (c) and (e);

■ b. Removing and reserving paragraph (g); and

■ c. Adding paragraph (h).

The revision and addition read as follows:

§ 262.24 Use of the electronic manifest.

* * * * *

(c) *Restriction on use of electronic manifests.* A generator may use an electronic manifest for the tracking of waste shipments involving any RCRA hazardous waste only if it is known at the time the manifest is originated that all waste handlers named on the manifest participate in the use of the electronic manifest, except that:

(1) A generator may sign by hand and retain a paper copy of the manifest signed by hand by the initial transporter, in lieu of executing the generator copy electronically, thereby enabling the transporter and subsequent waste handlers to execute the remainder of the manifest copies electronically.

(2) [Reserved]

* * * * *

(e) *Special procedures when electronic manifest is unavailable.* If a generator has prepared an electronic manifest for a hazardous waste shipment, but the electronic manifest system becomes unavailable for any reason prior to the time that the initial transporter has signed electronically to acknowledge the receipt of the hazardous waste from the generator, then the generator must obtain and complete a paper manifest and if necessary, a continuation sheet (EPA Forms 8700–22 and 8700–22A) in accordance with the manifest instructions, and use these paper forms from this point forward in accordance with the requirements of § 262.23.

* * * * *

(h) *Post-receipt manifest data corrections.* After facilities have certified to the receipt of hazardous wastes by signing Item 20 of the manifest, any post-receipt data corrections may be submitted at any time by any interested person (*e.g.,* waste handler) named on the manifest. Generators may participate electronically in the post-receipt data corrections process by following the process described in § 264.71(l) of this chapter, which applies to corrections made to either paper or electronic manifest records.

Appendix to Part 262 [Removed]

■ 7. Remove the appendix to part 262.

PART 263—STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

■ 8. The authority citation for part 263 is revised to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938, and 6939g.

■ 9. Section 263.20 is amended by removing and reserving paragraph (a)(8) and adding paragraph (a)(9) to read as follows:

§ 263.20 The manifest system.

* * * * *

(a) * * *

(9) *Post-receipt manifest data corrections.* After facilities have certified to the receipt of hazardous wastes by signing Item 20 of the manifest, any post-receipt data corrections may be submitted at any time by any interested person (*e.g.,* waste handler) named on the manifest. Transporters may participate electronically in the post-receipt data corrections process by following the process described in § 264.71(l) of this chapter, which applies to corrections made to either paper or electronic manifest records.

* * * * *

■ 10. Section 263.21 is revised to read as follows:

§ 263.21 Compliance with the manifest.

(a) Except as provided in paragraph (b) of this section, the transporter must deliver the entire quantity of hazardous waste which he or she has accepted from a generator or a transporter to:

(1) The designated facility listed on the manifest; or

(2) The alternate designated facility, if the hazardous waste cannot be delivered to the designated facility because an emergency prevents delivery; or

(3) The next designated transporter; or

(4) The place outside the United States designated by the generator.

(b)(1) *Emergency condition.* If the hazardous waste cannot be delivered in accordance with paragraph (a)(1), (2), or (4) of this section because of an emergency condition other than rejection of the waste by the designated facility or alternate designated facility, then the transporter must contact the generator for further instructions and must revise the manifest according to the generator's instructions.

(2) *Transporters without agency authority.* If the hazardous waste is not delivered to the next designated transporter in accordance with paragraph (a)(3) of this section, and the current transporter is without contractual authorization from the generator to act as the generator's agent with respect to transporter additions or substitutions, then the current transporter must contact the generator for further instructions prior to making any revisions to the transporter designations on the manifest. The current transporter may thereafter make such revisions if:

(i) The hazardous waste is not delivered in accordance with paragraph (a)(3) of this section because of an emergency condition; or

(ii) The current transporter proposes to change the transporter(s) designated on the manifest by the generator, or to add a new transporter during transportation, to respond to an emergency, or for purposes of transportation efficiency, convenience, or safety; and

(iii) The generator authorizes the revision.

(3) *Transporters with agency authority.* If the hazardous waste is not delivered to the next designated transporter in accordance with paragraph (a)(3) of this section, and the current transporter has authorization from the generator to act as the generator's agent, then the current transporter may change the transporter(s) designated on the manifest, or add a new transporter, during transportation without the generator's prior, explicit approval, provided that:

(i) The current transporter is authorized by a contractual provision that provides explicit agency authority for the transporter to make such transporter changes on behalf of the generator;

(ii) The transporter enters in Item 14 of each manifest for which such a change is made, the following statement of its agency authority: ''Contract retained by generator confers agency authority on initial transporter to add or substitute additional transporters on generator's behalf;'' and

(iii) The change in designated transporters is necessary to respond to an emergency, or for purposes of transportation efficiency, convenience, or safety.

(4) *Generator liability.* The grant by a generator of authority to a transporter to act as the agent of the generator with respect to changes to transporter designations under paragraph (b)(3) of this section does not affect the generator's liability or responsibility for complying with any applicable requirement under this chapter, or grant any additional authority to the transporter to act on behalf of the generator.

(c) If hazardous waste is rejected by the designated facility while the transporter is on the facility's premises, then the transporter must obtain the following:

(1) For a partial load rejection or for regulated quantities of container residues, a copy of the original manifest that includes the facility's date and signature, and the Manifest Tracking Number of the new manifest that will accompany the shipment, and a description of the partial rejection or container residue in the discrepancy block of the original manifest. The transporter must retain a copy of this manifest in accordance with § 263.22, and give the remaining copies of the original manifest to the rejecting designated facility. If the transporter is forwarding the rejected part of the shipment or a regulated container residue to an alternate facility or returning it to the generator, the transporter must obtain a new manifest to accompany the shipment, and the new manifest must include all of the information required in 40 CFR 264.72(e)(1) through (6) or (f)(1) through (6) or 40 CFR 265.72(e)(1) through (6) or (f)(1) through (6).

(2) For a full load rejection that will be taken back by the transporter, a copy of the original manifest that includes the rejecting facility's signature and date attesting to the rejection, the description of the rejection in the discrepancy block of the manifest, and the name, address, phone number, and Identification Number for the alternate facility or generator to whom the shipment must be delivered. The transporter must retain a copy of the manifest in accordance with § 263.22, and give a copy of the manifest containing this information to the rejecting designated facility. If the original manifest is not used, then the transporter must obtain a new manifest for the shipment and comply with 40 CFR 264.72(e)(1) through (6) or 40 CFR 265.72(e)(1) through (6).

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 11. The authority citation for part 264 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

Subpart E—Manifest System, Recordkeeping, and Reporting

■ 12. Section 264.71 is amended by revising paragraphs (a)(2) and (j) and adding paragraph (l) to read as follows:

§ 264.71 Use of manifest system.

(a) * * *

(2) If the facility receives a hazardous waste shipment accompanied by a manifest, the owner, operator, or his agent must:

(i) Sign and date each copy of the manifest;

(ii) Note any discrepancies (as defined in § 264.72(a)) on each copy of the manifest;

(iii) Immediately give the transporter at least one copy of the manifest;

(iv) Within 30 days of delivery, send a copy (Page 2) of the manifest to the generator;

(v) Paper manifest submission requirements are:

(A) *Options for compliance on June 30, 2018.* Beginning on June 30, 2018, send the top copy (Page 1) of any paper manifest and any paper continuation sheet to the e-Manifest system for purposes of data entry and processing, or in lieu of submitting the paper copy to EPA, the owner or operator may transmit to the EPA system an image file of Page 1 of the manifest and any continuation sheet, or both a data file and image file corresponding to Page 1 of the manifest and any continuation sheet, within 30 days of the date of delivery. Submissions of copies to the e-Manifest system shall be made at the mailing address or electronic mail/submission address specified at the e-Manifest program website's directory of services. Beginning on June 30, 2021, EPA will not accept mailed paper manifests from facilities for processing in e-Manifest.

(B) *Options for compliance on June 30, 2021.* Beginning on June 30, 2021, the requirement to submit the top copy (Page 1) of the paper manifest and any paper continuation sheet to the e-Manifest system for purposes of data entry and processing may be met by the owner or operator only by transmitting to the EPA system an image file of Page 1 of the manifest and any continuation sheet, or by transmitting to the EPA system both a data file and the image file corresponding to Page 1 of the manifest and any continuation sheet, within 30 days of the date of delivery. Submissions of copies to the e-Manifest system shall be made to the electronic mail/submission address specified at the e-Manifest program website's directory of services; and

(vi) Retain at the facility a copy of each manifest for at least three years from the date of delivery.

* * * * *

(j) *Imposition of user fee for manifest submissions.* (1) As prescribed in § 264.1311, and determined in § 264.1312, an owner or operator who is a user of the electronic manifest system shall be assessed a user fee by EPA for the submission and processing of each electronic and paper manifest. EPA shall update the schedule of user fees and publish them to the user community, as provided in § 264.1313.

(2) An owner or operator subject to user fees under this section shall make user fee payments in accordance with the requirements of § 264.1314, subject to the informal fee dispute resolution process of § 264.1316, and subject to the sanctions for delinquent payments under § 264.1315.

* * * * *

(l) *Post-receipt manifest data corrections.* After facilities have certified to the receipt of hazardous wastes by signing Item 20 of the manifest, any post-receipt data corrections may be submitted at any time by any interested person (*e.g.,* waste handler) shown on the manifest.

(1) Interested persons must make all corrections to manifest data by electronic submission, either by directly entering corrected data to the web based service provided in e-Manifest for such corrections, or by an upload of a data file containing data corrections relating to one or more previously submitted manifests.

(2) Each correction submission must include the following information:

(i) The Manifest Tracking Number and date of receipt by the facility of the original manifest(s) for which data are being corrected;

(ii) The item number(s) of the original manifest that is the subject of the submitted correction(s); and

(iii) For each item number with corrected data, the data previously entered and the corresponding data as corrected by the correction submission.

(3) Each correction submission shall include a statement that the person submitting the corrections certifies that to the best of his or her knowledge or belief, the corrections that are included in the submission will cause the information reported about the previously received hazardous wastes to be true, accurate, and complete:

(i) The certification statement must be executed with a valid electronic signature; and

(ii) A batch upload of data corrections may be submitted under one certification statement.

(4) Upon receipt by the system of any correction submission, other interested persons shown on the manifest will be provided electronic notice of the submitter's corrections.

(5) Other interested persons shown on the manifest may respond to the submitter's corrections with comments to the submitter, or by submitting another correction to the system, certified by the respondent as specified in paragraph (l)(3) of this section, and with notice of the corrections to other interested persons shown on the manifest.

■ 13. Section 264.1086 is amended by revising paragraphs (c)(4)(i) and (d)(4)(i) to read as follows:

§ 264.1086 Standards: Containers.

* * * * *

(c) * * *

(4) * * *

(i) In the case when a hazardous waste already is in the container at the time the owner or operator first accepts possession of the container at the facility and the container is not emptied within 24 hours after the container is accepted at the facility (*i.e.,* does not meet the conditions for an empty container as specified in 40 CFR 261.7(b)), the owner or operator shall visually inspect the container and its cover and closure devices to check for visible cracks, holes, gaps, or other open spaces into the interior of the container when the cover and closure devices are secured in the closed position. The container visual inspection shall be conducted on or before the date that the container is accepted at the facility (*i.e.,* the date the container becomes subject to the subpart CC container standards). For purposes of this requirement, the date of acceptance is the date of signature that the facility owner or operator enters on Item 20 of the Uniform Hazardous Waste Manifest (EPA Forms 8700–22 and 8700–22A), as required under subpart E of this part, at 40 CFR 264.71. If a defect is detected, the owner or operator shall repair the defect in accordance with the requirements of paragraph (c)(4)(iii) of this section.

* * * * *

(d) * * *

(4) * * *

(i) In the case when a hazardous waste already is in the container at the time the owner or operator first accepts possession of the container at the facility and the container is not emptied within 24 hours after the container is accepted at the facility (*i.e.,* does not meet the conditions for an empty container as specified in 40 CFR 261.7(b)), the owner or operator shall visually inspect the container and its cover and closure devices to check for visible cracks, holes, gaps, or other open spaces into the interior of the container when the cover and closure devices are secured in the closed position. The container visual inspection shall be conducted on or before the date that the container is accepted at the facility (*i.e.,* the date the container becomes subject to the subpart CC container standards). For purposes of this requirement, the date of acceptance is the date of signature that the facility owner or operator enters on Item 20 of the Uniform Hazardous Waste Manifest (EPA Forms 8700–22 and 8700–22A), as required under subpart E of this part, at 40 CFR 264.71. If a defect is detected, the owner or operator shall repair the defect in accordance with the requirements of paragraph (d)(4)(iii) of this section.

* * * * *

■ 14. Subpart FF, consisting of §§ 264.1300 through 264.1316, is added to part 264 to read as follows:

Subpart FF—Fees for the Electronic Hazardous Waste Manifest Program

Sec.

Subpart FF—Fees for the Electronic Hazardous Waste Manifest Program

§ 264.1300 Applicability.

(a) This subpart prescribes:

(1) The methodology by which EPA will determine the user fees which owners or operators of facilities must pay for activities and manifest related services provided by EPA through the development and operation of the electronic hazardous waste manifest system (e-Manifest system); and

(2) The process by which EPA will revise e-Manifest system fees and provide notice of the fee schedule revisions to owners or operators of facilities.

(b) The fees determined under this subpart apply to owners or operators of facilities whose activities receiving, rejecting, or managing federally- or state-regulated hazardous wastes or other materials bring them within the definition of ''user of the electronic manifest system'' under § 260.10 of this chapter.

§ 264.1310 Definitions applicable to this subpart.

The following definitions apply to this subpart:

Consumer price index means the consumer price index for all U.S. cities using the ''U.S. city average'' area, ''all items'' and ''not seasonally adjusted'' numbers calculated by the Bureau of Labor Statistics in the Department of Labor.

Cross Media Electronic Reporting Rule (CROMERR) costs are the sub-category of operations and maintenance costs that are expended by EPA in

implementing electronic signature, user registration, identity proofing, and copy of record solutions that meet EPA's electronic reporting regulations as set forth in the CROMERR as codified at 40 CFR part 3.

Electronic manifest submissions means manifests that are initiated electronically using the electronic format supported by the e-Manifest system, and that are signed electronically and submitted electronically to the e-Manifest system by facility owners or operators to indicate the receipt or rejection of the wastes identified on the electronic manifest. Electronic manifest submissions include the hybrid or mixed paper/electronic manifests authorized under § 262.24(c)(1).

EPA program costs mean the Agency's intramural and non-information technology extramural costs expended in the design, development and operations of the e-Manifest system, as well as in regulatory development activities supporting e-Manifest, in conducting its capital planning, project management, oversight and outreach activities related to e-Manifest, in conducting economic analyses supporting e-Manifest, and in establishing the System Advisory Board to advise EPA on the system. Depending on the date on which EPA program costs are incurred, these costs may be further classified as either system setup costs or operations and maintenance costs.

Help desk costs mean the costs incurred by EPA or its contractors to operate the e-Manifest Help Desk, which EPA will establish to provide e-Manifest system users with technical assistance and related support activities.

Indirect costs mean costs not captured as marginal costs, system setup costs, or operations and maintenance costs, but that are necessary to capture because of their enabling and supporting nature, and to ensure full cost recovery. Indirect costs include, but are not limited to, such cost items as physical overhead, maintenance, utilities, and rents on land, buildings, or equipment. Indirect costs also include the EPA costs incurred from the participation of EPA offices and upper management personnel outside of the lead program office responsible for implementing the e-Manifest program.

Manifest submission type means the type of manifest submitted to the e-Manifest system for processing, and includes electronic manifest submissions and paper manifest submissions.

Marginal labor costs mean the human labor costs incurred by staff operating the paper manifest processing center in conducting data key entry, QA, scanning, copying, and other manual or clerical functions necessary to process the data from paper manifest submissions into the e-Manifest system's data repository.

Operations and maintenance costs mean all system related costs incurred by EPA or its contractors after the activation of the e-Manifest system. Operations and maintenance costs include the costs of operating the electronic manifest information technology system and data repository, CROMERR costs, help desk costs, EPA program costs incurred after e-Manifest system activation, and the costs of operating the paper manifest processing center, other than the paper processing center's marginal labor costs.

Paper manifest submissions mean submissions to the paper processing center of the e-Manifest system by facility owners or operators, of the data from the designated facility copy of a paper manifest, EPA Form 8700–22, or a paper Continuation Sheet, EPA Form 8700–22A. Such submissions may be made by mailing the paper manifests or continuation sheets, by submitting image files from paper manifests or continuation sheets in accordance with § 264.1311(b), or by submitting both an image file and data file in accordance with the procedures of § 264.1311(c).

System setup costs mean all system related costs, intramural or extramural, incurred by EPA prior to the activation of the e-Manifest system. Components of system setup costs include the procurement costs from procuring the development and testing of the e-Manifest system, and the EPA program costs incurred prior to e-Manifest system activation.

§ 264.1311 Manifest transactions subject to fees.

(a) *Per manifest fee.* Fees shall be assessed on a per manifest basis for the following manifest submission transactions:

(1) The submission of each electronic manifest that is electronically signed and submitted to the e-Manifest system by the owners or operators of receiving facilities, with the fee assessed at the applicable rate for electronic manifest submissions;

(2) The submission of each paper manifest submission to the paper processing center signed by owners or operators of receiving facilities, with the fee assessed according to whether the manifest is submitted to the system by mail, by the upload of an image file, or by the upload of a data file representation of the paper manifest; and

(3) The submission of copies of return shipment manifests by facilities that are rejecting hazardous wastes and returning hazardous wastes under return manifests to the original generator. This fee is assessed for the processing of the return shipment manifest(s), and is assessed at the applicable rate determined by the method of submission. The submission shall also include a copy of the original signed manifest showing the rejection of the wastes.

(b) *Image file uploads from paper manifests.* Receiving facilities may submit image file uploads of completed, ink-signed manifests in lieu of submitting mailed paper forms to the e-Manifest system. Such image file upload submissions may be made for individual manifests received by a facility or as a batch upload of image files from multiple paper manifests received at the facility:

(1) The image file upload must be made in an image file format approved by EPA and supported by the e-Manifest system; and

(2) At the time of submission of an image file upload, a responsible representative of the receiving facility must make a CROMERR compliant certification that to the representative's knowledge or belief, the submitted image files are accurate and complete representations of the facility's received manifests, and that the facility acknowledges that it is obligated to pay the applicable per manifest fee for each manifest included in the submission.

(c) *Data file uploads from paper manifests.* Receiving facilities may submit data file representations of completed, ink-signed manifests in lieu of submitting mailed paper forms or image files to the e-Manifest system. Such data file submissions from paper manifests may be made for individual manifests received by a facility or as a batch upload of data files from multiple paper manifests received at the facility.

(1) The data file upload must be made in a data file format approved by EPA and supported by the e-Manifest system;

(2) The receiving facility must also submit an image file of each manifest that is included in the individual or batch data file upload; and

(3) At the time of submission of the data file upload, a responsible representative of the receiving facility must make a CROMERR compliant certification that to the representative's knowledge or belief, the data and images submitted are accurate and complete representations of the facility's received manifests, and that the facility acknowledges that it is obligated to pay

the applicable per manifest fee for each manifest included in the submission.

§ 264.1312 User fee calculation methodology.

(a) The fee calculation formula or methodology that EPA will use initially to determine per manifest fees is as follows:

$$Fee_i = \left(\frac{System\ Setup\ Cost}{Years \times N_t}\right) + \left(Marginal\ Cost_i + \frac{O\&M\ Cost}{N_t}\right) \times (1 + Indirect\ Cost\ Factor)$$

$$System\ Setup\ Cost = Procurement\ Cost + EPA\ Program\ Cost$$

$$O\&M\ Cost = Electronic\ System\ O\&M\ Cost + Paper\ Center\ O\&M\ Cost + Help\ Desk\ Cost + EPA\ Program\ Cost + CROMERR\ Cost + LifeCycle\ Cost\ to\ Modify\ or\ Upgrade\ eManfiest\ System\ Related\ Services$$

Where Fee_i represents the per manifest fee for each manifest submission type ''i'' and N_t refers to the total number of manifests completed in a year.

(b)(1) If after four years of system operations, electronic manifest usage does not equal or exceed 75% of total manifest usage, EPA may transition to the following formula or methodology to determine per manifest fees:

$$Fee_i = \left(\frac{System\ Setup\ Cost}{Years \times N_t}\right) + \left(Marginal\ Cost_i + \frac{O\&M_i\ Cost}{N_i}\right) \times (1 + Indirect\ Cost\ Factor)$$

$$System\ Setup\ Cost = Procurement\ Cost + EPA\ Program\ Cost$$

$$O\&M_{fully\ electronic} Cost = Electronic\ System\ O\&M\ Cost + Help\ Desk\ Cost + EPA\ Program\ Cost + CROMERR\ Cost + LifeCycle\ Cost\ to\ Modify\ or\ Upgrade\ eManfiest\ System\ Related\ Services$$

$$O\&M_{all\ other} Cost = Electronic\ System\ O\&M\ Cost + Paper\ Center\ O\&M\ Cost + Help\ Desk\ Cost + EPA\ Program\ Cost + CROMERR\ Cost + LifeCycle\ Cost\ to\ Modify\ or\ Upgrade\ eManfiest\ System\ Related\ Services$$

Where N_i refers to the total number of one of the four manifest submission types ''*i*'' completed in a year and *O&M*$_i$ *Cost* refers to the differential O&M Cost for each manifest submission type ''*i.*''

(2) At the completion of four years of system operations, EPA shall publish a notice:

(i) Stating the date upon which the fee formula set forth in paragraph (b)(1) of this section shall become effective; or

(ii) Stating that the fee formula in paragraph (b)(1) of this section shall not go into effect under this section, and that the circumstances of electronic manifest adoption and the appropriate fee response shall be referred to the System Advisory Board for the Board's advice.

§ 264.1313 User fee revisions.

(a) *Revision schedule.* (1) EPA will revise the fee schedules for e-Manifest submissions and related activities at two-year intervals, by utilizing the applicable fee calculation formula prescribed in § 264.1312 and the most recent program cost and manifest usage numbers.

(2) The fee schedules will be published to users through the e-Manifest program website by July 1 of each odd numbered calendar year, and will cover the two fiscal years beginning on October 1 of that year and ending on September 30 of the next odd numbered calendar year.

(b) *Inflation adjuster.* The second year of each two-year fee schedule shall be adjusted for inflation by using the following adjustment formula:

$$Fee i_{Year2} = Fee i_{Year1} \times (CPI_{Year2-2} / CPI_{Year2-1})$$

Where:

$Fee i_{Year2}$ is the Fee for each type of manifest submission ''*i*'' in Year 2 of the fee cycle;

$Fee i_{Year1}$ is the Fee for each type of manifest submission ''*i*'' in Year 1 of the fee cycle; and

$CPI_{Year2-2}/CPI_{Year2-1}$ is the ratio of the CPI published for the year two years prior to Year 2 to the CPI for the year one year prior to Year 2 of the cycle.

(c) *Revenue recovery adjusters.* The fee schedules published at two-year intervals under this section shall include an adjustment to recapture revenue lost in the previous two-year fee cycle on account of imprecise estimates of manifest usage. This adjustment shall be calculated using the following adjustment formula to calculate a revenue recapture amount which will be added to O&M Costs in the fee calculation formula of § 264.1312:

$$Revenue\ Recapture_i = (N_{iYear1} + N_{iYear2})_{Actual} - (N_{iYear1} + N_{iYear2})_{Est} \times Fee_{i(Ave)}$$

Where:

Revenue Recapture$_i$ is the amount of fee revenue recaptured for each type of manifest submission ''*i;*''

$(N_{iYear1} + N_{iYear2})_{Actual} - (N_{iYear1} + N_{iYear2})_{Est}$ is the difference between actual manifest numbers submitted to the system for each manifest type during the previous 2-year cycle, and the numbers estimated when we developed the previous cycle's fee schedule; and

$Fee_{i(Ave)}$ is the average fee charged per manifest type over the previous two-year cycle.

§ 264.1314 How to make user fee payments.

(a) All fees required by this subpart shall be paid by the owners or operators of the receiving facility in response to an electronic invoice or bill identifying manifest-related services provided to the user during the previous month and identifying the fees owed for the enumerated services.

(b) All fees required by this subpart shall be paid to EPA by the facility electronically in U.S. dollars, using one of the electronic payment methods supported by the Department of the Treasury's *Pay.gov* online electronic payment service, or any applicable additional online electronic payment service offered by the Department of Treasury.

(c) All fees for which payments are owed in response to an electronic invoice or bill must be paid within 30 days of the date of the invoice or bill.

§ 264.1315 Sanctions for delinquent payments.

(a) *Interest.* In accordance with 31 U.S.C. 3717(a)(1), delinquent e-Manifest user fee accounts shall be charged a minimum annual rate of interest equal to the average investment rate for Treasury tax and loan accounts (Current Value of Funds Rate or CVFR) for the 12-month period ending September 30th of each year, rounded to the nearest whole percent.

(1) E-Manifest user fee accounts are delinquent if the accounts remain unpaid after the due date specified in the invoice or other notice of the fee amount owed.

(2) Due dates for invoiced or electronically billed fee amounts shall be 30 days from the date of the electronic invoice or bill.

(b) *Financial penalty.* In accordance with 31 U.S.C. 3717(e), e-Manifest user fee accounts that are more than 90 days past due (*i.e.,* not paid by date 120 days from date of invoice) shall be charged an additional penalty of 6% per year assessed on any part of the debt that is past due for more than 90 days, plus any applicable handling charges.

(c) *Compliance with manifest perfection requirement.* A manifest is fully perfected when:

(1) The manifest has been submitted by the owner or operator of a receiving facility to the e-Manifest system, as either an electronic submission or a paper manifest submission; and

(2) All user fees arising from the submission of the manifest have been fully paid.

§ 264.1316 Informal fee dispute resolution.

(a) Users of e-Manifest services that believe their invoice or charges to be in error must present their claims for fee dispute resolution informally using the process described in this section.

(b) Users asserting a billing dispute claim must first contact the system's billing representatives by phone or email at the phone number or email address provided for this purpose on the e-Manifest program's website or other customer services directory.

(1) The fee dispute claimant must provide the system's billing representatives with information identifying the claimant and the invoice(s) that are affected by the dispute, including:

(i) The claimant's name, and the facility at which the claimant is employed;

(ii) The EPA Identification Number of the affected facility;

(iii) The date, invoice number, or other information to identify the particular invoice(s) that is the subject of the dispute; and

(iv) A phone number or email address where the claimant can be contacted.

(2) The fee dispute claimant must provide the system's billing representatives with sufficient supporting information to identify the nature and amount of the fee dispute, including:

(i) If the alleged error results from the types of manifests submitted being inaccurately described in the invoice, the correct description of the manifest types that should have been billed;

(ii) If the alleged error results from the number of manifests submitted being inaccurately described in the invoice, the correct description of the number of manifests that should have been billed;

(iii) If the alleged error results from a mathematical error made in calculating the amount of the invoice, the correct fee calculations showing the corrected fee amounts; and

(iv) Any other information from the claimant that explains why the invoiced amount is in error and what the fee amount invoiced should be if corrected.

(3) EPA's system billing representatives must respond to billing dispute claims made under this section within ten days of receipt of a claim. In response to a claim, the system's billing representative will:

(i) State whether the claim is accepted or rejected, and if accepted, the response will indicate the amount of any fee adjustment that will be refunded or credited to the facility; and

(ii) If a claim is rejected, then the response shall provide a brief statement of the reasons for the rejection of the claim and advise the claimant of their right to appeal the claim to the Office Director for the Office of Resource Conservation and Recovery.

(c) Fee dispute claimants that are not satisfied by the response to their claim from the system's billing representatives may appeal their claim and initial decision to the Office Director for the Office of Resource Conservation and Recovery.

(1) Any appeal from the initial decision of the system's billing representatives must be taken within 10 days of the initial decision of the system's billing representatives under paragraph (b) of this section.

(2) The claimant shall provide the Office Director with the claim materials submitted to the system's billing representatives, the response provided by the system's billing representatives to the claim, and a brief written statement by the claimant explaining the nature and amount of the billing error, explaining why the claimant believes the decision by the system's billing representatives is in error, and why the claimant is entitled to the relief requested on its appeal.

(3) The Office Director shall review the record presented to him or her on an appeal under this paragraph (c), and shall determine whether the claimant is entitled to relief from the invoice alleged to be in error, and if so, shall state the amount of the recalculated invoice and the amount of the invoice to be adjusted.

(4) The decision of the Office Director on any appeal brought under this section is final and non-reviewable.

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 15. The authority citation for part 265 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

Subpart E—Manifest System, Recordkeeping, and Reporting

■ 16. Section 265.71 is amended by revising paragraphs (a)(2) and (j) and adding paragraph (l) to read as follows:

§ 265.71 Use of manifest system.

(a) * * *

(2) If the facility receives a hazardous waste shipment accompanied by a manifest, the owner, operator, or his agent must:

(i) Sign and date, by hand, each copy of the manifest;

(ii) Note any discrepancies (as defined in § 265.72(a)) on each copy of the manifest;

(iii) Immediately give the transporter at least one copy of the manifest;

(iv) Within 30 days of delivery, send a copy (Page 2) of the manifest to the generator;

(v) Paper manifest submission requirements are:

(A) *Options for compliance on June 30, 2018.* Beginning on June 30, 2018, send the top copy (Page 1) of any paper manifest and any paper continuation sheet to the e-Manifest system for purposes of data entry and processing, or in lieu of submitting the paper copy to EPA, the owner or operator may transmit to the EPA system an image file of Page 1 of the manifest and any continuation sheet, or both a data file and image file corresponding to Page 1 of the manifest and any continuation sheet, within 30 days of the date of delivery. Submissions of copies to the e-Manifest system shall be made at the mailing address or electronic mail/submission address specified at the e-Manifest program website's directory of services. Beginning on June 30, 2021, EPA will not accept mailed paper manifests from facilities for processing in e-Manifest.

(B) *Options for compliance on June 30, 2021.* Beginning on June 30, 2021, the requirement to submit the top copy (Page1) of the paper manifest and any paper continuation sheet to the e-Manifest system for purposes of data entry and processing may be met by the owner or operator only by transmitting to the EPA system an image file of Page 1 of the manifest and any continuation sheet, or by transmitting to the EPA system both a data file and the image file corresponding to Page 1 of the manifest and any continuation sheet, within 30 days of the date of delivery. Submissions of copies to the e-Manifest system shall be made to the electronic mail/submission address specified at the e-Manifest program website's directory of services; and (vi) Retain at the facility a copy of each manifest for at least three years from the date of delivery.

* * * * *

(j) *Imposition of user fee for electronic manifest use.* (1) As prescribed in § 265.1311, and determined in § 265.1312, an owner or operator who is a user of the electronic manifest system shall be assessed a user fee by EPA for the submission and processing of each electronic and paper manifest. EPA shall update the schedule of user fees and publish them to the user community, as provided in § 265.1313.

(2) An owner or operator subject to user fees under this section shall make user fee payments in accordance with the requirements of § 265.1314, subject to the informal fee dispute resolution process of § 265.1316, and subject to the sanctions for delinquent payments under § 265.1315.

* * * * *

(l) *Post-receipt manifest data corrections.* After facilities have certified to the receipt of hazardous wastes by signing Item 20 of the manifest, any post-receipt data corrections may be submitted at any time by any interested person (*e.g.,* waste handler) shown on the manifest.

(1) Interested persons must make all corrections to manifest data by electronic submission, either by directly entering corrected data to the web based service provided in e-Manifest for such corrections, or by an upload of a data file containing data corrections relating to one or more previously submitted manifests.

(2) Each correction submission must include the following information:

(i) The Manifest Tracking Number and date of receipt by the facility of the original manifest(s) for which data are being corrected;

(ii) The Item Number(s) of the original manifest that is the subject of the submitted correction(s); and

(iii) For each Item Number with corrected data, the data previously entered and the corresponding data as corrected by the correction submission.

(3) Each correction submission shall include a statement that the person submitting the corrections certifies that to the best of his or her knowledge or belief, the corrections that are included in the submission will cause the information reported about the previously received hazardous wastes to be true, accurate, and complete.

(i) The certification statement must be executed with a valid electronic signature; and

(ii) A batch upload of data corrections may be submitted under one certification statement.

(4) Upon receipt by the system of any correction submission, other interested persons shown on the manifest will be provided electronic notice of the submitter's corrections.

(5) Other interested persons shown on the manifest may respond to the submitter's corrections with comments to the submitter, or by submitting another correction to the system, certified by the respondent as as specified in paragraph (l)(3) of this section, and with notice of the corrections to other interested persons shown on the manifest.

■ 17. Section 265.1087 is amended by revising paragraphs (c)(4)(i) and (d)(4)(i) to read as follows:

§ 265.1087 Standards: Containers.

(c) * * *

(4) * * *

(i) In the case when a hazardous waste already is in the container at the time the owner or operator first accepts possession of the container at the facility and the container is not emptied within 24 hours after the container is accepted at the facility (*i.e.,* does not meet the conditions for an empty container as specified in 40 CFR 261.7(b)), the owner or operator shall visually inspect the container and its cover and closure devices to check for visible cracks, holes, gaps, or other open spaces into the interior of the container when the cover and closure devices are secured in the closed position. The container visual inspection shall be conducted on or before the date that the container is accepted at the facility (*i.e.,* the date the container becomes subject to the subpart CC container standards). For purposes of this requirement, the date of acceptance is the date of signature that the facility owner or operator enters on Item 20 of the Uniform Hazardous Waste Manifest (EPA Forms 8700–22 and 8700–22A), as required under subpart E of this part, at 40 CFR 265.71. If a defect is detected, the owner or operator shall repair the defect in accordance with the requirements of paragraph (c)(4)(iii) of this section.

* * * * *

(d) * * *

(4) * * *

(i) In the case when a hazardous waste already is in the container at the time the owner or operator first accepts possession of the container at the facility and the container is not emptied within 24 hours after the container is accepted at the facility (*i.e.,* does not meet the conditions for an empty container as specified in 40 CFR 261.7(b)), the owner or operator shall visually inspect the container and its cover and closure devices to check for visible cracks, holes, gaps, or other open spaces into the interior of the container when the cover and closure devices are secured in the closed position. The container visual inspection shall be conducted on or before the date that the

container is accepted at the facility (*i.e.,* the date the container becomes subject to the subpart CC container standards). For purposes of this requirement, the date of acceptance is the date of signature that the facility owner or operator enters on Item 20 of the Uniform Hazardous Waste Manifest (EPA Forms 8700–22 and 8700–22A), as required under subpart E of this part, at § 265.71. If a defect is detected, the owner or operator shall repair the defect in accordance with the requirements of paragraph (d)(4)(iii) of this section.

* * * * *

■ 18. Subpart FF, consisting of §§ 265.1310 through 265.1316, is added to part 265 to read as follows:

Subpart FF—Fees for the Electronic Hazardous Waste Manifest Program

Sec.

Subpart FF—Fees for the Electronic Hazardous Waste Manifest Program

§ 265.1300 Applicability.

(a) This subpart prescribes:

(1) The methodology by which EPA will determine the user fees which owners or operators of facilities must pay for activities and manifest related services provided by EPA through the development and operation of the electronic hazardous waste manifest system (e-Manifest system); and

(2) The process by which EPA will revise e-Manifest system fees and provide notice of the fee schedule revisions to owners or operators of facilities.

(b) The fees determined under this subpart apply to owners or operators of facilities whose activities receiving, rejecting, or managing federally- or state-regulated wastes or other materials bring them within the definition of ''user of the electronic manifest system'' under § 260.10 of this chapter.

§ 265.1310 Definitions applicable to this subpart.

The following definitions apply to this subpart:

Consumer price index means the consumer price index for all U.S. cities using the ''U.S. city average'' area, ''all items'' and ''not seasonally adjusted'' numbers calculated by the Bureau of Labor Statistics in the Department of Labor.

CROMERR costs are the sub-category of operations and maintenance costs that are expended by EPA in implementing electronic signature, user registration, identity proofing, and copy of record solutions that meet EPA's electronic reporting regulations as set forth in the Cross Media Electronic Reporting Rule (CROMERR) as codified at 40 CFR part 3.

Electronic manifest submissions means manifests that are initiated electronically using the electronic format supported by the e-Manifest system, and that are signed electronically and submitted electronically to the e-Manifest system by facility owners or operators to indicate the receipt or rejection of the wastes identified on the electronic manifest. Electronic manifest submissions include the hybrid or mixed paper/electronic manifests authorized under § 262.24(c)(1) of this chapter.

EPA program costs mean the Agency's intramural and non-information technology extramural costs expended in the design, development and operations of the e-Manifest system, as well as in regulatory development activities supporting e-Manifest, in conducting its capital planning, project management, oversight and outreach activities related to e-Manifest, in conducting economic analyses supporting e-Manifest, and in establishing the System Advisory Board to advise EPA on the system. Depending on the date on which EPA program costs are incurred, these costs may be further classified as either system setup costs or operations and maintenance costs.

Help desk costs mean the costs incurred by EPA or its contractors to operate the e-Manifest Help Desk, which EPA will establish to provide e-Manifest system users with technical assistance and related support activities.

Indirect costs mean costs not captured as marginal costs, system setup costs, or operations and maintenance costs, but that are necessary to capture because of their enabling and supporting nature, and to ensure full cost recovery. Indirect costs include, but are not limited to, such cost items as physical overhead, maintenance, utilities, and rents on land, buildings, or equipment. Indirect costs also include the EPA costs incurred from the participation of EPA offices and upper management personnel outside of the lead program office responsible for implementing the e-Manifest program.

Manifest submission type means the type of manifest submitted to the e-Manifest system for processing, and includes electronic manifest submissions and paper manifest submissions.

Marginal labor costs mean the human labor costs incurred by staff operating the paper manifest processing center in conducting data key entry, QA, scanning, copying, and other manual or clerical functions necessary to process the data from paper manifest submissions into the e-Manifest system's data repository.

Operations and maintenance costs mean all system related costs incurred by EPA or its contractors after the activation of the e-Manifest system. Operations and maintenance costs include the costs of operating the electronic manifest information technology system and data repository, CROMERR costs, help desk costs, EPA program costs incurred after e-Manifest system activation, and the costs of operating the paper manifest processing center, other than the paper processing center's marginal labor costs.

Paper manifest submissions mean submissions to the paper processing center of the e-Manifest system by facility owners or operators, of the data from the designated facility copy of a paper manifest, EPA Form 8700–22, or a paper Continuation Sheet, EPA Form 8700–22A. Such submissions may be made by mailing the paper manifests or continuation sheets, by submitting image files from paper manifests or continuation sheets in accordance with § 265.1311(b), or by submitting both an image file and data file in accordance with the procedures of § 265.1311(c).

System setup costs mean all system related costs, intramural or extramural, incurred by EPA prior to the activation of the e-Manifest system. Components of system setup costs include the procurement costs from procuring the development and testing of the e-Manifest system, and the EPA program costs incurred prior to e-Manifest system activation.

§ 265.1311 Manifest transactions subject to fees.

(a) *Per manifest fee.* Fees shall be assessed on a per manifest basis for the following manifest submission transactions:

(1) The submission of each electronic manifest that is electronically signed and submitted to the e-Manifest system by the owners or operators of receiving facilities, with the fee assessed at the applicable rate for electronic manifest submissions;

(2) The submission of each paper manifest submission to the paper processing center signed by owners or

operators of receiving facilities, with the fee assessed according to whether the manifest is submitted to the system by mail, by the upload of an image file, or by the upload of a data file representation of the paper manifest; and

(3) The submission of copies of return shipment manifests by facilities that are rejecting hazardous wastes and returning hazardous wastes under return manifests to the original generator. This fee is assessed for the processing of the return shipment manifest(s), and is assessed at the applicable rate determined by the method of submission. The submission shall also include a copy of the original signed manifest showing the rejection of the wastes.

(b) *Image file uploads from paper manifests.* Receiving facilities may submit image file uploads of completed, ink-signed manifests in lieu of submitting mailed paper forms to the e-Manifest system. Such image file upload submissions may be made for individual manifests received by a facility or as a batch upload of image files from multiple paper manifests received at the facility.

(1) The image file upload must be made in an image file format approved by EPA and supported by the e-Manifest system; and

(2) At the time of submission of an image file upload, a responsible representative of the receiving facility must make a CROMERR compliant certification that to the representative's knowledge or belief, the submitted image files are accurate and complete representations of the facility's received manifests, and that the facility acknowledges that it is obligated to pay the applicable per manifest fee for each manifest included in the submission.

(c) *Data file uploads from paper manifests.* Receiving facilities may submit data file representations of completed, ink-signed manifests in lieu of submitting mailed paper forms or image files to the e-Manifest system. Such data file submissions from paper manifests may be made for individual manifests received by a facility or as a batch upload of data files from multiple paper manifests received at the facility.

(1) The data file upload must be made in a data file format approved by EPA and supported by the e-Manifest system;

(2) The receiving facility must also submit an image file of each manifest that is included in the individual or batch data file upload; and

(3) At the time of submission of the data file upload, a responsible representative of the receiving facility must make a CROMERR compliant certification that to the representative's knowledge or belief, the data and images submitted are accurate and complete representations of the facility's received manifests, and that the facility acknowledges that it is obligated to pay the applicable per manifest fee for each manifest included in the submission.

§ 265.1312 User fee calculation methodology.

(a) The fee calculation formula or methodology that EPA will use initially to determine per manifest fees is as follows:

$$Fee_i = \left(\frac{System\ Setup\ Cost}{Years \times N_t}\right) + \left(Marginal\ Cost_i + \frac{O\&M\ Cost}{N_t}\right) \times (1 + Indirect\ Cost\ Factor)$$

$$System\ Setup\ Cost = Procurement\ Cost + EPA\ Program\ Cost$$

$$O\&M\ Cost = Electronic\ System\ O\&M\ Cost + Paper\ Center\ O\&M\ Cost + Help\ Desk\ Cost + EPA\ Program\ Cost + CROMERR\ Cost + LifeCycle\ Cost\ to\ Modify\ or\ Upgrade\ eManfiest\ System\ Related\ Services$$

Where Fee_i represents the per manifest fee for each manifest submission type ''i'' and N_t refers to the total number of manifests completed in a year.

(b)(1) If after four years of system operations, electronic manifest usage does not equal or exceed 75% of total manifest usage, EPA may transition to the following formula or methodology to determine per manifest fees:

$$Fee_i = \left(\frac{System\ Setup\ Cost}{Years \times N_t}\right) + \left(Marginal\ Cost_i + \frac{O\&M_i\ Cost}{N_i}\right) \times (1 + Indirect\ Cost\ Factor)$$

$$System\ Setup\ Cost = Procurement\ Cost + EPA\ Program\ Cost$$

$$O\&M_{fully\ electronic} Cost = Electronic\ System\ O\&M\ Cost + Help\ Desk\ Cost + EPA\ Program\ Cost + CROMERR\ Cost + LifeCycle\ Cost\ to\ Modify\ or\ Upgrade\ eManfiest\ System\ Related\ Services$$

$$O\&M_{all\ other} Cost = Electronic\ System\ O\&M\ Cost + Paper\ Center\ O\&M\ Cost + Help\ Desk\ Cost + EPA\ Program\ Cost + CROMERR\ Cost + LifeCycle\ Cost\ to\ Modify\ or\ Upgrade\ eManfiest\ System\ Related\ Services$$

Where N_i refers to the total number of one of the four manifest submission types ''*i*'' completed in a year and *O&M*$_i$ *Cost* refers to the differential O&M Cost for each manifest submission type ''*i.*''

(2) At the completion of four years of system operations, EPA shall publish a notice:

(i) Stating the date upon which the fee formula set forth in paragraph (b)(1) of this section shall become effective; or

(ii) Stating that the fee formula in paragraph (b)(1) of this section shall not go into effect under this section, and that the circumstances of electronic manifest adoption and the appropriate fee response shall be referred to the System Advisory Board for the Board's advice.

§ 265.1313 User fee revisions.

(a) *Revision schedule.* (1) EPA will revise the fee schedules for e-Manifest submissions and related activities at two-year intervals, by utilizing the applicable fee calculation formula prescribed in § 265.1312 and the most recent program cost and manifest usage numbers.

(2) The fee schedules will be published to users through the e-Manifest program website by July 1 of each odd numbered calendar year, and will cover the next two fiscal years beginning on October 1 of that year and ending on September 30 of the next odd numbered year.

(b) *Inflation adjuster.* The second year of each two-year fee schedule shall be adjusted for inflation by using the following adjustment formula:

$$Fee i_{Year\ 2} = Fee i_{Year1} \times (CPI_{Year2-2}/CPI_{Year2-1})$$

Where:

$Fee i_{Year2}$ is the Fee for each type of manifest submission ''*i*'' in Year 2 of the fee cycle;

$Fee i_{Year1}$ is the Fee for each type of manifest submission ''*i*'' in Year 1 of the fee cycle; and

$CPI_{Year2-2}/CPI_{Year2-1}$ is the ratio of the CPI published for the year two years prior to Year 2 to the CPI for the year one year prior to Year 2 of the cycle.

(c) *Revenue recovery adjusters.* The fee schedules published at two-year intervals under this section shall include an adjustment to recapture revenue lost in the previous two-year fee cycle on account of imprecise estimates of manifest usage. This adjustment shall be calculated using the following adjustment formula to calculate a revenue recapture amount which will be added to O&M Costs in the fee calculation formula of § 265.1312:

$$Revenue\ Recapture_i = [(N_{iYear1} + N_{iYear2})_{Actual} - (N_{iYear1} + N_{iYear2})_{Est}] \times Fee_{i(Ave)}$$

Where:

$Revenue\ Recapture_i$ is the amount of fee revenue recaptured for each type of manifest submission ''*i*;''

$(N_{iYear1} + N_{iYear2})_{Actual} - (N_{iYear1} + N_{iYear2})_{Est}$ is the difference between actual manifest numbers submitted to the system for each manifest type during the previous 2-year cycle, and the numbers estimated when we developed the previous cycle's fee schedule; and

$Fee_{i(Ave)}$ is the average fee charged per manifest type over the previous two-year cycle.

§ 265.1314 How to make user fee payments.

(a) All fees required by this subpart shall be paid by the owners or operators of the receiving facility in response to an electronic invoice or bill identifying manifest-related services provided to the user during the previous month and identifying the fees owed for the enumerated services.

(b) All fees required by this subpart shall be paid to EPA by the facility electronically in U.S. dollars, using one of the electronic payment methods supported by the Department of the Treasury's *Pay.gov* online electronic payment service, or any applicable additional online electronic payment service offered by the Department of Treasury.

(c) All fees for which payments are owed in response to an electronic invoice or bill must be paid within 30 days of the date of the invoice or bill.

§ 265.1315 Sanctions for delinquent payments.

(a) *Interest.* In accordance with 31 U.S.C. 3717(a)(1), delinquent e-Manifest user fee accounts shall be charged a minimum annual rate of interest equal to the average investment rate for Treasury tax and loan accounts (Current Value of Funds Rate or CVFR) for the 12-month period ending September 30th of each year, rounded to the nearest whole percent.

(1) E-Manifest user fee accounts are delinquent if the accounts remain unpaid after the due date specified in the invoice or other notice of the fee amount owed.

(2) Due dates for invoiced or electronically billed fee amounts shall be 30 days from the date of the electronic invoice or bill.

(b) *Financial penalty.* In accordance with 31 U.S.C. 3717(e), e-Manifest user fee accounts that are more than 90 days past due (*i.e.,* not paid by date 120 days from date of invoice) shall be charged an additional penalty of 6% per year assessed on any part of the debt that is past due for more than 90 days, plus any applicable processing and handling charges.

(c) *Compliance with manifest perfection requirement.* A manifest is fully perfected when:

(1) The manifest has been submitted by the owner or operator of a receiving facility to the e-Manifest system, as either an electronic submission or a paper manifest submission; and

(2) All user fees arising from the submission of the manifest have been fully paid.

§ 265.1316 Informal fee dispute resolution.

(a) Users of e-Manifest services that believe their invoice or charges to be in error must present their claims for fee dispute resolution informally using the process described in this section.

(b) Users asserting a billing dispute claim must first contact the system's billing representatives by phone or email at the phone number or email address provided for this purpose on the e-Manifest program's website or other customer services directory.

(1) The fee dispute claimant must provide the system's billing representatives with information identifying the claimant and the invoice(s) that are affected by the dispute, including:

(i) The claimant's name, and the facility at which the claimant is employed;

(ii) The EPA Identification Number of the affected facility;

(iii) The date, invoice number, or other information to identify the particular invoice(s) that is the subject of the dispute; and

(iv) A phone number or email address where the claimant can be contacted.

(2) The fee dispute claimant must provide the system's billing representatives with sufficient supporting information to identify the nature and amount of the fee dispute, including:

(i) If the alleged error results from the types of manifests submitted being inaccurately described in the invoice, the correct description of the manifest types that should have been billed;

(ii) If the alleged error results from the number of manifests submitted being inaccurately described in the invoice, the correct description of the number of manifests that should have been billed;

(iii) If the alleged error results from a mathematical error made in calculating the amount of the invoice, the correct fee calculations showing the corrected fee amounts; and

(iv) Any other information from the claimant that explains why the invoiced amount is in error and what the fee amount invoiced should be if corrected.

(3) EPA's system billing representatives must respond to billing

dispute claims made under this section within ten days of receipt of a claim. In response to a claim, the system's billing representative will:

(i) State whether the claim is accepted or rejected, and if accepted, the response will indicate the amount of any fee adjustment that will be refunded or credited to the facility; and

(ii) If a claim is rejected, then the response shall provide a brief statement of the reasons for the rejection of the claim and advise the claimant of their right to appeal the claim to the Office Director for the Office of Resource Conservation and Recovery.

(c) Fee dispute claimants that are not satisfied by the response to their claim from the system's billing representatives may appeal their claim and initial decision to the Office Director for the Office of Resource Conservation and Recovery.

(1) Any appeal from the initial decision of the system's billing representatives must be taken within 10 days of the initial decision of the system's billing representatives under paragraph (b) of this section.

(2) The claimant shall provide the Office Director with the claim materials submitted to the system's billing representatives, the response provided by the system's billing representatives to the claim, and a brief written statement by the claimant explaining the nature and amount of the billing error, explaining why the claimant believes the decision by the system's billing representatives is in error, and why the claimant is entitled to the relief requested on its appeal.

(3) The Office Director shall review the record presented to him or her on an appeal under this paragraph (c), and shall determine whether the claimant is entitled to relief from the invoice alleged to be in error, and if so, shall state the amount of the recalculated invoice and the amount of the invoice to be adjusted.

(4) The decision of the Office Director on any appeal brought under this section is final and non-reviewable.

PART 271—REQUIREMENTS FOR AUTHORIZATION OF STATE HAZARDOUS WASTE PROGRAMS

■ 19. The authority section for part 271 is revised to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6926, and 6939g.

■ 20. Section 271.3 is amended by revising paragraph (b)(4) to read as follows:

§ 271.3 Availability of final authorization.

* * * * *

(b) * * *

(4) Any requirement imposed under the authority of the Hazardous Waste Electronic Manifest Establishment Act:

(i) Shall take effect in each State having a finally authorized State program on the same date as such requirement takes effect in other States;

(ii) Shall supersede any less stringent or inconsistent provision of a State program; and

(iii) Shall be carried out by the Administrator in an authorized state except where, pursuant to section 3006(b) of RCRA, the State has received final authorization to carry out the requirement in lieu of the Administrator.

* * * * *

■ 21. Section 271.10 is amended by revising paragraph (h) introductory text to read as follows:

§ 271.10 Requirements for generators of hazardous wastes.

* * * * *

(h) The state must follow the federal manifest format for the paper manifest forms (EPA Forms 8700–22 and 8700–22A) and their instructions and must follow the federal electronic manifest format and instructions as obtained from the Electronic Manifest System described in § 260.10 of this chapter.

* * * * *

■ 22. Section 271.12 is amended by revising paragraph (i) and adding paragraph (k) to read as follows:

§ 271.12 Requirements for hazardous waste management facilities.

* * * * *

(i) Compliance with the manifest system including the requirement that facility owners or operators return a signed copy of the manifest:

(1) To the generator to certify delivery of the hazardous waste shipment or to identify discrepancies;

(2) To the EPA's e-Manifest system, in lieu of submitting a signed facility copy directly to either the origination state or the destination state; and

(3) After listing the relevant consent number from consent documentation supplied by EPA to the facility for each waste listed on the manifest, matched to the relevant list number for the waste from Item 9b, to EPA using the allowable methods listed in 40 CFR 262.84(b)(1) until the facility can submit such a copy to the e-Manifest system per 40 CFR 264.71(a)(2)(v) and 265.71(a)(2)(v).

* * * * *

(k) Requirements for owners or operators of facilities to pay user fees to EPA to recover EPA's costs related to the development and operation of an electronic hazardous waste manifest system, in the amounts specified by the user fee methodology included in subpart FF of 40 CFR parts 264 and 265, for all paper and electronic manifests submitted to the e-Manifest system.

[FR Doc. 2017–27788 Filed 1–2–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 262, 264, 265, 266, 268, 270, and 273

[EPA–HQ–RCRA–2007–0932; FRL–9988–26–OLEM]

RIN 2050–AG39

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. This final rule adds regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under this new set of sector-specific standards in lieu of the existing hazardous waste generator regulations. Among other things, these new regulations prohibit the disposal of hazardous waste pharmaceuticals down the drain and eliminates the dual regulation of RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances. The new rules also maintain the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while ensuring their proper disposal. The new rules codify Environmental Protection Agency (EPA)'s prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics. Additionally, EPA is excluding certain U.S. Food and Drug Administration (FDA) approved over-the-counter (OTC) nicotine replacement therapies (NRTs) from regulation as hazardous waste and is establishing a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics, fulfilling the commitment we made in the Retail Strategy of September 2016.

DATES: This final rule is effective on August 21, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2007–0932. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kristin Fitzgerald, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 308–8286; email address: *Fitzgerald.Kristin@epa.gov*, or Brian Knieser, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (703) 347–8769; email address: *Knieser.Brian@epa.gov.* Also see the EPA's website at *https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste.*

SUPPLEMENTARY INFORMATION:

Table of Contents

The information presented in this preamble is organized as follows:

I. General Information

A. Does this action apply to me?

This final rule applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. The list of North American Industry Classification System (NAICS) codes for the potentially affected entities, other than RCRA transfer, storage, and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in sections VII and IX of this preamble and the Regulatory Impact Analysis (RIA) which is available in the docket for this final rule.[1]

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS

NAICS codes	Description of NAICS code
4242	Drug Wholesalers.
44511	Supermarkets and Other Grocery (except convenience) Stores.
44611	Pharmacies and Drug Stores.
452311	Warehouse Clubs and Supercenters.
54194	Veterinary Services.
6211	Physicians' Offices.
6212	Dentists' Offices.
6213	Other Health Practitioners (e.g., chiropractors).
6214	Outpatient Care Centers.
6219	Other Ambulatory Health Care Services.
622	Hospitals.

[1] EPA–HQ–RCRA–2007–0932.

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS—Continued

NAICS codes	Description of NAICS code
6231	Nursing Care Facilities (e.g., assisted living facilities, nursing homes).
623311	Continuing Care Retirement Communities (e.g., assisted living facilities with on-site nursing facilities).
Various NAICS	Reverse Distributors.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities EPA knows could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether your entity, company, business, organization, etc., is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section of this document.

B. What action is the Agency taking?

On September 25, 2015, EPA proposed new regulations under part 266 subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors.[2] This final rule promulgates part 266 subpart P. However, in response to public comments, we have made a number of changes to the proposed rulemaking. The comments and the changes are discussed in detail below. When this final rule becomes effective in their states, a process that is explained in section XX of this preamble, healthcare facilities and reverse distributors must manage their hazardous waste pharmaceuticals under this new set of regulations in part 266 subpart P in lieu of operating under part 262 as they have been. These operating standards include a prohibition on the sewering of hazardous waste pharmaceuticals. Part 266 subpart P also includes a conditional exemption for hazardous waste pharmaceuticals that are also identified as controlled substances by the Drug Enforcement Administration (DEA). Further, subpart P redefines when containers that held hazardous waste pharmaceuticals are considered ''RCRA empty.'' Healthcare facilities that are very small quantity generators (VSQGs) must comply with the sewer prohibition for their hazardous waste pharmaceuticals under part 266 subpart P and have the option of complying with the entire subpart in lieu of operating under the conditional exemption of § 262.14.

EPA is also taking two actions in addition to promulgating part 266 subpart P. First, this final rule amends the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration (FDA)-approved over-the counter (OTC) nicotine replacement therapies (NRTs) are not included in the listing. Second, the preamble to this final rule also establishes EPA's policy on the regulatory status of unsold retail items, including nonprescription pharmaceuticals, managed at reverse logistics centers, fulfilling the commitment we made in the Retail Strategy of September 2016.

Although the proposed rulemaking sought comment on ideas for how to expand the universe of pharmaceuticals that are hazardous waste, this final rule does not add pharmaceuticals to the hazardous waste listings or expand the hazardous waste characteristics to include additional pharmaceuticals. At the time of proposal, we indicated that any action to expand the universe of hazardous waste pharmaceuticals would be part of a separate, future action.

Note that throughout the preamble and the RIA for this final rule, the terms ''EPA,'' ''Agency'' and ''we'' are used interchangeably.

C. What is the Agency's statutory authority for taking this action?

These regulations are promulgated under the authority of §§ 2002, 3001, 3002, 3004, and 3018 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912, 6921, 6922, 6924, and 6939.

D. What are the incremental costs and benefits of this action?

As discussed in section XXI, the Regulatory Impact Analysis (RIA) for this rule estimates the annualized cost to industry to comply with the requirements is between $6.59 and $7.99 million (at a 7 percent discount rate).[3] The streamlined management standards for healthcare facilities and the regulatory relief in regard to FDA-approved OTC NRT products (*i.e.,* patches, gums and lozenges) is estimated to result in an annualized cost-savings of between $19.58 and $22.95 million (at a 7 percent discount rate). This results in a net annualized cost savings for the rule of $12.99 to $14.96 million at a 7 percent discount rate.

The provisions of the final rule are expected to improve regulatory clarity and reduce regulatory burden. As an example of the increased regulatory clarity and certainty provided in the rule, EPA eliminated the dual regulation of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances by finalizing a conditional exemption. Additionally, to the extent that the rule reduces concentrations of hazardous waste pharmaceuticals in surface and drinking waters, this rule may result in improved ecosystems and human health outcomes. Ideally, the Agency would prefer to quantify and monetize the rule's human health benefits. However, only some categories of cost savings are quantifiable; sufficient data are not available to support a detailed quantitative analysis for many benefit categories. In these cases, the benefits are described qualitatively.

II. List of Acronyms

3PL Third Party Logistics Provider
AARP American Association of Retired Persons
AEA Atomic Energy Act
API Active Pharmaceutical Ingredient
ASHP American Society of Hospital Pharmacists
BDAT Best Demonstrated Available Technology
BR Biennial Report
CAA Central Accumulation Area
CCP Commercial Chemical Product
CERCLA Comprehensive Environmental Response, Compensation and Liability Act
CFR Code of Federal Regulations
CISWI Commercial, Industrial Solid Waste Incinerator
CMS Centers for Medicare and Medicaid Services
CPSC Consumer Product Safety Commission
CWA Clean Water Act
DEA Drug Enforcement Administration
DOE Department of Energy
DOT Department of Transportation
DSCSA Drug Supply Chain Security Act
DQSA Drug Quality and Security Act
EPA Environmental Protection Agency
E.O. Executive Order
FDA Food and Drug Administration

[2] September 25, 2015; 80 FR 58014.

[3] See the Regulatory Impact Analysis for the final rule in the rulemaking docket EPA–HQ–RCRA–2007–0932.

FD&C Act Federal Food, Drug, and Cosmetic Act
FR Federal Register
HIPAA Health Insurance Portability and Accountability Act
HMIWI Hospital, Medical, Infectious Waste Incinerator
HSWA Hazardous and Solid Waste Amendments
LQG Large Quantity Generator
LTCF Long-term Care Facility
LTCP Long-term Care Pharmacy
MSWLF Municipal Solid Waste Landfill
MWC Municipal Waste Combustor
NAICS North American Industry Classification System
NIOSH National Institute for Occupational Safety and Health
NODA Notice of Data Availability
NPRM Notice of Proposed Rulemaking
NRC Nuclear Regulatory Commission
NRT Nicotine Replacement Therapy
OIG Office of Inspector General
OLEM Office of Land and Emergency Management
OMB Office of Management and Budget
ONDCP Office of National Drug Control Policy
OSHA Occupational Safety and Health Administration
OSWER Office of Solid Waste and Emergency Response
OSWI Other Solid Waste Incinerators
OTC Over-the-counter
POTW Publicly Owned Treatment Works
RCRA Resource Conservation and Recovery Act
SAA Satellite Accumulation Area
SQG Small Quantity Generator
SWDA Solid Waste Disposal Act
TC Toxicity Characteristic
TCLP Toxicity Characteristic Leaching Procedure
TSDF Treatment, Storage and Disposal Facility
VSQG Very Small Quantity Generator

III. Rationale for the Final Rule

The impetus behind this final rule is to address the various concerns raised by stakeholders regarding the difficulty in implementing the RCRA Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities. EPA has met with various stakeholders to learn about compliance challenges and has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in a notice of data availability (NODA) and request for comment, ''Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the Resource Conservation and Recovery Act Program'' (''Retail NODA''), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores.[4] Further, EPA's Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on the Retail NODA and the OIG report, see section VI of this preamble).[5] The Retail NODA and the OIG Report, along with input from healthcare facilities and retailers, identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program to the generation and management of hazardous waste pharmaceuticals.

First, under the current hazardous waste regulatory scheme, healthcare personnel, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (*e.g.,* a patient's bedside). Yet, healthcare personnel, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations. In general, healthcare personnel are not prepared to assume hazardous waste management responsibilities, nor is it EPA's expectation that they assume primary hazardous waste management responsibilities. EPA recognizes this challenge and provides a framework through this final rule that allows healthcare personnel to focus on healthcare while still ensuring that hazardous waste is directed to proper management.

Second, in the healthcare setting, a wide variety of hazardous waste pharmaceuticals are generated in relatively small quantities by a number of different employees across the facility. This situation differs from a typical manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes. Data from the Biennial Report (BR) show that in 2013, approximately 46 percent of large quantity generators (LQGs) generated between one and five waste streams.[6] Further, a typical manufacturing facility generates a more predictable set of hazardous waste streams. In contrast, a healthcare facility can have thousands of items in its inventory at any one time and these may vary over time, based on the needs of the patients. In addition, pharmaceutical wastes come in many different forms, such as tablets (pills), transdermal patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare personnel to make appropriate hazardous waste determinations when pharmaceuticals are disposed.

Third, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated with more stringent requirements at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month, it is regulated more rigorously as an LQG. Aside from the pharmaceuticals themselves, residues within pharmaceutical containers that contained P-listed commercial chemical products (CCPs) must be managed as acute hazardous waste even if the pharmaceutical was fully administered, unless the container is RCRA-empty (*e.g.,* by triple-rinsing the container).[7] Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often manage these containers as hazardous waste, which can result in being subject to the most stringently regulated generator category (*i.e.,* LQG).[8]

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is finalizing a new set of sector-specific regulations to improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities.

In addition to improving compliance and responding to stakeholder concerns, the Agency has three additional goals for this final rule. The first is to reduce

[4] See 79 FR 8926; February 14, 2014 for the Retail NODA. Also see the associated docket EPA–HQ–RCRA–2012–0426 for public comments.

[5] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12–P–0508, dated May 25, 2012). For a copy of the report, please see: *https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf* or see the docket for this final rule: EPA–HQ–RCRA–2007–0932–0177.

[6] 81 FR 85735; November 28, 2016, Hazardous Waste Generator Improvements Final Rule.

[7] P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered ''RCRA empty'' either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).

[8] On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors (RCRA Online #14827). As discussed in section XV of this preamble, this final rule supersedes this memo.

the amount of pharmaceuticals that are disposed of down the drain. Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal (*e.g.,* flushing) as a routine disposal method for pharmaceutical wastes, including those that are hazardous waste. Until this final rule, drain disposal has been an allowable disposal method for hazardous waste pharmaceuticals under RCRA (however, since 1990, the Clean Water Act regulations have prohibited the drain disposal of ignitable wastes and those wastes that result in toxic gases, vapors of fumes within the publicly owned treatment works.)[9] Although pharmaceuticals are thought to be primarily entering the environment through excretion, reducing intentional sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters.[10] See section XIII for more information about how this final rule reduces sewer disposal and pharmaceuticals in water.

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the DEA regulations for controlled substances. Some stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and therefore are expensive to manage and dispose of in accordance with both sets of regulations. In addition, stakeholders have indicated that the RCRA hazardous waste pharmaceuticals that are also DEA controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA eliminates this regulatory overlap in this final rule, as it has been an unnecessary burden for healthcare facilities. Additionally, we expect that eliminating the overlap will help reduce intentional sewer disposal of pharmaceuticals.

The third goal is to clarify the regulatory status of a major practice used by healthcare facilities, including retailers in particular, for the management of unused and/or expired pharmaceuticals, known as reverse distribution (see section VI for a detailed discussion of reverse distribution). A number of states have taken enforcement actions against retailers that have raised awareness about the reverse distribution of pharmaceuticals. In particular, California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012), Rite-Aid (2013), and Safeway (2015). In at least two settlement agreements, California directed the defendants (CVS and Costco) to ''initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of non-dispensable pharmaceuticals, including OTC medications, through 'reverse distribution.' ''[11] Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

Additionally, the California legislature directed the DTSC to convene a Retail Waste Working Group with the aim of developing recommendations to the legislature for how to address many retail waste issues, including reverse distribution/logistics.[12] The Retail Waste Working Group, which consisted of large retailers, small retailers, district attorneys, certified unified program agencies, non-government organizations, local governments, other relevant state agencies as determined by DTSC (such as the California Department of Public Health, and the California Department of Resources Recycling and Recovery), manufacturers, reverse distributors, and other interested stakeholders, produced their final report in August 2017.[13] Although the group was convened by and reported to the California legislature, its membership was drawn from across the country. EPA participated in an observer role, but neither contributed to developing recommendations nor to writing the group's report. The group's work has highlighted the need for a national policy in this area.

IV. Background

A. Summary of the Proposal

On September 25, 2015, EPA proposed to add subpart P under 40 CFR part 266 (see 80 FR 58014). Part 266 is entitled ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.'' In this new subpart P, we proposed a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. We proposed that healthcare facilities that are small quantity generators (SQGs) or LQGs and all reverse distributors, regardless of their RCRA generator category, would be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of the generator regulations in 40 CFR part 262. The standards were not proposed as a voluntary or optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they were proposed as mandatory standards.

We discuss the proposed provisions in greater detail in subsequent sections of the preamble, but offer a brief summary of the proposal here. For healthcare facilities, we proposed different management standards for non-creditable and potentially creditable hazardous waste pharmaceuticals. We proposed that non-creditable hazardous waste pharmaceuticals (*i.e.,* those that are not expected to be eligible to receive manufacturer credit) would be managed on site at the healthcare facility similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste.[14] We proposed that when shipped off site, the non-creditable hazardous waste pharmaceuticals must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA-designated facility, such as an interim status or permitted TSDF. Additionally, we proposed to revise our policy regarding pharmaceuticals going through reverse distribution (*i.e.,* those which are ''potentially creditable'') such that they would be considered hazardous wastes at the healthcare facility. However, given the value associated with these potentially

[9] See the Clean Water Act regulations of 40 CFR 403.5(b)(1) and (7).

[10] C.G. Daughton, I.S. Ruhoy, Environmental footprint of pharmaceuticals: The significance of factors beyond direct excretion to sewers, Environ. Toxicol. Chem., 28 (2009), pp. 2495–2521, 10.1897/08–382.1.

[11] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0169.

[12] California SB–423. *http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB423.*

[13] *https://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[14] 73 FR 73520; December 2, 2008.

creditable hazardous waste pharmaceuticals, EPA proposed flexibilities for some of the regulatory requirements. For instance, we proposed that healthcare facilities would continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to reverse distributors for them to be evaluated for manufacturer credit. After considering comments received on the prior Universal Waste proposal regarding the lack of tracking of shipments, EPA's 2015 proposed standards included provisions to ensure the safe, secure and documented delivery of the potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Under the proposal, reverse distributors would no longer be regulated under 40 CFR part 262 as hazardous waste generators, nor would they be regulated under 40 CFR parts 264, 265, and 270 as TSDFs. Rather, the proposal established a new category of hazardous waste entity, called pharmaceutical reverse distributors. EPA also proposed that reverse distributors would have different standards for those hazardous waste pharmaceuticals destined for another reverse distributor (and still considered potentially creditable hazardous waste pharmaceuticals) versus those that are destined for a TSDF (considered to be evaluated hazardous waste pharmaceuticals.) [15] The proposed standards for pharmaceutical reverse distributors were, in many respects, similar to the LQG standards, but with additional standards to respond to concerns expressed by commenters to the proposal to add pharmaceuticals to the Universal Waste program.

EPA proposed several additional standards that apply to both healthcare facilities and reverse distributors. First, EPA proposed to prohibit healthcare facilities and reverse distributors from disposing of hazardous waste pharmaceuticals down a toilet or drain (*i.e.,* flushed or sewered). Second, EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted toward calculating the site's generator category. Third, EPA proposed a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Fourth, EPA proposed management standards for determining when a container with hazardous waste pharmaceutical residues is considered RCRA empty.

B. Retail Sector Notice of Data Availability (NODA)

In 2014, EPA published a NODA for the Retail Sector, in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores face in complying with RCRA regulations.[16] Many retail commenters to the NODA mentioned that because nicotine is an acute hazardous waste (P075), retailers are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (*e.g.,* e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide some regulatory relief with regard to nicotine-containing products. See section V of this preamble for a discussion of EPA's amendment of the acute hazardous waste listing for nicotine and salts (P075).

C. Retail Strategy

On September 12, 2016, as a follow-up to the comments we received on the Retail NODA, EPA released its Retail Strategy. In the strategy, EPA committed to two sets of activities. First, we committed to completing rulemakings that were already underway, that, although were not specifically developed with retail in mind, contained provisions that might be helpful in resolving some issues that retailers faced in complying with RCRA regulations. This included completing the 2016 Hazardous Waste Generator Improvements final rule and the Hazardous Waste Pharmaceuticals final rule. Second, we committed to three new activities that specifically address concerns identified by commenters. First, EPA committed to developing guidance on aerosol cans. Second, EPA committed to exploring the potential for adding certain retail items, such as aerosol cans, pesticides, and/or electronics, to the federal universal waste regulations. A proposed rulemaking for adding aerosol cans to the federal universal waste regulations was published in **Federal Register** on March 16, 2018.[17] Third, EPA committed to developing a policy that addresses the reverse distribution process for the retail sector as a whole. This policy is articulated in detail in section VI of the preamble of this final rule.

D. EPA Inspector General Report

On May 25, 2012, the EPA's Office of Inspector General (OIG) issued the report, ''EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal.'' [18] The OIG reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER): [19]

(1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing hazardous waste pharmaceuticals.

As detailed in OSWER's response to OIG, this final rule fulfills our obligation for addressing the third recommendation.[20] In the preamble to the proposed rulemaking we solicited comment as part of our ongoing efforts to identify additional pharmaceuticals as hazardous wastes. EPA does not address the OIG's first two recommendations as part of this final rulemaking directly. That said, the Agency believes that provisions in the final rule, such as the streamlined standards for healthcare facilities and the elimination of LQG status for the management of hazardous waste pharmaceuticals, address the first two recommendations indirectly by encouraging healthcare facilities to manage their non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals.

[15] The final rule defines an ''evaluated hazardous waste pharmaceutical'' as a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributed in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

[16] February 14, 2014; 79 FR 8926.

[17] See 83 FR 11654; March 16, 2018.

[18] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12–P–0508, dated May 25, 2012). For a copy of the report, please see: *https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf* or see the docket for this final rule: EPA–HQ–RCRA–2007–0932–0177.

[19] OSWER has since been renamed the Office of Land and Emergency Management (OLEM).

[20] For a copy of OSWER's full response to OIG, please see: *http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf.*

V. Amendment to the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, EPA promulgated the P- and U-lists of CCPs or manufacturing chemical intermediates that are hazardous wastes if they are discarded or intended to be discarded (40 CFR 261.33(e) and (f)). Several hundred CCPs were listed on the P- and U-lists, including *nicotine and salts*.[21] The phrase ''commercial chemical product or manufacturing chemical intermediate'' refers to a ''chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient'' (see the *comment* following 40 CFR 261.33(d)).

The P-listed chemicals are identified as acute hazardous wastes and U-listed chemicals are identified as non-acute hazardous wastes when discarded in unused form. EPA listed nicotine and salts (referred to commonly as just nicotine) as acute hazardous waste P075 in 261.33(e). A chemical substance is listed in 40 CFR 261.33(e) as an acute hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which, as described below, are based on human toxicity data, or dose of a chemical given orally or dermally that is lethal to 50 percent of the test animals (LD50), or the concentration of a chemical in the air that is lethal to 50 percent of the test animals (LC50). That is, when the solid waste ''has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness.''

EPA listed nicotine as an acute hazardous waste based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg. The acute toxicity criterion for humans, as discussed above, is ''fatal to humans in low doses'' (see § 261.11(a)(2)).

EPA's Background Document from April 1981 prepared in support of the commercial chemical product hazardous waste listings in § 261.33 provides a basis for what is meant by ''fatal to humans in low doses'' for chemicals that have been given through the oral route: ''fatal to humans upon ingestion of ≤100 mg/kg''.[22] This Background Document cites an estimated oral LD50 toxicity to humans for nicotine and salts as 1 mg/kg, which corresponds to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg, and this estimated LD50 value falls within the criterion for ''fatal to humans in low doses.'' However, the Background Document does not provide any information regarding the nicotine product or concentration of nicotine that was used to establish this estimated oral LD50 toxicity in humans for nicotine. According to comments submitted to EPA on the proposal by the retailers, tobacco companies, and trade associations, the only nicotine products being marketed at the time when EPA listed nicotine were pesticides containing up to 40 percent nicotine sulfate. These commenters note that the low-concentration nicotine-containing products (specifically smoking cessation or NRT products) had not yet been developed and, therefore, were not considered when EPA listed nicotine as an acute hazardous waste.

Once the Agency lists chemicals on either the P- or U-lists, these chemicals are P- or U-listed hazardous wastes when discarded or intended to be discarded regardless of chemical concentrations, with two exceptions: Warfarin and salts (which are listed as waste number P001 when present at concentrations greater than 0.3% and U248 when present at concentrations of 0.3% or less) and zinc phosphide (which is listed as Waste Code P122 when present at concentrations greater than 10% and Waste Code U249 when present at concentrations of 10% or less). Therefore, the P075 hazardous waste listing is applicable to the commercial chemical product nicotine or a commercial chemical product containing nicotine as the sole active ingredient when disposed regardless of the concentration of nicotine. The Agency has previously stated that unused dermal patches containing nicotine, nicotine gum, and nicotine lozenges are listed hazardous waste P075 when discarded.[23] The Agency stated this because nicotine is a listed hazardous waste P075 when discarded, and nicotine is the sole active ingredient in patches containing nicotine, nicotine gum, and nicotine lozenges. However, once the nicotine patches, gums, and lozenges have been used for their intended purpose, regardless of the length of use, they are no longer commercial chemical products and would not be listed hazardous waste P075 when discarded.

B. Summary of Proposal

In the preamble to the proposed rulemaking, EPA provided a rationale for why it is considering the possibility of amending the P075 acute hazardous waste listing for nicotine and salts. Primarily, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the P075 hazardous waste listing under RCRA. This is because the retailers did not believe their low-concentration nicotine products meet RCRA's requirements for acute hazardous waste, when discarded. Thus, according to the retailers, the acute hazardous waste classification for their discarded low-concentration nicotine products is inappropriately making them subject to RCRA's LQG requirements. (for more information, see 80 FR 58071; September 25, 2015). Consequently, EPA, in the preamble to the proposed rulemaking, presented and sought comment on two possible approaches for amending the acute hazardous waste listing for nicotine and salts and stated that, depending on the information received during the comment period, EPA could finalize one of them. Under the first approach, EPA would exempt FDA-approved OTC nicotine-containing smoking cessation products (nicotine patches, gums, and lozenges) from the P075 hazardous waste listing if toxicity information received or collected for these products supported a finding that these products, when disposed, do not warrant regulation as acute hazardous wastes under RCRA Subtitle C. We note that this preamble will collectively refer to nicotine patches, gums, and lozenges as FDA-approved OTC NRTs. EPA also stated in the preamble to the proposed rulemaking that e-cigarettes would not be exempted under this approach, because they have not been approved by FDA and the concentration of nicotine in e-cigarettes is not limited by regulation (for more information, see discussion under Comments and Responses included later in this section). Under the second approach, EPA would establish a concentration-based exemption from the P075 listing for low-concentration nicotine-

[21] See 45 FR 33124, May 19, 1980.

[22] See pp. 21–22 and 33 in Background Document dated April 1981 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0171.

[23] See letter from Robert Dellinger, USEPA to Charlotte Smith, WM Healthcare Solutions, Inc., dated August 23, 2010, RCRA Online #14817.

containing products (including e-cigarettes); in other words, a maximum concentration of nicotine in these products below which the P075 listing would not apply. This approach would require submission to EPA of supporting human toxicological data or animal LD50 data for these products at the maximum concentration of nicotine found in these products.

C. Summary of Comments

The comments received were mainly from retailers, tobacco companies, individual states, trade and government associations. The retailers, tobacco companies, and trade associations supported an exemption from the P075 hazardous waste listing for FDA-approved OTC NRTs. In addition, these commenters also generally favored an exemption from the P075 listing for all other nicotine-containing products which they considered to have low nicotine concentrations, including e-cigarettes and e-liquids. Alternatively, if the EPA decided not to exempt all low-concentration nicotine-containing products from the P075 listing, the commenters indicated they would support the reclassification of such products as non-acute (*i.e.,* U-listed) hazardous wastes or otherwise require these products to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P. These commenters stated that classification of low-concentration nicotine-containing products as acute hazardous waste is unjustified. The commenters also expressed a concern that, because of this inappropriate classification, anyone generating more than 1 kg per month of this acute hazardous waste becomes subject to RCRA's LQG regulations, which result in increased economic burdens and reporting requirements. The commenters asserted that the original P075 listing was likely based on a concentration of nicotine that is orders of magnitude greater than today's low-concentration NRTs, and the human toxicity data that EPA relied upon to support the original P075 listing have been recently reassessed and could not be substantiated. They stated further that a U.S. Surgeon General's Report issued in 2014 could not find support for the 1 mg/kg median lethal dose for humans used to support the original listing.

Additionally, the retailers, tobacco companies, and the trade associations commented that EPA listed nicotine and salts as P075 acutely toxic hazardous wastes long before NRT products were in use and thus EPA did not consider if they presented a risk that should be covered by the P075 listing. According to these commenters, because the OTC NRTs (nicotine patches, gums, and lozenges) contain very low concentrations of nicotine, they clearly do not meet EPA's listing criteria for acute toxicity and in addition have been approved by FDA to be sold to the public over-the-counter (meaning these products can be purchased without a prescription). In summary, these commenters urged EPA to amend the P075 listing to exempt the low-concentration nicotine-containing products based on either (1) type of product and/or (2) a specified concentration of nicotine in these products below which the product would be exempt, because there are no credible toxicity data that would support keeping low-concentration nicotine-containing products listed as acute hazardous wastes.

All of the states and one government association (Northeast Waste Management Officials' Association or NEWMOA) that submitted comments on the proposal generally supported exempting FDA-approved OTC NRTs from the P075 listing, if EPA obtained the necessary toxicity data to show that these products are not acutely toxic. These same commenters, except for one (Oklahoma), did not support exempting e-cigarettes or nicotine-containing e-liquids from the P075 listing. Almost all of the states and NEWMOA wanted continued regulation of e-cigarettes and nicotine-containing e-liquids because the safety of these products is less widely accepted.

In summary, the Agency did not receive any comments that disagreed with the proposed approach to exempt FDA-approved OTC NRTs from the P075 listing, provided this approach is supported by sufficient toxicity information to conclude that concentrations of nicotine contained in these products are not acutely toxic.

D. Final Rule Provisions

The Agency is finalizing the first approach for amending the P075 listing discussed in preamble of the proposal. That is, EPA is amending the hazardous waste listing for hazardous waste number (commonly called ''hazardous waste code'') P075 in § 261.33(e) to exempt FDA-approved OTC NRTs. Specifically, the P075 listing for nicotine is being amended with a parenthetical phrase stating that the listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.

The Agency has concluded that FDA-approved OTC NRTs do not meet the acute listing criteria under 40 CFR 261.11(a)(2), based on review of available toxicity information for nicotine and nicotine-containing FDA-approved OTC NRTs (see discussion under Comments and Responses below).

E. Comments and Responses

1. Nicotine Toxicity Data

Some commenters stated that human toxicity data that EPA originally relied upon to list nicotine as P075 acutely toxic hazardous wastes are not credible and do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. In addition, they also stated that available animal toxicity data do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. The commenters provided references to several recent reports and an article (see discussion of these references in the following paragraphs) to support their assertions. The commenters stated that these recent reports and article provide evidence that nicotine is not as toxic as originally thought.

Commenters argued that the validity of an estimated oral LD50 toxicity to humans of 1 mg/kg (corresponding to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg) for nicotine used by EPA to support the acute hazardous waste listing for nicotine has been questioned by government entities and researchers, most recently by the U.S. Surgeon General's Report, ''The Health Consequences of Smoking—50 Years of Progress'' (2014) [24] and in an article published in *Archives of Toxicology,* ''How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century'' (Mayer, 2014).[25] The U.S. Surgeon General's Report cited by commenters states that the toxicity of nicotine is dependent on dose, dose duration and frequency, route of exposure, formulation of the nicotine product, and interpersonal variability. This report also states that numerous poisonings have been documented in the literature since the use of nicotine as a pesticide became widespread in the early part of twentieth century; however, there has not been a systematic assessment of the literature to characterize the dose-response relationship. Furthermore, based on an extensive literature search, the report states that no study was located as a source for the 50–60 mg estimated dose that is commonly

[24] *https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.*

[25] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/.*

reported to be fatal to humans. Finally, according to the report, the literature has also shown that in one case a relatively large dose of 240 mg nicotine administered to a patient accidently did not prove to be fatal.

The Mayer article cited by commenters also points out that fatal nicotine intoxications are relatively rare and that there are countless records of subjects who have survived consumption of nicotine in amounts far higher than 60 mg. One example referenced by Mayer in his article was a person surviving following a suicide attempt with 4 grams (4000 milligrams) of pure nicotine. Mayer asserts that this example and many other literature reports on nonfatal nicotine poisonings show that the oral LD50 toxicity of nicotine to humans of 1 mg/kg does not appear to be reliable. Although Mayer did not conduct any lab testing on nicotine, he uses previously reported nonfatal poisonings to develop an estimate of the oral LD50 toxicity of nicotine to humans in the range of 6.5–13 mg/kg (based on an adult weight of 50–60 kg, this would correspond to an estimated range of 325–780 mg of nicotine as the lethal dose for adults). Mayer concludes that nicotine is less toxic than originally thought. That said, his new estimate of the oral LD50 toxicity of nicotine to humans still falls well within the range of ≤ 100 mg/kg, which was one of the reasons for listing nicotine and salts as P075 acute hazardous waste.

EPA regulations in § 261.11(a)(2) state that, in the absence of adequate human toxicity data, the criteria for identifying acute toxicity should be based on the toxicity of the materials to laboratory animals. Commenters directed us to a recently-issued report summarizing available toxicity information on nicotine by the Committee for Risk Assessment of the European Chemicals Agency (ECHA).[26] The acute toxicity of nicotine to laboratory animals presented in the report issued by the Committee for Risk Assessment in comparison to the regulatory criteria for these animals presented in 40 CFR 261.11(a)(2) are as follows: The acute oral LD50 for rat is in the range of 52.5–70 mg/kg (ECHA) compared to the acute oral LD50 regulatory criterion for rat of < 50 mg/kg (§ 261.11(a)(2)). The acute oral LD50 values for rats reported by ECHA fall just outside the acute toxicity criterion in EPA's regulations. The acute dermal LD50 for rabbit is 70.4 mg/kg (ECHA) compared to acute dermal LD50 regulatory criterion for rabbit of < 200 mg/kg (§ 261.11(a)(2)). The acute dermal LD50 for rabbit falls well below the acute toxicity criterion in our regulations. There were no comparable data available for the acute inhalation LC50 for rat.

Based on the toxicity information discussed above, and the listing criteria in 40 CFR 262.11(a)(2), the evidence is clear that nicotine is still acutely toxic to both humans and animals under the RCRA hazardous waste regulations and must continue to be listed as acute hazardous waste number P075 under § 261.33(e). As already noted, under the hazardous waste regulations the Agency generally lists commercial chemical products, if they are discarded or intended to be discarded, regardless of chemical concentrations. However, EPA is not precluded from amending (through rulemaking) an existing listing, for example, if a particular subset of wastes within that listing can be identified as not posing the risk for which the original listing was established.

2. Food and Drug Administration-Approved Nicotine Replacement Therapies

A number of commenters urged EPA to exempt low-concentration nicotine-containing products (specifically OTC NRTs) from the P075 listing. The commenters stated that millions of people use OTC NRTs daily without showing any signs of acute toxicity, and these products have been approved by FDA to be sold over the counter without a prescription. Therefore, they believe this is the best evidence that these products are not acutely toxic and safe for people to use.

As noted above, the Agency stated in the proposal that if it obtained toxicity data to support the conclusion that FDA-approved OTC NRTs do not meet the criteria for listing as an acutely hazardous waste, then it will exempt these products from the P075 listing. The FDA-approved OTC NRTs are designed to help people quit smoking by delivering controlled amounts of nicotine to ease symptoms of withdrawal and craving. The Consumer Health Products Association stated in its comments that nicotine gums and lozenges contain 2–4 mg nicotine (approximately 0.2–2 percent by weight depending on lozenge size) and nicotine patches contain 7 mg, 14 mg, or 21 mg of nicotine (approximately 2–7 percent by weight). Comments from Reynolds American Inc. Services Company (RAI Services or RAI) provided similar information on the amount of nicotine in these FDA-approved OTC NRTs.[27] According to information on FDA's website, FDA regulations ensure that OTC drug products are safe and effective for people to use.[28] In most cases, OTC drug products are regulated by FDA through OTC drug monographs. OTC drug monographs state the active ingredients and other conditions of use (including dose, dosage form, and route of administration) that are generally recognized as safe and effective to treat certain diseases or conditions without a prescription. OTC drug products that conform to a final monograph and other relevant requirements are not required to be reviewed by FDA before marketing. Products that do not conform to a final monograph must be reviewed under the new drug application process. The new drug application process is how manufacturers provide evidence to FDA to demonstrate that the new drug product is safe and effective for use as recommended in the product's labeling. Sometimes, an OTC drug product begins as an approved prescription drug and then a drug company will submit an application to FDA to switch the drug product from prescription status to OTC status. FDA reviews the information in the application, along with information about adverse events associated with the use of the drug, and determines whether the prescription drug can be used safely and effectively as an OTC drug. FDA allowed nicotine patches and gums, which were initially available by prescription only, to be switched to OTC status between 1996 and 2002. The nicotine lozenge and mini-lozenge were approved by FDA directly for OTC use in 2002 and 2009 via new drug applications.[29] [30]

FDA has determined that OTC NRTs can be used safely and effectively by people without a healthcare professional's supervision when used in accordance with their label instructions. Since FDA first approved NRTs for OTC use, FDA has reviewed a number of studies that examined use of OTC NRTs, including use of OTC NRTs in combination with other nicotine-containing products, use of OTC NRTs at higher than standard-dose, and use of OTC NRTs over periods longer than recommended, and it has not identified

[26] See ECHA's Committee for Risk Assessment Opinion Proposing Harmonized Classification and Labeling at EU Level of Nicotine, adopted 10 September 2015 (*https://echa.europa.eu/documents/10162/23665416/clh_opinion_nicotine_5579_en.pdf/0103fadb-e945-4839-c4f4-17d20854adf0).*

[27] See P.9 of RAI's comments dated December 23, 2015 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0329.

[28] *https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm342560.htm.*

[29] See 78 FR 19718; April 2, 2013.

[30] See FDA materials for New Drug Application Numbers 21–330 and 22–360 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

any significant safety concerns.[31] It is useful to recognize one characteristic of FDA-approved OTC NRTs when considering the toxicity of nicotine contained in these products, which is that they are designed for controlled release of nicotine to approximate the nicotine amounts obtained from smoking. This characteristic of FDA-approved OTC NRTs means that nicotine enters the body over a period of time and there is a gradual increase in the level of nicotine in the blood when used in accordance with the accompanying label. According to EPA's review of FDA information and RAI's comments, FDA's Center for Drug Evaluation and Research reviewed pharmacology and toxicology data for nicotine polacrilex lozenges and made a number of observations concerning nicotine's toxicology. FDA stated that ''oral doses of nicotine that have been reported to be lethal in animals are approximately 8- to 150-fold greater than nicotine exposures that would result from use of Nicotine Polacrilex Lozenges.'' In addition, the FDA noted that ''the toxicological profile of nicotine in animals has been largely superseded by the extensive human experience with this agent. Based on the established clinical experience with similar nicotine replacement therapy products, acute toxic reactions would not be anticipated from use of Nicotine Polacrilex Lozenges at the recommended dosage.'' [32]

In summary, the most common dosage of nicotine from OTC nicotine gums and lozenges (2–4 mg) and OTC nicotine patches (7–21 mg) is absorbed slowly and results in significantly lower concentrations of nicotine in blood levels compared to the amount of nicotine that has been determined or estimated to be lethal to animals and humans. The OTC nicotine patch, the strongest of which contains 114 mg of nicotine, delivers 21 mg of nicotine at a relatively steady rate over a 24-hour period when the patch is applied to the skin. The most frequently reported side effects from use of patches are local skin reactions, which can be reduced by moving the site of the patch application daily as instructed.[33] In addition, FDA has reviewed and approved these products as being safe and effective for people to use without a prescription. Furthermore, the FDA-approved OTC NRTs have been in the market for over two decades and although some serious adverse events have been reported, based on the available information, EPA has concluded that the serious adverse events do not meet EPA's criteria for acute toxicity under 40 CFR 261.11(a)(2) (*i.e.,* fatal to humans in low doses or capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness).[34] Finally, the serious adverse events that have been reported have not caused FDA to reverse its decision to allow the NRTs to be sold as OTCs. Therefore, the Agency finds that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing.

The FDA-approved OTC NRTs, prior to the effective date of this rule, were listed hazardous waste P075 when discarded. Therefore, these wastes have been required to be managed under RCRA Subtitle C hazardous waste regulations. Following exemption from the P075 listing, these OTC NRT wastes will be considered non-hazardous wastes and can be managed under applicable non-hazardous solid waste regulations. The Agency does not have any information at this time to suggest that these wastes will be improperly managed as non-hazardous wastes or have the potential to cause human or environmental exposures. The Agency believes, because of the low concentrations of nicotine in these wastes and their design to slowly release the nicotine, any risk from plausible mismanagement scenarios would not be sufficient to cause a substantial present or potential hazard to human health or the environment. Nevertheless, the Agency encourages healthcare facilities to first consider if their unused nicotine-containing products, which are to be discarded, can be legitimately recycled to recover the nicotine. The Agency has recently stated to one recycler that legitimately recycled nicotine-containing products would not be considered solid waste and thus would not be subject to RCRA hazardous waste regulation.[35] In addition, the Agency reminds healthcare facilities, especially retail-sector pharmacies, who may decide to discard expired FDA-approved OTC NRTs in their dumpsters or regular trash, that products' labels direct them to ensure that these products are kept out of the reach of children and pets. Therefore, the Agency recommends that healthcare facilities, including retailers, take the necessary security measures to discard unused, unwanted, or expired OTC NRTs where they are not freely accessible to the public. The recommended security measures could be simple as having locks on the dumpsters and trash cans that are used for discarding OTC NRTs or placing the dumpsters and trash cans in locked areas.

3. E-Cigarettes, E-Liquids, and Prescription Nicotine Replacement Therapies

There were mixed comments on exempting e-cigarettes, nicotine containing e-liquids, and NRTs requiring a prescription from the P075 hazardous waste listing when discarded (for more information, see Summary of Comments included previously in this section). The comments from retailers, tobacco companies, and trade associations generally favored exempting these categories of products from the P075 listing when discarded, whereas comments from four of five states and NEWMOA did not support exempting these products from the P075 listing when discarded.

The e-cigarettes and nicotine-containing e-liquids (or just e-liquids) are currently not regulated by FDA in the same manner as NRTs. NRTs are regulated as drugs by FDA while e-cigarettes and e-liquids are regulated as tobacco products by FDA. Consequently, the FDA has not been able to evaluate the health risks to the public from e-cigarettes and e-liquids to the same extent as it has been able to for drugs. Moreover, the concentrations of nicotine in e-cigarettes and e-liquids are not limited by any FDA regulation or approval process and are therefore unpredictable. The supplemental comments on the proposal submitted to EPA by the Retail Associations (June 29, 2016) [36] stated that a recent promulgation of a final rule by FDA referred to as the ''Deeming Rule'' (81 FR 28973; May 10, 2016) will ensure against ''unpredictable'' nicotine concentrations in e-cigarette products and, therefore, strengthens the case for reclassification or exemption of these

[31] See 78 FR 19718; April 2, 2013.

[32] See pages 5 and 6 of the Pharmacology Review for the New Drug Application Number 21–330 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[33] *International Journal of Health Sciences (Qassim).* ''Nicotine Replacement Therapy: An Overview'' (July, 2016) 10(3): pp. 425–435.

[34] See the following four FDA documents included in the docket for this rulemaking EPA–HQ–RCRA–2007–0932: (1) Letter from Janet Woodcock responding to a citizen petition, dated June 4, 2015; (2) Memo from Kellie Taylor et al. on citizen petition response, dated May 8, 2015; (3) Memo from Joslyn Swann providing a review of Abuse, Misuse, and Overdose associated with Nicotine Replacement Therapy products, dated October 1, 2010; and (4) Nicoderm OTC Switch Medical Officer Review (NDA 20–165), dated August 7, 1995.

[35] See letter from Barnes Johnson, USEPA to Scott DeMuth, g[2] Revolution, LLC., dated May 8, 2015, RCRAOnline #14851.

[36] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0392.

products from the P075 listing. The Deeming Rule extended FDA's regulatory authority to all tobacco products, including electronic nicotine delivery systems (or e-cigarettes). This rule allows FDA to evaluate factors such as ingredients (*e.g.,* nicotine and its concentration), product design, and health risks to both users and non-users. The Deeming Rule ensures that newly regulated tobacco products, before they are introduced into the market, meet certain requirements, including warning labels, prohibiting sales to minors, registering with FDA, and obtaining marketing authorization from FDA. It is, however, important to note that FDA's review and approval process for introducing new tobacco products to the market is not as rigorous in assessing their safe use as review and approval of drug products. Furthermore, in August 2017, the FDA extended the compliance deadline for the newly regulated noncombustible tobacco products in the Deeming Rule, such as e-cigarettes, from November 8, 2017 to August 8, 2022. Therefore, without controls on the concentration of nicotine in e-cigarettes and e-liquids or FDA's approval of these products as being safe and effective for people to use, the Agency lacks adequate information and certainty to conclude that these nicotine-containing products will not pose the risks similar to those for which the P075 listing was established. For all of the above reasons, at this time the Agency cannot support exempting e-cigarettes and nicotine-containing e-liquids from the P075 listing.

Furthermore, in the short time that e-cigarettes have been in the U. S. marketplace (since about 2007), the calls to poison control centers related to exposures to this product, mostly among young children, have increased substantially. This significant increase can be attributed largely to the rapid rise in the use of e-cigarettes by the public. According to an article published in the Journal *Pediatrics,* ''Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States'' (May 2016), the monthly number of exposures among young children (younger than six years old) associated with e-cigarettes increased by almost 1500 percent from January 1, 2012 (14 exposures) to April 30, 2015 (223 exposures).[37] During the same period, children under two years old accounted for 44.1 percent of the exposures associated with e-cigarettes. Exposures of children to unregulated nicotine concentrations in e-cigarette cartridges and refill solutions (e-liquids) have the potential to cause much more severe toxic effects compared to exposures of children to FDA-approved OTC NRTs. This is because e-liquid refill containers are available in concentrations up to 100 mg/mL that are then diluted before use. The liquid nicotine, ingested or absorbed through skin, is likely to result in more severe toxic effects because it is available in higher concentrations and absorbed rapidly by the body. In December 2014, a 1-year old child died from liquid nicotine poisoning, the first such death in the U.S.[38]

Prescription NRTs, like OTC NRTs, must be approved for use by FDA as drugs. However, the FDA considers OTC drug products to be safe enough to take without the guidance of a health professional. A prescription for a drug is written by a health professional for an individual at a specific dose after the health professional has diagnosed an illness. Generally, nicotine-containing prescription drugs (*e.g.,* nicotine inhaler and nicotine spray) contain an aqueous solution intended for administration as a metered spray, which means, in comparison to FDA-approved OTC NRTs, nicotine can be delivered rapidly to the body. When a prescription pharmaceutical is transitioned to OTC status, the key question for FDA is whether consumers can achieve the desired medical result without the intervention of a health care professional and without endangering their safety.[39] For example, FDA has to review information about adverse events and serious adverse events resulting from use of a prescription drug before it can make a determination on whether a prescription drug is safe to switch over to an OTC drug. FDA has not yet made that determination for the existing prescription NRTs and EPA also did not receive any toxicity or health effects information on prescription NRTs. Prescription NRTs are also expected to be used less frequently than FDA-approved OTC NRTs, and, thus, should not exist in the same quantities at retailers as FDA-approved OTC NRTs. Furthermore, prescription NRTs are not expected to be returned to retailers like FDA-approved OTC NRTs, because they are prescribed by health professionals for specific individuals and can't be resold once dispensed. Therefore, the comments from retailers also expressed less concern about the disposal of prescription NRTs causing a change in their hazardous waste generator category.

Based on the information discussed above and the comments from a majority of the states and NEWMOA, the Agency is not exempting e-cigarettes, e-liquids, or prescription NRTs from the P075 hazardous waste listing. The Agency believes that any plausible mismanagement or diversion of these waste products, if exempted and allowed to be managed as non-hazardous wastes, has the ability to cause substantial present or potential hazard to human health and the environment. This is because prescription NRT products can contain nicotine at much higher concentrations and in a more readily available form (*i.e.,* in liquid and mist), which acts faster on the body, than the nicotine contained in FDA-approved OTC NRTs. Instead, the Agency is allowing e-cigarettes, e-liquids, and prescription NRTs to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P when they are discarded.

4. Concentration-Based Exemption

Some commenters stated that the data and information they provided to EPA should be adequate to support a concentration-based exemption for nicotine-containing products. These commenters requested that EPA exempt from the P075 listing all present and future nicotine-containing products with less than a particular nicotine concentration (*e.g.,* less than 3% or 5%).

The Agency stated in the proposal that it would consider a concentration-based exemption for low-concentration nicotine-containing products if toxicology data (*e.g.,* animal LD50 data) for nicotine-containing products at maximum concentration of nicotine in these products became available. On June 9, 2017, Perrigo submitted additional comments along with oral and dermal LD50 toxicity studies for nicotine gums and lozenges manufactured by Perrigo.[40] The gums and lozenges tested contain 5% nicotine polacrilex. Nicotine polacrilex is a nicotine-containing resin which contains 15% nicotine. With 5% nicotine polacrilex in the gums and lozenges, the total nicotine in these products is less than 1%. The Perrigo LD50 studies reported oral and dermal rat LD50 toxicity values of greater than 5000 mg/kg for both nicotine gum and lozenge products. Based on their data, Perrigo asked the Agency to exempt

[37] *http://pediatrics.aappublications.org/content/early/2016/05/05/peds.2016-0041?utm_source=TrendMD&utm_medium=TrendMD&utm_campaign=Pediatrics_TrendMD_1.*

[38] *https://www.healthychildren.org/English/safety-prevention/at-home/Pages/Liquid-Nicotine-Used-in-E-Cigarettes-Can-Kill-Children.aspx.*

[39] *https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143547.htm.*

[40] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0398.

from the P075 listing nicotine at concentrations below 5%.

EPA's review of the Perrigo LD50 studies revealed several critical flaws in the way these studies were conducted. First, the studies were conducted using nicotine polacrilex instead of nicotine itself. A concentration-based listing for nicotine would require toxicity data for nicotine itself. The amount of nicotine in gums and lozenges with 5% nicotine polacrilex, as stated above, is less than 1% and it is in a form that is not readily available when ingested or applied (nicotine is designed to be released slowly when it is in the form of nicotine polacrilex). In fact, the nicotine will not release from the nicotine-containing resin (nicotine polacrilex) until it is exposed to an aqueous solution or proper pH, such as found in saliva. Therefore, nicotine polacrilex would not be expected to be absorbed dermally. In contrast, nicotine is readily absorbed dermally, as indicated by nicotine patches. To support a concentration-based exemption of nicotine, Perrigo should have conducted the toxicity studies for nicotine using the percent of nicotine (not nicotine polacrilex) in the gums and lozenges, since this would have provided data on toxicity of nicotine (the P075 listed chemical). Second, for acute oral testing, a single bolus dose of nicotine should have been administered to the test animals all at once (or over a short period of time) instead of over a period of 24 hours. Third, in EPA's listing regulations under § 261.11(a)(2), the dermal LD50 toxicity value is based on studies with rabbits, but Perrigo's studies used rats. Fourth, Perrigo did not provide LD50 toxicity data for nicotine patches (this could be because Perrigo does not manufacture nicotine patches). Finally, no explanation or justification was included for using their toxicity data which was for nicotine polacrilex with concentrations of nicotine at less than 1%, to extrapolate to exempting all nicotine with a concentration below 5%.

EPA, for the reasons previously stated, has already determined that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing. The toxicological data submitted by Perrigo are for nicotine polacrilex, instead of nicotine, and are not considered to be adequate to support a concentration-based exemption for nicotine-containing products. Therefore, the Agency has no other information to conclude that a particular nicotine concentration can be exempt from the P075 listing.

VI. Reverse Distribution and Reverse Logistics

A. Summary

Based on information collected from outreach efforts and comments received on the proposed rulemaking, EPA is finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals, codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals,[41] and establishing a policy for the reverse logistics of other unsold retail items.[42] In the case of prescription pharmaceuticals, EPA maintains its position as stated in the proposed rulemaking preamble that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility (*e.g.,* retail store).[43] In contrast, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store[44] if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose)[45] or reclaimed.[46] Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. The remainder of this section proceeds as follows. First, EPA provides a brief background on the Agency's work to better understand the retail sector and provide guidance on RCRA's applicability to the retail sector. EPA then describes the proposal to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors under the pharmaceuticals proposed rulemaking. Finally, EPA provides the rationale for finalizing distinct regulations and policies for the reverse distribution of prescription hazardous waste pharmaceuticals and the reverse logistics of other unsold retail items and nonprescription pharmaceuticals and describes new information received in comments on the proposed rulemaking.

B. Background

In 2008, EPA initiated a review of RCRA's applicability to the retail sector in order to understand the challenges the retail sector faces in complying with RCRA. EPA's review consisted of discussions with various members of the retail community and states through meetings, conferences, and site visits. In 2014, EPA published a NODA for the Retail Sector in order to better understand the concerns from all stakeholders regarding RCRA's applicability to that sector.[47]

Subsequent to issuance of the NODA, EPA continued conducting outreach efforts (*e.g.,* meetings, conferences, site visits) with stakeholders to gather information regarding the management of unsold retail items. EPA's outreach efforts, combined with an analysis of comments received on the NODA, improved the Agency's understanding of the challenges that the retail sector faces when managing items that have become unsalable at stores for a variety of reasons. Unsold retail items include excess inventory, such as expired or outdated items, seasonal items,

[41] Under the final rule, the definition of pharmaceutical includes, but is not limited to, prescription drugs, over-the-counter drugs, dietary supplements, and homeopathic drugs. See the definition of pharmaceutical in § 266.500. For the remainder of this section, EPA refers to over-the-counter drugs, dietary supplements, and homeopathic drugs as nonprescription pharmaceuticals. Prescription pharmaceuticals are defined by 21 CFR 203.3(y).

[42] Under the final rule, other unsold retail items can include any non-pharmaceutical unsold retail item from a retail store that if discarded would otherwise meet the definition of hazardous waste. Examples include but are not limited to aerosol cans, pool chemicals, mercury-containing lightbulbs, some pesticides, certain cleaning products, paint thinner, ammunition, and fireworks.

[43] Under the final rule, the definition of healthcare facility includes, but is not limited to, retail facilities such as pharmacies and retailers of over-the-counter medications. See the definition of healthcare facility in § 266.500.

[44] Throughout this section, EPA uses the term ''retail store'' to describe facilities that send nonprescription pharmaceutical and other unsold retail items through reverse logistics. EPA's understanding is that the retail sector is the only industry that sends nonprescription pharmaceuticals and other unsold items through reverse logistics. However, EPA's final policy that nonprescription pharmaceuticals and other unsold retail items, excluding prescription pharmaceuticals, that are sent through reverse logistics are not solid wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed, is not limited to the retail sector.

[45] Commenters from the retail industry commonly use the terms ''liquidation'' or ''donation'' to refer to legitimate methods of redistribution. For example, see comment numbers EPA–HQ–RCRA–2007–0932–0312 and EPA–HQ–RCRA–2007–0932–0340 in the docket. Under RCRA's definition of solid waste regulations in § 261.2(e), redistribution would be referred to as use/reuse.

[46] See § 261.1(b)(4) for the definition of reclamation and § 261.1(b)(5) for the definition of use/reuse.

[47] February 14, 2014 (79 FR 8926).

overstock, recalled items, and returned items that cannot be returned to stock/inventory. In the NODA, EPA used the terms ''reverse distribution'' and ''reverse logistics'' to describe the process or system employed by the retail sector to manage these unsold retail items.

Based on information gathered through outreach and comments to the Retail NODA, EPA developed a cohesive plan to address the unique challenges faced by the retail sector in complying with RCRA regulations. This plan is called the ''Strategy for Addressing the Retail Sector under the Resource Conservation and Recovery Act's Regulatory Framework'' (Retail Strategy) and was made publicly available on September 12, 2016.[48]

Throughout the Retail Strategy, EPA used the term ''reverse distribution'' to describe the system through which unsold retail items flow and the term ''reverse logistic center'' to describe the facilities managing the reverse flow of these items. In crafting the Retail Strategy, EPA recognized that the reverse distribution process that retail stores employ to send unsold retail items to reverse logistics centers is a well-established business practice in the retail sector and retail stores sometimes rely upon arrangements with manufacturers[49] to determine the ultimate disposition of these goods. EPA also noted that a number of questions have been raised by both retailers and regulators regarding how the reverse distribution process is regulated, or should be regulated, under RCRA. In addition, this issue becomes more complicated for national retailers with store locations in multiple states, as states have taken various positions on how RCRA regulations apply. The Agency's understanding when crafting the Retail Strategy was that ''reverse distribution'' is the term most commonly used for the return of all pharmaceuticals (both prescription and nonprescription) that have the potential to receive manufacturer credit, whereas ''reverse logistics'' is the term used for the reverse flow of retail items other than pharmaceuticals.[50]

Because of the challenges facing the retail sector in complying with RCRA, EPA stated in the Retail Strategy its intent to develop a policy addressing the reverse distribution process for the retail sector as a whole. In the Retail Strategy, EPA agreed to develop a comprehensive policy that applied to all unsold retail items, not just pharmaceuticals. In order to fulfill EPA's intent to address the reverse distribution process for the retail sector as a whole, EPA is establishing a policy for the reverse logistics of other unsold retail items in addition to finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals.

C. EPA's Proposed Regulations for Reverse Distribution of Pharmaceuticals

In the proposed Management Standards for Hazardous Waste Pharmaceuticals, EPA proposed to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturer credit. EPA's original position was outlined in two RCRA policy memos released in 1981 and 1991.[51] In the first memo, EPA agreed that pharmaceuticals did not become wastes until the decision to discard was made at a manufacturing plant. EPA's interpretation was based on the understanding that the decision to either return goods for reclamation or dispose of them took place only at the manufacturing plant. In the second memo, EPA agreed that pharmaceuticals returned to a manufacturer, wholesaler, or third-party service company would not be considered wastes until a decision to discard has been made. In this 1991 memo, EPA specifically noted that, ''to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered waste until a determination to discard them is made.'' Although EPA made a statement in the preamble to the 2008 Pharmaceutical Universal Waste proposal that linked the value of these pharmaceuticals, in the form of manufacturers credit, to the idea that these pharmaceuticals would not be considered waste, EPA never finalized this universal waste rule or that interpretation. Thus, the 1991 memo describes EPA's interpretation regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors prior to this final rulemaking.

In the preamble to the proposed rulemaking, EPA indicated the Agency's intent to modify its position regarding the point of generation in circumstances where a pharmaceutical is sent to a reverse distributor. EPA proposed that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. That is, EPA proposed that, once the decision is made to send a potentially creditable hazardous waste pharmaceutical[52] from a healthcare facility to a reverse distributor, a decision to discard has been made and the pharmaceutical is considered a solid waste. This proposed change of policy was based on the EPA's understanding that in almost all cases, pharmaceuticals returned to a reverse distributor for manufacturer credit are ultimately discarded.[53] Under the proposed rulemaking, the definition of ''pharmaceutical reverse distributor'' included any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Additionally, under the proposed rulemaking, the definition of ''pharmaceutical'' included not just prescription pharmaceuticals but also nonprescription pharmaceuticals. Therefore, under the proposal, potentially creditable prescription pharmaceuticals and nonprescription pharmaceuticals transported to a facility that facilitates or verifies manufacturer credit, even in cases where a credit determination is yet to be made, would be considered discarded and, therefore, solid wastes at the healthcare facility.

In proposing this shift, EPA specifically stated that, although a pharmaceutical may retain monetary value within the reverse distribution system (*i.e.,* potential exists for a manufacturer to issue credit), the

[48] EPA's Retail Strategy is available at *https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts.*

[49] EPA has not distinguished among the terms ''supplier'' and ''vendor'' (the latter more commonly used in the retail industry) versus ''manufacturer'' and these terms are used interchangeably in this preamble, although the Agency realizes that the flow of goods/products more commonly occurs between retailers and suppliers/vendors (or agents thereof) and that suppliers themselves may also be manufacturers or product formulators.

[50] As discussed subsequently in this preamble, the distinction between ''reverse distribution'' and ''reverse logistics'' has become important in light of the Agency's response to comments received on the proposed rule.

[51] Refer to the preamble of the proposed rule (pages 58042 and 58043), which includes discussion of the two EPA policy memos, dated May 13, 1981 (RCRA Online #11012) and May 16, 1991 (RCRA Online #11606).

[52] Potentially creditable hazardous waste pharmaceutical in the proposal was generally defined as a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. See 80 FR 58014.

[53] See further discussion in the proposed rule preamble at 80 FR 58043.

pharmaceutical would still be considered a solid waste. The ''decision point'' on whether a pharmaceutical is a solid waste is when it has been discarded or when the decision has been made to discard the material. That is, when a pharmaceutical is discarded determines whether it is a solid waste, not whether the pharmaceutical has value. This interpretation is consistent with EPA's approach under RCRA that materials that are discarded are solid wastes, regardless of their monetary value or the economics of the system in which those discarded materials are handled. EPA has long maintained, and continues to maintain, the interpretation that value is not determinative of solid waste status.

In 1986, EPA released a memo on the regulation of hazardous wastes that are recycled, and wrote that ''persons transporting and storing hazardous wastes before recycling are similar to persons transporting and storing hazardous waste before disposal: There is nothing about the waste that makes it so valuable that safe handling is assured absent regulation.'' [54] EPA reaffirmed this interpretation in a 1989 memo on the regulatory status of solder skimmings (tin/lead alloy) purchased for reclamation, writing that even though the skimmings have value, they are still considered a solid waste.[55]

In a more recent application of this interpretation, EPA outlined its position on chlorofluorocarbons (CFCs) that are processed back into the refrigerant market or sent for destruction, but receive carbon offset credits and thus have value, in two memos signed in 2017.[56] Irrespective of whether facilities pay for hazardous CFCs or receive carbon offsets for the destruction of CFCs, the material is considered a solid waste. As another example of a material that is discarded as solid waste but has monetary value, EPA maintains that spent lead acid batteries being reclaimed are regulated as hazardous waste under part 266 subpart G or under universal waste irrespective of the fact that the batteries may have value and that reclamation facilities sometimes buy batteries due to the monetary value of the lead.[57] This finding was upheld in *United States* v. *Ilco Inc.,* 996 F. 2d 1126, where the court found that the fact that the batteries were discarded ''does not change just because a reclaimer has purchased or finds value in the components.'' EPA also maintains that recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, and other various precious metals are still regulated as hazardous waste under part 266 subpart F despite the fact that the precious metals have monetary value. Additionally, the holdings of multiple court decisions is that simply because a hazardous waste has, or may have, monetary value does not mean the material loses its status as a solid waste. See *American Petroleum Institute* v. *EPA,* 906 F.2d 741 n.16 (D.C. Cir. 1990); *United States* v. *ILCO Inc.,* 996 F.2d 1126 1131–32 (11th Cir. 1993); *Owen Steel* v. *Browner,* 37 F.3d 146, 150 (4th Cir. 1994).

D. EPA's Final Reverse Distribution Regulation and Reverse Logistics Policy

1. Introduction

In light of comments received on the proposed rulemaking, along with EPA's understanding of current business practices, the Agency is making a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals. In addition to receiving information from comments on the proposed rulemaking, EPA gathered information from site visits and by participating as an observer in the Retail Waste Working Group.[58] In the case of prescription pharmaceuticals, EPA is finalizing, as proposed, that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility. However, EPA notes that these tailored RCRA regulations for prescription pharmaceuticals going through reverse distribution are designed with existing business practices in mind. For more explanation, see section 4 below and section XVII of this preamble. EPA is also codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals. EPA makes it clear in § 266.501(g)(2) that nonprescription pharmaceuticals are not solid wastes because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (also see section IX of this preamble). Also in this preamble, EPA is establishing a policy that other unsold retail items that are sent through reverse logistics are not solid wastes at the retail store because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

2. Comments on EPA's Proposed Reverse Distribution Regulation

EPA received numerous comments on the proposed position that the decision to send potentially creditable pharmaceuticals through reverse distribution is a decision to discard. States were generally supportive of the proposed change in position, while many comments from the retail industry objected to the Agency's proposed change in position.

EPA received many broad comments on EPAs proposed position regarding the waste status of pharmaceuticals going through reverse distribution and reverse logistics, which are discussed in further detail in section XVII. EPA also received many comments describing the potential burden that the revised interpretation would place on the retail industry, which are also discussed in further detail in section XVII. The remainder of this section focuses on comments received on the distinction between the reverse distribution of prescription pharmaceuticals and the reverse logistics of nonprescription pharmaceuticals and other unsold retail items.

EPA received numerous comments that described the key distinctions between reverse distribution and reverse logistics as they pertain to the waste status of pharmaceuticals and other unsold retail items going through these two processes. Multiple commenters argued that EPA mistakenly concluded that pharmaceuticals, including nonprescription pharmaceuticals, transported to facilities that facilitate or verify manufacturer credit are in most, if not all cases, discarded.[59] Commenters argued that the Agency failed to take into account the ability to donate, liquidate, or reclaim nonprescription pharmaceuticals that are sent through reverse logistics. However, commenters did confirm that prescription pharmaceuticals are in

[54] See RCRA Online #12762 for the October 8, 1986 letter from EPA to Senator John Glenn titled ''Hazardous Wastes that are Recycled, Handling.''

[55] See RCRA Online #11446 for the July 20, 1989 memo from EPA to Electrum Recovery Works, Inc.

[56] See docket number EPA–HQ–RCRA–2007–0932 for the January 30, 2017 letter from EPA Region 5 to Tradewater, LLC and the July 14, 2017 letter from EPA to A-Gas U.S. Holdings, Inc.

[57] See docket number EPA–HQ–RCRA–2007–0932 for notes from a November 19, 2013 site visit to a lead acid battery recycler.

[58] See the report prepared by the Retail Waste Working Group, ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[59] See the preamble to the proposed rule for a discussion of the comments received on the 2008 Pharmaceutical Universal Waste proposal and the 2014 Retail Notice of Data Availability that argued that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused (80 FR 58043).

most, if not all cases, discarded. Commenters argued that this fact contradicts EPA's rationale in proposing that all pharmaceuticals, including nonprescription pharmaceuticals, going through reverse distribution and reverse logistics are wastes at the healthcare facility.

Overall, commenters encouraged EPA to adopt the terminology used by industry where ''reverse distribution'' only refers to the process by which prescription pharmaceuticals are sent to a reverse distributor for the evaluation of manufacturers credit and ''reverse logistics'' refers to the process by which nonprescription pharmaceuticals and other unsold retail items are sent to a reverse logistics center and evaluated for legitimate use/reuse or reclamation. Commenters requested that if EPA intends to finalize that a decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical, that EPA also adopt separate and distinct policies regarding how RCRA applies to prescription pharmaceuticals going through ''reverse distribution'' and to nonprescription pharmaceuticals and other unsold retail items going through ''reverse logistics.'' [60] One commenter noted that reverse logistics is an integral component of inventory management, product recall confirmation, sale through liquidation, donation for use, and reclamation of commercial products—contributing billions of dollars to the retail industry annually.[61] Moreover, this commenter noted that the reverse logistics operations help maximize the amount of OTC pharmaceuticals and dietary supplements that can be reused or reclaimed. Another commenter made a similar argument, writing that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.[62]

One commenter honed in on the argument that EPA failed to take into account the ability to legitimately use/reuse or reclaim nonprescription pharmaceuticals that are sent through reverse logistics.[63] This commenter pointed out that stringent chain-of-custody documentation and disposal requirements under DEA regulations and state Board of Pharmacy Requirements only apply to prescription pharmaceuticals. In contrast, most nonprescription pharmaceuticals are not susceptible to the same diversion risks as prescription pharmaceuticals and do not face the same documentation and disposal requirements. This makes it possible to use/reuse or reclaim nonprescription pharmaceuticals.

Walmart Stores Inc. commented that pharmaceuticals going through reverse distribution that are ultimately discarded are likely prescription pharmaceuticals.[64] Walmart wrote that only a small percentage of the consumer goods [65] managed at Walmart's six Return Centers, which will be considered reverse logistics centers under EPA's final policy, are discarded. According to Walmart's data, only 2% of the consumer goods managed at Walmart's Return Centers are discarded by Walmart, while 28% are donated, recycled, or liquidated and 70% are returned to the vendor.[66] Further, for the consumer products that are considered RCRA hazardous waste when discarded, only 1% are discarded, 33% are liquidated or donated, and 66% are returned to the vendor.[67] Inmar, Inc. also argued that only a small percentage of the OTC pharmaceuticals returned to a reverse logistics center are disposed rather than liquidated, donated, or returned to the vendor.[68] Inmar does not maintain specific data on this issue, but wrote that it would not be unusual for one of their subsidiary reverse logistics centers handling nonprescription pharmaceuticals and other consumer goods to send as little as 5% of the products for destruction.

Retail Industry Leaders Association (RILA) et al. pointed out that nonprescription pharmaceuticals do not face the same restrictions that preclude the redistribution or donation of prescription pharmaceuticals.[69] RILA et al. added that nonprescription pharmaceuticals are regularly donated and liquidated and cited data from two retailers.

Inmar Inc. also noted that when an item is returned because an expiration date has been exceeded, disposal is more often the required disposition, but the products may be returned to the manufacturer for further evaluation for potential liquidation.[70] Inmar also wrote that nonprescription pharmaceuticals with ''best by'' dates (as opposed to expiration dates) can still be donated or liquidated after the date has passed.

Overall, these comments help to underscore the differences between how prescription pharmaceuticals and other unsold retail items, including nonprescription pharmaceuticals, are managed within the reverse supply chain. These comments led EPA to make a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of all other unsold retail items, including nonprescription pharmaceuticals.

3. Distinction Between Reverse Distribution and Reverse Logistics

EPA acknowledges that reverse distribution and reverse logistics processes share common elements in terms of the role each plays in the management of pharmaceuticals. However, based on the comments received on the proposal, especially those summarized above, the Agency recognizes that there is a key distinction between how prescription pharmaceuticals and nonprescription pharmaceuticals (see definition of pharmaceutical in § 266.500) are managed in the reverse supply chain. The key distinction is that there is not a reasonable expectation of legitimate use/reuse (*e.g.,* lawful redistribution for its intended purpose) or reclamation for prescription pharmaceuticals, except in very limited circumstances, but there is for other retail items, including nonprescription pharmaceuticals.

Prescription pharmaceuticals shipped from healthcare facilities to reverse distributors for the evaluation of manufacturer credit are almost always discarded. EPA is aware that prescription pharmaceuticals are sometimes lawfully donated, in which case the pharmaceuticals would not be

[60] For example, see comment number EPA–HQ–RCRA–2007–0932–0377.

[61] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket.

[62] See comment number EPA–HQ–RCRA–2007–0932–0312 in the docket.

[63] Ibid.

[64] See comment number EPA–HQ–RCRA–2007–0932–0340 in the docket.

[65] EPA uses the term ''unsold retail items'' to refer to excess inventory, such as expired or outdated items, seasonal items, overstock, recalled products, and returned items that cannot be returned to stock/inventory. Walmart and other commenters from the retail industry use the term ''consumer goods'' to refer to similar items.

[66] EPA has not distinguished among the terms ''supplier'' and ''vendor'' verses ''manufacturer'' and the terms are used interchangeably throughout the preamble. The Agency more frequently used the term ''manufacturer'' while retail industry commenters more frequently used the term ''vendor.''

[67] EPA did not receive data on the ultimate disposition of consumer products returned to the vendor. EPA further discusses our policy on unsold retail items that are returned to the vendor in section ''e.) Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes.''

[68] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket.

[69] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket.

[70] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket.

a solid waste.[71] In the case of nonprescription pharmaceuticals and other unsold retail items that are sent to a reverse logistics center, there is often a reasonable expectation that they will be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

EPA recognizes that the awarding of credit for unsold pharmaceuticals is a critical element of both the reverse distribution and reverse logistics processes as it provides a healthcare facility financial incentive to not only stock a particular pharmaceutical but also to defray costs associated with transporting a pharmaceutical to a reverse distributor or reverse logistics center. However, it is EPA's position that the inherent monetary ''value'' conferred on any pharmaceutical due to the potential to receive manufacturer credit is not a proper indicator of waste status. Rather, the decision to discard is determinative of when an unsold product becomes a solid waste. Under EPA's final rule and preamble, if a nonprescription pharmaceutical or other retail item becomes unsalable at a retail store it can continue to be considered a product until a reverse logistics center or other subsequent entity makes the decision to discard it, as long as there is a reasonable expectation of it being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

4. Prescription Pharmaceuticals Going Through Reverse Distribution Are Wastes at the Healthcare Facility

In the case of prescription pharmaceuticals, EPA maintains its position, as stated in the proposed rulemaking preamble and reflected in the regulatory text, that prescription pharmaceuticals moving through reverse distribution are solid wastes starting at the healthcare facility. This includes prescription pharmaceuticals that, as potentially creditable hazardous waste pharmaceuticals, are sent from a retail facility or healthcare facility to a reverse distributor for manufacturer credit evaluation (see definition of potentially creditable hazardous waste pharmaceutical in § 266.500). Although the potential exists for a manufacturer to issue credit for a prescription pharmaceutical, the ''decision point'' on when a pharmaceutical is a solid waste is when the decision has been made to discard the item. That is, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Although prescription pharmaceuticals are evaluated for, and in many cases ultimately receive, manufacturer credit, it remains apparent to EPA that these pharmaceuticals will seldom, if ever, be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed after they are sent to a reverse distributor. Thus, a decision to send prescription pharmaceuticals to a reverse distributor is a decision to discard the material. None of the comments on the proposed rule alter EPA's position regarding the likelihood of redistribution or reclamation of prescription pharmaceuticals being managed through reverse distribution. Rather, EPA received many comments that agreed with EPA's proposed interpretation that the decision to send a pharmaceutical to a reverse distributor is a decision to discard as it pertains to prescription pharmaceuticals because there are limited opportunities to legitimately use/reuse or reclaim prescription pharmaceuticals. In circumstances when prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered a solid waste and we have specifically noted this in the regulations (see § 266.501(g)(1) and the definition of hazardous waste pharmaceutical in § 266.500).

Many of the broad comments in support of the proposed reinterpretation provided examples but did not distinguish between prescription pharmaceuticals and nonprescription pharmaceuticals. For example, multiple commenters argued that pharmaceuticals transported to a reverse distributor are rarely redistributed or reclaimed, and are usually destroyed, but did not explain if this applied only to prescription pharmaceuticals. One commenter observed that many manufacturers contract with reverse distributors to dispose of unsold pharmaceuticals after review for credit eligibility is complete, suggesting that use/reuse or reclamation does not generally occur. This commenter was only aware of one instance of potential reuse of a pharmaceutical after being sent through reverse distribution.[72] That being said, based on what EPA has learned from retail industry commenters, site visits, and discussions with retailers about prescription pharmaceuticals verses nonprescription pharmaceuticals, EPA can infer that these comments likely refer to the reverse distribution of prescription pharmaceuticals.[73] EPA's inference is supported by other comments received on the proposal. For example, Walmart argued that the comments EPA received on the 2008 Pharmaceutical Universal Waste proposal (where pharmaceuticals were defined only as prescription pharmaceuticals) and the 2014 Retail Notice of Data Availability that pharmaceuticals going through reverse distribution are ultimately discarded were likely talking about prescription pharmaceuticals.[74]

In conclusion, a material is considered a solid waste if it is accumulated or stored before or in lieu of being disposed of, burned, or incinerated (§ 261.2(b)(3)). Even if the healthcare facility intends to receive credit for the prescription pharmaceutical and the reverse distributor intends to evaluate the prescription pharmaceutical for credit, the pharmaceutical is still considered a discarded material (§ 261.2(a)(2)(i)) because it is being accumulated and stored prior to being sent for treatment (rather than being accumulated or stored prior to being used/reused or reclaimed). Although the healthcare facility or reverse distributor intends to elicit credit from the prescription pharmaceutical in the interim period before it is sent for treatment, the pharmaceutical is still considered a discarded material. An intent to receive credit does not preclude the pharmaceuticals from being discarded; they are not mutually exclusive.

Although EPA maintains its position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility, this final rule establishes streamlined, practical standards for managing potentially creditable hazardous waste pharmaceuticals that will reduce regulatory burden on retailers and align with the existing practices of the retail sector. Thus, EPA's position that prescription pharmaceuticals moving

[71] EPA is aware of one non-profit organization that facilitates donations of prescription pharmaceuticals. See comment from SIRUM in the docket (EPA–HQ–RCRA–2007–0932–0353). EPA is also aware of multiple states, including Iowa, Wyoming, and Oklahoma, that run prescription pharmaceutical return and reuse programs. For more information, see ''State Prescription Drug Return, Reuse and Recycling Laws'' at *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.*

[72] The example cited was an unconfirmed claim that a rodent poison manufacturer could use discarded pharmaceutical warfarin tablets as feedstock in its process. See comment number EPA–HQ–RCRA–2007–0932–0358 in the docket.

[73] See docket number EPA–HQ–RCRA–2007–0932 for reverse distributor responses to EPA's questions about reverse distribution of pharmaceuticals, notes from Agency meetings with retail industry representatives, and notes from site visits to reverse distribution facilities.

[74] See comment number EPA–HQ-RCRA-2007-0932-0340 in the docket.

through reverse distribution are solid wastes at the healthcare facility only subjects these hazardous waste pharmaceuticals to the streamlined part 266 subpart P standards versus the full RCRA Subtitle C regulations. For example, EPA does not require healthcare facilities to use a hazardous waste manifest or a hazardous waste transporter when shipping potentially creditable hazardous waste pharmaceutical to a reverse distributor. See section XVI.D for a discussion of the shipping standards for potentially creditable hazardous waste pharmaceuticals.

Because the point of generation of potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, EPA can impose the RCRA Subtitle C cradle-to-grave management of hazardous wastes. Specifically, it allows us to impose consistent and enforceable tracking of hazardous waste pharmaceuticals from healthcare facilities en route to reverse distributors. Lack of tracking was identified as a regulatory gap by many commenters on our 2008 proposal to add pharmaceuticals to the Universal Waste program. The tracking provides the benefit of reducing the risk of diversion of these unused hazardous waste pharmaceuticals onto the black market, thus fulfilling our statutory mandate of protecting human health.

5. Nonprescription Pharmaceuticals and Other Retail Items Going Through Reverse Logistics Are Not Wastes if They Have a Reasonable Expectation of Being Legitimately Used/Reused or Reclaimed

Although EPA includes nonprescription pharmaceuticals in the definition of ''pharmaceutical'' under the final rule, the Agency makes it clear in the definition of ''hazardous waste pharmaceutical'' that nonprescription pharmaceuticals are not solid wastes, and therefore not hazardous waste pharmaceuticals, if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. The applicability of the final rule also has a new provision in § 266.501(g)(2) making it clear that a nonprescription pharmaceutical that is not a solid waste because it has a reasonable expectation of being legitimately used/reused or reclaimed is not subject to parts 260–273. Additionally, the final definition of reverse distributor has been revised so that it applies only to the reverse distribution of prescription pharmaceuticals.

In the final rule, EPA is reaffirming the Agency's previous policies on redistribution expressed in memos in 1981 and 1991 with respect to nonprescription pharmaceuticals and other retail items that have become unsalable at the retail store and are being managed by a reverse logistics center through the reverse logistics process. That is, EPA is maintaining a policy that nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. EPA recognizes that reverse logistics centers are designed to evaluate unsold retail items, analyze secondary markets, and assess the suitability of the unsold retail items for reuse in those secondary markets. These services promote the donation, liquidation, and reuse of unsold retail items and reduce overall waste. Importantly, these activities are distinct from the activities of reverse distributors of prescription pharmaceuticals. Reverse distributors of prescription pharmaceuticals are not designed to evaluate unsold prescription pharmaceuticals and assess the suitability of the prescription pharmaceuticals for reuse in secondary markets. As mentioned previously, commenters pointed out that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.

Although EPA is reaffirming this policy, EPA remains concerned about the potential for overuse of reverse logistics centers, a concern we originally raised in a 1991 memo related to reverse distribution: ''a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place . . . to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.'' [75] To reiterate, in order to avoid being considered solid waste, items, including nonprescription pharmaceuticals, sent through reverse logistics, must have some reasonable expectation of being legitimately used/reused or reclaimed. The 199l guidance allowing pharmaceuticals to go through reverse distribution without being considered solid waste was based on the notion that they had the potential for recycling by use/reuse. Over the years, however, many have come to disregard the intent behind this guidance and erroneously believed that it was a blanket statement that pharmaceuticals going through reverse distribution were not solid wastes, even if they did not have a reasonable expectation of being redistributed or recycled. We strongly encourage the use of reverse logistics centers to facilitate redistribution and legitimate recycling to the fullest extent possible, and thus, reduce the amount of waste being generated. But we also caution reverse logistic centers not to become *de facto* waste management facilities for their customers. If this were to occur, it could be the case that the decision to discard for nonprescription pharmaceuticals and other retail items would have occurred at the retail store or healthcare facility.

Of course, once a reverse logistics center makes a decision to discard an item, it becomes a solid waste and, if it is listed or exhibits a characteristic, a hazardous waste. The reverse logistics center is subject to the applicable RCRA regulations, such as part 262, for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals, but not part 266 subpart P.

EPA notes that although nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed, the items must be shipped in accordance will all applicable Department of Transportation (DOT) regulations. For example, DOT promulgated a final rule in March 2016 on the reverse logistics of hazardous materials. This rule includes provisions to help ensure that items, including consumer grade fireworks, are in original packaging when shipped from a retail store to a manufacturer, supplier, or distribution facility.[76]

There are six issues that came to EPA's attention when shaping this final reverse logistics policy. The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. The second issue regards unsold retail items that have expired. The third issue involves instances when retail items cannot be

[75] See memo dated May 16, 1991, From Lowrance to Schulz, RCRA Online #11606.

[76] See 81 FR 18527; March 31, 2016.

legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition.'' The fourth issue regards the crediting process for unsold retail items. The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. The final issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking.

a. *Unsold retail items returned to the manufacturer or vendor.* The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. As noted previously, data from commenters suggests a majority of unsold retail items moving through reverse logistics are returned to the manufacturer or vendor.[77] EPA did not receive data on the ultimate disposition of retail items that are returned to a manufacturer or vendor from a reverse logistics center. For this final action, EPA assumes the items are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. However, if nonprescription pharmaceuticals or other retail items do not have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed after they are returned to a manufacturer or vendor, then the nonprescription pharmaceutical or other unsold retail item would be a solid and potentially hazardous waste at the reverse logistics center.

b. *Unsold retail items that have expired.* The second issue regards unsold retail items that have expired.[78] As mentioned previously, commenters noted that when an item is sent to a reverse logistics center because an expiration date has been exceeded, disposal is most often the required disposition, however the items may be returned to the manufacturer for further evaluation for potential liquidation.[79] Furthermore, nonprescription pharmaceuticals with ''best by'' dates (as opposed to expiration dates) often can still be donated or liquidated after the date has passed. In addition to information received from commenters suggesting that expired products might be considered eligible for redistribution, FDA occasionally allows the donation of drugs that are past the expiration date shown on the label when provided sufficient information to show the expired pharmaceuticals are safe and effective and other specific criteria have been met.[80] Thus, for this final action, EPA assumes that nonprescription pharmaceuticals and other unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. These items are in their original, intact packaging and do not pose a high risk of release to the environment. Further, this position is consistent with the goal of the RCRA statute to reduce waste, as EPA is concerned that considering unsold retail items that have expired to be wastes at the retail store could introduce an unintended incentive for retailers to remove those items from shelves in advance of expiration dates, resulting in an unnecessary increase in overall waste generation.

c. *Unsold retail items subject to a destroy disposition.* The third issue involves instances when retail items cannot be legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition.'' A destroy disposition is when a manufacturer has established ''business rules'' that prohibit unsold retail items from being redistributed for their intended purpose (*i.e.,* liquidated or donated). The term ''business rules'' (*i.e.,* manufacturer return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[81] The Agency's understanding is that manufacturers adopt destroy dispositions over concerns related to liability and brand protection and that assigning a destroy disposition is not a common practice because it precludes income from potential redistribution and results in disposal costs.[82] For this final action, if a manufacturer has established business rules that prohibit unsold retail items from being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) because the items are subject to a ''destroy disposition,'' *and* that prohibit the unsold retail items from being reclaimed, the items are considered solid waste at the retail store or healthcare facility. However, if a manufacturer has established business rules that do not imply that disposal is the ultimate disposition for unsold retail items, and there is a reasonable expectation the items will be reclaimed, these items would not be solid wastes at the retail store when they are sent through reverse logistics. Thus, a manufacturer can adopt business rules that prohibit the lawful redistribution of retail items for their intended purpose (*i.e.,* liquidation or donation), but allow for the items to be sent through reverse logistics for reclamation. These items would not be wastes at the retail store if there is a reasonable expectation the items will be reclaimed.

d. *Crediting process for unsold retail items.* The fourth issue regards the crediting process for unsold retail items. It is the Agency's understanding that there are two primary credit models. The first is the ''traditional approach'' whereby credit is awarded after unsold retail items are returned to a reverse logistics center for processing. The second is the adjustable rate policy, which is also commonly referred to as a ''swell allowance,'' whereby credit is awarded up-front based on an assumption that a certain percentage of items will become unsalable for various reasons at the primary retailer.[83] EPA's understanding is that one of the goals of the adjustable rate policy is to reduce the amount of unsold items sent through to reverse logistics centers and to encourage sale at the primary retailer—even if this means discounting those items. EPA's understanding is that under such an approach, retailers are responsible for managing unsold retail items and determining the ultimate disposition since the manufacturer is not involved in the disposition decision. That being said, retailers can utilize reverse logistics to assist in the management and disposition of unsold retail items sold under an adjustable rate policy. More importantly, under EPA's final policy, although the

[77] See comment number EPA–HQ–RCRA–2007–0932–0340 in the docket.

[78] EPA uses the term ''expired'' consistent with Food and Drug Administration regulations. See 21 CFR part 201.66, part 201.17, and 211.137.

[79] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

[80] See U.S. Food and Drug Administration ''Question and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts'' available at: *https://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf.*

[81] This definition is derived from the definition of ''business rules'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[82] See discussion of ''destroy dispositions'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

[83] Additional information on the Adjustable Rate Policy and other reimbursement policies for unsalable items can be found in the publication entitled, 2008 Joint Industry Unsaleables Management Study: The Real Causes and Actionable Solutions. This publication is available at *http://www.gmaonline.org/downloads/research-and-reports/UnsaleablesFINAL091108.pdf.*

potential exists for a manufacturer to issue credit for an unsold retail item, the ''decision point'' on whether a retail item is a solid waste is when the decision has been made to discard the material. In other words, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Thus, for this final action, the credit model is not relevant to the waste status of unsold retail items. EPA assumes that nonprescription pharmaceuticals and other unsold retail items that receive credit up-front through an adjustable rate policy are not wastes if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

e. *Unsold retail items subject to a recall.* The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. Almost all pharmaceutical recalls are overseen by FDA. However, under the Poison Prevention Packaging Act, the U.S. Consumer Product Safety Commission (CPSC) has authority regarding special packaging (sometimes called child resistant packaging) of certain household products, including drugs (as that term is defined in the Federal Food, Drug, and Cosmetic Act).[84] Similarly, under the child Nicotine Poisoning Prevention Act of 2015, CPSC has authority for administering special packaging requirements for liquid nicotine containers.[85] Thus, CPSC oversees a recall if there is a problem with a pharmaceutical's special packaging or containers for liquid nicotine. Additionally, CPSC has jurisdiction over recalls of many other consumer products sold at retail stores.[86] EPA is choosing not to apply RCRA regulations to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall, provided the recall is regulated and overseen by FDA or CPSC. This is true whether they become subject to a recall at a reverse logistics center, healthcare facility, or retail store. It is possible that recalled nonprescription pharmaceuticals and other unsold retail items are not a solid waste if they are legitimately used/reused or reclaimed. For example, if CPSC oversees a recall if there is a problem with a pharmaceutical's packaging (*e.g.,* an item's packaging poses a threat because it is not sufficiently child resistant), it is possible the pharmaceutical could still be sent for reclamation. Although it is difficult for EPA to make a blanket determination on whether all recalled nonprescription pharmaceuticals and other unsold retail items are or are not solid wastes, EPA is choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items provided the recall is overseen by FDA or CPSC. When FDA directs the destruction of some or all of the recalled retail items, or CPSC grants permission to dispose or destroy some or all of the recalled items, the materials that are hazardous waste must be managed in accordance with RCRA, including the hazardous waste generator regulations standards in 40 CFR part 262.

Although FDA and CPSC are the federal agencies that primarily regulate recalled nonprescription pharmaceuticals and other unsold retail items, other federal agencies regulate some recalled retail items. For example, the National Highway Traffic Safety Administration oversees motor vehicle defects and safety recalls. Although other federal agencies may occasionally regulate recalled retail items, EPA is only choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. CPSC requires manufacturers to develop a recall strategy that outlines all of the actions to be taken on behalf of the manufacturer from start to finish. FDA requires firms that initiate a recall to develop a recall strategy and recommends that firms that initiate a FDA-requested recall develop a recall strategy.[87] Included as a required component of a comprehensive recall strategy is a requirement that FDA or CPSC approves a manufacturer's decision to take the action to discard some or all of the recalled items. Thus, EPA believes it is reasonable not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. However, the Agency will continue to evaluate recalled nonprescription pharmaceuticals and other unsold retail items managed by other federal agencies on a case-by-case basis. As an example, see the memo that EPA released in 2017 that describes how RCRA regulations apply to recalled Takata airbag inflators while they are being held under the 2015 DOT preservation order.[88] EPA's policy does not apply to unused pesticides that are suspended or canceled under the Federal Insecticide, Fungicide, and Rodenticide Act and recalled, as these can be managed as universal waste under 40 CFR part 273. Finally, while EPA is not applying RCRA regulations in these situations, we note that if recalled nonprescription pharmaceuticals and other unsold retail items are not managed and stored in a manner that prevents release to the environment, they may be considered a solid waste and a hazardous waste under sections 3007, 3013, and 7003 of RCRA.

f. *Unsold retail items that are broken, damaged, or leaking.* The sixth issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking. In recent years, EPA took multiple enforcement actions against national retailers for sending hazardous waste, in the form of broken and/or leaking items with hazardous contents, to unpermitted TSDFs (in the form of reverse distributors and reverse logistics centers), among other RCRA violations.[89] The resulting settlements specify that unsold retail items with broken and/or leaking packaging are waste at the retailer and, if they are hazardous, cannot be sent to a reverse distributor or reverse logistics center. CVS commented on the proposed rulemaking and asked that EPA clarify that when pharmaceutical packaging is in sufficiently poor condition that it is broken, leaking, or otherwise unable to be used for its intended purpose, that those pharmaceuticals become solid waste at the healthcare facility.[90] CVS noted that this is consistent with their current practice, whereby broken and leaking items are managed as waste at their facilities and are not sent through reverse distribution or reverse logistics.

Although EPA affirms the resulting settlements and agrees that nonprescription pharmaceuticals and other retail items cannot be sent through reverse logistics when they are broken, damaged, or leaking, the Agency is aware that there is inherent uncertainty

[84] See 15 U.S.C. 1471–1477 for the Poison Prevention Packaging Act.

[85] Public Law 114–116 (January 28, 2016).

[86] The CPSC has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation and schools. See *https://www.recalls.gov/cpsc.html* for more information.

[87] See 21 CFR 7.46(a)(8) and 21 CFR 7.45(b), respectively.

[88] See RCRA Online #14893 for the June 23, 2017 memo titled ''Recalled Takata Airbag Inflators.''

[89] Walmart Consent Agreement and Final Order, Docket Nos. RCRA–HQ–2013–4001 and FIFRA–HQ–2013–5056.

[90] See comment number EPA–HQ–RCRA–2007–0932–0312 in the docket.

surrounding when these items are considered broken, damaged, or leaking. For example, a nonprescription pharmaceutical could experience damage to the outer packaging while the inner container remains intact. For this final action, unsold retail items, including nonprescription pharmaceuticals, are not considered waste at the retail store if their packaging is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the materials to the environment,[91] and they are contained to prevent releases to the environment,[92] and they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed. Thus, the Agency intends that nonprescription pharmaceuticals and other unsold retail items can be sent to a reverse logistics center and are not considered wastes at the retail store if they meet this standard. For example, if an outer cardboard box containing vials of nonprescription pharmaceuticals is damaged, but the vials are intact and not damaged or leaking, EPA does not consider the item to be damaged such that it cannot go through reverse logistics.

In order to prevent exposures to personnel, the public, and the environment, if items are not in good condition, or are leaking or releasing to the environment, these items must be managed as wastes at the stores in accordance with the applicable hazardous waste regulations. Specifically, if the broken, damaged, or leaking item is a hazardous waste pharmaceutical, the retail store must manage it under the streamlined standards of part 266 subpart P (unless it is a VSQG for all its hazardous waste). Otherwise, the retail store would manage hazardous wastes under the applicable RCRA regulations, including part 262 generator regulations.

E. Applicability of the Household Hazardous Waste Exemption to Retail Items

One commenter suggested that the ''household hazardous waste'' exclusion at 40 CFR 261.4(b)(1) apply to retail items purchased by a customer and subsequently returned to the retailer.[93] The Agency has already addressed the issue of retail wastes as part of a previous rulemaking that responded to a petition from the American Retail Federation. As explained in a November 13, 1984, final rule[94], EPA excluded household hazardous waste because the legislative history of RCRA indicated an intent to exclude such wastes and not because these wastes can never pose the risks associated with hazardous wastes. Additionally, consistent with legislative history, when evaluating the American Retail Federation's petition, EPA determined that it was necessary to establish two criteria that must be met to qualify for this exclusion. First, the waste must be generated by individuals on the premises of a temporary or permanent residence and, second, the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. In this final rule, EPA denied the American Retail Federation's petition to exempt consumer household hazardous waste generated by retail sources because these wastes fail to meet both criteria. The Agency reaffirmed this position in the Retail Strategy, arguing that retail goods, including those that could become wastes when discarded, do not satisfy the criteria for this exclusion.

The Agency believes that this interpretation extends to retail items purchased by a customer and subsequently returned to a retail store. Hazardous waste generated at retail stores, including retail items purchased by a customer that are subsequently returned, does not meet the first criterion for the household hazardous waste exemption. Specifically, the decision to discard does not occur at the residence, it occurs at the retail store. In fact, many retail items that are returned are restocked and sold at the store (*e.g.* lawfully redistributed for their intended purpose) and are not solid wastes.

On the other hand, the Agency notes that a household pharmaceutical that is collected from individuals by a healthcare facility (*e.g.,* retail store) as part of a DEA pharmaceutical take-back program maintains the household hazardous waste exemption as long as it is not sewered, and is destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the types of combustors identified in § 266.506(b). For more discussion on DEA take-backs of household pharmaceuticals, please see section XIV of this preamble.

VII. Scope of the Final Rule

A. What facilities are subject to the final rule?

This final rule is a sector-based rule that applies to the management of hazardous waste pharmaceuticals that are generated and managed by healthcare facilities and reverse distributors. Subsequent sections of the preamble will discuss in detail the definitions of these terms, as well as what provisions of the rule apply to each type of facility (see section VIII for a discussion of each definition and section IX for Applicability). Healthcare facilities and reverse distributors will use the regulations finalized under 40 CFR part 266 subpart P in lieu of the RCRA generator regulations in 40 CFR part 262 to which they were previously subject.

B. What facilities are not subject to the final rule?

1. Pharmaceutical Manufacturers

Part 266 subpart P does not apply to the management of hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers. A pharmaceutical manufacturer remains subject to part 262 and all applicable RCRA subtitle C regulations for the management of its hazardous waste, including its hazardous waste pharmaceuticals. Pharmaceutical manufacturers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals in accordance with the federal RCRA subtitle C regulations (for an explanation of the challenges healthcare facilities face, see discussion in section III of the preamble). The types of hazardous waste pharmaceuticals generated by manufacturers are less variable and therefore more predictable, and the staff have the necessary expertise to determine which pharmaceutical waste is hazardous waste. However, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a reverse distributor, it would be subject to the final regulations for reverse distributors with respect to those operations.

2. Households

The Agency emphasizes that the regulatory requirements in this final rule do not apply to households that discard pharmaceuticals. Pharmaceuticals that are discarded by households are not regulated as hazardous waste and are generally considered municipal solid waste. While a small percentage of these

[91] As defined in § 260.10, unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures.

[92] These conditions are derived from the definition of contained as defined in § 260.10.

[93] See comment number EPA–HQ–RCRA–2007–0932–0277 in the docket for this rulemaking.

[94] See 49 FR 44978; November 13, 1984.

household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households.[95] Thus household hazardous waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

Despite the fact that household hazardous wastes are not regulated as hazardous wastes, it is important to note that ''EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though *not* because they necessarily pose no hazard.'' [96] Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a household hazardous waste collection program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous waste as hazardous waste, even though it is not required by RCRA.[97]

Similarly, the Agency recommends that, whenever possible, households utilize pharmaceutical collection events as the preferred disposal option for their unwanted pharmaceuticals.[98] For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash.[99]

In a 2012 memo, the Agency recommended that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[100] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the non-retrievable standard of destruction required by DEA for controlled substances collected from consumers (''ultimate users,'' as DEA refers to them). The Agency included this recommendation as a requirement for household waste pharmaceuticals that have been collected (see § 266.506).[101] See section XIV of this preamble for a detailed discussion of this provision.

3. Farmers, Ranchers and Fisheries

This final rule is a sector-specific rulemaking that applies to healthcare facilities and reverse distributors. As such, this final rule does not apply other generators of hazardous waste pharmaceuticals such as farmers, ranchers, and fisheries. Although these businesses might administer pharmaceuticals to their animals in the regular course of their business, they would not fall within the definition of a healthcare facility or a reverse distributor. The Agency designed this final rule to address the unique needs of the healthcare sector and concluded that it would not be appropriate to apply it to all sectors that generate hazardous waste pharmaceuticals. Other generators of hazardous waste pharmaceuticals, such as farmers, ranchers and fisheries, remain subject to the part 262 generator regulations. As discussed in detail in section VIII of this preamble, the definition of healthcare facility does include veterinary clinics and veterinary hospitals.

4. RCRA-Permitted or Interim Status Treatment, Storage and Disposal Facilities

This final rule does not affect how RCRA-permitted or interim status TSDFs manage hazardous waste pharmaceuticals at their facilities, except indirectly when they treat hazardous waste pharmaceuticals to meet the land disposal restrictions (LDRs). See section X.H. of this preamble for additional detail.

C. Scope of Hazardous Wastes Addressed by This Final Rule

1. Hazardous Waste Pharmaceuticals

These final regulations pertain only to those pharmaceutical wastes that are RCRA hazardous wastes that are generated by healthcare facilities or managed by reverse distributors. Under this rulemaking, EPA has not added additional pharmaceuticals to the hazardous waste listings or expanded the hazardous waste characteristics to include additional pharmaceuticals. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would be a separate action taken by the Agency in the future and is not part of this final rulemaking.

2. Related Federal or State Regulations

The generation, accumulation, transportation, treatment, storage, and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA) and pharmaceuticals that are hazardous waste as defined in 40 CFR 261.3 that are subject to OSHA's Hazardous Waste Operations and Emergency Response standard. These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this final rule on various dually regulated hazardous waste pharmaceuticals.

a. *Controlled substances.* Under prior regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a DEA controlled substance listed in Schedule II–V[102] had to comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. DEA regulations from 2014 to implement the Secure and Responsible Drug Disposal Act of 2010 require that

[95] See the household waste exclusion at § 261.4(b)(1), which is often referred to as the household hazardous waste or HHW exclusion.

[96] See 49 FR 44978; November 13, 1984.

[97] See memo November 1, 1988, from Porter to Regions (RCRA Online #11377).

[98] For pharmaceuticals, these collection events are often referred to as pharmaceutical take-back events. As used in this preamble, a take-back event refers to one-day collection events, such as the DEA bi-annual pharmaceutical take back days, while a take-back program refers to an ongoing collection program, such as a DEA-approved collection receptacle at a retail store.

[99] For more information on the safe disposal of household waste pharmaceuticals, please see: *http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[100] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833).

[101] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[102] See 21 CFR part 1308 for a complete list of controlled substances.

controlled substances be destroyed so that they are ''non-retrievable.'' [103] In the preamble to both the proposed and final DEA rules, DEA stated that flushing alone will not meet DEA's new non-retrievable standard.[104] Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is finalizing a conditional exemption from the RCRA regulatory requirements for the handful of pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance. That is, this final rule eliminates the dual regulation for RCRA hazardous waste pharmaceuticals that are also DEA controlled substances. A more detailed discussion of this conditional exemption is found in section XIV of this final rule.

b. *Medical wastes.* There are instances when a hazardous waste pharmaceutical will also pose a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as ''dual wastes,'' and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste TSDF that is also permitted by their state to accept medical wastes. Some examples of dual wastes include partially administered syringes containing hazardous waste pharmaceuticals (*e.g.,* physostigmine) or intravenous (IV) bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste pharmaceutical component of these dual wastes are included within these final subpart P management standards so that healthcare facilities can obtain the benefits of this new subpart, while ensuring the hazardous waste component of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. Healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving alone is not an acceptable method of treating hazardous wastes (pharmaceutical or non-pharmaceutical) that are also medical waste. In addition, as discussed in section XV of this preamble, EPA is exempting from RCRA regulation the residues of hazardous waste pharmaceuticals remaining in empty (*i.e.,* fully administered) syringes.

c. *Hazardous waste pharmaceuticals with a radioactive component.* Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (which are often referred to as ''mixed waste'') are also regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA Subtitle C programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA.[105] Healthcare facilities can use this final rule to meet the obligation of complying with the RCRA Subtitle C hazardous waste regulations for hazardous waste pharmaceuticals while also complying with the appropriate AEA regulations. Although we do not believe that anything in this subpart is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations.[106] Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); the healthcare facility would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

d. *Clean Air Act.* The combustion of hazardous waste pharmaceuticals is subject to both RCRA and to § 112 of the Clean Air Act. In general, the Clean Air Act protects human health and the environment from the harmful effects of air pollution by requiring reductions in the emissions of air pollutants. These pollutants, which are known or suspected to cause serious health problems, such as cancer or birth defects, are referred to as hazardous air pollutants (HAPs) and include several metals that are found in pharmaceuticals, such as selenium, mercury, and chromium compounds. Under § 112 of the Clean Air Act, EPA is required to list categories of major and area sources of HAPs; EPA has listed Hazardous Waste Combustors as one of these categories.

EPA is also required to establish National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the control of HAP emissions from listed sources. The NESHAPs are to reflect the maximum degree of reduction in emissions of HAPs that is achievable. This is known as ''maximum achievable control technology'' (MACT) and is based on emission levels that are achieved by the best-performing sources within a source category. On October 12, 2005, EPA promulgated NESHAP for Hazardous Waste Combustors that set MACT standards for HAPs from this source category.[107] The owner or operator of a hazardous waste combustor is required to comply with specific emission standards that control HAPs to levels that reflect MACT. These standards vary based on the type of hazardous waste combustion source (*e.g.,* incinerator, cement kiln, boiler), and in some instances based on the amount of HAPs that are emitted by the facility (*e.g.,* boilers that are area sources can elect to comply with fewer HAP emission standards). Generally speaking; however, hazardous waste combustors are required to comply with emission standards for chlorinated dioxins and furans, mercury, lead, cadmium, arsenic, beryllium, chromium, hydrochloric acid/chlorine gas, as well as particulate matter as a surrogate to control five additional metals, and carbon monoxide, hydrocarbon, and destruction removal efficiency as surrogates to control nondioxin/furan organic HAPs.

Hazardous waste combustors may be subject to more stringent emission limitations issued under the RCRA omnibus authority provisions (§ 3005(c)(3)). This is usually where site-specific circumstances indicate that a MACT standard is not protective of health and the environment. In other words, some hazardous waste combustors also have a RCRA permit

[103] Final rule: September 9, 2014; 79 FR 53520.

[104] Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548).

[105] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[106] 62 FR 62079, 62085; November 20, 1997.

[107] 70 FR 59402; October 12, 2005.

limit that further reduces emissions of certain HAPs (*e.g.,* mercury) beyond that which is required by the Clean Air Act MACT standard.

The combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act and implementing regulations. These regulations established emission limits for nine substances or mixtures (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium, as well as opacity where appropriate) from several categories incineration units, including: municipal waste combustors (MWCs); hospital, medical and infectious waste incinerators (HMIWIs); commercial and industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs). The emission limits are based on the application of MACT and reflect the emission levels achieved by the best performers in each category.

3. Drug Supply Chain Security Act

On November 27, 2013, the Drug Quality and Security Act was signed into law, amending the Federal Food, Drug and Cosmetic Act (FD&C Act).[108] The Drug Quality and Security Act consists of two titles: Title I is known as the Compounding Quality Act and Title II is known as the Drug Supply Chain Security Act (DSCSA). The FDA was given the responsibility of developing the implementing regulations for both titles of the Drug Quality and Security Act. In a summary of the DSCSA written by the Congressional Research Service, a nonpartisan division of the Library of Congress, it states that the Act ''Establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain.'' [109] Prior to enactment of this federal law, several states had passed similar laws to ensure the pedigree of the drug supply chain. Because each state law was slightly different, it made compliance difficult for companies operating in multiple states. As a result, Congress amended the FD&C Act to add § 585, entitled Uniform National Policy, which moots the pedigree laws already in effect (to the extent they are inconsistent with the DSCSA) and prevents states (and others) from enacting inconsistent pedigree laws in the future. This section, which was added by the DSCSA, includes sub-sections that are sometimes referred to as ''preemption clauses.'' [110]

Since the DSCSA was signed into law, some have argued to EPA and RCRA-authorized states that § 585 of the FD&C Act (as amended by the DSCSA) preempts all state hazardous waste regulatory authority as it may relate to the documentation of the disposition of hazardous waste pharmaceuticals. EPA disagrees with this interpretation of the DSCSA. Section 585 specifically avoids preempting state requirements, such as RCRA hazardous waste laws, that are unrelated to the tracing of products within the prescription drug distribution supply chain and other issues expressly addressed by the DSCSA. As stated in § 585(c), ''Nothing in this section shall be construed to preempt State Requirements related to the distribution of prescription drugs *if such requirements are not related to product tracing* as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under § 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder)'' (emphasis added).

This provision makes clear that § 585 applies only to state requirements related to distribution of prescription drugs and only to the extent that these requirements are related to product tracing or other issues specifically addressed by the DSCSA, such as licensure. Thus, as EPA interprets § 585, it would not apply to state requirements related to documentation of RCRA hazardous waste management activities, including disposal, because those activities are distinct and unrelated to the product tracing and other requirements of the DSCSA.

And indeed, in EPA's consultation with FDA on this issue, FDA agreed with EPA's conclusion that § 585 does not preempt state hazardous waste regulations related to the documentation of the management of hazardous waste pharmaceuticals. EPA's position is based upon our review of both the direct language and intent of the statute.[111]

To understand the connection between state hazardous waste regulations and the DSCSA, it is important to understand the relationship between the federal and state hazardous waste regulations. The federal RCRA program is implemented by state RCRA programs that are authorized by EPA under RCRA section 3006, 42 U.S.C. 6926. Authorized state hazardous waste regulations must, at a minimum, be equivalent to federal RCRA hazardous waste regulations. Under RCRA, EPA authorizes state hazardous waste programs to operate in lieu of the federal hazardous waste program.[112] Authorized state requirements are federally enforceable as requirements under RCRA Subtitle C.

Nothing in the DSCSA indicates that Congress intended to impliedly repeal federal RCRA requirements. Such an implied repeal would leave gaps in RCRA coverage and result in no hazardous waste regulations of any kind—federal or state—applying to the documentation of the management of hazardous waste pharmaceuticals. Given that (i) there is no indication of Congressional intent to repeal hazardous waste documentation regulations via the DSCSA (indeed, there is no mention of hazardous waste in the DSCSA at all), and (ii) § 585(c) of the FD&C Act, as added by the DSCSA, expressly notes the limits of the statute's preemptive effect, we believe it is clear that Congress did not intend to impliedly repeal RCRA authorized state hazardous waste requirements as they apply to the documentation of the management, including disposal, of hazardous waste pharmaceuticals. The general rule enunciated by the U.S. Supreme Court is that ''when two [federal] statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'' [113] Here, both RCRA and the DSCSA coexist easily, because neither the language nor the purpose of the DSCSA is in conflict with RCRA.

In addition, some commenters have argued that, in the case of nonsaleable pharmaceutical products, DSCSA requirements preempt RCRA requirements and that nonsaleable pharmaceutical products are regulated exclusively by the FDA pursuant to the provisions of the DSCSA.[114] Commenters have also argued that under the DSCSA, nonsaleable pharmaceutical products that are sent from wholesale distributors, dispensers, and repackagers as nonsaleable may be sent to a returns processor reverse

[108] Public Law 113–54.

[109] *https://www.congress.gov/bill/113th-congress/house-bill/3204/summary/49;* accessed September 13, 2017.

[110] See sections 585(a) and 585(b)(1) of the FD&C Act, as amended by the DSCSA.

[111] For a more thorough legal analysis of this issue, see EPA's letter to the Minnesota Pollution Control Agency, dated April 9, 2015, in the docket for this rulemaking EPA–HQ–RCRA–2007–0932. EPA consulted with FDA in the development of this letter and FDA agrees with the analysis and conclusions set forth in the letter.

[112] RCRA section 3006(b), 42 U.S.C. 6926(b).

[113] Morton v. Macari, 417 U.S. 535, 551(1974).

[114] The DSCSA uses the term ''drug product.''

logistics provider for handling as products. These commenters believed that, at a minimum, the mere fact that a pharmaceutical product becomes nonsaleable does not mean that such pharmaceutical product is now a solid waste under the RCRA hazardous waste regulations.

EPA does not agree with these comments. The preemption provisions added to the FD&C Act by the DSCSA—both § 585(a) and § 585(b)—only apply to the protection of the drug supply chain and do not apply to waste management requirements under RCRA.[115] Under RCRA, EPA regulates pharmaceuticals differently than FDA does under the DSCSA since the goals of the statutes serve different purposes. The purpose of the DSCSA is to protect the security, pedigree, and quality of pharmaceutical products in the drug supply chain. One of the many purposes of RCRA is to ensure that any waste that is generated is ''treated, stored or disposed of so as to minimize the present and future threat to human health and the environment.'' [116] In addition, we note that the DSCSA applies only to prescription drug products (not to OTC drug products), so there can be no conflict between DSCSA and RCRA for nonsaleable OTC drug products.

As explained in further detail throughout this preamble, whether a pharmaceutical has monetary value (such as when it receives manufacturer credit) is not determinative of whether it is a waste under RCRA. Under RCRA, one considers whether a material is discarded—and not whether it receives credit, or holds value or no value—to determine whether it is waste. Thus, prescription pharmaceuticals that are sent by healthcare facilities to reverse distributors and that will be discarded (even if these pharmaceuticals receive credit) will first be considered wastes at the healthcare facility when the decision is made by the healthcare facility to send them to a reverse distributor.

Furthermore, EPA disagrees with commenters that a nonsaleable pharmaceutical product sent to reverse distributors should not be considered a waste. Nonsaleable pharmaceutical products sent to reverse distributors are not sent for reuse or donation, but are sent for disposal, and thus would be considered wastes at the healthcare facility. In its comments to the FDA on the Draft Guidance for Industry, Identifying Trading Partners Under the Drug Supply Chain Security Act,[117] an industry trade association appears to confirm this point when it says, ''Most fundamentally, returns processors are unlike the trading partners described in the DSCSA. Trading partners are dedicated to moving products forward for dispensing and administration to patients. Returns processors' activities come at the end, when the product is no longer retained for distribution or dispensing and is safely removed from the supply chain.''[118] The commenter goes on to say that ''the assumptions that product is being distributed for further use, rather than only for credit assessment and/or disposition'' do not appear to apply to returns processors (known as reverse distributors in this final rule.[119] Similarly, a reverse distributor also submitted comments to the FDA on the same draft guidance, stating that ''once these products reach the returns processors for creditability assessment and final disposition management, they are forever removed from commerce.'' [120] Furthermore, during a site visit to a large reverse distributor, EPA was told that none of the pharmaceuticals on site would be donated or redistributed or otherwise returned to commerce.[121] After they are evaluated for manufacturer credit, the pharmaceuticals are sent for incineration. Under § 261.2(b)(3) of the RCRA regulations, ''Materials are solid waste if they are abandoned by being . . . Accumulated, stored, or treated (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated.'' The pharmaceuticals at reverse distributors are being accumulated prior to being incinerated and therefore are solid wastes. Additionally, in a 2013 memo EPA includes a series of questions to help determine whether a commercial chemical product is a solid and hazardous waste. One set of questions relates to whether the facility appears to be selling into commerce the material being evaluated. If the facility has no customers or market for the material, it can be an indication that the material is a solid waste.[122]

As explained elsewhere in the preamble, EPA distinguishes between reverse distributors (as defined in this rule) and reverse logistics centers. Reverse distributors do not reuse or donate, but in fact, dispose of the pharmaceuticals they receive. In sum, what DSCSA would consider to be a nonsaleable product is still considered to be a solid waste under RCRA when it is discarded according to the RCRA regulations, and the DSCSA does not preclude pharmaceuticals from being waste under RCRA.

EPA notes that many of the implementing regulations for the DSCSA are still under development by the FDA and the FDA has announced that it is delaying enforcement of certain requirements.[123] Section 584(d) of the FD&C Act, as added by the DSCSA, directs the FDA to issue licensing regulations for third party logistics providers (3PLs) within two years of the date of enactment of the DSCSA.[124] Draft FDA guidance issued in August 2017 indicates that FDA plans to consider a returns processor or reverse logistics provider to be a type of 3PL.[125] However, FDA has not yet finalized this guidance or issued proposed or final regulations for licensing 3PLs. The listing for the relevant regulation in the most recent version of the public list of planned federal rulemaking (the Unified Agenda of Regulatory and Deregulatory Actions, or ''Unified Agenda'') indicates that FDA plans to issue a *proposed* DSCSA licensing regulation within the next year.[126]

Furthermore, since 3PLs, such as reverse logistics providers, do not take ownership of the drugs that they manage at their facilities, the DSCSA requirements related to tracing drugs

[115] Section 585(a) of the DSCSA contains a preemption provision for state requirements for tracing drug products through the distribution system. Section 585(b) of the DSCSA contains a preemption provision for state requirements for wholesale prescription drug distributors and third-party logistics providers.

[116] See 42 U.S.C. 6902(b).

[117] August 2017, docket number FDA–2017–D–1956.

[118] See page 6 of comment FDA–2017–D–1956–0013.

[119] See page 7 of comment FDA–2017–D–1956–0013.

[120] See page 14 of comment FDA–2017–D–1956–0011.

[121] See notes from site visit to Med-Turn, October 10, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932. Med-Turn is a subsidiary of Inmar.

[122] See Section 3 of Attachment A of memo entitled Checklist to Assist in Evaluating Whether Commercial Chemical Products or Solid and Hazardous Waste Under the Resource Conservation and Recovery Act, May 14, 2013, Devlin to RCRA Division Directors, RCRA Online #14837.

[123] On June 30, 2017, FDA issued a draft guidance, Product Identifier Requirements Under the Drug Supply Chain Security Act—Compliance Policy. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.*

[124] The DSCSA was enacted on November 27, 2013; therefore, the 3PL licensing regulations were scheduled to be issued by FDA by November 27, 2015.

[125] August 2017, Identifying Trading Partners Under the Drug Supply Chain Security Act—Guidance for Industry. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572252.pdf.*

[126] See the Spring 2018 Unified Agenda, available at *https://www.reginfo.gov/public/do/eAgendaMain.*

through the supply chain, including transaction information (TI), transaction history (TH), and transaction statements (TS), do not apply to them. In the absence of relevant FDA regulations, it is difficult for EPA to consider the possibility of deferring to FDA for the regulation of reverse distributors, who we consider to be managing hazardous wastes. In the future, if there are duplicative regulations, EPA may need to revisit the regulation of reverse distributors after the FDA issues proposed and final licensing regulations for 3PLs in accordance with the DSCSA.

D. Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of This Final Rule

Wastes that are not included in the scope of this proposed rulemaking include non-hazardous wastes and non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

1. How should non-hazardous waste pharmaceuticals be disposed?

A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This final rule, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA Subtitle C hazardous waste regulations, including this final rule. However, a healthcare facility may choose to manage its non-hazardous and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under the new subpart P regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of hazardous waste pharmaceuticals generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility's hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals that are not managed under subpart P are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state, and/or local regulatory requirements. Moreover, some waste pharmaceuticals that do not qualify as ''hazardous wastes'' under RCRA can nonetheless be extraordinarily hazardous thus, extreme care may be warranted.[127] These are discussed below in section VII.D.1.a.

If a healthcare facility decides to segregate its hazardous and non-hazardous waste pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in ''Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States,'' (Blueprint) [128] an EPA guidance document for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C.

a. *Recommended best management practices for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities.* Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These ''non-RCRA-hazardous'' pharmaceuticals can be divided into two categories: Those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint's recommendation of hazardous waste incineration as the BMP for healthcare facilities and reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists,[129] chemotherapeutic agents characterized as bulk wastes,[130] pharmaceuticals which meet the hazardous drug criteria set by the National Institute for Occupational Safety and Health (NIOSH),[131] pharmaceuticals with LD50s ≤ 50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

b. *Recommended best management practices for other non-hazardous waste pharmaceuticals (not possessing hazardous waste-like qualities).* As far as other non-hazardous waste pharmaceuticals (*i.e.,* those not possessing hazardous waste-like qualities), disposing of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint's recommendation of municipal solid waste incineration or medical waste incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if medical waste autoclaves or municipal solid waste landfills are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, when wastewater is generated either by cleaning an autoclave, or during automatic blow down from autoclaves equipped with steam generators, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill leachate collected in municipal solid waste landfill leachate

[127] See, for example, *https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html* or NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016–161 (Supersedes 2014–138). *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*

[128] Practice Greenhealth, Revised August 2008. Published in 2006, the development of the original Blueprint was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the Blueprint was funded by the Healthcare Environmental Resource Center. *http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteblueprint.pdf.*

[129] As noted in the comment after § 261.33(d), the phrase ''commercial chemical product'' includes formulations in which the P- or U-listed chemical is the sole active ingredient. Therefore, formulations with more than one active ingredient do not meet the specifications of the P- and U-listings even if one, two or all of the active ingredients are listed on the P- and/or U-lists.

[130] The descriptions ''bulk'' and ''trace'' when applied to chemotherapeutic wastes are industry terms and are not defined by the federal RCRA regulations.

[131] See NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016–161 (Supersedes 2014–138). *https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.*

systems.[132] [133] Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See section XIII for more information regarding the prohibition on sewering hazardous waste pharmaceuticals).

2. How should non-pharmaceutical hazardous waste be disposed?

These newly promulgated subpart P regulations will pertain only to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities and reverse distributors that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with this new subpart (as previously discussed, non-hazardous waste pharmaceuticals may be managed under this new subpart). For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not considered hazardous waste pharmaceuticals and are not included within the scope of this final rule. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals. Also note that the 2016 Hazardous Waste Generator Improvements final rule added new flexibility for episodic generators of non-pharmaceutical hazardous waste under part 262 subpart L.

VIII. What terms are defined in this final rule? (§ 266.500)

A. Definition of Pharmaceutical

1. Summary of Proposal

EPA proposed to define ''pharmaceutical'' as any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition included, but was not limited to dietary supplements as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), prescription drugs, OTC drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals. This proposed definition of ''pharmaceutical'' was intended to include all dose forms, including, but not limited to, tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, IV or other compound solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical.

EPA relied on the FD&C Act's definition of ''drug'' to develop the proposed definition of ''pharmaceutical'' but expanded on the definition based on comments to the 2008 Universal Waste proposed rulemaking. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards applied broadly. Thus, the proposed definition of ''pharmaceutical'' did not exclude pharmaceuticals with a radioactive component and included items not specifically recognized by the FDA as drugs, such as dietary supplements, pharmaceutical residues in non-empty containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

2. Summary of Comments

The most frequent comment EPA received on the definition of ''pharmaceutical'' was on the inclusion of personal protective equipment and clean-up material in the definition of pharmaceutical. Many commenters argued that personal protective equipment and clean-up material should not be included in the final definition. One commenter suggested that loose tablets be included in the definition of pharmaceutical but that personal protective equipment should not be included. Waste Management National Services, Inc. suggested that only ''overtly contaminated'' personal protective equipment or clean-up materials be included in the definition, but not personal protective equipment and clean-up materials with trace contamination.[134] Two commenters asked EPA to clarify which personal protective equipment is included in the definition of ''pharmaceutical.''

One state expressed concern that EPA proposed to take a broad view in delineating what items are included in the definition of ''pharmaceutical.'' The New Jersey Department of Environmental Protection pointed out that although ''sharps'' did not meet the proposed definition of ''pharmaceutical'' that IV bags, tubing and syringes that come in contact with blood or pathogens could fall under the definition of ''pharmaceutical.'' They asked that EPA exclude these items from the definition.[135]

EPA requested comment on the Agency's decision to include dietary supplements in the definition of ''pharmaceutical'' under the final rule. Four states and one industry association supported the Agency's proposal to include dietary supplements under the definition of ''pharmaceutical.'' One state and five industry associations did not support including dietary supplements in the definition of ''pharmaceutical.'' Multiple commenters requested that EPA only include dietary supplements that are regulated as drugs and exclude supplements regulated as foods.

EPA requested comment on the possibility of including low-concentration nicotine products, such as electronic nicotine delivery systems (e-cigarettes), in the definition of ''pharmaceuticals'' under the final rule. EPA received multiple comments on whether to include e-cigarettes and liquid nicotine (e-liquids) in the final definition. Hawaii State Department of Health and the Hematology/Oncology Pharmacy Association did not support including e-cigarettes or e-liquids in the final definition of ''pharmaceutical.'' [136] RILA requested that EPA exempt all low-concentration nicotine products from the P075 listing, including e-cigarettes and e-liquids, but agreed that if EPA did not exempt these products from the P075 listing, that e-cigarette products should fall under the definition of ''pharmaceutical.'' [137]

The American Dental Association asked that EPA specifically exclude

[132] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126

[133] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, V82.6:635–659.

[134] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[135] See comment number 0235 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[136] See comment numbers 0238 and 0264 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[137] See comment number 0295 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

dental amalgam from the final definition of ''pharmaceutical.'' [138]

Multiple commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use (*e.g.,* isopropyl alcohol is used to clean wounds and to clean instruments and surfaces). [139] Commenters asked EPA to clarify that they are regulated differently.

Stericycle, Inc. requested that investigational or research drugs be considered pharmaceuticals because they are difficult to characterize.[140]

3. Final Rule Provisions

In this final rule, ''pharmaceutical'' means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (*e.g.,* electronic cigarette or vaping pen), or any liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems (*e.g.,* pre-filled cartridges or vials). This definition includes, but is not limited to dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); OTC drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

The final definition of pharmaceutical includes both prescription drugs, as defined by 21 CFR 203.3(y) and OTC drugs. As previously mentioned, commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use.[141] If an OTC product is required by the FDA to include ''Drug Facts'' on the label, it would be considered a pharmaceutical for the purposes of this rule.[142] In rare cases, some items that are OTC pharmaceuticals may not be labeled appropriately with a ''Drug Facts'' label. It is the Agency's understanding, however, that all OTC drugs must contain a Drug Facts label. Therefore, if an item meets the criteria to be considered a pharmaceutical under subpart P but is not labeled with Drug Facts, it should still be managed as a pharmaceutical. Any non-pharmaceutical hazardous wastes must be managed pursuant to all other applicable RCRA regulations. The final definition of ''pharmaceutical'' also includes any pharmaceutical residuals remaining in non-empty containers, such as the pharmaceutical residuals remaining in dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devises, such as syringes and patches. However, the final definition does not include sharps (*e.g.,* needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the final definition of pharmaceutical because sharps are considered medical wastes, presently regulated at both the state and local level. Further, as discussed in section XV of this preamble, EPA is finalizing regulations for when pharmaceutical containers are considered empty.

The final definition of ''pharmaceutical'' also includes items contaminated with or containing pharmaceuticals, such as personal protective equipment contaminated with pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings). EPA's decision to include contaminated personal protective equipment under the definition of ''pharmaceutical'' reflects the Agency's interest in promoting a similar management scheme for the personal protective equipment containing pharmaceuticals and other types of pharmaceuticals. Only personal protective equipment that is already considered hazardous waste under the ''contained in'' policy because it is contaminated with pharmaceuticals will fall under the definition of pharmaceutical.[143] These items are included in the definition so that facilities can manage more types of hazardous waste commonly found in healthcare settings under the same standards. For example, the contained in policy would not apply to gloves that have touched a warfarin pill during the course of patient care. However, if a healthcare worker spills a hazardous waste pharmaceutical on their personal protective equipment and it cannot be removed from the personal protective equipment, the personal protective equipment would be considered a hazardous waste pharmaceutical. If the personal protective equipment only has trace amounts of contamination it would not be considered a hazardous waste and therefore not be considered a hazardous waste pharmaceutical.

The final definition of ''pharmaceutical'' includes dietary supplements for the same reason—in order to promote a consistent management scheme for similar waste streams. Dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.[144] Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements. When EPA uses the term ''dietary supplements'' in the definition of ''pharmaceutical,'' EPA is referencing the definition for dietary supplement used by the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321 (ff)).[145] If a dietary supplement is required by the FDA to include a ''Supplement Facts'' panel on the label, it would be considered a pharmaceutical for the purposes of this rule.[146] The FD&C Act categorizes dietary ingredients and dietary supplements under the general umbrella of foods and therefore does not review them before being marketed. In fact, several commenters suggested that because the FD&C Act does not regulate supplements as drugs, EPA does not have the authority to regulate them as pharmaceuticals under RCRA. EPA disagrees with the commenters, noting that any waste that is listed or exhibits a characteristic is regulated as a hazardous waste when discarded, including supplements. This final rule does not newly apply RCRA to the disposal of supplements that meet the definition of hazardous waste, as some commenters suggest; it changes which regulations apply when discarding supplements that are hazardous waste. EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with drugs under the

[138] See comment number 0294 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[139] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[140] See comment number 0280 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[141] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[142] See 21 CFR 201.66

[143] See memo from Lowrance to Fields, January 3, 1989 (RCRA Online #11387).

[144] Including dietary supplements under the definition of ''pharmaceutical'' does not supersede the requirements of the Dietary Supplement Health and Education Act of 1994, the Federal Food, Drug and Cosmetic Act, or FDA regulations.

[145] The substance of the definition is: A Product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A): A vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); For the complete definition of dietary supplement, please see: *https://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapII.pdf.*

[146] See 21 CFR 101.36.

final regulation, and thus, is including it in the final definition of ''pharmaceutical.'' Although dietary supplements are considered pharmaceuticals under this definition, only the dietary supplements that meet the definition of hazardous waste (*e.g.,* exhibits the toxicity characteristic for metal content) would be regulated under part 266 subpart P as hazardous waste pharmaceuticals (see the definition of ''hazardous waste pharmaceutical'').

The final rule specifically excludes dental amalgam from the final definition of pharmaceutical. EPA promulgated new pretreatment standards in June 2017 to reduce discharges of mercury from dental offices into publicly owned treatment works.[147] If EPA included dental amalgam in the final definition of pharmaceutical, it would subject dentists to duplicative regulatory requirements.

The final definition of ''pharmaceutical'' includes electronic nicotine delivery systems and liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems. These items are included in the definition ''pharmaceutical'' so that facilities can manage more types of hazardous waste commonly found in healthcare settings under part 266 subpart P. The final definition of ''pharmaceutical'' applies to finished product electronic nicotine delivery systems, including components and parts, sealed in final packaging intended for consumer use (*e.g.,* electronic cigarettes and vaping pens) and e-liquid that is packaged for retail for use in the electronic nicotine delivery systems (*e.g.,* pre-filled cartridges and vials that are sold separately to consumers or as part of kits). EPA intends that e-liquid used by manufacturers of tobacco products (as defined by the FD&C Act) not be included in the final definition of ''pharmaceutical.'' [148] That is, a pre-filled e-liquid cartridge sealed in final packaging that is to be sold or distributed to a consumer for use is included in the definition, but in contrast, an e-liquid that is sold or distributed for further manufacturing, mixing, or packaging into a finished electronic nicotine delivery system is not included.[149] EPA believes that finished products sealed in packaging intended for consumer use pose a lower risk for leaks and other releases to the environment than e-liquid that is sold or distributed for further manufacturing. E-liquid that is packaged for retail for use in electronic nicotine delivery systems, such as e-liquid that is in pre-filled cartridges and vials, is typically sold at lower concentrations and smaller quantities than e-liquid that is sold or distributed for further manufacturing.

The final definition of ''pharmaceutical'' includes investigational drugs. One commenter asked EPA to include investigational drugs in the definition because these drugs are difficult to characterize. The investigational drugs might have proprietary ingredients that the manufacturer might not be willing to divulge during trials. The final definition includes investigational drugs in order to provide clarity on how to manage these items when discarded. See section IX.B.2.e regarding the applicability of subpart P to discarded investigational drugs.

B. Definition of Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define ''hazardous waste pharmaceutical'' as a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261 subpart D, or exhibits one or more characteristics identified in part 261 subpart C. The Agency proposed to define the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals that meet the definition of hazardous waste when disposed or discarded need to be managed under the new subpart P management standards.

2. Summary of Comments

EPA requested comment on the proposed definition of ''hazardous waste pharmaceutical'' and specifically on whether any dietary supplements currently on the market meet or could potentially meet RCRA's definition of hazardous waste.

The New Mexico Environment Department requested that EPA broaden the definition of ''hazardous waste pharmaceutical'' to include antineoplastic agents. The New Mexico Environment Department argued that EPA has not updated the P- and U-hazardous waste lists even though new pharmaceuticals have been developed that should be considered hazardous waste.[150] Public Employees for Environmental Responsibility also argued that the definition of ''hazardous waste pharmaceutical'' is too narrow because not enough pharmaceuticals meet the definition.[151] American Pharmacists Association expressed concern that the definition is difficult to understand because the P- and U-hazardous waste lists are not comprehensive.[152]

Waste Management National Services Inc., supported the proposed definition of ''hazardous waste pharmaceutical'' and pointed out that there are dietary supplements on the market that meet the RCRA definition of hazardous waste because the supplements contain selenium or chromium.[153]

3. Final Rule Provisions and Response to Comments

In this final rule, ''hazardous waste pharmaceutical'' means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C, or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An OTC pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

The Agency is including in the final definition of ''hazardous waste pharmaceutical'' that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical if it is lawfully donated. The Agency included this language to clarify that pharmaceuticals are not solid waste if they are donated for use (see section IX.B for more discussion).

The Agency is defining the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals (as defined in this final rule) that are hazardous waste when disposed or discarded need to be managed under the final subpart P management standards. For example, warfarin (brand name Coumadin) is a listed hazardous waste and when discarded meets the definition of hazardous waste pharmaceutical. The Agency notes that hazardous waste pharmaceuticals are hazardous wastes; more specifically, they are a subset of

[147] 82 FR 27154; June 14, 2017.

[148] 26 U.S.C. 5702 (d)

[149] This distinction is adapted from the term ''finished tobacco product'' used by FDA in its regulations for e-cigarettes, cigars, and all other tobacco products. 81 FR 28973; May 10, 2016.

[150] See comment number 0211 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[151] See comment number 0247 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[152] See comment number 0321 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[153] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

hazardous waste. The term hazardous waste is defined in § 260.10 as ''a hazardous waste as defined in § 261.3.'' Therefore, even though we do not reference § 261.3 in the definition of hazardous waste pharmaceutical, a hazardous waste pharmaceutical is also hazardous waste as defined in § 261.3. This is relevant to the OSHA Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120), which apply to hazardous wastes, as defined by § 261.3. This final rule does not impact the applicability of the OSHA Hazardous Waste Operations and Emergency Response standards.

Multiple commenters suggested that the proposed definition of ''hazardous waste pharmaceutical'' was too narrow because the P- and U-hazardous waste lists have not been updated even though new pharmaceuticals have been developed. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would have to be a separate action taken by the Agency in the future and is not part of this final rulemaking. Therefore, these comments are considered to be out of the scope of this final action and we do not plan to address them at this time. That said, we do anticipate that because subpart P lowers regulatory barriers to over-managing non-hazardous waste pharmaceuticals, some healthcare facilities will choose to over-manage non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals even if they do not meet a current listing or exhibit a hazardous waste characteristic.

C. Definition of Reverse Distributor [154]

1. Summary of Proposal

EPA proposed to define reverse distributor as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. EPA proposed that any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer credit would be considered a reverse distributor. Pharmaceutical manufacturers often offer credit to healthcare facilities for unused and/or expired pharmaceuticals.[155] Manufacturers issue credit for a variety of reasons: it can be a marketing incentive tool, it helps protect against illicit diversion [156] or improper disposal, and it allows manufacturers to collect data on the returned items, which then can be used to help plan for future pharmaceutical production. Reverse distributors contract with both manufacturers and healthcare facilities to act as an intermediary to facilitate the crediting process.

EPA proposed new standards for shipping potentially creditable hazardous waste pharmaceuticals to reverse distributors and management standards of potentially creditable hazardous waste pharmaceuticals by reverse distributors. Thus, EPA proposed to define ''reverse distributor'' to clearly delineate which types of facilities were subject to the proposed rulemaking. The agency solicited public comment on its proposed definition of ''reverse distributor.'' Specifically, EPA asked for comment on whether the definition of ''reverse distributor'' captures the universe of facilities acting as reverse distributors for pharmaceuticals.

2. Summary of Comments

Commenters requested that EPA clarify who would be considered a reverse distributor and what the functions of a reverse distributor are. States and industry, including manufacturers, wholesalers, and waste management companies, wanted to know if any facility that performed reverse distribution functions would be encompassed in this definition. Reverse distributors asked for clarification in how 3PLs fit into the definition of reverse distributor and whether all functions performed by their business would fall under the definition.

3. Final Rule Provision

Under the final rule, reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

In response to comments, EPA made two changes to the definition of ''reverse distributor'' for the final rule. First, EPA proposed to use the term ''pharmaceutical reverse distributor'' but the final rule uses the term ''reverse distributor.'' EPA dropped the word ''pharmaceutical'' from reverse distributor because the definition of pharmaceutical is overly broad given that it refers to both prescription and nonprescription pharmaceuticals. EPA received comments from stakeholders pointing out that in the terminology of the industry, reverse distributors receive prescription pharmaceuticals, while reverse logistics centers receive nonprescription pharmaceuticals and other unsold retail items. This distinction is useful to EPA in making the same distinction in these regulations and EPA has adopted it.

The second change EPA made was to add the word prescription to the definition to further clarify that the definition does not include reverse logistics centers that receive nonprescription pharmaceuticals or other unsold retail items that are evaluated for legitimate use/reuse or reclamation. EPA's definition of ''reverse distributor'' only includes prescription hazardous waste pharmaceuticals that are evaluated for credit and then disposed. EPA made this clarification to be consistent with the policy for the reverse logistics of nonprescription pharmaceuticals and other unsold retail items. See section VI of this preamble for discussion of the regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and the policy for the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals.

EPA incorporated the changes to the final definition of ''reverse distributor'' in response to the comments summarized below.

4. Comments and Responses

EPA received comments from states and industry, including manufacturers, wholesalers and waste management companies, asking for clarification on who would be considered a reverse distributor. For example, commenters asked whether wholesalers, forward distributors and 3PLs meet the definition of ''reverse distributor'' even if reverse distribution is only a part of their business. For example, a facility

[154] The proposed rule used the term ''pharmaceutical reverse distributor'' but the final rule uses the term ''reverse distributor.'' To avoid confusion, we use the term ''reverse distributor'' in this preamble, even when discussing the proposed rulemaking.

[155] As noted in the definition of ''potentially creditable hazardous waste pharmaceutical,'' manufacturers provide credit for those pharmaceuticals that are less than one year past the expiration date.

[156] Through the return of pharmaceuticals by a pharmacy for manufacturer credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

might act as a sorting and shipping facility or a pharmacy might act as a consolidation center but not evaluate for manufacturer credit. The definition of ''reverse distributor'' specifically states that any person, including forward distributors (*e.g.,* wholesalers), 3PLs, or pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. Any person that is performing the function of a reverse distributor, even if it is a small part of their business, would need to operate under the reverse distributor standards. If a facility is not processing any hazardous waste prescription pharmaceuticals for facilitating or verifying manufacturer credit, then it would not meet the definition of ''reverse distributor.''

The retail industry was especially concerned with need to differentiate between reverse distributors and reverse logistics centers. Reverse logistics centers that receive nonprescription pharmaceuticals (such as OTC pharmaceuticals) would not fall under this definition. Likewise, wholesale distributors receiving returns from their customers would not be considered reverse distributors. This is because wholesale distributors do not facilitate manufacturer credit. Further, according to comments received from Healthcare Distribution Management Association, in 2013, approximately 94% of the returns to wholesale distributors, were saleable.[157] [158] As saleable products, the pharmaceuticals returned to wholesale distributors would remain subject to the track and trace requirements of the DSCSA. Reverse logistics centers, which evaluate nonprescription pharmaceuticals for legitimate use/reuse and reclamation do not fit this definition.

EPA is also finalizing the definitions for potentially creditable and non-creditable hazardous waste pharmaceuticals (in parts D and E of this section) to differentiate between reverse distributors' function in evaluation of credit versus the traditional TSDF role in waste disposal. It is the Agency's intent that potentially creditable hazardous waste pharmaceuticals can be sent to reverse distributors for the determination of credit under subpart P. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as storage facilities or TSDFs for other hazardous waste.

Multiple state commenters asked EPA to clarify what is meant by ''facilitate.'' The facilitation of credit encompasses the role that reverse distributors serve between healthcare facilities and manufacturers. A reverse distributor receives potentially creditable hazardous waste pharmaceuticals for evaluation of manufacturer credit. Once the evaluation is complete and it is determined that credit can be given, reverse distributors will issue the manufacturer credit on behalf of the manufacturer to the healthcare facility.

Reverse distributors wanted to add all the other functions performed by reverse distributors to the regulatory definition to more fully define their role. EPA did not add reverse distributors' other functions to the definition of ''reverse distributor'' in the final rule. While a reverse distributor may continue to perform other lawful activities, they are not relevant for the purpose of defining a reverse distributor under this final rule. EPA's definition of reverse distribution focuses on issuing of manufacturer credit because although the pharmaceuticals are hazardous waste, they have value to the healthcare facility and the reverse distributor. Since these hazardous waste pharmaceuticals have value, there is a greater economic incentive to manage them with more care than typical hazardous waste. The final definition captures the handling of prescription hazardous waste pharmaceuticals that fall under RCRA and the rest of the functions can be regulated, as needed, under local, state and other federal regulations.

The waste management industry requested clarification on the intersection of DEA reverse distributors and RCRA reverse distributors and how a reverse distributor that receives a DEA controlled substance as a waste would determine if they are also subject to subpart P. A hazardous waste pharmaceutical that is also a DEA controlled substance is not subject to subpart P, provided they meet the terms of the conditional exemption in § 266.506. The conditional exemption for DEA controlled substances that are also RCRA hazardous waste is covered in section XIV of the preamble.

The Agency also wants to clarify the difference between what is defined as a reverse distributor under this final rule and how DEA regulations define ''reverse distribute.'' The recently amended DEA regulatory definition of ''reverse distribute'' is to ''acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) Destruction.'' [159]

Under DEA's definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer credit: Often a reverse distributor's main function under DEA's definition is to destroy the controlled substances. Under EPA's definition, however, a reverse distributor is defined as a facility that accepts potentially creditable pharmaceuticals for the purposes of evaluating manufacturer credit. These potentially creditable hazardous waste pharmaceuticals may or may not be identified as controlled substances by DEA.[160] Therefore, a DEA-registered reverse distributor may or may not meet EPA's definition of a reverse distributor and vice versa. For example, a reverse distributor that accepts DEA controlled substances that are also hazardous waste pharmaceuticals for the purpose of destruction (*e.g.,* incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF (or other regulated incinerator, depending on what other wastes it combusts), but not as a reverse distributor under part 266 subpart P. Conversely, a reverse distributor that processes pharmaceuticals for manufacturer credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the subpart P reverse distributor definition, but not DEA's reverse distributor definition. However, EPA has heard from stakeholders that most, if not all, entities that facilitate manufacturer credit are also DEA-registered reverse distributors. Therefore, such reverse distributors would meet both EPA's definition of reverse distributor and the DEA's definition of reverse distributor. Lastly, EPA's definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the DOT's Pipeline and Hazardous Materials Safety Administration has defined the closely related term, ''reverse logistics,'' in a

[157] Healthcare Distribution Management Association has since been renamed Healthcare Distribution Alliance.

[158] See comment #EPA–HQ–RCRA–2007–0932–0276.

[159] See 21 CFR 1300.01. On September 9, 2014, DEA finalized new definitions for ''reverse distribute'' and ''reverse distributor.'' Please see 79 FR 53520. The term ''reverse distributor'' is defined as ''a person registered with the Administration [DEA] as a reverse distributor.''

[160] In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

recent rulemaking.[161] EPA coordinated with the Pipeline and Hazardous Materials Safety Administration to ensure that our rules are compatible, even if the definitions differ. It is important to note that their final rule does not supersede EPA's RCRA Subtitle C regulations for solid or hazardous waste determinations or hazardous waste management.

D. Definition of Potentially Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that are sent by a healthcare facility to RCRA TSDFs from those hazardous waste pharmaceuticals that are sent by a healthcare facility to a reverse distributor for a determination or verification of manufacturer credit, the Agency proposed a definition for ''potentially creditable hazardous waste pharmaceutical.''

EPA proposed to define ''potentially creditable hazardous waste pharmaceutical'' to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is

(1) unused or un-administered; and

(2) unexpired or less than one year past expiration date.

The proposed term did not include evaluated hazardous waste pharmaceuticals, residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals. These pharmaceuticals are typically unopened and in their original packaging and include both generic and name brand pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer credit is determined solely by the manufacturer's return policy. Based on comments received for the 2008 Universal Waste proposed rulemaking and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, healthcare facilities are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: If the pharmaceutical has been removed from the original container and repackaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer credit. It is the Agency's intent for the proposed definition of ''potentially creditable hazardous waste pharmaceutical'' to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers' policies often allow for credit to be issued on the return of ''partials.'' ''Partials'' is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency considered partials to be potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

States, manufacturers and waste management companies commented that word changes to this definition would clarify which hazardous waste pharmaceuticals could or could not be returned to reverse distributors. Manufacturers, some states and healthcare facilities argued that all pharmaceuticals should go to reverse distributors to relieve the burden on healthcare facilities to make these individual determinations. Pharmacists and reverse distributors wanted further clarification on what distinguishes a potentially creditable hazardous waste pharmaceutical and how it relates to credit.

3. Final Rule Provision

In response to comments, EPA has made five changes to the definition of ''potentially creditable hazardous waste pharmaceutical'' from the proposal. First, the final definition specifically includes prescription pharmaceuticals only. Second, we added the phrase ''reasonable expectation'' to clarify that the healthcare facility does not have to definitively know whether something will receive manufacturer credit but rather indicates that they should have a reasonable expectation that it will. We also note that EPA could have proposed to use the term ''creditable hazardous waste pharmaceuticals,'' but chose to use the term ''potentially creditable hazardous waste pharmaceutical'' to convey the same concept (*i.e.,* that a healthcare facility does not have to definitively know whether a specific item will receive manufacturer credit.) Third, we replaced ''unadministered'' with the term ''undispensed'' to make clear that it is not just that a patient refused to take a prescription pharmaceutical, but rather that it was never dispensed to a patient at all. Fourth, we removed the word ''unused'' from the definition since the use of this term could introduce some confusion given that ''partials'' can get manufacturer credit. Fifth, we specified that the pharmaceuticals be in the ''original manufacturer's packaging'' since repackaged prescription pharmaceuticals are not typically eligible for credit.[162]

For the final rule, a potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer's packaging (except pharmaceuticals that were subject to recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, OTC drugs, homeopathic drugs, and dietary supplements.

4. Comments and Responses

a. Definitional Wording. EPA received many comments from states and industry on revising the definition to clarify which hazardous waste pharmaceuticals could and could not be returned to reverse distributors. States especially stressed that ''potentially creditable'' should be changed to ''reasonable expectation of credit'' or that EPA should define potentially creditable hazardous waste pharmaceuticals as those that are

[161] 79 FR 46748; August 11, 2014. The Pipeline and Hazardous Material Safety Administration's definition of reverse logistics ''is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.''

[162] See email correspondence from Nicole Wilkinson of CVS dated February 21, 2018 and Erica Burwell of Inmar dated February 22, 2018, both in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

accepted by reverse distributors for evaluation, as compared to those that are not. Manufacturers and states asked us to clarify whether we mean ''unadministered'' or ''undispensed'' or whether the term ''unopened'' should be added to the definition. The waste management industry had some concern that adding expiration dates to the definition might prevent potentially creditable hazardous waste pharmaceuticals from being returned to the reverse distributor.

In the final definition of potentially creditable hazardous waste pharmaceuticals, EPA has added some new phrases such as ''reasonable expectation of credit'' to the definition to be clear that not all hazardous waste pharmaceuticals should be going back to reverse distributors. We have also changed words like ''unadministered'' to ''undispensed'' since the expectation of credit ends once a pharmaceutical has been dispensed to a patient regardless of whether the patient takes the pharmaceutical and deleted ''unused'' since that could imply it has been dispensed but not used and/or that it was never opened.

We are specifically not adding the word ''unopened'' to the definition as some commenters had suggested, since it is EPA's understanding that ''partials'' can be given credit under certain circumstances and some pharmaceuticals may be repackaged. Although the definition does not include the word ''intact'' when describing original manufacturer's packaging, the definition of ''potentially creditable hazardous waste pharmaceutical'' does not include anything that is leaking or damaged.

Some commenters also argued that EPA was limiting manufacturers from changing policies by defining potentially creditable hazardous waste pharmaceuticals and giving examples of what those are. EPA recognizes that special circumstances may arise where a prescription hazardous waste pharmaceutical may be given credit but not fit squarely within this definition. We have added an example of this in our definition by noting that a recalled pharmaceutical may be given credit although it is not in original packaging. This definition is meant to give examples of what is commonly done and to aid healthcare facilities in being able to more easily identify a potentially creditable from a non-creditable hazardous waste pharmaceutical. It is not intended to prevent a manufacturer from changing its credit policies.

b. Evaluation of Hazardous Waste Pharmaceuticals and Credit. In their comments regarding potentially creditable hazardous waste pharmaceuticals received by reverse distributors, manufacturers and reverse distributors expressed concern about the burden being added to healthcare facilities by not allowing them to send all the hazardous waste pharmaceuticals together and putting the onus on them to determine if something is ''potentially creditable''. Healthcare facilities were concerned that credit policies are frequently updated by manufacturers and that a healthcare facility would not know if credit would be issued for any given pharmaceutical or not.

Commenters also addressed the question of a bright line as to what is and what is not potentially creditable hazardous waste pharmaceuticals. Commenters asked whether generics were considered ''potentially creditable.'' The waste management industry commenters asked how many times credit must be rejected before a type of pharmaceutical is no longer considered potentially creditable.

It is the Agency's intent in our definition of ''potentially creditable hazardous waste pharmaceutical'' to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of manufacturer credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for certain hazardous waste pharmaceuticals.

EPA recognizes that in some cases a healthcare facility may not know if the hazardous waste pharmaceuticals will be given credit. We do not want to deter healthcare facilities from sending their hazardous waste pharmaceuticals to a reverse distributor if there is a reasonable expectation of credit. Whether or not credit is actually given is not a defining factor and it is not within EPA's expertise to know how many times a potentially creditable hazardous waste pharmaceutical needs to be rejected before it is considered ''non-creditable.'' Each pharmaceutical is different and is or is not creditable for various reasons as dictated by the manufacturer. EPA has learned since the proposal that generic prescription drugs can have a reasonable expectation of receiving manufacturer credit. EPA also agrees with commenters that ''partials'' can be given credit.

EPA's intent is to prevent hazardous waste pharmaceuticals that are clearly ineligible for credit and are ready for disposal, due to their condition, previous use with a patient, or other reason, from being sent to the reverse distributor. Hazardous waste pharmaceuticals that are in original packaging and have not been dispensed to a patient would fit under this definition of ''potentially creditable hazardous waste pharmaceutical.''

E. Definition of Non-Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency proposed to define the term ''non-creditable hazardous waste pharmaceutical.'' The proposed definition of a ''non-creditable hazardous waste pharmaceutical'' is a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer credit. Examples include, but are not limited to pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; a pharmaceutical refused by a patient after an attempt to administer it; hazardous waste pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy had already received compensation by a third-party payer (*e.g.,* health insurance company); or pharmaceuticals that are more than one year past their expiration dates. Non-creditable hazardous waste pharmaceuticals are typically opened and not in their original packaging and have been dispensed (though not administered) to a patient. These conditions of the non-creditable pharmaceutical are what makes them not creditable rather than the manufacturer's policy on the specific type of pharmaceutical.

2. Summary of Comments

Commenters expressed a variety of opinions on EPA's proposed definition of ''non-creditable hazardous waste pharmaceutical.'' Some states, manufacturers and the waste management industry stated that they were satisfied with the proposed definition of ''non-creditable hazardous waste pharmaceutical.'' Wholesalers argued that the definition should be struck and the regulations should allow all intact hazardous waste pharmaceuticals to go back to a reverse distributor. Pharmacists, some states, and the retail industry argued that EPA should define ''non-creditable hazardous waste pharmaceuticals'' as those hazardous waste pharmaceuticals that are not accepted by reverse distributors for manufacturer credit.

3. Final Rule Provision

For the final rule, EPA made three major changes to the definition of ''non-creditable hazardous waste pharmaceutical'' to address comments. First, EPA has added the word ''prescription'' to the first portion of the definition to be consistent with the use of terminology in the final rule that reverse distribution is the reverse flow of prescription hazardous waste pharmaceuticals. Second, the Agency has added new language to the definition to reflect the fact that nonprescription hazardous waste pharmaceuticals can also be considered non-creditable hazardous waste pharmaceuticals that must be managed under the healthcare facility standards in § 266.502 when they do not have a reasonable expectation to be legitimately used/reused or reclaimed. For purposes of this definition, the determination is being made that at the healthcare facility, prescriptions that have already been dispensed to a patient, and free samples given to healthcare facilities do not have a reasonable expectation of receiving manufacturers credit. Third, EPA has also added examples of non-creditable hazardous waste pharmaceuticals.

Under the final rule, non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

While not specifically laid out in the definition, other examples of non-creditable hazardous waste pharmaceuticals can be pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; pharmaceuticals in their original packaging when the packaging is leaking or otherwise damaged; a pharmaceutical refused by a patient after an attempt was made to administer it; pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy already received compensation by a third-party payer (*e.g.,* health insurance company); or pharmaceuticals at are more than one year past their expiration date.

4. Comments and Responses

Wholesalers and some reverse distributors recommended that we do not differentiate between potentially creditable and non-creditable hazardous waste pharmaceuticals and allow all hazardous waste pharmaceuticals that are intact and in original packaging to go to the reverse distributors. EPA disagrees with the commenters. EPA proposed this differentiation between potentially creditable and non-creditable hazardous waste pharmaceuticals to distinguish between a traditional TSDF and the function served by a reverse distributor. A reverse distributor should not act as a hazardous waste disposal facility for healthcare facilities. It is serving as the manufacturer's agent for determination of credit. If a reverse distributor is not determining credit, EPA views it as managing hazardous waste pharmaceuticals that do not have monetary value and thus would be subject to TSDF regulations. If a reverse distributor begins to routinely receive non-creditable hazardous waste pharmaceuticals, then it is serving as a TSDF. EPA has made this differentiation to correctly represent the reverse distributor role as a manufacturer's agent for facilitating credit and not like a more traditional hazardous waste management facility.

Pharmacists, the retail industry and some states recommended that we define non-creditable hazardous waste pharmaceuticals as those hazardous waste pharmaceuticals that do not receive credit. There are some situations in which pharmaceuticals are well known to not be eligible for credit, such as leaky containers, samples or when pharmaceuticals were already dispensed to patients. The Agency did not finalize the commenters' recommendation, however, because it could potentially lead to situations where a healthcare facility sends a hazardous waste pharmaceutical to a reverse distributor in good faith that manufacturer credit is forthcoming, but credit is not issued. If EPA accepted this recommendation, the reverse distributor could be determined to unlawfully be in possession of non-creditable hazardous waste pharmaceuticals. For this reason, the Agency added into the definition that non-creditable hazardous waste pharmaceuticals are prescription pharmaceuticals that do not have a reasonable expectation of receiving manufacture credit, or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. It should be clear to healthcare personnel that leaking containers, for example, are not eligible for credit and should be sent to a designated facility for disposal (*e.g.,* a TSDF). However, it is often not clear to the healthcare facility personnel making the determination which hazardous waste pharmaceuticals will receive manufacturer credit if they were not dispensed and/or are in their original packaging (*i.e.,* potentially creditable). The Agency does find it reasonable that healthcare personnel may not know if a manufacturer credit policy for a particular pharmaceutical has changed.

Because it is not always clear that all hazardous waste pharmaceuticals will be eligible for credit due to frequent changes in manufacturers' policies, it is inappropriate to create a bright line in the definition solely based on whether the hazardous waste pharmaceutical would or would not receive manufacturer credit. Instead, this final definition takes into account this uncertainty and the difficulty it poses for healthcare facilities and allows for instances where a potentially creditable hazardous waste pharmaceutical can be correctly sent to a reverse distributor under the subpart P regulations despite not actually receiving manufacturer credit.

F. Definition of Evaluated Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed a definition for evaluated hazardous waste pharmaceuticals. After potentially creditable hazardous waste pharmaceuticals arrive at a reverse distributor, they are evaluated by the reverse distributor to determine whether they are eligible for manufacturer credit or whether they need to be transferred to another reverse distributor for additional verification of manufacturer credit. Hazardous waste pharmaceuticals that need to be transferred to another reverse distributor for additional verification of manufacturer credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA proposed that hazardous waste pharmaceuticals for which manufacturer credit has been issued (and no further verification of credit is required), as well as those that do not receive credit, be referred to as ''evaluated hazardous waste pharmaceuticals.''

EPA proposed to define an ''evaluated hazardous waste pharmaceutical'' as a hazardous waste pharmaceutical that

was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a reverse distributor to establish whether it is eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification.

It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals and the regulations must therefore distinguish between them. For a discussion of the proposed shipping and management standards for potentially creditable hazardous waste pharmaceuticals, see section XVI.D. and for a discussion of the proposed shipping and management standards for evaluated hazardous waste pharmaceuticals, see section XVI.B.

2. Summary of Comments

There were few comments pertaining to this definition. One state sought clarification on whether under this definition, an evaluated pharmaceutical could be sent on to another reverse distributor. Pharmacists wanted further clarification that evaluated hazardous waste pharmaceuticals are not eligible for credit.

3. Final Rule Provision

For the final rule, EPA made two changes to the definition of ''evaluated hazardous waste pharmaceuticals'': (1) Adding the word ''prescription'' to be consistent with our decision to distinguish between reverse distribution and reverse logistics and (2) focusing the definition on the evaluation process and does not rely as heavily on manufacturer credit.

EPA is finalizing that ''evaluated hazardous waste pharmaceutical'' means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

Under the definition of evaluated hazardous waste pharmaceutical, if credit has been determined and no other verification is needed, then the waste would be considered evaluated. If the prescription hazardous waste pharmaceutical needs further evaluation for credit, it can be sent on to another reverse distributor for that determination. It will not be considered evaluated until the credit is verified.

The Agency notes that an evaluated pharmaceutical still at the reverse distributor is not precluded from ever being awarded manufacturer credit. A manufacturer may change a credit policy while an evaluated pharmaceutical is being accumulated at a reverse distributor. However, as an evaluated pharmaceutical, it is no longer managed as a potentially creditable pharmaceutical at the reverse distributor, then it must be managed as an evaluated hazardous waste pharmaceutical even if credit is awarded after the initial evaluation. Please refer to section XVII.C of this preamble for a detailed discussion of the reverse distributor standards.

G. Definition of Household Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term ''household waste pharmaceutical'' as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1).

We proposed this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart.

2. Summary of Comments

Commenters generally agreed with EPA's definition of ''household waste pharmaceutical'' as proposed but were concerned with applicability of this definition and where the household waste exclusion can be used. For example, one commenter asked if it extended to schools. A few commenters wanted to know if this applied to all DEA take back programs and requested that the words ''including those generated by DEA regulations'' be added. Lastly, commenters asked us to clarify the significance of the household waste pharmaceutical definition with respect to long-term care facilities (LTCFs).

3. Final Rule Provisions

EPA is finalizing the definition of ''household waste pharmaceutical'' as proposed with one minor change. EPA changed the word ''exempt'' to ''excluded'' to be consistent with the title of § 261.4(b). In the final rule, ''household waste pharmaceutical'' means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

4. Comments and Responses

In response to some of the commenters' concerns, EPA is defining the term ''household waste pharmaceutical'' as a matter of convenience in crafting the regulatory language as well as the preamble. By defining the term, we do not alter the criteria we have consistently relied on for determining whether a waste is considered a household hazardous waste. The two criteria that must be met to be a household hazardous waste are (1) the waste must be generated by individuals on the premise of a temporary or permanent residence and (2) the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. Section 261.4(b)(1) defines household to include single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas. This exclusion does not include schools. Schools generate hazardous waste from various sources throughout the school grounds such as chemicals from labs, cleaning supplies and hazardous waste pharmaceuticals from medical clinics. These wastes are not being generated at a temporary or permanent residence and are not the types of wastes that would ordinarily be generated by a consumer at their home. Pharmaceuticals generated at schools would not be considered household waste pharmaceuticals. However, hazardous waste pharmaceuticals generated at dormitories at schools would be considered household waste pharmaceuticals and thus excluded, because the dormitories are residences.

Some types of healthcare facilities could be considered households. This final rule defines the term LTCF in § 266.500. LTCF means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities. The types of healthcare facilities listed at the end of this definition that are not considered to be LTCFs are not subject to subpart P requirements and hazardous waste pharmaceuticals generated there continue to be excluded from RCRA as household hazardous wastes. For a more thorough discussion of the applicability

of the household hazardous waste exclusion at LTCFs, see section VIII.K of this preamble.

While DEA controlled substances can sometimes be household waste pharmaceuticals, once these wastes are collected at a take back event or by law enforcement, DEA regulations require that any proper disposal must meet the DEA non-retrievable standards of destruction. Furthermore, this EPA rule finalizes specific requirements for the destruction of collected household waste pharmaceuticals, see section XIV of this preamble for details. Therefore, it could have been confusing to add ''including waste under DEA regulations'' to the definition of household waste pharmaceutical.

H. Definition of Non-Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term ''non-hazardous waste pharmaceutical.'' While hazardous waste pharmaceuticals are regulated under this new subpart, non-hazardous waste pharmaceuticals are not regulated under RCRA Subtitle C, including this new subpart. The Agency proposed this definition since we believed it was important to clearly delineate what is and is not regulated under this new subpart.

The Agency proposed to define the term ''non-hazardous waste pharmaceutical'' as a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C. The characteristics of hazardous waste are ignitability, corrosivity, reactivity, and toxicity.

2. Summary of Comments

Most commenters agreed with the definition of ''non-hazardous waste pharmaceutical'' as proposed. There were some comments concerning commingling of hazardous and non-hazardous waste. These comments are addressed in detail in section X.C. and XI.A. of this preamble.

3. Final Rule Provision

The Agency is finalizing the definition of ''non-hazardous waste pharmaceutical'' as proposed, with no changes. In this rule, a ''non-hazardous waste pharmaceutical'' is a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

I. Definition of Non-Pharmaceutical Hazardous Waste

1. Summary of Proposal

Like the previous definition, we proposed to define non-pharmaceutical hazardous waste to help delineate what is and what is not regulated under this new subpart. We proposed to define the term ''non-pharmaceutical hazardous waste'' as a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in this section.

The proposed definition was needed because the management of non-pharmaceutical hazardous wastes is not regulated under subpart P; rather, generators of non-pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to part 262 and other applicable Subtitle C hazardous waste regulations for the management of those hazardous wastes.

2. Summary of Comments

There were only a few comments on the proposed definition of ''non-pharmaceutical hazardous waste.'' Commenters generally agreed with the definition, but two commenters wanted EPA to clarify how to classify a waste with an ingredient that is used in both pharmaceutical and non-pharmaceutical items.

3. Final Rule Provisions

EPA is finalizing the definition of non-pharmaceutical hazardous waste, as proposed, with no changes. In this final rule, ''non-pharmaceutical hazardous waste'' is a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in § 266.500.

4. Comments and Responses

Multiple commenters asked EPA to clarify how a hazardous waste should be managed when it is used as an ingredient in both pharmaceuticals and non-pharmaceutical, *e.g.,* isopropyl alcohol, which can be used both as an antiseptic and a degreaser. Please see the definition in section VIII.A. for discussion about what meets the definition of pharmaceutical, including how to apply the definition in this type of scenario. Any hazardous waste not meeting the definition of pharmaceutical is considered a non-pharmaceutical hazardous waste and should be managed under all applicable RCRA standards.

J. Definition of Healthcare Facility

1. Summary of Proposal

EPA proposed to define ''healthcare facility'' as any person that provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or sells or dispenses OTC or prescription pharmaceuticals. The proposed definition was adapted from the definition of ''health care'' that the Department of Health and Human Services promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).[163] The proposed definition of ''healthcare facility'' included, but was not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of OTC medications; and veterinary clinics and hospitals.

EPA proposed to include coroners and medical examiners in the definition of ''healthcare facility'' despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death, and commonly sewer dispose of pharmaceuticals by putting them down the drain.[164] In order to reduce sewer disposal of pharmaceuticals and provide these facilities with the same management options that are available to other healthcare facilities, EPA included coroners in the proposed definition of healthcare facility.

The proposed definition of healthcare facility did not include pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing, or wholesale distribution of pharmaceuticals. EPA proposed to

[163] 45 CFR part 160 *http://aspe.hhs.gov/admnsimp/final/pvctxt01.htm.*

[164] For more information on the disposal process, please see: Ruhoy, I.S. and Daughton, C.G. ''Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage—Revealed by Coroner Records,'' Sci. Total Environ., 2007, 388(1–3):137–148. *https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=168384.*

exclude manufacturing facilities from the definition of healthcare facility because the Agency did not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

2. Summary of Comments

EPA requested comment on including coroners in the definition of ''healthcare facility.'' EPA received three comments supporting the inclusion of coroners in the definition of ''healthcare facility.'' One stakeholder was aware of coroner facilities that sewer dispose of pharmaceuticals and argued to include them in the definition in order to reduce the sewer disposal of pharmaceuticals. Two commenters expressed concern about including coroners in the definition of ''healthcare facility.'' One commenter stated that including coroners in the definition could discourage coroners from promoting take-back programs.

EPA also took comment on including compounding pharmacies in the definition of ''healthcare facility.'' Three commenters supported the inclusion of compounding pharmacies in the definition. One commenter stated that compounding pharmacies should be included because they do not predictably generate a known range of hazardous wastes and face problems similar to that of a healthcare facility.

The most frequent comment the Agency received on the definition of ''healthcare facility'' was that EPA should define wholesale distributors and third-party logistics providers as healthcare facilities or to create a separate definition for wholesale distributors and third-party logistics providers, but allow them to operate under the same standards as healthcare facilities.

3. Final Rule Provisions

EPA is finalizing a definition for ''healthcare facility'' so that it is clear to whom these final regulations apply. EPA is finalizing that ''healthcare facility'' means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, and veterinary clinics and hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Although EPA uses the term ''person,'' in the definition of healthcare facility, the definition of healthcare facility does not necessarily apply to individual healthcare providers at a site. As defined in § 260.10, ''person'' means ''an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.'' Accordingly, a healthcare facility can have multiple healthcare providers or a sole healthcare provider. For example, an individual healthcare provider who works at a hospital with multiple healthcare providers is not considered a healthcare facility, but the hospital is considered a healthcare facility, under the final definition. Additionally, a doctor's office with a sole healthcare provider would also be considered a healthcare facility under this final rule.

The proposed definition of ''healthcare facility'' did not apply to pharmaceutical manufacturers' representatives, wholesale distributors, third-party logistics providers, or any other entity that is involved in the wholesale distribution of prescription or OTC pharmaceuticals. Commenters argued that excluding wholesale distributors and third-party logistics providers from the definition of ''healthcare facility,'' in combination with the revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, could hinder wholesale distributors' and third-party logistics providers' ability to send potentially creditable pharmaceuticals through reverse distribution. These commenters were concerned that if they were not included in the definition of ''healthcare facility'' they would be precluded from using reverse distributors. Commenters also pointed out that wholesale distributors and third-party logistics facilities are likely to generate hazardous waste pharmaceuticals unpredictably and that their workers typically do not have the expertise to make hazardous waste determinations. Due to these comments, the Agency anticipates that wholesale distributors and third-party logistics facilities face similar issues as healthcare facilities and therefore is including them in the final definition of ''healthcare facility.''

The final definition of ''healthcare facility'' includes wholesale distributors, third-party logistics providers that engage in forward distribution, and military medical logistics facilities. Including wholesale distributors and third-party logistics facilities in the definition of ''healthcare facility'' ensures that these facilities can continue sending potentially creditable hazardous waste pharmaceuticals through reverse distribution. EPA recognizes that wholesale distributors and third-part logistics providers are not accustomed to referring to themselves as healthcare facilities. However, it is helpful to have a single, umbrella term when discussing who is subject to this subpart.

The final definition of ''healthcare facility'' does not apply to pharmaceutical manufacturers or any other entity that is involved in the manufacturing of OTC or prescription pharmaceuticals. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. The Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities, and therefore are excluded from the definition of ''healthcare facility'' under this rule.

The final definition of ''healthcare facility'' includes locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms. A pharmacy does not necessarily have to have a ''brick and mortar'' or ''store front'' presence to be considered a healthcare facility for the purposes of this final rule. The final definition of a ''healthcare facility'' also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. EPA solicited comment on including compounding

pharmacies in the definition of healthcare facility and received three comments supporting and no comments opposing the inclusion of compounders in the definition. The final definition of ''healthcare facility'' applies to state-licensed pharmacies, federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act.

4. Comments and Responses

The final definition does not include independently located coroners and medical examiners. EPA made this change in response to commenter concern that including coroners and medical examiners in the definition could discourage coroners and medical examiners from promoting take-back programs for household pharmaceuticals. However, coroners and medical examiners that are co-located with healthcare facilities, such as hospitals, will fall under the definition of ''healthcare facility,'' because they are physically part the healthcare facility.

K. Definition of Long-Term Care Facility

1. Summary of Proposal

The proposed definition of healthcare facility specifically included LTCFs as an example of a type of healthcare facility. Since the term ''long-term care facility'' does not have a standardized, industry definition, EPA proposed to define the term for purposes of this rule. We proposed to define a LTCF as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

The facilities we proposed to include as LTCFs are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care facilities, they are typically very small (fewer than 10 beds) and therefore were not included within the proposed definition. Similarly, independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments and therefore were not included within the proposed definition. Finally, we clarified in the preamble to the proposed rulemaking that private residences with visiting nurses would not be considered long-term care facilities.

By proposing to define a LTCF as a type of healthcare facility, EPA was proposing to revise its policy regarding the regulatory status of hazardous waste from long-term care facilities. We proposed that hazardous waste from LTCFs would no longer be excluded as household hazardous waste; rather, it would be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards proposed for hazardous waste pharmaceuticals under part 266 subpart P. In other words, the proposed revision to our policy regarding long-term care facilities pertained to all of the facilities' hazardous waste, not just the hazardous waste pharmaceuticals.

The Agency proposed revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order to qualify for the household hazardous waste exclusion of § 261.4(b)(1), waste must meet two criteria: (1) The hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes.[165] In the preamble to the proposed rulemaking, EPA explained that hazardous waste generated at LTCFs, even those pharmaceuticals that are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

In brief, the explanation provided in the preamble to the proposed rulemaking was two-fold. First, a LTCF is more similar to a hospital than it is a typical residence and EPA does not consider a hospital to be a household. LTCFs are licensed, residential care settings that offer their residents a wide range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse's aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing and eating. Given that LTCFs are licensed settings for the care of their residents and routinely provide healthcare services, EPA believes that LTCFs more closely resemble hospitals than typical residences.

Second, we explained, the hazardous wastes generated by LTCFs do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity and breadth of pharmaceutical wastes that are often generated on the premises of LTCFs when compared to a typical residence. This distinction about volume and breadth of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from households: Waste from ''routine residential maintenance'' is exempt as household hazardous waste, while waste from ''building construction, renovation, demolition'' is not excluded.[166]

2. Summary of Comments

EPA received a number of comments requesting changes to the proposed definition of ''LTCF'' that were instrumental in the final definition in the rule. We also received a number of comments related to whether hazardous waste from LTCFs should be excluded from RCRA Subtitle C regulations as household hazardous waste.

3. Final Rule Provisions

Based on comments, we have made some changes to the proposed definition of LTCF. The final definition retains the descriptive portion of the definition, but the list of types of facilities included as a LTCF has been revised to be more consistent with how the term is used by DEA and the Centers for Medicare and Medicaid Services (CMS). This final rule defines ''LTCF'' as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

The primary change we have made to the proposed definition relates to assisted living facilities. Under the proposed definition, an assisted living facility was considered a type of LTCF.

[165] See November 13, 1984; 49 FR 44978.

[166] Memo from Petruska to McNally, February 28, 1995; RCRA Online #11897 that discusses the distinction about what renovation waste is household hazardous waste and what is not.

Under the final definition, an assisted living facility is not considered a type of LTCF. This change is responsive to commenter's concerns and will make EPA's definition more consistent with how the term is used by both DEA and CMS. The DEA's definition of ''long term care facility'' is ''a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.'' [167] DEA does not consider assisted living facilities to be long-term care facilities. CMS also does not consider assisted living facilities to be long-term care facilities. One commenter pointed out that ''As primary regulatory oversight of [assisted living] resides at the state level, regulatory requirements and applicable definitions differ state by state. This is why the Centers for Medicare and Medicaid Services (CMS) excluded [assisted living] in its definition of Long Term Care Facilities.'' [168]

Furthermore, commenters argued, and EPA agrees, that assisted living facilities differ from LTCFs in at least two ways. First, some assisted living facilities do not provide medication management.[169] In some cases, assisted living facilities are actually prohibited from managing medications.[170] Second, many assisted living facilities do not have on-site nursing or other medical staff.[171] EPA believes it is easier for implementation of this rule, to make a determination about assisted living facilities as a category, rather than on the basis of whether they provide medication management of have on-site medical staff. Therefore, for ease of implementation as well as consistency with DEA and CMS, EPA is not considering assisted living facilities to be long-term care facilities for purposes of subpart P.

4. Comments and Responses

a. *Long-term care facilities and the household hazardous waste exclusion.* Aside from the comments about what types of facilities should and should not be considered LTCFs, we received many comments about whether LTCFs should be eligible to use the household hazardous waste exclusion of § 261.4(b)(1). Three states, the Hematology/Oncology Pharmacy Association, Stericycle, Inc., Healthcare Waste Institute, National Waste and Recycling Association, and Public Employees for Environmental Responsibility agreed that LTCFs should be considered healthcare facilities and therefore not eligible to use the household hazardous waste exemption. The American Society of Consultant Pharmacists and the National Community Pharmacists Association disagreed with EPA's proposed change of interpretation that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be considered exempt as household hazardous waste. The American Society of Consultant Pharmacists expressed concern that this change would be a substantial learning curve for LTCFs and the costs may be significant. Covanta Energy LLC expressed concern that the impacted facilities do not have robust financials and would pass the costs on to consumers. An assisted living community commented that the facility does not have the authority to compel residents to surrender their medications for disposal and therefore the new requirement would cause the assisted living community to be perpetually in noncompliance. One state opposed classifying group homes as healthcare facilities rather than as households. Waste Management National Services, Inc. suggested that self-administered pharmaceuticals that are under residents' control should be considered household waste.

EPA is finalizing that LTCFs are included within the final definition of healthcare facility. Accordingly, EPA is also finalizing that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be excluded as household hazardous waste: It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the final subpart P management standards for hazardous waste pharmaceuticals. EPA is revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exclusion of § 261.4(b)(1), it must meet the two criteria. EPA continues to believe that hazardous waste generated at LTCFs, does not meet either criterion for the household waste exclusion.

In summary, EPA is finalizing that LTCFs may no longer use the household hazardous waste exclusion. LTCFs need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this final rule and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator regulations in § 262.14 (for VSQGs), § 262.16 (for SQGs), or § 262.17 (for LQGs), as well as § 262.15 (for satellite accumulation areas (SAAs)). However, even though LTCFs will no longer be eligible to use the household hazardous waste exclusion, EPA estimates that there are between 2,875 and 4,770 LTCFs that generate hazardous waste and that 98–99 percent of the facilities are VSQGs regulated under § 262.14 and therefore not subject to part 266 subpart P (except the sewer prohibition, the empty container provisions and the optional provisions of § 266.504).[172] This means that this change in policy will primarily affect the larger long-term care facilities, which are far fewer in number (1–2 percent of LTCFs).

It is also important to note that, because of the change to the definition of LTCF, this change in policy regarding the household hazardous waste exclusion and LTCFs will not impact residents in assisted living facilities. As discussed previously, assisted living facilities will not be considered healthcare facilities and therefore will continue to be considered residences that are eligible to use the household hazardous waste exclusion in 40 CFR 261.4(b)(1). Under the household hazardous waste exclusion, assisted living facilities are not required to manage their residents' hazardous waste, including their hazardous waste pharmaceuticals, under the RCRA regulations. Commenters confirmed our data that two-thirds of assisted living facilities are small facilities with 25 residents or less, many of whom would presumably be VSQGs.[173] Therefore, we believe that this revised interpretation will have minimal environmental impact: instead of assisted living facilities being exempt as VSQGs, residential waste from assisted living facilities will be exempt as household hazardous waste. That said, under RCRA, states may be more stringent than the federal government and we are aware that some states already have a more stringent interpretation and do not consider assisted living facilities to be exempt from RCRA as households.

[167] See 21 CFR 1300.01.

[168] Medicare Prescription Drug Benefit Manual—Chapter 5, § 10.2, as cited by commenter EPA–HQ–RCRA–2007–0932–0289.

[169] See comment EPA–HQ–RCRA–2007–0932–0242.

[170] See comment EPA–HQ–RCRA–2007–0932–0289.

[171] Overview of Assisted Living, 2009, A collaborative research project of American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of American (ALFA), National Center for Assisted Living (NCAL), and National Investment Center for the Seniors Housing and Care Industry (NIC).

[172] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[173] See commenter EPA–HQ–RCRA–2007–0932–0289.

As noted previously, EPA's household hazardous waste exclusion in 40 CFR 261.4(b)(1) exempts hazardous waste that meets two criteria: (1) It is generated on the premises of a temporary or permanent residence for individuals and (2) the waste stream is composed primarily of materials found in the waste generated by consumers in their homes.[174] Therefore, only hazardous wastes that are generated in the residential areas of an assisted living facility would be excluded as household hazardous waste. On the other hand, hazardous wastes that are generated by an assisted living facility outside of the residential areas would not be considered excluded as household hazardous waste. This interpretation regarding non-residential hazardous waste generated at assisted living is consistent with our interpretation regarding dry cleaning wastes generated at hotels. Specifically, our interpretation has been that while hazardous waste generated in hotel rooms is excluded as household waste, ''dry cleaning wastes produced by the hotel do not meet both criteria for household waste and will not qualify for the household waste exclusion.'' [175] Similarly, when it comes to assisted living facilities, this final rule will rely on the interpretation that we initially expressed in the preamble to the proposed rulemaking to add pharmaceuticals to Universal Waste: ''the [long-term care] facility itself may generate hazardous waste as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by the facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the control of the patient or resident of this LTCF, when discarded, would be subject to RCRA's household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from the household.'' [176]

Under the final rule, group homes and independent living communities are also not defined as LTCFs but rather are considered residences that are eligible to use the household hazardous waste exclusion. An assisted living facility, group home and independent living facility are eligible for the household hazardous waste exclusion whether they are stand-alone facilities, or whether they are part of a continuing care retirement community. Conversely, a nursing facility or skilled nursing facility is considered a LTCF, and hence a healthcare facility, whether it is a stand-alone facility or part of a continuing care retirement community. Therefore, a continuing care retirement community will likely have portions of the facility that are excluded from RCRA regulation as households, while other portions of the facility will be regulated under RCRA for their hazardous waste generation and management, including hazardous waste pharmaceuticals.

b. *Other comments.* Commenters asked us to clarify the difference in regulatory status between in-home hospice care and in-patient hospice facilities. One commenter points out that ''Most hospice care is provided in the private residence of a patient.'' [177] Hazardous waste pharmaceuticals that are generated by in-home medical care, such as in-home hospice care, would be eligible for the household hazardous waste exclusion. On the other hand, hospice *facilities* are not considered residences and are not eligible for the household hazardous waste exclusion. Nevertheless, as discussed in section XII.D. of this preamble, long-term care facilities, including hospice facilities, that have 20 beds or fewer will be presumed to be VSQGs. Healthcare facilities that are VSQGs are subject to the sewer prohibition for hazardous waste pharmaceuticals under this final rule, the empty container standards in § 266.507, and the optional provisions of § 266.504, but otherwise are regulated by the reduced regulations of 40 CFR 262.14 for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals.

IX. Applicability (§ 266.501)

Part 266 subpart P was proposed to replace the standard RCRA generator regulations in part 262 for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. We proposed separate regulations for healthcare facilities and reverse distributors. Further, we proposed separate regulations for the management of the two types of hazardous waste pharmaceuticals—potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. When a healthcare facility disposes hazardous waste pharmaceuticals directly by sending it to a hazardous waste treatment, storage, or disposal facility, we proposed that these would be considered non-creditable hazardous waste pharmaceuticals. On the other hand, when a healthcare facility disposes of hazardous waste pharmaceuticals indirectly through a reverse distributor that facilitates manufacturer credit, we proposed that these would be considered potentially creditable hazardous waste pharmaceuticals. We proposed that when a reverse distributor receives the potentially creditable pharmaceuticals, it must evaluate them to determine whether they need to go onto another reverse distributor, in which case the pharmaceuticals would still be considered potentially creditable, or whether they will go to a TSDF, in which case they will be considered evaluated hazardous waste pharmaceuticals. Although EPA proposed that potentially creditable pharmaceuticals destined for reverse distributors would be considered hazardous wastes, we also recognized that due to the considerable value they retain in the form of potential credit from manufacturers, there was a strong incentive to manage them appropriately and we did not need to apply the standard RCRA regulations to them or to the reverse distributors that manage them. In contrast, once the credit has been established for the evaluated hazardous waste pharmaceuticals, the incentive to manage them appropriately no longer exists and we needed to apply more rigorous regulations. This section of the preamble discusses the types of facilities and pharmaceuticals that are and are not subject to this rulemaking. Subsequent sections of the preamble discuss the details of the regulations for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals as well as the regulations that pertain to reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated pharmaceuticals.

A. What facilities are subject to the final rule?

1. Healthcare Facilities (§§ 262.10(n) and 266.501(d))

a. *Summary of proposal.* The Agency proposed that healthcare facilities that

[174] 49 FR 44978; November 13, 1984.

[175] See RCRA Online #13736, March 1995.

[176] See 73 FR 73525, December 2, 2008. Note that while the Universal Waste proposal used the term ''hazardous pharmaceutical wastes,'' this final rule uses the term ''hazardous waste pharmaceuticals''.

[177] CareFirst, Commenter EPA–HQ–RCRA–2007–0932–0239.

are not VSQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the new part 266 subpart P (see § 262.10(n)) in lieu of the part 262 generator regulations. In other words, we proposed that these new management standards apply to any healthcare facility that generates more than 100 kg of hazardous waste per calendar month *or* more than 1 kg of acute hazardous waste per calendar month (*e.g.,* P-listed hazardous waste) *or* more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. We proposed that part 266 subpart P applies to all healthcare facilities that generate above the VSQG monthly quantity limits, including LTCFs.

Further, we proposed that subpart P is not optional for healthcare facilities that generate above the VSQG monthly quantity limits. EPA proposed to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. We reasoned that having one set of standards applicable to hazardous waste pharmaceuticals would be less confusing to the regulated community, which should lead to better compliance.

We also proposed that any healthcare facility that generates hazardous waste above VSQG limits is subject to the same set of standards for the management of its hazardous waste pharmaceuticals. That is, unlike under part 262, the stringency of the proposed regulations for healthcare facilities operating under part 266 subpart P does not increase as the amount of hazardous waste generated increases. Put another way, we proposed that there is no generator category for hazardous waste pharmaceuticals under part 266 subpart P. The SQG and LQG categories under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remains subject to those 40 CFR part 262 generator regulations (along with other applicable sections of the subtitle C regulations).

We proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508.

We proposed that healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509.

We expect that most potentially creditable hazardous waste pharmaceuticals will be sent to reverse distributors; however, that may not always be the case. For example, in some cases, manufacturer credit can get awarded without having to physically send the potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In such cases, we proposed that if they are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals.

b. *Summary of comments.* Comments on the applicability section addressed several main areas of concern. First, commenters weighed in on whether the VSQGs should be subject to part 266 subpart P in its entirety, as opposed to just the sewer prohibition. Second, commenters weighed in on whether the new subpart should be mandatory. Third, commenters weighed in on our proposed revision to our policy related to the reverse distribution of pharmaceuticals. While some commenters agreed with our proposed revised position that pharmaceuticals going through reverse distribution would be considered solid waste, many commenters strongly objected to our proposed revised position. We have made several changes to the final regulations that affect applicability, although several of these changes are to definitions, rather than to the applicability section of § 266.501. The primary focus of this section is to discuss changes made to the applicability section of § 266.501, although changes to definitions that affect applicability are also noted.

c. *Final rule provisions.* The final rule applies to all healthcare facilities that generate above any of the VSQG monthly quantity thresholds. Healthcare facilities that are not VSQGs do not have the choice of opting into part 266 subpart P in lieu of part 262. Further, all healthcare facilities that are subject to part 266 subpart P are regulated the same with respect to their hazardous waste pharmaceuticals, regardless of how much hazardous waste pharmaceuticals they generate. Note that we have made two changes to § 262.10(n). First, we have revised the regulations so that only a healthcare facility that *generates* above the VSQG quantity thresholds are subject to part 266 subpart P. A healthcare facility that *accumulates* above the VSQG quantity thresholds would not be subject to part 266 subpart P; it would remain subject to part 262 (although as with any VSQG, it would be allowed to opt into subpart P). The 2016 Hazardous Waste Generator Improvements final rule amended the part 262 regulations to make it clear that a VSQG that accumulates above the quantity thresholds must manage its hazardous waste in accordance with the conditions of either the SQG or LQG regulations, but the generator would remain a VSQG.[178] Second, in response to comments, we have added the following clarifying sentence at the end of the paragraph: A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.[179]

We have made four changes to the proposed regulatory language of § 266.501(d). First, we have made a conforming change to reflect the change in terminology in this final rule. That is, in § 266.501(d)(1)(ii), ''pharmaceutical reverse distributor'' has now been replaced by ''reverse distributor.'' The second change we made is to omit the reference to § 266.504 in both § 266.501(d)(1) and (2). Section 266.504 only applies to healthcare facilities that are VSQGs and should not have been referenced when discussing the requirements for other healthcare facilities. The third change is to clarify in § 266.501(d)(2), that healthcare facilities managing potentially creditable hazardous waste pharmaceuticals are also subject to the notification and withdrawal standards of § 266.502(a). While EPA believes it is extremely unlikely that a healthcare facility would only manage potentially creditable hazardous waste pharmaceuticals, as proposed, in this situation a healthcare facility would not need to notify as a healthcare facility. EPA is clarifying in the final rule, that

[178] See § 262.14(a)(3) for accumulating >1 kg of acute hazardous waste and § 262.14(a)(4) for accumulating >1000 kg non-acute hazardous waste.

[179] See comment number EPA–HQ–RCRA–2007–0932–0341.

should this situation arise, a healthcare facility only managing potentially creditable hazardous waste pharmaceuticals and no non-creditable hazardous waste pharmaceuticals is subject to notification.

The fourth, and far more substantive change we made is to § 266.501(d)(2). This paragraph has been revised to reflect our decision that healthcare facilities are regulated under part 266 subpart P for the management of prescription hazardous waste pharmaceuticals going through reverse distribution but healthcare facilities are not regulated under part 266 subpart P for the management of nonprescription pharmaceuticals, such as OTCs, homeopathic drugs, and dietary supplements, going through reverse logistics because they are not considered solid or hazardous wastes, provided they have the potential to be lawfully redistributed or legitimately reused or reclaimed. To summarize, part 266 subpart P applies to healthcare facilities managing *non-creditable* hazardous waste pharmaceuticals, whether the pharmaceuticals are prescription or nonprescription. But part 266 subpart P applies to healthcare facilities managing *potentially creditable* hazardous waste pharmaceuticals only if they are prescription hazardous waste pharmaceuticals. The comments we received in this area and the reasoning for our decision have been discussed at length in section VI of the preamble to this final rule.

Due to changes in the definition of healthcare facility and LTCF, there are effectively additional substantial changes to the applicability of the final rule. These two definitional changes have already been discussed, but are summarized here. In short, due to changes to the definition of ''healthcare facility,'' wholesale distributors will now be regulated under part 266 subpart P as healthcare facilities for the management of their hazardous waste pharmaceuticals. This includes 3PLs when they perform the function of a wholesale distributor. Unlike wholesale distributors, 3PLs do not take ownership of the pharmaceuticals; however, both wholesale distributors and 3PLs take physical custody of pharmaceuticals. Under RCRA, a 3PL would meet the definition of a hazardous waste generator, regardless of whether they own the hazardous waste pharmaceuticals.

The final rule still applies to long-term care facilities, because they are still considered healthcare facilities. However, we have amended the proposed definition of LTCF such that assisted living facilities will not be considered long-term care facilities. Further, we have finalized a rebuttable presumption that long-term care facilities with 20 beds or fewer will be presumed to be VSQGs. The combined impact of these changes is that this final rule will apply to far fewer long-term care facilities than the when the rule was proposed.

In other respects, § 266.501(d) of the final rule remains the same as the proposal. That is, healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508. And healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509. Finally, if potentially creditable hazardous wastes are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals. For example, if a healthcare facility receives manufacturer credit for a prescription pharmaceutical without shipping it to a reverse distributor, then the healthcare facility is required to manage the hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals.

d. *Comments and responses.* Several commenters asked us to consider making part 266 subpart P an optional alternative to part 262, instead of mandatory. They argued that EPA's previous sector- or waste-specific regulations, such as the Academic Laboratories Rule or Universal Waste, are not mandatory and that generators have the option to use them in lieu of the standard RCRA generator regulations under part 262. On the other hand, several states agreed that having ''one set of standards will be less confusing to the regulated community.'' [180]

As discussed previously, part 266 subpart P will be mandatory for all healthcare facilities generating above VSQG monthly quantity thresholds. Previous sector or waste specific regulations have all been considered either less stringent (Universal Waste) or equally stringent (Academic Laboratories rule) as the standard RCRA generator regulations. In contrast, part 266 subpart P is considered, on the whole, more stringent than the standard RCRA regulations. EPA has never made a more stringent RCRA regulation optional. In part, this is because it seems unlikely that anyone would opt into a more stringent regulatory scheme. If healthcare facilities chose to remain operating under part 262, they would not be subject to the sewer prohibition, which is a cornerstone of this new subpart.

Further, if part 266 subpart P were not mandatory, another result would be that healthcare facilities would not be able to use the new provisions for empty containers or the conditional exemptions for hazardous waste pharmaceuticals that are also DEA controlled substances. But the most important consideration is that this final rule revises our previous policy regarding pharmaceuticals being sent to reverse distributors for manufacturer credit such that they are now considered solid, and possibly hazardous, wastes. Under part 262, a generator can only send its hazardous waste to an off-site facility that has a RCRA permit or interim status. This would require reverse distributors to get RCRA storage permits to be able to accept hazardous waste from off-site. In light of all these considerations, with the exception of VSQG healthcare facilities, EPA has concluded that it is not feasible to make part 266 subpart P an optional alternative to part 262.

That said, we recognize that some commenters are concerned that this final rule will impact their established programs for managing hazardous waste pharmaceuticals. In response, we would point out that, in some cases, compliant practices by healthcare facilities under part 262 would also meet the standards under part 266 subpart P. For example, the training provisions for SQGs (§ 262.16(a)(9)(iii)) and LQGs (§ 262.17(a)(7)) would meet the training provisions for healthcare facilities under part 266 subpart P (§ 266.502(b)). In fact, the subpart P regulatory language for training personnel at healthcare facilities in managing non-creditable hazardous waste pharmaceuticals is identical to the regulatory language in part 262 for SQGs. For labeling, under part 266 subpart P, containers of non-creditable hazardous waste pharmaceuticals part 266 subpart must

[180] See comment numbers: EPA–HQ–RCRA–2007–0932–0242 and EPA–HQ–RCRA–2007–0932–0304.

be labeled with the words ''hazardous waste pharmaceuticals,'' but nothing would prohibit additional labeling by the healthcare facility. Likewise, under part 266 subpart P, healthcare facilities are not required to accumulate their non-creditable hazardous waste pharmaceuticals in a central accumulation area (CAA), but nothing would prohibit them from being accumulated in a CAA. Furthermore, healthcare facilities have up to one year to accumulate non-creditable hazardous waste pharmaceuticals on site under part 266 subpart P, but nothing would prohibit a healthcare facility from accumulating for the shorter time-frames dictated by the SQG (180 days) or LQG (90 days) regulations in part 262.

2. Reverse Distributors (§§ 262.10(m), 264.1, 265.1, 266.501(e), and 270.1)

a. *Summary of proposal.* The proposed rulemaking responded to stakeholders who have asked EPA to clarify how reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to reverse distributors.[181] EPA proposed specific standards in 40 CFR part 266 subpart P for reverse distributors (as defined in this proposed rulemaking) that incorporated various generator standards, as well as some TSDF standards. EPA proposed that reverse distributors that accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this new subpart. We proposed that reverse distributors are only subject to part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, we proposed that it would be subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. We proposed that all reverse distributors would be regulated the same for the accumulation of hazardous waste pharmaceuticals under part 266 subpart P, including any reverse distributors that would be considered VSQGs under part 262 (see § 262.10(m)). Under the applicability section in § 266.501(e), we proposed that reverse distributors would be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals. As with healthcare facilities, if a reverse distributor generates other, non-pharmaceutical hazardous waste, it remains subject to part 262 and all other applicable portions of the Subtitle C regulations (see § 266.501(c)).

b. *Summary of comments.* We received a large number of comments regarding the foundational question of whether the pharmaceuticals going through reverse distribution should be considered solid or hazardous wastes. In section VI of the preamble we have responded thoroughly to that threshold question; therefore, we do not elaborate here. We received a few comments on other areas related to the applicability of part 266 subpart P to reverse distributors, which have led to some conforming changes in the final rule.

c. *Final rule provisions.* Other than changing the term ''pharmaceutical reverse distributor'' to ''reverse distributor,'' we are finalizing the regulatory text of § 262.10(m) and § 266.501(e), as proposed. As a result, all reverse distributors will be subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals instead of part 262. This includes any reverse distributors that would have been considered VSQGs under part 262. This also includes third-party logistics providers (3PLs) when they perform the function of a reverse distributor. Reverse distributors and 3PLs acting as reverse distributors do not take ownership of the pharmaceuticals; however, both take physical custody of hazardous waste pharmaceuticals from off-site healthcare facilities and both facilitate the awarding of manufacturer credit for potentially creditable hazardous waste pharmaceuticals.

Under part 266 subpart P, there are no generator categories for the accumulation of hazardous waste pharmaceuticals; all reverse distributors will be regulated the same with respect to the management of their hazardous waste pharmaceuticals, regardless of the quantity. All reverse distributors will be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals.

d. *Comments and responses.* It is important to note that, although we have not made any substantive changes to the applicability section of the regulations pertaining to reverse distributors, a change we have made to the definition of reverse distributor has effectively made a change to the applicability of the final rule. Under the final rule, the term ''reverse distributor'' has been narrowed considerably, so that it only includes reverse distributors of prescription pharmaceuticals. This change has been described and explained thoroughly in previous sections of the preamble and will be discussed here only briefly. In short, under the proposed rulemaking, the term ''pharmaceutical reverse distributor'' included facilities that facilitated manufacturer credit for both prescription and nonprescription pharmaceuticals (*e.g.,* OTCs and dietary supplements). In this final rule, we have adopted the distinction drawn by commenters between reverse distributors, who manage prescription pharmaceuticals, and reverse logistics centers, who manage nonprescription pharmaceuticals (and all other, non-pharmaceutical retail items). While reverse distributors are regulated by part 266 subpart P, reverse logistics centers are not regulated by part 266 subpart P.

Additionally, we have made several conforming changes to §§ 264.1, 265.1 and 270.1. Specifically, we added paragraphs §§ 264.1(g)(13), 265.1(c)(16), and 270.1(c)(2)(x). Together, these paragraphs make it clear that reverse distributors complying with the conditions for accumulating hazardous waste pharmaceuticals under part 266 subpart P are not required to operate under the regulations for permitted TSDFs in part 264 or interim status TSDFs in part 265; nor are they required to get a RCRA permit under part 270.

3. Very Small Quantity Generators (§§ 266.501(a) and (b))

a. *Summary of proposal.* VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[182] We proposed that subpart P would preserve

[181] Note that the proposed rule used the term ''pharmaceutical reverse distributor'' but final rule uses the term ''reverse distributor;'' therefore, the preamble will use the term ''reverse distributor,'' even when discussing the proposed rule.

[182] Not all authorized states recognize the VSQG (or CESGQ) category and may have more stringent regulatory requirements for VSQGs. Therefore, as noted previously, EPA recommends that facilities that qualify as VSQGs under the federal regulations contact their state and/or local environmental regulatory agencies to determine whether more stringent regulatory requirements apply to VSQGs in their state.

this current regulatory structure for the most part, such that healthcare facilities that generate hazardous waste pharmaceuticals and qualify as VSQGs would maintain their conditional exemption under § 262.14 and would not be subject to *most* aspects of the proposal. However, as part of this rulemaking, EPA proposed a prohibition on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities, including VSQG healthcare facilities (and all reverse distributors). (See section XIII of this preamble for a more detailed discussion on the sewer prohibition.) We also proposed that healthcare facilities that are VSQGs would be able to use the standards in § 266.504 for the management of their hazardous waste pharmaceuticals, as well as the standards in § 266.507 for determining when their containers of pharmaceutical are considered empty (See sections XII and XV for detailed discussion of those sections of the regulations). We also proposed that VSQG healthcare facilities would have the ability to opt into using part 266 subpart P in lieu of the conditional exemption in § 262.14.

b. *Summary of comments.* Many of the comments on the applicability section for VSQG healthcare facilities were related to whether EPA should maintain the conditional exemption for VSQG healthcare facilities or whether we should make them fully subject to subpart P. Several commenters urged us to be clearer in our regulatory language and preamble about how a healthcare facility determines whether it is a VSQG or not. Although this section will address this area of confusion, see section IX.C of the preamble for additional information about not counting hazardous waste pharmaceuticals toward generator category when they are managed under subpart P.

c. *Final rule provisions.* In the final rule, healthcare facilities that are VSQGs (when counting all their hazardous waste, both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste) remain mostly exempt from part 266 subpart P. Note that all healthcare facilities, including healthcare facilities that are VSQGs, and all reverse distributors are subject to the sewer prohibition of § 266.505.

Healthcare facilities that are VSQGs are also subject to § 266.504 which includes optional provisions specifically for healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. We note that although § 266.501(a) states that VSQGs are subject to § 266.504, all of the provisions in § 266.504 are optional. For example, a healthcare facility that is a VSQG operating under § 262.14 for all of its hazardous waste is not required to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Rather, we are providing a regulatory mechanism that allows a VSQG healthcare facility to use a reverse distributor to obtain manufacturer credit. Nor is a VSQG healthcare facility required to send its hazardous waste pharmaceuticals off site to be consolidated at another healthcare facility that is operating under subpart P. Again, subpart P provides a regulatory mechanism for those VSQG healthcare facilities that wish to manage their hazardous waste pharmaceuticals in a more environmentally protective manner. A VSQG that elects to use any of the optional provisions of § 266.504 will not be considered to be opting into subpart P. See section XII of the preamble for a further discussion of § 266.504.

Several states asked us to expand the applicability of the final rule so that all of the healthcare facility standards in part 266 subpart P would be mandatory for all healthcare facilities, including VSQGs. For example, Colorado wrote that ''. . . healthcare professionals can be highly mobile across the healthcare industry. As a result, professionals that leave a hospital setting and move to the [long-term care] setting have to relearn a new process for waste management, adding opportunity for more confusion and mismanagement. Colorado strongly encourages EPA to consider regulating all healthcare facilities (including CESQGs) that generate hazardous waste pharmaceuticals under the proposed regulations to minimize confusion and promote consistency across the entire spectrum of the healthcare industry settings.'' [183] Although we agree with Colorado, we also believe that it would pose a burden on the large number of small healthcare facilities and divert resources from regulatory agencies to expand the applicability of the final rule to include healthcare facilities that are VSQGs. We have concluded that it would be best to let the individual states that adopt this new subpart to decide whether to expand the applicability to healthcare facilities that are VSQGs.

Additionally, in the final rule we have retained the ability for healthcare facilities that are VSQGs to opt into part 266 subpart P in lieu of operating under § 262.14. A VSQG healthcare facility may choose this option if it does not want to have to keep track of how much hazardous waste pharmaceuticals and acute hazardous waste pharmaceuticals it is generating on a monthly basis or if it generates an unpredictable or fluctuating amount of hazardous waste pharmaceuticals each month that might exceed one or more of the VSGQ monthly quantity thresholds. If a healthcare facility that is a VSQG (counting all of its hazardous waste, including pharmaceuticals and non-pharmaceuticals) chooses to opt into subpart P, it must comply with all the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals, including notification as a healthcare facility.[184] The VSQG healthcare facility may not selectively pick which provisions of part 266 subpart P it chooses to comply with; it would be treated the same as any other healthcare facility that is subject to part 266 subpart P. More specifically, if a VSQG healthcare facility chooses to opt into subpart P, then it would be subject to all the provisions identified in § 266.501(d) rather than the optional provisions of § 266.504 for VSQGs or § 262.14. The final regulatory language has been amended to be more specific in this regard. That is, rather than saying a healthcare facility has the option of complying with ''this subpart,'' we have changed the regulations to say that a healthcare facility has the option of complying with ''§ 266.501(d),'' which identifies the specific sections of the regulations that non-VSQG healthcare facilities must comply with. Further, the final regulatory language clarifies that a VSQG healthcare facility that opts into part 266 subpart P would no longer be able to use the optional provisions for VSQG healthcare facilities in § 266.504.

We have made four additional changes to the applicability section of the regulations pertaining to healthcare facilities that are VSQGs. The first two changes are conforming changes to reflect the 2016 Hazardous Waste Generator Improvements final rule; this includes changing the term ''conditionally exempt small quantity generator'' to ''very small quantity generator'' and changing the regulatory citation for VSQGs from § 261.5 to § 262.14.

[183] See comment number: EPA–RCRA–HQ–2007–0932–0242.

[184] A VSQG healthcare facility that opts into part 266 subpart P for managing its hazardous waste pharmaceuticals would still have to keep track of its monthly generation of non-pharmaceutical hazardous waste to verify that it is, in fact, a VSQG. Assuming it is a VSQG, the healthcare facility could manage its non-pharmaceutical hazardous waste under § 262.14.

The third change was made to address commenters' concerns that the use of the term VSQG in § 266.501(a) and (b) was confusing. The Generator Improvements final rule has now defined the term VSQG in 260.10, which should help reduce confusion. Nevertheless, in response to the comments, we also have added language to § 266.501(a) and (b) to make it clearer that we are referring to VSQGs that are below the VSQG quantity thresholds for all of their hazardous waste combined—including both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. Such VSQGs are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. In large part, VSQGs are not subject to subpart P for the management of their hazardous waste pharmaceuticals (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional standards of § 266.504). This type of VSQG stands in contrast to what might be referred to as a ''subpart P VSQG,'' meaning a healthcare facility that generates over one or more of the VSQG quantity thresholds and is therefore subject to subpart P for its hazardous waste pharmaceuticals but becomes a VSQG for its non-pharmaceutical hazardous waste after complying with subpart P because it is no longer required to count its hazardous waste pharmaceuticals toward its generator category.

The fourth change to § 266.501(a) is to the reference to the new empty container regulations of § 266.507. We proposed in § 266.501(a) that a VSQG would be subject to § 266.507(a) and (b). In both the proposed and final rules, these two paragraphs of § 266.507 define when unit dose containers and dispensing vials, and syringes, respectively, are empty. The purpose of the reference was to allow a healthcare facility to use the new empty container provisions in determining how much hazardous waste pharmaceuticals it generates and therefore whether it is subject to subpart P. Under the final rule, a healthcare facility is still able to use the new empty container provisions in § 266.507 when determining how much hazardous waste pharmaceuticals it generates, but we have concluded that this reference should include all of § 266.507, rather than just paragraphs (a) and (b) because § 266.507 (c) and (d) include provisions for determining whether IV bags and other types of containers of hazardous waste pharmaceuticals are empty. Additionally, we have also amended the associated language in § 261.7 which defines when a container of hazardous waste is considered empty. We had already proposed to add a new paragraph (c) to § 261.7 to direct healthcare facilities and reverse distributors to § 266.507. The final rule modifies the proposed paragraph such that the new empty container regulations in § 266.507 are no longer limited to healthcare facilities and reverse distributors operating under part 266 subpart P. Section 266.507 defines when containers of hazardous waste pharmaceuticals are empty and apply regardless of whether they are being managed by a healthcare facility, a reverse distributor, or another entity. Generators, including healthcare facilities, can use the new provisions in § 266.507 in determining when the containers of hazardous waste pharmaceuticals are empty and the residues are no longer regulated as hazardous waste. In turn, this will help generators determine how much hazardous waste they generate and; therefore, whether they are subject to part 266 subpart P and/or part 262. See section XV of this preamble for further information about § 266.507.

d. *Comments and responses.* A few commenters had suggestions for alternative organization or placement of the applicability section pertaining to healthcare facilities that are VSQGs. One commenter suggested that we combine all of the subpart P regulations that pertain to VSQG healthcare facilities in one place, under § 266.504, rather than have some in § 266.501 and others in § 266.504.[185] We generally agree with the commenter and have included all substantive standards for VSQG healthcare facilities in § 266.504 (see section XII of the preamble for a further discussion of § 266.504). However, we believe that, when discussing the central question of who the subpart applies to, it is best to keep together in § 266.501 all the regulations that address applicability. And since the applicability section of § 266.501 appears before the VSQG healthcare facility standards of § 266.504, we believe that it is more helpful to the reader to know, up front in the regulations, whether the subpart applies. Another commenter thought we should move the entire applicability section so that it appears before the definitions section in the regulations, in order to allow ''the reader to determine if [s]ubpart P applies to his facility before reviewing any of its requirements.'' [186] Although we agree that the applicability section is critical to the reader, we believe that the reader must have a full understanding of terms used in the applicability section in order to accurately determine whether the subpart applies. As a result, we have declined to make this suggested change. We requested comment on whether the applicability section for VSQG healthcare facilities should appear in § 262.14 (formerly § 261.5) rather than in subpart P and a couple of commenters responded that we should.[187] Although that would have been an acceptable option for crafting the new regulations, we have concluded that we prefer the option of keeping the regulatory language related to hazardous waste pharmaceuticals contained within the same subpart when possible. As a result, we have declined to make this suggested change, as well.

B. What facilities or pharmaceuticals are not subject to the final rule? (§§ 266.501(c) and 266.501(f) and 266.501(g))

1. Summary of Proposal

EPA proposed that the new part 266 subpart P management standards would apply only to hazardous waste pharmaceuticals generated or managed by healthcare facilities and reverse distributors. This new subpart was designed as a sector-specific rulemaking to address the unique circumstances of the healthcare sector and the reverse distribution of their hazardous waste pharmaceuticals. In § 266.501(f), we proposed that other entities that generate or manage hazardous waste pharmaceuticals would not be subject to part 266 subpart P, but would remain subject to the standard generator regulations in part 262, along with other applicable Subtitle C regulations. For example, in the preamble to the proposed rulemaking we stated that pharmaceutical manufacturers and wholesalers would remain subject to part 262 generator regulations because they do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals. We reasoned that manufacturers and wholesalers generate hazardous waste pharmaceuticals that are more predictable and the staff have the necessary expertise to determine which pharmaceuticals are considered hazardous waste. However, we noted in the proposal that when any facility, including a pharmaceutical

[185] See comment number: EPA–HQ–RCRA–2007–0932–0280.

[186] See comment number: EPA–HQ–RCRA–2007–0932–0231.

[187] See comment numbers: EPA–HQ–RCRA–2007–0932–0231 and 0280.

manufacturer, meets the definition of a reverse distributor, it would be subject to the new regulations for reverse distributors with respect to those operations.

In § 266.501(c), we also proposed that this new subpart would only apply to the management of hazardous waste pharmaceuticals. The proposed new subpart was sector-specific as well as waste stream-specific. We proposed that other, non-pharmaceutical hazardous wastes generated or managed by healthcare facilities and reverse distributors would remain subject to all applicable hazardous waste regulations.

2. Final Rule Provisions and Comments and Responses

This final rule remains a sector-specific rule as well as a waste stream-specific rule. Accordingly, § 266.501(c) of the final rule remains as proposed. That is, a healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste. Likewise, as discussed previously, a number of commenters requested that we include wholesale distributors in part 266 subpart P as healthcare facilities and in response we have amended the definition of healthcare facility to include wholesale distributors. This, of course, affects which entities are subject to the rule, but as we have made this change through amending the definition of healthcare facility, it does not necessitate a change to § 266.501 of the regulations, which is entitled Applicability. Therefore, the final rule applies to the generation and management of hazardous waste pharmaceuticals only by healthcare facilities and reverse distributors and not to others that might generate or manage hazardous waste pharmaceuticals, such as pharmaceutical manufacturers.

We have added paragraph (g) to § 266.501 of the final rule, substantially expanding the list of types of wastes that are not subject to part 266 subpart P or to RCRA regulation in general. In some cases, the additions grew out of comments and in some cases, the additions grew out the need for additional clarity. Each of the types of waste that are not subject to this subpart are discussed individually below.

a. *Donations.* As discussed previously, we have amended the definition of hazardous waste pharmaceutical to make it clear that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore, not a hazardous waste, if it is lawfully donated for its intended purpose. We have made the same change to the applicability section of this subpart to similarly indicate that pharmaceuticals are not subject to subpart P when they are lawfully donated for their intended purpose.[188] In fact, because pharmaceuticals that are lawfully donated or are otherwise legitimately used/reused or reclaimed are not solid wastes, as defined by § 261.2, they would not be subject to RCRA at all. Although this is common for nonprescription pharmaceuticals, it is rare for prescription pharmaceuticals. Sirum, a commenter that is a non-profit organization that ''helps implement State-based programs to recycle unused medication to indigent patients'' in four states, concurred that ''repurposing pharmaceuticals happens under narrow circumstances'' and that ''in most cases, pharmaceuticals transported back to a reverse distributor are discarded by the reverse distributor.'' [189] State donation and repository laws dictate the conditions under which pharmaceuticals may be donated. These laws are tracked by the National Conference of State Legislatures.[190] EPA would note that, in addition to the state regulations, the FDA has guidelines for the donation of pharmaceuticals for international relief efforts,[191] as does the World Health Organization (WHO).[192]

Sirum is providing a valuable and commendable service and EPA does not wish to impede their operations, which support the waste minimization goal of RCRA. We have amended both the definition of hazardous waste pharmaceutical and the applicability section to clarify that pharmaceuticals that are lawfully donated are not solid or hazardous wastes and therefore are not subject to RCRA, including this subpart. This would include donations to a charity, non-governmental organization, or to a healthcare facility that is participating in a donation or repository program that is authorized by the state. EPA concurs with Sirum that this should act ''as an incentive and path forward for socially responsible reverse distributors [and others] to donate rather than destroy pharmaceuticals within the safety of existing state laws that allow for these practices.'' [193]

b. *Over-the-counter pharmaceuticals going through reverse logistics.* As discussed at length in section VI of the preamble, OTC pharmaceuticals, and other items meeting our definition of pharmaceutical that do not require a prescription, such as dietary supplements, or homeopathic drugs, will only be subject to this subpart when they are discarded by a healthcare facility. OTCs and other nonprescription pharmaceuticals are not considered solid or hazardous wastes when they are sent through reverse logistics for the purpose of determining whether they can be redistributed for their intended purpose or legitimately reused or reclaimed. We have added § 266.501(g)(2) to the applicability section to codify this position regarding OTC pharmaceuticals, dietary supplements and homeopathic drugs.

c. *Recalled hazardous waste pharmaceuticals.* The Agency initially proposed standards for recalled non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(g)(3), and for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors in § 266.510(a)(5). The finalized recall provisions for all hazardous waste pharmaceuticals are now in the applicability section in § 266.501(g)(3) and (4).

The Agency proposed that healthcare facilities managing recalled non-creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted one-year period. Likewise, the Agency proposed that reverse distributors managing recalled potentially creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted 90-day period. In the proposed regulations, the reasons for requesting an extension were characterized as ''any unforeseen circumstances beyond the control'' of the healthcare facility or reverse distributor. In the proposed preamble, we gave the specific examples of recalls and litigation as circumstances that are the beyond the control of the healthcare facility or reverse distributor, which could require longer accumulation than the proposed time frames. The proposed provision in both sections required that an extension

[188] See 40 CFR 266.501(g)(1).

[189] See comment number EPA–HQ–RCRA–2007–0932–0353.

[190] *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.*

[191] See Questions and Answers for the Public Donating Drugs to International Humanitarian Relief Efforts *https://www.fda.gov/downloads/newsevents/publichealthfocus/ucm249617.pdf.*

[192] *http://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/.*

[193] See comment number EPA–HQ–RCRA–2007–0932–0353.

request be sent in writing (electronic or paper) to the EPA Regional Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the corresponding time period, and the amount of extra time requested. The Agency also proposed to allow the Regional Administrator discretion to grant, modify, or deny extension requests on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

The proposed recall provisions only applied to hazardous waste pharmaceuticals that had limited accumulation times, *i.e.,* non-creditable hazardous waste pharmaceuticals at healthcare facilities, and potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. The finalized recall provisions, however, apply to all recalled hazardous waste pharmaceuticals.

These proposed extension provisions were opposed by many commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would arise from having to generate, transmit, and maintain an additional set of records every time they would need to request an extension of the accumulation time period. The commenters suggested that these situations occur more often than EPA indicated in the proposal. Similarly, many state agencies were concerned about the added burden imposed on them by requiring notifications that must be processed, analyzed, afforded appropriate consideration, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with other federal oversight authorities, in particular, recalls overseen by the FDA and CPSC. Commenters were also wary of the discretion these proposed provisions afforded the Regional Administrator to grant extensions, primarily due to the lack of a mechanism to coordinate those extensions with other agencies that might require longer accumulation times. Commenters were concerned this would likely lead to a scenario in which the EPA Regional Administrator does not grant sufficient accumulation time needed to comply with other federal requirements for recalls.

To address these adverse comments, the Agency has modified the final rule. The modifications also address the fact that the duration of a recall is highly variable, making it unreasonable to prescribe a specific time frame for accumulation. The Agency is finalizing provisions to ensure that recalled hazardous waste pharmaceuticals are properly managed without imposing requirements that are superfluous or conflict with other federal regulations and procedures.

In an effort to avoid overreach and potentially overlapping regulations, the Agency consulted with FDA and CPSC to better understand their procedures and policies in regulating and overseeing recalls of OTC and prescription pharmaceuticals. We learned that almost all pharmaceutical recalls are overseen by FDA, however, CPSC occasionally oversees a recall if an item's packaging does not comply with special (also called child resistant) packaging requirements. We also learned that third-party companies (typically reverse distributors, as defined in subpart P) serve as recall facilitators contracted by the manufacturer of the recalled item, to provide recall logistics such as aggregating recalled items, tracking recall progress, and making disposition determinations. Nearly all pharmaceuticals sent to a recall facilitator as part of a recall are ultimately destroyed. However, in some cases, the content of a recalled item is reclaimed and put back into commerce. For example, if the outer packaging has incorrect information, the manufacturer may choose to place the contents in updated packaging so they can be lawfully sold.

Although retailers are not permitted to sell a pharmaceutical that is subject to a CPSC recall, participation in a recall is not compulsory on the part of every consignee (entity that has purchased those items), which means that there is no way to compel participation, whether the recall is voluntary or federally mandated. The Agency had considered taking the position that all pharmaceuticals subject to a recall are waste when the recall is issued. However, because some recalled pharmaceuticals have the potential to be legitimately used/reused or reclaimed, combined with the fact that they sometimes can be lawfully dispensed by the consignee (but not sold by a retailer), we concluded that pharmaceuticals subject to a recall do not necessarily become waste simply by virtue of being subject to that recall.

Although many pharmaceuticals being sent by a healthcare facility to a recall facilitator as part of a recall could be considered solid waste, the Agency has determined that the combination of regulations, guidance and/or oversight provided by FDA and CPSC is sufficiently protective of human health and the environment while pharmaceuticals are subject to a recall. Therefore, EPA is choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are subject to a voluntary or federally-mandated recall until the decision is made to send some or all items for destruction (see below for further discussion).

EPA is not attaching any requirements to recalled hazardous waste pharmaceuticals while subject to a recall. In the final rule, healthcare facilities and reverse distributors will not be required to request an extension of the accumulation time period for recalled non-creditable hazardous waste pharmaceuticals or potentially creditable hazardous waste pharmaceuticals as proposed. This decision is also responsive to commenters who were concerned about having to operate under multiple and possibly conflicting federal regulatory schemes. It is also worth noting again that FDA and CPSC are the only federal agencies that regulate recalled pharmaceuticals and special packaging for pharmaceuticals, respectively.

When a pharmaceutical recall is initiated, the manufacturer must develop, and the corresponding agency must accept, a recall strategy which outlines all of the actions to be taken on behalf of the manufacturer from start to finish. A disposition determination is a required component of a comprehensive recall strategy. It is EPA's understanding that items being managed under an FDA or CPSC recall may be periodically sent for destruction as part of the disposition strategy (other disposition options allowed by FDA and CPSC can include redirection, and in rare circumstances, reconditioning). It is at this point (upon the decision to send some or all of the recalled pharmaceuticals for destruction) that the Agency will apply RCRA regulations these hazardous waste pharmaceuticals.

Any recalled pharmaceutical that is sent for destruction as part of the disposition strategy and is a RCRA hazardous waste, must be managed according to RCRA Subtitle C and any applicable provisions of this new subpart. This strategy is also in line with FDA and CPSC recall procedures in that they both specify that items being sent for destruction must comply with other applicable state, local and federal regulations, which may include DOT's Hazardous Material Regulations (HMR) and RCRA. In other words, this rule maintains the framework that any entity sending recalled items for destruction under a FDA or CPSC recall must comply with RCRA regulations but imposes these new subpart P regulations

at the point at which RCRA regulations already applied in lieu of the generator regulations in 40 CFR part 262.

d. *Preservation orders, investigations, and judicial proceedings.* In addition to recalls, the proposed rulemaking included litigation holds as an example of a circumstance that is beyond the control of a healthcare facility or reverse distributor, which would be a valid reason to request an extension of the accumulation period. Similar to the proposed standards for recalled hazardous waste pharmaceuticals, the standards for hazardous waste pharmaceuticals under litigation holds were also included in § 266.502(f)(3) for non-creditable hazardous waste pharmaceuticals at healthcare facilities, and in § 266.510(a)(5) for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. As with recalls, we have moved the section of the regulations that addressed accumulation time extensions for litigation holds out of the healthcare facility standards and reverse distributor standards and into the applicability section of § 266.501(g)(5). The final rule also uses terminology that is more encompassing than just litigation holds, such that we are choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are being held pursuant to preservation orders, investigations, and judicial proceedings (which would include litigation holds).[194] Accordingly, the hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding are not subject to part 266 subpart P until after the preservation order, investigation or judicial proceeding has concluded and/or a decision is made to discard the hazardous waste pharmaceuticals. As with recalled hazardous waste pharmaceuticals, the final rule no longer requires healthcare facilities and reverse distributors to request an extension of the accumulation time period for hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding, as was originally proposed.

Some commenters were concerned that the Agency had proposed that any item under a preservation order, investigation, or judicial proceeding would be considered waste. We would like to emphasize that non-waste hazardous pharmaceuticals do not automatically become a waste upon being directed to participate in a preservation order.

The Agency has determined that any pharmaceuticals that were, prior to a preservation order, investigation, or judicial proceeding, determined to be waste, are not subject to RCRA when under the preservation order, investigation, or judicial proceeding. The Agency believes that sufficient protections are in place to be duly protective of human health and the environment while the preservation order, investigation, or judicial proceeding is ongoing. In addition, the extreme variability and multijurisdictional nature of judicial actions and Agency investigations make it impractical to impose RCRA standards while a corresponding preservation order, investigation, or judicial proceeding is ongoing. When lifted—for any portion or the entire complement of items—a new waste determination must be made. The location at which the waste determination is made will be the new point of generation. If the items are ultimately determined to be hazardous waste pharmaceuticals, all applicable standards in this subpart apply and the time frames for accumulation, inventory, etc., begin anew.

e. *Investigational drugs.* Similar to recalls, FDA has specific regulations pertaining to investigational new drugs, including that an investigational new drug application must be developed and approved by FDA, in accordance with 21 CFR part 312. These regulations include a requirement that ''The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug.'' [195] Because FDA requires these investigational drugs to be returned to the sponsor of the new drug application, EPA would not consider these returned investigational new drugs to be solid wastes and therefore, they would not be subject to RCRA, including this subpart. However, when a decision is made to discard the investigational new drug, or when the FDA approves the destruction of the investigational new drug, at that point it would be considered a solid waste, and if it is a hazardous waste, then it would be subject to subpart P, if the investigational new drug is discarded by a healthcare facility or a reverse distributor. However, typically, investigational new drugs that are part of a clinical trial are returned to the manufacturer at the conclusion of the clinical trial. In that case, if the investigational new drug is discarded by a manufacturer, then it would be subject to part 262, not part 266 subpart P. We have added § 266.501(g)(6) to carve out investigational new drugs for which an investigational new drug application is in effect in accordance with the FDA regulations in 21 CFR part 312. But we have also included a sentence to make it clear that, when the decision of discard has been made, the investigational new drug is subject to subpart P, if it meets the definition of hazardous waste and it is discarded by a healthcare facility or a reverse distributor.

f. *Household pharmaceuticals.* In the proposed rulemaking, we indicated that pharmaceuticals from households would continue to be excluded as household hazardous waste under § 261.4(b)(1). However, this was only a discussion in the preamble, we did not include regulatory language in part 266 subpart P. Additionally, we proposed a conditional exemption for collected household pharmaceuticals in § 266.507. For added clarity in the final rule, we have included in the applicability section a new paragraph § 266.501(g)(7). This paragraph indicates that household waste pharmaceuticals are not regulated under part 266 subpart P or other RCRA regulations. A household waste pharmaceutical is defined as a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1). This exclusion is for the residential generator of the household waste pharmaceuticals, as well as the collection and disposal of the residential trash as municipal solid waste.

As discussed later in this preamble, we are finalizing a conditional exemption in § 266.506(a)(2) for household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration). To remain exempt as household waste pharmaceuticals, these collected pharmaceuticals may not be sewered and have to be destroyed by a method that the Drug Enforcement

[194] See the following three memos: (1) June 23, 2017, from Johnson to Regional RCRA Division Directors, RCRA Online #14893; (2) August 11, 1988, from Lowrance to McGuire, RCRA Online #11363; and (3) January 6, 2014, from Devlin to Mitlo, RCRA Online #14881.

[195] See 21 CFR 312.59.

Administration has publicly deemed in writing to meet their non-retrievable standard of destruction, or combusted at one of the types of combustors identified in § 266.506(b). We have included in the applicability section in § 266.501(g)(7) references to the conditional exemption in § 266.506(a)(2) and the conditions in § 266.506(b) to clarify that household waste pharmaceuticals that are collected as part of a take-back event or program are distinct and different from those that are not part of a collection program. That is, when discarded directly at a residence, the household waste pharmaceuticals remain excluded as household hazardous waste, without any conditions; however, when the household waste pharmaceuticals are collected in a take-back event or program, they must be destroyed in accordance with the conditions in § 266.506 to remain exempt. See section XIV of this preamble for a more detailed discussion of the conditional exemption for household waste pharmaceuticals that are collected in a take-back event or program.

C. Do Not Count Hazardous Waste Pharmaceuticals Managed Under Subpart P Toward Determining Generator Category (§§ 262.13(c)(9))

1. Summary of Proposal

EPA proposed that hazardous waste pharmaceuticals that are managed under part 266 subpart P are not required to be counted in determining a facility's hazardous waste generator category under part 262. There were two primary reasons this provision was proposed. First, we received support for this provision when we initially proposed it as part of the 2008 proposal to add pharmaceuticals to the Universal Waste program. Second, and more importantly, under part 266 subpart P, there are no generator categories; therefore, it is not necessary to know the quantity of hazardous waste pharmaceuticals being generated. EPA emphasized that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category (see section XIX for further discussion).

2. Summary of Comments

There was widespread support among commenters for this proposed provision. However, a number of the commenters expressed some confusion and asked for further explanation and clarity regarding the effect this may have on determining a facility's hazardous waste generator category.

3. Final Rule Provisions

We are finalizing this provision with a minor edit. Additionally, the provision is now in a different place in the final regulations. First, the minor edit was made in response to Connecticut Depart of Energy and Environmental Protection's (CT DEEP) objection to the phrasing of the proposed regulatory language. Specifically, CT DEEP thought the phrase ''managed under 40 CFR part 266 subpart P'' could lead to confusion if a healthcare facility was operating under part 266 subpart P, but was not in full compliance with part 266 subpart P and whether that would be considered to be ''managed under 40 CFR part 266 subpart P.'' [196] In response, and to avoid this potential area of confusion, we have changed the regulatory language so that ''a hazardous waste pharmaceutical *subject to* or managed in accordance with 40 CFR part 266 subpart P'' does not have to be counted toward determining a facility's generator category. The second change is a conforming change necessitated by the reorganization of the generator regulations in the 2016 Hazardous Waste Generator Improvements final rule. The list of hazardous wastes that do not have to be counted toward generator category had been listed in § 261.5(c), but when the Hazardous Waste Generator Improvements final rule reorganized the generator regulations, this list was moved to § 262.13(c). Under this final rule, hazardous waste pharmaceuticals that are subject to part 266 subpart P do not have to be counted toward determining a facility's generator category. This provision now appears in § 262.13(c)(9). Finally, for clarity we have added that the hazardous waste pharmaceuticals that are also DEA controlled substances and are conditionally exempt under § 266.506, do not have to be counted toward determining generator category.

4. Comments and Responses

Several commenters asked us to clarify when a healthcare facility does and does not count its hazardous waste pharmaceuticals toward determining a facility's generator category. A healthcare facility must count all of its hazardous waste—including hazardous waste pharmaceuticals—to determine whether it is subject to part 266 subpart P. If a healthcare facility generates below all of the VSQG monthly quantity limits, then it remains subject to § 262.14 for all of its hazardous waste and it is not subject to subpart P for its hazardous waste pharmaceutical, except for the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. On the other hand, if a healthcare facility generates above any of the VSQG monthly quantity limits, then the healthcare facility is subject to subpart P for its hazardous waste pharmaceuticals. But since subpart P is only for the management of hazardous waste pharmaceuticals, the healthcare facility remains subject to part 262 for its non-pharmaceutical hazardous waste.

The next step is for the healthcare facility to determine its new generator category under part 262 so it knows how to manage its non-pharmaceutical hazardous waste. At this point, a healthcare facility does not need to count its hazardous waste pharmaceuticals in determining its generator category for its non-pharmaceutical hazardous waste. EPA continues to emphasize that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category. Put another way, a healthcare facility managing its hazardous waste pharmaceuticals under subpart P does not have a generator category for the hazardous waste pharmaceuticals, but it will be a VSQG, SQG or LQG for its non-pharmaceutical hazardous waste.

When a healthcare facility that manages its hazardous waste pharmaceuticals under subpart P no longer counts the hazardous waste pharmaceuticals to determine its part 262 generator category, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LQG to an SQG or even VSQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced part 262 generator regulations for a smaller category.

For reverse distributors, it works somewhat differently than with healthcare facilities, because all reverse distributors are subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals, including reverse distributors that are

[196] See comment number: EPA–HQ–RCRA–2007–0932–0341.

VSQGs. In other respects, the regulations work the same, because reverse distributors also are not required to count their hazardous waste pharmaceuticals when determining their part 262 generator category for their non-pharmaceutical hazardous waste.

Again, we emphasize, such dropping down in generator category only pertains to non-pharmaceutical hazardous waste and is only possible when the hazardous waste pharmaceuticals are being managed under subpart P. Further, EPA points out that universal wastes also are not counted toward a facility's generator category and what we are finalizing for hazardous waste pharmaceuticals has been implemented successfully for years within the universal waste program for facilities that generate both universal waste and other hazardous waste.

Below are a diagram and a table to help summarize the preceding sections of the preamble related to the applicability of the final rule and the provision that allows a healthcare facility or a reverse distributor to not count hazardous waste pharmaceuticals when determining the facility's generator category for its non-pharmaceutical hazardous waste.

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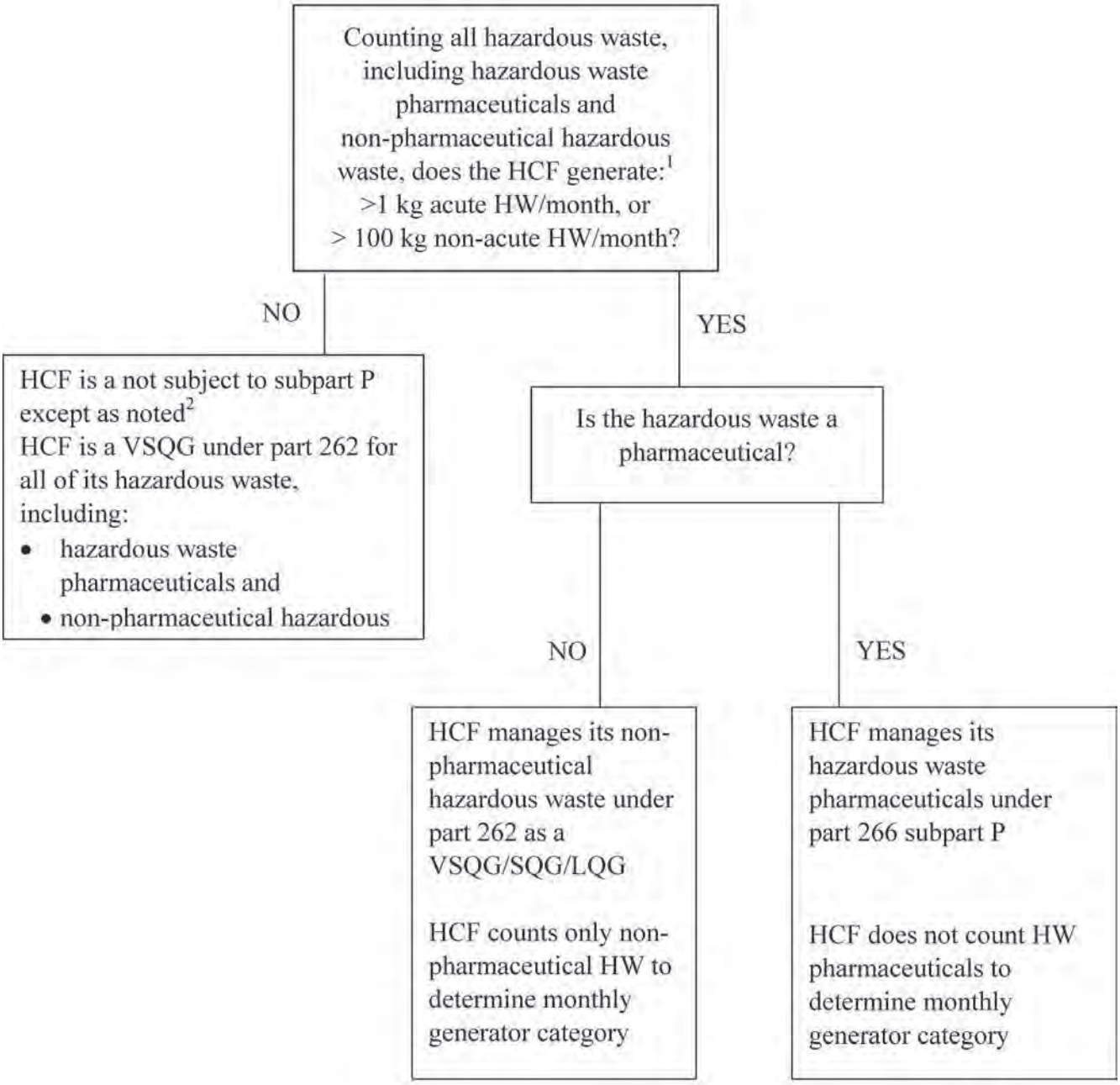
Diagram 1: When is a Healthcare Facility Subject to Part 266 Subpart P?



HW = Hazardous Waste HCF = Healthcare Facility RD = Reverse Distributor Rx = Prescription

[1] Non-Rx pharmaceuticals are not solid or hazardous waste if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed. Reverse logistics facilities are subject to the generator standards in part 262.

[2] All VSQGs are subject to the sewer prohibition of § 266.505 and the empty container standards of § 266.507, and can use the optional provisions of § 266.504.

Table 2: Applicability of Subpart P and Part 262 Generator Category for Healthcare Facilities

Hazardous Waste Pharmaceutical			Non-Pharmaceutical Hazardous Waste		Total Hazardous Waste		Part 266 Subpart P?	Part 262 Generator Category of Healthcare Facility		
Acute	Non-Acute		Acute	Non-Acute	Acute	Non-Acute		LQG	SQG	VSQG
Any amount		and	>1 kg and/or	≥1000 kg	>1 kg and/or	≥1000 kg	Yes	✓		
Any amount		and	≤1 kg and	>100 and <1000 kg	≤1 kg and	>100 and <1000 kg	Yes		✓	
>1 kg and/or >100 kg		and	≤1 kg and	≤100 kg	>1 kg and/or	>100 kg	Yes			✓[2]
≤1 kg and	≤100 kg	and	≤1 kg and	≤100 kg	>1 kg and/or	>100 kg	Yes			✓[2]
≤1 kg and	≤100 kg	and	≤1 kg and	≤100 kg	≤1 kg and	≤100 kg	No[1]			✓[3]
Long-Term Care Facilities with ≤ 20 beds							No[1]			✓[4]

[1] All VSQGs healthcare facilities are subject to the sewer prohibition of § 266.505, and the empty container standards of § 266.507, and can use the optional provisions in § 266.504

[2] VSQGs for non-pharmaceutical hazardous waste only ("subpart P VSQG")

[3] VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

[4] Presumed to be a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

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X. Standards for Healthcare Facilities That Manage Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502)

A. Notification/Withdrawal Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(a))

1. Summary of Proposal

To address commenters' concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA proposed to require that a healthcare facility that does not qualify as a VSQG to submit a one-time notification as a ''healthcare facility'' to the appropriate EPA Regional Administrator. EPA proposed that healthcare facilities subject to 40 CFR part 266 subpart P will have to submit a notification even if the healthcare facility has previously obtained an EPA identification number. The required notification was meant to enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266 subpart P requirements.

At any point, a healthcare facility's hazardous waste pharmaceutical generation may change due to waste minimization efforts or other reasons, causing the facility to legitimately decrease its total monthly hazardous waste generation enough to qualify as a VSQG. In this case, if the healthcare facility withdraws from the 40 CFR part 266 subpart P requirements due to qualifying as a VSQG, EPA proposed that the healthcare facility must re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a VSQG, but does not want to keep track of the amount of hazardous waste pharmaceuticals it generates and whether it is above or below the VSQG threshold, we proposed that it can choose to operate under subpart P. By choosing to operate under subpart P, the VSQG healthcare facility must comply with all of the requirements, including the one-time notification that it is operating under 40 CFR part 266 subpart P. We proposed that healthcare facilities that are not VSQGs, however, are required to operate under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals.

The Agency proposed that this notification occur using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form). EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (*e.g.,* Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We proposed that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. This was intended to take advantage of an existing reporting mechanism for LQGs or other generators already required to submit the Biennial Report and avoid duplicative notification requirements. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart. We also proposed that a healthcare facility would have to keep a record of its notification as long as it is subject to this subpart.

The Agency did not anticipate that the proposed notification requirement would place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rulemaking in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under the proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266 subpart P towards a healthcare facility's generator category. As a result, EPA anticipates that many healthcare facilities will reduce their generator category to either an SQG or VSQG for their other non-pharmaceutical hazardous wastes. So, while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266 subpart P requirements, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe.

The Agency solicited comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

2. Summary of Comments

While there was general support for requiring healthcare facilities to notify the EPA Regional Administrator that they are operating under this subpart, a number of states and industry commenters provided opposition to the proposed 60-day time frame. States supported notification but were concerned that they would not be able to process all of the notifications in a timely manner given that all VSQG and SQG facilities operating under subpart P would have to notify within 60 days of the effective date of this rule. One suggestion was to instead require notification on a rolling or staggered basis to give resource-limited states enough time to process the notices within a timely manner.

States also voiced concern about the provision allowing healthcare facilities that are LQGs because of their non-pharmaceutical waste to notify as part of their normal Biennial Reporting schedule.[197] Depending on the timing of the Final Rule, states were concerned about the possibility that LQGs would not have to notify that they are operating under this subpart for up to two years, during the course of which they could be generating large amounts of pharmaceutical waste and managing it under the reduced restrictions of this subpart unbeknownst to the state or EPA. Meanwhile VSQGs and SQGs would have to notify within 60 days.[198] Another state recommended that healthcare facilities be required to list on the notification what their generator category would be if they were to count their pharmaceutical waste. The state was concerned that a healthcare facility could be generating LQG amounts of pharmaceutical waste but because they are now VSQGs, would be a much lower inspection priority.[199]

There was, however, no opposition to the provision that a healthcare facility

[197] § 262.18(d)(2) requires LQGs to renotify EPA by March 1 of each even-numbered year thereafter using EPA Form 8700–12. An LQG may submit this renotification as part of its Biennial Report required under § 262.41.

[198] EPA–HQ–RCRA–2007–0932–0341.

[199] EPA–HQ–RCRA–2007–0932–0235.

be required to maintain a copy of its notification on file as long as it is subject to this subpart.

3. Final Rule Provisions

EPA is finalizing the notification provisions for healthcare facilities managing non-creditable hazardous waste pharmaceuticals as proposed, with no changes.

All healthcare facilities as defined in § 266.500 that are subject to the requirements of this subpart (all healthcare facilities that generate above the VSQG thresholds and healthcare facilities that are VSQGs choosing to operate under this subpart) will have to submit a notification to the EPA Regional Administrator using the Site ID Form (EPA Form 8700–12) stating that they are a healthcare facility and will be operating under this subpart. A healthcare facility that already has an EPA Identification Number must re-notify the EPA Regional Administrator that it will be operating under this subpart within 60 days of becoming subject to subpart P. Healthcare facilities that do not have an EPA Identification Number will be required to obtain one by submitting the Site Identification Form (EPA Form 8700–12) within 60 days from the effective date of this rule if they are not otherwise required to submit Biennial Reports. A healthcare facility that undergoes a change in generator category causing them to become subject to the requirements of this subpart must notify the EPA Regional Administrator within 60 days of the event that triggered the change in generator category.

Healthcare facilities that are LQGs for their non-pharmaceutical hazardous waste, and therefore must submit a Biennial Report, may notify the EPA Regional Administrator according to their normal reporting cycle. SQGs that are required by their state to submit a Biennial Report may also notify EPA that they are operating under subpart P on their normal reporting cycle. Healthcare facilities that are required to submit a Biennial Report are not, however, required to wait to notify EPA that they are operating under subpart P on their Biennial Report, and may notify EPA at any point prior to submitting the Biennial Report. The Agency notes that any healthcare facility that is required to operate under subpart P must begin complying with its requirements as soon as the final rule becomes effective. VSQGs that opt into subpart P may notify the EPA whenever they choose, but they become subject to the requirements of this subpart on the date they submit the notification. All healthcare facilities must retain a copy of the notification as long as they are operating under this subpart.

4. Comments and Responses

Some states were concerned about their ability to process notifications in a timely manner given the 60-day time frame after the effective date of this rule within which all non-LQG healthcare facilities must notify EPA that they are operating under this subpart. The Agency reasserts, however, that the added burden is reasonable and necessary for the Agency and implementing states to gain a timely understanding of the facilities within the universe of this rule.

The Agency also notes that this final rule goes into effect six months from the date it is published in the **Federal Register** in EPA Territories and states that do not have an authorized RCRA program. That time frame could be even longer in authorized states which must first adopt this rule for it to become effective. Therefore, healthcare facilities in all states have a minimum of six months from the day this rule is published in the **Federal Register**, plus the 60 days in this requirement, to notify their state that they are operating under this subpart.

One commenter suggested that the agency implement a staggered roll-out of this notification provision to prevent them from becoming inundated with incoming notifications, preventing them from processing notifications in a timely manner. The Agency would note, however, that there is no provision requiring a healthcare facility to receive approval before it can operate under this subpart and states and regions can process the notifications by whatever time frames and methods they choose. All healthcare facilities must operate under this subpart immediately upon becoming subject to this rule. Therefore, as long as a healthcare facility that does not submit a BR notifies its state within 60 days that it is operating under this subpart, it will be in compliance. In addition, we did not propose and are not finalizing any time frames within which regional or state offices must process notifications, therefore, we defer to those agencies to develop their own best practices.

Another state suggested that EPA develop a ''smart-form'' tool for RCRAInfo—EPA's database of RCRA-related information from required reporting— that would allow healthcare facilities to notify the state electronically that they are operating under subpart P, directly input their own information, and update their information on a regular basis. EPA notes that it has developed an online tool called myRCRAid which allows generators to complete and submit the Site Identification Form electronically, which the Agency expects will reduce states' administrative burden by reducing the number of notifications that have to be manually input, while simultaneously reducing the potential for error while transferring data.

In addition, the Site Identification Form will be modified by EPA in a separate action to add a section for a healthcare facility to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the new section which will allow a healthcare facility to indicate that its generator category is changing to a VSQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266 subpart P.

Some states disagreed with the provision that allows healthcare facilities that file a BR to notify EPA that they are operating under subpart P on their normal reporting schedule, as opposed to notifying within 60 days of this rule becoming effective, or becoming subject to subpart P. This means that healthcare facilities that file a BR could potentially operate under this subpart for up to two years without having to notifying the Agency, depending on when their normal BR date falls in relation to the effective date of this rule. They recommended that all facilities, regardless of generator category, be required to notify within 60 days. While the Agency agrees that the possibility for a healthcare facility to operate for up to two years under this subpart without notifying EPA does, in fact, exist, we do not wish to impose duplicative notification requirements.

One state requested that a healthcare facility be required to list on the notification what its generator category would be if it were required to count its hazardous waste pharmaceuticals. They were concerned that some facilities that are LQGs because of their hazardous waste pharmaceuticals would reduce their generator category as a result of this rule, making them a low priority for inspections, even though they could still be generating LQG quantities of pharmaceutical waste. We understand the state's concern, however, making a change like this would not be in line with the goals of this rule to provide streamlined standards. However, options available to the states with similar concerns are adopting more stringent requirements or using

historical notifications and Biennial Report data.

B. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(b))

1. Summary of Proposal

a. Performance-based training standards. EPA believes that the part 262 LQG training regulations are excessive for healthcare personnel who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believes it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose, making the VSQG training standards insufficient. Therefore, the Agency proposed healthcare facility-specific personnel training requirements that are akin to the training requirements for SQGs and small quantity universal waste handlers, for all healthcare facilities subject to subpart P. Specifically, we proposed that healthcare facilities managing hazardous waste pharmaceuticals in accordance with subpart P must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. We indicated in the preamble to the proposed rulemaking that this training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs.

Under part 262 regulations, an LQG healthcare facility had to provide full RCRA training to its personnel involved in the generation and/or management of hazardous waste according to the standards in § 262.17(a)(7). These personnel training requirements include either classroom instruction, on-line training, or on-the-job training in RCRA and require the facility to maintain documentation of that training. On the other hand, before this rule was finalized, under the part 262 regulations, an SQG healthcare facility had to meet a performance-based standard when training personnel involved in the generation and/or management of hazardous waste pharmaceuticals. Specifically, this entailed ensuring ''that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.'' [200] For comparative purposes, healthcare facilities that are considered VSQGs did not have any personnel training requirements under the part 262 regulations. Similarly, SQGs and LQGs, including healthcare facilities, were not required to provide RCRA training to personnel that only work in SAAs regulated under § 262.15. That said, healthcare personnel that are involved in the generation of hazardous waste pharmaceuticals must be familiar enough with the pharmaceuticals with which they work to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

b. Documentation of training. Although no regulations were proposed, EPA also sought comment in the preamble to the proposed rulemaking on whether documentation of training is necessary in order to verify compliance with the training requirement.

2. Summary of Comments

a. Performance-based training standards. There were a variety of comments on the proposed training standards, both in support and opposition. Although most states agreed with the assessment that standard LQG regulations would be excessive if applied to healthcare facilities, some wanted EPA to provide more stringent and prescriptive language. Commenters from the waste management industry were also opposed to the proposed performance-based standards for similar reasons.

Pharmacy trade groups generally agreed with the proposed standards, citing the same rationale provided in the preamble of the proposed rulemaking, which states that the variability in waste generated and turnover in employees warrants a performance-based standard, and any subsequent training should be left up the healthcare facility. They stated that most pharmacy staff are trained on proper handling and management of radiation and other pharmaceuticals that can pose significant risks as required by other accreditation and standard-setting agencies and any prescriptive training standards under subpart P would be duplicative.

b. Documentation of training. There were mixed comments on whether to require that a healthcare facility document that its personnel have been trained according to the standards set forth in 40 CFR 266.502(b). All of the states that commented on this issue were supportive of the requirement to document training. These states were mostly concerned with their ability to cite specific violations of the training provisions during inspections. Another state mentioned that many facilities already maintain documentation of training as a best management practice.

Waste management companies also wanted EPA to require healthcare facilities to document that employees have been trained. They argued that the training standards will not have their intended effect if there is no requirement for documentation because healthcare facilities will not feel compelled to comply with them.

Pharmacy trade groups were concerned that requiring documentation of training would result in added burden and generally opposed this provision. They argued that there are a number of standard-setting and accreditation agencies that already require documentation that employees have been trained, and as such, this requirement would be redundant and overly burdensome.

3. Final Rule Provisions

a. Performance-based training standards. EPA is finalizing the performance-based training standards as proposed. A healthcare facility must train employees to the extent that they are thoroughly familiar with the proper handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The information can be disseminated verbally, via printed materials, or other means. These standards are similar to the training standards for SQGs and small quantity handlers of universal waste.[201] [202] The agency feels that these standards provide consistency across generator types and do not impose any added burden on inspection and enforcement actions beyond what is already in place within the Universal Waste program.

b. Documentation of training. EPA has decided not to finalize a standard that would have required healthcare facilities to document that the performance-based training standards have been met. The Agency thinks this requirement would have resulted in an undue increase in the regulatory burden for healthcare facilities. Also, there is no such requirement in the part 262 SQG training requirements or for small quantity handlers of universal waste.

[200] § 262.16(b)(9)(iii)

[201] 40 CFR part 262.16 (a)(9)(iii).

[202] 40 CFR part 273.16.

The agency feels this approach is consistent with other RCRA regulations and would improve consistency with the Universal Waste program, especially since the requirements for healthcare facilities managing hazardous waste pharmaceuticals were purposefully modeled after the requirements for small quantity handlers of universal waste. The Agency ultimately concluded that, because this approach is sufficient for universal waste, it is also acceptable for hazardous waste pharmaceuticals.

4. Comments and Responses

a. Performance-based training standard. There were a number of commenters from states and the waste management industry that recommended more rigorous and prescriptive training standards such as more specific minimum requirements, recurring training, and that the Agency specify the job titles subject to the training requirements. The Agency is not finalizing any of these recommendations, however, because we believe that the proposed performance-based standards are protective of human health and the environment without imposing undue burden either on states or industry. These standards strike an appropriate balance between ensuring proper management of hazardous waste pharmaceuticals and reducing the regulatory burden on healthcare facilities and healthcare personnel in a manner that also encourages compliance with these new regulations.

One commenter mentioned that prescriptive RCRA training requirements would be duplicative given the training requirements of the various accreditation entities. The Agency responds that any waste management training for healthcare personnel would not be duplicative because accreditation training typically focusses on managing pharmaceuticals prior to becoming a waste, whereas the training required in subpart P is targeted specifically at management practices after the pharmaceuticals have become waste. As mentioned previously, the Agency is not finalizing prescriptive training standards in an effort to minimize regulatory burden and allow healthcare facilities to tailor their training programs in a way that best fits their circumstances.

These training standards apply only to healthcare personnel. Healthcare personnel includes any person that manages hazardous waste pharmaceuticals at a healthcare facility (*e.g.,* employees, volunteers, students). Environmental health and safety personnel are likely to manage hazardous wastes other than just hazardous waste pharmaceuticals at a healthcare facility, in which case, they would be subject to other RCRA Subtitle C training requirements.

The Agency acknowledges that there are many pharmaceuticals that pose significant risk to human health and the environment, yet are not RCRA hazardous when they become waste. We in no way intend to imply that these items pose any less of a risk by virtue of being considered non-hazardous under RCRA and encourage healthcare facilities to provide all relevant training to healthcare personnel and observe industry best management practices.

b. Documentation of training. After requesting comment on documentation of training, the Agency decided not to finalize any requirements for healthcare facilities to document and maintain records verifying that healthcare personnel have met the training requirements. We considered the many adverse comments and ultimately agreed that such requirements would be overly burdensome and more stringent than the training requirements in the Universal Waste rule, which were largely emulated in this rule. Many comments that advocated for a requirement to document training were from states. Although such a requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require documentation of training, that would be considered more stringent and permissible under RCRA.

C. Healthcare Facilities Making a Hazardous Waste Determination for Non-Creditable Pharmaceuticals (§ 266.502(c))

1. Summary of Proposal

EPA proposed that, similar to the current part 262 generator requirements, healthcare facilities operating under subpart P would be required to make hazardous waste determinations on pharmaceutical wastes in order to determine the applicable management standards. Specifically, we proposed that when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the discarded pharmaceutical is listed in 40 CFR part 261 subpart D and/or if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261 subpart C. We proposed that, if the non-creditable pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the non-creditable hazardous waste pharmaceuticals in accordance with part 266 subpart P instead of 40 CFR part 262. Pharmaceutical wastes—both potentially creditable and non-creditable—not meeting the definition of a hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire consultants to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These healthcare facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in an on-site hazardous waste accumulation area, also known as a CAA. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency did not propose that a specific approach be utilized when making the hazardous waste determination, only that the facility performs the hazardous waste determination.

We also proposed that healthcare facilities have the option to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations. Instead, they would have made a generic decision that all of their discarded pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P. Accumulating all non-creditable waste pharmaceuticals in one container (except for those that are incompatible or cannot be incinerated according to the dilution prohibition) [203] and

[203] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

managing them under subpart P would relieve healthcare facilities from the burden associated with making individual hazardous waste determinations.

2. Summary of Comments

There were a wide variety of comments on this provision. Many in the regulated community requested some sort of a reference or compendium containing a comprehensive and up-to-date list of the waste pharmaceuticals that would be considered RCRA hazardous.

Commenters from states were generally supportive of the provision allowing all waste pharmaceuticals to be managed as hazardous waste pharmaceuticals. They believe the provision will encourage healthcare facilities to manage all of their waste pharmaceuticals in an environmentally protective manner. One commenter did suggest that healthcare facilities be required to choose whether they will make individual hazardous waste determinations for their waste pharmaceuticals or manage all of them as hazardous waste pharmaceuticals under this subpart and maintain documentation reflecting their decision.

Retail industry commenters were opposed to what they believe are contrary requirements, specifically, allowing a healthcare facility to manage all of its waste pharmaceuticals as hazardous but still require them to segregate incompatible hazardous waste and those prohibited from combustion as required by § 266.502(d)(4). They believe having to segregate incompatible and non-combustible waste significantly diminishes the intended relief.

3. Final Rule Provisions

EPA has finalized the provisions of this section with minor edits that further clarify that this section applies only to non-creditable pharmaceuticals. A healthcare facility that generates solid waste that is a non-creditable pharmaceutical has two options for hazardous waste determination. It may choose to either; (1) determine if each non-creditable pharmaceutical is a listed or characteristic hazardous waste to determine whether it is subject to the subpart P requirements, or (2) manage all of its non-creditable waste pharmaceuticals under the subpart P requirements as non-creditable hazardous waste pharmaceuticals. A healthcare facility that chooses the latter option, instead of making individual hazardous waste determinations at the point of generation, would have made a generic decision that all of their non-creditable pharmaceutical waste is hazardous and place it into a container or containers that are managed under part 266 subpart P.

The Agency wanted to provide maximum flexibility to healthcare facilities managing non-creditable waste pharmaceuticals while ensuring protection of human health and the environment, which is why we are finalizing the provision to allow healthcare facilities the option of managing all of their waste pharmaceuticals under subpart P. If a healthcare facility chooses to manage all of its non-creditable waste pharmaceuticals under the subpart P requirements, healthcare personnel are relieved from having to make individual hazardous waste determinations which might otherwise distract from their efforts in providing patient care.

4. Comments and Responses

A number of commenters asked if a third party can come on site and make individual hazardous waste determinations for commingled non-creditable waste pharmaceuticals. If a healthcare facility chooses to use a third party, typically a hazardous waste transport company, to come on site and make hazardous waste determinations at any time (typically in preparation for transport off site), that would also be permissible under this subpart.

Many comments were focused on the lack of an EPA-provided reference guide of which pharmaceuticals are hazardous waste when discarded. The RCRA generator regulations have always placed the onus on the generator of a waste to determine whether it is solid and hazardous waste. Nevertheless, EPA has made efforts to aid healthcare facilities in making hazardous waste determinations by developing the Hazardous Waste Pharmaceuticals wiki.[204] The website has served as a central location where users (*e.g.,* healthcare facilities, states) can share their knowledge about which pharmaceuticals are listed or characteristic hazardous waste, and other related information. EPA has also funded a compliance assistance center for healthcare facilities, which provides information on which pharmaceuticals are hazardous waste as well as other hazardous wastes found in a healthcare setting.[205] [206]

[204] Hazardous Waste Pharmaceuticals Wiki. *http://hwpharms.wikispaces.com.* Wiki spaces is phasing out its business of hosting wiki pages. The Agency plans to preserve the information that has been contributed to the wiki on EPA's website, but the content will be static.

[205] Healthcare Environmental Resource Center. *http://www.hercenter.org.*

D. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

1. Summary of Proposal

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the part 262 generator regulations, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered an SAA and is subject to volume accumulation limits and other provisions. Of particular concern regarding the SAA regulations for healthcare facilities is the one-quart accumulation limit for acute hazardous wastes (*i.e.,* P-listed wastes) and the requirement that hazardous waste must be accumulated at or near the point of generation. In particular, hospitals have noted that their difficulties are with having an SAA in each hospital room. As a result, the proposed December 2008 Pharmaceutical Universal Waste rule did not require the establishment of any accumulation areas (neither central nor satellite) for hazardous waste pharmaceuticals. This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes, nor are they required to have SAAs for universal wastes. Nevertheless, EPA understands that healthcare facilities will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas. The part 262 generator regulations, including the SAA and CAA regulations, were designed more for industrial and manufacturing operations. Part 266 subpart P is a sector-based regulatory approach designed to work better with how the healthcare sector operates. Therefore, consistent with the approach initially taken in the Universal Waste proposed rulemaking, the Agency designed the proposed standards for healthcare facilities accumulating hazardous waste pharmaceuticals under subpart P to operate in lieu of the SAA regulations or the CAA regulations (also sometimes called '' less than 90- or 180-day are as'').

[206] EPA makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the contents of these sites.

2. Summary of Comments

The majority of commenters on this provision were states. All but one state and all other commenters agreed with the proposal to eliminate requirements for SAAs and CAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The lone dissenting state agreed with eliminating requirements for SAAs but expressed concern about not requiring CAAs. They recommended that hazardous waste pharmaceuticals be accumulated in or near a 90-day or 180-day accumulation area for LQGs and SQGs respectively.

3. Final Rule Provisions

The agency is finalizing the approach for part 266 subpart P to operate in lieu of requiring CAAs and SAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The SAA regulations, in particular, were not a good fit for how healthcare facilities operate. Additionally, there was near-unanimous agreement among commenters that SAAs and CAAs are not necessary to accumulate hazardous waste pharmaceuticals, further supporting the agency's decision.

Although there is no requirement that a healthcare facility accumulate its hazardous waste pharmaceuticals in a CAA, doing so is, nonetheless, acceptable. A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90-day or 180-day CAA if it has one established for its other hazardous wastes, as long as it maintains compliance with the accumulation time limit and container requirements of 40 CFR part 266 subpart P. If a healthcare facility chooses to accumulate its hazardous waste pharmaceuticals in a CAA, those hazardous waste pharmaceuticals will only be subject to the requirements of part 266 subpart P and not the part 262 hazardous waste generator standards.

E. Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(d))

1. Summary of Proposal

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals. First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we only proposed standards for containers as defined in 40 CFR 260.10. However, the Agency solicited comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency proposed to require that healthcare facilities place hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding non-creditable hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, nor deterioration. EPA also proposed that containers also must not have any evidence of leakage, spillage, or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency proposed to require that incompatible wastes not be placed in the same container, unless the commingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or the environment. For example, the majority of a healthcare facility's non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17(b) for interim status TSDFs,[207] would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment, while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency also proposed that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the diversion of hazardous waste pharmaceuticals or inadvertent exposures to them. Unlike most other hazardous wastes, some hazardous waste pharmaceuticals might still retain considerable value to individuals or on the black market, which can increase the likelihood of diversion for illicit purposes.

Some non-creditable hazardous waste pharmaceuticals, such as metal-bearing wastes not containing sufficient organics (*e.g.,* P012, arsenic trioxide), are prohibited from being incinerated under the dilution prohibition.[208] Dilution is not a substitute for treatment of certain restricted wastes because the hazardous constituents are not destroyed, removed, or immobilized before being disposed of on the land.[209] EPA proposed that the hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

2. Summary of Comments

There was considerable interest in this section with a broad range of comments in support, in opposition, and suggesting modifications. While some states were in support of the proposed standards, others were concerned that they would not be easily understood by healthcare facility workers, and that we should provide more detail about what constitutes a closed container. There was also a comment that recommended we clarify that hazardous waste pharmaceuticals can only be accumulated in containers, and not tanks or other accumulation units, and also what would constitute an acceptable container. For example, the commenter asked if re-sealable plastic storage bags or plastic pill bottles are considered a container under this subpart.

[207] § 265.17 General requirements for ignitable, reactive, or incompatible wastes is available. *https://www.gpo.gov/fdsys/pkg/CFR-2017-title40-vol28/pdf/CFR-2017-title40-vol28-part265.pdf.*

[208] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

[209] See RCRA Policy Statement: Clarification of the Land Disposal Restrictions' Dilution Prohibition and the Combustion of Inorganic Metal-Bearing Hazardous Waste. *https://www.epa.gov/hw/policy-statement-clarification-dilution-prohibition-and-combustion-inorganic-metal-bearing.*

Commenters from the waste management industry were generally in support of the proposed container standards although one commenter took issue with the security standards in 40 CFR 266.502(d)(3), stating that they are not adequate and recommending that we incorporate existing DEA guidance on container security standards. The commenter also suggested the final regulations incorporate an additional security provision stating that hazardous waste pharmaceuticals be put into a ''product or container that is specifically designed to render them inaccessible, non-consumable, and/or irretrievable prior to final disposal.'' A different waste management company echoed the concerns shared by the previously mentioned state that the final rule should specify that hazardous waste pharmaceuticals can only be accumulated in containers and not in other types of waste accumulation units.[210] No commenters indicated that any other types of waste management units are used to accumulate hazardous waste pharmaceuticals.

Trade associations representing a range of stakeholders also generally supported the proposed provisions but were concerned about the requirements to segregate hazardous waste pharmaceuticals that cannot be incinerated. One waste treatment trade association recommended that the regulatory language that allows the incineration of certain mercury-bearing hazardous waste pharmaceuticals be changed to discourage the incineration of such wastes even though it is permissible. They believe that the proposed language may be interpreted as advocating for their incineration. A state association was concerned about the possible subjectivity of the language in 40 CFR 262.502(d)(2), which contains standards for facilities that manage ignitable or hazardous waste pharmaceuticals or that mix or commingle incompatible wastes in the same container. They recommend instead, that the final rule employ the ''traditional prohibition'' on incompatibility.[211]

3. Final Rule Provisions

The Agency is finalizing the container standards for non-creditable hazardous waste pharmaceuticals as proposed. A healthcare facility must place its non-creditable hazardous waste pharmaceuticals in containers that are structurally sound, compatible with the contents, and that would prevent any leaks or spills under reasonably foreseeable conditions. If incompatible hazardous waste pharmaceuticals are commingled in a container, the healthcare facility must manage the container such that it does not have the potential to generate dangerous heat and/or pressure, emit any toxic substances (*e.g.,* mists, fumes, dust), produce flammable fumes or gases, damage the structural integrity of the container, or otherwise endanger human health and the environment.

To address the concerns of commenters, EPA would like to emphasize that, while it is permissible for hazardous waste pharmaceuticals containing metals such as mercury to be incinerated if the total organic carbon is greater than 1%,[212] we strongly recommend that they be segregated out and treated via other acceptable methods that comply with the land disposal restrictions.

EPA is clarifying that the container standards like the other standards for non-creditable hazardous waste pharmaceuticals do not apply to hazardous waste pharmaceuticals that are also DEA controlled substances because these DEA controlled substances are conditionally exempt from RCRA.[213] Section XIV further discusses hazardous waste pharmaceuticals that are also DEA controlled substances.

To reduce the risk of illicit diversion, the Agency is finalizing the requirement preventing unauthorized access to the contents of containers used to accumulate non-creditable hazardous waste pharmaceuticals. EPA intended this requirement to be performance-based and did not finalize prescriptive regulatory requirements for this standard. Healthcare facilities may choose to utilize containers that are designed to prevent unauthorized access to their contents when located in areas with uncontrolled access or store containers in areas with controlled access, such as locked storage lockers, locked closets, or locked rooms, to prevent unauthorized access to the contents of the containers. Containers used to accumulate non-creditable hazardous waste pharmaceuticals may also be kept behind a pharmacy counter because of the restricted access to those areas.

The Agency received no comments indicating that non-creditable hazardous waste pharmaceuticals are accumulated in any waste management units other than containers. Therefore, these standards apply only to containers used to accumulate non-creditable hazardous waste pharmaceuticals. Other types of hazardous waste accumulation units are not permitted for the accumulation of non-creditable hazardous waste pharmaceuticals.

4. Comments and Responses

Section (d)(4) of this provision regarding the requirement to segregate certain metal-bearing non-creditable hazardous waste pharmaceuticals was added as a reminder that, due to existing LDR regulations, a few hazardous waste pharmaceuticals cannot be incinerated and therefore must be segregated. This is not a new requirement for healthcare facilities and does not represent a change in the regulatory burden.

One commenter asked if plastic bags are considered a container as defined in § 260.10. If hazardous waste is placed inside a plastic bag, it meets the definition of a RCRA container and is subject to all applicable standards in 40 CFR 264 subpart I and 40 CFR 265 subpart I. Specifically, to be in compliance, a plastic bag must be compatible with the waste, able to prevent the contents from leaking, kept closed during storage except when it is necessary to add or remove waste, and handled or stored in a manner that prevents rupture and/or causes leaking. EPA would also note that, even though this commenter did not mention other types of containers, that cups, pill bottles, vials, etc. are also considered a container under RCRA.[214]

Regarding the state association that suggested EPA apply the ''traditional prohibition'' on mixing or commingling incompatible wastes in the same container because they were concerned about the possible subjectivity of the five specified conditions in 40 CFR 262.502(d)(2), that regulatory language was taken directly from the general requirements for ignitable, reactive, or incompatible wastes, in the General Facility Standards at 40 CFR 265.17(b). This is not a newly designed requirement. Healthcare facilities that manage hazardous waste pharmaceuticals are already required to comply with this provision.

[210] See comment number EPA–HQ–RCRA–2007–0932–0257.

[211] See comment number EPA–HQ–RCRA–2007–0932–0216.

[212] § 268.3 (c) Dilution prohibited as a substitute for treatment.

[213] § 266.506.

[214] See memo November 11, 2011, Rudzinski to the Regional RCRA Division Directors (RCRA Online #14827).

F. Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(e))

1. Summary of Proposal

During the period of accumulation, the Agency proposed that containers of hazardous waste pharmaceuticals be marked with the words ''Hazardous Waste Pharmaceuticals.'' The Agency did not propose to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. Healthcare personnel (*e.g.,* nurses) typically generate the hazardous waste pharmaceuticals. Healthcare personnel are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a hazardous waste pharmaceutical is generated. For these reasons, EPA did not believe it would be practical to require individual hazardous waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility.

The Agency solicited comment on the appropriateness of the proposed general labeling requirement. The Agency also requested comment on security concerns regarding having the word ''pharmaceutical'' marked on the containers.

2. Summary of Comments

The issues of determining waste codes and whether they should be required on labels and/or manifests cuts across a number of provisions in this rule. Many commenters intertwined their opinions on container labeling standards with manifest requirements, waste code determinations by healthcare workers, and LDRs. While the Agency understands the inter-relatedness of these issues, this section pertains specifically to the proposed standards of requiring the words ''Hazardous Waste Pharmaceuticals'' on containers used to accumulate hazardous waste pharmaceuticals, and whether having the word ''Pharmaceutical'' displayed on those containers increases the risk of illicit diversion. Many of the comments alluded to these container labeling requirements during on-site accumulation, but did not address them directly, instead focusing on how the proposed labeling standards to not require hazardous waste codes on containers will affect the manifesting, shipping, and LDR processes. We will address those comments in subsequent sections as appropriate.

States had mixed views with a few voicing support for the proposed labeling standards, while another asked that the Agency provide more leeway in the required wording on the container label. Another state agreed with not requiring individual waste codes, but recommended that EPA require some sort of identification of potentially incompatible wastes to help prevent their inadvertent mixing. Two states were opposed to the proposed standards and recommended requiring individual hazardous waste codes on container labels to reduce the risk of mismanagement and incorrect treatment.

One reverse logistics company tacitly agreed with the proposal to not require hazardous waste codes on containers (or manifests) and instead, write ''Hazardous Waste Pharmaceuticals'' on the container and comply with DOT requirements. They expressed agreement with the agency's proposal to not require hazardous waste codes on the manifest, which leads the Agency to conclude that not requiring hazardous waste codes on containers is acceptable to them as well.

Comments from the waste treatment sector were mixed as well. One commenter agreed with the proposal to not require hazardous waste codes on container labels but wanted more flexibility in labeling. Other commenters from the waste treatment industry were wholly opposed to the proposed labeling requirements citing the need for waste codes by TSDFs to meet LDR standards.[215]

One medical waste trade association did not explicitly agree that hazardous waste codes should not be required on container labels, but they did request that, at a minimum, hazardous waste codes should be included on the manifest.

Stericycle initially disagreed with the proposal to require the word ''pharmaceutical'' on labels in addition to ''Hazardous Waste'' when it commented on the 2008 proposal to add pharmaceuticals to the Universal Waste rule. It has subsequently, through first-hand experience, determined that including the word ''pharmaceutical'' on containers does not increase the risk for illicit diversion. Therefore, in its comments to this proposed rulemaking, it is now in support of labeling containers of hazardous waste pharmaceuticals with the words ''Hazardous Waste Pharmaceuticals.''

Multiple commenters representing regional and national healthcare systems currently label their containers with the word ''pharmaceuticals'' and feel it is appropriate.[216] A commenter from the healthcare waste association also agrees that including the word ''pharmaceutical'' on containers is current practice and does not present any additional risk of diversion.[217]

3. Final Rule Provisions EPA is finalizing the container labeling requirements as proposed. Specifically, containers of non-creditable hazardous waste pharmaceuticals must be marked with the words ''Hazardous Waste Pharmaceuticals'' when accumulating on-site. This final rule provision is consistent with the container labeling requirements in the Hazardous Waste Generator Improvements rule,[218] in that generators are not required to label containers with hazardous waste codes during on-site accumulation. Previously, the regulations did not specify when hazardous waste codes needed to be added to container labels.

The Agency was concerned about increasing the risk of diversion resulting from displaying the word ''pharmaceutical'' on a container. However, given the general support from commenters, in this final rule, EPA is comfortable including the word ''pharmaceutical'' on the label of containers used to accumulate hazardous waste pharmaceuticals. There was no opposition from commenters representing healthcare systems and pharmacy trade groups. In fact, many commented that this is has been standard practice for some time and has not resulted in any increased diversion.

4. Comments and Responses

One state was concerned that allowing the commingling of hazardous waste pharmaceuticals could inadvertently lead to incompatible hazardous waste pharmaceuticals being mixed together, and suggested that EPA add a requirement to label containers with potentially incompatible wastes. It is the Agency's understanding that there are only a few pharmaceuticals that are incompatible according to DOT. Pressurized aerosols are the most common, although both DOT and EPA are considering relaxing their

[215] See comment numbers EPA–HQ–RCRA–2007–0932–0333 and EPA–HQ–RCRA–2007–0932–0297.

[216] See comment number EPA–HQ–RCRA–2007–0932–0297.

[217] See comment number EPA–HQ–RCRA–2007–0932–0296.

[218] Final rule: November 28, 2016; 81 FR 85808.

management requirements in the near future. Other DOT incompatible wastes include oxidizers, acids, and bases, yet they occur infrequently in dosage form.[219] In addition, there are a limited number of cases in which commingled incompatible pharmaceutical waste has caused a problem. Therefore, the Agency has determined that the risk does not rise to the level of requiring a specific provision and is not finalizing any additional labeling requirement for incompatible hazardous waste pharmaceuticals.

One commenter from the waste management industry suggested that EPA add the flexibility to label containers of hazardous waste pharmaceuticals with the words ''hazardous waste'' or other words that communicate the hazards per § 262.34(c)(1)(ii).[220] The Agency is not finalizing this suggestion. EPA recently revisited these provisions in the 2016 Hazardous Waste Generator Improvements rule to require that generators label containers with both the words ''hazardous waste'' and other words that indicate the nature of the hazard partially because the Agency felt that the previous requirements were too vague. In addition, § 262.34 applied only to containers in SAAs whereas there are no SAAs in a subpart P healthcare facility.

G. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(f))

1. Summary of Proposal

a. One-year accumulation time limit. A few hazardous waste pharmaceuticals are P-listed acute hazardous wastes, the most common being warfarin. Under the part 262 generator regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month, the generator is regulated as an LQG and subject to a 90-day limit on accumulation. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient total amounts of hazardous waste pharmaceuticals within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 proposed amendment to add pharmaceuticals to the Universal Waste program, handlers of pharmaceutical universal waste would have had one year to accumulate their hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the proposed 2008 Pharmaceutical Universal Waste rule indicated support for the one-year accumulation time limit. Thus, under part 266 subpart P, the Agency proposed to allow healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals for up to one year without triggering interim status or the need to obtain a RCRA permit. EPA proposed one year as an appropriate time frame because it strikes a balance between allowing healthcare facilities enough time to accumulate enough non-creditable hazardous waste pharmaceuticals to make it economically viable to transport their hazardous waste pharmaceuticals off site while ensuring that the hazardous wastes are not accumulated beyond the one-year storage limit under the LDR program (see § 268.50). Under the LDR storage prohibition, the Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal.

EPA proposed that healthcare facilities could use various approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. For example, EPA proposed that a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste, or any other method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste.

b. Extensions to accumulation time limits. In the proposed time frames to accumulate non-creditable hazardous waste pharmaceuticals, EPA included a provision that allowed any healthcare facility needing longer than the one-year accumulation time frame to request an extension from the appropriate EPA Regional Administrator. The Agency provided several examples of situations when a healthcare facility might request an extension. The reasons included litigation (now referred to as preservation orders, investigations or judicial proceedings),[221] recalls, and circumstances that are beyond the control of the healthcare facility. The proposed extension provision required that healthcare facilities send a request in writing (electronic or paper) to the Regional EPA Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals to be accumulated beyond the one year, and the amount of extra time requested. The Agency then proposed to allow the Regional Administrator the discretion to grant, modify, or deny the requested extension on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

2. Summary of Comments

a. One-year accumulation time limit. One commenter from industry agreed with the proposed time limits, but expressed concern about the ability of a healthcare facility to track accumulation times of their waste, and recommended that there be an additional requirement to inventory container contents in a manner that will ensure that the 1-year limit is not exceeded. Another state commenter also recommended that § 266.502(f)(2)(iv), which would have allowed containers to be marked in ''any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste,'' be eliminated because it is too vague.

b. Extensions to accumulation time limits. The proposed extension provisions were opposed by a majority of commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would likely arise from having to generate, transmit, and maintain an additional set of records for a scenario (the need to accumulate hazardous waste pharmaceuticals beyond the one-year allotment) that they say occurs more often than EPA seems to have been aware of at the time of proposal. Similarly, many state agencies were concerned about the added burden that would be imposed by a novel

[219] Smith, Charlotte A. ''Managing Pharmaceutical Waste: A New Implementation Blueprint.'' Pharmacy Practice News, Special Edition, 2011.

[220] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking. The regulation cited by the commenter has been since moved to 262.16(b)(6) as part of the 2016 Hazardous Waste Generator Improvements Final Rule.

[221] Subsequent to the proposal, the Agency became aware that the term ''litigation'' was not sufficiently broad to encompass all of the legal actions that might require a hazardous waste pharmaceutical to be preserved. To maintain consistency throughout the final rule, all instances where the term ''litigation'' or ''litigation holds'' appeared in the proposed rule have been changed to ''preservation order, investigation, or judicial proceeding,'' except in this section which discusses what was proposed.

source of administrative workload in the form of written requests that must be processed, analyzed, afforded appropriate consideration/discretion, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with existing federal regulations, those of FDA for recalls, in particular. Other commenters brought up similar concerns about pharmaceuticals being stored pursuant to a litigation hold because of their protracted and unpredictable nature.

3. Final Rule Provisions

a. One-year accumulation time limit. The Agency is finalizing a one-year accumulation time limit for healthcare facilities accumulating non-creditable hazardous waste pharmaceuticals. Healthcare facilities may use one of three approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. A healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, or identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste.

The Agency reiterates that the one-year accumulation time limit only applies to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of non-pharmaceutical hazardous waste generated on-site nor to potentially creditable hazardous waste pharmaceuticals.

The provision in § 266.502(f)(2)(iv) has been eliminated. It would have allowed for the accumulation start date to be labeled in any manner that clearly indicates the length of time that it first began accumulating non-creditable hazardous waste pharmaceuticals. One commenter argued that the provision was overly broad and EPA agreed.

b. Extensions to accumulation time limits. The Agency is not finalizing any of the proposed provisions in § 266.502(f)(3) that would have allowed a healthcare facility to request an extension of the one-year accumulation period for non-creditable hazardous waste pharmaceuticals and has addressed commenter concerns in other areas of the rule.

Recalls and preservation orders, investigations, or judicial proceedings (formerly referred to as litigation in the proposed rulemaking) were the two specific situations that the Agency attempted to address in the proposal as examples of unforeseen circumstances beyond the control of the healthcare facility. Pharmaceuticals that are subject to a voluntary or federally-mandated recall (most likely overseen by FDA, rarely CPSC) must be managed according to the requirements of either one or both agencies, as appropriate. Although many of these items could likely be considered RCRA solid waste, EPA is choosing not to apply RCRA regulations upon recalled pharmaceuticals that are managed under a voluntary or federally-mandated recall until a decision is made to destroy those items either in part or in whole. Similarly, the agency also determined that pharmaceuticals being stored pursuant to a preservation order, investigation, or judicial proceeding are not RCRA hazardous waste. Both scenarios are addressed in the Applicability section of the final rule in the preamble and regulations (see §§ 266.501(g)(4) and 266.501(g)(5)). Because pharmaceuticals that have been recalled and/or are being stored pursuant to a preservation order, investigation, or judicial proceeding are not subject to this subpart, the Agency does not see the need to include a provision for extending accumulation time. Recall managers (likely reverse distributors) and states will not be burdened by producing and responding to such requests.

The proposed rulemaking also discussed other unforeseen circumstances (other than a recall or preservation order, investigation, or judicial proceeding) as a legitimate reason for requesting an extension of the one-year period to accumulation of non-creditable hazardous waste pharmaceuticals. However, the only circumstances mentioned by commenters that would necessitate an extension were recalls and litigation (preservation orders, investigations, or judicial actions). Because both of those scenarios are now addressed individually in the finalized Applicability section of the preamble and regulations, and have no associated accumulation time limits, the Agency saw no need to codify a provision to allow a healthcare facility to request an extension of the accumulation time limit for other reasons beyond their control. Therefore, the EPA is not finalizing the proposal to allow healthcare facilities to request an extension of the one-year accumulation time frame from the Regional Administrator for any reason.

H. Land Disposal Restrictions for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(g) and § 266.502(d)(4))

1. Summary of Proposal

As required by HSWA and consistent with part 262 generator requirements, EPA proposed that healthcare facilities must comply with the LDR requirements prior to land disposal of the hazardous waste pharmaceuticals they generate. Since healthcare facilities are generators, even though they are not subject to the 40 CFR part 262 requirements for the management of hazardous waste pharmaceuticals, we proposed that they must comply with the LDR requirements found at 40 CFR part 268. The LDRs required by HSWA are in place to ensure that toxic constituents present in hazardous waste are properly treated to reduce their mobility or toxicity before hazardous waste is placed into or onto the land (*i.e.,* land disposed). With limited exceptions, hazardous waste must be treated by a RCRA-permitted or interim status TSDF.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers (commonly called hazardous waste codes) to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to label the containers with the words ''hazardous waste'' or the hazardous waste codes when transporting them off site, but rather must label the containers with the words ''hazardous waste pharmaceuticals.'' Healthcare facilities do, however, need to make determinations as to whether wastes must be treated to meet LDR treatment standards. While most hazardous waste pharmaceuticals are likely organic in nature and may be incinerated, some hazardous waste pharmaceuticals may not be suitable for incineration and, therefore, must be segregated from the organic wastes. The hazardous waste pharmaceuticals not suitable for incineration include characteristic metal wastes (*i.e.,* D004–D043) prohibited from being combusted because of the dilution prohibition of § 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. Put another way, hazardous waste pharmaceuticals with these metals that also contain greater than 1% total organic carbon may be incinerated.

In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic hazardous waste pharmaceuticals so that they can be properly treated by the TSDF. Although the Agency did include a requirement to segregate these metal-bearing low total organic carbon hazardous waste pharmaceuticals in proposed § 266.502(d)(4), the Agency requested comment on whether it is necessary to incorporate into the regulations at § 266.502(g) a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Because EPA proposed that containers of non-creditable hazardous waste pharmaceuticals would not be required to list the hazardous waste codes on the label, we also proposed that waste codes are not required on the LDR notification.

2. Summary of Comments

There were a variety of comments on this provision, primarily regarding four issues: (1) The segregation of hazardous waste pharmaceuticals unsuitable for incineration, (2) the incineration of hazardous waste pharmaceuticals with numeric treatment standards, (3) the LDR notification, and (4) the need for hazardous waste pharmaceuticals-specific waste code and treatment standard.

Commenters from both states and the waste management industry requested that the agency add a requirement for healthcare facilities to segregate any hazardous waste pharmaceuticals that are unsuitable for incineration into separate containers and label them with the appropriate waste codes. They argued that there would be an increased likelihood that pharmaceuticals containing metals subject to the dilution prohibition would be inadvertently incinerated, resulting in noncompliance with LDR standards.

Many waste management companies expressed concern about their ability to meet LDR standards without knowing specific waste codes and the added burden they would incur from having to test their ash for the seven hazardous waste pharmaceuticals with numeric treatment standards—lindane, chloroform, m-cresol, dichlorodifluoromethane, trichloromonofluoromethane, phenacetin and phenol.[222] They did, however, agree that healthcare workers should not have to make hazardous waste determinations. They stated that they would have to alter or augment their testing protocols for residual ash which would add undue burden. One commenter suggested that, at a minimum, segregation be performed before a shipment of hazardous waste pharmaceuticals are transported off site for disposal, but having waste codes either on a label or the manifest would be preferable. They generally stated that they do not feel waste management should bear all of the added burden of LDR compliance under this rule.

Another common theme among commenters, from the waste management industry in particular, was a recommendation for a new, single hazardous waste code for all hazardous waste pharmaceuticals with a corresponding alternate treatment of standard of combustion (CMBST). One commenter representing the retail industry expressed concern that the relief provided by this rule will be negated by the requirement to list waste codes on the LDR notice.

3. Final Rule Provisions

The Agency is finalizing the LDRs for non-creditable hazardous waste pharmaceuticals as proposed. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the LDRs of 40 CFR part 268. A healthcare facility that generates hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the LDR notification.

To address commenters' concerns about whether hazardous waste codes are required on the LDR notification, the Agency has added clarifying language to specify that waste codes are, in fact, not required on the LDR notification. The Agency would note, however, that the proposed regulatory language did, in fact, specify in § 266.502(g) that waste codes are not required on the LDR notice. Due to the number of commenters who were under the impression that waste codes would still be required on the LDR notice, we added an additional clarification to make it more obvious that waste codes are not required on the LDR notice.

The final rule requires healthcare facilities that generate non-creditable hazardous waste pharmaceuticals to comply with the LDRs. In response to comments, we have made one minor change for added clarity. The Agency has added a requirement to § 266.502(d)(4) for healthcare facilities that generate non-creditable hazardous waste pharmaceuticals that are unsuitable for incineration to segregate them into separate containers from those containing commingled non-creditable hazardous waste pharmaceuticals, and label them with the appropriate hazardous waste codes. We would note, however, that the dilution prohibition of § 268.3 already necessitates such segregation, therefore, this addition in § 266.502 (d)(4) is for the purposes of clarity and does not substantially change any of the proposed LDR requirements for hazardous waste pharmaceuticals.

4. Comments and Responses

Waste management companies opposed the provision to not require healthcare facilities to label containers with hazardous waste codes because of the added burden they argue would result from having to conduct additional testing for pharmaceuticals with numeric treatment standards. Nevertheless, the Agency is not finalizing a requirement for healthcare facilities to label containers of non-creditable hazardous waste pharmaceuticals with hazardous waste codes, nor is the Agency finalizing any additional requirements for healthcare facility personnel to segregate the seven pharmaceuticals that have numeric treatment standards, although a vendor could include such a requirement in its contract with a healthcare facility.

Unlike metal-bearing hazardous waste pharmaceuticals that may not be incinerated, the seven hazardous waste pharmaceuticals with numerical treatment standards may be incinerated or treated using any other treatment method to meet LDR values. Therefore, the Agency thinks it would cause confusion and add burden to require healthcare facilities to segregate the hazardous waste pharmaceuticals with numeric treatment standards. Further, the Agency has determined that several of the seven organics with numeric treatment standards also appear in non-pharmaceutical hazardous waste, which means that hazardous waste combustors are already required to test their ash to ensure compliance with LDRs for those constituents.

Because this rule does not require that healthcare facilities label their waste with the hazardous waste codes, TSDFs will now have to analyze their incinerator residue (ash) for the seven organics that have numerical treatment standards according to the conditions established in the facility waste analysis plan, as they could possibly be present in any shipment of organic hazardous

[222] See 40 CFR 268.40 table ''Treatment Standards for Hazardous Wastes,'' which identifies maximum concentration values for all hazardous constituents in the waste/treatment residue prior to land disposal.

waste pharmaceuticals or treatment residues. Organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA-permitted or interim status hazardous waste combustors. Most organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics have numerical treatment standards, such that no particular treatment technology is required to achieve the numerical LDR treatment standards. While these wastes may be incinerated, the ash must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be land disposed. The Agency is not finalizing any standards that would affect the frequency of testing, simply that TSDFs test their ash for these seven constituents as part of their existing protocol.

EPA is not finalizing recommendations from commenters that the Agency implement a new waste code or alternative treatment standards specifically for hazardous waste pharmaceuticals. Because the Agency did not propose any new waste codes or treatment standards for hazardous waste pharmaceuticals, the recommendation is outside the scope of this rule. The Agency does agree that implementing an alternative treatment standard of combustion for hazardous waste pharmaceuticals that currently have numeric treatment standards would be a viable solution to mitigate any added burden imposed on TSDFs that will have to modify their testing protocol; however, we did not receive the necessary data to propose such a change prior to proposal, and therefore cannot finalize an alternative treatment standard in this rule. The Agency is, however, open to considering alternative treatment standards for hazardous waste pharmaceuticals in possible future rulemakings.

In their comments on this rule and the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of combustion. Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards.[223] EPA explored the feasibility of making combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric LDR treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible, to allow maximum flexibility. Furthermore, it is not clear that pharmaceuticals would be the sole source of the seven organic constituents in question. Therefore, even if we proposed an alternative treatment standard of combustion for the seven organic pharmaceuticals, hazardous waste combustors would still be required to test their ash for these constituents to demonstrate compliance with numeric treatment standards if they received the organics from another, non-pharmaceutical source.

Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.[224]

I. Procedures for Healthcare Facilities Managing Rejected Shipments of Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(h))

1. Summary of Proposal

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we proposed that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

2. Summary of Comments

There were relatively few comments on this section of the proposed rulemaking. One state and one waste management company agreed with the standards as proposed. Another state suggested that, as written, the regulatory language contradicts itself. Specifically, the commenter said that proposed § 266.502(h)(4) implies that a healthcare facility that receives a rejected shipment of non-creditable hazardous waste pharmaceuticals (a shipment that it initiated) must offer it for shipment to a new designated facility upon receipt, as opposed to the 90-day additional accumulation period mentioned in § 266.502(h). They reason that, because there are no time frames in the requirement, the Agency intended to mean upon receipt.

3. Final Rule Provisions

The agency is finalizing the provisions in this section as proposed with the added clarification that a healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility must have an understanding that the designated facility can accept and manage the waste. However, if the healthcare facility later receives the shipment back as a rejected load, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within 30 days to the designated facility that returned the shipment and ship the non-creditable hazardous waste pharmaceuticals to a new designated facility. The Agency also added additional clarification to § 266.502(h)(4), to respond to comments, specifying that a healthcare facility has up to 90 days to ship the rejected shipment to a new designated facility.

J. Reporting Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(i))

1. Summary of Proposal

We proposed that healthcare facilities that are required to submit a BR would no longer be required to include their non-creditable hazardous waste pharmaceuticals in the report. In addition, the Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to generators regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c).

We proposed to incorporate and adapt the generator exception reporting procedures of 262.44(b) for this new subpart. Specifically, we proposed that if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not

[223] Prohibited waste may be land disposed if it is treated using the technology specified in the table (*e.g.,* CMBST:''), which are described in detail in § 268.42, Table 1—Technology Codes and Description of Technology-Based Standards.

[224] See section VII.D.1.b for further discussion.

receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery, along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts. Likewise, we proposed that if a shipment of non-creditable hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

Finally, the Agency proposed that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required.

2. Summary of Comments

The Agency received few comments on this subsection. Comments primarily addressed there being no requirement to include hazardous waste pharmaceuticals on the BR, and opinions were mixed. All pharmacy trade groups that commented were in favor of the proposal to not require hazardous waste pharmaceuticals managed under part 266 to be reported on the BR. States that commented were split. One state opposed the proposal and argued it would hinder the state's ability to reconcile what is treated at a TSDF with what is generated at a healthcare facility. Another state disagreed with the proposed provision and argued states will be forced to establish their own reporting requirements at the state level, leading to inconsistency in the way states determine their reporting fees. Another state was in agreement with the proposed provision, stating that information regarding amounts of non-creditable hazardous waste pharmaceuticals generated and treated can be captured from reverse distributor and TSDF reporting. One other state pointed out that the lack of a requirement for healthcare facilities to determine waste codes would make reporting in the BR difficult, if not impossible.

Regarding the exception reporting requirements, one state suggested that § 266.502(i)(2)(ii)(A) and (B) are unnecessary because the requirements in § 266.502 (i)(2)(i)(A) and (B) for a healthcare facility that does not receive a signed copy of the manifest within 60 days of being accepted by the initial transporter are the same, whether the shipment is lost or rejected and transferred to a new designated facility. The state suggested that § 266.502(i)(2) should be rewritten to simply state that an exception report is only necessary if the healthcare facility has not received the signed manifest from the TSDF within 60 days. One healthcare provider suggested that the proposed 60-day period for a healthcare facility to receive the manifest from the TSDF should be shortened to 45 days because shipments of other non-pharmaceutical hazardous waste require receipt of the manifest from the TSDF within 45 days.

3. Final Rule Provisions

The reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals are being finalized as proposed. That is, non-creditable hazardous waste pharmaceuticals managed under this subpart at a healthcare facility are not required to be reported on the BR, healthcare facilities must submit an exception report to the Regional Administrator if they have not received a signed copy of the manifest within 60 days of the initial transporter accepting the shipment, and the Agency may require a healthcare facility to furnish additional reports regarding the quantity and disposition of non-creditable hazardous waste pharmaceuticals. When managing rejected shipments, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

To clarify, the exception reporting regulations for healthcare facilities differ from the exception reporting regulations for reverse distributors because they were based on the differing § 262.42 exception reporting for LQGs and SQGs. The exception reporting regulations for healthcare facilities were based on the corresponding § 262.42(b) SQG regulations, whereas the reverse distributor exception reporting regulations were based on the § 262.42(a) LQG regulations.

Although commenters voiced some concern about not knowing the volume of non-creditable hazardous waste pharmaceuticals being generated at healthcare facilities, the Agency believes it is unnecessary to require healthcare facilities generating non-creditable hazardous waste pharmaceuticals to report this information. If a state or region wants to obtain such information, it can examine hazardous waste received forms in the BR submission from TSDFs. Further, one of the goals of this final rule is to reduce burden on healthcare facilities so that they will be encouraged to manage all of their waste pharmaceuticals under part 266 subpart P. Requiring a healthcare facility to report hazardous waste pharmaceuticals on its BR would discourage them from managing non-hazardous waste pharmaceuticals as hazardous. Finally, we would note that this approach is consistent with the Universal Waste program upon which the healthcare facility standards are based. Universal wastes managed under part 273 are not reported on the BR.

4. Comments and Responses

As part of the part 262 generator regulations, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR under part 262. However, it need not include in its BR hazardous waste pharmaceuticals managed under part 266. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals managed under part 266 when determining their generator category under part 262. Instead, all healthcare facilities, with the exception of VSQGs, will be subject to this final rule for the management of hazardous waste pharmaceuticals. The Agency has determined that it does not need the information to be included in the BR because this final rule will bring a consistent approach to managing hazardous waste pharmaceuticals.

One commenter suggested that the time frame within which a healthcare facility must receive a signed manifest be shortened from 60 days to 45. The Agency did not finalize that request

because many standards in this final rule were based upon SQG and universal waste standards. Since no manifest is required for transport and there is no exception reporting standard in the Universal Waste program, the Agency used the 60-day time frame in the part 262 SQG standards. LQGs have a 45-day time frame to receive a signed manifest from a designated facility. Therefore, shortening the exception reporting time frame from 60 days to 45 would not be consistent with the goals of this rule to relieve the burden of LQG standards on healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

The Agency is not finalizing the suggestion to unify the language in § 266.502(i)(2) to cover both missing and rejected shipments. The proposed language was taken from the generator requirements in § 262.42, which addresses both situations separately. The Agency is not aware of the existing approach creating any problems for generators and is finalizing the regulatory language as proposed.

K. Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(j))

1. Summary of Proposal

The Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, we proposed that healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report. In addition, EPA proposed that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination. The Agency also proposed that any of the retention periods be automatically extended during the course of ongoing enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

2. Summary of Comments

There were very few comments on this proposed provision. All but one of the commenters were states, all of which agreed with the proposed standard. One commenter suggested that we specify that all three types of records (manifest, exception reports, and test results/analysis/waste determinations) be kept on site.

3. Final Rule Provisions

The recordkeeping requirement is being finalized as proposed, with two changes. First, the Agency added a fifth provision in § 266.502(j)(5) to address comments requesting that all records be kept on site. The added provision also requires that all records must be readily available upon request by an inspector. The Agency understands that some records may be kept at off-site locations (*e.g.,* headquarters), which is acceptable as long as those records are able to be produced in a timely manner upon the request of an inspector.

The second change was an addition to § 266.502(j)(3) that relieves a healthcare facility from the requirement to retain documentation of hazardous waste determinations in § 266.502(c) if it chooses to manage all of its non-creditable waste pharmaceuticals as hazardous waste under subpart P. As discussed elsewhere, a goal of this rule is to encourage healthcare facilities to manage all of their waste pharmaceuticals under subpart P to reduce the amount of pharmaceuticals entering surface and groundwater via sewering and landfill leachate. The relief provided in § 266.502(j)(3) provides additional incentive for healthcare facilities to manage their non-creditable non-hazardous pharmaceutical waste under subpart P.

A healthcare facility must keep a copy of the signed manifest for a period of at least three years from the date the shipment was accepted by the initial transporter. A healthcare facility must also keep a copy of any exception report for a period of at least three years from the date of the report. To make the recordkeeping consistent with the 2016 Generator Improvements final rule, a healthcare facility must keep any information used to support its hazardous waste determination for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal, unless it chooses to manage all of its non-creditable pharmaceutical waste as hazardous waste under subpart P. The periods of retention will be automatically extended in the event of any enforcement activity or as requested by the Regional Administrator.

L. Response to Spills for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals (§ 266.502(k))

1. Summary of Proposal

For non-creditable hazardous waste pharmaceuticals generated and managed by healthcare facilities under this subpart, the Agency proposed basic spill response requirements, including the requirement that healthcare facilities immediately contain all spills of, and other residues from, hazardous waste pharmaceuticals. In addition, we proposed that healthcare facilities determine whether any material (*e.g.,* residue, contaminated clean-up materials, or debris resulting from the spill) is or contains a hazardous waste pharmaceutical and, if so, that the healthcare facility manage it under the management standards for non-creditable hazardous waste pharmaceuticals. Commenters to the original 1993 proposed rulemaking for establishing the Universal Waste program overwhelmingly supported these release response measures (60 FR 25528; May 11, 1995). Thus, we believe it was appropriate to include them again in this proposal for healthcare facilities managing non-creditable hazardous waste pharmaceuticals since it was based on the Universal Waste program.

2. Summary of Comments

One waste management company was in support of the proposed standards while another voiced its concern with the proposed preamble language discussing the requirement to report releases into the environment greater than the reportable quantity without knowing the waste codes of the wastes that had been spilled. They recommended that the Agency establish a reportable quantity for hazardous waste pharmaceuticals so large releases are appropriately reported to EPA. Similarly, one pharmacist trade association recommended that the Agency define what constitutes a release because the proposed regulatory language and preamble are unclear, and therefore it is also unclear when a release needs to be reported to the Agency.

One state commenter pointed out that these standards should also apply to healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals. They recommend that this standard apply to all hazardous waste pharmaceuticals and that after a spill is cleaned up, the determination of credit potential must be made again. All other states agreed with the proposed standards for responding to spills.

3. Final Rule Provisions

The standards in this subsection are being substantially finalized as proposed with two changes.

First, we changed the word ''release'' to ''spill'' in the regulations in response to a commenter that expressed concern about having to comply with CERCLA requirements for spills of non-creditable hazardous waste pharmaceuticals. It was not the Agency's intent to imply that spills occurring inside a healthcare facility are automatically subject to CERCLA. The proposed preamble language was intended to differentiate between three scenarios: Spills that are cleaned up immediately, spills that are not cleaned up immediately, and releases to the environment. Spills that are cleaned up immediately must be managed under this subpart. Spills that are not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state. The proposal also mentioned that hazardous waste is included in the definition of hazardous substance under CERCLA, and any release to the environment would trigger CERCLA authority in addition to RCRA. In many cases, a spill of a hazardous waste pharmaceuticals that occurs inside a healthcare facility does not constitute a release to the environment under CERCLA.[225] Therefore, this standard applies to spills that do not constitute a release to the environment, and there are no reporting requirements for spills unless they result in a release to the environment. This requirement makes no assertions about when or how CERCLA applies to spills of both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals. The new terminology is also consistent with the term used in the definition of non-creditable hazardous waste pharmaceuticals in § 266.500, which refers to spills as opposed to releases.

Second, we addressed the comment from the state that requested a clarification regarding whether the spill response requirements apply to potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. The Agency agrees that the applicability of this proposed provision—whether it applies only to non-creditable hazardous waste pharmaceuticals or to both potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals—was unclear. The regulatory language has been changed to reflect that the standards in this subsection apply only to spilled non-creditable hazardous waste pharmaceuticals. Further, the proposed regulations required that a healthcare facility determine whether, after being cleaned up, spilled non-creditable hazardous waste pharmaceuticals are potentially creditable or non-creditable, implying that non-creditable hazardous waste pharmaceuticals could become potentially creditable. The Agency did not intend to imply that spilled non-creditable hazardous waste pharmaceuticals could become potentially creditable. The regulatory language has been modified to simply require that spilled non-creditable hazardous waste pharmaceuticals and clean-up material be contained and managed as non-creditable hazardous waste pharmaceuticals. To address this regulatory gap that commenters identified regarding spilled potentially creditable hazardous waste pharmaceuticals, the Agency has added a corresponding subsection containing standards for response to spills of potentially creditable hazardous waste pharmaceuticals at a healthcare facility to the regulatory language at § 266.503(f).

M. Management of Non-Creditable Hazardous Waste Pharmaceuticals by Long-Term Care Facilities That Collect Them From Individuals Who Self-Administer

1. Summary of Proposal

The Agency proposed that a LTCF must collect hazardous waste pharmaceuticals from its residents that self-administer their medication and manage them under this subpart. This provision was proposed in order to require the proper management of all hazardous waste pharmaceuticals at LTCFs. LTCFs are similar to hospitals in that they are both healthcare providers, but they differ with respect to who owns the pharmaceuticals dispensed to patients. While hospitals own the pharmaceuticals they dispense, the pharmaceuticals dispensed at long-term care facilities belong to the residents of the facility. EPA understands that, while long-term care facilities often maintain each individual's pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals at some types of LTCFs may keep and self-administer their own pharmaceuticals. Under the proposal, long-term care facilities would have had to collect and manage all hazardous waste pharmaceuticals generated on site, regardless of ownership, in accordance with these same proposed subpart P management standards for healthcare facilities. EPA believed this approach would prohibit and prevent sewering of hazardous waste pharmaceuticals at these locations.

2. Summary of Comments

There was very little agreement with the proposed requirement for LTCFs to collect hazardous waste pharmaceuticals from patients that self-administer their medication. Most commenters argued that hazardous waste pharmaceuticals generated by residents who self-administer are household hazardous waste and that LTCFs are not allowed by law to perform any mandatory collection actions and have no authority to compel residents to surrender their unused medications. In addition, they commented that medication prescribed under Medicare Subpart D is considered the property of the resident. One commenter also pointed out that this provision would be unlawful and even dangerous to enforce because it would entail inspectors having to enter private residences, which is prohibited by many state statutes, and search through garbage bags and dumpsters to ensure that hazardous waste pharmaceuticals have not been illegally disposed.

Also, one commenter mentioned that this provision would add significant cost to the residents because waste management expenses are not covered under Medicare and pharmacies are not allowed to offer waste collection services for less than cost and would therefore be required to pass the full cost onto the residents.

3. Final Rule Provisions

The Agency is not finalizing the proposed provisions in this subsection. As discussed previously, after consideration of the comments, the Agency modified the definition of LTCF

[225] Spills are likely to occur upon impermeable surfaces both inside of and outside of a healthcare facility which limits the potential for release into the environment. Under CERCLA, a release to the environment also includes releases into the atmosphere. Since many pharmaceuticals are in pill form, spilled pharmaceuticals would rarely, constitute a release to the environment under CERCLA.

to specifically exclude assisted living facilities, group homes, independent living communities, and the independent/assisted living portions of continuing care retirement communities. The Agency agrees that the hazardous waste pharmaceuticals generated at these types of facilities meet the criteria for the household hazardous waste exclusion in § 261.4(b)(1) and are therefore not under the purview of RCRA regulations. Accordingly, we have also deleted proposed § 266.502(l) and the final rule does not require LTCFs to collect hazardous waste pharmaceuticals for their residents that have custody of and self-administer their medication. The Agency does, however, reiterate that this definition of LTCFs classified them as a type of healthcare facility. As such, LTCFs are subject to all the provisions being finalized for hazardous waste pharmaceuticals that are present in an LTCF's central pharmacy, because the hazardous waste being generated is not the property of the residents. Additionally, hazardous waste pharmaceuticals that are in the custody of the LTCF on behalf of the resident must be managed under this subpart. That said, the Agency expects that most LTCFs will be VSQGs and therefore only subject to a limited subset of the regulations in this rule, including the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. In fact, § 266.504(d) of the final rule includes a presumption that an LTCF with fewer than 20 beds is a VSQG.

Although not regulated under this subpart, the Agency recommends that assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities develop voluntary pharmaceutical collection programs for both hazardous and non-hazardous waste pharmaceuticals as a best management practice, as allowed by DEA regulations, to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse.

N. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Very Small Quantity Generator Healthcare Facilities (§ 266.502(l))

1. Summary of Proposal

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable, or to a permitted or interim status hazardous waste TSDF, if it is not. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility.

Until EPA finalized the Hazardous Waste Generator Improvements rule on November 28, 2016, CESQG regulations of § 261.5 did not allow a generator to send its hazardous waste off site to another generator, unless the receiving generator was one of the seven types of facilities listed in § 261.5(f)(3)(i)–(vii) or § 261.5(g)(i)–(vii), which included landfills permitted by state law.[226] The 2016 Hazardous Waste Generator Improvements final rule added a new provision for the consolidation of hazardous waste from VSQGs to LQGs under the control of the same person.[227] Person is defined under RCRA in § 260.10 and control is defined as ''the power to direct policies at the facility under RCRA in § 260.10.'' [228] [229] This provision now allows the same company to consolidate its VSQG hazardous waste at its LQG sites.

Specific to healthcare facilities, EPA is aware of two situations in which VSQGs would like to consolidate their hazardous waste pharmaceuticals at other healthcare facilities. The first situation is LTCFs that are VSQGs that return their hazardous waste pharmaceuticals to long-term care pharmacies that they contract with. The second situation involves military bases, where the off-post clinics that are generally VSQGs would like to send their hazardous waste pharmaceuticals back to the base clinics or pharmacies on the nearby base.[230]

Since long-term care pharmacies are not generally under the control of the same person as the LTCF, the proposed healthcare facility consolidation provision was broader than what was finalized in the 2016 Hazardous Waste Generator Improvements rule to accommodate the contractual relationship between long-term care facilities and long-term care pharmacies. The Agency proposed this consolidation provision to allow healthcare facilities that are VSQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal solid waste landfill.

Specifically, EPA proposed to allow VSQG healthcare facilities to send their hazardous waste pharmaceuticals to an off-site healthcare facility without a hazardous waste manifest, provided the receiving healthcare facility meets four conditions. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the VSQG LTCF, or the VSQG healthcare facility and the receiving healthcare facility must both be under the control of the same person, as defined by § 260.10.[231] Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with subpart P. Third, the hazardous waste pharmaceuticals from the VSQG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with subpart P once it arrives at the receiving healthcare facility. Fourth, the receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site VSQG healthcare facilities for three years from receipt of shipment.

As proposed, these conditions would ensure the proper management of the hazardous waste pharmaceuticals: Once they are received by the healthcare facility, they are subject to the same management standards EPA proposed for hazardous waste pharmaceuticals managed by healthcare facilities.

EPA took comment on two aspects of this exclusion: (1) Whether any additional conditions should be imposed in this provision and (2) whether to expand the scope of the provision to facilities that do not meet the proposed definition of a healthcare facility in this rule.

2. Summary of Comments

Overall, states, waste management and the healthcare industry were supportive of the proposal to allow VSQG healthcare facilities to consolidate their hazardous waste

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[226] The Hazardous Waste Generator Improvements final rule renamed CESGGs as VSQGs, moved the regulations from § 261.5 to § 262.14 and added an eighth type of facility.

[227] 40 CFR 262.14(a)(5)(viii).

[228] *Person* means an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.

[229] For purposes of this provision, ''control'' means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

[230] See notes from 11–28–12 meeting with U.S. Army Institute of Public Health in the docket for this rule (EPA–HQ–RCRA–2007–0932–0209).

[231] For purposes of this provision, ''control'' means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

pharmaceuticals at another healthcare facility, provided the four conditions outlined above are met. One state, however, did oppose this provision unless the receiving healthcare facility is subject to all of the LQG requirements under part 262. They recommended that hazardous waste pharmaceuticals from VSQGs be consolidated at larger healthcare facilities under the 2016 Hazardous Waste Generator Improvements final rule to ensure more stringent standards are met by the receiving facility. Some states and pharmacists raised concerns that some of the language within the conditions was too narrow to serve the purpose that the language was trying to achieve.

3. Final Rule Provision

EPA is finalizing the provision to allow healthcare facilities that are operating under subpart P to receive hazardous waste pharmaceuticals from VSQGs with minor changes. Healthcare facilities that are VSQGs for their pharmaceutical and non-pharmaceutical waste may send their potentially creditable and non-creditable hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, without a hazardous waste manifest, provided the receiving healthcare facility meets the four conditions in § 266.502(l)(1)–(4) or § 266.503(b)(1)–(4), as applicable.

Several conforming changes were made to reflect the change in terminology from CESQG to VSQG and to reflect the reorganization of the VSQG regulations from § 261.5 to § 262.14. There are three more substantive changes from the proposal. First, under § 266.502(l)(1) where we proposed that one way a healthcare facility could receive hazardous waste pharmaceuticals from an off-site VSQG healthcare facility was to have a contractual relationship to provide the pharmaceutical products to the LTCF, we broadened the language to allow cases in which a ''business relationship'' between the LTCF and long-term care pharmacy exists.

Under the final rule, a healthcare facility under subpart P may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to send their waste for consolidation to an off-site healthcare facility is not considered to be operating under subpart P and does not need to notify as a VSQG operating under subpart P.

The second substantive change was to include a parallel provision in § 266.503 for potentially creditable hazardous waste pharmaceuticals. This addition allows healthcare facilities that are VSGQs two options for where to send their potentially creditable hazardous waste pharmaceuticals. The first option is to send them directly to a reverse distributor.[232] The second option is to send them to a healthcare facility operating under part 266 subpart P, provided the receiving facility meets the conditions of 266.503(b)(1)–(4).

The third change related to off-site consolidation of hazardous waste pharmaceuticals is to add paragraph § 262.14(a)(5)(x). Section 262.14(a)(5) of the VSQG regulations consists of a list of types of facilities to which VSQGs can send their hazardous waste. Section 262.14(a)(5)(viii) allows VSQGs to send their hazardous waste to large quantity generators under the control of the same person as the VSQG, provided certain conditions are met. This provision is similar to the provision we are finalizing in this rule for healthcare facilities that are VSQGs. Therefore, for consistency, we have added paragraph (x) to the list of facilities in § 262.14(a)(5) such that a healthcare facility that is a VSQG can send its non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals to an off-site healthcare facility (as defined in § 266.500) that meets the conditions in § 266.502(l) and § 266.503(b), as applicable.

4. Comments and Responses

Some states and pharmacists noted that language in the first condition may have the unintended consequence of prohibiting healthcare facilities from consolidating their hazardous waste pharmaceuticals due to their relationship with the consolidating facility. The first condition that a receiving healthcare facility must be under the control of the same person or contracted to supply pharmaceutical products to the VSQG's LTCF might prevent some long-term care facilities from taking advantage of this provision. Long-term care facilities that would otherwise be eligible to take advantage of this exclusion might not use it since CMS does not prevent long-term care facilities and/or their residents from using more than one long-term care pharmacy. This allows the long-term care facilities and the residents to shop for the ''best and most competitive'' pricing for medications and to change as needed.[233] Commenters believed that adding ''business relationship'' in addition to a contractual relationship for the healthcare facility and receiving facility to both be under the control of the same person would relieve this concern.

Furthermore, pharmacists raised the concern that a long-term care pharmacy would not want to take responsibility for returned pharmaceuticals under this condition as proposed unless they could confirm that they were the ones that distributed the pharmaceuticals in the first place (a receipt of purchase or similar documentation), since the management of these wastes is costly and may not be covered by the various healthcare programs. According to the CMS website, the managing of returned pharmaceuticals at long-term care pharmacies varies from state to state and is not a specific requirement of the Medicare/Medicaid program.[234] This consolidation provision was created so that VSQGs could consolidate their hazardous waste pharmaceuticals for proper management. If the provision as written is preventing long-term care facilities from potentially consolidating their hazardous waste, then it is thwarting the intended outcome of this provision and that is why EPA decided to add ''business relationship'' to the first condition for VSQG consolidation.

One state commenter recommended that the receiving healthcare facilities must either be an LQG or comply with the LQG requirements under part 262, since LQGs have more protective management standards during accumulation. First, under part 266 subpart P, healthcare facilities do not

[232] As allowed by 40 CFR 266.504(a).

[233] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

[234] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

have a generator category for their hazardous waste pharmaceuticals; all healthcare facilities are regulated the same under part 266 subpart P. Second, if EPA limited this consolidation provision to LQGs, then there would be a very small subset of receiving healthcare facilities that would be able to take advantage of this provision. Since subpart P allows healthcare facilities operating under this subpart to not count their hazardous waste pharmaceuticals towards their generator category, some healthcare facilities may no longer be LQGs for their other hazardous waste. It is highly unlikely that a long-term care pharmacy would remain an LQG under this rule since the majority of the hazardous waste that would be handled at these pharmacies would be pharmaceuticals. If we were to limit this provision to only LQG receiving facilities, then we would be preventing LTCFs from consolidating at long-term care pharmacies. Therefore, we determined that requiring the receiving facilities to be LQGs or to comply with LQG standards as a condition of the consolidation provision would severely limit the value of this provision.

In addition, the Agency is not finalizing a requirement for healthcare facilities that receive hazardous waste pharmaceuticals from VSQG healthcare facilities to manage the received pharmaceutical waste under the part 262 LQG standards. The Agency does not see the necessity in having more stringent management standards for healthcare facilities that receive pharmaceutical waste, because subpart P management standards are the same for all non-VSQG healthcare facilities, regardless of the amount of hazardous waste pharmaceuticals they generate. The Agency has determined that the subpart P standards are sufficiently protective of human health and the environment since all pharmaceuticals at a receiving healthcare facility must be managed under the same subpart P standards, regardless of whether they were generated on site or received from off site. If a state determines that the standards being finalized for healthcare facilities that receive hazardous waste pharmaceuticals from off-site are not adequate, that state may implement its own standards, provided they are more stringent.

The waste management industry, as well as some states, recommended that EPA require a notification when a facility was receiving hazardous waste pharmaceuticals and at least some minimal requirements for labeling, recordkeeping, and documentation of shipments. One state also recommended that we issue licenses to facilities that were receiving hazardous waste pharmaceuticals in order to track who was taking advantage of this provision. Consistent with our rationale for the limited shipping requirements for ''potentially creditable hazardous waste pharmaceuticals'' in this rule, the Agency believes that the shipping of hazardous waste pharmaceuticals poses a relatively low risk of release to the environment but a high risk for diversion of the pharmaceuticals when labeled ''pharmaceuticals.'' The hazardous waste that are being shipped often are in pill form or blister packs and not fifty-gallon drums of liquids that can be easily spilled. They are not likely to pose the same risks that typical hazardous waste could cause during shipping and transport, but there is a real risk to them being stolen if attention is brought to the contents of the containers. If the four conditions are met, the Agency believes this ensures the proper management of hazardous waste pharmaceuticals and adding new labeling and shipping requirements is unnecessary to accomplish that goal. Furthermore, the part 262 VSQG regulations do not require labeling or recordkeeping, and VSQGs might not take advantage of this consolidation provision if the requirements are too onerous, thus continuing to put their hazardous waste pharmaceuticals in municipal solid waste landfills.

The waste management industry asked for clarification on hazardous waste pharmaceuticals consolidation across state lines that have different requirements for VSQGs. There is nothing in this section that prevents a healthcare facility from sending their hazardous waste pharmaceuticals to a healthcare facility in another state provided both states have adopted this provision. Each state has their own requirements, so it would be prudent for VSQG healthcare facilities to make sure that the state in which they are consolidating has adopted this provision and does not impose any additional requirements on the receiving healthcare facility that accepts this waste.

EPA also received comments on what types of facilities could take advantage of this provision, specifically whether this provision will include wholesale drug distribution centers. In the final rule, EPA has defined wholesale distributors as a type of healthcare facility under § 266.500. Wholesale distributors were not an example that was given to us at proposal for this consolidation provision, but if all four conditions were met and there was a contractual or business relationship between the VSQG healthcare facility and the wholesale distributor, they would not be precluded from using this provision. However, we would note that when a wholesale distributor receives hazardous waste pharmaceutical return from a healthcare facility, the pharmaceuticals are usually restocked, which means they are pharmaceutical products and not hazardous waste pharmaceuticals.

Lastly, a non-profit organization asked us to clarify if these consolidated hazardous waste pharmaceuticals would be eligible for redistribution or evaluation for donation once consolidated to the receiving facility. In regard to redistribution or evaluation for donation, if the receiving healthcare facility can lawfully donate or redistribute the consolidated hazardous waste pharmaceuticals, there is nothing in this provision that prevents that from occurring, but those shipments would not fall under the consolidation provision in subpart P. If a VSQG is sending products to another facility, then the receiving facility should evaluate the received pharmaceuticals as they would any other products they receive for continued use, redistribution to secondary markets, donation and/or any other lawful possibilities. At this point, they are not a solid or hazardous waste and not subject to the requirements in § 266.502(l) or § 266.503(b).

EPA would also note that this provision is optional and it is not meant to impose undue burden on healthcare facilities. This section does not require a VSQG healthcare facility to ship their hazardous waste pharmaceuticals to a receiving healthcare facility. VSQG healthcare facilities continue to have the option, unless the state regulations are more stringent, of sending their hazardous waste pharmaceuticals to any of the types of facilities specified in § 262.14, including a municipal solid waste landfill.

XI. Standards for Healthcare Facilities That Accumulate Potentially Creditable Hazardous Waste Pharmaceuticals Prior to Shipment to Reverse Distributors (§ 266.503)

A. Healthcare Facilities Making a Hazardous Waste Determination for Potentially Creditable Pharmaceuticals (§ 266.503(a))

1. Summary of Proposal

EPA proposed standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals in § 266.503 of subpart P. As with non-creditable hazardous waste pharmaceuticals, a healthcare

facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart.

Accordingly, we proposed that a healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C).

We also proposed that a healthcare facility may choose to manage all of its potentially creditable waste pharmaceuticals (both hazardous and non-hazardous) together as potentially creditable hazardous waste pharmaceuticals while accumulating on site and when shipping off site under § 266.509. If a healthcare facility chooses this approach of commingling its hazardous and non-hazardous potentially creditable waste pharmaceuticals, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of its potentially creditable waste pharmaceuticals are hazardous and would manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P.

We proposed that healthcare facilities may choose to manage potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under the shipping standards of § 266.509. Additionally, EPA proposed that healthcare facilities would be prohibited from sending hazardous waste other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. This was in keeping with our position that a reverse distributor's function in managing hazardous waste should be limited to managing hazardous waste pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and not non-creditable hazardous waste pharmaceuticals or other non-pharmaceutical hazardous waste.

2. Summary of Comments

Pharmacists, some wholesalers, and manufacturers expressed concern that making hazardous waste determinations at their facilities would require additional staff, additional training on making hazardous waste determination, as well as more storage space in which to hold the hazardous waste as the determinations are being made.

We received mixed comments on commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. Healthcare facilities and pharmacists were in favor of EPA allowing commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals, and the benefit it offers in handling their pharmaceutical waste or continuing the common practice of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals when sent to reverse distributors. On the other hand, waste management and states raised concerns that commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may prevent healthcare facilities from sending their waste across state lines or to certain reverse distributors, due to state regulations and/or reverse distributors' policies.

3. Final Rule Provisions

EPA is finalizing the standards as proposed, with some minor changes. Under this section, a healthcare facility has two choices: (1) Make a hazardous waste determination on each potentially creditable waste pharmaceutical and determine individually which are hazardous waste and thus subject to regulation under this subpart or, (2) commingle all potentially creditable pharmaceutical waste whether or not it is hazardous waste and manage the commingled pharmaceuticals under this subpart and thereby not have to make individual hazardous waste determinations.

EPA removed ''even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261 subpart C and are not listed in 40 CFR part 261 subpart D'' from the non-hazardous waste provision of this section since it was redundant with determinations of solid waste pharmaceuticals and whether they are potentially creditable or not.

EPA has also modified the regulatory language in the final rule to make clear that when a healthcare facility commingles potentially creditable non-hazardous and hazardous waste pharmaceuticals, the healthcare facility is choosing to subject the potentially creditable non-hazardous waste pharmaceuticals to all of subpart P while being managed at a healthcare facility and in preparation for shipping off-site. Once potentially creditable non-hazardous and hazardous waste pharmaceuticals are commingled they are subject to all applicable subpart P management standards while they remain commingled. As a practical matter, however, we expect that the primary impact to healthcare facilities will be that potentially creditable non-hazardous waste pharmaceuticals are subject to the shipping standards of § 266.509. Once potentially creditable non-hazardous waste pharmaceuticals are shipped off site to a reverse distributor, a reverse distributor may choose to segregate the non-hazardous waste pharmaceuticals from the hazardous waste pharmaceuticals. This process of segregation by the reverse distributor would require the reverse distributor to make new hazardous waste determinations on the commingled pharmaceuticals.

4. Comments and Responses

We received many comments on making hazardous waste determinations and commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. While the commenters raised valid concerns on why making hazardous waste determinations can be burdensome on a healthcare facility, or why commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may not work for all facilities, EPA made only minor editorial changes to this section of the final rule. The Agency determined that more substantive changes were unnecessary because this provision contains sufficient flexibility by providing healthcare facilities with two options.

a. *Making hazardous waste determinations.* Pharmacists, some wholesalers, and manufacturers expressed concern that being required to make hazardous waste determinations at their facilities would impose undue burden because they would have to hire additional staff and train them to make accurate waste determination. They argue that they would also need to allocate more space in which to store waste as the determinations are being made. Some commenters stated that making hazardous waste determinations may prevent healthcare facilities from sending their hazardous waste pharmaceuticals to reverse distributors at all. In support of the comments above, manufacturers and wholesalers argued that reverse distributors have the appropriate RCRA expertise to make accurate waste determinations, that they have served as a consolidation point for unused and hazardous waste pharmaceuticals for many years, and that the process has been effective and successful. The Agency notes, however, that allowing potentially creditable

pharmaceuticals to be sent to a reverse distributor without a hazardous waste determination being made at the point of generation violates a basic tenet of RCRA, because the decision to send them to a reverse distributor is effectively a decision to discard. In addition, the burden mentioned by commenters associated with making individual waste determinations would likely be significantly mitigated by exercising the option to manage all potentially creditable waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals.

b. *Commingled waste stream.* As previously noted, we received mixed comments on commingling potentially creditable non-hazardous hazardous waste pharmaceuticals.

EPA proposed the option of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals to mitigate the burden of complying with the management standards, particularly for healthcare personnel making hazardous waste determinations. Given that many healthcare facilities currently commingle their potentially creditable non-hazardous and hazardous waste pharmaceuticals, we expect the practice to continue. However, if commingling causes undue burden on a facility due to state regulations, reverse distributor policies, or other reasons, then the healthcare facility does not have to utilize this option and can make individual hazardous waste determinations in accordance with § 266.503(a). This is an individual decision for each healthcare facility and each healthcare facility may choose what works best for managing its potentially creditable pharmaceutical waste.

Retailers and reverse distributors recommended that healthcare facilities should be allowed to make a determination about whether the item will be managed as hazardous when it becomes a waste at the time of arrival at the retail store or healthcare facility. They believe this practice would be impeded if all pharmaceuticals must be managed as potentially creditable hazardous waste pharmaceuticals when they become waste. If this is common practice among healthcare facilities, then the need to commingle their waste may not be something that is important. Allowing the commingling of all solid waste pharmaceuticals is meant to ease the burden on healthcare facilities that are not currently making hazardous waste determinations, or do not wish to make them, by allowing them to manage and ship all of their potentially creditable waste pharmaceuticals together.

B. Accepting Potentially Creditable Hazardous Waste Pharmaceuticals From an Off-Site Healthcare Facility That Is a Very Small Quantity Generator (§ 266.503(b))

1. Summary of Proposal

EPA proposed to allow healthcare facilities operating under subpart P to accept potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site VSQG healthcare facility without a hazardous waste manifest, provided four conditions are met. We proposed this provision in § 266.502(m) under the standards for managing non-creditable hazardous waste pharmaceuticals.[235] We proposed that healthcare facilities operating under subpart P could accept both potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG. Previously, the part 262 VSQG regulations did not allow a healthcare facility to send its hazardous waste off-site to another healthcare facility, unless the receiving healthcare facility is one of the eight types of facilities listed in § 262.14(a)(5)(i–viii). For more detailed information on our proposal, please refer to section X.N.

2. Summary of Comments

EPA only received one comment in this section concerning changes to the generator category of the receiving facility. A trade association of pharmacists was concerned that allowing VSQG consolidation would affect the generator category of the receiving healthcare facility, and that it would need to report as an LQG.

3. Final Rule Provision

In the proposed rulemaking, EPA intended to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility, provided the receiving healthcare facility complies with the four conditions of § 266.502(m) (now in § 266.502(l)). In the final rule, we clarified our intention to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility by placing similar standards in § 266.503(b) under the standards for managing potentially creditable hazardous waste pharmaceuticals. This does not reflect a change from what was proposed, only that the consolidation standards apply to healthcare facilities receiving both non-creditable and potentially creditable hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG can send both its potentially creditable hazardous waste pharmaceuticals and non-creditable (including commingled) hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, provided the receiving healthcare facility complies with the four requirements of the respective sections. Regulations for the receiving healthcare facilities now appear in § 266.502(l) for non-creditable hazardous waste pharmaceuticals and in § 266.503(b) for potentially creditable hazardous waste pharmaceuticals. VSQG healthcare facilities that send their hazardous waste pharmaceuticals to an off-site healthcare facility are subject to the regulations in § 266.504(b), with further discussion in section XII.B of the preamble.

Under § 266.503(b) of the final rule, a healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to consolidate its hazardous waste pharmaceuticals at an off-site healthcare facility is not considered to be operating under subpart P, and does not need to notify as a VSQG operating under subpart P.

[235] This provision is now found at § 266.502(l).

4. Comments and Responses

A pharmacists' association was concerned that allowing for VSQG consolidation would change the generator category of the receiving healthcare facilities and that the consolidating facility would need to report as an LQG. All healthcare facilities operating under part 266 subpart P are regulated the same, regardless of the amount of hazardous waste pharmaceuticals they generate. Further, healthcare facilities managing their hazardous waste pharmaceuticals under this subpart do not count their hazardous waste pharmaceuticals toward their generator category so consolidation of this additional hazardous waste pharmaceuticals at their facilities would not change the generator category of the receiving healthcare facility.

C. Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

Under the hazardous waste generator regulations in part 262, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals pose a lower risk of release into the environment than traditional industrial hazardous waste. The risk of release is lower for several reasons.

First, potentially creditable hazardous waste pharmaceuticals must be in original manufacturers' packaging by definition and are often in their outer packaging as well, providing two layers of protection from leaks or spills.[236] Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable waste pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment.

For the reasons listed above, EPA did not propose specific standards for managing and labeling containers of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. For the same reasons, we also did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals.

This is not to say that all potentially creditable hazardous waste pharmaceuticals waste pharmaceuticals are safe and pose no risk of spill or release into the environment. It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk due to possible spills or leaks than solid pills. However, EPA believes that the small quantities in which liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), significantly reduces the risks of spills or releases to the environment.

In addition, to further mitigate the potential for spills or leaks, as a best management practice, EPA encourages healthcare facilities to place the original containers, and packaging containing liquids and aerosols pharmaceuticals, in separate individual containers (*e.g.,* sealed storage bag) before placing them in the accumulation container.

1. Accumulation Time and Container Management of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals or specific standards for how the containers must be managed during accumulation.

b. Summary of comments. Most commenters were in favor of adding some guidelines for accumulation time and container management. Some states commented that the proposed standards for non-creditable hazardous waste pharmaceuticals should be applied to both non-creditable and potentially creditable hazardous waste pharmaceuticals to prevent confusion from having multiple accumulation standards, and to provide extra protection of human health and the environment.

c. Final rule provisions. EPA is not finalizing a time limit for accumulating containers of potentially creditable hazardous waste pharmaceuticals. EPA is also not finalizing specific container management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals

d. Comments and responses. Several states expressed concern about the security of potentially creditable hazardous waste pharmaceuticals during accumulation. These commenters agreed that potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated area that is labeled and kept locked or sealed according to best management practices for that facility as an additional deterrent to illicit diversion. Commenters also expressed concerned that not having designated accumulation areas could lead to situations where healthcare facility personnel may misplace or forget the locations of accumulation containers. States were concerned that the potential for healthcare facilities to receive manufacturer credit does not sufficiently encourage proper management.

As previously discussed, potentially creditable hazardous waste pharmaceuticals do not pose the same risks as other hazardous wastes. We received many comments, especially from the retail industry, about the condition of packages being important for being eligible and receiving manufacturer credit. For example, broken and/or leaking containers cannot be sent to a reverse distributor per the definition of ''potentially creditable hazardous waste pharmaceuticals,'' so there is an incentive to manage these items carefully. There is also an incentive to not overaccumulate wastes in healthcare facilities since manufacturer credit is only issued by reverse distributors and in many cases, cannot be collected by a healthcare facility until the reverse distributor receives them.

It is also important to note that many of these potentially creditable hazardous waste pharmaceuticals are already being generated and stored in secure areas, such as pharmacies, and being handled by personnel that have pharmaceutical expertise. EPA is also recommending that liquids and aerosols be put in sealed plastic bags, containers, or other management practices during accumulation to reduce the risk of spills and releases.

As for labeling the accumulation area with the words pharmaceutical waste, the concern still remains for increasing the potential for illicit diversion of these potentially creditable hazardous waste pharmaceuticals by bringing attention to the fact that it contains pharmaceuticals. Therefore, the Agency is not finalizing a requirement for healthcare facilities to label accumulation areas for potentially creditable hazardous waste pharmaceuticals.

Finally, if a state is uncomfortable with our approach to the accumulation of potentially creditable hazardous waste pharmaceuticals, it may choose to be more stringent in this regard when it adopts the rule.

[236] See 73 FR 73529; December 2, 2008.

2. Labeling Requirements for Containers of Potentially Creditable Hazardous Waste Pharmaceuticals

a. Summary of proposal. EPA did not propose specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals while they are accumulated on-site at a healthcare facility because they are in original manufacturer packaging, they are already labeled, and any additional labeling would be duplicative or apply to secondary containers, such as boxes used to ship to reverse distributors.

In addition, due to concerns regarding illicit diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor or patient care pharmaceutical waste, the potentially creditable hazardous waste pharmaceuticals returned to a reverse distributor often have high black-market value that makes them susceptible to diversion. Thus, EPA did not propose to require a label for containers used to accumulate potentially creditable hazardous waste pharmaceuticals.

b. Summary of comments. Many states believe that labeling should be required for all containers of hazardous waste to ensure proper management and disposal. Proper management, according to comments, includes accumulation in designated locations with individual containers labeled for inspection.

Other commenters expressed concerns that containers that are not labeled are subject to inaccurate waste determinations and will be mishandled and treated as non-creditable hazardous waste pharmaceuticals and sent to a TSDF rather than as potentially creditable which could ultimately be destined for a reverse distributor.

c. Final rule provision. EPA is not finalizing labeling standards for containers of potentially creditable hazardous waste pharmaceuticals accumulated by healthcare facilities.

d. Comments and responses. While the commenter's concerns apply to hazardous waste in general and for hazardous waste going to a TSDF, we do not believe they are equally applicable to containers of potentially creditable hazardous waste pharmaceuticals. First, containers of potentially creditable hazardous waste pharmaceuticals are in original manufacturer's packaging (or have been repackaged for use in a LTCF) and thus the contents are easily identifiable. Second, if a healthcare facility does not label an accumulation container on site and then forgets about it or misidentifies where it needs to go, then no manufacturer credit will be issued for those potentially creditable hazardous waste pharmaceuticals. Likewise, if a healthcare facility does label the containers on site and the contents are illicitly diverted, then the healthcare facility will not receive the manufacturer credit for those items. Healthcare facilities have a monetary incentive to keep track of what is in these containers, regardless of whether they are labeled, and to make sure they arrive unmolested at the reverse distributor.

Additionally, by imposing labeling requirements, EPA does not want to deter the practice of commingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported together to a reverse distributor.

Therefore, EPA concludes that it is not necessary to require any labeling standards for potentially creditable hazardous waste pharmaceuticals.

D. No Biennial Reporting for Potentially Creditable Hazardous Waste Pharmaceuticals Generated at Healthcare Facilities (§ 266.503(d))

1. Summary of Proposal

The Agency proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

2. Summary of Comments

One state commented that it would prefer to be notified about who is handling this waste to ensure that healthcare facilities are adhering to the prohibition on sewering, since they will not know who is handling this waste.

3. Final Rule Provision

The Agency is finalizing as proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart. Potentially creditable hazardous waste pharmaceutical quantities will be captured by the reverse distributors' required biennial reports,[237] therefore, a requirement for healthcare facilities to report quantities of potentially creditable hazardous waste pharmaceuticals generated would be duplicative.

[237] This provision is found at § 266.510(c)(9)(i)

4. Comments and Responses

One state was concerned that they would not know which healthcare facilities are generating potentially creditable hazardous waste pharmaceuticals. All healthcare facilities operating under this subpart will be required to submit a one-time notification that they are subject to subpart P (§ 266.502(a)(1)). States will, therefore, be informed of what healthcare facilities are operating under subpart P and can inspect accordingly.

E. Recordkeeping Requirements for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(e))

1. Summary of Proposal

EPA proposed to require healthcare facilities to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Specifically, we proposed that healthcare facilities that initiate a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor keep (1) records of advance notification, (2) shipping papers or bills of lading, and (3) records of delivery confirmation. We proposed that a healthcare facility must retain these records for three years after the shipment was initiated. These records document that shipments of potentially creditable hazardous waste pharmaceuticals have been taken into the control and custody of the receiving reverse distributor and have not been diverted. In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator.

2. Summary of Comments

One state agreed that three years was a sufficient retention period to enable inspectors to identify issues upon inspection. State and local governments requested clarification about what types of documentation (*e.g.,* shipping papers/bills of lading) satisfies the requirement. One commenter argued that the receiving facility should document efforts made to locate shipments that did not arrive.

3. Final Rule Provision

EPA is finalizing the proposed recordkeeping provision for potentially creditable hazardous waste pharmaceuticals for healthcare facilities and reverse distributors that initiate a

shipment to another reverse distributor with two changes. First, as we discuss later in the shipping standards, we have eliminated the requirement for healthcare facilities to provide advance notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Thus, we have removed the requirement to keep a record of the advance notification. Second, EPA removed the reference to bills of lading from the recordkeeping requirement while keeping shipping papers since bills of lading are a type of shipping papers under DOT regulations. This is also responsive to comments asking for clarification. Healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep, (1) delivery confirmation for each shipment and (2) shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable. EPA is finalizing that these records must be retained for three years unless there is an unresolved enforcement activity or a request by the EPA Regional Administrator to keep them longer. In that case, the period of retention is automatically extended. EPA is finalizing this requirement as proposed despite input from commenters, as this is standard practice with enforcement activity. At the request of commenters, we have added a requirement that all records must be readily available upon request by an inspector.

F. Response to Spills for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(f))

1. Summary of Proposal

EPA proposed response requirements for spills of non-creditable hazardous waste pharmaceuticals but did not propose similar response requirements for releases of potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

A commenter suggested that spills of potentially creditable hazardous waste pharmaceuticals should also be subject to the same containment and cleanup requirements as non-creditable hazardous waste pharmaceuticals. The commenter also asked whether EPA intended that all spills of potentially creditable hazardous waste pharmaceuticals render them non-creditable.

3. Final Rule Provision

EPA agrees with comments that all spills of hazardous waste pharmaceuticals, both potentially creditable and non-creditable, must be contained, and that all spills of potentially creditable hazardous waste pharmaceuticals renders them non-creditable. Therefore, in response to this comment, we have added a similar provision to the healthcare facility standards of § 266.503(f) for responding to releases of potentially creditable hazardous waste pharmaceuticals.

The standards in this section are based upon what is being finalized in the standards for response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(k). The final rule requires that a healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with subpart P.

It is EPA's understanding that unused/undispensed pharmaceuticals that remain in original manufacturer's packaging often receive manufacturer credit even if the packaging has been opened. In the event of a spill, a healthcare facility should reevaluate whether any pharmaceuticals that remain in their containers (not spilled) are still eligible to receive manufacturer credit per the definition of potentially creditable hazardous waste pharmaceutical in § 266.500. The healthcare facility must determine whether the pharmaceuticals that remain in the containers are potentially creditable and manage them according to subpart P. Even if a healthcare facility determines that the remaining pharmaceuticals are potentially creditable, it must also ensure that the decision is consistent with the manufacturer's policies. It is important to note that this only applies to whatever might be left in the container and was not spilled.

XII. How does this rule apply to healthcare facilities that are very small quantity generators for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste? (§ 266.504)

A. Very Small Quantity Generators Using Reverse Distributors (§ 266.504(a))

1. Summary of Proposal

VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[238] Under § 262.14, VSQGs are limited in where they may send their hazardous waste for treatment and disposal.[239] In § 266.504(a), we proposed to allow VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Without this change, VSQGs would have been required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 262.14, which does not include a reverse distributor. Although we proposed to make this change within part 266 subpart P, we requested comment on whether stakeholders would prefer this change to be made within the VSQG regulations in § 262.14 (formerly the CESQG regulations in § 261.5) instead. VSQGs are still required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 262.14.[240]

2. Summary of Comments

States, waste management and reverse distributors supported allowing VSQG healthcare facilities to send their potentially creditable hazardous waste to reverse distributors. These same commenters were also in favor of including their change in both this rule and § 262.14 to ensure that all healthcare facilities that might have potentially creditable hazardous waste pharmaceuticals would be aware of this provision and be able to take advantage of it.

3. Final Rule Provision

We are finalizing this provision as proposed, with minor edits. In general, this final rulemaking will preserve the current regulatory scheme for VSQGs: healthcare facilities that qualify as VSQGs for their total count of hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste will maintain their conditional exemption under § 262.14 and will not be subject

[238] Since the hazardous waste pharmaceutical rule was proposed, § 261.5 has been renumbered to § 262.14 as part of the reorganization of the generator regulations in the Generator Improvements final rule and this will be referenced later in this section.

[239] Since the Pharmaceutical rule was proposed§ 261.5(f)(3)(i)–(vii) for acute hazardous waste and § 261.5(g)(3)(i)–(vii) for non-acute hazardous waste has been combined and renumbered to § 262.14(a)(5)(i)–(vii) for acute and non-acute hazardous waste in the Hazardous Waste Generator Improvements final rule.

[240] A VSQG healthcare facility may be able to send its hazardous waste pharmaceuticals for consolidation at another healthcare facility operating under subpart P as allowed by § 266.504(b), or a large quantity generator and 262.14(a)(5)(viii), see section X of the preamble for further discussion.

to most aspects of this proposal. Healthcare facilities that are VSQGs are subject to three provisions of part 266 subpart P: The sewer ban in § 266.505, the empty container standards in § 266.507, and the optional provisions in § 266.504.

In response to commenter's request for clarity, the final rule makes it clear that § 266.504 applies to VSQG healthcare facilities that are VSQGs when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. Section 266.504 does not apply to healthcare facilities that become VSQGs under this rule as a result of not having to count their hazardous waste pharmaceuticals. Such healthcare facilities are VSQGs with respect to their non-pharmaceutical hazardous waste only and must operate under subpart P for their hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In response to comments, EPA has added a conforming change to the VQSG generator provision in § 262.14(a)(5)(ix) for added clarity on this point. It is a restatement of § 266.504(a) which allows VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste is given a choice. The healthcare facility may

- Operate as a standard VSQG under part 262 rules, and can use the optional provisions in § 266.504, or
- Operate under as a healthcare facility under part 266 subpart P.

4. Comments and Responses

The waste management industry requested that EPA regulate all healthcare facilities under the proposed subpart P requirements regardless of generator category. While this rule's requirements are meant to create uniformity for healthcare facilities managing hazardous waste pharmaceuticals, we want to avoid creating undue burden on VSQGs and have declined to make them subject to part 266 subpart P except for the sewer prohibition in § 266.505, the empty container provisions in § 266.507 and the optional provisions in § 266.504..

B. Off-Site Collection of Hazardous Waste Pharmaceuticals Generated by Healthcare Facilities (§ 266.504(b))

1. Summary of Proposal

EPA proposed that a healthcare facility that is a VSQG may send its hazardous waste pharmaceuticals to another healthcare facility provided the receiving healthcare facility meets certain conditions. These conditions were proposed in § 266.502(m) of this subpart.

2. Summary of Comments

One state was concerned about how consolidation might affect the generator category of the receiving facility. The commenter also raised concerns about the receiving facility performing some functions of a reverse distributor.

3. Final Rule Provision

EPA is finalizing the proposed provision with conforming changes that correspond with other sections within this rule and one additional change. The first conforming change added the words ''hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste'' to clarify that only healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste may take advantage of this provision. The second conforming change converted the term CESQG to VSQG according to the 2016 Hazardous Waste Generator Improvements final rule. EPA notes that the consolidation provisions for healthcare facilities that receive both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from off-site were added to the regulations in §§ 266.502(l) and 266.503(b) (sections X.N and XI.B of the preamble), respectively. The final change added flexibility for VSQGs to meet the consolidation provisions that were added as part of the 2016 Hazardous Waste Generator Improvements final rule in lieu of the subpart P off-site consolidation provisions. In this case, the receiving LQG would have to meet the conditions in § 262.17(f) while the VSQG healthcare facility would have to meet the conditions in § 262.14(a)(5)(viii).

The final rule provision allows a healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste to send its hazardous waste pharmaceuticals off-site provided either of the following is met: (1) The receiving healthcare facility meets the conditions in § 266.502(1) and § 266.503(b) of this subpart, as applicable, or (2) the VSQG healthcare facility meets the conditions in § 262.14(a)(5)(viii), and the receiving large quantity generator meets the conditions in § 262.17(f).

4. Comments and Responses

One commenter asked for clarification about whether EPA will allow consolidation of a healthcare facility's potentially creditable or non-creditable hazardous waste pharmaceuticals at a reverse distributor. In response, the Agency is clarifying that subpart P does not allow healthcare facilities to consolidate any pharmaceutical waste at a reverse distributor. Healthcare facilities may only consolidate their waste at another facility that meets the definition of a healthcare facility as defined in § 266.500. See sections X.N and XI.B, respectively, for further discussion about healthcare facilities that receive non-creditable and potentially creditable hazardous waste pharmaceuticals from off-site healthcare facilities.

C. Long-Term Care Facilities That Are Very Small Quantity Generators Can Dispose Hazardous Waste Pharmaceuticals in Drug Enforcement Administration Collection Receptacles (§ 266.504(c))

1. Summary of Proposal

We proposed that a LTCF that is a VSQG that has an on-site DEA collection receptacle could use the collection receptacle for its hazardous waste pharmaceuticals, even if they are not controlled substances. We reasoned that since DEA already allows controlled substances to be commingled with non-controlled substances, it was consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA authorized collection receptacles along with controlled substances. Further, we reasoned that the management of VSQG hazardous waste pharmaceuticals as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors, and workers at LTCFs to have the hazardous waste pharmaceuticals in DEA authorized collection receptacles than down the sewer or in the facility's regular trash.

2. Summary of Comments

The few comments we received on this specific provision of the proposed rulemaking were mostly supportive.

3. Final Rule Provisions

We are finalizing the provision that allows an LTCF that is a VSQG to use

a DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals with three minor changes. The first change is to clarify again that this provision only applies to LTCFs that are VSQGs for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and are therefore not subject to subpart P (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504). The second change is to clarify that the DEA authorized collection receptacle that the VSQG LTCF uses to dispose of its hazardous waste pharmaceuticals must be on-site. The third change is to exclude items such as contaminated personal protective equipment or clean-up residues from being placed into the DEA authorized collection receptacle. Although these items meet our new definition of pharmaceutical, a DEA authorized collection receptacle is designed for the collection of the pharmaceuticals themselves and not larger items that might be contaminated by the pharmaceuticals, such as contaminated PPE or clean-up residues. For instance, they are required to have small openings and limited volumes, making their use for contaminated PPE and clean-up residues impractical.

4. Comments and Responses

One commenter thought that this proposed provision was ''not feasible'' because ''take-back kiosks for controlled substances are intended to be used by end users and not the DEA registrant.'' [241] In many, if not most, cases at an LTCF, the hazardous waste pharmaceuticals will be from an ultimate user and the DEA regulations permit the collection receptacles to be used for collecting both controlled and non-controlled substances from ultimate users. There are more limited cases where an LTCF may have its own inventory of non-controlled hazardous waste pharmaceuticals.

Although EPA concurs with the commenters that the DEA authorized collection receptacles are only for controlled substances from ultimate users, EPA does not believe that the same limitation needs to be placed on the pharmaceuticals from VSQGs that are hazardous waste but not controlled substances. In fact, it could be argued that long-term care facilities that are VSQGs would be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.,* facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that an LTCF that is a VSQG can place its hazardous waste pharmaceuticals in an on-site DEA collection receptacle.

However, as the commenter pointed out, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from ultimate users (patients) to be placed in collection receptacles that are at long-term care facilities. As a result, if a LTCF (or any other healthcare facility) is a DEA registrant, it may not place its inventory of controlled substances in a collection receptacle, even if it is a VSQG.

D. Long-Term Care Facilities With 20 Beds or Fewer Are Presumed To Be Very Small Quantity Generators (§ 266.504(d))

1. Summary of Proposal

EPA took comment on whether we should provide a rebuttable presumption that LTCFs with fewer than 10 beds are assumed to be VSQGs and thus would not be required to keep track of the amount of hazardous waste generated each month. The Agency did not propose regulatory language for this provision. EPA asked commenters to submit data to support a 10-bed cutoff to show that LTCFs with fewer than 10 beds are generally VSQGs. Alternatively, if commenters supported a different cutoff for the rebuttable assumption, EPA asked that the commenters submit information to support their suggested cutoff.

2. Summary of Comments

Comments on the rebuttable presumption for LTCFs with fewer than 10 beds varied. One state did not support providing a rebuttable presumption for LTCFs with fewer than 10 beds and argued that all generators should be required to count the hazardous waste they generate.[242] One state expressed support for providing a rebuttable presumption and requested that EPA keep the cutoff at 10 beds.[243] One state did not support providing the rebuttable presumption because most healthcare facilities in their state, including LTCFs, have more than 10 beds but generate only VSQG quantities of hazardous waste.[244]

Two healthcare industry commenters that supported the rebuttable presumption asked that EPA increase the cutoff from 10 beds to 20 beds.[245] One healthcare industry commenter supported the rebuttable presumption and asked that EPA increase the bed cutoff from 10 beds to 15 beds.[246]

3. Final Rule Provisions

Under the final rule, EPA is finalizing a rebuttable presumption in § 266.504(d) that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month. Under this presumption, LTCFs are only subject to the requirements for VSQG healthcare facilities as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals (§ 266.505), the empty container standards (§ 266.507), and the optional provisions of § 266.504. Under the final rule, the EPA Regional Administrator has the responsibility to demonstrate that a LTCF with 20 beds or fewer generates quantities of hazardous waste that are in excess of the VSQG limits as defined in § 260.10 if the EPA Regional Administrator wishes to mandate that the LTCF operate under subpart P. A LTCF with more than 20 beds that operates as a VSQG under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits as defined by § 260.10.

Based on available data, EPA believes it is reasonable to be responsive to the healthcare industry commenters who supported the rebuttable presumption and to increase the cutoff to 20 beds. The available information on hazardous waste generation at LTCFs suggests that LTCFs with 20 beds or fewer are generally VSQGs. Although EPA did not receive any data from the healthcare industry commenters, one state commented that most healthcare facilities in their state, including LTCFs, have many more than 10 beds but generate only VSQG quantities of

[241] See comment number EPA–HQ–RCRA–2007–0932–0280.

[242] See comment number EPA–HQ–RCRA–2007–0932–0238 in the docket for this rulemaking.

[243] See comment number EPA–HQ–RCRA–2007–0932–0242 in the docket for this rulemaking.

[244] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[245] See comment numbers EPA–HQ–RCRA–2007–0932–0239 and EPA–HQ–RCRA–2007–0932–0282 in the docket for this rulemaking.

[246] See comment number EPA–HQ–RCRA–2007–0932–0328 in the docket for this rulemaking.

hazardous waste.[247] Additionally, EPA estimates that there are between 2,875 and 4,770 long-term care facilities that generate hazardous waste and that 98 to 99 percent of the facilities are VSQGs.[248] Although EPA estimates that there are few LTCF hazardous waste generators that are SQGs or LQGs, EPA does not have data on the number of beds at each facility, making it difficult to estimate a facility size threshold at which a LTCF becomes an SQG or an LQG. EPA conducted additional analysis using data on the average size of LTCFs in the United States and data on the average volume of hazardous waste generated annually at LTCFs that submitted a biennial hazardous waste report between 2001 and 2015 in order to estimate the average size at which a LTCFs become SQGs or LQGs.[249] The estimates suggest that LTCFs with fewer than 20 beds will generally be VSQGs. Therefore, EPA concludes that it is reasonable to provide a rebuttable presumption that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month.

XIII. Sewer Disposal Prohibition (§ 266.505)

A. Regulatory Background on the Domestic Sewage Exclusion

Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, ''Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment'' is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that ''Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTWs) will be subject to controls under the Clean Water Act (CWA). The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems.'' [250]

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the § 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the appropriate existing regulations to ''ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment.''

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking on August 22, 1986; [251] a response to comments on the advanced notice of proposed rulemaking on June 22, 1987; [252] a notice of proposed rulemaking (NPR) on November 23, 1988; [253] and a final rule on July 24, 1990.[254] That final rule expanded an existing prohibition on the discharge of pollutants which create a fire or explosion hazard in the POTW, so that it included, but was not limited to, ''waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21.'' [255] Although the RCRA characteristic of reactivity (D003) was not specifically mentioned in the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section of the CWA regulations: (1) Chemicals that react violently with water [256] and (2) chemicals that form potentially explosive mixtures with water.[257]

The 1990 CWA final rule added a new prohibition such that no discharge shall ''result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems.'' [258] Similarly, although the RCRA characteristic of reactivity (D003) was not specifically mentioned in this section of the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section: (1) Chemicals that, when mixed with water, generate toxic gases, vapors or fumes in quantity sufficient to present a danger to human health or the environment [259] or (2) cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.[260]

In addition, some D002 corrosive hazardous wastes were prohibited prior to the 1990 CWA final rule and remain prohibited. Under RCRA, a waste is considered D002 for corrosivity if it has a pH of less than or equal to 2 (strongly acidic) or greater than or equal to 12.5 (strongly basic). Section 403.5(b)(2) of the CWA regulations prohibits discharges with a pH of less than 5.0, except under limited circumstances. Therefore, acidic D002 hazardous waste is prohibited from being discharged under the CWA regulations.

Note that although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), and it was HSWA, which is an amendment to RCRA, that directed the review of and amendments to that exclusion, the sewer ban of liquid ignitable D001 hazardous wastes and some D002 and D003 hazardous wastes was established under 40 CFR 403.5(b), which is under the CWA regulations. Also note that EPA left open the possibility of additional future action when it stated in the preamble to the July 24, 1990, final rule, its intent ''to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs.'' [261]

[247] See comment number EPA–HQ–RCRA–2007–0932–0332 in the docket for this rulemaking.

[248] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[249] See memorandum ''Long-Term Care Facility Summary Data and Hazardous Waste Generation Data'' in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[250] May 19, 1980; 45 FR 33097.

[251] See the advance notice of proposed rulemaking in August 22, 1986; 51 FR 30166.

[252] See the response to comments in June 22, 1987; 52 FR 23477.

[253] See the proposed rule November 23, 1988; 53 FR 47632.

[254] See the final rule in July 24, 1990; 55 FR 30082.

[255] See the prohibition in 40 CFR 403.5(b)(1).

[256] See 40 CFR 261.23(a)(2).

[257] See 40 CFR 261.23(a)(3).

[258] See 40 CFR 403.5(b)(7).

[259] See 40 CFR 261.23(a)(4).

[260] See 40 CFR 261.23(a)(5).

[261] July 24, 1990 **Federal Register**; 55 FR 30084.

B. Summary of Proposal

In 2015, EPA proposed to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and reverse distributors. That is, healthcare facilities and reverse distributors subject to part 266 subpart P would not be able to use the RCRA domestic sewage exclusion in § 261.4(a)(1)(ii) any longer for their hazardous waste pharmaceuticals. They would be prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.,* ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.,* sink, toilet, or floor drain).

EPA proposed this sewer prohibition of hazardous waste pharmaceuticals for several reasons. First, as described in detail in the preamble to the proposed rulemaking, a number of studies had shown that flushing of leftover medications had become a prevalent practice used in lieu of proper hazardous waste management and that experience had, indeed, revealed that additional regulations were ''necessary to improve control over hazardous waste and other industrial user discharges to POTWs.'' [262]

Second, although EPA establishes national regulations under the CWA (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs, currently there are no national effluent limitations or pretreatment standards that apply to healthcare facilities discharging pharmaceuticals to POTWs. Furthermore, traditional wastewater treatment operations implemented at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies, these technologies are not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.[263] Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove active pharmaceutical ingredients (APIs).[264] In a more recent study, EPA measured concentrations of 56 APIs in effluent samples from 50 large POTWs across the country and discovered at least one API in each sample.[265] In addition, as stated in EPA's Health Services Industry study, ''synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters.'' [266]

Third, the pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. A recent article highlighted the scientific literature that examines the effect of pharmaceuticals on freshwater ecosystems, particularly the effect of pharmaceuticals on key ecological processes.[267] The RIA for the proposed rulemaking more fully summarized the scientific literature with regard to ecological effects.[268] The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows: [269]

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they can potentially impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration and disposal.

While healthcare facilities that are VSQGs were generally not subject to the proposed rulemaking, EPA proposed that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are VSQGs. The RIA for the rule projects that the vast majority of healthcare facilities are VSQGs (81–86 percent).[270] Some particular types of healthcare facilities have an even larger proportion of VSQGs: For example, the RIA estimates that of the LTCFs that generate hazardous waste, 98–99 percent of LTCFs are VSQGs.[271] EPA was and remains concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are between 50,900 and 84,800 healthcare facilities that are VSQGs.[272] Given this large number, the combined impact of sewer disposal by healthcare facilities that are VSQGs has an even greater potential to provide a substantial impact on the environment, as well as human health. EPA solicited comment on whether it was appropriate to apply the proposed ban on the sewer disposal of hazardous waste pharmaceuticals to all healthcare facilities, including healthcare facilities that are VSQGs. Comments submitted to the Agency in response to this request are discussed in the next section.

We note that EPA's proposed ban on sewering hazardous waste pharmaceuticals is consistent with other federal state, and local actions. For example, the DEA has finalized regulations to implement the Secure and Responsible Drug Disposal Act of 2010.[273] DEA's regulations require a ''non-retrievable'' method of destruction of controlled substances. The preamble to DEA's proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.[274] According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against

[262] July 24, 1990 **Federal Register**; 55 FR 30084.

[263] EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA–821–R–09–009.

[264] Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, ''Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant.'' Environmental Science and Technology 2014, 48(14) 7683–7689.

[265] Kostich MS, Batt AL, Lazorchak JM, ''Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation.'' Environmental Pollution 2014, 184:354–9.

[266] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA–821–R–08–013.

[267] Richmond EK, Grace MR, Kelly JJ, Reisinger AJ, Rosi EJ, Walters, DM. ''Pharmaceuticals and personal care products (PPCPs) are ecological disrupting compounds (EcoDC).'' Elem Sci Anth 2017, 5:66.

[268] See page 147 of the Regulatory Impact Analysis for the proposed rule in the docket EPA–HQ–RCRA–2007–0932–0151.

[269] A. Ginebreda et al., Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

[270] See the Regulatory Impact Analysis for the final rule in the docket EPA–HQ–RCRA–2007–0932.

[271] Ibid.

[272] Ibid.

[273] September 9, 2014; 79 FR 53520.

[274] Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803); and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

flushing controlled substances.[275] The comments supporting the prohibition against sewering came from states, regional, and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewering is not allowable as a means of destruction.

In addition, four states, the District of Columbia, and local California jurisdictions have taken action to limit the sewering of pharmaceuticals and another state has introduced a bill. ''Colorado has prohibited the discharging of solid/hazardous waste down the drain since the adoption of RCRA in the 1980s.'' [276] In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any solid dosage form other than DEA schedule II drugs into public sewers or septic systems.[277] In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.[278] In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper ''Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts state that ''This is the first time that a pharmaceutical has been outlawed to protect water quality.'' [279] After researching and documenting environmental benefits of the ban, the authors conclude, ''This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals.'' Also in California, some county departments, such as Sacramento County and Contra Costa County, prohibit sewering of hazardous waste pharmaceuticals.[280] And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.[281] The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private wastewater collection systems or septic systems, although it has not yet become law.[282] Nevertheless, the Connecticut Department of Energy and Environmental Protection's (CT DEEP) ''current hazardous waste management regulations essentially ban sewer disposal of RCRA waste by requiring all generators in Connecticut, including [VSQGs], to ensure delivery by a licensed waste transporter with an EPA ID Number to a facility authorized to receive the waste.'' [283]

The Agency sought comment on several areas related to the prohibition on sewering hazardous waste pharmaceuticals. First, the Agency requested comment on whether the sewer ban should apply to healthcare facilities that are VSQGs. Second, we requested comment on the trade-offs inherent in prohibiting sewer disposal; that is, would the benefit of the reduction in aquatic risk be outweighed by additional opportunities for diversion and the possibility of inadvertent exposures for certain workers? Third, we sought comment on whether it would be appropriate to allow any exceptions to the sewer ban, such as for leftover portions of hazardous wastes that are also controlled substances.[284] Finally, the Agency sought comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations that prohibit the sewering of certain hazardous wastes.

C. Summary of Comments

Nearly a third of the commenters to the proposed rulemaking commented on the proposed prohibition of sewering hazardous waste pharmaceuticals. Commenters were nearly unanimous in their support for the prohibition on sewering of hazardous waste pharmaceuticals. Support was expressed by a broad and diverse set of commenters, including state and local governments, sewer districts, environmental groups, and waste management companies. Although some commenters had suggestions for minor exceptions, few commenters expressed complete opposition to the prohibition on sewering. Furthermore, there was widespread support from commenters for applying the prohibition on sewering hazardous waste pharmaceuticals to healthcare facilities that are VSQGs. As one commenter noted, ''given the large number of small generators . . . If each of these small generators were allowed to discharge even a small amount of pharmaceuticals, the overall volume would be significant.'' [285]

D. Final Rule Provisions

Given the environmental concerns described above combined with the overwhelming support that we received from commenters, we are finalizing the prohibition of sewering hazardous waste pharmaceuticals. The prohibition on sewering hazardous waste pharmaceuticals applies to all reverse distributors and all healthcare facilities, including healthcare facilities that are VSQGs. Furthermore, EPA is not providing any exceptions to the prohibition on sewering. Therefore, the prohibition on sewering hazardous waste pharmaceuticals applies to all hazardous waste pharmaceuticals that are generated by any healthcare facilities and reverse distributors, including hazardous waste pharmaceuticals that are also controlled substances and any pharmaceutical wastage from partial administration of hazardous waste pharmaceuticals. How the sewer prohibition intersects with the disposal of pharmaceutical wastage will be discussed in greater detail in section XIV.D.2. rather than this section.

In response to commenters' suggestions, we are making some minor editorial changes, including adding two cross references to the CWA prohibitions on sewering hazardous wastes in § 403.5(b). One cross reference will be added to § 261.4(a)(1)(ii) and the other cross reference will be added to § 266.505. We also eliminated the second sentence of the proposed prohibition, which read: The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works does not apply to hazardous waste pharmaceuticals.

[275] September 9, 2014; 79 FR 53520 (see page 53548).

[276] See comment number: EPA–HQ–RCRA–2007–0932–0242.

[277] Illinois Public Act 096–0221.

[278] Nicknamed Bateman's Law, after Senator Christopher ''Kip'' Bateman (R-Somerset) that sponsored the legislation.

[279] Humphreys, et al. Environmental Health Perspectives. 2008 March; 116(3) 297–302.

[280] See comment number: EPA–HQ–RCRA–2007–0932–0378.

[281] DCMR Title 22–B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities

[282] State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

[283] See comment number EPA–HQ–RCRA–2007–0932–0341.

[284] In a DEA letter dated October 17, 2014, DEA refers to leftover, partially administered drugs as ''pharmaceutical wastage.'' *https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf*

[285] See comment number EPA–HQ–RCRA–2007–0932–0337.

Oklahoma Department of Environmental Quality (OK DEQ) expressed concern that this ''second sentence could be interpreted that EPA is exerting RCRA authority over domestic sewage if it contains [hazardous waste pharmaceuticals]—an area that has been exclusively under Clean Water Act jurisdiction since the first regulations were promulgated in 1980.'' [286] EPA had proposed the second sentence in an attempt to be abundantly clear that the proposed prohibition on sewering hazardous waste pharmaceuticals supersedes the exclusion in § 261.4(a)(1)(ii). We did not intend to assert RCRA jurisdiction over domestic sewage; therefore, we have concluded that it is better to remove the sentence in order to avoid the concern expressed by OK DEQ. Nevertheless, we wish to emphasize that the prohibition on sewering hazardous waste pharmaceuticals being finalized in § 266.505 does, in fact, supersede the exclusion in § 261.4(a)(1)(ii). To make that point clear, we are amending § 261.4(a)(1)(ii) to state that any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, *except as prohibited by §§ 266.505 and Clean Water Act requirements at 40 CFR 403.5(b),* is not a solid waste.

E. Comments and Responses

Many comments suggested various ways in which we should broaden the applicability of the prohibition on sewering hazardous waste pharmaceuticals. In some cases, commenters urged us to apply the prohibition to all pharmaceuticals, not just hazardous waste pharmaceuticals. Subtitle D of RCRA, which governs the management of non-hazardous (solid) waste, does not provide EPA the statutory authority to apply the prohibition to non-hazardous waste pharmaceuticals. Nevertheless, EPA strongly recommends against sewering any pharmaceuticals. The American Water Works Association asked us to extend the prohibition to prevent the sewering of pharmaceuticals that are radioactive and patient waste containing radioactive pharmaceuticals. As discussed previously, hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (*i.e.,* ''mixed waste'') are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the NRC or the Department of Energy regulates the radioactive component of the waste under the Atomic Energy Act.[287] Therefore, a ''mixed waste'' pharmaceutical that is both radioactive and RCRA hazardous waste is prohibited from being discharged to the sewer. We strongly recommend against sewering other radioactive pharmaceuticals and patient waste containing radioactive pharmaceuticals.

Other commenters suggested that the prohibition should not be limited to discharges to POTWs; rather, it should also apply to discharges to septic tanks, privately owned treatment works and federally owned treatment works. Section 261.4(a)(1)(ii) allows the discharge of what would otherwise be a hazardous waste to POTWs, without being considered a solid or hazardous waste. The prohibition on discharges of hazardous waste pharmaceuticals being finalized today is intended to reduce the scope of that exclusion in the existing regulations. Discharges of hazardous waste to other types of sewage systems, such as septic tanks, privately owned treatment works and federally owned treatment works are not allowed by exclusion in § 261.4(a)(1)(ii). Therefore, the discharge of hazardous wastes to septic tanks, privately owned treatment works and federally owned treatment works is already prohibited, even though it is not explicitly stated.

We note that although our RCRA statutory authority limits us to apply the prohibition on sewering narrowly to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.,* hazardous or non-hazardous) from any source or location. This recommendation against sewering pharmaceuticals includes households and assisted living facilities, except in the relatively rare situation when households and assisted living facilities are specifically directed by FDA guidance to flush certain potentially dangerous drugs down the toilet (as noted on pharmaceutical packaging), when a drug take-back option is not readily available, to help ensure that they are not misused or accidentally ingested or touched.[288] In lieu of sewering, we recommend that households, including residents of assisted living facilities, follow the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, the guidelines for households disposing of pharmaceuticals are as follows (in order of preference):

(1) Use a drug take-back event or program, when available;

(2) Dispose in household trash, after mixing the unwanted medicines with an unpalatable substance such as dirt, cat litter, or used coffee grounds and placing in a sealed container; and

(3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.[289]

We also note that the CWA prohibitions on discharges of hazardous waste in § 403.5(b) are broader than just pharmaceuticals and apply beyond healthcare facilities and reverse distributors. Like all of the prohibited discharges under the CWA regulations, the prohibitions of hazardous waste discharges apply to any industrial user. Additionally, the CWA prohibitions on hazardous waste discharges apply to all D001 ignitable liquids, acidic D002 hazardous wastes, and D003 reactive hazardous wastes that (1) react violently with water,[290] (2) form potentially explosive mixtures with water,[291] or (3) result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems,[292] not just pharmaceuticals that exhibit those characteristics.

Some commenters asked us to include some exceptions to the prohibition on discharges of hazardous waste pharmaceuticals. Specifically, one commenter who supported our proposed ban on sewering of hazardous waste pharmaceuticals, and even supported extending it to non-hazardous waste pharmaceuticals, suggested that we allow exceptions ''for those that do not contain active pharmaceutical ingredients, such as sterile water and 0.9% sodium chloride for injection and irrigation.'' [293] First, as a point of clarification, because sterile water and 0.9% sodium chloride are not hazardous waste, they would not be subject to the prohibition of discharging hazardous waste pharmaceuticals to the

[286] See commenter number EPA–HQ–RCRA–2007–0932–0231.

[287] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

[288] *https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.*

[289] *https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

[290] See 40 CFR 261.23(a)(2).

[291] See 40 CFR 261.23(a)(3).

[292] See 40 CFR 403.5(b)(7).

[293] See comment number EPA–HQ–RCRA–2007–0932–0230.

sewer. And even though, as a general rule, we strongly recommend against sewering any pharmaceutical, regardless of whether it meets our definition of hazardous waste, we agree with the commenter that it seems unnecessary to prohibit the sewering of sterile water and 0.9% sodium chloride.

Other commenters asked us to make other exceptions to the prohibition on discharging hazardous waste pharmaceuticals. For example, the Healthcare Waste Institute suggested that we allow the discharge of hazardous waste pharmaceuticals that are specifically allowed by the local wastewater treatment agency or POTW.[294] CT DEEP made a similar suggestion, saying that we should allow discharges if they are ''explicitly authorized by a National Pollutant Discharge Elimination System (NPDES) or State pretreatment permit.'' [295] We have concluded that such an allowance is unnecessary because no known pretreatment standards or local limits have been established that specifically allow for the discharge of any pharmaceuticals. Note that 40 CFR part 439 separately regulates discharges from pharmaceutical manufacturers to POTWs and waters of the U.S. Furthermore, in the absence of water quality standards for specific drugs, we would like to avoid a situation where local wastewater treatment agencies might feel pressured to make judgments on which discharges would be acceptable without knowing the effects on aquatic life or the synergistic effects of multiple drugs.

We received few comments related to our inquiry about trade-offs inherent in prohibiting sewer disposal. Sharps Compliance did note that as ''our experience as a DEA authorized collector has shown, regulations that ban the sewering in conjunction with a proactive collection and destruction program offer the best protection against both environmental harm and the risk of diversion.'' [296] In addition, CT DEEP commented they do ''not believe there is an unfavorable risk trade-off inherent in prohibiting sewer disposal,'' indicating both risks are manageable.[297]

Eli Lilly was one of the few commenters that opposed the prohibition on sewering hazardous waste pharmaceuticals, even though, as a manufacturer, they are not subject to the prohibition.[298] They expressed two reasons for their opposition: (1) They do not believe that a total prohibition is based on sound risk management decisions and should be more flexible to exclude pharmaceuticals which FDA says should be disposed of down the drain, and (2) they believe that an effluent guideline under the CWA regulations is more appropriate and that EPA's Office of Water has decided not to promulgate an effluent guideline for the healthcare industry. As discussed previously, the prohibition on sewering hazardous waste pharmaceuticals and the FDA flush list do not conflict with one another. The prohibition applies to healthcare facilities (which does not include assisted living facilities) and reverse distributors, while the FDA flush list is directed to households and assisted living facilities and includes the caveat that flushing takes place only when a drug take-back option is not readily available. As to the commenter's second point, while it is true that the Office of Water has not yet promulgated an effluent guideline for the healthcare industry, this should not be taken as a sign that a decision has been made affirmatively that an effluent guideline is not appropriate at some time in the future. Rather, the Office of Water has preferred that the Office of Resource Conservation and Recovery (ORCR) first focus on preventing intentional discharges of hazardous waste pharmaceuticals. We firmly believe that the prohibition of sewering hazardous waste pharmaceuticals would complement any future action taken by the Office of Water to issue effluent guidelines for the healthcare industry.

XIV. Conditional Exemptions for Hazardous Waste Pharmaceuticals That Are Also Drug Enforcement Administration Controlled Substances and Household Waste Pharmaceuticals Collected in Take-Back Programs (§ 266.506)

A. Summary of Proposal

Prior to this final rulemaking, the management and disposal of a pharmaceutical that was both a RCRA hazardous waste and a DEA controlled substance was regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act and its implementing regulations, which is under DEA's purview. At the time of the proposal, EPA was aware of only a handful of pharmaceuticals in common usage that are both hazardous waste and controlled substances and therefore subject to regulation by both EPA and the DEA. These are identified in Table 3:

TABLE 3—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034, toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001, ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001, ignitable	IV	Ignitable due to alcohol content.
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001, ignitable	III	Ignitable due to gel base.
Valium injectable	Diazepam	Anti-anxiety	D001, ignitable	IV	Ignitable due to alcohol content.

[294] See comment number EPA–HQ–RCRA–2007–0932–0296.

[295] See comment number EPA–HQ–RCRA–2007–0932–0341.

[296] See comment number EPA–HQ–RCRA–2007–0932–0248.

[297] See comment number EPA–HQ–RCRA–2007–0932–0341.

[298] See comment number EPA–HQ–RCRA–2007–0932–0249.

Chloral hydrate (U034), which is listed for toxicity, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste.[299] The other four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). While the active ingredient is not ignitable, these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 4.

TABLE 4—DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES PHARMACEUTICALS THAT ARE NOT IN COMMON USE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use.
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal.	D001 ignitable	III	No longer in common use.
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use.

Similarly, as noted in Table 5, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing.[300]

TABLE 5—PHARMACEUTICALS THAT ARE DEA CONTROLLED SUBSTANCES AND RCRA HAZARDOUS WASTES SALT(S) NO LONGER CONSIDERED HAZARDOUS WASTE

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl.	Appetite suppressant.	P046, Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts.

EPA requested comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, as RCRA hazardous waste.

To eliminate duplicative regulation for these handful of hazardous wastes that are also controlled substances, EPA proposed to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA proposed that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266 subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln) and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition we proposed was to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). At the time of proposal, DEA had not specified or endorsed a method by which the controlled substances should be destroyed to meet the non-retrievable standard. Although many hazardous wastes/controlled substances were being destroyed by incineration, it was not required by DEA. At the time, EPA was concerned that in the future DEA might allow a technology that lacks environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, was proposed as a condition of the exemption. However, EPA requested comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances.

The second condition we proposed was to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. EPA requested comment on whether the tracking that DEA requires for controlled substances is sufficient to act in lieu of the RCRA manifest.

We considered proposing a third condition that the hazardous waste pharmaceuticals that are also DEA controlled substances would be subject

[299] Note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175

[300] See memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831.

to the sewer prohibition of § 266.505. At the time of proposal, however, we concluded that because combustion in specific units was a condition of the exemption, that it was unnecessary to state that the hazardous waste/controlled substances may not be sewered.

EPA also proposed a related conditional exemption for household pharmaceuticals, including those that are collected in DEA authorized collection receptacles and commingled with DEA controlled substances. Specifically, we proposed that collected household pharmaceuticals will continue to be excluded from RCRA regulation as household hazardous waste, provided they comply with the same two conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste.[301] As such, the Agency recommends that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[302] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the ''non-retrievable'' standard of destruction required by DEA for controlled substances collected from consumers (ultimate users, as DEA refers to them). Nevertheless, the Agency proposed to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.[303] We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we proposed to codify our policy that pharmaceuticals that are household hazardous waste (*i.e.,* ''household waste pharmaceuticals'') and are collected in DEA authorized collection receptacles where they may be commingled [304] with controlled substances continue to be excluded from RCRA regulation, provided they are (1) combusted at a municipal solid waste or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations.[305]

B. Summary of Comments

Many of the commenters, including states, healthcare facilities, and waste management companies, supported both conditional exemptions as a way to eliminate the duplicative regulation by DEA and EPA and commenters thought that the DEA tracking, shipping and recordkeeping are sufficient to operate in lieu of RCRA. Several commenters suggested that we expand the types of treatment that are allowed to destroy the hazardous waste pharmaceuticals that are also controlled substances. In some cases, commenters suggested that we allow additional combustion units such as hospital, medical, infectious waste incinerators (HMIWIs); commercial, industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs) to combust hazardous waste pharmaceuticals that are also controlled substances. Other commenters suggested that we allow forms of destruction beyond combustion, such as oxidation treatment[306] or chemical digestion,[307] or any technology that achieves DEA's standard of non-retrievable.[308]

C. Final Rule Provisions

We are finalizing both conditional exemptions for hazardous wastes that are also controlled substances, with some changes. First, we have amended the regulatory language in § 266.506(a)(2) to be more consistent with the preamble to the proposed rulemaking and to be more consistent with how the conditional exemption in § 266.506(a)(1) was crafted. In the preamble to the proposed rulemaking, we discussed the conditional exemption in terms of the waste pharmaceuticals from take-back events and programs, while in the proposed regulatory language, the conditional exemption was focused on the collector of the waste pharmaceuticals. We revised the regulatory language in § 266.506(a)(2) to conditionally exempt the collected household waste pharmaceuticals, as opposed to the collector of the household waste pharmaceuticals. Additionally, one commenter pointed out that the proposed regulatory language could be read to mean that if the household waste pharmaceuticals were not commingled with DEA controlled substances, then the requirement to combust them would not apply.[309] EPA did not intend to make this distinction. Although we understand that most, if not all, take-back events and programs do, in fact, commingle controlled substances with non-controlled substances, EPA proposed to place conditions on collectors of household waste pharmaceuticals with the understanding that this proposed regulatory language would capture all pharmaceuticals collected at take-back events and programs. The revised regulatory language in this final rule makes it clearer that the household waste pharmaceuticals collected during a take-back event or program must be destroyed by combustion or other DEA-approved method, whether or not the household waste pharmaceuticals are commingled with DEA controlled substances.

Also in response to comments, we are expanding the types of combustors that are allowed to destroy the conditionally exempt hazardous waste pharmaceuticals. Under the final rule, five types of combustors will be allowed to destroy hazardous waste pharmaceuticals that are also DEA controlled substances and the pharmaceuticals from take-back events and programs: (1) Permitted large municipal waste combustors (MWCs), (2) permitted small MWCs, (3) permitted HMIWIs, (4) permitted CISWIs and (5) permitted hazardous waste combustors (either an incinerator or other combustor, such as a cement kiln).

In addition to the five types of permitted combustors allowed to destroy the conditionally exempt

[301] See memo from J. Winston Porter to Regions, dated November 1, 1988; RCRA Online #11377.

[302] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online#14833) and memo October 2, 2015, Johnson to RCRA Division Directors (RCRA Online #14853).

[303] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

[304] DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

[305] See 40 CFR 26.506(a)(2).

[306] See Comment number EPA–HQ–RCRA–2007–0932–0287.

[307] See Comment number EPA–HQ–RCRA–2007–0932–0375.

[308] See Comment number EPA–HQ–RCRA–2007–0932–0333.

[309] See comment number EPA–HQ–RCRA–2007–0932–0261.

pharmaceuticals, EPA is building in flexibility to the final regulation to allow for the possibility that future technologies might be developed that meet the DEA non-retrievable standard. Specifically, we are allowing any method of destruction for the conditional exemption that DEA has publicly approved in writing as able to meet its non-retrievable standard. While it is reasonable to defer to the DEA's judgement in this matter to approve methods of destruction that are environmentally protective, we feel it is necessary to limit future allowable destruction technologies for the conditionally exempt pharmaceuticals to those that are publicly approved by the DEA as meeting the non-retrievable standard. This is intended to avoid a situation where parties might make unsubstantiated claims that their product is capable of meeting the DEA non-retrievable standard in order to qualify for the conditional exemption. Furthermore, any method that DEA might specify must not conflict with federal environmental laws or regulations. Also, because combustion is no longer specified as the only allowable method of destruction, we have concluded that an additional change to the regulations is needed to make it clear that the hazardous waste pharmaceuticals that are also DEA controlled substances are subject to § 266.505, and therefore, may not be sewered.

Both types of conditionally exempt hazardous waste pharmaceuticals (*i.e.,* those that are DEA controlled substances and those that are collected household waste pharmaceuticals) will be able to take advantage of the expanded list of allowable types of combustors. For healthcare facilities and reverse distributors that generate and manage the handful of hazardous waste pharmaceuticals that are also controlled substances, we think it will be helpful to have additional destruction methods for these previously dually regulated wastes. Also, the expanded list of allowable types of combustors will be helpful for those operating take-back programs and events. The Agency is a strong supporter of take-back programs and events for household pharmaceuticals as an alternative to disposing of leftover, unwanted medications in the trash or in the toilet or down the sink (except in cases where the FDA-approved labeling instructs patients to immediately flush the unneeded medication down the toilet if a take-back option is not readily available). In expanding the types of combustors that are allowed to burn the pharmaceuticals from take-back events, we strive to strike a balance between maximizing flexibility while still being protective of human health and the environment. Under the revised list in the final rule, the universe of allowable combustors will substantially increase in number. There are 77 municipal solid waste combustion facilities (also referred to as waste-to-energy facilities) in 22 states,[310] and 21 commercial hazardous waste combustion facilities (*i.e.,* those that accept waste from off-site) in 12 states.[311] There are currently 33 HMIWIs units in the U.S.: 11 of the 33 are commercial HMIWIs, while the other 22 HMIWI units only combust their own waste.[312] There are approximately 75 CISWIs facilities in the U.S.[313] We note that the types of combustors we are allowing to accept the conditionally exempt pharmaceuticals are not obligated to accept the conditionally exempt pharmaceuticals. Of course, we strongly encourage all the various types of allowable combustors to work with their communities and regulators in developing viable options for destroying the pharmaceuticals from take-back events. In particular, we encourage the ''captive'' combustors that currently only combust their own waste to consider amending their permits to allow them to accept pharmaceuticals from take-back events and programs.

We have concluded that it is reasonable to expand the list of allowable combustors able to accept the conditionally exempt pharmaceuticals because the combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (*i.e.,* non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act. The statute requires EPA to establish emission limits for nine air pollutants (*i.e.,* particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from several categories of solid waste incineration units, including MWCs; HMIWIs; and CISWIs. EPA has established emission limits for each of the categories based on the application of maximum available control technology (MACT) which reflect the emission levels achieved by the best performers in each category.

In addition to complying with emission limitations, solid waste incineration units are also subject to comprehensive operating, monitoring and reporting requirements. In light of the common framework used to develop emission limits and requirements for MWC, CISWI, and HMIWI units, we believe that it is appropriate to include HMIWIs and CISWIs as types of combustors that are allowed to burn the pharmaceuticals from take-back events.

While the Agency has expanded the list of allowable combustors to include HMIWIs and CISWIs, we have not expanded the list to include other solid waste incinerators (OSWIs). OSWIs are small units that have fewer emission controls than other types of combustors. Further, there are only a handful of new OSWIs in operation and the legal status of existing OSWIs is uncertain due to litigation. EPA is also not expanding the list of allowable combustors to include human and pet crematoriums. Crematoriums are not regulated under the Clean Air Act and typically do not use air pollution control devices to limit toxic air pollutants such as mercury and dioxins and furans. We believe that crematoriums would not provide adequate public health and environmental protection when burning non-hazardous waste pharmaceuticals. If solid or hazardous wastes are burned in a crematorium, it would make the crematorium subject to the Clean Air Act.

D. Comments and Responses

In its comment, Cardinal Health included a list of pharmaceuticals that it manages as both RCRA hazardous waste and DEA controlled substances.[314] In most cases, their comments reinforced the list that we included in the proposed rulemaking. In two cases, Cardinal Health identified additional forms of drugs that were included in the table of DEA controlled substances and hazardous wastes in the preamble to the proposed rulemaking. First, Cardinal Health identified Axiron as the brand name of an additional form of testosterone that is a solution applied to the underarms that is also ignitable. Second, Cardinal Health identified Diastat as the brand name of an additional form of valium that is a gel intended for rectal administration that is also ignitable. We have amended our list of DEA controlled substances and RCRA hazardous wastes by including Axiron and Diastat in Table 6 below to be more

[310] Energy Recovery Council, 2016 Directory of Waste-to-Energy Facilities; *http://energyrecoverycouncil.org/wp-content/uploads/2016/06/ERC-2016-directory.pdf.*

[311] Memo from Rudzinski to Regions, dated September 26, 2012; RCRA Online #14833.

[312] See comment number EPA–HQ–RCRA–2007–0932–0280.

[313] See CISWI inventory EPA–HQ–OAR–2016–0664–0002.

[314] See comment number EPA–HQ–RCRA–2007–0932–0250.

complete and accurate. However, there is no corresponding regulatory change being made. The regulations conditionally exempt all RCRA hazardous wastes that are also DEA controlled substances; the table identifying which drugs are both is included in the preamble for informational purposes:

TABLE 6—PHARMACEUTICALS STILL USED IN HEALTHCARE THAT ARE DEA CONTROLLED SUBSTANCES & RCRA HAZARDOUS WASTES

[Amendments in bold based on comments]

Name of drug	Other name(s)	Medical uses	RCRA HW code	DEA CS schedule	Comment
Chloral; chloral hydrate.	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes.	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics.
Fentanyl sublingual spray.	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content.
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content.
Testosterone gels/solutions.	Androgel, Axiron, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to alcohol content.
Valium injectable/gel	Diazepam, Diastat	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content.

Cardinal Health's comment also indicated that the company manages Somatropin (brand names Humatrope and Genotropin) as a DEA controlled substance and a RCRA hazardous waste. M-cresol, which is a contaminant identified on the toxicity characteristic list in § 261.24 (D024), is used as a preservative in Somatropin. Per legislations, all anabolic steroids are considered controlled substances; [315] however, Somatropin is considered a human growth hormone, not an anabolic steroid.[316] Therefore, although Somatropin may be a RCRA hazardous waste for its m-Cresol content, it is not a DEA controlled substance.

The two conditional exemptions we are finalizing in this rule are intended to eliminate any duplicative regulations for pharmaceuticals that are RCRA hazardous wastes and DEA controlled substances. Nevertheless, there are several remaining areas where DEA and EPA regulations intersect, even if they are not duplicative. The Agency would like to address these intersecting areas in effort to reduce confusion and aid compliance.

1. Only Household (Ultimate User) Waste May Be Collected in DEA Authorized Collection Receptacles

It is important to note that in order to qualify for the conditional exemption, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households (DEA refers to this as waste from ''ultimate users'') and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.[317] Depending on the amount generated, the hazardous waste pharmaceuticals generated by the retail pharmacy and store must be managed under either § 262.14 (as a VSQG) or under part 266 subpart P. Furthermore, states generally regulate non-hazardous waste and it is possible that they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the DEA authorized collection receptacles.

2. Sewer Prohibition, Conditional Exemption and Pharmaceutical Wastage

In response to comments, EPA has decided against making any exceptions to the sewer prohibition. Some commenters suggested that EPA should allow RCRA hazardous wastes that are also DEA controlled substances to be sewered. On the other hand, many commenters suggested, and EPA agrees, that it would be inappropriate to make exceptions to the sewer prohibition, even for the handful of hazardous wastes that are also controlled substances. In part, commenters thought it was bad environmental policy to allow sewering of any hazardous waste pharmaceuticals. Commenters were also concerned that it would send a mixed message to the regulated community about our goals and lead to confusion about which hazardous waste pharmaceuticals could and could not be sewered. As a result, all hazardous waste pharmaceuticals are prohibited from being sewered, including the handful that are also DEA controlled substances.

Under the DEA regulations, a registrant's inventory of controlled substances is already prohibited from being sewered as a means of meeting the non-retrievable standard.[318] Likewise, under the CWA regulations, RCRA ignitable hazardous wastes (D001) are prohibited from being discharged to the sewer.[319] As noted in Table 6, four out of the five RCRA hazardous wastes that are also DEA controlled substances are hazardous waste due to being ignitable and hence are already prohibited from being sewered by the CWA regulations. In effect, this new RCRA regulation only prohibits the sewering of one additional DEA controlled substance that is also a RCRA hazardous waste: Chloral hydrate, which is listed for toxicity. In summary, a RCRA hazardous waste that is also DEA controlled substance that is part of a DEA registrant's inventory may not be sewered.

[315] The Anabolic Steroids Control Act of 1990 placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) as of February 27, 1991.

[316] *https://www.fda.gov/Drugs/DrugSafety/ucm237839.htm;* accessed 8/24/2017.

[317] DEA also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

[318] See the preamble to DEA's final rule 79 FR 53548; September 9, 2014 and the preamble to DEA's proposed rule 77 FR 75803; December 21, 2012.

[319] See the Clean Water Act regulations at 40 CFR 403.5(b)(1).

DEA does allow controlled substance ''pharmaceutical wastage'' to be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, including sewering or putting down the drain.[320] DEA uses the term ''pharmaceutical wastage'' to refer to leftover, unadministered pharmaceuticals (''*e.g.,* some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized'' [321]). While DEA allows pharmaceutical wastage of controlled substances to be sewered, the CWA regulations already prohibit the discharge of any RCRA ignitable hazardous waste and, under this RCRA rule, EPA is not creating any exceptions to the sewer prohibition. As a result, neither inventory nor pharmaceutical wastage of DEA controlled substances that are also RCRA hazardous wastes may be sewered.

Even though inventory and pharmaceutical wastage are prohibited from being sewered, both inventory and pharmaceutical wastage would be eligible for the conditional exemption being finalized in this rule in § 266.506 for RCRA hazardous wastes that are also DEA controlled substances. As discussed previously, EPA is finalizing the conditional exemption that the few RCRA hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation, on the condition that they are (1) managed in accordance with DEA regulations and (2) incinerated by one of five types of permitted combustors or destroyed by another method that has been publicly approved by DEA, and (3) are not sewered.

Therefore, if inventory or pharmaceutical wastage is both a RCRA hazardous waste and a DEA controlled substance it would not be allowed to be sewered, it would have to be incinerated (or destroyed by another method publicly approved by DEA). Prior to incineration, however, the inventory and pharmaceutical wastage, both of which are conditionally exempt under RCRA, are regulated differently by DEA. The leftover inventory of DEA controlled substances remains fully subject to DEA regulations, which includes tracking and witnessed destruction. On the other hand, controlled substance pharmaceutical wastage is no longer regulated by DEA. Therefore, only pharmaceutical wastage could be collected in a container at the healthcare facility prior to incineration. If this container were used to collect only conditionally exempt pharmaceutical wastage prior to incineration, it would not be subject to the subpart P container standards. It is more likely, however, that a container used to collect the conditionally exempt pharmaceutical wastage would also be used to collect regulated hazardous waste, in which case the container would be subject to subpart P container standards. In either case, as DEA states in its guidance, ''Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage.'' [322] In support of DEA's guidance, EPA strongly recommends that any container that is used to collect pharmaceutical wastage that will include DEA controlled substances contain some sort of absorbent or chemical reactant in order to bind or chemically alter the contents and thus deter the diversion of the collection container for controlled substance recovery.

3. Long-Term Care Facilities and the DEA Regulations

This section will discuss the intersection of the DEA regulations and the RCRA hazardous waste regulations that pertain to LTCFs.

Under the DEA regulations, most LTCFs are not registrants and until recently have had few options for properly and securely disposing of the controlled substances from its patients (ultimate users). DEA's 2014 final regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are designed to help alleviate the problem that LTCFs face when discarding their patients' controlled substances. DEA's 2014 final rule allows, but does not require, retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations to become ''collectors'' and to place collection receptacles at LTCFs (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users. Per the DEA regulations, if a DEA authorized collection receptacle is placed in a LTCF, only the ultimate users' controlled substances may be placed in the DEA collection receptacle. If an LTCF is a DEA registrant and discards DEA controlled substances from its inventory, they may not be placed in the DEA authorized collection receptacle and must be otherwise destroyed to meet the non-retrievable standard.

Under the 2014 DEA final rule, LTCFs now have three options for managing their patients' controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at an LTCF, the staff from the LTCF may place the patients' controlled substances in the collection receptacles. Second, although LTCFs are not allowed to conduct a facility-wide collection event for their patients' controlled substances for mail-back programs, they are allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement can pick up patients' controlled substances for disposal. With these changes to DEA's regulation, LTCFs can now dispose of patients' controlled substances in a more environmentally protective way and EPA strongly encourages the use of any of these three collection methods. It should be noted that the 2014 DEA regulations do not mandate the placement of collection receptacles at long-term care facilities or patient participation in mail-back programs or take-back events.

As for the RCRA regulations, this rule finalizes the provision that hazardous waste from LTCFs will no longer be considered exempt as household hazardous waste. Instead, it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a LTCF, not just its hazardous waste pharmaceuticals (although the Agency expects that much of the hazardous waste generated by LTCFs consists of hazardous waste pharmaceuticals). Notwithstanding this revised interpretation, there are four other regulatory provisions that might affect how a LTCF will actually have to manage its hazardous waste pharmaceuticals under this final rule

First, we have added to the final rule a presumption that LTCFs with 20 beds or fewer will be VSQGs.[323] And those LTCFs that have more than 20 beds may still qualify as VSQGs (for all of their hazardous waste) if they generate less than 100 kg of hazardous waste and less

[320] See DEA letter to registrants re: Clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; *http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf.*

[321] Ibid.

[322] Ibid.

[323] See 40 CFR 266.504(d).

than 1 kg of acute hazardous waste per calendar month. In fact, based on the RIA for the final rule, EPA estimates that 98–99 percent of LTCFs that generate hazardous waste are VSQGs.[324] As VSQGs, the long-term care facilities will be subject to the reduced regulatory provisions of 40 CFR 262.14 for all of their hazardous waste (including those that are controlled substances), and only the sewer prohibition provision of this new subpart for their hazardous waste pharmaceuticals. Only the other 1–2 percent of LTCFs that generate hazardous waste will be subject to part 266 subpart P.

Second, this final rule allows an LTCF that is a VSQG (for all of its hazardous waste) to send its hazardous waste pharmaceuticals to an off-site healthcare facility that either supplies the LTCF with its pharmaceuticals (*e.g.,* a long-term care pharmacy) or is under the control of the same person and that is operating under subpart P.[325] Note that this provision is limited to hazardous waste pharmaceuticals and not to those that are also controlled substances because the DEA allows controlled substances to be returned to a long-term care pharmacy only when they are subject to a recall.

Third, this final rule also allows a healthcare facility, including a LTCF that is a VSQG, to use an on-site DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals (see § 266.504(c)). It could be argued that VSQGs would already be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (*e.g.,* facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that healthcare facilities that are VSQGs can place their hazardous waste pharmaceuticals in an on-site DEA collection receptacle. DEA already allows controlled substances to be commingled with non-controlled substances. Therefore, EPA believes it is consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of VSQGs' hazardous waste pharmaceuticals as DEA controlled substances is preferable because it provides greater protection to patients, visitors, and workers at healthcare facilities to have the hazardous waste pharmaceuticals accumulating in DEA-authorized collection receptacles rather than in the regular trash. However, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from patients to be placed in collection receptacles that are at LTCFs. To reiterate, under the DEA regulations, if a LTCF, or any other healthcare facility, is a DEA registrant it may not place its own inventory of controlled substances in a collection receptacle, even if it is a VSQG under RCRA.

Fourth, for the LTCFs that are not VSQGs, the handful of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances will not be subject to RCRA, provided they meet three conditions: (1) They are combusted at a small or large MWC, a HMIWI, a CISWI or a hazardous waste combustor (or destroyed by another method publicly approved by DEA), (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances, and (3) they are not sewered. DEA allows LTCFs to put their patients' controlled substances into an on-site collection receptacle; therefore, an LTCF could also place its patients' controlled substances that are also RCRA hazardous waste into a DEA authorized collection receptacle (alternatively, patients could use another allowable take-back method, such as mail-back envelopes) in order to meet the conditional exemption. However, we must stress that only LTCFs would be able to use collection receptacles (or another allowable take-back method) to meet the conditional exemption for RCRA hazardous wastes that are also DEA controlled substances, because they are the only type of facility that DEA allows to place their patients' wastes into an on-site collection container. Other healthcare facilities, such as hospitals, could not meet the conditional exemption by placing their DEA controlled substances that are also RCRA hazardous wastes in a collection receptacle because DEA does not allow patients at hospitals to use on-site collection receptacles. No registrant healthcare facility, including an LTCF, would be able to use the collection receptacle to meet the terms of the conditional exemption for any of its own inventory of DEA controlled substances that are also RCRA hazardous wastes because DEA does not allow registrants to use collection receptacles for their own inventory.

For those LTCFs that are not VSQGs, the hazardous waste pharmaceuticals that are not controlled substances (and therefore not conditionally exempt) will be subject to part 266 subpart P, while the other hazardous wastes will be subject to the SQG or LQG regulations, as applicable, in part 262.

See Table 7 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at LTCFs:

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
Hazardous Waste Pharmaceuticals that are NOT Controlled Substances:			
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. § 266.504(c)	Yes.
if LTCF is *not* a VSQG	part 266 subpart P	No	No.
Hazardous Waste Pharmaceuticals that are also Controlled Substances:			

[324] See the Regulatory Impact Analysis for this final rule in the docket EPA–HQ–RCRA–2007–0932.

[325] See 40 CFR 266.502(l) and 266.503(b) for non-creditable and creditable hazardous waste pharmaceuticals, respectively.

TABLE 7—INTERSECTION OF RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES—Continued

Types of pharmaceutical waste at long-term care facilities	RCRA regulatory requirements		
	How RCRA applies	DEA authorized collection methods allowed for HW pharmaceuticals?	Can be returned to an off-site HCF owned by the same person or LTC pharmacy?
if LTCF is a VSQG	§ 262.14 and sewer prohibition.	Yes. Only from patients	Only if subject to a recall.
if LTCF is *not* a VSQG	Conditionally exempt from RCRA (§ 266.506) if: • Combusted (or other DEA approved destruction method). • Comply with DEA regulations.	Yes. Only from patients (DEA collection methods meet the terms of the RCRA conditional exemption).	Only if subject to a recall.

XV. Management of Residues in Pharmaceutical Containers (§ 266.507)

A. Regulatory Background

Over the years, EPA has received numerous inquiries regarding the regulatory status of residues in various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded. Stakeholders have been particularly concerned about residues in containers that once held pharmaceuticals that are on the ''P-list'' of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month.[326] The regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

''The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded . . . (c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b).''

In § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered ''empty.'' The container is considered empty if all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.,* pouring, pumping, aspirating, *and* (1) no more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or* (2) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or no more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, it is important to note that if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice even though it has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,[327] the container is still *not* considered ''RCRA empty.'' If the container is not ''RCRA empty,'' then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste).

According to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered empty:

(1) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(2) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(3) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

According to these requirements, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered ''RCRA empty,'' even though the pharmaceutical may have been fully removed. If the container is not ''RCRA empty,'' then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals [328] that provides three possible regulatory approaches for generators:

(1) Count only the weight of the hazardous waste residues toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations. In 2015, we proposed to amend the regulations that pertain to residues in containers that once held pharmaceuticals that are RCRA hazardous wastes. EPA proposed different regulatory solutions for different types of containers found in healthcare settings. Specifically, the proposal addressed the following three categories of containers: (1) Unit-dose containers (*e.g.,* packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. Generally, commenters were supportive of the need for these new empty container standards specifically developed for the types of small containers used in the healthcare setting, although they did have suggestions for changes. Each category

[326] Additionally, acute hazardous wastes are included on the F-list of § 261.31; however, none of those acute hazardous wastes are pharmaceuticals.

[327] We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

[328] Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.

of container is discussed separately below. Today's new ''empty container'' regulations in § 266.507 will replace the November 2011 guidance as it pertained to residues of hazardous waste pharmaceuticals in containers, although the memo will remain in effect for non-pharmaceutical hazardous wastes.

B. Stock, Dispensing and Unit-Dose Containers (§ 266.507(a))

1. Summary of Proposal

We proposed that a dispensing bottle, vial, or ampule (not to exceed 1 liter or 1,000 pills) or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack or delivery device) would be considered empty and the residues would not be regulated as hazardous waste if the hazardous waste pharmaceuticals have been removed from the dispensing or unit-dose container by commonly employed methods.

This proposal applied to containers that once held acute or non-acute hazardous waste pharmaceuticals. Under the proposal, for containers that once held non-acute hazardous waste pharmaceuticals, it would not be necessary to measure the remaining contents. Likewise, under the proposal, for containers that once held acute hazardous waste pharmaceuticals, it would not be necessary to triple rinse the containers or demonstrate an equivalent removal method. Rather, we proposed that a dispensing or unit-dose container would be considered empty if all pharmaceuticals have been removed using the practices commonly employed to remove materials from that type of container—thus, the residues (and therefore the container as well) may be disposed of as non-hazardous waste.

We proposed this new ''RCRA empty'' standard for containers used within a healthcare setting for two reasons. First, this approach will help eliminate the sewering of pharmaceuticals. In a healthcare setting, if containers are triple rinsed, the rinsate will likely be poured down the drain, which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as in municipal solid waste landfills— rather than poured down the drain. Second, although the ''empty container'' regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals are smaller in size than a 55-gallon drum; therefore, the amount of residue will likely be much less in these containers. In the preamble to the proposed rulemaking, we explained that we selected the 1,000-pill/1-liter limit because, in our observation, EPA had rarely seen dispensing bottles larger than that. We specifically sought comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes would apply.

In the proposal, EPA presented data from three stakeholders helping to confirm the assumption that very little residue remains in containers after the pharmaceuticals (*e.g.,* pills) have been removed. In addition, EPA's Office of Research and Development conducted similar research.[329] A summary of the results is in the preamble to the proposed rulemaking, while the full results from each of the four sources are included in the docket for the proposed rulemaking.[330] [331]

EPA is aware that there are certain limitations with the data from the four sources. For instance, in one of the studies, no replicate samples were tested. In another study, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency proposed to allow the residues in dispensing bottles, vials and ampules, and single-unit dose containers that once held hazardous waste pharmaceuticals to be managed as non-hazardous waste provided the pharmaceutical product has been removed (*e.g.,* all pills have been removed).

As part of the proposal, EPA raised the concern of potential diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. The Agency proposed that RCRA-empty pharmaceutical containers that are original pharmaceutical packages (and therefore susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials, or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. In the preamble to the proposal, we explained that the means of destruction could include crushing or shredding the container.

2. Summary of Comments

The comments for this section can be broken into two major groups. One group of comments expressed concern with the 1,000-pill/1-liter size limit to pharmaceutical dispensing containers and commenters asked EPA to consider allowing the new RCRA-empty standard for pharmaceutical dispensing containers to apply to larger pharmaceutical containers or even to all dispensing containers, regardless of size.

As part of its comments, CVS Health included results from an analysis conducted on containers that held warfarin.[332] Their tests included brand name and generic warfarin stock bottles, testing the largest stock bottles with the highest prescription strength warfarin typically found in a CVS Health Pharmacy, although their comments do not specify the size of the largest stock bottle, nor do they specify the highest prescription strength of warfarin. That said, their results do offer similar results as the studies used in support of the proposal, indicating the range of total residues detected was 0.0–19.8 mg (excluding outliers).

Another group of comments objected to the proposed requirement to destroy the containers before disposing of them in municipal solid waste landfills. Commenters objected to this proposed provision for several reasons. First, the most common reason given by commenters that objected to this provision was they disagreed with EPA that diversion of these containers is occurring. Many states commented that this has never been a problem in their state and that the issues with these types of containers arise from purchase of empty vials on the internet and counterfeit labels made on home computers, not from dumpster diving. Second, there was concern that this would be a costly option since many healthcare facilities would now need to hire someone or buy equipment to destroy the containers. Many commenters thought the same goals could be reached through more cost-effective means such as defacing the label to render the containers unusable for illicit purposes. Third, a few commenters were also concerned with the release of the residues in these containers upon destruction and the effect that could have on the workers. This set of commenters included the one state that favored destruction of the containers. Finally, some commenters noted that these empty containers are already being disposed of in locked

[329] Tolaymat, T. and A. El Badawy. Evaluation of P-Listed Pharmaceutical Residues in Empty Pharmaceutical Containers. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R–14/167, 2015.

[330] September 25, 2018; 80 FR 58052.

[331] EPA–HQ–RCRA–2007–0932–0153 through 0156.

[332] See comment number EPA–HQ–RCRA–2007–0932–0312.

dumpsters and there are adequate institutional controls to address any public health risk from use of discarded containers in counterfeit drug sales.

3. Final Rule Provisions

In response to comments, we have made three substantive changes to the regulations proposed in § 266.507(a) that define when a dispensing or unit-dose container is empty. First, based on comments, we now recognize that we used the term ''dispensing'' bottle, vial, or ampule incorrectly. Dispensing bottles are those that are provided to patients when they get a prescription filled. Although a healthcare facility such as a pharmacy may dispose of some dispensing bottles, they are more likely to dispose of the stock bottles that they use to fill the dispensing bottles provided to the patients. As a result, we have modified the regulatory language to include stock bottles in addition to dispensing bottles, vials or ampules, and unit-dose containers.

Second, after reviewing comments and asking for additional support and clarification from commenters, including the Army Public Health Center, CVS Health and the Department of Veterans Affairs, the Agency has increased the size of the dispensing containers from 1,000 pills to 10,000 pills.[333] The Army Public Health Center states that they ''routinely procure containers containing 1K, 2K, and even 5K or 10K pill counts'' for refilling the automated dispensing machines at their facilities.[334] This exceeds the size of dispensing containers that we and others tested, but given that the contents are solid pills, capsules and tablets, and that the residues we and others detected are very small, we determined that it is appropriate to increase the size of the stock or dispensing container to 10,000 pills.

However, we have kept the maximum volume for stock and dispensing containers at a maximum of 1 liter since this volume limit would apply to liquids (and other non-pill formulations), which are harder to fully remove, and commenters did not provide sufficient information to support increasing the volume limit. Further, it is not clear from comments or subsequent correspondence whether any containers larger than 1 liter are in use for pharmaceuticals that would be hazardous waste when discarded. Stock or dispensing containers that exceed 1 liter would be considered ''other containers'' under § 266.507(d). As such, under the final rule, if they held pharmaceuticals that are non-acute hazardous waste, then they would be able to use § 261.7(b)(1) to show that they are empty.

The third substantive change is that we have removed the proposed requirement to destroy the empty pharmaceutical containers prior to disposal. We share commenters' concerns about possible worker exposure during the process of crushing or shredding the containers. However, EPA remains concerned about the diversion of the empty containers for illicit purposes. Therefore, we strongly encourage healthcare facilities to use best management practices, such as locked dumpsters and defacing labels, to prevent the diversion of these containers, but the extra step of destroying these containers will not be required.

Thus, under the final rule, a stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

In § 261.33(c), we have also added a reference to the new empty container provisions for hazardous waste pharmaceuticals in § 266.507 as a conforming change. Previously, § 261.33(c) referenced only the empty container provisions of § 261.7(b).

4. Comments and Responses

One commenter asked us to add an explicit reference to acute/P-listed hazardous waste in this section of the regulations. We believe this is unnecessary since § 261.7(c) indicates that containers of hazardous waste pharmaceuticals (which includes acute and non-acute hazardous waste pharmaceuticals) are subject to § 266.507 in lieu of § 261.7 for determining when they are empty. Nevertheless, we agree with the commenter that all of the new empty container provisions in § 266.507 apply to containers that held either non-acute or acute hazardous waste pharmaceuticals. Under the new subpart P provisions, for containers that once held non-acute waste pharmaceuticals to be considered empty, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous waste pharmaceuticals, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method.

C. Syringes (§ 266.507(b))

1. Summary of Proposal

EPA proposed that the residues remaining in a syringe would not be regulated as hazardous waste provided the syringe had been used to administer a pharmaceutical to a patient, the syringe is placed in a sharps container (if appropriate), and is managed in accordance with all applicable federal, state, and local medical waste or regulated waste regulations. As with all of the new empty container standards proposed in § 266.507, this proposed provision applied to syringes used to administer pharmaceuticals that are acute or non-acute hazardous waste when discarded.

Prior to the proposal, EPA issued guidance regarding the regulatory status of residues in syringes in December 1994 and April 2008.[335] [336] In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine residues in a discarded syringe would be P042, EPA stated, ''Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.'' [337] In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe.

EPA thinks that it is important to clarify in regulation when syringes are considered RCRA empty as this has been a source of many questions over the years. As part of the decision making, EPA is aware of the need to

[333] See the email correspondence from Lisa Strutz (APHC); Donald Dempsey (CVS Health); and Peter Carbrey (VA) in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[334] See the email correspondence from Lisa Strutz (APHC) to Kristin Fitzgerald (EPA), dated February 9, 2017, in the supporting materials of the docket for this final rulemaking (EPA–HQ–RCRA–2007–0932).

[335] December 1994, RCRA Online #13718.

[336] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

[337] Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778).

minimize the potential for exposures of healthcare workers to the sharps, which may be contaminated with bloodborne pathogens, as well as to the contents of the syringes.

The preamble to the proposed rulemaking also noted that sharps containers containing syringes are typically autoclaved prior to disposal. EPA expressed concern that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks via pulmonary exposure to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.[338] As a result, EPA requested comment on whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this new provision would apply or whether any other conditions would be appropriate.

2. Summary of Comments

As noted above, commenters generally supported EPA's goal of codifying new standards for defining when containers are considered empty, including syringes. EPA received many comments requesting that the Agency clarify what it means when it uses the term ''dispensed.'' Further, they noted that although the proposed regulations used the term ''dispensed,'' in several cases in the preamble, we used the term ''fully dispensed'' and they requested clarification about which was correct. Commenters also noted that EPA used the term ''dispensed'' inappropriately and stated that the term ''administered'' was more appropriate. The Agency received mixed comments on whether any residues or contents should be left in the syringes when disposing of the syringe. In the case of autoclaving residues in syringes, almost all commenters agreed that the hazardous waste pharmaceutical residues should not be autoclaved. Some commenters believed that the contents should be disposed of in a gauze pad or equivalent while others argued that this was in contradiction to NIOSH recommendations for minimizing exposure to hazardous drugs. Some commenters were comfortable with leaving contents in the syringes, suggesting that would be in compliance with OSHA [339] and DOT.[340]

3. Final Rule Provisions

We have made two substantive changes to this section of the regulations that define when syringes are considered empty for the sake of RCRA regulation. First, EPA agrees with commenters that we used the term ''dispensed'' inappropriately in the proposed rulemaking. FDA defines ''dispense to patients to mean the act of delivering a prescription drug product to a patient or an agent of the patient.'' [341] Dispensed pharmaceuticals are then administered directly to the patient. EPA has revised the regulations to address commenters' concerns. In the final rule, to avoid confusion, when discussing syringes we do not use the term dispensed, fully dispensed, or administered. Instead, under the final rule, a syringe is considered empty and the residues are not regulated as hazardous waste provided the contents have been removed by fully depressing the plunger of the syringe. Thus, the final regulations convey an intent that is more similar to the proposed preamble use of the term ''fully dispensed.'' This reflects commenters' and EPA's desire to avoid the possibility of autoclaving syringes that may have a large portion of their hazardous waste pharmaceutical contents remaining.

Commenters affirmed EPA's concerns about aerosolizing the autoclaved hazardous waste in sharps containers and we have concluded that hazardous waste incineration of hazardous waste pharmaceuticals remaining in non-empty syringes is more appropriate. A recent literature search also supports this position. The NIOSH and the American Society of Hospital Pharmacists (ASHP) have both published articles regarding autoclaving of sharps. The 2004 NIOSH alert states, ''Do not place hazardous drug-contaminated sharps in red sharps containers that are used for infectious wastes, since these are often autoclaved or microwaved.'' [342] The ASHP article states, ''Sharps used in the preparation of hazardous drugs should not be placed in red sharps containers or needle boxes, since these are most frequently disinfected by autoclaving or microwaving, not by incineration, and pose a risk of aerosolization to waste-handling employees.'' [343]

A syringe with a fully depressed plunger will have a minute amount of residue and the syringe can be considered empty under the final rule. Thus the residue in the empty syringe (as well as the syringe) will not be regulated as hazardous waste. A syringe that does not have a fully depressed plunger could have anything from a small amount to 99% of hazardous waste pharmaceutical contents still left in it. Therefore, we have concluded that it is impracticable to impose an alternate bright line for determining whether a partially administered syringe is empty. Further, we concur with ASHP and NIOSH regarding concerns about the safety of autoclave operators and believe the standard in this final rule will help prevent exposing workers to volatilized hazardous waste pharmaceutical residues during the autoclaving process.

The second substantive change we made in the final rule is to clarify that if a syringe contains a pharmaceutical that is a hazardous waste and it is not empty because the plunger is not fully depressed, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart as well as any applicable federal, state, and local requirements for sharps containers and medical or regulated waste. We note that the new empty syringe provisions being finalized today supersedes the previous EPA interpretations expressed in guidance memos in December 1994 and April 2008.[344] [345]

We note that a syringe can become empty in three ways: (1) Fully depressing the plunger of the syringe by administering the contents of the syringes to a patient, or (2) fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag, or (3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.

[338] Daughton CG, Drugs and the Environment: Stewardship & Sustainability, National Exposure Research Laboratory, Environmental Sciences Division, US EPA, Las Vegas, NV; NERL–LV–ES 10/081, EPA/600/R–10/106; September 2010 (*https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=228503*).

[339] OSHA Title 29 CFR 1910.1030 Bloodborne Pathogens.

[340] DOT Title 49 CFR 172.343 subpart D—Marking; 172 subpart E—Labeling Standards; 172.432 Subpart E.

[341] See 21 CFR 208.3.

[342] NIOSH. ''Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings.'' Publication Number 2004–165, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, 2004. 58 pp; *http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.*

[343] ASHP. ''ASHP guidelines on handling hazardous drugs.'' American Journal of Health-System Pharmacy 2006, 63:1172–1193; *http://dx.doi.org/10.2146/ajhp050529.*

[344] December 1994, RCRA Online #13718.

[345] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.

4. Consultation With OSHA

As part of the final rule process, EPA consulted with OSHA to gain a better understanding of its Bloodborne Pathogens standard and how it interacts with other regulations for the disposal of sharps and the contents within the syringes. The Bloodborne Pathogens standard states that ''[u]niversal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.'' [346] It also states that disposal of a sharp shall be done ''immediately or as soon as feasible.'' [347] Further, OSHA requires that containers for contaminated sharps shall be ''easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can reasonably anticipated to be found.'' [348] When workers travel to a remote location to discard a sharp, it increases the possibility of an accidental needlestick, increases the chances that needles and other sharps will be improperly discarded, and creates potential hazards for other staff members. The determination of whether or not a sharps disposal container is as close as feasible should be made on a case-by-case basis by OSHA.[349]

Therefore, the practice of emptying the contents of the syringe would not violate the OSHA standard if the containers are as close as feasible. Any related work practices must also be such that they do not create additional hazards to workers (*e.g.,* containers are located in close proximity to the work area to avoid employees travelling with used sharps to disposal receptacles located outside the point of use). Furthermore, nothing in this new subpart requires workers to recap needles or other sharps, or otherwise manually manipulate the sharp or needle during emptying, such as unscrewing the needle from the syringe.

As part of this consultation, OSHA addressed the issue of waste disposal. OSHA's Bloodborne Pathogens compliance directive states: ''[W]hile OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations'' (''Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories'' (1910.1030(d)(4)(iii)(C))).[350]

The Agency also received comment that we should recommend the extra protective step that all syringes/sharps be incinerated. Any sharps container that contains hazardous waste must be treated to meet the LDR requirements in part 268. In most cases, the LDR treatment standard for hazardous waste pharmaceuticals is incineration. On the other hand, if a sharps container does not contain hazardous waste pharmaceuticals because all the syringes have been emptied by fully depressing the plunger, then the RCRA hazardous waste regulations would not apply to these sharps containers (although these sharps containers are still solid wastes).

Regardless of whether sharps containers have regulated hazardous waste pharmaceutical residues, they could contain bloodborne pathogens or other infectious materials. Thus, OSHA's Bloodborne Pathogens standard requires that ''disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.'' [351] Many states have medical waste regulations that require the treatment of regulated medical waste, including sharps containers, to render it non-infectious, which is often achieved by autoclaving, prior to disposal as solid waste.

D. Other Containers, Including Delivery Devices (§ 266.507(c) & (d))

1. Summary of Proposal

EPA proposed that the residues remaining in other types of unused or used containers, including delivery devices, such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams, would be regulated as hazardous waste if the residues are acute or non-acute hazardous waste. In some cases, such as with IV bags, the volume of hazardous waste being disposed is much larger than with residues contained in syringes or unit-dose containers. It is extremely difficult to determine how much residue remains in tubes of ointments, gel, or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted towards a facility's generator category, we argued that managing these residues and containers as hazardous waste under the proposed provisions should not pose the same burden that generators had been facing in with keeping track of the monthly amount of residues in containers that are not ''RCRA empty.''

2. Summary of Comments

Comments were mixed in this section. Some commenters agreed with EPA that it is difficult to determine if containers such as inhalers, aerosol cans, tubes of ointments, gels, or creams meet the RCRA empty standards within § 261.7 and, therefore, managing them under the streamlined requirements of subpart P would be protective. Other commenters wanted EPA to allow these other containers to continue to meet the definition of empty within § 261.7 or develop specific empty container standards for them within subpart P. One commenter recommended that EPA revise the regulations to state that IV bags and their tubing, inhalers, aerosols, nebulizers, tubes of ointments, and gels or creams are RCRA empty and not subject to hazardous waste regulations if they contain non-acute hazardous waste and their contents are fully administered.

3. Final Rule Provision

In response to comments, the final rule contains an empty container standard for IV bags separate from other containers, including delivery devices. The Agency stated in the proposal that it is very hard to determine if aerosols, tubes of ointments, gels and creams, inhalers, and nebulizers are empty due to their containers and contents. As commenters pointed out, this is not the case for IV bags and tubing since they are transparent and the liquids inside can be easily observed.

Taking approaches suggested from commenters, EPA is finalizing in § 266.507(c) that an IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. In cases where the IV bag has not been fully administered and the IV bag held non-acute hazardous waste pharmaceuticals, then IV bag can be shown to be empty and the remaining residues not regulated as hazardous waste per § 261.7(b)(1). If an IV bag is not empty through either of these means because it either has not been fully

[346] See 29 CFR 1910.1030(d)(1).

[347] See 29 CFR 1910.1030(d)(4)(iii)(A)(*1*).

[348] See 29 CFR 1910.1030(d)(4)(iii)(A)(*2*)(*i*).

[349] OSHA Compliance Directive CPL 02–02–069 Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens *https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-069.pdf.*

[350] Ibid.

[351] See 29 CFR 1910.1030(d)(4)(iii)(C).

administered or cannot meet the requirements of § 261.7(b)(1) or because it contained an acute hazardous waste pharmaceutical, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart.

In the final rule, EPA has also altered the requirements for other types of containers including delivery devices. Commenters pointed out that a healthcare facility should not be precluded from proving that these containers meet the RCRA-empty standards in § 261.7 simply due to the type of container or contents. EPA agrees with the commenters that these types of containers which held non-acute hazardous waste pharmaceuticals should be able to use the RCRA empty container standards under § 261.7 and has changed the final rule to allow this. If the containers meet the RCRA empty standard under § 261.7 then the non-acute hazardous waste pharmaceutical residues (and the container) are not regulated as hazardous waste and can be managed as solid waste.

If these other containers, a category that includes but is not limited to inhalers, aerosols, nebulizers, tubes of ointments, gels or creams, once held an acute hazardous waste pharmaceutical or if they held a non-acute hazardous waste pharmaceutical but cannot meet the RCRA empty container standard of § 261.7, then the residues of these hazardous waste pharmaceuticals (and their containers) must be managed as non-creditable hazardous waste pharmaceuticals under this subpart.

4. Comments and Responses

One commenter was concerned that managing all other containers that held hazardous waste pharmaceuticals as non-empty could cause a VSQG healthcare facility to bump up in generator category to an LQG. This will no longer be a concern since a healthcare facility now has the option to prove that their other containers that held non-acute hazardous waste pharmaceuticals meet the RCRA empty container standards in § 261.7 and they can manage the residues (and containers) as non-hazardous waste. Otherwise, if these other containers are not considered empty, then the residues (and containers) must be managed as non-creditable hazardous waste pharmaceuticals under subpart P and hazardous waste pharmaceuticals managed under subpart P do not count towards determining the generator category. Further, we note that a healthcare facility can use the new empty container provisions in § 266.507 when determining whether they generate enough hazardous waste to become subject to part 266 subpart P.

XVI. Shipping Standards for Hazardous Waste Pharmaceuticals (§§ 266.508 and 266.509)

A. Shipping Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

Under part 266 subpart P, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable hazardous waste pharmaceuticals (*e.g.,* partially administered for patient care), and (2) potentially creditable hazardous waste pharmaceuticals (*e.g.,* unused, unadministered). This section discusses the proposed requirements for shipping non-creditable hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and reverse distributors, see section XVI.D. of this preamble.

Generally, non-creditable hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, since there is not a reasonable expectation that prescription non-creditable hazardous waste pharmaceuticals are eligible to receive manufacturer credit, they are shipped off site to a TSDF rather than a reverse distributor. Due to concerns that a healthcare facility might send all of its hazardous waste pharmaceuticals to a reverse distributor even if there is not a reasonable expectation of receiving manufacturer credit—essentially using the reverse distributor as a TSDF—EPA proposed that non-creditable hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off site, must be shipped to a designated facility (*e.g.,* an interim status or permitted hazardous waste TSDF), as was required under part 262 (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste and chooses to store or treat the non-creditable hazardous waste pharmaceuticals on site instead of shipping them to a designated facility).

Specifically, EPA proposed that healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility for treatment or disposal must continue to comply with the existing Department of Transportation (DOT) pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and be tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who the Agency assumes are typically unfamiliar with RCRA, EPA proposed that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA proposed that the words, ''hazardous waste pharmaceuticals'' must be entered in the ''special handling and additional information'' box on the manifest (this box was called Item 14 at the time of the proposal).

We also proposed that all existing RCRA recordkeeping requirements regarding hazardous waste manifesting as well as all applicable DOT shipping requirements continue to apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF for treatment or disposal (see section X.K).

2. Summary of Comments

Comments on this section of the proposed rulemaking were mixed. Commenters generally agreed with the proposed standards for packaging, labeling, marking, placarding, and shipping papers. Adverse comments were mostly in regard to the decision to not require individual waste codes on the manifest for a healthcare facility sending non-creditable hazardous waste pharmaceuticals to a TSDF for disposal. In fact, commenters were generally concerned about the proposal to not require individual waste codes anywhere in the management standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. Whether the comments were regarding waste code determinations, labeling containers with waste codes, or including waste codes on the manifest, the overarching concern was that TSDFs would not know the specific contents of shipments received, resulting in an increase to their burden, and possibly would be detrimental to human health and the environment. Therefore, the adverse comments regarding the lack of a proposed requirement to input individual waste codes on the manifest are applicable more broadly to the subject of whether or not the

information that individual waste codes convey should somehow be provided to a TSDF by the healthcare facility shipping non-creditable hazardous waste pharmaceuticals.

Some states agreed with the proposal to not require individual waste codes on the manifest, while others commented that it is important to have waste codes at all steps where they would otherwise be required under previous RCRA regulations. Comments from waste management companies were also mixed, with some supporting the proposal to not require individual hazardous waste codes on the manifest, while others agreed with the proposal but suggested including a profile of likely constituents to alert TSDFs of potential waste contents to aid in LDR compliance.

Those waste management companies that disagreed with the proposed standards cited the added burden imposed by not knowing the specific waste constituents included in a shipment, which would make compliance with LDR standards more difficult. They were primarily concerned about the added burden of having to either begin testing their ash for wastes that have a numeric treatment standard, or modify existing testing protocols. One commenter from the healthcare industry disagreed with the elimination of individual hazardous waste codes on manifests from healthcare facilities shipping non-creditable hazardous waste pharmaceuticals, arguing that healthcare workers are capable of making accurate hazardous waste determinations. They also stated that hazardous waste codes are integral to properly managing hazardous waste. One waste management commenter stated that continuing to require waste codes on LDR notices altogether negates any actual relief because healthcare facilities will have to determine appropriate waste codes before sending hazardous waste pharmaceuticals off site to a TSDF whether or not they are required on the container label or manifest.

One reverse distributor also agreed with the proposed standards under the condition that the Agency agree that pharmaceuticals being sent to a reverse distributor are not waste.

3. Final Rule Provisions

The agency is finalizing the majority of the proposed requirements in this section. Before being shipped off site, all shipments of non-creditable hazardous waste pharmaceuticals must comply with applicable DOT pre-transport requirements for packaging (49 CFR parts 173, 178, and 180), labeling (49 CFR part 172 subpart E), and marking (49 CFR part 172 subpart D). There are, however, three notable changes being finalized.

First, § 266.508(a)(1)(v) has been removed and a healthcare facility shipping hazardous waste pharmaceuticals to a TSDF for disposal must instead comply with § 266.508(a)(2)'s manifest requirement to meet DOT's shipping papers requirement.

Second, the agency has decided to modify the proposal to not require any hazardous waste codes in Item 13 (Waste Codes) of the hazardous waste manifest for shipments of non-creditable hazardous waste pharmaceuticals being sent to a TSDF, and write the words ''Hazardous Waste Pharmaceuticals'' in Item 14 (Special Handling Instructions and Additional Information). The Agency is instead finalizing a requirement to write only one waste code— ''PHARMS''—in Item 13, and not impose any requirements for what must be written in Item 14. After further consideration of the impacts this proposed requirement would impose on implementation and data collection, the Agency decided it had to be modified. During the development of this rule, the Agency has also been developing the electronic manifest system (e-Manifest) which requires that some code be written in Item 13. We chose the PHARMS code because it both meets the required number of characters and communicates the nature of the waste. Since the waste will now be sufficiently characterized in Item 13, the Agency feels there is no longer the need to require the words ''hazardous waste pharmaceuticals'' in Item 14.

This new PHARMS code is for manifesting and reporting purposes only and is not an official EPA hazardous waste code. Because it will be written in the same place as other official EPA hazardous waste codes, it may also be referred to colloquially as a ''hazardous waste code.'' However, it does not modify any existing LDR treatment standards, nor does it enact any new or alternate LDR treatment standards for hazardous waste pharmaceuticals. Many commenters throughout the proposed rulemaking suggested that EPA promulgate an alternative treatment standard of the ''CMBST'' code specifically for hazardous waste pharmaceuticals with numeric treatment standards. The agency considered incorporating these suggestions into the proposed rulemaking, but did not receive the necessary data to support such an action. The Agency does, however, generally agree that implementing a new alternative treatment standard for hazardous waste pharmaceuticals might help mitigate burden on the regulated community while remaining protective of human health and the environment. The Agency remains open to considering the addition of an alternative treatment standard for hazardous waste pharmaceuticals in future rulemakings.

Although the Agency is now requiring the PHARMS code in Item 13 for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF, hazardous waste codes are not required on the manifest, which was preferred by some commenters. As a result, TSDFs treating hazardous waste pharmaceuticals will have to assume that shipments of hazardous waste pharmaceuticals contain the few that have numeric treatment standards in order to demonstrate compliance with LDRs.

The third change made to the regulations was to modify the regulatory language in § 266.508(a) slightly to clarify that shipments of non-creditable hazardous waste pharmaceuticals being sent from a healthcare facility for disposal must be sent to a designated facility and accompanied by a hazardous waste manifest. As part of the manifest requirements in 40 CFR part 262 subpart B, shipments of non-creditable and evaluated hazardous waste pharmaceuticals must be sent to a designated facility via a hazardous waste transporter. One commenter noted that the proposed language could have been interpreted to mean that such shipments are also allowed to go elsewhere, which was not the Agency's intent.

Another substantive change to the regulatory language that resulted from incorporating commenters' concerns was to remove the requirements for shipping papers in § 266.508(a)(1)(v). A commenter pointed out that the requirement is unnecessary given the requirements in § 266.508(a)(2) and the Agency agreed. Section 266.508(a)(1)(v) would have required a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF to prepare shipping papers in accordance with 49 CFR 172 subpart C; however, the subsequent paragraph (§ 266.508(a)(2)) outlines the requirements for manifesting a shipment of non-creditable hazardous waste pharmaceuticals. Requiring both shipping papers and a manifest is redundant and could have possibly resulted in confusion and contradictory requirements. The hazardous waste manifest requirements, if complied

with, duly satisfy DOT's shipping paper requirements.

The wording in § 266.508(a) was modified slightly to clarify that healthcare facilities and reverse distributors that ship non-creditable and evaluated hazardous waste pharmaceuticals off site, respectively, are required to send them to a designated facility.

Finally, to be consistent with the Hazardous Waste Generator Improvements final rule, we have added paragraph 266.508(a)(1)(iii)(C) to mirror § 262.32(d), which addresses marking for lab packs. Specifically, lab packs of hazardous waste pharmaceuticals that will be treated using the alternative treatment standard of incineration, as allowed by § 268.42(c), do not have to marked or labeled with EPA hazardous waste numbers. However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), the EPA hazardous waste number must be marked or labeled with the EPA hazardous waste numbers (or electronic means may be used). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal.

B. Shipping Evaluated Hazardous Waste Pharmaceuticals From Reverse Distributors to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

For reverse distributors, once a potentially creditable hazardous waste pharmaceutical has been evaluated and it has been determined that it is not destined for another reverse distributor for further evaluation or verification of credit, EPA proposed that the hazardous waste pharmaceuticals be referred to as ''evaluated hazardous waste pharmaceuticals.'' As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA proposed that they must be shipped in accordance with the existing DOT pre-transport requirements under 49 CFR parts 172–80 for packaging, labeling, marking, placarding, and shipping papers. We also proposed that they must be shipped in accordance with the existing RCRA manifest requirements of 40 CFR part 262 subpart B, which requires all relevant waste codes be listed in Item 13 and that they be shipped via a hazardous waste transporter to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA argued that the use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been verified, the potential for mismanagement is greater because evaluated pharmaceuticals no longer retain any value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA proposed that a reverse distributor must list all appropriate hazardous waste codes on the manifest when shipping evaluated hazardous waste pharmaceuticals to a TSDF. This differs from the requirements for a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Unlike non-creditable hazardous waste pharmaceuticals generated at a healthcare facility, hazardous waste pharmaceuticals received by reverse distributors are typically in the manufacturer's original, intact, and labeled packaging (if not, they are likely non-creditable hazardous waste pharmaceuticals and should be sent to a TSDF), so the information needed to determine the appropriate hazardous waste codes once evaluated should be readily available to the reverse distributor. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare personnel lack. Under the reverse distributor standards in § 266.510(c)(10)(ii), EPA also proposed that reverse distributors must keep copies of hazardous waste manifests for three years from the date evaluated hazardous waste pharmaceuticals are shipped to a TSDF.

2. Summary of Comments

Comments in this section were mixed. Many commenters addressed the standards for healthcare facilities sending shipments of non-creditable hazardous waste pharmaceuticals to a TSDF but did not specifically mention the standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF. Nevertheless, many of the concerns expressed by commenters with the standards for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF are relevant because the standards in § 266.508 are the same for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals as they are for reverse distributors shipping evaluated hazardous waste pharmaceuticals, with the exception of § 266.508(a)(2)(i) and (ii). The few that commented directly on the proposed shipping standards for evaluated hazardous waste pharmaceuticals being shipped from a reverse distributor to a TSDF agreed with the standards as proposed.

Reverse distributor and waste management industry commenters were in agreement with the proposed standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF, but to reiterate, did not agree with the standards for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF (no waste codes on the manifest). Many commenters on this section simply stated that waste codes should be included on a manifest, referring to the requirements in § 266.508(a)(2)(i) and (ii) which do not require waste codes on the manifest for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Since those standards only apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF and not reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF, the agency assumes that those same commenters are generally in agreement with the requirement for reverse distributors shipping evaluated hazardous waste pharmaceuticals to a TSDF to comply with all of the manifest standards in 40 CFR part 262 subpart B, which includes a requirement to list all applicable EPA hazardous waste codes on the manifest.

3. Final Rule Provisions

The Agency is finalizing the standards for shipping evaluated hazardous waste pharmaceuticals from a reverse distributor to a TSDF with minor changes. First, § 266.508(a)(1)(v) has been removed. The standards for shipping papers for reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF are contained instead in subparagraph § 266.508(a)(2) (*i.e.,* the manifest).

Second, the clarification to the regulatory language mentioned previously, which specifies that non-creditable hazardous waste

pharmaceuticals must go only to a TSDF, also applies to evaluated hazardous waste pharmaceuticals. As mentioned above, commenters were concerned that the proposed regulatory language appeared to make it optional for a reverse distributor to ship evaluated hazardous waste pharmaceuticals to a TSDF for disposal, although it was not intended to read that way. The finalized regulatory language was modified to clarify that a reverse distributor shipping evaluated hazardous waste pharmaceuticals must send them to a TSDF for treatment and disposal. This change pertains to both evaluated pharmaceuticals being shipped from a reverse distributor as well as non-creditable hazardous waste pharmaceuticals being shipped from a healthcare facility.

To summarize, reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF for disposal are required to comply with all standards in § 266.508(a), which includes a requirement to list all applicable waste codes in Item 13 of the manifest, even though healthcare facilities sending non-creditable hazardous waste pharmaceuticals to a TSDF do not. They are not, however, required to write the word PHARMS in Item 13 or on the container label in addition to all other applicable waste codes.

C. Shipping Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals for Import or Export (§§ 266.508(b) and 266.508(c))

1. Summary of Proposal

Under part 262, a healthcare facility or reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off site and complies with the requirements for importing hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under part 262, a healthcare facility or reverse distributor may not export (non-creditable nor evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.[352]

EPA requested comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA did not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262 subpart H; however, we also requested comment on whether this is the case.

2. Summary of Comments

We received no comments on the proposed standards for importing and exporting non-creditable or evaluated hazardous waste pharmaceuticals.

3. Final Rule Provisions

Since part 266 subpart P was proposed, the hazardous waste import and export regulations under part 262 have been revised.[353] The export regulations which had been in part 262 subpart E are now in part 262 subpart H. Likewise, the import regulations which had been in part 262 subpart F are also now in part 262 subpart H. The requirements for both importing and exporting non-creditable hazardous waste pharmaceuticals are being substantially finalized as proposed. The only change being made from the proposed requirements is to update the reference to the revised part 262 regulations, in order to conform to the changes implemented in the Hazardous Waste Imports and Exports Improvement Rule. Whereas the proposed § 266.508(b) and (c) refer to the standards in 40 CFR part 262 subpart E and F, they now refer to 40 CFR part 262 subpart H.

D. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.509).

1. Summary of Proposal

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility to a reverse distributor and between reverse distributors. The return of potentially creditable waste pharmaceuticals (hazardous and non-hazardous) to a reverse distributor can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,[354] reverse distributors described various scenarios. For example, a healthcare facility typically sends waste pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the pharmaceuticals back to them so they can perform the verification and issue credit themselves. The estimated amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors indicated that the percent of potentially creditable hazardous waste pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent of total volume, depending on the contractual agreement between the reverse distributor and the manufacturer. The scenarios described previously occur routinely and are an integral part of the process by which manufacturers issue credit.

As explained in section IV.A, EPA proposed that all pharmaceuticals transported to reverse distributors for manufacturer credit are solid wastes, some of which would also be considered hazardous wastes. The finalized regulations have been modified, however, such that only prescription pharmaceuticals going through reverse distribution for manufacturer credit are solid wastes, while OTC pharmaceuticals going through reverse logistics are outside of this rule. Under the part 262 regulations, hazardous waste, including hazardous waste pharmaceuticals, must be manifested to a permitted or interim

[352] In the proposed rule we referenced part 262 subparts E and F when discussing this provision. Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[353] See the final Hazardous Waste Export-Import Revisions rule, 81 FR 85696; December 31, 2016.

[354] See the survey of reverse distributors in docket number: EPA–HQ–RCRA–2007–0932–0158 through 0160.

status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous waste pharmaceuticals during accumulation and transport is relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials. These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor. Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in section XI.C.1). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk to human health and release to the environment, EPA proposed to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without the use of hazardous waste transporters when the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor or when a reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another reverse distributor. The same DOT shipping requirements would continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals (provided they are classified as DOT hazardous materials) that applied prior to this final rule. Nothing in this final rule changes how DOT shipping requirements apply to shipments of prescription pharmaceuticals to reverse distributors.

EPA proposed an alternate tracking method for potentially creditable hazardous waste pharmaceuticals—with two requirements in lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters. First, EPA proposed that for each shipment, healthcare facilities and reverse distributors must provide in writing (via letter or electronic communication), advance notice of the intent to send a shipment to the receiving reverse distributor. We also proposed that the receiving reverse distributor must provide acknowledgement to the shipper that they received the advance notice. This requirement was intended to function like a manifest, tracking the potentially creditable hazardous waste pharmaceuticals en route to the reverse distributor. Second, EPA proposed that for each shipment, the receiving reverse distributor must provide confirmation to the healthcare facility or reverse distributor that initiated the shipment, that the shipment of potentially creditable hazardous waste pharmaceuticals has been received. The Agency proposed this requirement in direct response to concerns expressed by commenters over the lack of tracking of pharmaceutical waste in the 2008 Pharmaceutical Universal Waste proposal.

The Agency proposed that, if a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within seven calendar days, that the healthcare facility or reverse distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received, and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped.

The Agency proposed that if a healthcare facility or reverse distributor exports potentially creditable hazardous waste pharmaceuticals, it must generally comply with 40 CFR part 262 subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals. The Agency also proposed that any person that imports potentially creditable hazardous waste pharmaceuticals, must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals, in lieu of the requirements for hazardous waste imports found at 40 CFR part 262 subpart F.[355]

[355] Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

EPA proposed to require healthcare facilities (§ 266.503(d)) and reverse distributors (§ 266.510(b)(4)) to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we proposed that healthcare facilities and reverse distributors that initiate a shipment to a reverse distributor must keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) delivery confirmation for three years after the shipment was initiated, and (3) shipping papers or bills of lading. The Agency argued that these records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals reach their intended destination and are not diverted.

In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention would be automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency sought comment on whether additional recordkeeping is necessary to document the cases when the reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within seven calendar days and the steps must be taken to locate the shipment.

2. Summary of Comments

The majority of comments focused on the provision to allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carrier (*i.e.,* not by hazardous waste transporter), the requirements for advance notice of shipment and delivery confirmation, and the time frame within which delivery confirmation is received before the shipper must take action to locate a missing shipment.

Comments on whether the Agency should allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carriers such as USPS, UPS, and FedEx without a manifest were mixed. Only a few states commented on this provision specifically. The majority of states agreed that shipping via carriers provides sufficiently low risk of release or illicit diversion. However, one state was concerned that we did not propose a requirement to reconcile the contents of what was shipped with what was received. That same commenter, as well as a handful of others, also voiced concern about whether DOT regulations would permit hazardous waste

pharmaceuticals to be lawfully shipped via carrier in the first place. Manufacturers, waste management companies, healthcare industry groups, and pharmacy trade associations were all generally in agreement with the proposed shipping standards for potentially creditable hazardous waste pharmaceuticals.

One of the primary points of contention in this subsection was the proposed standard that would require a shipper to provide advance notice of its intent to ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Reverse distributors objected, arguing it would impart undue financial and administrative burden, which would require them to hire additional staff to adequately process advance notices, track, and confirm the delivery of thousands of shipments per year. A national trade association of retailers expressed similar concerns. They did not support the proposed advance notice and delivery confirmation requirements and argued the requirements would add undue burden due to the high volume of shipments large retailers send per year. The commenters suggested that the proposed notification and delivery standards either be removed or modified to match current inventory and accounting practices.[356] One pharmaceutical manufacturer also disagreed with the proposed standard, but gave no reasoning as to why, other than they thought it was unnecessary. States generally agreed with the proposed standard and a few suggested the Agency finalize additional requirements like reconciling what was in the notice with the contents of the package after delivery which would also require an inventory of each container. One state was concerned about its ability to confirm that a shipment has reached its final destination (TSDF) in scenarios where a shipment is sent to an out-of-state reverse distributor or a second reverse distributor. Healthcare facilities and pharmacist trade groups either agreed with the proposed standards or did not mention these standards specifically. One pharmacist trade group said they want some clarification about what constitutes advance notice.[357]

There were numerous comments both in agreement with and opposition to the proposed requirement to take action to locate a shipment of potentially creditable hazardous waste pharmaceuticals if no delivery confirmation is received within seven days from the day the shipment leaves the shipper's facility. Most comments were related to the time frame within which the shipper must receive delivery confirmation, but a few commenters from the retail and reverse distribution industries opposed the requirement altogether because of the added financial, procedural, and administrative burden they argue it would impose. Many commenters were concerned that the proposed time frame was too short and would result in frequent situations in which the shipper would be required to undertake efforts to locate a shipment that eventually arrives without intervention sometime after the seven days. Some commenters noted that seven days is the minimum transit time for a standard cross-country shipment under ideal conditions, which provides no buffer for unforeseen circumstances that may cause delays such as inclement weather or some other service disruption. One state suggested a 35-day time frame as an alternative because it would be the same as the time frame specified for delivery confirmation of universal waste shipped via carrier per the universal waste rule.[358]

There were limited comments regarding the proposed standards for healthcare facilities and reverse distributors importing and/or exporting potentially creditable hazardous waste pharmaceuticals. The only concern raised was whether shipments sent to or received from U.S. territories (*e.g.,* Puerto Rico, Guam) are considered exports/imports, and if so, they recommended that the Agency confer with other appropriate federal agencies and their reverse distributor contractors.

3. Final Rule Provisions

In response to comments, the Agency has made several changes to the proposed standards for shipping potentially creditable hazardous waste pharmaceuticals. First, we have made a minor change to make our regulatory language more consistent with DOT's terminology and clarify to whom the regulations refer. Specifically, in § 266.509(c), we changed the word shipper to carrier. As originally proposed, the word shipper could have been interpreted to refer to the party that prepares and offers a shipment of potentially creditable hazardous waste pharmaceuticals, whereas the regulations apply to the company providing transportation of a shipment of potentially creditable hazardous waste pharmaceuticals. To clarify, a shipper is the party that prepares and offers a shipment to be transported by a carrier.

Second, we have eliminated the requirement in § 266.509(a)(1) for a healthcare facility or reverse distributor that ships potentially creditable hazardous waste pharmaceuticals to provide advance notice of the shipment. The Agency believes that the proposed advance notice requirement goes beyond the manifest requirements and would have resulted in undue burden on both the shippers and the receiving reverse distributors while only nominally more protective of human health and the environment. We would, however, recommend that, as a best practice, shippers of potentially creditable hazardous waste pharmaceuticals provide advance notice to the recipients to the extent practicable. Conforming changes have been made throughout the regulations that reflect the elimination of the requirement to provide advance notice of shipments of potentially creditable hazardous waste pharmaceuticals.

Third, the proposed requirement that a reverse distributor that receives a shipment of potentially creditable hazardous waste pharmaceuticals must provide delivery confirmation to the facility that initiated the shipment is being finalized as proposed, with the added clarification that the shipment is not considered delivered until it is under the custody and control of the receiving reverse distributor. Requiring delivery confirmation provides assurance that the shipment was actively received by the reverse distributor and the chain of custody maintained. Without this confirmation from the receiving reverse distributor personnel, it is possible for a shipment to be delivered to the destination location but not necessarily taken into their custody and control (*e.g.,* left unattended outside the building).

Under this final rule, healthcare facilities and reverse distributors may use carriers, such as USPS, UPS, and FedEx for shipments of potentially creditable hazardous waste pharmaceuticals to and between reverse distributors, as long as personnel are present to receive and take control of the shipments upon arrival. EPA believes that carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low risk of release during transport.

In addition, all of the carriers EPA is aware of offer services that meet the delivery confirmation requirement.

[356] See comment number EPA–HQ–RCRA–2007–0932–0295.

[357] See comment number EPA–HQ–RCRA–2007–0932–0284.

[358] See comment number EPA–HQ–RCRA–2007–0932–0238.

Delivery confirmation can be paper-based or electronic and must indicate that personnel from the receiving reverse distributor have taken the shipment into their custody and control. One way for healthcare facilities and reverse distributors sending shipments of potentially creditable hazardous waste pharmaceuticals to a reverse distributor via carrier may comply with the delivery confirmation requirement would be to utilize the delivery confirmation service provided by most carriers (*e.g.,* Return Receipt from USPS, Delivery Confirmation from UPS, or Signature Proof of Delivery from FedEx). Typically, personnel at the receiving reverse distributor will sign for a shipment confirming that it is now in their custody and control. That signature will then be made available to the shipper, which satisfies the delivery confirmation requirement.

EPA has learned that some stakeholders use alternative electronic tracking methods outside of those offered by carriers. One alternative electronic tracking method is to apply barcoding on pharmaceutical packaging or on containers containing multiple pharmaceutical packages. A barcode is a unique identifier that links the container to a database with detailed information about its contents and includes the exact quantities of each item included in the shipment (inventories). Typically, when a reverse distributor receives a barcoded shipment, it will scan the barcodes upon receipt, and the sender will receive electronic notification that the shipment has arrived at its destination and is in the custody and control of the reverse distributor. This type of barcode tracking would meet the delivery confirmation requirement of this final rule. Another type of alternative electronic tracking that would satisfy the delivery confirmation requirement is radio frequency identification (RFID). Similar to barcodes, RFID tags are placed inside a container, or integrated into the container itself, and linked to inventories and other detailed information. The RFID tags are read when they arrive at the receiving facility and that information is made available to the shipper, confirming that the shipment has been taken into the custody and control of the receiving reverse distributor.[359]

Fourth, we have eliminated the regulatory language that was proposed in § 266.509(a)(2). We had referenced the DOT pre-transport regulations that apply to shipments of non-creditable hazardous waste pharmaceuticals. However, in 2016, DOT revised the Hazardous Materials Regulations (HMR) as they apply to shipments of items in reverse logistics.[360] As a result, many of the DOT pre-transport requirements we had referenced no longer apply to shipments of hazardous materials in reverse logistics. In response, we have eliminated the reference to the DOT pre-transport requirements and instead modified our final regulations in § 266.509(a) to refer to the entire HMR, rather than specific provisions within the HMR. Healthcare facilities and reverse distributors that send shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors need only comply with the applicable sections of DOT's HMR for shipments in reverse logistics.

We note that healthcare facilities and reverse distributors must meet the applicable DOT hazardous material shipping requirements only when shipping potentially creditable hazardous waste pharmaceuticals that meet the definition of DOT hazardous material. Under the DOT regulations, a RCRA hazardous waste that requires a manifest is considered a Class 9 hazardous material. Potentially creditable hazardous waste pharmaceuticals do not require a manifest; therefore, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to reverse distributors only when the hazardous wastes are otherwise classified as DOT hazardous materials (*i.e.,* DOT hazard class 1–8). We added regulatory language (that was adapted from the Universal Waste regulations) to reflect this.

Fifth, the Agency has finalized the requirement that the shipper of potentially creditable hazardous waste pharmaceuticals must receive a delivery confirmation from the reverse distributor, however, the Agency has extended the time frame within which the shipper must receive the delivery confirmation from the reverse distributor from the proposed seven days to 35 days, after which the shipper must begin taking actions to locate a shipment if the delivery confirmation is not received. Many commenters suggested 14 days as an alternative to the proposed seven-day time frame, while others suggested far longer or to eliminate the time frame altogether. Upon reconsideration of the issue and how it pertains more generally to other RCRA hazardous waste programs, the Agency decided that 35 days was more appropriate, while remaining duly protective of human health and the environment and reducing burden on the regulated community. The time frame to receive delivery confirmation for shipments of potentially creditable hazardous waste pharmaceuticals is also now in line with the standard for delivery confirmation under universal waste, which is also 35 days. In addition, one of the overarching goals of this rule was to enact universal waste-like standards for hazardous waste pharmaceuticals, to which this provision conforms. Some states wanted the Agency to go further and require that the EPA Regional Administrator be notified whenever a shipment has not been received within the allotted time frame. Although the Agency understands the utility of such a provision, it is not being adopted because of the added burden it would impose on both states and the regulated community. In addition, the Agency prefers, in this instance, to allow states the flexibility to implement more stringent reporting standards for missing shipments of potentially creditable hazardous waste pharmaceuticals according to their individual circumstances and preferences.

After considering these comments, the Agency determined that it is necessary to require a delivery confirmation in order to ensure shipments of potentially creditable hazardous waste pharmaceuticals have been received and taken into the custody and control of the destination facility as a way to approximate the manifest system without requiring the use of hazardous waste transporters or manifests. In response to comments, we have reconsidered the proposed seven-day time frame for the shipper to receive delivery confirmation; the Agency decided that 35 days is more appropriate. It strikes a balance between being duly protective of human health and the environment, reducing burden, and is now in line with universal waste standards.

Sixth, we have made several changes to the pre-transport requirements that we proposed in § 266.509(a)(1) and (2). Because of the removal of the requirement for advance notice of shipments of potentially creditable hazardous waste pharmaceuticals, we renumbered the section such that it all appears in § 266.509(a) now. What was proposed in § 266.509(a)(2) and is now in § 266.509(a), has been modified to reflect the removal of § 266.508(a)(1)(v) which previously contained a requirement that DOT shipping papers be generated. The Agency believes that the shipping papers requirement—

[359] See comment number EPA–HQ–RCRA–2007–0932–0268.

[360] March 31, 2016; 62 FR 18527.

although duplicative for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor—is appropriate for shipments of potentially creditable hazardous waste pharmaceuticals given that they are not manifested. Therefore, the requirement for DOT shipping papers has been added to § 266.509(a). Language was also added to clarify that shipments of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or reverse distributor to a reverse distributor do not require a manifest. This language was taken from the universal waste standards in § 273.52(a) which is consistent with the goal of developing universal waste-like shipping standards for potentially creditable hazardous waste pharmaceuticals.

As with the export of non-creditable hazardous waste pharmaceuticals, the proposed standards for healthcare facilities or reverse distributors that export potentially creditable hazardous waste pharmaceuticals to a foreign destination have also been modified to reflect the changes made to the import/export rules of part 262. Specifically, the Agency is finalizing requirements that exporters of potentially creditable hazardous waste pharmaceuticals must comply will all applicable sections of 40 CFR part 262 subpart H, except for the manifest requirements of § 262.83(c), in addition to the requirements for shipping potentially creditable hazardous waste pharmaceuticals in § 266.509(a) through (c).

Subsequent to when this rule was proposed in September 2015, the Hazardous Waste Import-Export Revisions rule was finalized in 2016.[361] As a result, the Agency has had to make conforming changes to this final rule to reflect the changes made by the Import-Export Revisions final rule. Because the regulations for importing and exporting hazardous waste were previously located in separate subparts—exports in subpart E and imports in subpart F—the proposed requirements in this rule were also separated into discreet subsections and referred to their respective subparts (exporting and importing) of 40 CFR part 262. A significant change enacted by the Import-Export Revisions Rule was to consolidate into subpart H the multiple related subparts in 40 CFR 262 regarding import, export, and transboundary movements of hazardous waste that had been in subparts E and F.

The essence of the proposed regulations has not changed in the finalized requirements. That is, a healthcare facility or reverse distributor exporting potentially creditable hazardous waste pharmaceuticals is still subject to the same or similar provisions as were proposed, only now they must comply with 40 CFR part 262 subpart H instead, except for the manifesting requirements, and paragraphs (a) through (c) of § 266.509.

For healthcare facilities and reverse distributors that import potentially creditable hazardous waste pharmaceuticals, the requirements are being finalized as proposed, except that due to the conforming changes necessitated by the Hazardous Waste Export-Import Revisions Final Rule, they must now comply with the shipping standards for potentially creditable hazardous waste pharmaceuticals in lieu of 40 CFR part 262 subpart H (instead of part 262 subpart F). One other clarification was added to the regulatory language specifying that potentially creditable hazardous waste pharmaceuticals are subject to all applicable provisions in this subpart immediately after entering the United States.

4. Comments and Responses

The commenter that requested an official definition of advance notice also requested an official definition for delivery confirmation.[362] The Agency is purposely leaving this standard sufficiently broad as to allow the implementing agencies discretion to determine the best implementation strategies on a case-by-case basis.

EPA notes that a reverse distributor is not required to segregate the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not segregated, the reverse distributor must follow the tracking procedures for the entire shipment. On the other hand, if a reverse distributor chooses to segregate the potentially creditable hazardous waste pharmaceuticals from the non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these standards.

XVII. Standards for Reverse Distributors (§ 266.510)

A. Background on Reverse Distributor Operations

Reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input, EPA site visits, and comments on the proposed rulemaking, EPA's understanding is that when a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' ''business rules'' (*i.e.,* manufacturers' return policies), the reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can receive manufacturer credit, as well as which must be sent on to another reverse distributor for completion of the crediting process. ''Business rules'' (*i.e.* manufacturers' return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[363]

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the manufacturer credit process.

Because manufacturers' business rules change over time, sometimes a reverse distributor receives a potentially creditable hazardous waste

[361] See the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[362] See comment number EPA–HQ–RCRA–2007–0932–0284.

[363] This definition is derived from the definition of ''business rules'' in the ''Surplus Household Consumer Products and Wastes: Report to the Legislature.'' Available at: *http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.*

pharmaceutical that is not eligible for credit immediately, and the reverse distributor retains the potentially creditable hazardous waste pharmaceutical on site until it is credit eligible (often called ''aging'' a pharmaceutical). For example, manufacturers only issue credit for expired pharmaceuticals. As a result, sometimes a reverse distributor receives an unexpired hazardous waste pharmaceutical that is otherwise creditable but awaiting its expiration date. The reverse distributor then retains the potentially creditable hazardous waste pharmaceutical on site until after it has expired and thus becomes eligible for manufacturer credit. In some cases, even after the reverse distributor has awarded manufacturer credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to verify the amount of pharmaceuticals and manufacturer credit.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent on to another reverse distributor and the reverse distributor awards the manufacturer credit to the healthcare facility itself, it then manages the hazardous waste pharmaceuticals on site until they are sent off site for treatment and disposal. As discussed previously, after a potentially creditable hazardous waste pharmaceutical has been evaluated and no additional reverse distributors will be involved in the manufacturer's crediting process, EPA uses the term ''evaluated hazardous waste pharmaceutical.'' This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor for evaluation. Both are considered hazardous waste pharmaceuticals, but they are managed differently under this subpart.

EPA is not aware of any reverse distributor that facilitates manufacturer credit that also has interim status or a permit to treat or dispose of hazardous waste on-site.[364] Therefore, EPA anticipates that reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off site for treatment and disposal.

[364] Several DEA reverse distributors have RCRA interim status or a permit to treat or dispose of hazardous waste, but these DEA reverse distributors do not facilitate manufacturer credit.

B. EPA's Rationale for Finalizing New RCRA Management Standards for Reverse Distributors

This final rule establishes standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that reverse distributors receive and manage. The management standards discussed in this section apply only to reverse distributors of prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. The management standards discussed in this section do not apply to the reverse logistics systems that may exist for other retail items. In response to comments, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see the definition of hazardous waste pharmaceutical under section VIII and section IX, the applicability section). Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed (see section VI). Therefore, reverse logistics centers that receive and manage nonprescription pharmaceuticals will not be regulated under this subpart and will not be subject to the standards for reverse distributors.

The current federal RCRA hazardous waste generation regulations at 40 CFR part 262 provide that only designated facilities, such as RCRA-permitted and interim status TSDFs, may receive hazardous waste from off site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA is finalizing a new category of hazardous waste management facilities under RCRA called a ''reverse distributor,'' which is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. The definition specifies that any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription hazardous waste pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. EPA is finalizing that reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off site provided they comply with the standards in this final rule. Reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed earlier in this document, EPA's previous interpretation allows reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a hazardous waste generator, a reverse distributor had to comply with the LQG, SQG, or VSQG generator regulations, depending on the total volume of hazardous waste generated in a calendar month. Some smaller reverse distributors might have stayed under the hazardous waste quantity limits for VSQGs, which would mean that under the federal RCRA regulations, these VSQG reverse distributors would not have had to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 262.14). However, the Agency has concerns with VSQG reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about reverse distributors that currently qualify as VSQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.[365] [366] Landfill leachate is generally transported to a wastewater treatment

[365] Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126.

[366] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, 82.6:635–659.

plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

In this final rule, EPA is revising its position regarding prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals, such that they will be considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that prescription pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a reverse distributor is a decision to discard the pharmaceutical (as discussed previously in section VI). Comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

Although EPA maintains its position as stated in the proposed rulemaking preamble that hazardous waste pharmaceuticals going to reverse distributors are solid wastes at the healthcare facility, there are important differences between reverse distributors and traditional TSDFs. Only between 2–6 percent of the potentially creditable pharmaceuticals that are received by reverse distributors are listed or characteristic hazardous wastes.[367] Therefore, the vast majority of the potentially creditable pharmaceutical waste that a reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, whose primary function is to manage hazardous waste. As a result, a reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving manufacturer credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year.[368] Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging, which in some cases includes inner and outer packaging (*e.g.,* plastic bottle inside a box). Since there is a relatively low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that it is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is taking a tailored approach to regulating reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a reverse distributor. This approach balances EPA's revised interpretation that the point of generation for prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor, with the fact that potentially creditable hazardous waste pharmaceuticals have value which provides an incentive for proper management.

EPA is establishing new management standards for reverse distributors in 40 CFR part 266 subpart P. These entities will not be subject to 40 CFR parts 262, 264, 265, or 270. Generally, EPA is finalizing that reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for reverse distributors to comply with the new subpart, in part because the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA is finalizing that a reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the final reverse distributor standards. As mentioned previously, the on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals generally presents low risk of release to the environment because they are typically in the manufacturer's packaging. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a reverse distributor must either obtain a RCRA permit or have interim status, as these activities pose a higher risk of release. EPA has determined that requirements similar to LQG standards for on-site accumulation of hazardous waste that are found in § 262.17 are appropriate. As discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many reverse distributors are already LQGs and, therefore, this final rule should not represent a large shift in current practices or increased burden.[369] However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, EPA is finalizing additional standards for the management of evaluated hazardous waste pharmaceuticals at reverse distributors.

EPA received numerous comments that expressed concern that the standards for reverse distributors would be burdensome for reverse logistics

[367] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[368] Meeting with representatives from CVS (August 11, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932–0188).

[369] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

centers that handle nonprescription pharmaceuticals. For example, one commenter expressed concern that the reverse distributor inventory requirements for both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals would be burdensome for facilities that receive and manage nonprescription pharmaceuticals because these reverse logistics centers do not currently maintain an inventory for these retail items.[370] EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed (see section VI for more discussion). Therefore, reverse logistics centers will not be regulated under part 266 subpart P and will not be subject to the standards for reverse distributors. As a result, comments received on the impact of the reverse distributor standards on reverse logistics centers that receive and manage nonprescription pharmaceuticals are outside the scope of the final rule and are not discussed in this section. EPA also received numerous general comments expressing concern that finalizing new RCRA management standards for reverse distributors would be burdensome. However, some specific provisions included in the proposed reverse distributor standards received few comments.

C. Detailed Discussion of Final Reverse Distributor Standards

The final standards for reverse distributors are organized into three sections. The first section applies to the reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals (§ 266.510(a)). The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals (§ 266.510(b)). The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor, but instead will be sent to a permitted or interim status TSDF (§ 266.510(c)).

1. Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(a))

This portion of the preamble discusses the standards that apply to reverse distributors for the management of all hazardous waste pharmaceuticals on site, including potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Unlike the following two sections, the standards discussed in this section apply to all prescription hazardous waste pharmaceuticals at a reverse distributor, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a reverse distributor must follow these standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262. Note that we have reorganized § 266.510(a) since the proposal to more accurately reflect the flow of hazardous waste pharmaceuticals at a reverse distributor. The subsequent preamble section follows the organization of the final regulations.

a. Notification

Summary of Proposal. EPA proposed that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). Under the RCRA Subtitle C program, SQGs, LQGs, and TSDFs must submit a Site ID Form to EPA. EPA proposed that a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one and that a reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor.

Summary of Comments. EPA received two comments in support of the proposed notification requirements. One state supported all of the proposed notification requirements.[371] Inmar, Inc. supported the requirement that reverse distributors must notify EPA using EPA Form 8700–12.[372]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(1) that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). The Agency will revise the Site ID Form to include a box to allow notifications by reverse distributors. EPA believes it is appropriate, and in line with comments received on the proposal, to require reverse distributors to notify EPA. Under the final rule, a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one. A reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor. The time frame in both cases is within 60 days of the effective date of this subpart or within 60 days of becoming subject to this subpart. Some reverse distributors may also be generators of other types of hazardous waste (*e.g.,* from cleaning and maintenance operations). Therefore, it is possible that a reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a reverse distributor.

b. Inventory

Summary of Proposal. EPA proposed that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. EPA proposed that the inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical. EPA also proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor.

Summary of Comments. EPA received comments from states and industry in support of the proposed inventory requirement.[373] One state suggested that EPA also require reverse distributors to include the name of the healthcare facility that shipped the potentially creditable hazardous waste pharmaceuticals to the reverse distributor.[374]

Retail Industry Leaders Association argued that the inventory requirements for reverse distributors should be reduced.[375] Inmar, Inc. did not support the inventory requirements and argued

[370] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[371] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[372] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[373] See comment numbers EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, EPA–HQ–RCRA–2007–0932–0300, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[374] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[375] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

that they are duplicative because reverse distributors must already inventory and track prescription pharmaceuticals.[376] Inmar, Inc. wrote that at least four states currently require the maintenance of drug inventories by law.[377] Both Inmar, Inc. and RILA expressed concern that the inventory requirements would be particularly burdensome for their facilities that handle nonprescription pharmaceuticals. Inmar, Inc. pointed out that their reverse logistics centers do not maintain an inventory for nonprescription pharmaceuticals.[378]

EPA received multiple comments from industry that expressed concern that the reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival.[379] One commenter expressed concern that the reverse distributor must complete an inventory upon arrival because packages of potentially creditable hazardous waste pharmaceuticals can remain unopened for up to 5 business days.[380] Healthcare Distribution Management Association [381] pointed out that reverse distributors sometimes receive tens of thousands of products in a day and do individual product accounting when the credit determination is made.[382]

Commenters on the proposed rulemaking also pointed out that reverse distributors are already required to inventory and track prescription pharmaceuticals under licensing and accreditation programs overseen by the National Association of Boards of Pharmacy.[383]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(2) that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. In response to comments, we have made several changes to what was proposed but have determined that an inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the reverse distributor to know which hazardous waste pharmaceuticals they have on-site at any time. Based on stakeholder input and site visits, the Agency believes that in many cases, reverse distributors already maintain inventories of pharmaceuticals and this requirement is not expected to be burdensome for the reverse distributors to implement. According to responses from reverse distributors to a 2011 request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.[384] The inventory must include the identity (*e.g.,* name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. In response to commenter concern that the inventory requirement would be duplicative, EPA clarified in the regulatory language of the final rule that if the reverse distributor already meets the inventory requirements because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory.

EPA proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor. The final rule has been revised to state that reverse distributors must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor. EPA made this change in response to commenter concern that the Agency did not provide enough time for reverse distributors to inventory potentially creditable hazardous waste pharmaceuticals. As previously mentioned, comments pointed out that reverse distributors sometimes receive tens of thousands of products in one day and need additional time to inventory each potentially creditable hazardous waste pharmaceutical.[385] EPA is also aware that many reverse distributors inventory the potentially creditable hazardous waste pharmaceutical at the same time that they evaluate the potentially creditable hazardous waste pharmaceutical to determine if it will receive manufacturer credit. When a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system and make a credit determination. EPA believes that 30 days is an adequate amount of time for the reverse distributor to sort through shipments of hazardous waste pharmaceuticals and inventory the potentially creditable hazardous waste pharmaceuticals. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, increasing the amount of time reverse distributors have to complete the inventory will not increase risk of release to the environment.

c. Evaluating Potentially Creditable Hazardous Waste Pharmaceuticals Within 30 Days

Summary of Proposal. The key role the reverse distributor plays in managing the issuing of credit from a manufacturer to a healthcare facility is sorting through shipments of potentially creditable hazardous waste pharmaceuticals and evaluating them to determine which must be transported to another reverse distributor for further evaluation of manufacturer credit and which will be sent off site for treatment and disposal. The reverse distributors often use barcodes to scan items into their systems.

EPA proposed that this evaluation process must be completed within 21 days of arriving at the reverse distributor. Likewise, EPA proposed that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals. The Agency proposed that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that each reverse distributor is allowed to accumulate hazardous waste pharmaceuticals on site.

Summary of Comments. The most frequent comment EPA received on the proposed requirement that reverse distributors complete the evaluation process within 21 days of arriving at the reverse distributor is that the proposed time frame was too short. Waste Management National Services, Inc.

[376] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[377] See the EPA correspondence with Inmar dated March 29, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[378] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[379] See comment numbers EPA–HQ–RCRA–2007–0932–0295, EPA–HQ–RCRA–2007–0932–0276, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0340 in the docket for this rulemaking.

[380] See comment number EPA–HQ–RCRA–2007–0932–0278 in the docket for this rulemaking.

[381] Now renamed Heathcare Distribution Alliance.

[382] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[383] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[384] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932–0157, EPA–HQ–RCRA–2007–0932–0158, EPA–HQ–RCRA–2007–0932–0159, EPA–HQ–RCRA–2007–0932–0160, EPA–HQ–RCRA–2007–0932–0161, EPA–HQ–RCRA–2007–0932–0162, EPA–HQ–RCRA–2007–0932–0163, EPA–HQ–RCRA–2007–0932–0164.

[385] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

requested that EPA allow additional time for reverse distributors to evaluate potentially creditable hazardous waste pharmaceuticals.[386] One state requested that EPA allow reverse distributors to have 30 days to complete the evaluation process.[387] RILA and PharmaLink, Inc. requested that EPA allow reverse distributors to have 60 days to complete the evaluation process.[388] GENCO, Qualanex, LLC, and Healthcare Waste Institute of the National Waste and Recycling Association requested that there be no time limit set for reverse distributors to complete the evaluation process.[389] One state suggested that it is not critical to require the evaluation to take place in a certain number of days if the days count toward the total number of days that hazardous waste pharmaceuticals are allowed to accumulate on site.[390]

EPA also received multiple comments in support of the requirement that reverse distributors complete the evaluation process in a short time frame. One state supported the requirement that reverse distributors complete the evaluation process in a short time frame.[391] Clean Harbors Environmental Services argued that 21 days is more than adequate for a reverse distributor to evaluate potentially creditable hazardous waste pharmaceuticals.[392]

Final Rule Provisions. Under the final rule, EPA is requiring in § 266.510(a)(3) that reverse distributors evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Likewise, EPA is finalizing in § 266.510(a)(4) that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 30 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA is now aware that reverse distributors sometimes receive tens of thousands of products in one day and that sometimes reverse distributors need more than 21 days to evaluate the potentially creditable hazardous waste pharmaceuticals.[393] As mentioned previously, commenters pointed out that many reverse distributors inventory the potentially creditable hazardous waste pharmaceuticals at the same time that they evaluate the potentially creditable hazardous waste pharmaceuticals to determine if they will be credited.[394] Therefore, the Agency is finalizing that both the inventory and the evaluation process must be completed in 30 days to ensure that reverse distributors have adequate time to sort through shipments of potentially creditable hazardous waste pharmaceuticals.[395] In the case where healthcare facilities do not segregate hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals as part of the evaluation process, reverse distributors will effectively make a hazardous waste determination in order to determine which pharmaceuticals are hazardous waste pharmaceuticals and thus subject to this subpart.

The Agency is finalizing that the 30 calendar days for evaluating the potentially creditable hazardous pharmaceuticals do not count as part of the total 180 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on site at the reverse distributor. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals and the low risk these materials present, increasing the amount of time reverse distributors have to evaluate shipments of potentially creditable hazardous waste pharmaceuticals will not increase risk of release to the environment. Additionally, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard, and therefore EPA has determined that having a longer accumulation time is not a hazard to human health and the environment.[396]

EPA is finalizing that once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this subpart at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals. If, however, they are destined for an interim status or permitted TSDF, they are considered ''evaluated hazardous waste pharmaceuticals.'' There are additional regulations in this rule at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals.

d. Accumulation Time Limit

Summary of Proposal. EPA proposed that, like LQGs, reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present because they are in original manufacturer's packaging that would meet our typical requirement for closed containers, the Agency decided not to propose specific container management standards.

The Agency proposed that the 90-day time limit begin when the potentially creditable hazardous waste pharmaceuticals initially arrive at the reverse distributor. The Agency also proposed that there is a 90-day accumulation limit for the hazardous waste pharmaceuticals at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. The Agency proposed that in such cases, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a 90-day accumulation limit.

EPA did not propose a specific method that reverse distributors must use to document that accumulation does not exceed 90 calendar days. EPA

[386] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[387] See comment number EPA–HQ–RCRA–2007–0932–0313 in the docket for this rulemaking.

[388] See comment numbers EPA–HQ–RCRA–2007–0932–0295 and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[389] See comment numbers EPA–HQ–RCRA–2007–0932–0336, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[390] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

[391] See comment number EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

[392] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[393] See comment numbers EPA–HQ–RCRA–2007–0932–0276 and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[394] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[395] Although RILA requested that EPA allow reverse distributors to have 60 days to complete the evaluation process, RILA was primarily concerned that it would be difficult for reverse distributors to sort through over-the-counter pharmaceuticals and dietary supplements within the proposed time frame (see comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking). However, the Agency thinks that 30 days is a sufficient amount of time for reverse distributors to sort through shipments of potentially creditable hazardous waste pharmaceuticals, which does not include over-the-counter pharmaceuticals and dietary supplements under the final regulations (see the definition of ''potentially creditable hazardous waste pharmaceuticals'' in 266.500).

[396] For more discussion of the closed container standard see memo from Devlin to RCRA Division Directors, November 3, 2011 (RCRA Online #14826).

anticipated that most reverse distributors would use the inventory system to verify the 90-calendar day time frame rather than taking the extra step of labeling containers with dates for verification. EPA also proposed to allow a reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the reverse distributor. Under the part 262 generator regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA proposed to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis.

Summary of Comments. The most frequent comment EPA received on the proposed on-site accumulation time limit was that the 90-day accumulation limit was too short. Waste Management National Services, Inc. did not support the 90-day accumulation limit, arguing that there are many reasons why a reverse distributor would experience significant changes in the volumes of returns it receives, including recalls.[397] Inmar, Inc. did not support the 90-day accumulation limit, arguing that its facilities receive thousands of shipments every day and it would be impractical to ensure a 90-day accumulation limit.[398] Healthcare Distribution Management Association pointed out that the 90-day accumulation limit is too short because manufacturers frequently take longer than 90 days to make credit determinations.[399] Waste Management National Services, Inc., Qualanex, LLC, and PharmaLink, Inc. requested that EPA not require the 90-day accumulation to begin until the potentially creditable hazardous waste pharmaceuticals become evaluated hazardous waste pharmaceuticals.[400] Stericycle, Inc. requested that EPA extend the accumulation time limit from 90 days to 180 days and suggested that there should not be an accumulation time limit for hazardous waste pharmaceuticals being held due to recall.[401] GENCO and Healthcare Waste Institute of the National Waste and Recycling Association also requested that EPA extend the accumulation time limit from 90 days to 180 days.[402] RILA Association requested that EPA extend the accumulation time limit from 90 days to one year.[403] National Pharmaceutical Returns requested that EPA place no accumulation time limit on potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.[404]

EPA received multiple comments suggesting that the accumulation time limits did not accommodate situations where reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date or situations where reverse distributors ''age'' potentially creditable pharmaceuticals until they are eligible for manufacturer credit.[405]

One state supported the 90-day accumulation limit.[406] One state agreed that the 90-day accumulation limit is reasonable but did not support allowing each reverse distributor to have a 90-day accumulation period because it increases the potential for mismanagement.[407]

Final Rule Provisions. In response to comments, EPA is providing additional time for reverse distributors accumulating hazardous waste pharmaceuticals. Specifically, EPA is finalizing in § 266.510(a)(5) that reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for up to 180 calendar days without having interim status or a permit as long as they meet the conditions of this subpart. The Agency is finalizing that the 180-day time limit begins once the reverse distributor evaluates the potentially creditable hazardous waste pharmaceutical and determines if the potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor for further evaluation of manufacturer credit or if it will be sent off site for treatment and disposal. As mentioned in the previous section, reverse distributors are required to inventory and evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Therefore, the potentially creditable hazardous waste pharmaceuticals can be accumulated at each reverse distributor for no more than 210 days in total after arrival.

The Agency is finalizing that there is a 180-day accumulation limit for the hazardous waste pharmaceutical at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. Under the final rule, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 180-day accumulation limit. Under the final rule, the 180-day time limit begins when the reverse distributor evaluates potentially creditable hazardous waste pharmaceuticals and to determine which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be sent off site for treatment and disposal.

Under the final rule, EPA is not requiring a specific method that reverse distributors must use to document that accumulation does not exceed 180 calendar days. EPA anticipates that most reverse distributors will use the inventory system to verify the 180-calendar day time frame rather than taking an addition step of labeling containers with dates for verification. As discussed previously, EPA is finalizing that a reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Many reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives.

Because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency is not requiring specific container management standards in the final rule. Furthermore, potentially creditable hazardous waste pharmaceuticals are typically still in the manufacturer's packaging, which would meet our typical requirement for closed containers.

Under the final rule, EPA has eliminated the proposed provision allowing reverse distributors to request an extension of the accumulation time limit. In order to accommodate situations where hazardous waste

[397] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[398] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[399] See comment number EPA–HQ–RCRA–2007–0932–0276 in the docket for this rulemaking.

[400] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0352, and EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[401] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[402] See comment numbers EPA–HQ–RCRA–2007–0932–0336 and EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[403] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[404] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[405] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[406] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[407] See comment number EPA–HQ–RCRA–2007–0932–0300 in the docket for this rulemaking.

pharmaceuticals are involved in unforeseen circumstances beyond the control of the reverse distributor, the Agency increased the accumulation time limit from 90 days to 180 days. As discussed previously, the Agency also increased the amount of time reverse distributors can take to evaluate potentially creditable hazardous waste pharmaceuticals from 21 to 30 days. Additionally, in order to accommodate situations when hazardous waste pharmaceuticals are involved in litigation or a recall, under the final rule, the Agency decided that hazardous waste pharmaceuticals that are either involved in an investigation or judicial proceeding or are subject to a voluntary or federally-mandated recall are not required to be managed under subpart P (see section IX for a detailed discussion). As a result, we do not anticipate the need for reverse distributors to seek accumulation time extensions and therefore we have deleted proposed § 266.510(a)(5).

In order to accommodate situations when reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue), EPA has added a provision in § 266.510(a)(5)(ii) to allow reverse distributors to accumulate these unexpired pharmaceuticals for up to 180 days after the expiration date provided that the unexpired pharmaceuticals are managed in accordance with the container labeling and management standards for evaluated hazardous waste pharmaceuticals found at § 266.510(c)(4)(i)–(vi) while they are aging. This includes labeling containers with the words ''hazardous waste pharmaceuticals;'' ensuring the containers are in good condition, managed to prevent leaks and compatible with the contents; and keeping containers closed.

Once a reverse distributor evaluates a hazardous waste pharmaceutical and determines that it is not destined for another reverse distributor, the reverse distributor must manage that hazardous waste pharmaceutical according to the standards for evaluated hazardous waste pharmaceuticals (unless, as previously mentioned, the hazardous waste pharmaceuticals are unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date). The evaluated hazardous waste pharmaceuticals can be accumulated for up to 180 calendar days without having interim status or permits and they must be managed in accordance with the standards for evaluated hazardous waste pharmaceuticals in § 266.510(c). Although reverse distributors must manage the hazardous waste pharmaceuticals that are not destined for another reverse distributor in accordance with the standards for evaluated hazardous waste pharmaceuticals, the reverse distributor can decide at any point during the accumulation time that the evaluated hazardous waste pharmaceuticals have become eligible for manufacturer credit. If the evaluated hazardous waste pharmaceuticals become eligible for manufacturer credit, the reverse distributor does not get additional calendar days beyond the 180-day accumulation time limit to accumulate the hazardous waste pharmaceuticals. If the evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit, and the hazardous waste pharmaceutical will still not be sent to another reverse distributor for further evaluation, the reverse distributor must continue to manage the hazardous waste pharmaceutical in accordance with the standards for evaluated hazardous waste pharmaceuticals.

EPA does not anticipate a scenario where an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor needs to send the hazardous waste pharmaceutical to another reverse distributor for further evaluation. A reverse distributor is unlikely to utilize resources to accumulate a pharmaceutical that another reverse distributor is required to evaluate due to contractual arrangements with pharmaceutical manufacturers. Although EPA does not anticipate this scenario, if an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor determines that it should go to another reverse distributor to be further evaluated for manufacturer credit, the reverse distributor can then resume managing the hazardous waste pharmaceutical pursuant to the standards for potentially creditable hazardous waste pharmaceuticals that are going on to another reverse distributor (§ 266.510(b)). However, the reverse distributor does not get additional time to accumulate the hazardous waste pharmaceuticals. That is, the reverse distributor can only accumulate the hazardous waste pharmaceuticals for a total of 180 days after the initial evaluation process is complete. Overall, this approach balances the requests from commenters to accommodate situations where reverse anticipate that a manufacturer's policy might change and that evaluated hazardous waste pharmaceuticals might become eligible for manufacturer credit with EPA's belief that it is necessary to limit total accumulation time to 180 days.

e. Security

Summary of Proposal. EPA proposed that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Due to increased thefts of pharmaceuticals from pharmacies reported in recent years in major media outlets, EPA was concerned that reverse distributors could face such thefts since they accumulate unused pharmaceuticals.[408] Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agreed with the commenters that the requirements in the interim status TSDF security regulations would be appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals, thereby safeguarding human health. EPA's proposal required that they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Summary of Comments. Inmar, Inc. and RILA did not support the proposed security requirements and argued that they are duplicative because protective security measures are already required by other state and federal laws.[409] One state and two industry commenters expressed support that reverse distributors must meet a performance-based security standard.[410] One industry commenter pointed out that this requirement should not be an added burden since reverse distributors should already have significant security systems in place and one industry commenter pointed out that the requirements are consistent with the

[408] ''Pharmacies Besieged by Addicted Thieves'' by Abby Goodnough Published: February 6, 2011 *http://www.nytimes.com/2011/02/07/us/07pharmacies.html.*

[409] See comment numbers EPA–HQ–RCRA–2007–0932–0377 and EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[410] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0280, and EPA–HQ–RCRA–2007–0932–0315 in the docket for this rulemaking.

way that reverse distributors operate.[411] [412]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(6) that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. EPA believes that the requirements that appear in the interim status TSDF security regulations are appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals thereby safeguarding human health. The security requirement of § 265.14(a) requires a facility to ''prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.'' EPA is finalizing a similar requirement for reverse distributors: they must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Based on site visits and comments received on the proposed rulemaking, EPA recognizes that many reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but reverse distributors are not limited to the examples provided. Further, EPA does not believe this requirement is duplicative because we included a provision in the regulations that if a reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA's regulations, then the reverse distributor would not need to install additional security. Furthermore, in response to comments we added a reference to the State Board of Pharmacy regulations as a second example of other regulations that could be used to fulfill the performance based security requirement.

f. Contingency Plan and Emergency Procedures

Summary of Proposal. The Agency proposed to require that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265 subpart D. EPA noted in the proposal that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many reverse distributors are already LQGs, they should already have contingency plans to address the hazards on site. It may be possible that the reverse distributors would have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but the Agency pointed out in the proposal that such modifications should not impose much burden.

Summary of Comments. One state and two industry commenters supported the requirement that reverse distributors meet the same contingency planning standards as LQGs at 40 CFR part 265 subpart D.[413] Inmar, Inc. supported the proposed contingency plan and emergency procedures requirements and pointed out that most of their facilities are LQGs and already follow these requirements.[414] RILA argued that the contingency planning and emergency procedures requirements should not apply to reverse distributors that handle lower volumes of hazardous waste than an SQG generates because the nature of the waste does not warrant the more stringent requirements.[415]

Final Rule Provisions. EPA is finalizing in § 266.510(a)(7) that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures. Since this rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has placed the contingency plan and emergency procedures for LQGs in part 262 subpart M, entitled ''Preparedness, Prevention and Emergency Procedures for Large Quantity Generators.'' As a result, this final rule now references the LQG standards in part 262 subpart M rather than the interim status TSDF standards part 265 subpart D. EPA believes that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Reverse distributors that are LQGs should already have contingency plans to address the hazards on-site. Commenters pointed out that reverse distributors that currently operate as SQGs will face a burden under this requirement, but EPA's data shows that most reverse distributors are already LQGs.[416] It is possible that the reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but EPA does not believe that such modifications will impose much burden.

Comments and Responses. One state recommended that EPA establish a similar requirement to 40 CFR 264.31 (failure of a facility owner or operator to maintain or operate facility to minimize possibility of fire, explosion or releases of hazardous waste or hazardous waste constituents) for reverse distributors.[417] EPA included similar language in the regulations at § 266.510(c)(4)(v).

g. Closure

Summary of Proposal. Due to the generally low risk of release to the environment of the hazardous waste pharmaceuticals that reverse distributors will accumulate on site, as well as the value of the hazardous waste pharmaceuticals, EPA proposed a performance-based closure standard for reverse distributors that incorporated the federal LQG closure standard found at § 265.111. Specifically, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, EPA proposed that it must control or minimize post-closure releases of hazardous waste into the environment. EPA expected that this would entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure.

Summary of Comments. Waste Management National Services, Inc., the California Department of Toxic Substances Control, and the Connecticut Department of Energy and Environmental Protection support the requirement for a performance-based closure standard that is based on the

[411] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[412] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[413] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[414] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[415] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[416] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[417] See comment number EPA–HQ–RCRA–2007–0932–0235 in the docket for this rulemaking.

federal LQG closure standard.[418] Inmar, Inc. requested that EPA clarify that the reverse distributor closure requirement only apply to the closure of the facility and not to the closure of accumulation areas.[419]

Final Rule Provisions. Under the final rule at § 266.510(a)(8), EPA is requiring a performance-based closure standard that is based on the federal LQG closure standard. Since the rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has incorporated the LQG closure standards into the new LQG regulations in § 262.17. As a result, this final rule now references the LQG closure standard in §§ 262.17(a)(8)(ii) and (iii) rather than incorporating the regulatory language of § 265.111. The LQG closure standards are substantially the same as before. Therefore, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure. The closure standards apply when the reverse distributor closes its operations related to hazardous waste pharmaceuticals rather than when the reverse distributor closes an accumulation area.

h. Reporting

Summary of Proposal. In some instances, a shipment arriving at a reverse distributor may inadvertently include items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (*e.g.,* IV bags and tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a reverse distributor and should have been manifested from the healthcare facility to a designated facility, such as a permitted or interim status TSDF.

EPA proposed that if a shipment including these unauthorized wastes arrives at a reverse distributor from a healthcare facility, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days. EPA adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for situations when unauthorized waste arrives at a reverse distributor. EPA also proposed additional requirements for when inappropriate hazardous waste arrives at a reverse distributor.

First, EPA proposed that the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. This requirement was intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste.

Second, EPA proposed that the reverse distributor must manage the unauthorized waste that it receives in accordance with all applicable regulations. Third, the Agency proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Summary of Comments. The most frequent comment that EPA received on the proposed reporting requirements is that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator. Four commenters argued that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator.[420] Two industry commenters pointed out that it may take up to 30 days for shipments to be processed.[421] Healthcare Waste Institute of the National Waste and Recycling Association suggested that reverse distributors be required to submit an unauthorized waste report within 15 days of processing a shipment of hazardous waste rather than within 15 days of receiving the hazardous waste.[422]

CT DEEP supported the reporting requirements and wrote that the requirement might incentivize healthcare facilities not to ship unauthorized wastes to reverse distributors.[423] RILA did not support the reporting requirements and wrote that reverse distributors should not be required to submit an unauthorized waste report when shipments of non-creditable hazardous waste pharmaceuticals arrive at the reverse distributors because the healthcare facilities are not capable of evaluating creditworthiness.[424] Waste Management National Services, Inc. requested that EPA only require reverse distributors to send a copy of the unauthorized waste report to a specific healthcare facility three times, arguing that it is not the reverse distributor's responsibility to continue this reporting.[425] National Pharmaceutical Returns pointed out that reverse distributors receive a large amount of unauthorized waste pharmaceuticals that healthcare facilities think are potentially creditable and therefore the reporting requirements will be time consuming.[426] One state requested the EPA clarify if a reverse distributor may refuse to take a shipment.[427]

Final Rule Provisions. In response to comments, EPA is finalizing at § 266.510(a)(9) that if a shipment from a healthcare facility arrives at a reverse distributor that includes hazardous waste that it is not authorized to receive, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 45 days of receiving the hazardous waste rather than the proposed 15 days. However, EPA is finalizing, as proposed, the additional requirements for when shipments of unauthorized waste arrive at reverse distributors. First, the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. Second, the reverse distributor cannot reject the shipment of non-creditable hazardous waste and must manage the unauthorized waste in accordance with all applicable

[418] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0315, and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[419] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[420] See comment numbers EPA–HQ–RCRA–2007–0932–0257, EPA–HQ–RCRA–2007–0932–0278, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[421] See comment numbers EPA–HQ–RCRA–2007–0932–0257 and EPA–HQ–RCRA–2007–0932–0352 in the docket for this rulemaking.

[422] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

[423] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[424] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[425] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[426] See comment number EPA–HQ–RCRA–2007–0932–0310 in the docket for this rulemaking.

[427] See comment number EPA–HQ–RCRA–2007–0932–0259 in the docket for this rulemaking.

regulations (*e.g.,* part 262 or medical waste regulations). Healthcare facilities are not equipped as well as reverse distributors to manage the hazardous waste and EPA is concerned that rejecting shipments of non-creditable hazardous waste will prolong mismanagement. Third, the Agency is finalizing as proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. This provides the Agency with some flexibility in what reports may be required.

Comments and Responses. The Agency believes that commenters understood this provision to apply more broadly than we intended. We are aware that healthcare facilities often do not know whether a hazardous waste pharmaceutical will receive manufacturer credit at the reverse distributor. EPA did not intend for a reverse distributor to generate an unauthorized waste report each time a hazardous waste does not receive credit. Rather, a reverse distributor must generate an unauthorized waste report when it receives waste that it is not authorized to receive or manage. EPA reworded the regulations to include better examples of unauthorized waste, which includes, but is not limited to, non-pharmaceutical hazardous waste and medical or infectious waste.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that reverse distributors keep to a minimum the sorting of shipments that contain unauthorized waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a reverse distributor that receives a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that reverse distributors work with their clients to reduce the occurrence of further inappropriate shipments.

i. Recordkeeping

Summary of Proposal. EPA proposed three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA proposed that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. EPA proposed that a reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, EPA proposed that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This included a copy of the proposed advance notification from the healthcare facility or other reverse distributor, a copy of delivery confirmation, shipping papers or bills of loading, and any unauthorized waste reports. The Agency proposed that these shipping records must be kept for three years from the date the reverse distributor receives the shipment. Third, EPA proposed that a reverse distributor must keep a copy of its inventory at all times as long as the reverse distributor remains subject to this subpart. Finally, EPA proposed that periods of record retention indicated previously for a reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Summary of Comments. EPA received multiple comments on the recordkeeping requirements. GENCO did not support the recordkeeping requirements, arguing the requirements would impose burden.[428] Inmar, Inc. argued that reverse distributors are already required to keep records under other regulatory requirements related to receipt, storage, duration, and shipping of controlled and uncontrolled substances.[429]

Stericycle, Inc., the Healthcare Waste Institute of the National Waste and Recycling Association, and Waste Management National Services, Inc. expressed concern about the requirement that a reverse distributor must keep a copy of its inventory for as long as the facility is subject to this subpart.[430] Stericycle, Inc. argued that it is not reasonable to require the inventory be maintained for the life of the facility.[431] The Illinois Council of Health-System Pharmacists requested that EPA clarify whether reverse distributors must maintain only a current inventory or that all inventories as they change must be maintained.[432]

Final Rule Provisions. EPA is finalizing the proposed recordkeeping requirements at § 266.510(a)(10) with some minor changes in order to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA is finalizing that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. A reverse distributor must keep the record of notification for as long as it is subject to these requirements.

Second, EPA is finalizing that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of delivery confirmation, shipping papers or bills of lading, and any unauthorized waste reports. We have revised the regulation language such that these shipping records must be kept for three years from the date the shipment arrives at the reverse distributor rather than when the reverse distributor ''receives'' the shipment since this standard is more precise.

Third, EPA is finalizing that a reverse distributor must keep a copy of its current inventory at all times as long as the reverse distributor remains subject to this subpart. The inventory is a living document that will constantly be updated and must be available for inspection. In order to clarify that a reverse distributor must maintain only a current inventory rather than all inventories even if they have changed, EPA revised the final regulatory language in § 266.510(a)(2) such that a reverse distributor must keep a copy of its current inventory. This recordkeeping change is being made to be consistent with that change in § 266.510(a)(2).

Finally, EPA is finalizing that periods of record retention referred to in this section are automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any

[428] See comment number EPA–HQ–RCRA–2007–0932–0336 in the docket for this rulemaking.

[429] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[430] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[431] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[432] See comment number EPA–HQ–RCRA–2007–0932–0228 in the docket for this rulemaking.

enforcement action. The Agency recommends reverse distributors keep electronic versions of these records rather than paper or hard copy versions of these records.

Note that additional recordkeeping requirements may also pertain to reverse distributors. For example, a reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor (§ 266.510(b)) and others that apply to reverse distributors for the management of evaluated hazardous waste pharmaceuticals (§ 266.510(c)).

2. Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor (§ 266.510(b))

This section discusses the additional standards that apply to a reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer credit at another reverse distributor. Since these pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer credit, EPA is requiring few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor.

a. *Where potentially creditable hazardous waste pharmaceuticals can be sent.*

Summary of Proposal. EPA proposed a limit of three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are ultimately transported to a permitted or interim status TSDF. The Agency proposed that the three possible types of transfers were: [433]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer;

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer.

Because EPA proposed that each reverse distributor could accumulate hazardous waste pharmaceuticals up to 90 days after arriving at the reverse distributor, this proposed chain of transfers ensured that the potentially creditable hazardous waste pharmaceuticals would be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal.[434] As described previously, this is consistent with current practice among reverse distributors because of the contractual arrangements that reverse distributors have with specific manufacturers.

Summary of Comments. One state did not support allowing three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are required to be transported to a TSDF and requested that EPA consider a maximum of two transfers prior to transportation to a TSDF.[435] Two industry commenters opposed EPA's proposed limit on the number of times a potentially creditable hazardous waste pharmaceutical may be transferred before it must be transported to a TSDF.[436] One of the industry commenters argued that reverse distributors have no knowledge about the pedigree of products prior to receipt and as such cannot be held accountable as to how many times a product is handled before transport to a TSDF.[437]

Final Rule Provisions. The final regulations for reverse distributors continue to be structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with reverse distributors and reviewing comments received on the proposed rulemaking, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceutical is ultimately transported to a TSDF. The three possible types of transfers are: [438]

(1) A healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer (§ 266.510(b)(1)); and

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer (§ 266.510(b)(2)).

Therefore, if a reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c). However, a reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

The Agency disagrees with the commenter who argued that reverse distributors cannot be accountable for how many times a hazardous waste pharmaceutical is transferred because reverse distributors do not have a record of transfers of the potentially creditable hazardous waste pharmaceuticals prior to receipt.[439] It is not necessary for a reverse distributor to have a record of previous transfers. It is only necessary for a reverse distributor to know

[433] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[434] Although the proposal did allow for the possibility to request an accumulation time limit, the final rule does not.

[435] See comment number EPA–HQ–RCRA–2007–0932–0261 in the docket for this rulemaking.

[436] See comment numbers EPA–HQ–RCRA–2007–0932–0349 and EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[437] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

[438] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

[439] See comment number EPA–HQ–RCRA–2007–0932–0349 in the docket for this rulemaking.

whether a shipment of potentially creditable hazardous waste pharmaceuticals originated from a healthcare facility or another reverse distributor. EPA believes it is reasonable for a reverse distributor to know the origin of a shipment that arrives at their facility.

Regardless of the origin or the destination of the potentially creditable hazardous waste pharmaceuticals, each reverse distributor must make an evaluation of them within 30 calendar days and may only accumulate the hazardous waste pharmaceuticals on site for no more than 180 calendar days after the evaluation before it ships them off-site to another reverse distributor or a RCRA-permitted or interim status TSDF (resulting in a maximum of 210 days). The 180 calendar day accumulation time starts after the 30 calendar days to make an evaluation. In the proposal, reverse distributors only had 90 days to accumulate hazardous waste pharmaceuticals on-site, including the 21 calendar days to make an evaluation. EPA made this conforming change to align with the change in § 266.510(a)(5) that allows reverse distributors to accumulate hazardous waste pharmaceuticals on-site for up to 180 calendar days without having interim status or a permit. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to § 266.509.

Although this chain of transfers will allow potentially creditable hazardous waste pharmaceuticals to be accumulated for up to 630 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal, EPA does not expect that potentially creditable hazardous waste pharmaceuticals will be accumulated for this time period in practice. First, it is unlikely that a reverse distributor will expend resources to accumulate potentially creditable hazardous waste pharmaceuticals on site for the full 180 calendar days if the potentially creditable hazardous waste pharmaceuticals are destined for another reverse distributor. Second, the desire to receive manufacturer credit in a timely manner will also make it unlikely that reverse distributors will accumulate potentially creditable hazardous waste pharmaceuticals for the full 180 days.

EPA anticipated that some healthcare facilities that are VSQGs will send their potentially creditable hazardous waste pharmaceuticals directly to reverse distributors. We allow for this under § 266.504(a). On the other hand, healthcare facilities that are VSQGs may choose to consolidate all their hazardous waste pharmaceuticals (both creditable and non-creditable) at an off site healthcare facility, as allowed by § 266.504(b). In this later case, the consolidated potentially creditable hazardous waste pharmaceuticals at an off-site VSQG in § 266.504(b) are not counted as one of the 3 allowable transfers of potentially creditable hazardous waste pharmaceuticals under § 266.510(b).

Under the final rule, manufacturers cannot send hazardous waste pharmaceuticals to a reverse distributor because the hazardous waste pharmaceuticals are no longer considered potentially creditable hazardous waste pharmaceuticals. Since manufacturers are unable to issue credit to themselves, it is not possible for the hazardous waste pharmaceuticals to be considered potentially creditable hazardous waste pharmaceuticals.

b. *Recordkeeping for reverse distributors shipping potentially creditable hazardous waste pharmaceuticals to another reverse distributor.*

Summary of Proposal. EPA proposed that reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This included a copy of the advance notification provided to the other reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. EPA proposed that the reverse distributor must keep these shipping records for three years from the date it initiates the shipment.

Summary of Comments. EPA received few comments on the recordkeeping requirements for reverse distributors that ship potentially creditable hazardous waste pharmaceuticals to another reverse distributor. One state asked EPA to clarify what it means by ''shipping papers.'' [440]

Final Rule Provisions. EPA is finalizing in § 266.510(b)(4) that reverse distributors must keep records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This includes a copy of delivery confirmation, as well as DOT shipping papers. EPA has clarified in the regulations that it is the DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C we are referring to as ''shipping papers''; EPA is not adding a requirement for additional shipping papers. The regulations do not specifically mention that reverse distributors keep a copy of a bill of lading, as this is only one type of shipping paper that reverse distributors can use to comply with 49 CFR part 172 subpart C. EPA is finalizing that these shipping records must be kept for three years from the date of shipment.

3. Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(c))

This section discusses the additional standards that apply to a reverse distributor for the management of evaluated hazardous waste pharmaceuticals. In general, the term evaluated hazardous waste pharmaceuticals refers to hazardous waste pharmaceuticals that were potentially creditable hazardous waste pharmaceuticals but have been evaluated by a reverse distributor to establish whether they are eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification. While potentially creditable hazardous waste pharmaceuticals have value in the form of manufacturer credit, evaluated hazardous waste pharmaceuticals do not. Therefore, in order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals. These standards generally resemble the standards for LQG CAAs.

a. *Accumulation area.*

Summary of Proposal. EPA proposed that once a reverse distributor completes its evaluation of a potentially creditable hazardous waste pharmaceutical and the reverse distributor knows that the hazardous waste pharmaceutical is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. EPA proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the

[440] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

potentially creditable hazardous waste pharmaceuticals.

Summary of Comments. One state supported the requirement for reverse distributors to establish on-site accumulation areas for evaluated hazardous waste pharmaceuticals.[441]

Final Rule Provisions. EPA is finalizing as proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals in § 266.510(c)(1). An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals that have fewer requirements and are destined for another reverse distributor.

b. *Weekly inspections.*

Summary of Proposal. EPA proposed that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the evaluated hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for reverse distributors, the Agency proposed that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

Summary of Comments. One state commented that weekly inspections are not sufficient to determine whether or not diversion of evaluated hazardous waste pharmaceuticals is occurring and requested EPA require additional security provisions.[442] Washington State Department of Ecology requested that EPA clarify the intent of ''at least weekly'' and argued that they interpret ''at least weekly'' to mean once within every seven days.[443]

Final Rule Provisions. In response to comments, EPA is finalizing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least once every seven days to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. We agree with the commenter that phrasing the standard as ''at least once every seven days'' is more precise than ''at least weekly'' and will avoid the situation where a reverse distributor could inspect early in one week and late the following week and still claim it is inspecting weekly. Under the recordkeeping requirements for reverse distributors in § 266.510(c)(10), the Agency is finalizing that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

c. *Personnel training.*

Summary of Proposal. EPA proposed to require that reverse distributors meet the same federal classroom or on-the-job personnel training regulations that LQGs must meet (§ 265.16). However, the Agency specified in the proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA argues that these personnel are the individuals handling and managing the evaluated hazardous waste pharmaceuticals and must have appropriate hazardous waste training.

Summary of Comments. Two industry commenters and one state supported the personnel training criteria for reverse distributors.[444] One state argued that the training requirements should be applied to the personnel who handle potentially creditable hazardous waste pharmaceuticals in addition to the personnel who handle evaluated hazardous waste pharmaceuticals on site.[445] Inmar, Inc. pointed out that personnel at reverse distributors are already required to receive training under other regulatory requirements.[446]

Final Rule Provisions. Under the final rule, reverse distributors must meet the same classroom or on-the-job personnel training requirements that LQGs must meet. EPA is finalizing that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals. Since these personnel are the individuals handling and managing the hazardous waste pharmaceuticals, they must have appropriate hazardous waste training. As mentioned previously, EPA received multiple comments in support of the training requirements for reverse distributors. Additionally, EPA does not believe the training requirements will add burden because EPA believes most reverse distributors currently operate as LQGs.[447] Since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of its reorganization, the personnel training regulations for LQGs are now incorporated into § 262.17(a)(7) and no longer refer to § 265.16. As a result, the § 266.510(c)(3) training requirements for personnel managing evaluated hazardous waste pharmaceuticals at reverse distributors now reference § 262.17(a)(7) instead of § 265.16.

d. *Labeling and management of containers in on-site accumulation area.*

Summary of Proposal. EPA proposed that while containers of evaluated hazardous waste pharmaceuticals are in the on-site accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' EPA proposed this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. The Agency did not propose to require an accumulation start date on the label for the containers of evaluated hazardous waste pharmaceuticals.

In terms of container management standards, the Agency proposed requirements that are similar to the container management standards for LQGs, but the Agency proposed to include some requirements specific to evaluated hazardous waste pharmaceuticals. For example, LQGs must keep all containers of hazardous waste closed. However, EPA proposed to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release to the environment for those hazardous waste pharmaceuticals that are in a solid form. The Agency did not propose to require other containers of evaluated hazardous waste pharmaceuticals to be closed during accumulation, although we expect that reverse distributors would choose to do so as a best management practice. Further, because most evaluated hazardous waste pharmaceuticals are in their original packaging, we proposed that if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are

[441] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[442] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[443] See comment number EPA–HQ–RCRA–2007–0932–0272 in the docket for this rulemaking.

[444] See comment numbers EPA–HQ–RCRA–2007–0932–0280, EPA–HQ–RCRA–2007–0932–0296, and EPA–HQ–RCRA–2007–0932–0304 in the docket for this rulemaking.

[445] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[446] See comment number EPA–HQ–RCRA–2007–0932–0377 in the docket for this rulemaking.

[447] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

considered to meet the proposed closed container standard.

As with LQGs, EPA proposed that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the evaluated hazardous waste pharmaceuticals placed in the container. Another requirement that was tailored to reverse distributors was the proposal that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

The LQG regulations in part 262 include management standards for several types of accumulation units that EPA did not propose to include for the management of evaluated hazardous waste pharmaceuticals. For instance, the proposal only set standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA did not think it was necessary to include standards for accumulation units such as tanks, containment buildings, or drip pads because reverse distributors do not currently use these types of accumulation units. In addition, the Agency did not propose to require reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required in § 262.34(a)(1)(i) for LQGs because the Agency anticipated that they will not be applicable. Additionally, 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor.

Summary of Comments. EPA received numerous comments on the proposed requirements for labeling and management of containers of evaluated hazardous waste pharmaceuticals in on-site accumulation areas at reverse distributors. One state supported that containers be marked with the words ''hazardous waste pharmaceuticals,'' but three states and one industry commenter requested that EPA require reverse distributors to label containers with the accumulation start date.[448] Stericycle, Inc. agreed that there is not a need to include standards for accumulation units such as tanks, containment buildings, or drip pads.[449] Clean Harbors argued that the only way to prevent diversion of hazardous waste pharmaceuticals is for all containers to be closed and sealed.[450] One state requested that EPA prohibit reverse distributors from mixing or commingling incompatible hazardous waste pharmaceuticals in the same container rather than only requiring reverse distributors to manage containers to prevent dangerous situations, such as fire explosion or release of toxic fumes.[451] One commenter agreed that the 40 CFR part 265 subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor and its management of hazardous waste pharmaceuticals.[452]

Final Rule Provisions. Final standards for labeling and management of containers at an on-site accumulation area are found at § 266.510(c)(4). EPA is finalizing that while containers of evaluated hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' Under the final rule, reverse distributors are not required to mark an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a reverse distributor may choose an alternate method, such as marking the date on each container, to ensure that the containers of evaluated hazardous waste pharmaceuticals are not accumulated at the reverse distributor for more than 180 days. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 180-day accumulation time rather than require dating on the container labels. Most of the commenters that requested accumulation start dates on labels were states. Although the requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require the accumulation start date on the container label, that would be considered more stringent and permissible under RCRA.

In terms of container management standards, the Agency is finalizing the proposed requirements that are similar to the container management standards for LQGs as well as the additional management requirements specific to evaluated hazardous waste pharmaceuticals. Specifically, only containers with evaluated hazardous waste pharmaceuticals that are liquids or gels must be kept closed during accumulation, although EPA expects that all containers of evaluated hazardous waste pharmaceuticals will be closed given that evaluated hazardous waste pharmaceuticals are in their original packaging. As with the proposal, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard.

EPA is also finalizing that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, a reverse distributor that manages any container of ignitable or reactive evaluated hazardous waste pharmaceuticals or any container of commingled incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes. These regulations are consistent with the LQG container management regulations in part 262 and already apply to LQG reverse distributors accumulating hazardous waste on site. The Agency is also finalizing that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals. The dilution prohibition of § 268.3(c) already prohibits the incineration of some hazardous waste pharmaceuticals. This new provision highlights this prohibition to the reverse distributors accumulating the hazardous waste pharmaceuticals prior to sending off site for treatment and disposal.

Comments and Responses. EPA is finalizing management standards only for containers used to accumulate evaluated hazardous waste pharmaceuticals because commenters

[448] See comment numbers EPA–HQ–RCRA–2007–0932–0211, EPA–HQ–RCRA–2007–0932–0235, EPA–HQ–RCRA–2007–0932–0341, and EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[449] See comment number EPA–HQ–RCRA–2007–0932–0280 in the docket for this rulemaking.

[450] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[451] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[452] See comment number EPA–HQ–RCRA–2007–0932–0296 in the docket for this rulemaking.

confirmed that reverse distributors do not use other types of hazardous waste accumulation units, such as tanks, containment buildings, or drip pads.

In addition, the Agency is not requiring reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required for LQGs in § 262.17(a)(1)(i) because the Agency anticipates that they will not be applicable. Specifically, § 265.1083(c) of subpart CC exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) of subpart CC exempts containers with a capacity of less than 0.1 m^3 (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265 subpart CC air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because evaluated hazardous waste pharmaceuticals are often in their original packaging, and EPA is requiring that liquid and gel evaluated hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will have a capacity of less than 0.1 m^3 (26 gallons) further limiting the applicability of the container air emission standards. Similarly, EPA does not anticipate that the 40 CFR part 265 subpart AA (air emissions standards for process vents) and subpart BB (air emission standards for equipment leaks) are applicable to the activities of a reverse distributor and its management of evaluated hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265 subpart CC discussed previously, EPA is not requiring that 40 CFR part 265 subparts AA and BB apply to reverse distributors.

e. *Hazardous waste numbers (codes).*

Summary of Proposal. EPA proposed that RCRA hazardous waste numbers (commonly called ''hazardous waste codes'') must be marked on the container label in order to ensure that they are readily visible and cannot be separated from the hazardous waste. In the proposal, the Agency did not require that the reverse distributor be the party that adds the hazardous waste codes to the containers. The proposed regulations allowed a vendor to perform this duty on behalf of the reverse distributor.

Summary of Comments. Two states supported the requirement that hazardous waste codes be placed on containers of evaluated hazardous waste pharmaceuticals.[453] Waste Management National Services, Inc. argued that it is not practical to include all hazardous waste codes on each container label and instead suggested that codes be listed on the hazardous waste profile developed with the TSDF and on the manifest.[454]

Final Rule Provisions. Under the final rule, EPA is requiring that the containers of evaluated hazardous waste pharmaceuticals be marked with the applicable RCRA hazardous waste numbers (codes) at § 266.510(c)(5). The hazardous waste codes must be added prior to shipping evaluated hazardous waste pharmaceuticals off site, although they may be placed on the container label at any time during on-site accumulation. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. It is necessary that the hazardous waste numbers are on the containers so that transporters, transfer facilities, and TSDFs know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. In the final rule, the Agency is not requiring that the reverse distributor be the party that adds the hazardous waste numbers to the containers. The regulations allow a vendor to perform this duty on behalf of the reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the reverse distributor may need to assist in the process. To be consistent with the Hazardous Waste Generator Improvements final rule, we have added a sentence to § 266.510(c)(5) indicating that a nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste number(s).

f. *Shipping evaluated hazardous waste pharmaceuticals.*

Summary of Proposal. Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, EPA proposed to repeat in the § 266.510 the reverse distributor regulations that reverse distributors that ship evaluated hazardous waste pharmaceuticals off site must do so in accordance with the proposed shipping requirements in § 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

Summary of Comments. Two states generally supported the shipping requirements for evaluated hazardous waste pharmaceuticals.[455] One state supported that EPA repeat in § 266.510 the requirements pertaining to shipping standards although it is already stated in § 266.508(a).[456]

Final Rule Provisions. For clarity, the final reverse distributor regulations state that a reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a permitted or interim status TSDF.

g. *Procedures for managing rejected shipments.*

Summary of Proposal. The Agency proposed to require that reverse distributors meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Specifically, if a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a reverse distributor and the TSDF returns the shipment to the reverse distributor, EPA proposed that the reverse distributor must sign either item 18c of the original manifest or item 20 of a new manifest. In addition, the proposal allowed the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they were managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. EPA also proposed that reverse distributors send a copy of

[453] See comment numbers EPA–HQ–RCRA–2007–0932–0300 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[454] See comment number EPA–HQ–RCRA–2007–0932–0257 in the docket for this rulemaking.

[455] See comment numbers EPA–HQ–RCRA–2007–0932–0261 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[456] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

the manifest to the designated facility that returned the shipment to the reverse distributor within 30 days of delivery.

Summary of Comments. One state requested the EPA clarify that a reverse distributor that receives a rejected shipment does not have to transport it off site upon receipt by the reverse distributor.[457] One state argued that a reverse distributor does not need 90 days to accumulate rejected hazardous waste pharmaceuticals in the on-site accumulation area and argued that 30 days is sufficient.[458]

Final Rule Provisions. The Agency is finalizing in § 266.510(c)(7) that reverse distributors must meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Under part 262, these rejected shipment procedures already apply to LQG reverse distributors. Furthermore, EPA anticipates that a rejected shipment is a relatively infrequent occurrence and therefore should not be a burden to reverse distributors. In addition, the final rule allows the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. Although one state requested EPA only allow accumulation for 30 days, any authorized state has the ability to impose more stringent regulations. If a state chooses to shorten the accumulation time, that would be considered more stringent and permissible under RCRA.

h. *Land disposal restrictions.*

Summary of Proposal. EPA proposed that reverse distributors are subject to the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA proposed to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, ''pharmaceutical reverse distributors'' to the title of that section to make the applicability of the treatment standards clear.

Summary of Comments. EPA received multiple comments in support of the requirement that reverse distributors meet the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals, including two states.[459] The Oregon Association of Clean Water Agencies wrote that applying the LDRs will reduce mobility of pharmaceutical constituents in landfill leachate, which is frequently routed to POTWs in Oregon.[460]

Final Rule Provisions. As required by HSWA, EPA is finalizing that reverse distributors are subject to the same land disposal restrictions that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is amending the titles at §§ 268.7 and 268.7(a) to add the words, ''reverse distributors'' to make the applicability of the land disposal restrictions clear. SQG and LQG reverse distributors are already subject to LDRs for their hazardous waste pharmaceuticals. Therefore, this provision does not impose additional burden on reverse distributors.

i. *Reporting.*

Summary of Proposal. EPA proposed that reverse distributors submit a biennial report (BR) for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The Agency proposed that the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. Specifically, EPA proposed that a reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The Agency did not propose that a reverse distributor provide such information because it does not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from healthcare facilities, and thus has no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals.

EPA proposed that reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the reverse distributor for shipments of evaluated hazardous waste pharmaceuticals. Likewise, EPA proposed that reverse distributors meet LQG exception reporting when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility. These proposed standards were adapted from the exception reporting for LQGs in § 262.42(a).

Summary of Comments. One state supported both of the proposed reporting requirements for reverse distributors managing evaluated hazardous waste pharmaceuticals that are transported to a TSDF.[461] RILA argued that the requirement that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF is effectively more stringent than current generator requirements that only require generators to submit a biennial report if they generate over 1000 kg of hazardous waste in a month.[462]

Final Rule Provisions. EPA is finalizing at § 266.510(c)(9)(i) that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. EPA does not expect that requiring reverse distributors to submit a BR for evaluated hazardous waste pharmaceuticals will be burdensome because most reverse distributors currently operate as LQGs and already submit a BR.[463] Specifically, under the final rule, reverse distributors must comply with the LQG BR requirements in § 262.41. EPA proposed that reverse distributors had to comply with the LQG BR requirements in § 262.41 except § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. However, since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of that final rule, § 262.41(a)(7) was removed from the generator requirements. Thus, the final rule only states that reverse distributors must

[457] See comment number EPA–HQ–RCRA–2007–0932–0231 in the docket for this rulemaking.

[458] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[459] See comment numbers EPA–HQ–RCRA–2007–0932–0315 and EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[460] See comment number EPA–HQ–RCRA–2007–0932–0288 in the docket for this rulemaking.

[461] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[462] See comment number EPA–HQ–RCRA–2007–0932–0295 in the docket for this rulemaking.

[463] See the Regulatory Impact Analysis in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

comply with the LQG BR requirements in § 262.41.

Consistent with the LQG regulations in part 262, EPA is finalizing at § 266.510(c)(9)(ii) that reverse distributors must provide an exception report when a TSDF does not return the signed hazardous waste manifest to the reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility within 45 days of shipment. Likewise, EPA is finalizing that reverse distributors must provide an exception report when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility and the reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days. These standards were adapted from the exception reporting for LQGs in § 262.42(a), while the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals were adapted from the exception reporting for SQGs § 262.42(b). EPA is finalizing that a reverse distributor that does not receive a copy of the manifest within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or TSDF to determinate the status of the evaluated hazardous waste pharmaceuticals. EPA is also finalizing that a reverse distributor must submit a copy of an exception report if it has not received a copy of the manifest within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter explaining efforts taken to locate the evaluated hazardous waste pharmaceuticals.

j. *Recordkeeping.*

Summary of Proposal. In total, EPA proposed five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors. First, EPA proposed that a reverse distributor keep a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA proposed for reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.17(a)(7)(iv) and (v), 262.40, and 262.42; these include training documentation, hazardous waste manifest records, records of biennial reports, and exception reporting.

Summary of Comments. Hennepin County supported the requirement for reverse distributors to document training.[464]

Final Rule Provisions. Many of the final recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In total, EPA is finalizing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors that can be found listed at § 266.510(c)(10). First, EPA is requiring that a reverse distributor keep a log (written or electronic) of its inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA is requiring under the final rule for reverse distributors are the same as the LQG recordkeeping requirements in part 262. These include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

4. When a Reverse Distributor Must Have a RCRA Hazardous Waste Permit (§ 266.510(d))

a. *Summary of proposal.* In the proposed rulemaking, EPA did not require that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. However, EPA proposed that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.

b. *Summary of comments.* One state supported the proposed requirement that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.[465] Clean Harbors argued that EPA's rationale for not requiring a hazardous waste storage permit is flawed and argued that the requirement for obtaining a full RCRA permit be based on the amount of time a potentially creditable hazardous waste pharmaceutical is stored.[466] The Environmental Technology Council argued that reverse distributors should be required to obtain permits or interim status for storage.[467]

c. *Final rule provisions.* Under the final rule, EPA is not requiring that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a reverse distributor will be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, EPA is finalizing that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site. A reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off site because a reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste shipped with a manifest. EPA believes that this approach to regulation of reverse distributors that accumulate potentially creditable and evaluated hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

XVIII. Amendments to the Part 268 Prohibitions on Storage

The Agency is finalizing conforming changes that we proposed to the prohibitions on storage of restricted waste in § 268.50. We are finalizing two new subparagraphs in § 268.50(a) to make it clear that the storage prohibitions apply to both healthcare facilities and reverse distributors operating under part 266 subpart P. Specifically, we are adding paragraph (4) for healthcare facilities and paragraph (5) for reverse distributors to extend the application of the existing storage prohibition to facilities operating under subpart P. Under the LDR storage prohibition the storage of restricted hazardous wastes is

[464] See comment number EPA–HQ–RCRA–2007–0932–0386 in the docket for this rulemaking.

[465] See comment number EPA–HQ–RCRA–2007–0932–0341 in the docket for this rulemaking.

[466] See comment number EPA–HQ–RCRA–2007–0932–0333 in the docket for this rulemaking.

[467] See comment number EPA–HQ–RCRA–2007–0932–0297 in the docket for this rulemaking.

prohibited unless certain conditions are met. Healthcare facilities must comply with the applicable requirements in §§ 266.502 and 266.503 and reverse distributors must comply with § 266.510 when accumulating hazardous waste pharmaceuticals on site.

XIX. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility Is Subject to Part 266 Subpart P

EPA is finalizing that healthcare facilities that are currently considered LQGs or SQGs are subject to the final 40 CFR part 266 subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates more than 100 kg of hazardous waste per month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266 subpart P requirements. In addition, healthcare facilities that are VSQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.505, the empty container standards in § 266.507, and the optional standards of § 266.504.

To determine whether a healthcare facility is subject to 40 CFR part 266 subpart P or is a VSQG regulated under § 262.14, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. Note that in the final rule EPA has revised which pharmaceuticals are considered hazardous wastes. Specifically, EPA is finalizing that potentially creditable hazardous waste pharmaceuticals transported to a reverse distributor are considered a solid and hazardous waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a VSQG regulated under § 262.14 or whether it is regulated under 40 CFR part 266 subpart P for its hazardous waste pharmaceuticals. This differs from previous healthcare facility practice of not counting the potentially creditable hazardous waste pharmaceuticals it sends to a reverse distributor towards its hazardous waste generator category. Therefore, although a healthcare facility may have been considered a VSQG under that previous practice, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a VSQG. In that case, the healthcare facility would be subject to the 40 CFR part 266 subpart P requirements for its hazardous waste pharmaceuticals.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all healthcare facilities operating Under part 266 subpart P will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward determining the facility's monthly hazardous waste generator category. Therefore, although a facility that previously may have been considered an LQG, once it no longer counts its hazardous waste pharmaceuticals towards its monthly hazardous waste generator category, it may no longer be an LQG. As a result, it is possible that the healthcare facility may not need to manage its non-pharmaceutical hazardous waste pursuant to the LQG regulations in § 262.17, but rather can operate under the reduced regulations for SQGs in § 262.16 or for VSQGs in § 262.14. In addition, if a healthcare facility that is a VSQG does not want to keep track of the amount of hazardous waste pharmaceuticals it generates to ensure it does not exceed the VSQG quantity limits, it can choose to operate under this final rule. If it chooses to operate under this final rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

Following publication of the final rule, EPA plans extensive outreach to educate healthcare facilities and reverse distributors on the provisions of this final rule.

B. Reverse Distributors and Reverse Logistics Centers

1. Prescription Pharmaceuticals Sent to Reverse Distributors Are Solid Wastes

EPA proposed to change how RCRA would apply to pharmaceuticals returned to reverse distributors to obtain manufacturers credit. EPA proposed that the decision by a healthcare facility to send a pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical. Due to many comments on this proposed change, the Agency is now making a clear distinction in the final rule between reverse distribution, in the case of prescription pharmaceuticals, and reverse logistics in the case of all other pharmaceuticals—including over-the counter pharmaceuticals and dietary supplements, as well as other unsold consumer items (see section VI for a discussion of the comments). EPA is finalizing that the decision by a healthcare facility to send a prescription pharmaceutical to a reverse distributor is the decision to discard the prescription pharmaceutical. Therefore, under this final rule, once the healthcare facility makes the decision to send a prescription pharmaceutical to a reverse distributor for credit, it is a solid waste at the healthcare facility. A portion of the potentially creditable solid waste prescription pharmaceuticals at healthcare facilities that are destined for a reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste prescription pharmaceuticals would need to be managed in accordance with the final 40 CFR part 266 subpart P requirements.

In addition, the Agency notes that the change in EPA's position concerning reverse distribution and the management standards discussed in this final rule pertain only to the reverse distribution of prescription hazardous waste pharmaceuticals and does not apply to the reverse logistics of other pharmaceuticals or to the reverse logistics systems that may exist for other unsold consumer items.

2. Nonprescription Pharmaceuticals Sent to Reverse Logistics Centers Are Not Solid Wastes

EPA proposed that the decision by a healthcare facility to send any pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical, but is now making a clear distinction in the final rule between reverse distribution of prescription pharmaceuticals and reverse logistics of nonprescription pharmaceuticals and other unsold retail items. In response to comments, EPA is codifying our previous policy that the decision by a healthcare facility to send nonprescription pharmaceuticals to a reverse logistics center is not a decision to discard if the nonprescription pharmaceuticals have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. In other words, EPA is finalizing that nonprescription pharmaceuticals are not

solid wastes, and therefore not hazardous waste pharmaceuticals if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

3. Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all reverse distributors are subject to 40 CFR part 266 subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even reverse distributors that are currently VSQGs will be regulated under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals. Therefore, a reverse distributor subject to 40 CFR part 266 subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273 (i.e., Complying With ''More Than One RCRA'')

Most, if not all, healthcare facilities and reverse distributors generate at least some hazardous wastes other than pharmaceuticals. These non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). The standards established by this rulemaking apply only to the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Healthcare facilities and reverse distributors likely generate or manage other types of hazardous wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the part 262 generator regulations (such as the RCRA SAA regulations (§ 262.15)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262 subpart K). Retail stores, including pharmacies and grocery stores, may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 regulations and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For reverse distributors, this rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA Subtitle C regulations will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding hazardous waste pharmaceuticals. One major goal of this final rule is to provide clarity on this topic, and thereby promote national consistency, which should promote better compliance among healthcare facilities, including pharmacies.

In 2012, Connecticut's Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from CT DEEP direct CVS stores in the state to follow a set of best management practices.[468] A number of the practices developed in these consent orders mirror some of the practices EPA is finalizing in this rule, particularly with regard to pharmaceuticals destined for a reverse distributor. CT DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for reverse distributors by applying specific management practices. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the receiving reverse distributor. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.[469] This interim enforcement discretion policy had some elements in common with this final rule for hazardous waste pharmaceuticals. For instance, a healthcare facility was required to notify the Department of Ecology that it was operating under the policy and had to train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applied to the accumulation of the hazardous waste pharmaceuticals on site. Of particular note is that Washington State prohibited disposing of most hazardous waste pharmaceuticals down the toilet or drain. In anticipation of this final rule, Washington State updated the interim policy in June 2017 to provide regulated facilities with the opportunity to use some of the provisions outlined in the proposed rulemaking, such as allowing facilities to send creditable pharmaceuticals to a reverse distributor for evaluation without providing hazardous waste codes.[470]

In 2011, Minnesota's Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.[471] In this guidance, Minnesota states, ''Whether a pharmaceutical is eligible for return credit does not affect its product or waste status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste. The MPCA considers health care practitioners and pharmacies to be generators of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.'' This is similar to the approach that EPA is finalizing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA's final rule, MPCA does not require hazardous waste pharmaceuticals destined for a reverse distributor to be

[468] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0173.

[469] See the 2008 interim enforcement policy in the docket for this rulemaking EPA–HQ–RCRA–2007–0932–0181.

[470] See the 2017 interim enforcement policy at *https://fortress.wa.gov/ecy/publications/documents/0704024.pdf* or in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[471] See the guidance document in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932–0178).

counted toward determining a healthcare facility's generator category. In addition, MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a reverse distributor. By finalizing a rule that is consistent with state approaches, EPA is bringing national consistency to the management of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

E. Intersection of Part 266 Subpart P With the Hazardous Waste Generator Improvements Rule

The Hazardous Waste Generator Improvements rule was finalized on November 28, 2016.[472] This rule finalized a much-needed update to the hazardous waste generator regulations in part 262 to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed and close important gaps in the regulations. This section of preamble discusses three portions of the Hazardous Waste Generator Improvements final rule that might impact healthcare facilities and reverse distributors that are subject to part 266 subpart P.

1. Episodic Generation

One of the key provisions with which EPA added regulatory flexibility allows a hazardous waste generator to avoid increased burden of a higher generator category when generating episodic waste provided the episodic waste is properly managed in accordance with part 262 subpart L. Healthcare facilities and reverse distributors will be able to take advantage of this added regulatory flexibility (assuming their state has adopted this provision).

A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste can use the episodic generation provision of part 262 subpart L for all of its hazardous waste, including its hazardous waste pharmaceuticals. If a healthcare facility is generally operating under § 262.14 as a VSQG, but has an episodic event, it would be far less burdensome to comply with part 262 subpart L than to come into compliance with all the provisions of part 266 subpart P for the short duration of the episodic event. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 subpart L to avoid an increase in hazardous waste generator category. However, if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG,[473] and it chooses not to use the episodic generator provisions in part 262 subpart L, it would become subject to part 266 subpart P for its hazardous waste pharmaceuticals.

As discussed previously, healthcare facilities and reverse distributors that are subject to part 266 subpart P for their hazardous waste pharmaceuticals may still be subject to part 262 for the management of their non-pharmaceutical hazardous waste. A healthcare facility or reverse distributor operating under part 266 subpart P for its hazardous waste pharmaceuticals may not use the episodic generator standards of part 262 subpart L with respect to its hazardous waste pharmaceuticals. Under part 266 subpart P, all healthcare facilities are regulated the same regardless of amounts of hazardous waste pharmaceuticals generated and all reverse distributors are regulated the same, regardless of amounts of hazardous waste pharmaceuticals managed, making the need for episodic generation provisions unnecessary. On the other hand, if a healthcare facility or reverse distributor is generally operating as a VSQG or SQG for its non-pharmaceutical hazardous waste, but has an episodic event, the healthcare facility may use the provisions in part 262 subpart L for its non-pharmaceutical hazardous waste.

2. Small Quantity Generator Re-Notification

The 2016 Hazardous Waste Generator Improvements final rule added a new requirement for periodic re-notification by SQGs.[474] Under this new provision, SQGs must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700–12. This re-notification must be submitted by September 1st of each year in which re-notifications are required.[475] Healthcare facilities and reverse distributors operating under part 266 subpart P may also be subject to part 262 for the management of its non-pharmaceutical hazardous waste. If a healthcare facility or reverse distributor is an SQG for its non-pharmaceutical hazardous waste, then it will be subject to this re-notification requirement under part 262. Therefore, in order to avoid duplicative notification requirements, under part 266 subpart P, EPA is not requiring re-notification by healthcare facilities and reverse distributors.

3. Very Small Quantity Generators That Accumulate More Than 1 Kg of Acute Hazardous Waste

The 2016 Hazardous Waste Generator Improvements final rule clarified in § 262.14(a)(3) that if a VSQG accumulates at any time greater than 1 kg of acute hazardous waste,[476] all quantities of that acute hazardous waste are subject to the additional conditions for exemption for LQGs. More specifically, the acute hazardous waste must be held on site for no more than 90 days beginning on the date when more than 1 kg is exceeded, and the acute hazardous waste is subject to the LQG conditions for exemption in § 262.17(a) through (g). In other words, while the acute hazardous waste becomes subject to the stricter standards for LQGs when the accumulation limits are exceeded, the generator continues to be considered a VSQG, provided the generator continues to generate within the VSQG thresholds identified in the definition of VSQG in § 260.10.

If a healthcare facility that is a VSQG accumulates more than 1 kg of acute hazardous waste,[477] then it will remain subject to § 262.14(a)(3); the healthcare facility will not become subject to part 262 subpart P.

XX. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in

[472] See November 28, 2016; 81 FR 85732.

[473] See the definition of very small quantity generator in 40 CFR 2601.10.

[474] See 40 CFR 262.18(d)(1).

[475] See 81 FR 85777–8; November 28, 2016 for the preamble discussion explaining the need for re-notification.

[476] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

[477] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA-related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.[478] RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action adds a new subpart P to 40 CFR part 266, and it is being finalized in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266 subpart P is being finalized under non-HSWA authority. Thus, the amendments promulgated under non-HSWA authority are applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Only the prohibition of sewering hazardous waste pharmaceuticals (§ 266.504) is being finalized under HSWA authority in section 3018 of RCRA. The amendments promulgated under the authority of HSWA (*i.e.,* the prohibition on sewering hazardous waste pharmaceuticals) are applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs.

While some provisions of part 266 subpart P are considered less stringent than the current federal standards, other provisions of the final rule are considered more stringent than the current federal standards. Taken as a whole, we consider the entire new subpart P under 40 CFR part 266 entitled ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities'' (sections VIII–XVII of this preamble) to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

On the other hand, one final revision is less stringent than the current hazardous waste regulations. The amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies is less stringent that the current hazardous waste regulations (section V of this preamble). Thus, authorized states may, but are not required to, adopt the change to the P075 listing.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add waste streams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because the added subpart P under CFR part 266 is considered more stringent than either the ''traditional RCRA'' standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may choose to add non-hazardous waste pharmaceuticals to their Universal Waste program or may regulate them more stringently as part of their hazardous waste program but states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future. Accordingly, we have amended the regulations in § 273.80(a) and added § 273.80(d) to reflect this decision that states may not add hazardous waste pharmaceuticals to their Universal Waste program.

XXI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Pursuant to the terms of Executive Order 12866, as affirmed in Executive Order 13563, the Agency has determined that this rule is a significant regulatory action because it contains novel policy issues, as defined under section 3(f)(4) of the Order. Any changes made in response to OMB recommendations have been documented in the docket.

As discussed in section I above, EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* indicates that the rule is projected to result in net annual cost savings of approximately $12.99 million to $14.96 million based on a discount rate of 7 percent or $12.98 to $14.95 million based on a discount rate of 3 percent. The full analysis is available in the docket for this rule.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory

[478] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2486.02, OMB control number 0250–0212. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is finalizing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and reverse distributors. These requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. In addition, the requirements include provisions for tracking of hazardous waste pharmaceuticals that are sent to reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

Respondents/affected entities: Drug wholesalers, supermarkets and other grocery stores, pharmacies and drug stores, warehouse clubs and supercenters, veterinary clinics, physicians' offices, dentists' offices, other health practitioners, outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities, continuing care retirement communities, and reverse distributors.

Respondent's obligation to respond: The recordkeeping and notification requirements are mandatory and are being promulgated under section 3001 of RCRA.

Estimated number of respondents: 13,373.

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimated the total annual burden to respondents to be approximately 43,577 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimated the total estimated annual cost of this paperwork burden to respondents to be approximately $2,543,409.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the Regulatory Impact Analysis found in the docket for this proposal, EPA does not expect the rule to result in an adverse impact to a significant number of small entities. EPA estimates that there are at least 10,481 to 15,114 small entities that will be impacted by this rule. However, small entities are expected to experience a net cost savings under the final rule, and for the small entities that are expected to experience a net cost under the final rule, the RIA estimates the costs, at most, to represent 0.013 percent of annual revenues for small entities. We have therefore concluded that this action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost savings is estimated to be between approximately $13 million and $15 million (based on a discount rate of 7%). Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rulemaking. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

F. Executive Order 13132: Federalism

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation With Tribal Governments

This action may have tribal implications as specified in Executive Order 13175. The final rule will neither impose substantial direct compliance costs on tribal government, not preempt tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the final rule would not impose any direct costs on tribal governments.

To assess the potential tribal implications of the action, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of this action for these facilities. As documented in the Regulatory Impact Analysis in the docket for this rule, the rule is not expected to impose a substantial burden on tribal governments.

EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its

development. A summary of that consultation is provided in the docket for this rule (see EPA–HQ–RCRA–2008–0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

H. Executive Order 13045: Children's Health

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this proposed action present a disproportionate risk to children. This action's health and risk assessments are contained in the *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals,* found in the docket for this action.

I. Executive Order 13211: Energy Supply

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The final rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in this action are not expected to impact energy production or distribution and will have minimal impact on energy consumptions.

J. National Technology Transfer and Advancement Act

This final rulemaking does not involve technical standards.

K. Executive Order 12898: Environmental Justice

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Regulatory Impact Analysis, which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewering of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, this final action may result in positive environmental justice impacts.

Overall, EPA expects that this action may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. A reduction in sewering expected under the final rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the final action may benefit environmental justice populations.

L. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until sixty (60) days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final authorization will be effective August 22, 2019.

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: December 11, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Section 261.4 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(1) * * *

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by § 266.505 and Clean Water Act requirements at 40 CFR 403.5(b). ''Domestic sewage'' means

untreated sanitary wastes that pass through a sewer system.

* * * * *

■ 3. Section 261.7 is amended by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Containers of hazardous waste pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d).

■ 4. Section 261.33 is amended by:

■ a. Revising paragraph (c); and

■ b. Revising the four entries for ''P075'' in the table in paragraph (e).

The revisions read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b) or § 266.507 of this chapter.

[*Comment:* Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

* * * * *

(e) * * *

Hazardous waste No.	Chemical abstracts No.	Substance
*	*	* * * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *
P075	[1] 54–11–5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *
P075	[1] 54–11–5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
*	*	* * * * * *

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, 6938, and 6939g.

■ 6. Section 262.10 is amended by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

■ 7. Section 262.13 is amended by adding paragraph (c)(9) to read as follows:

[1] CAS Number given for parent compound only.

§ 262.13 Generator category determination.

* * * * *

(c) * * *

(9) Is a hazardous waste pharmaceutical, as defined in § 266.500, that is subject to or managed in accordance with 40 CFR part 266 subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under § 266.506.

* * * * *

■ 8. Section 262.14 is amended by adding paragraphs (a)(5)(ix) and (x) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) * * *

(5) * * *

(ix) A reverse distributor (as defined in § 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in § 266.500).

(x) A healthcare facility (as defined in § 266.500) that meets the conditions in §§ 266.502(l) and 266.503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

* * * * *

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 9. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

■ 10. Section 264.1 is amended by adding paragraph (g)(13) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

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PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 11. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

■ 12. Section 265.1 is amended by adding paragraph (c)(16) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

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PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 13. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O—[Reserved]

■ 14. Add reserved subpart O.

■ 15. Add subpart P, consisting of §§ 266.500 through 266.510, to read as follows:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (*e.g.,* lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for its intended purpose) or reclaimed.

Healthcare facility means any person that is lawfully authorized to—

(1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (*e.g.,* electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (*e.g.,* pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—

(1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(2) Undispensed; and

(3) Unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

§ 266.501 Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is *not* subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with § 262.14 and the optional provisions of § 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of parts 262 through 265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (*e.g.,* pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 40 CFR parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (*e.g.,* lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as

defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals*—(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA Form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (*i.e.,* it exhibits a characteristic identified in 40 CFR part 261 subpart C or is listed in 40 CFR part 261 subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and

labeled with all applicable hazardous waste numbers (*i.e.,* hazardous waste codes).

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase ''Hazardous Waste Pharmaceuticals.''

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR part 268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the land disposal restrictions notification.

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals*—(1) *Biennial reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception reporting by healthcare facilities for a missing copy of the manifest*—(i) *For shipments from a healthcare facility to a designated facility.* (A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) *For shipments rejected by the designated facility and shipped to an alternate facility.* (A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with § 262.11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as

non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(5) All records must be readily available upon request by an inspector.

(k) *Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) *Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person (as defined in § 260.10) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site (''control,'' for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to ''control'' such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) *Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) *Prohibition.* Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) *Biennial Reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(3) All records must be readily available upon request by an inspector.

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in § 266.502(l) of this subpart and § 266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in § 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in § 262.17(f).

(c) *Long-term care facilities that are very small quantity generators.* A long-

term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to this subpart, except for §§ 266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in § 260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 260.10.

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under § 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from 40 CFR parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of § 266.505; and

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.

(a) *Stock, dispensing and unit-dose containers.* A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1).

(d) *Other containers, including delivery devices.* Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) *Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-

site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____

Healthcare Facility's or Reverse distributor's EPA Identification Number _____

Manifest Tracking Number _____

(C) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of 40 CFR part 262 subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (*i.e.,* hazardous waste codes) in Item 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word ''PHARMS'' in Item 13 of EPA Form 8700–22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) *Shipping potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) *Delivery confirmation.* Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) *Procedures for when delivery confirmation is not received within 35 calendar days.* If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (*i.e.,* the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262 subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*—(1) *Notification.* A reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse

distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700–12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the reverse distributor.* A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (*e.g.,* name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) *Evaluation by a reverse distributor that is not a manufacturer.* A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a ''potentially creditable hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an ''evaluated hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (c) of this section.

(4) *Evaluation by a reverse distributor that is a manufacturer.* A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) *Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.* (i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (*i.e.,* potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (*i.e.,* evaluated hazardous waste pharmaceuticals).

(ii) *Aging pharmaceuticals.* Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (*i.e.,* aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in 266.510(c)(4)(i) through (vi).

(6) *Security at the reverse distributor facility.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) *Contingency plan and emergency procedures at a reverse distributor.* A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

(8) *Closure of a reverse distributor.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with § 262.17(a)(8)(ii) and (iii).

(9) *Reporting by a reverse distributor*—(i) *Unauthorized waste report.* A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (*e.g.,* non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) *Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with § 266.509.

(4) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable

(c) *Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the reverse distributor.* A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a reverse distributor.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of § 262.17(a)(7).

(4) *Labeling and management of containers at on-site accumulation areas.* A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, ''hazardous waste pharmaceuticals'';

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (*e.g.,* arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (*i.e.,* hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) *Shipments.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b).

(7) *Procedures for a reverse distributor for managing rejected shipments.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on

site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with § 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals*—(i) *Biennial reporting by a reverse distributor.* A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41.

(ii) *Exception reporting by a reverse distributor for a missing copy of the manifest.*

(A) *For shipments from a reverse distributor to a designated facility.* (*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B*) For shipments rejected by the designated facility and shipped to an alternate facility.* (*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with § 262.17(a)(7)(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(d) *When a reverse distributor must have a permit.* A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 16. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 17. Section 268.7 is amended by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and reverse distributors.* * * *

* * * * *

■ 18. Section 268.50 is amended by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in §§ 266.502 and 266.503 of this chapter.

(5) A reverse distributor accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with § 266.510 of this chapter.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 19. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 20. Section 270.1 is amended by adding paragraph (c)(2)(x) to read as follows:

§ 270.1 Purpose and scope of these regulations.

* * * * *

(c) * * *

(2) * * *

(x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 21. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 22. Section 273.80 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d) of this section, any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Hazardous waste pharmaceuticals are regulated by 40 CFR part 266 subpart P and may not be added as a category of hazardous waste for management under this part.

[FR Doc. 2019–01298 Filed 2–21–19; 8:45 am]

BILLING CODE 6560–50–P

Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is an Executive Order 13771 (82 FR 9339, January 30, 2017) regulatory action because this action is not significant under Executive Order 12866.

Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this state operating permit program will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Unfunded Mandates Reform Act

Because this action approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132: Federalism

This action also does not have Federalism implications because it does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state operating permit program, and does not alter the relationship or the distribution of power and responsibilities established in the Act.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

In addition, the state operating permit program is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the state operating permit program does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

This action also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it proposes to approve a state operating permit program.

Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Because it is not a ''significant regulatory action'' under Executive Order 12866 or a ''significant energy action,'' this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001).

National Technology Transfer Advancement Act

In reviewing state submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Act. In this context, in the absence of a prior existing requirement for the state to use voluntary consensus standards (VCS), EPA has no authority to disapprove a state submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a state submission, to use VCS in place of a state submission that otherwise satisfies the provisions of the Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Executive Order 12898: Federal Actions to Address Environmental

Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this action. In reviewing state operating permit program submissions, EPA's role is to approve or disapprove state choices, based on the criteria of the Act. Accordingly, this action merely approves certain state requirements and will not in-and-of itself create any new requirements. Accordingly, it does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898.

List of Subjects in 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Operation permits, Reporting and recordkeeping requirements.

Dated: November 19, 2019.

Cathy Stepp,

Regional Administrator, Region 5.

40 CFR part 70 is amended as follows:

PART 70—STATE OPERATING PERMIT PROGRAMS

■ 1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

■ 2. Amend appendix A to part 70 by adding paragraph (d) under Wisconsin to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Wisconsin

* * * * *

(d) Department of Natural Resources: Title V operating permit program revisions and updates received on March 8, 2017. Wisconsin's Title V program is hereby updated to include these requested changes.

* * * * *

[FR Doc. 2019–26296 Filed 12–6–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 264, 265, 268, 270, and 273

[EPA–HQ–OLEM–2017–0463; FRL–10002–49–OLEM]

RIN 2050–AG92

Increasing Recycling: Adding Aerosol Cans to the Universal Waste Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is adding hazardous waste aerosol cans to the universal waste program under the Federal Resource Conservation and Recovery Act (RCRA) regulations. This change will benefit the wide variety of establishments generating and managing hazardous waste aerosol cans, including the retail sector, by providing a clear, protective system for managing discarded aerosol cans. The streamlined universal waste regulations are expected to ease regulatory burdens on retail stores and others that discard hazardous waste aerosol cans; promote the collection and recycling of these cans; and encourage the development of municipal and commercial programs to reduce the quantity of these wastes going to municipal solid waste landfills or combustors.

DATES: This final rule is effective on February 7, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–RCRA–2017–0463. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Laura Stanley, Office of Land and Emergency Management (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 703–308–7285; email address: *stanley.laura@epa,gov*, or Tracy Atagi, Office of Land and Emergency Management (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 703–308–8672; email address: *atagi.tracy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This final rule will affect persons who generate, transport, treat, recycle, or dispose of hazardous waste aerosol cans, herein referred to as aerosol cans, unless those persons are households or very small quantity generators (VSQGs). Entities potentially affected by this action include over 25,000 industrial facilities in 20 different industries (at the 2-digit North American Industry Classification System (NAICS) code level). An estimated 7,483 of these facilities are large quantity generators (LQG). Most of these industries have relatively few entities that are potentially affected. The two top economic sectors (at the 2-digit NAICS code level) with the largest percentage of potentially affected entities are the retail trade industry (NAICS code 44–45), representing 69% of the affected LQG universe, and manufacturing (NAICS code 31–33), representing 17% of the affected LQG universe. Potentially affected categories and entities include, but are not necessarily limited to:

2 Digit NAICS code	Primary NAICS description	Total affected large quantity generators	Generated tons
44–45	Retail Trade	5,194	303
31–33	Manufacturing	1,238	7,771
48–49	Transportation and Warehousing	168	1,033
62	Health Care and Social Assistance	184	13
81	Other Services (except Public Administration)	169	4
92	Public Administration	113	190
61	Educational Services	116	32
54	Professional, Scientific, and Technical Services	89	16
42	Wholesale Trade	75	511
22	Utilities	40	14
56	Administrative and Support and Waste Management and Remediation Services	51	1,906
	All Other NAICS Codes	46	49
Total		7,483	11,843

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. Other entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in section V of this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What action is the agency taking?

The Environmental Protection Agency (EPA) is adding hazardous waste aerosol cans to the list of universal wastes regulated under the RCRA regulations. This revision will benefit the wide variety of establishments generating and managing aerosol cans, including the retail sector, by providing a clear, practical system for handling discarded aerosol cans.

C. What is the agency's authority for taking this action?

These regulations are promulgated under the authority of sections 2002(a), 3001, 3002, 3004, and 3006 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), and as amended by the Hazardous and Solid Waste Amendments (HSWA), 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

D. What are the incremental costs and benefits of this action?

This final action is estimated to result in an annual cost savings of $5.3 million to $47.8 million. Information on the estimated economic impacts of this action is presented in section VIII of this document, as well as in the Regulatory Impact Analysis (RIA) available in the docket for this final action. In addition to cost savings, EPA's analysis shows qualitative benefits to adding aerosol cans to the universal waste program, including improved implementation of and compliance with the hazardous waste program and increased recovery and recycling of aerosol cans.

II. List of Acronyms

CFR Code of Federal Regulations

DOT Department of Transportation
EPA Environmental Protection Agency
E.O. Executive Order
FR Federal Register
LQG Large Quantity Generator
LQHUW Large Quantity Handler of Universal Waste
NAICS North American Industry Classification System
NODA Notice of Data Availability
OMB Office of Management and Budget
RCRA Resource Conservation and Recovery Act
SQG Small Quantity Generator
SQHUW Small Quantity Handler of Universal Waste
TSDF Treatment, Storage and Disposal Facility
VSQG Very Small Quantity Generator

III. Background

A. Summary of Proposal

On March 16, 2018, EPA published the proposal to add aerosol cans to the Federal universal waste program (83 FR 11654). EPA's proposal recognized that inclusion of this common waste stream as universal waste could better ensure that aerosol cans are managed appropriately at the end of their lives, remove these wastes from the municipal waste stream, potentially encourage recycling, and reduce unnecessary burden for generators.

In its proposal, EPA analyzed the factors for inclusion of a waste stream in the universal waste program and took public comment on its conclusions. In addition, EPA defined what materials would qualify as aerosol cans for the purposes of management as universal waste. EPA proposed management standards for handlers of these materials and took public comment on the proposed standards.

In addition to the universal waste management standards that apply to all universal waste handlers, such as labeling and marking, accumulation time limits, employee training, responses to releases, export requirements, and, for large quantity handlers of universal waste, notification and tracking, EPA proposed specific standards that relate to the puncturing and draining of aerosol cans.

EPA proposed that puncturing and draining of aerosol cans be conducted by a commercial device specifically designed to safely puncture aerosol cans and effectively contain the residual contents as well as any emissions from the puncturing and draining activities. In addition, EPA proposed that handlers establish written procedures for safely puncturing and draining universal waste aerosol cans and ensure that employees operating the device be trained in the proper procedures. EPA proposed that puncturing of aerosol cans be done in a manner designed to prevent fires and releases and that any residuals from puncturing cans be transferred to a tank or container, at which point the handler must make a hazardous waste determination on the residuals, as required in 40 CFR 262.11. The proposal also included that written procedures be in place in the event of a spill or release, that a spill clean-up kit be provided, and that any spills or leaks be cleaned up promptly.

In addition to these proposed standards, EPA analyzed the existing state universal waste programs that include aerosol cans and requested comment on including further limitations on puncturing and draining of cans that might contain materials that pose an incompatibility hazard with other materials or establishing further limits on which types of handlers are allowed to puncture and drain aerosol cans within the universal waste program.

EPA has analyzed all the comments received in response to its proposed rule and responds to those comments in this final rule or in the Response to Comment document available in the docket for this rulemaking.

B. Description of Aerosol Cans

Aerosol cans are widely used for dispensing a broad range of products including paints, solvents, pesticides, food and personal care products, and many others. The Household and Commercial Products Association estimates that 3.75 billion aerosol cans were filled in the United States in 2016 for use by commercial and industrial facilities as well as by households.[1]

A typical aerosol can consists of several components, including (but not limited to) the following: (1) The can or container storing both propellant and the product; (2) an actuator or button at the top of the can that is pressed to deliver the product; (3) a valve, which controls delivery or flow of the product; (4) the propellant (a compressed gas or liquefied gas), which provides the pressure in the container to expel or release the product when the actuator is pressed to open the valve; (5) the product itself; and (6) a dip tube, which is connected to the valve to bring the product up through the can to be released when the actuator is pressed.[2]

The can itself is typically a small steel or aluminum container, designed to be hand-held, which is sealed with its contents under pressure. The can's design is intended to prevent unwanted releases of the contents to the environment under normal handling and storage conditions. However, when aerosol cans are mismanaged, particularly when exposed to excessive heat, the resulting increase in internal pressure can reach a point beyond the design strength of the can, thereby causing it to burst and release its contents. At the point of bursting, the contents of the can have been heated to a temperature and pressure far above ambient environmental conditions, causing the contents to rapidly vaporize and be forcefully released. If the propellant or product is ignitable, the contents of the can may readily catch fire as they are released and exposed to atmospheric oxygen, creating a rapidly burning vapor ''fireball.'' In addition, the bottom of the can may detach as a result of a manufacturing defect or an external force, potentially causing the upper part of the can to become a projectile.

Aerosol cans frequently contain flammable propellants such as propane or butane which can cause the aerosol can to demonstrate the hazardous characteristic for ignitability (40 CFR 261.21).[3] In addition, the aerosol can may also be a hazardous waste for other reasons when discarded. More specifically, an aerosol can may contain materials that exhibit hazardous characteristics per 40 CFR part 261, subpart C. Similarly, a discarded aerosol can may also be a P- or U-listed hazardous waste if it contains a commercial chemical product found at 40 CFR 261.33(e) or (f).

C. Current Federal Regulation of Aerosol Cans

1. Regulation of Aerosol Cans Under RCRA

Any person who generates a solid waste, as defined in 40 CFR 261.2, must determine whether the solid waste qualifies as hazardous waste. The waste may be hazardous either because it is listed as a hazardous waste in subpart D of 40 CFR part 261 or because it exhibits one or more of the characteristics of hazardous waste, as provided in subpart C of 40 CFR part 261. As discussed above, aerosol cans are frequently hazardous due to the ignitability characteristic and in some cases may also contain listed waste or

[1] Household and Commercial Products Association, Aerosol Products Survey Shows Strong, Stable Industry, May 2017. *https://www.thehcpa.org/aerosol-products-survey-shows-strong-stable-industry/* retrieved October 21, 2019.

[2] National Aerosol Association, *History of the Aerosol, http://www.nationalaerosol.com/history-of-the-aerosol/,* retrieved December 11, 2017.

[3] University of Vermont, *Paint and Aerosol Safety, http://www.uvm.edu/safety/art/paint-aerosol-safety,* retrieved December 11, 2017.

exhibit other hazardous waste characteristics.[4]

Until this rulemaking goes into effect, many, but not all, generators of aerosol cans identified or listed as a hazardous waste have been subject to the full RCRA Subtitle C hazardous waste management requirements, including all applicable requirements of 40 CFR parts 260 through 268. Depending on their activities, some generators have only to meet the requirements of part 262, including on-site management, pre-transport, and manifesting. Under 40 CFR 262.14, VSQGs, defined as facilities that generate less than or equal to 100 kilograms of hazardous waste in a calendar month, are not subject to the RCRA Subtitle C hazardous waste management standards, provided they send their waste to a municipal solid waste landfill or non-municipal nonhazardous waste facility approved by the state for the management of VSQG wastes and meet other conditions. In addition, households that generate waste aerosol cans are exempt from the Federal hazardous waste management requirements under the household hazardous waste exemption in 40 CFR 261.4(b)(1).[5]

Facilities that treat, store, and/or dispose of hazardous waste aerosol cans are subject to the requirements of 40 CFR part 264 (for permitted facilities) or the requirements of 40 CFR part 265 (for interim status facilities). However, when hazardous waste aerosol cans are recycled, the recycling process itself is not subject to regulation, except as indicated in 40 CFR 261.6(d). EPA has interpreted the current hazardous waste regulations to mean that puncturing and draining an aerosol can, if performed for the purpose of recycling (*e.g.,* for scrap metal recycling), is considered part of the recycling process and is exempt from RCRA permitting requirements under 40 CFR 261.6(c).[6] However, until this rulemaking goes into effect, facilities receiving hazardous waste aerosol cans from off site would require a RCRA permit for storage prior to the recycling activity and the recycling process would be subject to subparts AA and BB of 40 CFR part 264 or 265, or subject to part 267.

2. Regulation Under the Federal Insecticide, Fungicide, and Rodenticide Act

Hazardous waste aerosol cans that contain pesticides are also subject to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including compliance with the instructions on the label. In general, the statement on aerosol pesticide product FIFRA labels prohibits the puncturing of the cans. However, in April 2004, EPA issued a determination that puncturing aerosol pesticide containers in the process of recycling aerosol cans is consistent with the purposes of FIFRA. The purpose of the label prohibiting puncturing of pesticide-containing aerosol cans is to protect the ordinary users of pesticides from the hazards of pressurized containers. The hazards associated with recycling aerosol pesticide containers are adequately, and more appropriately, addressed under Federal, state and local laws concerning solid and hazardous wastes and occupational safety and health. Such puncturing is therefore lawful pursuant to FIFRA section 2(ee)(6) provided that the following conditions are met:

- The puncturing of the container is performed by a person who, as a general part of his or her profession, performs recycling and/or disposal activities;
- The puncturing is conducted using a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof; and
- The puncturing, waste collection, and disposal, are conducted in compliance with all applicable Federal, state, and local waste (solid and hazardous waste) and occupational safety and health laws and regulations.[7]

D. Retail Strategy and Aerosol Cans

The retail sector as a whole handles a very large number of diverse products, which change over time and may, in many instances, become regulated as hazardous waste under RCRA when discarded. As a result, retailers are required to make hazardous waste determinations for a variety of products being discarded at stores located across the country.

In 2014, EPA published a Notice of Data Availability (NODA) for the Retail Sector as part of the Agency's continuing efforts to better understand concerns from all stakeholders regarding RCRA's applicability to the retail sector, as well as to obtain information and feedback on issues affecting the retail sector (79 FR 8926, February 14, 2014). In the NODA, EPA requested comment on a series of topics related to retail operations, waste management practices, and management of materials that may become hazardous waste when discarded. This specifically included requests for information regarding aerosol cans (*e.g.,* quantity generated, classification, and management options, including handling them as universal waste), since aerosol cans comprise a large percentage of the retail sector's hazardous waste stream. Approximately 35% of NODA commenters specifically suggested that discarded aerosol cans be managed as universal waste.

In response to comments on the Retail Sector NODA, the Agency published the *Strategy for Addressing the Retail Sector under RCRA's Regulatory Framework,* which lays out a cohesive plan to address the unique challenges faced by the retail sector in complying with RCRA regulations while reducing burden and protecting human health and the environment.[8] One of the action items under the Retail Strategy is to explore adding hazardous waste aerosol cans to the Universal Waste Rule. This final rule, which adds aerosol cans to the Federal universal waste program, completes EPA's commitment in the Retail Strategy to explore this option. Further, with this action, EPA has completed all commitments made in the Retail Strategy.

E. Universal Waste Rule

In 1995, EPA promulgated the Universal Waste Rule (60 FR 25492, May 11, 1995) to establish a streamlined hazardous waste management system for widely generated hazardous wastes as a way to encourage environmentally sound collection and proper management of the wastes within the system. Hazardous waste batteries, certain hazardous waste pesticides, mercury-containing equipment, and hazardous waste lamps are already included on the Federal list of universal wastes. The universal waste regulations in 40 CFR part 273 are a set of alternative hazardous waste management standards that operate in lieu of regulation under 40 CFR parts

[4] Aerosol cans that have not been discarded are not solid or hazardous wastes.

[5] Under 40 CFR 261.4(b)(1), ''household waste'' means any material (including garbage, trash and sanitary wastes in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas).

[6] EPA first explained this interpretation in 1993. *See* U.S. EPA *1993 Regulatory Status of Used Residential And Commercial/Industrial Aerosol Cans,* Memo from Jeff Denit, Acting Director, Office of Solid Waste to John DiFazio, Chemical Specialties Manufacturers Association, October 7, 1993. RO# 11780.

[7] 2004 U.S. EPA *Puncturing of Aerosol Pesticide Products Under FIFRA for the Purpose of Recycling,* Letter from Lois Rossi and William Diamond, Office of Pollution Prevention and Toxic Substances, U.S. EPA, to John A. Wildie, Randolph Air Force Base, April 30, 2004, Docket ID# EPA–HQ–OLEM–2017–0463–0007.

[8] EPA 2016. *Strategy for Addressing the Retail Sector under RCRA's Regulatory Framework.* September 12, 2016. *https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts,* retrieved on January 24, 2018.

260 through 272 for specified hazardous wastes.

Handlers and transporters who generate or manage items designated as a universal waste are subject to the management standards under 40 CFR part 273, rather than the full RCRA Subtitle C regulations. Handlers include both facilities that generate universal waste and facilities that receive universal waste from other universal waste handlers, accumulate the universal waste, and then send the universal waste to another handler, a destination facility, or a foreign destination. Handlers do not include facilities that treat, dispose of, or recycle universal waste except as provided in the universal waste regulations. The regulations distinguish between ''large quantity handlers of universal waste'' (those who handle more than 5,000 kilograms of total universal waste at one time) and ''small quantity handlers of universal waste'' (those who handle 5,000 kilograms or less of universal waste at one time). The 5,000-kilogram accumulation limit applies to the quantity of all universal wastes accumulated. The streamlined standards include requirements for storage, labeling and marking, preparing the waste for shipment off site, employee training, response to releases, and, in the case of large quantity handlers, notification and tracking of universal waste shipments. Transporters of universal waste are also subject to less stringent requirements than the full Subtitle C hazardous waste transportation regulations.

Under the Universal Waste Rule, destination facilities are those facilities that treat, store, dispose, or recycle universal wastes. Universal waste destination facilities are subject to all currently applicable requirements for hazardous waste treatment, storage, and disposal facilities (TSDFs) and must receive a RCRA permit for such activities. Destination facilities that recycle universal waste and that do not store that universal waste prior to recycling in accordance with 40 CFR 261.6(c)(2) may be exempt from permitting under the Federal regulations (see 40 CFR 273.60(b)). Finally, states implementing the universal waste program are authorized to add wastes that are not Federal universal wastes to their lists of universal wastes. Therefore, in some states, aerosol cans are already regulated as a universal waste.

F. State Universal Waste Programs That Include Aerosol Cans

Five states—California, Colorado, New Mexico, Ohio, and Utah—already have universal waste aerosol can programs in place, and Minnesota plans to propose to add aerosol cans to their universal waste regulations in 2019.[9] The universal waste programs in all these states include streamlined management standards similar to 40 CFR part 273 for small and large quantity handlers of universal waste and a one-year accumulation time limit for the aerosol cans. In addition, the five current state universal waste programs set standards for puncturing and draining of aerosol cans by universal waste handlers.

The aerosol can universal waste programs in California, Colorado, New Mexico, Ohio, and Utah allow for puncturing and draining of aerosol cans by universal waste handlers, as long as specific management standards and waste characterization requirements are met. In addition, California does not allow off-site commercial processors[10] to puncture and drain aerosol cans without a permit and requires those handlers that do puncture and drain cans to submit a notification. Guidance in effect in Minnesota at the time of publication of this final rule also allows handlers to puncture and drain their aerosol cans.

IV. Rationale for Including Aerosol Cans in the Universal Waste Rule

A. Factors for Inclusion in the Universal Waste Rule

EPA is adding aerosol cans to the list of universal wastes because this waste meets the factors found at 40 CFR 273.81 that describe hazardous waste appropriate for management under the streamlined universal waste system. Adding aerosol cans to the Universal Waste Rule simplifies handling and disposal of the wastes for generators, while ensuring that universal waste aerosol cans are sent to the appropriate destination facilities, where they will be managed as a hazardous waste with all applicable Subtitle C requirements to ensure protection of human health and the environment. Management as universal waste under the final requirements is also expected to facilitate environmentally sound recycling of the metal used to make the cans.

The universal waste regulations include eight factors to consider in evaluating whether a waste is appropriate for including in the regulations as a universal waste. These factors, codified at 40 CFR 273.81, are to be used to determine whether regulating a particular hazardous waste under the streamlined standards would improve overall management of the waste, and, therefore, whether the waste is a good candidate to be a universal waste. As the Agency noted in the preamble to the final Universal Waste Rule (60 FR 25513), not every factor must be met for a waste to be appropriately regulated under the universal waste system. However, consideration of the weight of evidence should result in a conclusion that regulating a particular hazardous waste under 40 CFR part 273 will improve waste management.

EPA has examined information on aerosol cans, including information submitted in the public comments on the proposed rule and the public comments on the 2014 Retail NODA using the criteria in 40 CFR 273.81.[11] In light of its evaluation of this information, the Agency has determined that on balance, hazardous waste aerosol cans meet the factors in 40 CFR 273.81 warranting inclusion on the Federal list of universal wastes for management under part 273. EPA received numerous comments on the proposed rule agreeing that aerosol cans are appropriate for inclusion in the Universal Waste Rule. EPA believes that adding aerosol cans to the list of universal wastes will make collection and transportation of this waste to an appropriate facility easier, and therefore will help facilitate recycling and reduce the amount of aerosol cans disposed of in municipal landfills. A summary of how the criteria in 40 CFR 273.81 apply to aerosol cans is described below.

1. The Waste, as Generated by a Wide Variety of Generators, Should Be a Listed or Characteristic Hazardous Waste (40 CFR 273.81)(a))

As discussed in section III, aerosol cans frequently demonstrate the hazardous characteristic for ignitability (40 CFR 261.21) due to the nature of the propellant used. In addition, the contents (propellant or product) may also exhibit another hazardous characteristic per 40 CFR part 261, subpart C, and may also be a P- or U-

[9] See supporting document number 0004 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463). See also Minnesota Pollution Control Agency 2016, *Public Rulemaking Docket, https://www.pca.state.mn.us/sites/default/files/mm-rule1-00.pdf,* retrieved August 21, 2019.

[10] According to California's guidance for their regulations, a ''commercial processor'' is any person that processes aerosol cans in exchange for compensation. Some examples include individuals from another generator's site, registered hazardous waste transporters, operators of hazardous waste treatment, storage and/or disposal facilities, and operators of transportable treatment units.

[11] Public comments on the 2014 Retail NODA can be found in docket number EPA–HQ–RCRA–2012–0426.

listed hazardous waste found at 40 CFR 261.33(e) or (f).

2. The Waste, or Category of Waste, Should Not Be Exclusive to a Particular Industry or Group of Industries, But Generated by a Wide Variety of Establishments (40 CFR 273.81(b))

EPA has documented in the RIA for this final rule that large and small quantity generators managing hazardous waste aerosol cans can be found in 20 different industries (at the 2-digit NAICS code level). Thus, aerosol cans are commonly generated by a wide variety of types of establishments, including retail and commercial businesses, office complexes, very small quantity generators, small businesses, government organizations, as well as large industrial facilities.

3. The Waste Should Be Generated by a Large Number of Generators and Frequently Generated in Relatively Small Quantities (40 CFR 273.81(c))

As documented in the RIA, more than 25,000 large and small quantity generators manage hazardous waste aerosol cans. Quantities generated vary depending on the type of generator and the situations associated with generation. For example, a retail store may determine that large quantities of aerosol cans that can no longer be sold or donated must be discarded as hazardous waste. On the other hand, entities that use aerosol cans in their day-to-day operations may generate small quantities of partially-used hazardous waste aerosol cans on a sporadic basis. Data from the RIA demonstrate that in 2017, LQGs generated an average of 1.6 tons per year each (approximately 3,600 cans).

4. Systems to Be Used for Collecting the Waste (Including Packaging, Marking, and Labeling Practices) Would Ensure Close Stewardship of the Waste (40 CFR 273.81(d))

The baseline universal waste requirements of notification, labeling, training, and response to releases found in 40 CFR part 273, subparts B and C, and the final specific requirements for management of aerosol cans in 40 CFR 273.13 and 40 CFR 273.33, discussed in section V, are designed to ensure close stewardship of the hazardous waste aerosol cans.

5. Risks Posed by the Waste During Accumulation and Transport Should Be Relatively Low Compared to the Risks Posed by Other Hazardous Waste, and Specific Management Standards Would Be Protective of Human Health and the Environment During Accumulation and Transport (40 CFR 273.81(e))

Aerosol cans are designed to contain the products they hold during periods of storage and transportation as they move from the manufacturer to the retailer, and ultimately to the final customer. Because of their design, hazardous waste aerosol cans present a relatively low risk compared to other types of hazardous waste that are not contained as-generated under normal management conditions and the risk posed by intact waste aerosol cans during storage and transport is similar to the risk posed by intact product aerosol cans. Retail and other entities that generate waste aerosol cans are accustomed to safely handling aerosol can products. In addition, the ignitability risk posed during accumulation and transport is addressed by standards set by local fire codes, the Office of Safety and Health Administration, and the Department of Transportation (DOT).[12] These standards include requirements for outer packaging, can design, and general pressure conditions.

Finally, the Agency has determined that the requirements of the universal waste program are effective in mitigating risks posed by hazardous waste aerosol cans. Specifically, the requirements for handlers to accumulate aerosol cans in a container that is structurally sound and compatible with the contents of the aerosol cans will ensure safe management and transport. In addition, the universal waste program requires proper training for employees when handling universal waste, responding to releases, and shipment in accordance with DOT regulations. These requirements will make the risks posed during accumulation and transport low. Additionally, the final specific requirements for management of aerosol cans that are punctured and drained at the handler, described in section V, address the ignitability risk and are designed to help prevent releases. Thus, the specific aerosol can universal waste management standards address the risks posed by hazardous waste aerosol cans.

[12] For example, DOT—49 CFR 173.306 for Shipping of Limited Quantities, Aerosol Cans and 49 CFR 173.115 for Flammable Gas, OSHA—29 CFR 1910.106(d)(6), Flammable Liquids, 2015 NFPA—Chapter 30, Flammable and Combustible Liquids Code, and Chapter 30B, Code for the Manufacture and Storage of Aerosol Products.

6. Regulation of the Waste Under 40 CFR Part 273 Will Increase the Likelihood That the Waste Will Be Diverted From Non-Hazardous Waste Management Systems (*e.g.,* the Municipal Solid Waste Stream) to Recycling, Treatment, or Disposal in Compliance With Subtitle C of RCRA (40 CFR 273.81(f))

Managing hazardous waste aerosol cans under the universal waste program is expected to increase the number of these items collected and to increase the number of aerosol cans being diverted from the non-hazardous waste stream into the hazardous waste stream because it would allow generators, especially those that generate this waste sporadically, to send it to a central consolidation point. Under the Universal Waste Rule, a handler of universal waste can send the universal waste to another handler, where it can be consolidated into a larger shipment for transport to a destination facility. Therefore, under the final rule it will be more economical to send hazardous waste aerosol cans for recycling for recovery of metal values. The final rule will advance the RCRA goal of increased resource conservation and increase proper disposal of hazardous waste, making it less likely that aerosol cans will be sent for improper disposal in municipal landfills or municipal incinerators. In addition, because the streamlined structure of the universal waste regulations makes aerosol can collection programs more economical, hazardous waste aerosol cans that might otherwise be sent to a municipal landfill under a VSQG or household hazardous waste exemption will be more easily collected and consolidated for hazardous waste disposal. This waste will be diverted from the municipal solid waste stream to universal waste management.

7. Regulation of the Waste Under 40 CFR Part 273 Will Improve the Implementation of and Compliance With the Hazardous Waste Regulatory Program (40 CFR 273.81(g))

The structure and requirements of the Universal Waste Rule are well suited to the circumstances of handlers of hazardous waste aerosol cans and their inclusion in the universal waste program will improve compliance with the hazardous waste regulations. In particular, handlers of hazardous waste aerosol cans who are infrequent generators of hazardous waste and who might otherwise be unfamiliar with the more complex Subtitle C management structure, but who generate hazardous waste aerosol cans, will be able to more

easily send this waste for proper management. Therefore, adding aerosol cans to the list of universal wastes would offer a protective hazardous waste management system that is likely to be more accessible, particularly for the retail sector, which can face unique compliance challenges as compared to manufacturing and other ''traditional'' RCRA-regulated sectors.[13]

8. Additional Factor (40 CFR 273.81(h)): States' Experience Under Existing State Universal Waste Programs Indicates That Regulation Under 40 CFR Part 273 Will Improve Management of Aerosol Cans

The factors included in 40 CFR 273.81 are designed to determine whether regulating a particular hazardous waste under the streamlined standards for universal waste would improve the overall management of the waste; 40 CFR 273.81(h) includes other factors as may be appropriate. Under 40 CFR 273.81(h), EPA considered states' experience of already managing aerosol cans under state universal waste programs. As discussed in section III, five states have added aerosol cans to their universal waste programs, and those states' experiences with management of aerosol cans under their respective universal waste programs provides a useful source of information to inform EPA's judgment on whether to add aerosol cans to the national universal waste program.

Information supplied to EPA from officials in those five states indicates that their programs improve the implementation of the hazardous waste program. Specifically, waste management officials from the four states whose programs were operating at the time of the proposed rule have represented to EPA that these programs have been operating well and achieving their objective of facilitating safe management of hazardous waste aerosol cans.[14] In particular, State officials from both California and Colorado stated to EPA that their respective aerosol can universal waste programs have been in effect since 2002 and they have not identified any problems with enforcing compliance with the standards. Accordingly, this information weighs in favor of concluding that management of aerosol cans under the Federal universal waste regulations is likely to be successful.

B. Expected Changes in Management of Aerosol Cans

EPA expects that under this final rule, the number of aerosol cans that are diverted from municipal solid waste landfills and incinerators to recycling or disposal in Subtitle C facilities will increase. Small and large quantity generators are already required to manage their hazardous waste aerosol cans under RCRA Subtitle C. Following implementation of this rule, some of these generators will likely begin managing their aerosol cans as a universal waste, either to save money or to improve implementation of their existing waste management program. One of the streamlined provisions of the Universal Waste Rule allows consolidation of aerosol cans at central locations, which makes it easier for smaller generators to arrange for hazardous waste recycling or disposal of these materials when they are generated. Because the streamlined structure of the universal waste standards makes aerosol can collection programs more economical, hazardous waste aerosol cans that might otherwise be sent to a municipal landfill under a VSQG or household hazardous waste exemption would be more easily collected and consolidated for hazardous waste disposal by those who are interested in managing it this way. EPA intends to encourage individual households and VSQGs to participate in such programs.

In summary, EPA believes that management of hazardous waste aerosol cans will best be implemented through a universal waste approach where handlers are operating within a simple, streamlined management system. The universal waste program addresses the environmental concerns surrounding the management of such wastes, while at the same time putting into place a structure that will allow for and encourage increased collection of aerosol cans for recycling.

V. Discussion of Final Rule

A. Waste Covered by Final Rule

1. Definition of Aerosol Can

a. Discussion of Proposed Rule

EPA proposed that an ''aerosol can'' be defined as an ''intact container in which gas under pressure is used to aerate and dispense any material through a valve in the form of a spray or foam.'' This definition is the same as the definition of aerosol can in the California, Colorado, New Mexico and Utah universal waste programs, with the exception of a twenty-four ounce size limit in Utah's definition of aerosol can. EPA proposed to adopt this definition of aerosol can to be consistent with the existing state programs.

This proposed definition was intended be limited to sealed containers whose intended use is to dispense a material by means of a propellant or compressed gas. Aerosol cans are designed to contain those materials until they are intended for release and to present minimal risk during normal storage and transport. Other types of containers, including compressed gas canisters and propane cylinders, present a greater risk than aerosol cans and would not be included. EPA also requested comment on limiting the definition of aerosol cans to those under twenty-four ounces, consistent with Utah's aerosol can universal waste program.

b. Summary of Comments

Several commenters recommended that EPA model the definition of aerosol can after language used in the DOT regulations in 49 CFR 171.8 and U.N. Model Regulations. An aerosol is defined in 49 CFR 171.8 as an article consisting of any non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas. Commenters noted that, in addition to harmonizing the RCRA regulations with DOT requirements, this language would be more inclusive, making it clear that aerosol cans containing products that are not dispensed as a spray or foam, such as aerosol cans that dispense product in the form of paste or powder, may be managed as universal waste. In addition, this definition would address the risk of gas cylinders if managed as universal waste, since those cylinders would not be considered ''non-refillable receptacles'' with a ''self-closing release device'' and therefore not eligible to be managed as universal waste under the alternative wording.

Most commenters supported EPA's proposal to exclude compressed gas cylinders from the definition of universal waste aerosol can, noting that such devices pose a higher risk than aerosol cans pose. Two industry commenters requested that compressed gas cylinders be included as universal waste, with one commenter asserting that ''as long as facilities have procedures in place to safely

[13] EPA 2016. *Strategy for Addressing the Retail Sector under RCRA's Regulatory Framework.* September 12, 2016. *https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts,* retrieved on January 24, 2018.

[14] See supporting document number 0004 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

depressurize these devices, potential risks can be mitigated.'' [15]

Finally, most commenters (including industry, most states, and local government) supported EPA's proposal to not set a specific size limit on aerosol cans. One state association and a few individual states did support limiting the size of aerosol cans to twenty-four ounces.

c. Final Rule Provisions

EPA is finalizing a definition of ''aerosol can'' that is consistent with language in the DOT regulations.[16] In the final rule, aerosol can is defined as a non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas. Using language from the DOT regulation will help ensure consistency across Federal regulatory programs, avoid unnecessarily narrowing the scope of the rule to aerosol cans that aerate their product, and will not inadvertently include compressed gas cylinders in the definition of aerosol can. Because compressed gas cylinders, unlike aerosol cans, require special procedures to safely depressurize, it would not be appropriate to include them in the final rule. Finally, because the DOT language is more inclusive than the proposed language, it better matches the intent of the proposal to apply to all types of aerosol cans, including cans that dispense product in the form of paste or powder, and would not require states that have already added aerosol cans to their universal waste program to change their regulations.

2. Applicability

a. Discussion of Proposed Rule

The proposed rule excluded from the universal waste requirements those cans that are not yet a waste under 40 CFR part 261 and those cans that are not hazardous waste. In addition, at proposed 40 CFR 273.6(b)(1)–(3), the proposal specifically excluded aerosol cans that have been emptied of their contents (both propellant and product). Aerosol cans that fall under these categories would not be subject to hazardous waste requirements or universal waste requirements.

Finally, the proposed rule also proposed to exclude aerosol cans that show evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. This proposed rule language would mean that hazardous waste aerosol cans that are not intact would continue to be subject to the full hazardous waste standards.

b. Summary of Comments

Several commenters requested that EPA allow leaking and damaged aerosol cans to be managed as universal waste. Commenters point out that the rules for other types of universal wastes (lamps, pesticides, batteries, mercury-containing equipment) allow damaged or leaking items to be managed as universal waste as long as they are in an appropriate container (*e.g.,* overpacked with absorbents). Commenters were concerned that determining whether an aerosol can shows ''evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions'' is a subjective standard that would be confusing to implement. Commenters noted that Colorado allows damaged aerosol cans to be managed as universal waste as long as they are managed in a separate individual container and that Ohio allows damaged aerosol cans to be managed as universal waste as long as they are overpacked with absorbents or immediately punctured to remove the contents of the can.

c. Final Rule Provisions

EPA is finalizing as proposed the language in 40 CFR 273.6(b)(1)–(3). These provisions designate aerosol cans that are not subject to hazardous waste requirements because they are either not solid waste, not hazardous waste, or they met the definition of empty container in 40 CFR 261.7.

However, EPA is not finalizing the proposed language in 40 CFR 273.6(b)(4), which would have barred leaking or damaged aerosol cans from being managed as universal waste, instead leaving such cans subject to 40 CFR part 262 hazardous waste requirements. Rather, EPA is requiring that universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents, or immediately punctured and drained in accordance with the aerosol can universal waste requirements. (See 40 CFR 273.13(e)(2) and 40 CFR 273.33(e)(2)).

EPA agrees with those commenters who indicated that such an approach is more consistent with how other universal wastes are regulated and how the states that currently regulate aerosol cans as universal waste operate their programs. In addition, setting specific protective management standards for leaking aerosol cans under the universal waste regulations would ensure the risk from these cans is addressed and that they are ultimately sent to appropriate destination facilities per 40 CFR 273.18 and 40 CFR 273.38 instead of potentially being diverted to municipal waste streams as VSQG waste per the requirements in 40 CFR 262.14. Such an approach is also consistent with DOT requirement that aerosols that are damaged, defective, or leaking to the point where they do not meet applicable design standards be transported in special aerosol salvage drums. See 49 CFR 173.306(k)(2).

3. Comments and Responses Related to ''Emptied'' Aerosol Cans

a. Comment: Empty Aerosol Cans Should be Allowed To Be Managed as Universal Waste

Summary of Comments. Several commenters requested that EPA clarify that handlers should be able to continue to manage their punctured and drained aerosol cans as a universal waste and send them to another handler or destination facility. The proposed § 273.6(b)(3) designated aerosol cans that meet the standard for empty containers under § 261.7 of the chapter as being excluded from universal waste requirements, and the proposed definition for aerosol cans included the requirement that they be ''intact,'' implying that punctured aerosol cans would not meet the definition. Commenters stated that including empty aerosol cans would provide a clear decision process for generators to include all aerosol cans—empty, full, or partially full—for proper handling and disposal as universal waste. However, commenters noted it would not be necessary to require empty aerosol cans to be managed under the universal waste regulations because generators may still want to manage empty aerosol cans as scrap metal for recycling.

EPA Response. EPA agrees that while aerosol cans that meet the standard for empty containers found at 40 CFR 261.7 should not be required to meet the universal waste requirements, they also should not be barred from being managed as universal waste if a handler chooses to do so. Residues in empty containers that meet the requirements of 40 CFR 261.7 are not subject to RCRA hazardous waste requirements. However, a handler is nevertheless allowed under the regulation to manage

[15] See comment number 0088 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[16] The DOT definition is also similar to the definition used in U.N. Model regulations. EPA chose the DOT version in order to promote consistency between the U.S. Federal regulatory programs.

aerosol cans that meet the empty container standards as universal waste if they would prefer to do so. Likewise, non-hazardous aerosol cans may be managed as universal waste, although they are not required to be managed as such. EPA notes that the final definition of aerosol can is based on the DOT definition and no longer specifies that the cans must be ''intact,'' thus removing a potential source of confusion.

b. Comment: Additional Guidance Needed on How To Determine if an Aerosol Can Meets the Empty Container Standard

Summary of Comments. Several commenters suggested that EPA provide additional guidance on how to determine if an aerosol can meets the empty container standard found at 40 CFR 261.7. One commenter suggested that EPA adopt guidance used by the State of Minnesota which recognizes an aerosol can as ''empty'' when (1) the container contains no compressed ignitable gas propellant or product; (2) all liquid product that can be dispensed through the valve has been; and (3) less than 3% of the product capacity of the container remains. Minnesota's guidance also recognizes that documenting that an aerosol can meets this standard can be impractical and therefore provides that aerosol cans may be assumed empty when both of the following criteria are satisfied: (1) No liquid is felt or heard when the can is shaken by hand; and (2) no gas or liquid is released when the spray/discharge valve is activated and the container is rotated through all directions, and the valve is not observably or known to be clogged.[17] Another commenter suggested that EPA add a provision to 40 CFR 261.7 stating that an aerosol can is empty when it has been punctured and drained. The commenter stated that this provision should apply to cans that hold characteristic or listed wastes.[18]

EPA Response. Under 40 CFR 261.7(b),[19] a container that has held non-acute hazardous waste is ''empty'' if (1) all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.,* pouring, pumping, and aspirating (applicable in all cases), *and* (2) no more than 2.5 centimeters (one inch) of residue remains on the bottom of the container or inner liner, or (3) no more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size. In addition, a container that has held a hazardous waste that is a compressed gas is empty when the pressure in the container approaches atmospheric pressure.

In the case of a container that has held an acute hazardous waste listed in 40 CFR 261.31 or 261.33(e), the container is considered empty when it has been triple rinsed or has been cleaned by another method that has been shown in scientific literature, or by tests conducted by the generator to achieve equivalent removal, per 40 CFR 261.7(b)(3). EPA also considers a container that has held an acute hazardous that is a compressed gas to meet the definition of empty when it approaches atmospheric pressure, as defined in 40 CFR 261.7(b)(2).[20] EPA is not aware of a chemical commonly found in aerosol cans that would be listed as an acute hazardous waste, but if such an aerosol can product does exist, it would have to meet the 40 CFR 261.7(b)(2) or (3) standard to be considered ''empty'' under the regulations. The commenter request for a revision to 40 CFR 261.7 that would allow aerosol cans that have held acutely hazardous waste to be disposed of without meeting the current standard in 40 CFR 261.7(b)(3) when punctured and drained is being beyond the scope of this rulemaking.

However, in the case of aerosol cans being recycled, rather than disposed of, aerosol cans that have been punctured and drained prior to recycling are considered exempt scrap metal under 40 CFR 261.6(a)(3)(ii), and therefore all such punctured cans would be exempt from hazardous waste requirements when recycled.

c. Comment: EPA Should Clarify That an Aerosol Can Does Not Need To Be ''Empty'' To Be Exempt Scrap Metal

Summary of Comments. One commenter noted that EPA said in the proposed rule that aerosol containers that meet the definition of empty in 40 CFR 261.7 are not subject to hazardous waste regulation and may be recycled as scrap metal. They found this statement misleading because it implies that the aerosol can must be RCRA empty, per 40 CFR 261.7, to be classified as exempt scrap metal. The commenter stated that an aerosol container does not need to be completely empty or triple rinsed (if it held a P-listed waste) to be classified and recycled as scrap metal. However, it is a good management practice to remove as much of the waste from the aerosol can as possible.

EPA Response. Under 40 CFR 261.1, ''scrap metal'' is defined as bits and pieces of metal parts (*e.g.,* bars, turnings, rods, sheets, wire) or metal pieces that may be combined together with bolts or soldering (*e.g.,* radiators, scrap automobiles, railroad box cars), which when worn or superfluous can be recycled. Under 40 CFR 261.6(a)(3)(ii), exempt scrap metal is not subject to regulation under parts 262 through 268, part 270, or part 124, and is not subject to the notification requirements of section 3010 of RCRA.

However, an aerosol can that still contains hazardous liquid and/or hazardous compressed gas would not meet the definition of scrap metal and would not be eligible for the scrap metal exemption. As EPA has clearly stated, materials containing significant amounts of liquid cannot be eligible to be exempt scrap metal.[21] Thus while EPA agrees that aerosol cans do not need to be triple rinsed prior to being recycled as scrap metal, they do need to have their contents removed to be considered scrap metal.

d. Comment: Universal Waste Handlers Should Not Be Required To Make a Hazardous Waste Determination on the Emptied Cans

Summary of Comments. One commenter noted that 40 CFR 273.13(e)(3)(v) and 273.33(e)(3)(v) of the proposed rule require that the universal waste handler ''Conduct a hazardous waste determination on the emptied aerosol can and its contents per 40 CFR 262.11.'' While the commenter agreed on the need for a hazardous waste determination to be made on the contents, they stated that requiring it for the emptied cans contradicts prior EPA guidance regarding scrap metal. The proposed rule only allows for puncturing of cans on the condition that the empty punctured aerosol cans be recycled. EPA has previously stated that a formal hazardous waste determination is not required for scrap metal being recycled under 40 CFR 261.6(a)(3)(ii).[22]

[17] See comment number 0086 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[18] See comment number 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[19] EPA did not request comment on or otherwise reopen the empty container provisions of 40 CFR 261.7 and comments requesting changes to the empty container regulations are outside the scope of this rule.

[20] EPA first explained this interpretation in 2017. *See* U.S. EPA *2017 RCRA Regulatory Status of Permeation Device,* Memo from Barnes Johnson, Director, Office of Resource Conservation and Recovery to Alex Chaharom, GeNO LLC, February 9, 2017. RO# 14887

[21] EPA 1985 *Definition of Solid Waste Final Rule,* 50 FR 614 at 624–625, January 4, 1985.

[22] EPA 1993 Memorandum from Jeffrey D. Denit, Acting Director, Office of Solid Waste to Gregory L. Crawford. *Regulatory Status of Used Residential And Commercial/Industrial Aerosol Cans,* October

EPA response. EPA agrees with the comment and has removed the language in 40 CFR 273.13(e)(3)(v) and 273.33(e)(3)(v) requiring a waste determination to be made on the emptied aerosol can destined for recycling.

B. Management Requirements for Aerosol Cans

1. Requirements for Small and Large Quantity Handlers

Under the final rule, the existing universal waste requirements currently applicable to small quantity handlers of universal waste (SQHUW) and large quantity handlers of universal waste (LQHUW) are also applicable to handlers of discarded aerosol cans.[23] For both SQHUWs and LQHUWs, these requirements include waste management standards, labeling and marking, accumulation time limits, employee training, responses to releases, requirements related to off-site shipments, and export requirements. LQHUWs are subject to additional notification and tracking requirements. For the labeling requirement, EPA is finalizing in 40 CFR 273.14 and 273.34 that either each aerosol can, or a container in which the aerosol cans are contained, must be labeled or marked clearly with any of the following phrases: ''Universal Waste—Aerosol Can(s),'' ''Waste Aerosol Can(s),'' or ''Used Aerosol Can(s).''

In addition, EPA is finalizing that small and large quantity universal waste handlers must follow certain specific management standards while handling their universal waste aerosol cans. Under the final rule, all handlers must manage their universal waste aerosol cans in a manner designed to prevent releases to the environment. This management includes accumulating universal waste aerosol cans in containers that are structurally sound and compatible with the contents of the can, and show no evidence of leaks, spills, or damage that could cause leaks under reasonably foreseeable conditions. The accumulation requirements in this final rule are similar to the existing accumulation requirements for small and large quantity universal waste handlers for other types of universal waste in 40 CFR 273.13 and 273.33 and are found in new paragraph (e) of each of these sections. Handlers may sort aerosol cans by type and consolidate intact aerosol cans in larger containers, remove actuators to reduce the risk of accidental release, and, under certain conditions, may puncture and drain aerosol cans when the emptied cans are to be recycled, as described below.

Other than the comments on the requirements for puncturing and draining at small and large quantity handlers, which are described below, EPA received few comments on the requirements for small and large quantity universal waste handlers. One state association urged EPA to place limits on the accumulation requirements for universal waste handlers by requiring separation of incompatible wastes because of the wide array of products aerosol cans contain.[24] EPA is finalizing the performance-based standard that handlers must manage their universal waste aerosol cans in a manner that prevents releases, but EPA is not requiring separation of specific types of aerosol cans whose contents may pose an incompatibility risk because EPA expects the intact aerosol cans will ensure the contents of these cans will not mix and therefore will not pose incompatibility risks. In addition, EPA is requiring that universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents, or immediately punctured and drained in accordance with the aerosol can universal waste requirements. (See 40 CFR 273.13(e)(2) and 40 CFR 273.33(e)(2)), thus removing the risk of incompatible contents mixing during storage and transport.

A waste management industry commenter suggested EPA require that handlers accumulate universal waste aerosol cans in strong outer packaging that will not be allowed to build pressure, that the contents of the aerosol cans are compatible, and that protective caps are in place or valve stems are removed to prevent the accidental release of the contents of the aerosol cans during storage and handling.[25] EPA is finalizing, as proposed, the performance-based standards that require the aerosol cans to be accumulated in containers that are structurally sound and compatible with the contents of the cans. EPA is not requiring handlers to remove the actuators to reduce the risk of accidental release but is allowing handlers to do so prior to accumulation if they choose.

A state commenter suggested that EPA include more specific safety measures to address the risk of cans bursting when exposed to excessive heat during accumulation, regardless of whether the handler punctures and drains the universal waste aerosol cans.[26] In order to address this risk, EPA added language to 40 CFR 273.13(e)(1) and 40 CFR 273.33(e)(1) to require the universal waste aerosol cans be accumulated in a container that is protected from sources of heat. Sources of heat include, but are not limited to, open flames; lighting; smoking; cutting and welding; hot surfaces; frictional heat; static, electrical, and mechanical sparks; and heat-producing chemical reactions.[27] For example, handlers should not allow smoking or open flames near containers accumulating universal waste aerosol cans. It is the responsibility of the operator to ensure that the containers accumulating universal waste aerosol cans are protected from sources of heat.

2. Requirements on Puncturing and Draining at Small and Large Quantity Handlers

a. Summary of Proposal

EPA proposed specific management standards for the puncturing and draining of aerosol cans at universal waste handlers, similar to the requirements being implemented in states that added aerosol cans to their list of universal waste. EPA proposed that puncturing and draining activities be conducted by a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof.

EPA proposed that handlers must establish a written procedure detailing how to safely puncture and drain universal waste aerosol cans (including operation and maintenance of the unit; segregation of incompatible wastes; and proper waste management practices to prevent fires or releases), maintain a copy of the manufacturer's specification and instruction on site, and ensure that employees operating the devices are trained in the proper procedures.

EPA also proposed that the actual puncturing of the cans should be done in a manner designed to prevent fires and to prevent the release of the aerosol can contents to the environment so as to minimize human exposure. This included, but was not limited to,

7, 1993, RO#11782; EPA 1994; Memorandum from to Michael H. Shapiro, Director, Office of Solid Waste, to Michael C. Campbell, *Regulatory Status of Waste Aerosol Cans,* January 1, 1994, RO#11806.

[23] Note that EPA did not ask for comment or otherwise reopen the pre-existing universal waste requirements that will now also apply to universal waste aerosol cans. Comments on the pre-existing universal waste requirements are beyond the scope of this rulemaking.

[24] See comment number 0073 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[25] See comment number 0063 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[26] See comment number 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[27] This list is derived from OSHA's definition of ''sources of ignition'' in 29 CFR 1910.106(h)(7)(i)(*a*).

locating the equipment on a solid, flat surface in a well-ventilated area.

In addition, EPA proposed that the contents from the cans should be immediately transferred from the waste aerosol cans or puncturing device (if applicable), to a container or tank and that the contents are subject to a hazardous waste determination under 40 CFR 262.11. If the contents are hazardous waste, the handler becomes the hazardous waste generator of the hazardous aerosol can contents and must manage those wastes in accordance with applicable RCRA regulations.

The proposed rule also required that a written procedure be in place in the event of a spill or release and a spill clean-up kit must be provided. All spills or leaks of the contents must be cleaned up promptly.

EPA requested comment on establishing further limitations on the puncturing and draining of aerosol cans that may contain wastes incompatible with the puncturing and draining equipment or the contents of other cans being drained. EPA also requested comment on limiting puncturing and draining to handlers that are not commercial processors (*i.e.,* a person that processes aerosol cans received from other entities in exchange for compensation). Such a limitation would be consistent with California's universal waste program. Handlers that are off-site commercial processors could still accept aerosol cans and process the cans by sorting and consolidating them but would be unable to puncture and drain the cans. Under this option, off-site commercial processors that would like to puncture and drain aerosol cans would have to first meet the requirements for a universal waste destination facility (*e.g.,* obtaining a permit for the storage of the hazardous waste aerosol cans prior to recycling).

b. Summary of Comments

The most frequent comment EPA received on puncturing and draining was on limiting handlers from puncturing and draining aerosol cans received from off-site handlers. For example, waste management industry commenters and some state commenters requested that EPA not allow off-site handlers to puncture and drain aerosol cans collected from other handlers unless they first meet the requirements for a universal waste destination facility.[28] On the other hand, an industry commenter and a state commenter requested that EPA not limit which handlers can puncture and drain aerosol cans.[29] Multiple industry commenters requested that, at a minimum, if EPA limits off-site handlers from puncturing and draining, EPA still allow off-site handlers to puncture and drain aerosol cans collected from other handlers in the same company or handlers that are related entities.[30]

EPA also received numerous comments on the specific management standards for the puncturing and draining of aerosol cans at universal waste handlers. EPA received broad comments from industry commenters supporting the proposed standards for the puncturing and draining of aerosol cans as sufficient and arguing that further limitations are not necessary.[31] EPA also received specific suggestions from industry commenters on the management standards. For example, one commenter recommended that EPA should not place additional limitations on puncturing and draining designed to address potential incompatibility concerns because they are not necessary.[32] On the other hand, one state requested that EPA prohibit handlers from puncturing and draining aerosol cans with possible incompatibility with the puncturing and draining equipment or the contents of other cans being drained.[33]

State associations commented that EPA should require puncturing and draining to be conducted in a commercially-manufactured device and not allow handlers to use ''homemade'' devices.[34] A commenter from the waste management industry argued that there is no basis for requiring puncturing and draining to be conducted in a commercial device and pointed out that many companies have designed and operated their own equipment for such purposes based on their engineering expertise.[35]

Commenters also asked for the requirement that puncturing and draining activities be conducted in a device designed to effectively contain the residual contents and emissions to be clarified.[36] Specifically, commenters requested EPA clarify what ''effectively contain'' means in relation to emissions and what constitutes breakthrough.[37] A state association commenter wrote that the only way to ensure the puncturing and draining activities are containing emissions it to implement an air monitoring program or to ensure the devices are equipped with ''end of life'' filters that show when breakthrough is occurring.[38] An industry commenter wrote that a requirement that allows for no breakthrough is not practical, but that handlers can maximize collection of emissions by following manufacturer instructions.[39]

EPA also received comments from state associations urging EPA to require handlers that puncture and drain to establish and follow a written procedure detailing how to safely puncture aerosol cans rather than only require handlers to establish a written procedure as proposed.[40] Commenters also pointed out that it is common practice to operate puncturing and draining devices on spill catchment pallets to aid in capturing accidental leaks or spills and asked EPA to allow this under the final rule.[41]

c. Final Rule Provisions

EPA expects puncturing and draining activities at universal waste handlers will differ from those currently performed by hazardous waste generators. Because handlers receive universal waste from many other handlers, the volume of aerosol cans punctured and drained at a commercial universal waste handler is likely to be much greater than at a typical hazardous waste generator (which can only puncture and drain its own hazardous waste aerosol cans). In addition, under universal waste regulations, handlers may store their universal waste up to a year, which could increase the number of cans punctured and drained at one time if the facility processes the cans in batches. Thus, EPA believes it is appropriate to include performance-

[28] See comment numbers 0063, 0074, 0085, and 0091 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[29] See comment numbers 0029 and 0080 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[30] See comment numbers 0077, 0087, and 0093 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[31] See comment numbers 0075 and 0083 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[32] See comment number 0087 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[33] See comment number 0077 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[34] See comment numbers 0073 and 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[35] See comment number 0074 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[36] See comment numbers 0073 and 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[37] See comment numbers 0001, 0073, and 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[38] See comment number 0073 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[39] See comment number 0001 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[40] See comment numbers 0073 and 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[41] See comment number 0064 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

based management standards to address the risk of puncturing and draining aerosol cans at universal waste handlers.

Despite the differences between recycling of aerosol cans at hazardous waste generators versus recycling of aerosol cans at universal waste handlers, under the final rule, EPA is not limiting off-site handlers from puncturing and draining aerosol cans collected from other handlers. Based on an observed lack of damage cases from puncturing and draining aerosol cans in the manner described in this rule, it appears that risks posed by universal waste handlers puncturing and draining aerosol cans collected from other handlers is relatively low. EPA has determined that the final management standards for the puncturing and draining of aerosol cans at universal waste handlers at 40 CFR 273.13(e)(4) and 40 CFR 273.33(e)(4) adequately address the low risks. Additionally, the five of the six states that have added aerosol cans to their list of universal wastes allow off-site handlers to puncture and drain aerosol cans collected from other handlers, and EPA is not aware of any damage cases resulting specifically from the puncturing and draining under universal waste in these states.[42] In particular, State officials from Colorado stated to EPA that their respective aerosol can universal waste programs have been in effect for over 15 years, and they have not identified any damage cases associated with puncturing and draining.[43]

As mentioned, EPA is finalizing management standards for the puncturing and draining of aerosol cans at universal waste handlers to increase protections. Under the final rule, puncturing and draining activities must be conducted by a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof. EPA is not finalizing that the puncturing and draining activities must be conducted in a commercial device or a commercially-manufactured device and is instead finalizing a performance-based standard. In response to comments, EPA is not limiting universal waste handlers that have designed their own equipment for puncturing and draining and operated it safely from continuing to use that equipment. If a universal waste handler uses specifically custom designed or retrofitted equipment to ensure that the device safely punctures aerosol cans, it should ensure the equipment is designed or retrofitted according to accepted engineering practices based on established codes, standards, published technical reports, or similar peer reviewed documents. Although EPA received comments from the waste management industry arguing that their members have safely designed and operated their own equipment for puncturing and draining aerosol cans, EPA expects most universal waste handlers will choose to purchase commercial devices designed to puncture aerosol cans. Puncturing and draining systems for aerosol cans are available from multiple commercial vendors. These devices generally consist of an enclosed puncturing device that punctures an aerosol can, allowing the contents to be drained into an attached container. In many cases, these containers are 55-gallon drums with a filter made of carbon or similar materials to capture any gases that may escape the 55-gallon drum during the puncturing and draining process.

Manufacturers of aerosol can puncturing and draining devices include instructions for their use.[44] These instructions include operating devices in a well-ventilated area that is free from sparks and ignition sources in order to prevent fires, use of personal protective equipment such as safety goggles, and segregating incompatible products from being drained into the same container. Operators of puncturing and draining devices are also instructed to ensure that the container remains closed, that it does not become overfilled, and that the container or tank storing the contents of the drained aerosol cans is also kept in a well-ventilated area free from sparks or ignition sources.

EPA received multiple comments arguing that the requirement that puncturing and draining activities be conducted in a device designed to effectively contain the residual contents and emissions needs to be clarified.[45] Specifically, commenters requested EPA clarify what ''effectively contain'' means in relation to emissions.[46] The performance of aerosol can puncturing and draining devices will vary by manufacturer and it remains the responsibility of the operator to ensure breakthrough is not occurring. Although commenters pointed out that handlers could ensure devices are equipped with ''end of life'' filters that show when breakthrough is occurring, it is impractical to impose this requirement on all universal waste handlers who use puncturing and draining equipment because the manufacturer's guidance with respect to containing emissions varies across the industry.[47] For example, some manufacturers recommend limiting the number of cans drained per filter while other manufacturers recommend weighing the filter before and during use.[48] Given the variability in the market, it is impractical for EPA to determine a single, appropriate standard for ensuring breakthrough is not occurring. Rather, EPA is finalizing as proposed the performance-based standard that universal waste handlers must use a device designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof. Universal waste handlers can minimize the potential for breakthrough by maintaining the puncturing and draining device and replacing air filters according to the manufacturer's specifications.

Because handlers are responsible for ensuring that the puncturing device is properly draining the contents of the aerosol cans into the drum, EPA is finalizing that handlers must establish and follow a written procedure to ensure that handlers take the necessary precautions to protect human health and the environment while puncturing and draining universal waste aerosol cans. At a minimum, EPA is requiring that the written procedure address the operation and maintenance of the unit, including its proper assembly; segregation of incompatible wastes; and proper waste management practices (*e.g.,* ensuring that ignitable wastes are stored away from heat or open flames). In order to increase protections, EPA is clarifying in the final rule that handlers must follow the written procedure. Additionally, EPA is finalizing that handlers must maintain a copy of the manufacturers' instructions on site and ensure employees operating the device are trained in the proper procedures.

Although some states have issued guidelines for recommending against puncturing and draining certain types of aerosol cans, there is limited publicly

[42] See supporting document number 0004 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[43] See docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[44] See supporting document 0003 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[45] See comment numbers 0073 and 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[46] See comment numbers 0001, 0073, and 0085 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[47] See supporting document 0003 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

[48] See comment number 0005 and supporting document 0003 in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

available data on the subset of aerosol cans that pose an incompatibility risk. Additionally, since new products enter the market and products are constantly changing, it is not practical to codify a finite list of aerosol cans that pose an incompatibility risk. Therefore, EPA is not providing a list of certain types of aerosol cans that might pose incompatibility issues with puncturing devices or the contents of other aerosol cans that are drained. However, it remains the responsibility of the operator to ensure that the puncturing device does not puncture aerosol cans that are incompatible with its materials or the contents of other aerosol cans that are being drained. Because aerosol cans are consumer products, aerosol cans have labels that identify the products contained within, including any hazardous posed by the contents which can assist handlers in ensuring they have addressed incompatibility issues. As mentioned above, EPA is requiring handlers to establish and follow a written procedure that addresses the operation of the unit, including the segregation of incompatible wastes. The operator can look to state guidance and manufacturer's guidance for information. For example, manufacturers make information available regarding potential incompatibilities between aerosol can propellants and puncturing devices container rubber seals or gaskets.[49]

EPA is also finalizing that the actual puncturing of the cans be done in a manner designed to prevent fires and to prevent the release of the aerosol can contents to the environment so as to minimize human exposure. This manner includes, but is not limited to, locating the equipment on a solid, flat surface in a well-ventilated area. Commenters pointed out that it is common practice to operate puncturing and draining devices on spill catchment pallets to aid in capturing accidental leaks or spills, which is allowed under the final rule if the spill catchment pallet is located on a solid, flat surface.

In addition, EPA is finalizing that the handler must immediately transfer the contents from the waste aerosol can, or the puncturing device (if applicable), to a container or tank and conduct a hazardous waste determination of the contents under 40 CFR 262.11. The handler becomes the generator of any hazardous aerosol can contents and must manage those wastes in accordance with applicable RCRA regulations.

The final rule also requires that a written procedure be in place in the event of a spill or leak and a spill clean-up kit should be provided. All spills or leaks of the contents of the aerosol cans should be cleaned up promptly.

Finally, EPA notes that all puncturing, waste collection, and disposal must be conducted in compliance with all applicable Federal, state and local waste (solid and hazardous waste) and occupational safety and health laws and regulations.

3. Requirements for Transporters

This final rule will not change any of the existing requirements applicable to universal waste transporters. Under 40 CFR 273.9, the definition of a universal waste transporter is a person engaged in the off-site transportation of universal waste by air, rail, highway, or water. Persons meeting the definition of universal waste transporter include those persons who transport universal waste from one universal waste handler to another, to a processor, to a destination facility, or to a foreign destination. These persons are subject to the universal waste transporter requirements of part 273, subpart D. EPA notes that this final rule also will not affect the applicability of shipping requirements under the hazardous waste materials regulations of DOT. Transporters continue to be subject to these requirements, if applicable (*e.g.,* 49 CFR 173.306 for shipping of limited quantities of aerosol cans, or 49 CFR 173.115(l), which sets limits in the definition of ''aerosol'' for the purpose of shipping flammable gas).

4. Requirements for Destination Facilities

This final rule will not change any of the existing requirements applicable to universal waste destination facilities (subpart E of part 273). Under 40 CFR 273.9, the definition of a destination facility is a facility that treats, disposes of, or recycles a particular category of universal waste (except certain activities specified in the regulations at §§ 273.13(a) and (c) and 273.33(a) and (c)).

5. Effect of This Rule on Household Wastes and Very Small Quantity Generators

Adding hazardous waste aerosol cans to the Federal definition of universal wastes would not impose any requirements on households or VSQGs for managing these cans. Household waste continues to be exempt from RCRA Subtitle C regulations under 40 CFR 261.4(b)(1). However, under the Universal Waste Rule provisions, VSQGs may choose to manage their hazardous waste aerosol cans in accordance with either the VSQG regulations under 40 CFR 262.14 or as a universal waste under part 273 (40 CFR 273.8(a)(2)). It should be noted, however, that 40 CFR 273.8(b) will continue to apply. Under this provision, if household or VSQG wastes are mixed with universal waste subject to the requirements of 40 CFR part 273 (*i.e.,* universal waste that is not generated by households or VSQGs), the commingled waste must be handled as universal waste in accordance with part 273. Under this final rule, handlers of universal waste who accumulate 5,000 kilograms or more of this commingled aerosol can waste at any time will be considered large quantity handlers of universal waste and must meet the requirements of that category of universal waste handler.

Hazardous waste aerosol cans that are managed as a universal waste under 40 CFR part 273 will not be required to be included in a facility's determination of hazardous waste generator status (40 CFR 262.13(c)(6)). Therefore, a generator that manages such cans under the requirements for universal waste and does not generate any other hazardous waste will not be subject to other Subtitle C hazardous waste management regulations, such as the hazardous waste generator regulations in part 262. A universal waste handler that meets the definition of a small quantity generator or large quantity generator in 40 CFR 260.10 for its other hazardous waste will be subject to the hazardous waste generator regulations in part 262.

6. Applicability of Land Disposal Restriction Requirements

This final rule does not change the applicability of land disposal restriction (LDR) requirements to universal waste. Under the existing regulations (40 CFR 268.1(f)), universal waste handlers and transporters are exempt from the LDR requirements regarding testing, tracking, and recordkeeping in 40 CFR 268.7, and the storage prohibition in 40 CFR 268.50. EPA is amending 40 CFR 268.1(f) to add aerosol can universal waste for consistency. This final rule also does not change the regulatory status of destination facilities; they remain subject to the full LDR requirements.

VI. Technical Corrections

As part of this rulemaking, EPA is finalizing four technical corrections to the universal waste standards for mercury-containing equipment in 40

[49] See *Compilation of Manufacturer's Guidance on Devices for Puncturing and Draining Aerosol Cans,* December 2017, in the docket for this rulemaking (EPA–HQ–RCRA–2017–0463).

CFR 273.13(c)(2)(iii) and (iv) and 273.33(c)(2)(iii) and (iv). Each of these paragraphs contained a reference to 40 CFR 262.34, which was removed and reserved as part of the November 28, 2016, Hazardous Waste Generator Improvements Rule (81 FR 85732). EPA neglected to update these references as part of its corresponding changes in that rule and is correcting that mistake here. In all four places, EPA proposed revisions to make the regulations refer to 40 CFR 262.16 or 262.17, as applicable. As a result of a comment stating that this revision did not include references to other potentially applicable paragraphs of the hazardous waste generator regulations in part 262, EPA has revised the language and is finalizing language that matches references in §§ 273.13(a) and 273.33(a). The final language states that mercury from broken ampules must be transferred to a container subject to all applicable requirements of 40 CFR parts 260 through 272.

VII. State Authority

A. Applicability of Final Rule in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified states to administer and enforce the RCRA hazardous waste program within the state. Following authorization, EPA retains enforcement authority under sections 3008, 3013, and 7003 of RCRA, although authorized states have enforcement responsibility. The standards and requirements for state authorization are found at 40 CFR part 271. Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that state. The Federal requirements no longer applied in the authorized state, and EPA could not issue permits for any facilities in that state, since only the state was authorized to issue RCRA permits. When EPA promulgated new, more stringent Federal requirements for these pre-HSWA regulations, the state was obligated to enact equivalent authorities within specified time frames. However, the new Federal requirements did not take effect in an authorized state until the state adopted the Federal requirements as state law. In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. EPA is directed by the statute to implement these requirements and prohibitions in authorized states, including the issuance of permits, until the state is granted authorization to do so. While states must still adopt HSWA-related provisions as state law to retain final authorization, EPA implements the HSWA provisions in authorized states until the states do so.

Authorized states are required to modify their programs only when EPA enacts Federal requirements that are more stringent or broader in scope than existing Federal requirements. RCRA section 3009 allows the states to impose standards more stringent than those in the Federal program (see also 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt Federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous Federal regulations.

B. Effect on State Authorization

This final rule will be less stringent than the current Federal program. Because states are not required to adopt less stringent regulations, they will not have to adopt the universal waste regulations for aerosol cans, although EPA encourages them to do so. Some states have already added aerosol cans to the list of universal wastes, and others may do so in the future. If a state's standards for aerosol cans are less stringent than those in the final rule, the state would have to amend its regulations to make them at least equivalent to the Federal standards and pursue authorization.

VIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *http://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This regulatory action was determined to be not significant and was therefore not submitted to the Office of Management and Budget (OMB) for review. This regulatory action was determined to be not significant for purposed E.O. 12866 review. The Office of Management and Budget (OMB) waived review.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the costs and benefits associated with this action.

C. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) documents that the EPA prepared have been assigned EPA ICR number 1597.13 and ICR number 2513.04. You can find a copy of the ICRs in the docket for this rule, and they are briefly summarized here.

Because aerosol cans managed under the final rule are not counted toward a facility's RCRA generator status, respondents will see a reduction in burden. This reduction is because the aerosol cans will not be subject to recordkeeping and reporting requirements as hazardous waste, and the respondent may no longer be subject to hazardous waste generator recordkeeping and reporting requirements, depending on the quantity of hazardous waste they generate (that is not hazardous waste aerosol cans or other universal wastes). The existing universal waste requirements currently applicable to SQHUWs and LQHUWs will also be applicable to handlers of aerosol can universal waste. For both SQHUWs and LQHUWs, these requirements include labeling and marking, employee training, response to releases, and export requirements. LQHUWs are also subject to additional notification and tracking requirements. EPA ICR number 1597.13 focuses on the increased burden to the universal waste program resulting from new facilities becoming universal waste handlers. EPA ICR number 2513.04 focuses on the decrease in burden associated with this regulation.

Respondents/affected entities: The information collection requirements of the final rule affect facilities that handle aerosol can universal waste and vary based on facility generator and handler status.

Respondent's obligation to respond: The recordkeeping and notification requirements are required to obtain a benefit under 40 CFR part 273.

Estimated number of respondents: 970.

Frequency of response: One-time notification for LQHUWs; annual

training requirements for all universal waste handlers; per-shipment costs for labeling (all handlers) and tracking (LQHUWs).

Total estimated burden: EPA estimates the annual burden to respondents to be *a net reduction in burden of* approximately 62,621 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The total estimated annual cost of this rule is a *cost savings* of approximately $2.77 million. This cost savings is composed of approximately $2.65 million in annualized avoided labor costs and $23,000 in avoided capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment in 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the Regulatory Impact Analysis found in the docket for this final rule, EPA does not expect the rule to result in an adverse impact to a significant number of small entities, since the rule is expected to result in net cost savings for all entities affected by the rule. We have therefore concluded that this action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

F. Executive Order 13132: Federalism

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Because the rule is expected to result in net cost savings, EPA does not expect that it will result in any adverse impacts on tribal entities. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in the Regulatory Impact Analysis found in the docket for this rule.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Regulatory Impact Analysis found in the docket for this rule.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: November 15, 2019.

Andrew R. Wheeler,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, of the Code of Federal Regulations, parts 260, 261, 264, 265, 268, 270, and 273 are amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, 6939g, and 6974.

Subpart B—Definitions

■ 2. Section 260.10 is amended by:
■ a. Adding the definition of ''Aerosol can'' in alphabetical order;
■ b. Republishing the introductory text for the definition ''Universal waste'' and revising paragraphs (3) and (4) and adding paragraph (5); and
■ c. In the definition of ''Universal waste handler,'' revising paragraph (2)(i).

The additions and revisions read as follows:

§ 260.10 Definitions.

* * * * *

Aerosol can means a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

* * * * *

Universal waste means any of the following hazardous wastes that are managed under the universal waste requirements of part 273 of this chapter:

* * * * *

(3) Mercury-containing equipment as described in § 273.4 of this chapter;

(4) Lamps as described in § 273.5 of this chapter; and

(5) Aerosol cans as described in § 273.6 of this chapter.

* * * * *

Universal waste handler:

* * * * *

(2) * * *

(i) A person who treats (except under the provisions of 40 CFR 273.13(a) or (c), or 40 CFR 273.33(a) or (c)), disposes of, or recycles (except under the provisions of 40 CFR 273.13(e) or 40 CFR 273.33(e)) universal waste; or

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 3. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

Subpart A—General

■ 4. Section 261.9 is amended by revising paragraphs (c) and (d) and adding paragraph (e) to read as follows:

§ 261.9 Requirements for Universal Waste.

* * * * *

(c) Mercury-containing equipment as described in § 273.4 of this chapter;

(d) Lamps as described in § 273.5 of this chapter; and

(e) Aerosol cans as described in § 273.6 of this chapter.

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 5. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

Subpart A—General

■ 6. Section 264.1 is amended by revising paragraphs (g)(11)(iii) and (iv) and adding paragraph (g)(11)(v) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(11) * * *

(iii) Mercury-containing equipment as described in § 273.4 of this chapter;

(iv) Lamps as described in § 273.5 of this chapter; and

(v) Aerosol cans as described in § 273.6 of this chapter.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 7. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

Subpart A—General

■ 8. Section 265.1 is amended by revising paragraphs (c)(14)(iii) and (iv) and adding paragraph (c)(14)(v) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(14) * * *

(iii) Mercury-containing equipment as described in § 273.4 of this chapter;

(iv) Lamps as described in § 273.5 of this chapter; and

(v) Aerosol cans as described in § 273.6 of this chapter.

* * * * *

PART 268—LAND DISPOSAL RESTRICTIONS

■ 9. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

Subpart A—General

■ 10. Section 268.1 is amended by revising paragraphs (f)(3) and (4) and adding paragraph (f)(5) to read as follows:

§ 268.1 Purpose, scope, and applicability.

* * * * *

(f) * * *

(3) Mercury-containing equipment as described in § 273.4 of this chapter;

(4) Lamps as described in § 273.5 of this chapter; and

(5) Aerosol cans as described in § 273.6 of this chapter.

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 11. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

Subpart A—General Information

■ 12. Section 270.1 is amended by revising the section heading and paragraphs (c)(2)(viii)(C) and (D) and adding paragraph (c)(2)(viii)(E) to read as follows:

§ 270.1 Purpose and scope of the regulations in this part.

* * * * *

(c) * * *

(2) * * *

(viii) * * *

(C) Mercury-containing equipment as described in § 273.4 of this chapter;

(D) Lamps as described in § 273.5 of this chapter; and

(E) Aerosol cans as described in § 273.6 of this chapter.

* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 13. The authority for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

Subpart A—General

■ 14. Section 273.1 is amended by revising paragraphs (a)(3) and (4) and adding paragraph (a)(5) to read as follows:

§ 273.1 Scope.

(a) * * *

(3) Mercury-containing equipment as described in § 273.4;

(4) Lamps as described in § 273.5; and

(5) Aerosol cans as described in § 273.6.

* * * * *

■ 15. Section 273.3 is amended by revising paragraph (b)(2) to read as follows:

§ 273.3 Applicability—pesticides.

* * * * *

(b) * * *

(2) Pesticides not meeting the conditions set forth in paragraph (a) of this section. These pesticides must be managed in compliance with the hazardous waste regulations in 40 CFR parts 260 through 272, except that aerosol cans as defined in § 273.9 that contain pesticides may be managed as aerosol can universal waste under § 273.13(e) or § 273.33(e);

* * * * *

■ 16. Section 273.6 is added to read as follows:

§ 273.6 Applicability—Aerosol cans.

(a) *Aerosol cans covered under this part.* The requirements of this part apply to persons managing aerosol cans, as described in § 273.9, except those listed in paragraph (b) of this section.

(b) *Aerosol cans not covered under this part.* The requirements of this part do not apply to persons managing the following types of aerosol cans:

(1) Aerosol cans that are not yet waste under part 261 of this chapter. Paragraph (c) of this section describes when an aerosol can becomes a waste;

(2) Aerosol cans that are not hazardous waste. An aerosol can is a hazardous waste if the aerosol can exhibits one or more of the characteristics identified in part 261, subpart C, of this chapter or the aerosol can contains a substance that is listed in part 261, subpart D, of this chapter; and

(3) Aerosol cans that meet the standard for empty containers under § 261.7 of this chapter.

(c) *Generation of waste aerosol cans.* (1) A used aerosol can becomes a waste on the date it is discarded.

(2) An unused aerosol can becomes a waste on the date the handler decides to discard it.

■ 17. Section 273.9 is amended by:

■ a. Adding the definition of ''Aerosol can'' in alphabetical order;

■ b. Revising the definitions of ''Large Quantity Handler of Universal Waste'' and ''Small Quantity Handler of Universal Waste'';

■ c. Revising the introductory text and paragraphs (3) and (4) and adding paragraph (5) to the definition of ''Universal Waste'';

■ d. In the definition of ''Pesticide'':

■ i. Redesignating paragraphs (a), (b), and (c) as paragraphs (1), (2), and (3), respectively;

■ ii. In newly redesignated paragraphs (1) and (2), removing the comma and adding a semicolon in its place; and

■ iii. In newly redesignated paragraph (3), removing ''(a) or (b) of this section'' and adding in its place ''(1) or (2)'' of this definition;

■ e. In the definition of ''Universal Waste Handler'':

■ i. Removing ''Waste Handler'' and adding ''waste handler'' in its place;

■ ii. Redesignating paragraphs (a) introductory text, (a)(1) and (2), (b) introductory text, and (b)(1) and (2) as paragraphs (1) introductory text, (1)(i) and (ii), (2) introductory text, and (2)(i) and (ii), respectively; and

■ iii. Revising newly redesignated paragraph (2)(i);

■ f. In the definition of ''Universal Waste Transfer Facility,'' removing ''Waste Transfer Facility'' and adding ''waste transfer facility'' in its place; and

■ g. In the definition of ''Universal Waste Transporter,'' removing ''Waste Transporter'' and adding ''waste transporter'' in its place.

The revisions and additions read as follows:

§ 273.9 Definitions.

Aerosol can means a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

* * * * *

Large quantity handler of universal waste means a universal waste handler (as defined in this section) who accumulates 5,000 kilograms or more total of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or aerosol cans, calculated collectively) at any time. This designation as a large quantity handler of universal waste is retained through the end of the calendar year in which the 5,000-kilogram limit is met or exceeded.

* * * * *

Small quantity handler of universal waste means a universal waste handler (as defined in this section) who does not accumulate 5,000 kilograms or more of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or aerosol cans, calculated collectively) at any time.

* * * * *

Universal waste means any of the following hazardous wastes that are subject to the universal waste requirements of this part:

* * * * *

(3) Mercury-containing equipment as described in § 273.4;

(4) Lamps as described in § 273.5; and

(5) Aerosol cans as described in § 273.6.

* * * * *

Universal waste handler:

* * * * *

(2) * * *

(i) A person who treats (except under the provisions of § 273.13(a) or (c), or § 273.33(a) or (c)), disposes of, or recycles (except under the provisions of § 273.13(e) or § 273.33(e)) universal waste; or

* * * * *

Subpart B—Standards for Small Quantity Handlers of Universal Waste

■ 18. Section 273.13 is amended by revising paragraphs (c)(2)(iii) and (iv) and adding paragraph (e) to read as follows:

§ 273.13 Waste management.

* * * * *

(c) * * *

(2) * * *

(iii) Ensures that a mercury clean-up system is readily available to immediately transfer any mercury resulting from spills or leaks from broken ampules from that containment device to a container that is subject to all applicable requirements of 40 CFR parts 260 through 272;

(iv) Immediately transfers any mercury resulting from spills or leaks from broken ampules from the containment device to a container that is subject to all applicable requirements of 40 CFR parts 260 through 272;

* * * * *

(e) *Aerosol cans.* A small quantity handler of universal waste must manage universal waste aerosol cans in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) Universal waste aerosol cans must be accumulated in a container that is structurally sound, compatible with the contents of the aerosol cans, lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions, and is protected from sources of heat.

(2) Universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents, or immediately punctured and drained in accordance with the requirements of paragraph (e)(4) of this section.

(3) A small quantity handler of universal waste may conduct the following activities as long as each individual aerosol can is not breached and remains intact:

(i) Sorting aerosol cans by type;

(ii) Mixing intact cans in one container; and

(iii) Removing actuators to reduce the risk of accidental release; and

(4) A small quantity handler of universal waste who punctures and drains their aerosol cans must recycle the empty punctured aerosol cans and meet the following requirements while puncturing and draining universal waste aerosol cans:

(i) Conduct puncturing and draining activities using a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof.

(ii) Establish and follow a written procedure detailing how to safely puncture and drain the universal waste aerosol can (including proper assembly, operation and maintenance of the unit, segregation of incompatible wastes, and proper waste management practices to prevent fires or releases); maintain a copy of the manufacturer's specification and instruction on site; and ensure employees operating the device are trained in the proper procedures.

(iii) Ensure that puncturing of the can is done in a manner designed to prevent fires and to prevent the release of any component of universal waste to the environment. This manner includes, but is not limited to, locating the equipment on a solid, flat surface in a well-ventilated area.

(iv) Immediately transfer the contents from the waste aerosol can or puncturing device, if applicable, to a container or tank that meets the applicable requirements of 40 CFR 262.14, 262.15, 262.16, or 262.17.

(v) Conduct a hazardous waste determination on the contents of the emptied aerosol can per 40 CFR 262.11. Any hazardous waste generated as a result of puncturing and draining the aerosol can is subject to all applicable requirements of 40 CFR parts 260 through 272. The handler is considered the generator of the hazardous waste and is subject to 40 CFR part 262.

(vi) If the contents are determined to be nonhazardous, the handler may manage the waste in any way that is in compliance with applicable Federal, state, or local solid waste regulations.

(vii) A written procedure must be in place in the event of a spill or leak and a spill clean-up kit must be provided. All spills or leaks of the contents of the aerosol cans must be cleaned up promptly.

■ 19. Section 273.14 is amended by adding paragraph (f) to read as follows:

§ 273.14 Labeling/marking.

* * * * *

(f) Universal waste aerosol cans (*i.e.,* each aerosol can), or a container in which the aerosol cans are contained, must be labeled or marked clearly with any of the following phrases: ''Universal Waste—Aerosol Can(s),'' ''Waste Aerosol Can(s),'' or ''Used Aerosol Can(s)''.

Subpart C—Standards for Large Quantity Handlers of Universal Waste

■ 20 Section 273.32 is amended by revising paragraph (b)(4) to read as follows:

§ 273.32 Notification.

* * * * *

(b) * * *

(4) A list of all the types of universal waste managed by the handler (*e.g.,* batteries, pesticides, mercury-containing equipment, lamps, and aerosol cans); and

* * * * *

■ 21. Section 273.33 is amended by revising paragraphs (c)(2)(iii) and (iv) and adding paragraph (e) to read as follows:

§ 273.33 Waste management.

* * * * *

(c) * * *

(2) * * *

(iii) Ensures that a mercury clean-up system is readily available to immediately transfer any mercury resulting from spills or leaks of broken ampules from that containment device to a container that is subject to all applicable requirements of 40 CFR parts 260 through 272;

(iv) Immediately transfers any mercury resulting from spills or leaks from broken ampules from the containment device to a container is subject to all applicable requirements of 40 CFR parts 260 through 272;

* * * * *

(e) *Aerosol cans.* A large quantity handler of universal waste must manage universal waste aerosol cans in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) Universal waste aerosol cans must be accumulated in a container that is structurally sound, compatible with the contents of the aerosol cans, lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions, and is protected from sources of heat.

(2) Universal waste aerosol cans that show evidence of leakage must be packaged in a separate closed container or overpacked with absorbents, or immediately punctured and drained in accordance with the requirements of paragraph (e)(4) of this section.

(3) A large quantity handler of universal waste may conduct the following activities as long as each individual aerosol can is not breached and remains intact:

(i) Sorting aerosol cans by type;

(ii) Mixing intact cans in one container; and

(iii) Removing actuators to reduce the risk of accidental release; and

(4) A large quantity handler of universal waste who punctures and drains their aerosol cans must recycle the empty punctured aerosol cans and meet the following requirements while puncturing and draining universal waste aerosol cans:

(i) Conduct puncturing and draining activities using a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof.

(ii) Establish and follow a written procedure detailing how to safely puncture and drain the universal waste aerosol can (including proper assembly, operation and maintenance of the unit, segregation of incompatible wastes, and proper waste management practices to prevent fires or releases); maintain a copy of the manufacturer's specification and instruction on site; and ensure employees operating the device are trained in the proper procedures.

(iii) Ensure that puncturing of the can is done in a manner designed to prevent fires and to prevent the release of any component of universal waste to the environment. This includes, but is not limited to, locating the equipment on a solid, flat surface in a well ventilated area.

(iv) Immediately transfer the contents from the waste aerosol can or puncturing device, if applicable, to a container or tank that meets the applicable requirements of 40 CFR 262.14, 262.15, 262.16, or § 262.17.

(v) Conduct a hazardous waste determination on the contents of the emptied can per 40 CFR 262.11. Any hazardous waste generated as a result of puncturing and draining the aerosol can is subject to all applicable requirements of 40 CFR parts 260 through 272. The handler is considered the generator of the hazardous waste and is subject to 40 CFR part 262.

(vi) If the contents are determined to be nonhazardous, the handler may manage the waste in any way that is in compliance with applicable Federal, state, or local solid waste regulations.

(vii) A written procedure must be in place in the event of a spill or release and a spill clean-up kit must be provided. All spills or leaks of the contents of the aerosol cans must be cleaned up promptly.

■ 22. Section 273.34 is amended by adding paragraph (f) to read as follows:

§ 273.34 Labeling/marking.

* * * * *

(f) Universal waste aerosol cans (*i.e.,* each aerosol can), or a container in which the aerosol cans are contained, must be labeled or marked clearly with any of the following phrases: ''Universal Waste—Aerosol Can(s)'', ''Waste Aerosol Can(s)'', or ''Used Aerosol Can(s)''.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 10–90; FCC 19–104]

Connect America Fund

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) reviews performance measures established by the Wireline Competition Bureau (WCB), the Wireless Telecommunications Bureau, and the Office of Engineering and Technology (collectively the Bureaus) for recipients of Connect America Fund (CAF) high-cost universal service support to ensure that those standards strike the right balance between ensuring effective use of universal service funds while granting the flexibility providers need given the practicalities of network deployment in varied circumstances.

DATES: Effective January 8, 2020.

FOR FURTHER INFORMATION CONTACT: Suzanne Yelen, Wireline Competition Bureau, (202) 418–7400 or TTY: (202) 418–0484.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration in WC Docket No. 10–90; FCC 19–104, adopted on October 25, 2019 and released on October 31, 2019. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW, Washington, DC 20554 or at the following internet address: *https://docs.fcc.gov/public/attachments/FCC–19–104A1.pdf*

I. Introduction

1. The Commission has long recognized that ''[a]ll Americans [should] have access to broadband that is capable of enabling the kinds of key applications that drive the Commission's efforts to achieve universal broadband, including education (*e.g.,* distance/online learning), health care (*e.g.,* remote health monitoring), and person-to-person communications (*e.g.,* Voice over internet Protocol (VoIP) or online video chat with loved ones serving overseas).'' To that end, the Commission has invested significant Universal Service Fund support for the deployment of broadband-capable networks in high cost, rural areas.

2. But only fast and responsive networks will allow Americans to fully realize the benefits of connectivity. That is why the Commission requires recipients of universal service support in high cost areas to deploy broadband networks capable of meeting minimum service standards. These standards protect taxpayers' investment and ensure that carriers receiving this support deploy networks that meet the performance standards they promised to deliver to rural consumers. At the same time, the Commission recognizes that each carrier faces unique circumstances, and that one set of prescriptive rules may not make sense for every one of them. To accommodate this practical reality, the Commission's rules provide flexibility, taking into account the operational, technical, and size differences among providers when establishing minimum standards, to ensure that even the smallest rural carriers can meet testing requirements without facing excessive burdens.

3. In the Order on Reconsideration, the Commission reviews performance measures established by the Bureaus for recipients of CAF high-cost universal service support to ensure that those standards strike the right balance between ensuring effective use of universal service funds while granting the flexibility providers need given the practicalities of network deployment in varied circumstances. Several petitions for reconsideration and applications for review of the Performance Measures Order, 83 FR 42052, August 20, 2018, propose changes to these performance measures. Here, the Commission rejects the proposed changes where it finds that the Bureaus' approach strikes the right balance. Where the Commission finds that the Bureaus' approach does not—for example, where it concludes that greater flexibility is warranted than was offered under the Bureaus' original methodology—the Commission adjusts its rules accordingly. Finally, the Commission clarifies the Bureaus' approach where doing so will help resolve stakeholder confusion.

II. Discussion

4. In the Order on Reconsideration, the Commission reexamines each of the described performance measure requirements in this document. As a result, the Commission adopts several modifications. The Commission believes these changes will alleviate concerns expressed by carriers by increasing the time for carriers to meet certain deadlines and further minimizing the costs associated with compliance, yet still ensure that carriers meet their performance obligations. In short, the refinements to the Bureau's approach adopted in the Performance Measures Order will further the overarching goal of the *Performance Measures Order;* namely, to ensure that carriers deliver broadband services with the speed and latency required while providing flexibility to enable carriers of all sizes to choose how to conduct the required performance testing in the manner most appropriate for each individual carrier.

5. Under the Performance *Measures Order,* all high-cost support recipients serving fixed locations must perform speed and latency tests from the customer premises of an active subscriber to a remote test server located at or reached by passing through an FCC-designated internet Exchange Point (IXP). In the *USF/ICC Transformation Order,* 76 FR 73830, November 29, 2011, the Commission decided that speed and latency should be measured on each eligible telecommunications carriers (ETCs) access network from the end-user interface to the nearest internet access point, *i.e.,* the internet gateway, which is the closest peering point between the broadband provider and the public internet for a given consumer connection. Subsequently, in the *CAF Phase II Price Cap Service Obligation Order,* 78 FR 70881, November 27, 2013, WCB stated that latency should be tested to an IXP, defined as occurring in any of ten different U.S. locations, almost all of which are locations used in the MBA program because they are geographically distributed major peering locations. The Bureaus expanded the list to permit testing to six additional metropolitan areas to ensure that most mainland U.S. locations are within 300 miles of an FCC-designated IXP and that all are within approximately 500 air miles of one. Further, the Bureaus permitted providers to use any FCC-

The Texas Commission on Environmental Quality (TCEQ, agency, or commission) adopts amendments to §§335.1, 335.2, 335.9, 335.10, 335.12, 335.13, 335.15, 335.18, 335.19, 335.24, 335.26, 335.27, 335.31, 335.41, 335.46, 335.91, 335.94, 335.112, 335.152, 335.221, 335.241, 335.251, 335.261, 335.272, 335.431, 335.471, 335.474, 335.477, 335.503, 335.504, 335.510, 335.511, 335.513, 335.521, 335.590, 335.602, 335.702, and 335.703. The commission also adopts the repeal of §§335.6, 335.11, 335.14, 335.61 - 335.63, 335.65 - 335.71, and 335.73 - 335.79. The commission further adopts new §§335.6, 335.11, 335.14, 335.51 - 335.61, 335.751, 335.753, 335.755, 335.757, 335.759, 335.761, 335.763, 335.765, 335.767, 335.769, and 335.771.

New §335.6 and amended §335.13 and §335.272 are adopted with changes to the proposed text as published in the July 30, 2021, issue of the *Texas Register* (46 TexReg 4586) and therefore will be republished. Amended §§335.1, 335.2, 335.9, 335.10, 335.12, 335.13, 335.15, 335.18, 335.19, 335.24, 335.26, 335.27, 335.31, 335.41, 335.46, 335.91, 335.94, 335.112, 335.152, 335.221, 335.241, 335.251, 335.261, 335.431, 335.471, 335.474, 335.477, 335.503, 335.504, 335.510, 335.511, 335.513, 335.521, 335.590, 335.602, 335.702, and 335.703; repealed §§335.6, 335.11, 335.14, 335.61 - 335.63, 335.65 - 335.71, and 335.73 - 335.79; and new §§335.11, 335.14, 335.51 - 335.61, 335.751, 335.753, 335.755, 335.757, 335.759, 335.761, 335.763, 335.765, 335.767, 335.769, and 335.771 are adopted without changes to the proposed text and will not be republished.

Background and Summary of the Factual Basis for the Adopted Rules

The federal hazardous waste program is authorized under the federal Resource Conservation and Recovery Act of 1976 (RCRA), §3006. States may obtain authorization from the United States Environmental Protection Agency (EPA) to administer the hazardous waste program. State authorization is a rulemaking process through which the EPA delegates the primary responsibility of implementing the RCRA hazardous waste program to individual states. This process ensures national consistency and minimum standards while providing flexibility to states in implementing rules. State RCRA programs must always be at least as stringent as the federal requirements.

Texas received authorization of its hazardous waste "base program" under RCRA on December 26, 1984 and has continuously participated in the EPA's authorization program. To maintain the RCRA authorization, the commission must adopt regulations to meet the minimum standards of federal programs administered by the EPA. Because the federal regulations undergo regular revision, the commission must adopt new regulations regularly to meet the changing federal regulations.

The commission adopts in this rulemaking parts of the RCRA Rule Clusters XXIV - XXVIII that implement revisions to the federal hazardous waste program which were made by the EPA between November 28, 2016 and December 9, 2019. Both mandatory and optional federal rule changes are included in these adopted clusters. Although not

necessary to maintain authorization, the EPA also recommends that the optional federal rule changes be incorporated into the state rules. Maintaining equivalency with federal regulations will enable Texas to continue operating all delegated aspects of the federal hazardous waste program in lieu of the EPA.

Hazardous Waste Generator Improvements Rule

In the November 28, 2016 issue of the *Federal Register* (81 FR 85732), the EPA amended existing regulations applicable to generators of hazardous waste. The EPA's objectives for the revisions included: 1) reorganizing the hazardous waste generator regulations to make them more user-friendly and to improve their usability; 2) addressing gaps in the existing regulations; 3) providing greater flexibility for management of hazardous waste in a cost-effective and protective manner; and 4) making technical corrections to address errors and removing obsolete references.

The commission adopts the federal Hazardous Waste Generator Improvements Rule by repealing and replacing the standards applicable to generators of hazardous waste in Subchapter C (Standards Applicable to Generators of Hazardous Waste) and by amending sections of Subchapter R (Waste Classification). Because the generator standards are referenced throughout the chapter, the commission adopts multiple conforming amendments.

Export and Import Confidentiality Rule

In the December 26, 2017 issue of the *Federal Register* (82 FR 60894), the EPA further

revised existing regulations regarding the export and import of hazardous wastes from and into the United States. Specifically, the EPA applied a confidentiality determination such that no person can assert confidential business information claims for documents related to the export, import, and transit of hazardous waste and export of excluded cathode ray tubes. The import and export confidentiality determination regulations were promulgated under the Hazardous and Solid Waste Amendments and are administered by the EPA.

Electronic Manifest Fee Rule

In the January 3, 2018 issue of the *Federal Register* (83 FR 420), the EPA established the methodology for determining and revising the user fees applicable to the electronic and paper manifests submitted to the national electronic manifest (e-Manifest) system developed under the Hazardous Waste Electronic Manifest Establishment Act (e-Manifest Act). Certain users of the hazardous waste manifest are required to pay a prescribed fee to the EPA for each electronic and paper manifest they use and submit to the national system. Regulations promulgated under the e-Manifest Act took effect in all states on the effective date of the federal rule.

The commission adopted the federal Hazardous Waste Electronic Manifest Rule promulgated in the *Federal Register* February 7, 2014 (79 FR 7518) on June 10, 2016 (41 TexReg 4259). The EPA issued a Special Consolidated Checklist for the two e-manifest rulemakings which contains additional guidance and revisions for federal revisions adopted in the 2014 Electronic Manifest Rule. The commission adopts

conforming revisions to adopt the consolidated revisions associated with both federal e-manifest rulemakings.

Definition of Solid Waste Rule

In the May 30, 2018 issue of the *Federal Register* (83 FR 24664), the EPA revised existing hazardous secondary material recycling regulations associated with the definition of solid waste to comply with the United States Court of Appeals for the District of Columbia (D.C. Circuit) vacatur. The D.C. Circuit vacated portions of the 2015 Definition of Solid Waste Rule, promulgated in the *Federal Register* on January 13, 2015 (80 FR 1694), and reinstated portions of the 2008 Definition of Solid Waste Rule, promulgated in the *Federal Register* on October 30, 2008 (73 FR 64668). Specifically, the 2018 final rule: 1) vacated parts of the 2015 verified recycler exclusion and reinstated the 2008 transfer-based exclusion; 2) upheld the 2015 containment and emergency preparedness provisions for the reinstated transfer-based exclusion; and 3) vacated the fourth factor of the 2015 definition of legitimate recycling and reinstated the 2008 version of the fourth factor. The commission did not adopt the 2008 Definition of Solid Waste Rule. The commission adopted the 2015 Definition of Solid Waste Rule as published in the *Texas Register* on January 2, 2015 (40 TexReg 77).

Pharmaceutical Waste Rule

In the February 22, 2019 issue of the *Federal Register*, the EPA created a new 40 Code of Federal Regulations (CFR) Part 266, Subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the

generator regulations in 40 CFR Part 262. New 40 CFR Part 266, Subpart P standards include: 1) prohibiting the disposal of hazardous waste pharmaceuticals into sewer systems; 2) eliminating the dual regulation of the RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration controlled substances by finalizing a conditional exemption; 3) maintaining the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events; 4) codifying the EPA's prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics; 5) finalizing an amendment to the P075 acute hazardous waste listing of nicotine and salts to exclude certain United States Food and Drug Administration approved over-the-counter nicotine replacement therapies; and 6) establishing in the preamble a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics.

Aerosol Can Waste Rule

As part of this rulemaking, the commission adopts amendments to implement the EPA's final regulations promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202), which added hazardous waste aerosol cans to the universal waste program under the RCRA. The commission received a petition for rulemaking from Westlake Chemical Corporation on February 3, 2020, requesting that the commission amend its rules to incorporate the EPA's universal waste provisions for aerosol cans. On March 25, 2020, the commission considered the petition for rulemaking and ordered the executive director to initiate rulemaking (TCEQ Docket No. 2020-0220-PET). The

commission now adopts this rulemaking to add hazardous waste aerosol cans to the list of universal wastes so they can be managed as universal waste. The commission anticipates that these rules will benefit a wide variety of establishments generating and managing aerosol cans, including the retail sector, by providing a practical system for handling discarded aerosol cans.

Foundry Sands Exclusion

In addition to adopted federal rule changes, the commission adopts amendments to formalize the commission's regulation of spent foundry sands from the iron and steel casting industry. The rulemaking adoption will implement state-initiated revisions to clarify that spent foundry sands that are an intended output or result from the iron and steel casting process are not classified as an industrial solid waste when introduced into the stream of commerce and managed as an item of commercial value, including use constituting disposal. The executive director issued a regulatory determination letter dated June 22, 1995, which established that spent foundry sands reused as a substitute material will be considered a co-product and will not be regulated as industrial solid waste. Regulatory revisions implemented since the 1995 letter was issued have resulted in confusion regarding the status of the material.

All adopted new rules and rule changes are discussed further in the Section by Section Discussion portion of this preamble.

Section by Section Discussion

The commission adopts stylistic, non-substantive changes to conform to current *Texas Register* style and format requirements that are not specifically discussed in the Section by Section Discussion portion of this preamble.

Subchapter A: Industrial Solid Waste and Municipal Hazardous Waste in General

§335.1, Definitions

The commission adopts amendments to 335.1 to add seven new paragraphs in alphabetical order and to renumber each paragraph following the new definitions.

The commission adopts amendments to §335.1(6) to add the definition of "Acute hazardous waste" and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment adds the definition of "Acute hazardous waste" consistent with the new definition of "Acute hazardous waste" in 40 CFR §260.10.

The commission adopts amendments to §335.1(8) to add the definition of "Aerosol can" and to adopt federal revisions associated with the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202). This amendment adds the definition of "Aerosol Can" consistent with the new definition of "Aerosol can" in 40 CFR §260.10.

The commission adopts amendments to §335.1(29) to add the definition of "Central

accumulation area" and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment adds the definition of "Central accumulation area" consistent with the new definition of "Central accumulation area" in 40 CFR §260.10.

The commission adopts amendments to §335.1(38) to add a definition of "Conditionally exempt small quantity generator" (CESQG) and a person who generates no more than 100 kilograms of hazardous waste in a calendar month to mean a "very small quantity generator" (VSQG) as defined in this section. The commission adopts this definition to clarify that the new term for the lowest tier hazardous waste generator category, VSQG, is applicable when the former term or the description of the lowest tier hazardous waste generator category, CESQG, is used in publications, authorizations or rules that are not included in this rulemaking. The EPA changed the name of the lowest tier hazardous waste generator category from "conditionally exempt small quantity generator" to "very small quantity generator" in the Hazardous Waste Generator Improvements Rule.

The commission adopts amendments to §335.1(49) to revise the definition of "Designated facility," remove the reference to §335.12, and add that 40 CFR §264.72 is adopted by reference under §335.152 and 40 CFR §265.72 is adopted by reference under §335.112. These federal sections that were previously adopted under §335.12 are now adopted under §335.112 and §335.152 as described in the Section by Section

Discussions for those sections.

The commission adopts amendments to §335.1(70) to revise the definition of "Final closure" and replace the reference to §335.69 with a reference to Chapter 335, Subchapter C due to the adoption of regulations associated with the Hazardous Waste Generator Improvements Rule. The commission adopts the repeal of §335.69 and replaces it with the adoption of 40 CFR Part 262 provisions in Chapter 335, Subchapter C as described in the Section by Section Discussions for §§335.51 through 335.61.

The commission adopts amendments to §335.1(105) to add the definition of "Large quantity generator" and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment adds the definition of "Large quantity generator" consistent with the new definition of "Large quantity generator" in 40 CFR §260.10.

The commission adopts amendments to §335.1(111) to revise the definition of "Manifest" to remove the reference to "the instructions in §335.10", and to clarify that manifest users are subject to the applicable requirements of this chapter. The manifest requirements in 40 CFR Part 262, Subpart B that were previously adopted under §335.10 are now adopted by reference in §335.54 as described in the Section by Section Discussion for those sections.

The commission adopts amendments to §335.1(119) to revise the definition of "No free liquids" by clarifying that the test methods in 40 CFR §261.4(a)(26) and (b)(18) are incorporated by reference under §335.31.

The commission adopts amendments to §335.1(120) to add the definition of "Non-acute hazardous waste" and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment adds the definition of "Non-acute hazardous waste" consistent with the new definition of "Non-acute hazardous waste" in 40 CFR §260.10.

The commission adopts amendments to §335.1(159) to revise the definition of "Small quantity generator" and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment revises the definition of "Small quantity generator" to be consistent with the revised definition of "Small quantity generator" in 40 CFR §260.10. The revisions add the monthly quantities of acute hazardous waste generation that define the small quantity generator category.

The commission adopts amendments to §335.1(160)(A)(iv) to revise the definition of "Solid waste" by removing references to numbered paragraphs of 40 CFR §261.4(a), removing references to the CFR dated citations for 40 CFR §261.4 and §§261.39 - 261.41, and adding language clarifying that these CFR sections are adopted by

reference under §335.504 as described in the Section by Section Discussion for that section.

The commission adopts amendments to Figure: 30 TAC §335.1(154)(D)(iv) to rename the figure "Figure: 30 TAC §335.1(160)(D)(iv) (Table 1)" consistent with the renumbering of the paragraphs in §335.1, to revise the citations for Table 1 in renumbered §335.1(160)(D) and (D)(i) - (iv), and to revise the language in Footnote 2 of Table 1 to be consistent with the third column heading in 40 CFR §261.2(c)(4), Table 1.

The commission adopts amendments to §335.1(160)(N) to add a conditional exclusion from the definition of "Solid waste" for foundry sands that are an intended output or result from the iron and steel casting processes when such material is introduced into the stream of commerce, managed as an item of commercial value, including controlled use in a manner constituting disposal, and not managed as discarded material. This amendment formalizes existing state guidance.

The commission adopts amendments to §335.1(178)(E) to revise the definition of "Treatability study" to remove references to §335.69 and §335.78. Sections 335.69 and 335.78 are repealed as described in the Section by Section Discussion for these sections. Sections 335.69 and 335.78 contained statements clarifying the exemptions in 40 CFR §261.4(e) and (f) which are adopted by reference under §335.504. The exemption from permit requirements for treatability studies in §335.2(g) will not be impacted by this rulemaking and the reference to §335.2 is retained.

The commission adopts amendments to §335.1(186) to revise the definition of "Universal waste" by replacing the cross-reference to §335.261(b)(16)(F) with §335.261(b)(19)(F) to reflect the renumbering of the paragraphs in §335.261(b). The revision to §335.261(b) is adopted to conform with the adoption of federal revisions associated with the Aerosol Can Waste Rule as described in the Section by Section Discussion for that section.

The commission adopts amendments to §335.1(191) to revise the definition of "Used oil" by replacing the reference to "conditionally exempt small quantity generator" with "very small quantity generator" to conform with federal revisions associated with the adoption of the Hazardous Waste Generator Improvements Rule.

The commission adopts amendments to §335.1(192)(C) to revise the definition of "User of the electronic manifest system" by replacing the reference to §335.10 with references to 40 CFR §264.71(a)(2)(v) or §265.71(a)(2)(v). These federal sections are adopted by reference under §335.112 and §335.152 as described in the Section by Section Discussion for those sections. This revision makes the definition for "User of the electronic manifest system" consistent with the federal definition for "User of the electronic manifest system" in 40 CFR §260.10.

The commission adopts amendments to §335.1(193) to add the definition of "Very small quantity generator" and to adopt federal revisions associated with the Hazardous

Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The EPA changed the name of the lowest tier hazardous waste generator category from "conditionally exempt small quantity generator" to "very small quantity generator" in the Hazardous Waste Generator Improvements Rule. This amendment adds the definition of "Very small quantity generator" consistent with the new definition of "Very small quantity generator" in 40 CFR §260.10.

§335.2, Permit Required

The commission adopts amendments to §335.2(e) to replace "is a conditionally exempt small quantity generator as described in §335.78" with "meets the conditions for exemption for a very small quantity generator in 40 CFR §262.14" to conform with federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The conditions for exemption for a VSQG in 40 CFR §262.14 are adopted in §335.53(c) as described in the Section by Section Discussion for that section.

The commission adopts amendments to §335.2(f) and (g) to clarify that 40 CFR §261.4(c) - (f) are adopted under §335.504, and to remove the dated citation for 40 CFR §261.4(e) and (f) in §335.2(g). Revisions implementing 40 CFR §261.4 are described in the Section by Section Discussion for §335.504.

The commission adopts new §335.2(p) to add a new exemption from permit required and adopt federal revisions associated with the Pharmaceutical Waste Rule

promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission implements these revisions by adding language consistent with 40 CFR §270.1(c)(2)(x).

§335.6, Notification and Registration Requirements

The commission adopts the repeal of §335.6 and adopts new §335.6.

The commission adopts the requirements of repealed §335.6 under new §335.6 adding catch lines for quick reference of the subject matter of each subsection; retaining the subject matter addressed under each repealed subsection under the same new subsection with two exceptions; establishing notification requirements applicable to healthcare facilities under new Subchapter W; establishing registration requirements applicable to reverse distributers under new Subchapter W; and reorganizing and clarifying the requirements of repealed §335.6 as further described in the Section by Section Discussions for each subsection of §335.6.

The commission adopts new §335.6(a) to add the catch line "Notification of industrial solid waste and municipal hazardous waste activities not authorized by a permit"; adopt the requirements of repealed §335.6(a); to require notification to be made using a method approved by the executive director; reorganize requirements into new paragraphs (1) and (2) for clarity of the notification requirements; to not adopt the reference to §335.2(e); and to not adopt the large quantity generator notification requirements which are adopted in §335.6(c) as part of the reorganization of §335.6.

Additional information is described in the Section by Section Discussions for §335.6(c) and (e).

In response to comments, the commission adopts new §335.6(a) with changes from the proposed rule. The commission adopts new §335.6(a) with the catch line to clarify the scope of the subsection.

The commission adopts new §335.6(b) to add the catch line "Duty to notify of changed and new information"; adopt the requirements of repealed §335.6(b) except the notification requirements for large quantity generators which are reorganized under new §335.6(c); require persons to notify using a method approved by the executive director; and reorganize certain requirements of repealed §335.6(b) into new paragraphs (1) - (4) to provide additional clarification of renotification requirements. The notification requirements for large quantity generators as described in the Section by Section Discussion for §335.6(c).

The commission adopts new §335.6(c) to add the catch line "Generator registration"; adopt the requirements of repealed §335.6(c); reorganize the requirements into paragraphs, subparagraphs, and clauses; add the volumes of hazardous waste generated by a very small quantity generator and the volume of Class 1 industrial waste generated by a Class 1 industrial waste generator to describe the applicability of the notification requirements of this subsection; and to not adopt the quantity limits that described applicability of the notification requirements in repealed §335.78.

The commission adopts new §335.6(d) to add the catch line "Transporter registration"; adopt the requirements of repealed §335.6(d); require notification to be made using a method approved by the executive director; and to combine in one sentence the description of the maximum quantity of municipal hazardous waste and the descriptions of the maximum quantities of hazardous waste and Class 1 industrial waste that may be transported by the generator without registration being required.

The commission adopts new §335.6(e) to add the new catch line "Transfer facility registration"; adopt the requirements of repealed §335.6(e); and require notification to be made using a method approved by the executive director.

The commission adopts new §335.6(f) to add the catch line "Waste analysis"; adopt the requirements of repealed §335.6(f); and to require chemical analysis of a solid waste to be performed in accordance with Chapter 335, Subchapter R.

The commission adopts new §335.6(g) to add the catch line "Notification prior to facility expansion" and adopt the requirements of repealed §335.6(g).

The commission adopts new §335.6(h) to add the catch line "Notification of recycling activities"; adopt the requirements of repealed §335.6(h) except an obsolete reference to persons engaged in recycling prior to the effective date of §335.6; add recyclable materials and nonhazardous recyclable materials to the subject materials; require

notification to be made using a method approved by the executive director; and reorganize parts of repealed §335.6(h) into new paragraphs (1) and (2) to clarify recycling notification requirements.

The commission adopts new §335.6(i) to add the catch line "Notification of operating under the small quantity burner exemption" and adopt the requirements of repealed §335.6(i).

The commission adopts new §335.6(j) to add the catch line "Notification of used oil activities"; adopt the requirements of repealed §335.6(j) except the reference to CESQG hazardous used oil; and use the term VSQG to describe used oil generated by the lowest tier hazardous waste generator category to conform with the new definition of VSQG. Additional information is described in the Section by Section Discussion for the definition of VSQG in §335.1.

The commission does not adopt the references to the location of certain recycling requirements in Chapter 335 under repealed §335.6(k) because this information is repetitive of information provided in §335.24.

The commission adopts new §335.6(k) to include the catch line "Notification exemption for the disposal of animal carcasses" and adopt the provisions of repealed §335.6(l).

The commission adopts new §335.6(l) to establish the notification requirement for healthcare facilities operating under new Subchapter W of Chapter 335.

The commission adopts new §335.6(m) to establish the registration requirement for reverse distributors operating under new Subchapter W of Chapter 335.

§335.9, Recordkeeping and Annual Reporting Procedures Applicable to Generators

The commission adopts amendments to §335.9(a) to clarify the applicability of other recordkeeping and reporting requirements in this section.

The commission adopts amendments to §335.9(a)(1)(A) - (G) to clarify the applicability of Chapter 335, Subchapter R; replace the reference to the lowest hazardous waste generator category, "conditionally exempt small quantity generators"; describe the applicability of the requirement to report the amount of waste held in on-site storage at the end of the year with a description of the quantities of waste generated per month; and replace the reference to repealed §335.69(d) regarding hazardous waste accumulation areas at or near any point of generation with a reference to the satellite accumulation area regulations adopted under §335.53. Additional information is described in the Section by Section Discussion for §335.53 and §335.69.

The commission adopts amendments to §335.9(a)(2) to clarify the procedures for submitting an Annual Waste Summary and delete requirements adopted in subsequent reorganized paragraphs and subparagraphs.

The commission adopts amendments to §335.9(a)(2)(A) and (B) to clarify the applicability of an extension request and reorganize the requirements of §335.9(a)(2).

The commission adopts amendments to §335.9(a)(2)(C) to identify and reorganize the information required to be included in an Annual Waste Summary.

The commission adopts amendments to §335.9(a)(2)(D) to identify the requirement that large quantity generators submit the Annual Waste Summary electronically.

The commission adopts amendments to §335.9(a)(3) and (4) to clarify the applicability of the Annual Waste Summary by identifying the lowest hazardous waste generator category with the defined term, VSQG, requiring that a VSQG meet the conditions for exemption for a VSQG; adding a reference to §335.53; and removing a reference to repealed §335.78. Additional information is described in the Section by Section Discussion for adopted §335.53 and §335.78.

The commission adopts amendments to §335.9(b) to add a reference to the biennial reporting requirements in §335.56 and remove a reference to the biennial reporting requirements in repealed §335.71. Additional information is described in the Section by Section Discussion for adopted §335.56 and §335.71.

§335.10, Shipping and Reporting Procedures Applicable to Generators of Hazardous

Waste or Class 1 Waste

The commission adopts amendments to §335.10 to clarify the applicability of the use of the uniform hazardous waste manifest for the transportation of hazardous waste and for the transportation of industrial Class 1 waste; to add references to sections of this chapter where manifesting requirements are adopted; and to conform to adoption of the re-named lowest tier hazardous waste generator classification, VSQG.

The commission adopts amendments to §335.10(a) to establish manifesting requirements by requiring persons to comply with §§335.12, 335.13, 335.54 and §335.58; remove the adoption by reference of the Appendix to 40 CFR Part 262 which is repealed; and remove the adoption by reference of 40 CFR §§262.20 - 262.25, 262.27, 262.42, and 40 CFR Part 262, Subpart H which are adopted under new §335.54, and §335.58.

The commission adopts amendments to §335.10(a)(2) to clarify that manifesting is not required when the conditions for an applicable exemption from manifesting have been met; add new subparagraphs §335.10(a)(2)(A) and (B) to further clarify manifesting exemptions applicable to transporters of hazardous waste; and remove the reference to repealed §335.78.

The commission adopts amendments to §335.10(b) to retain the exception from manifesting requirements for the transportation of hazardous waste on a contiguous right of way and the reporting of discharges during such transportation by adding a

reference to requirements adopted in new §335.55 and removing a reference to repealed §335.67(b). Additional information is described in the Section by Section Discussion for §335.55 and §335.67.

The commission adopts amendments to §335.10(c) to add a reference to manifesting requirements adopted in new §335.54 and remove a reference to the manifesting requirements in subsection (a) of this section. Additional information is described in the Section by Section Discussion for §335.54.

The commission adopts amendments to §335.10(c)(1) and (2) to clarify manifest requirements for Class 1 waste by indicating that the TCEQ solid waste registration number or the EPA identification (ID) number may be used, adding the term of art designated facility and removing the term receiver.

The commission adopts amendments to §335.10(c)(3) - (7) clarifying the EPA ID number and Solid Waste Registration Number requirements when manifesting Class 1 waste and iterating changes to the federal manifesting rules applicable to the transportation of Class 1 waste in new paragraphs (1) through (7).

The commission adopts amendments to §335.10(d) to clarify the applicability of the exception from manifesting with the quantity limit for Class 1 waste and remove the reference to repealed §335.78.

The commission adopts amendments to §335.10(e) to clarify the applicability of specific exceptions from manifesting and reporting in new paragraphs (1) and (2), and clarify that the Annual Waste Summary is applicable to facilities that receive Class 1 industrial waste from off-site in new paragraph (3).

§335.11, Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste

The commission adopts the repeal of §335.11.

The commission adopts new §335.11(a) to incorporate by reference the manifest requirements of 40 CFR Part 263, Subpart B, including the revisions associated with the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420). The commission does not adopt the Appendix to 40 CFR Part 262 because EPA has repealed the Appendix.

The commission adopts new §335.11(b)(1) - (6) to clarify and establish applicability of the manifesting requirements for hazardous waste by indicating that the manifesting requirements adopted under §335.11(a), and the requirements in §§335.4, 335.6, 335.10, and 335.14 and Chapter 335, Subchapter D are applicable to persons who transport hazardous waste.

The commission adopts new §335.11(c) to clarify that the manifesting requirements for Class 1 waste are in §335.11(a); establish applicability for persons who transport Class 1 waste in new paragraphs §335.11(b)(1) - (6); and identify the changes to the

federal manifesting rules that are required for persons transporting Class 1 waste in new paragraphs §335.11(c)(1) - (8).

§335.12, Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities

The commission adopts amendments to §335.12(a) to clarify that 40 CFR Part 264, Subpart E is adopted in §335.152, 40 CFR Part 265, Subpart E is adopted in §335.112 and to remove the outdated citations for the appendix to 40 CFR Part 262 and for 40 CFR §264.71 and §265.71. The appendix to 40 CFR Part 262 was removed from federal regulations in the Electronic Manifest Fee Rule, and 40 CFR §264.71 and §265.71 are adopted in §335.112 and §335.152.

The commission adopts amendments to §335.12(b) clarifying that 40 CFR Part 264, Subpart E is adopted in §335.152; adding §335.12(b)(1) - (4) to clarify the use of federal manifesting requirements for Class 1 waste; and removing outdated references to 40 CFR §§264.71, 264.72, 264.76 and the Appendix to 40 CFR Part 262.

The commission adopts §335.12(c) to adopt by reference 40 CFR §260.4, a new federal requirement adopted in the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420) which implements manifest requirements applicable to designated facilities for interstate waste shipments.

The commission adopts §335.12(d) to adopt by reference 40 CFR §260.5, a new federal

requirement adopted in the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420) which clarifies the applicability of the electronic manifest system and fees for state-only regulated wastes.

§335.13, Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste

The commission adopts amendments to §335.13(a) to add a description of the quantities of hazardous waste that determine applicability and remove the reference to repealed §335.78 as part of the commission's implementation of the Hazardous Waste Generator Improvements Rule.

The commission adopts amendments to §335.13(b) and (c) to implement plain language clarifications.

The commission adopts amendments to §335.13(d) to clarify that the term registered generator means a generator with an active solid waste registration.

The commission adopts amendments to §335.13(e) organizing the conjunctive elements that describe an unregistered generator into three paragraphs, §335.13(e)(1) - (3); adding the quantities of waste generated; removing the reference to repealed §335.78; and clarifying that the term unregistered generator means an in-state generator that does not have an active solid waste registration.

In response to comments, the commission adopts amendments to §335.13(e)(3) that differ from the proposed rule. The adopted amendments clarify that the executive director assigns the four-character sequence number of the eight-digit Texas waste code when an unregistered generator requests a temporary Texas waste code for the shipment of hazardous waste and/or Class 1 industrial waste.

The commission adopts amendments to §335.13(f) to require generators to comply with the manifest and recordkeeping requirements in §335.10 and remove manifesting records retention requirements adopted in new §335.56 as part of the commission's implementation of the Hazardous Waste Generator Improvements Rule and the Electronic Manifest Fee Rule.

The commission adopts amendments to §335.13(g) - (i) to remove paragraphs (g) through (i), that contained manifesting requirements adopted in §335.56.

The commission adopts amendments to §335.13(j) to remove the reference to subsection (j) which required generators to comply with §335.12 and the hazardous waste import and export requirements in repealed §335.76. Generators are still required to comply with §335.12 and the hazardous waste import and export requirements are adopted in new §335.52(c).

§335.14, Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste

The commission adopts the repeal of §335.14 to remove manifest and recordkeeping requirements applicable to transporters of hazardous and Class 1 wastes that are adopted in §335.11 and in new §335.14.

The commission adopts new §335.14 to clarify which manifest and recordkeeping requirements are applicable to transporters of hazardous and Class 1 wastes.

§335.15, Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities

The commission adopts amendments to §335.15 to clarify the applicability of the section in implied subsection (a) and add catch lines to each of the paragraphs.

The commission adopts amendments to §335.15(1) to clarify the manifest requirements applicable to owners and operators of treatment, storage, or disposal facilities and delete the reference to "primary exporter" because the term "primary exporter" was removed from 30 TAC Chapter 335, June 5, 2020 (45 TexReg 3773).

The commission adopts amendments to §335.15(2) to clarify the Monthly Waste Receipt Summary requirements by reorganizing and rewording the requirements in new subparagraphs (A) - (D).

The commission adopts amendments to §335.15(3) to clarify the Unmanifested waste report requirements by reorganizing and rewording the requirements in

subparagraphs (A) and (B)

The commission adopts amendments to §335.15(6) to clarify the applicability of monthly waste receipt summary requirements by adding the term "very small quantity generator" and removing the term "conditionally exempt small quantity generator."

The commission adopts amendments to §335.15(7) to clarify the method by which the biennial report is submitted; clarify that information submitted by permitted or interim status facilities under Subchapter A of Chapter 335 is not required to be submitted in a biennial report; and add references to the adoption by reference of 40 CFR §264.75 and §265.75 in §335.112 and §335.152.

The commission adopts amendments to §335.15(8) to clarify the reporting requirements applicable to facilities that receive Class 1 industrial waste from off-site in a new paragraph.

§335.18, Non-Waste Determinations and Variances from Classification as a Solid Waste

The commission adopts amendments to §335.18(a)(6) to remove the exemption for hazardous secondary materials transferred to a verified-reclamation facility or intermediate facility where the management of hazardous secondary materials is not addressed under a RCRA Part B permit or interim status standards. This amendment implements the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018 which voided the verified-

reclamation exclusion and reinstated the transfer based exclusion, and conforms to the removal of 40 CFR §260.30(f) associated with the Definition of Solid Waste Rule promulgated in the *Federal Register* on May 30, 2018 (83 FR 24664).

§335.19, Standards and Criteria for Variances from Classification as a Solid Waste

The commission adopts amendments to §335.19(d) to remove the variance and variance criteria for hazardous secondary materials transferred to a verified-reclamation facility or intermediate facility where the management of hazardous secondary materials is not addressed under a RCRA Part B permit or interim status standards and renumbers the subsequent subsections. This amendment implements vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018 which voided the verified-reclamation exclusion, and conforms to the removal of 40 CFR §260.31(d) associated with the Definition of Solid Waste Rule promulgated in the *Federal Register* on May 30, 2018 (83 FR 24664).

§335.24, Requirements for Recyclable Materials and Nonhazardous Recyclable Materials

The commission adopts amendments to §335.24(b) to clarify that Subchapter A is applicable to recyclable materials.

The commission adopts amendments to §335.24(c)(1) to add a reference to §335.58, the new adoption by reference of 40 Code CFR Part 262, Subpart H, and remove adoption by reference of citation for 40 CFR Part 262, Subpart H from subsection (c).

The commission adopts amendments to §335.24(c)(2) to clarify that 40 CFR §261.4(a)(13) is adopted by reference under §335.504.

The commission adopts amendments to §335.24(c)(3) to remove the dated citation for 40 CFR §261.4(a)(12) and to clarify that the federal requirements is adopted by reference under §335.504.

The commission adopts amendments to §335.24(d) to clarify the applicability of Chapter 335, Subchapters A and R to generators and transporters of recyclable materials.

The commission adopts amendments to §335.24(f)(3) and (4) to require owners or operators of recycling facilities that do not store recyclable materials before recycling to comply with the monthly waste summary report requirements in §335.15 and clarify that such owners and operators are subject to the biennial reporting requirements of 40 CFR §264.75 or §265.75. These amendments conform with 40 CFR §261.6(c)(2)(iv) added to federal regulations in the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). Owners or operators of recycling facilities that do not store recyclable materials before recycling are subject to the biennial reporting requirements of 40 CFR §264.75 or §265.75, and the monthly waste summary report requirements in §335.15 fulfill the federal biennial reporting requirements.

The commission adopts amendments to §335.24(o) to add that 40 CFR Part 262, Subpart H is adopted by reference under §335.58 and remove the dated citation for the Subpart.

The commission adopts amendments to §335.24(p) to add references to §335.26, §335.27, and Chapter 335, Subchapter V to clarify that hazardous secondary materials requirements relate to solid waste recycling.

§335.26, Notification Requirements for Hazardous Secondary Materials

The commission adopts amendments to §335.26 to adopt by reference revisions associated with the Definition of Solid Waste Rule published in the May 30, 2018 issue of the *Federal Register* (83 FR 24664) by updating the federal citation for to 40 CFR §260.42. This revision is a consequence of the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018 which voided the verified-reclamation exclusion.

§335.27, Legitimate Recycling of Hazardous Secondary Materials

The commission adopts amendments to §335.27 to adopt by reference revisions associated with the Definition of Solid Waste Rule published in the May 30, 2018, issue of the *Federal Register* (83 FR 24664) by updating the federal citation for 40 CFR §260.43. This revision is a consequence of the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6,

2018.

§335.31, Incorporation of References

The commission adopts amendments to §335.31 to adopt by reference federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by updating the federal citation for 40 CFR §260.11. Specifically, the language in 40 CFR §260.11(d)(1) was modified in the Hazardous Waste Generator Improvements Rule.

Subchapter B: Hazardous Waste Management General Provisions

§335.41, Purpose, Scope and Applicability

The commission adopts amendments to §335.41(d)(4) to replace the reference to §335.77 with 40 CFR §262.70 adopted under new §335.57 as described in the Section by Section Discussion for that section.

The commission adopts amendments to §335.41(d)(9) to establish that Chapter 335, Subchapters E and F are not applicable to the owner or operator of an authorized municipal or industrial waste facility when the only hazardous waste managed at the facility is generated by a VSQG and excluded from regulation. This amendment will adopt revisions in 40 CFR §264.1(g)(1) and §265.1(c)(5) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

The commission adopts amendments to §335.41(d)(10) to establish that Chapter 335, Subchapters E and F are not applicable to a generator accumulating waste on-site in compliance with a condition for exemption adopted under §335.53. This amendment will adopt certain revisions in 40 CFR §264.1(g)(3) and §265.1(c)(7) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

The commission adopts amendments to §335.41(d)(11) to establish that Chapter 335, Subchapters E and F are not applicable to reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals in compliance with adopted new Subchapter W. This amendment will adopt revisions in 40 CFR §264.1(g)(13) and §265.1(c)(16) associated with the Pharmaceutical Waste Rule and promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816).

The commission adopts amendments to §335.41(e)(1) by replacing the reference to §335.78 with the new term for the lowest hazardous waste generator category, "very small quantity generator", and language making the exception from applicability of Chapter 335, Subchapter E dependent upon the VSQG meeting the conditions for exemption in 40 CFR §262.14 which is adopted under §335.53. The definition of VSQG is adopted under §335.1 as described in the Section by Section Discussion for that definition. This adopted amendment will implement the adoption of the Hazardous Waste Generator Improvements Rule as further described in the Section by Section

Discussion for §335.53.

The commission adopts amendments to §335.41(e)(2) to add an exception from applicability of Chapter 335, Subchapter E for generators accumulating hazardous waste on-site in compliance with conditions for exemption for eligible academic entities and episodic generation. This amendment will adopt revisions in 40 CFR §265.1(c)(7) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The existing provision in §335.41(e)(2) is deleted because it is duplicative of language adopted in §335.41(d)(9).

The commission adopts §335.41(f)(2)(D) to establish applicability of the adoption of requirements for residues of hazardous waste pharmaceuticals under the requirements for residues of hazardous waste in containers. This amendment will adopt revisions in 40 CFR §261.7(c) associated with the Pharmaceutical Waste Rule and promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816).

§335.46, Sharing of Information

The commission adopts §335.46(b) to adopt by reference 40 CFR §260.2(c) as amended in the federal Electronic Manifest Rule which was promulgated in the *Federal Register* on February 7, 2014 (79 FR 7518).

The commission adopts §335.46(c) to adopt by reference 40 CFR §260.2(d) as adopted

in the federal Export and Import Confidentiality Rule which was promulgated in the *Federal Register* on December 26, 2017 (82 FR 60894).

Subchapter C: Standards Applicable to Generators of Hazardous Waste

§335.51, Definitions

The commission adopts new §335.51(1) to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by adopting the definition of "Condition for exemption" consistent with the new definition of "Condition for exemption" in 40 CFR §262.1. If the conditions for exemption are not met, then the generator is subject to the permitting or interim facility regulations in Chapter 335, Subchapters E and F.

The commission adopts new §335.51(2) to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by adopting the definition of "Independent requirement" consistent with the new definition of "Independent requirement" in 40 CFR §262.1. All hazardous waste generators must comply with the independent requirements of 40 CFR Part 262, as adopted by reference under this subchapter.

§335.52, Purpose, Scope, and Applicability

The commission adopts new §335.52(a) to establish the purpose scope and applicability of Chapter 335, Subchapter C; conform with revisions to 40 CFR §262.10 associated with the Hazardous Waste Generator Improvements Rule promulgated in

the *Federal Register* on November 28, 2016 (81 FR 85732) and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816); and to require persons who import hazardous waste into the state to comply with the generator regulations in Chapter 335, Subchapter A because this requirement under §335.61 is repealed.

The commission adopts new §335.52(a)(1) to identify the independent requirements applicable to hazardous waste generators based on generator category and correspond with 40 CFR §262.10(a)(1).

The commission adopts new §335.52(a)(2) to identify the conditions for exemption for VSQGs, small quantity generators, and large quantity generators and correspond with 40 CFR §262.10(a)(2).

The commission adopts new §335.52(b) to identify the requirement for hazardous waste generators to conduct a generator category determination and correspond with 40 CFR §262.10(b).

The commission adopts new §335.52(c) to identify the provisions applicable to hazardous waste exporters or importers and correspond with 40 CFR §262.10(d).

The commission adopts new §335.52(d) to establish the applicability of this chapter to hazardous waste importers and correspond with 40 CFR §262.10(e).

The commission adopts new §335.52(e) to identify the provisions applicable to farmers that generate hazardous waste pesticides and correspond with 40 CFR §262.10(f).

The commission adopts new §335.52(f) to identify the consequences applicable to hazardous waste generators that violate an independent requirement or fail to comply with a condition for exemption and correspond with 40 CFR §262.10(g).

The commission adopts new §335.52(g) to identify the applicability of this subchapter to owners or operators of treatment, storage, or disposal facilities shipping hazardous wastes and correspond with 40 CFR §262.10(h).

The commission adopts new §335.52(h) to identify the exemption from this subchapter for a person responding to an explosives or munitions emergency and correspond with 40 CFR §262.10(i).

The commission adopts new §335.52(i) to identify exclusions applicable to laboratories owned by eligible academic entities and correspond with 40 CFR §262.10(l).

The commission adopts new §335.52(j) to identify the exemption for reverse distributors from this subchapter and correspond with 40 CFR §262.10(m).

The commission adopts new §335.52(k) to identify the exemption from this

subchapter for healthcare facilities that are not VSQGs, and to clarify the provisions of this subchapter applicable to healthcare facilities that are VSQGs and correspond with 40 CFR §262.10(n).

§335.53, General Standards Applicable to Generators of Hazardous Waste

The commission adopts new §335.53 to adopt by reference the federal regulations in 40 CFR §§262.11 - 262.18 as described further in this preamble.

The commission adopts new §335.53(a) to adopt by reference new 40 CFR §262.11(e) - (g) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state requirement to conduct a hazardous waste determination in repealed §335.62 is replaced by this section. The remainder of revised 40 CFR §262.11 is adopted in §335.504, as described in the Section by Section Discussion for that section.

The commission adopts new §335.53(b) to adopt by reference new 40 CFR §262.13 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The exclusion for hazardous wastes from the generator category determination in repealed §335.78(c) and (d) is replaced by this section.

The commission adopts new §335.53(c) to adopt by reference new 40 CFR §262.14

associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The state provisions for conditionally exempt small quantity generators (the term was replaced in the Hazardous Waste Generator Improvements Rule with "very small quantity generator") in repealed §335.78 are replaced by this section.

The commission adopts new §335.53(d) to adopt by reference new 40 CFR §262.15 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provisions for satellite accumulation in repealed §335.69(d) and (e) are replaced by this section.

The commission adopts new §335.53(e) to adopt by reference new 40 CFR §262.16 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provisions for small quantity generators in repealed §335.69(f) - (h) are replaced by this section.

The commission adopts new §335.53(f) to adopt by reference new 40 CFR §262.17 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provisions for large quantity generators in repealed §335.69(a) - (b) and (j) - (l) are replaced by this section.

The commission adopts new §335.53(g) to adopt by reference new 40 CFR §262.18 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provision for the EPA identification number requirement in repealed §335.63 is replaced by this section.

§335.54, Hazardous Waste Manifest

The commission adopts new §335.54 to adopt by reference federal regulations in 40 CFR Part 262, Subpart B and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420). This section will establish manifest requirements for generators. This section will replace the adoption of sections in 40 CFR Part 262, Subpart B previously in §335.10 so that the federal provisions are adopted only once in Chapter 335.

§335.55, Pre-transport Requirements Applicable to Small and Large Quantity Generators

The commission adopts new §335.55 to adopt by reference federal regulations in 40 CFR Part 262, Subpart C, and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section will establish the pre-transport requirements for small and large quantity generators of hazardous waste and will replace repealed

§§335.65 - 335.68.

§335.56, Recordkeeping and Reporting Applicable to Small and Large Quantity Generators

The commission adopts new §335.56 to adopt by reference federal regulations in 40 CFR Part 262, Subpart D and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section will establish the recordkeeping and reporting requirements for small and large quantity generators of hazardous waste. This federal language was previously adopted in repealed §§335.13(g) - (i), 335.70, 335.71, 335.73, and 335.74.

§335.57, Farmers

The commission adopts new §335.57 to adopt by reference federal regulations in 40 CFR Part 262, Subpart G and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section will establish the requirements for farmers disposing of hazardous waste pesticides and will replace repealed §335.77.

§335.58, Transboundary Movements of Hazardous Waste for Recovery or Disposal

The commission adopts new §335.58 to adopt by reference federal regulations in 40 CFR Part 262, Subpart H and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November

28, 2016 (81 FR 85732), and the Export and Import Confidentiality Rule promulgated in the *Federal Register* on December 26, 2017 (82 FR 60894), and amended in the *Federal Register* on August 6, 2018 (83 FR 38262). This section will establish the requirements for transboundary movements of hazardous waste and will reorganize the adoption by reference in repealed §335.76.

§335.59, Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

The commission adopts new §335.59 to adopt by reference federal regulations in 40 CFR Part 262, Subpart K and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section will establish the alternative requirements for laboratories owned by eligible academic entities and will replace repealed §335.79.

§335.60, Alternative Standards for Episodic Generation

The commission adopts new §335.60 to adopt by reference new federal regulations in 40 CFR Part 262, Subpart L and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section will establish requirements for alternative standards for episodic generation of hazardous waste applicable to VSQGs and small quantity generators.

§335.61, Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators

The commission adopts new §335.61 to adopt by reference new federal regulations in 40 CFR Part 262, Subpart M and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This new federal subpart was established to repeat the requirements in 40 CFR Part 265, Subparts C and D applicable to large quantity generators of hazardous waste in 40 CFR Part 262. 40 CFR Part 265, Subparts C and D remain adopted by reference in §335.112.

Repealed Subchapter C: Standards Applicable to Generators of Hazardous Waste

§335.61, Purpose, Scope and Applicability

The commission adopts the repeal of current §335.61. This section is replaced by adopted new §335.52 as described in the Section by Section Discussion for that section.

§335.62, Hazardous Waste Determination and Waste Classification

The commission adopts the repeal of §335.62. This section is replaced by adopted new §335.53 as described in the Section by Section Discussion for that section.

§335.63, EPA Identification Numbers

The commission adopts the repeal of §335.63. This section is replaced by adopted new §335.53 as described in the Section by Section Discussion for that section.

§335.65, Packaging

The commission adopts the repeal of §335.65. This section is replaced by adopted new §335.55 as described in the Section by Section Discussion for that section.

§335.66, Labeling

The commission adopts the repeal of §335.66. This section is replaced by adopted new §335.55 as described in the Section by Section Discussion for that section.

§335.67, Marking

The commission adopts the repeal of §335.67. This section is replaced by adopted new §335.55 as described in the Section by Section Discussion for that section.

§335.68, Placarding

The commission adopts the repeal of §335.68. This section is replaced by adopted new §335.55 as described in the Section by Section Discussion for that section.

§335.69, Accumulation Time

The commission adopts the repeal of §335.69. This section is replaced by adopted new §335.53 as described in the Section by Section Discussion for that section.

§335.70, Recordkeeping

The commission adopts the repeal of §335.70. This section is replaced by adopted new

§335.56 as described in the Section by Section Discussion for that section.

§335.71, Biennial Reporting

The commission adopts the repeal of §335.71. This section is replaced by adopted new §335.56 as described in the Section by Section Discussion for that section.

§335.73, Additional Reporting

The commission adopts the repeal of §335.73. This section is replaced by adopted new §335.56 as described in the Section by Section Discussion for that section.

§335.74, Special Requirements for Generators of Between 100 and 1,000 Kilograms per Month

The commission adopts the repeal of §335.74. This section is replaced by adopted new §335.56 as described in the Section by Section Discussion for that section.

§335.75, Notification Requirements for Interstate Shipments

The commission adopts the repeal of §335.75. This section is duplicative of requirements in §335.13 as described in the Section by Section Discussion for that section.

§335.76, Additional Requirements Applicable to International Shipments

The commission adopts the repeal of §335.76. This section is replaced by adopted new §335.58 as described in the Section by Section Discussion for that section.

§335.77, Farmers

The commission adopts the repeal of §335.77. This section is replaced by adopted new §335.57 as described in the Section by Section Discussion for that section.

§335.78, Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators

The commission adopts the repeal of §335.78. This section is replaced by adopted new §335.52 and §335.53 as described in the Section by Section Discussions for those sections.

§335.79, Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

The commission adopts the repeal of §335.79. This section is replaced by adopted new §335.59 as described in the Section by Section Discussion for that section.

Subchapter D, Standards Applicable to Transporters of Hazardous Waste

§335.91, Scope

The commission adopts amendments to §335.91(a) to implement plain language clarifications.

The commission adopts amendments to §335.91(c) to clarify additional sections and

subchapters applicable to hazardous waste transporters.

The commission adopts amendments to §335.91(e) to remove the dated citation for 40 CFR Part 262, Subpart H and to clarify that 40 CFR Part 262, Subpart H, 40 CFR §262.83(d), and 40 CFR §262.84(d) is adopted by reference under new §335.58.

§335.94, Transfer Facility Requirements

The commission adopts amendments to §335.94(a) to add the term "independent requirements", and replace the reference to repealed §335.65 with 40 CFR §262.30 as adopted under §335.55.

The commission adopts amendments to §335.94(c) to adopt the language added to 40 CFR §263.12(b) in the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

Subchapter E: Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities

§335.112, Standards

The commission adopts amendments to §335.112 to adopt by reference revisions associated with the adoption of the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission adopts these revisions by updating the federal citations for 40 CFR Part 265, Subparts B, E, I, J, AA, BB, and DD in §335.112(a)(1), (4), (8), (9), (19), (20), and (22)

respectively.

The commission adopts amendments to §335.112(a)(4) to adopt revisions associated with the Electronic Manifest Fee Rule by updating the federal citation for 40 CFR Part 265 Subpart E, and revising the list of CFR sections excepted from the adoption of 40 CFR Part 265, Subpart E.

The commission adopts amendments to §335.112(a)(7) to correct a typographical error by replacing the incorrect citation 40 CFR §264.146 with 40 CFR §265.146.

The commission adopts amendments to §335.112(a)(21) to adopt revisions associated with the Electronic Manifest Fee Rule by updating the federal citation for 40 CFR Part 265, Subpart CC.

The commission adopts §335.112(a)(24) to adopt revisions associated with the Electronic Manifest Fee Rule by adopting by reference 40 CFR Part 265, Subpart FF and renumbering the subsequent paragraphs.

The commission adopts amendments to §335.112(b) to adopt revisions associated with the Electronic Manifest Fee Rule by adding exception language clarifying that the changes listed in subsection (b) do not apply to the use of the manifest system requirements under 40 CFR §265.71 or the fees for the electronic hazardous waste manifest program requirements under 40 CFR Part 265, Subpart FF.

The commission additionally adopts amendments to §335.112(b)(7) to adopt revisions associated with the Electronic Manifest Fee Rule by removing 40 CFR §265.71 and §265.72 from the list of CFR sections that when referenced in regulations adopted by reference under this section must be substituted with references to sections in Chapter 335.

The commission adopts amendments to §335.112(c) because the necessity and practice of maintaining and making available to the public on demand an up-to-date physical copy of the CFR has been superseded by the CFR being maintained accessible and available to the public on the internet.

Subchapter F: Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities

§335.152, Standards

The commission adopts amendments to §335.152 to adopt by reference the changes associated with the adoption of the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission adopts these revisions by updating the federal citations for 40 CFR Part 264, Subparts B, E, I, J, AA, BB, and DD in §335.152(a)(1), (4), (7), (8), (17), (18), and (20) respectively.

The commission adopts amendments to §335.152(a)(4) to adopt revisions associated

with the Electronic Manifest Fee Rule by updating the federal citation for 40 CFR Part 264, Subpart E, and revising the list of CFR sections excepted from the adoption of 40 CFR Part 264, Subpart E.

The commission adopts amendments to §335.152(a)(4) and (19) and add §335.152(a)(22) to adopt by reference revisions associated with the Electronic Manifest Fee rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420). The commission adopts these revisions by updating the federal citation for 40 CFR Part 264, Subpart CC; adding new 40 CFR Part 264, Subpart FF as §335.152(a)(22); and renumbering the subsequent paragraph.

The commission adopts amendments to §335.152(c) to clarify that the changes listed in subsection (c) do not apply to the state adoption of 40 CFR §264.71 or 40 CFR Part 264, Subpart FF, and amended §335.152(c)(7) to remove 40 CFR §264.71 and §264.72 from the list of CFR references that are changed to references in Chapter 335.

The commission adopts amendments to §335.152(b) to delete the last sentence, and amendments to delete the entirety of §335.152(d), because the necessity and practice of maintaining and making available to the public on demand an up-to-date physical copy of the CFR has been superseded by the CFR being maintained accessible and available to the public on the internet.

Subchapter H: Standards for the Management of Specific Wastes and Specific Types of

Facilities

Division 2: Hazardous Waste Burned for Energy Recovery

§335.221, Applicability and Standards

The commission adopts amendments to §335.221(a)(19) to remove and replace the reference to §335.78 with the phrase "generated by a very small quantity generator" in order to conform with federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The definition for VSQG is adopted in §335.1 as described in the Section by Section Discussion for that definition.

The commission adopts amendments to §335.221(b) to remove and replace references to §335.78 and the term "conditionally exempt small quantity generator." In §335.221(b)(1), "conditionally exempt small quantity generator" is replaced with the phrase "a generator that meets the conditions for exemption for a very small quantity generator during the calendar month in which the hazardous waste was generated." The language in previous §335.221(b)(2) is separated into revised paragraph (2) and new paragraph (3), and the subsequent paragraphs are renumbered. Adopted §335.221(b)(3) replaces the references to CESQGs and §335.78 with VSQGs.

Division 3: Recyclable Materials Utilized for Precious Metal Recovery

§335.241, Applicability and Requirements

The commission adopts amendments to §335.241(b)(3) to add references to the hazardous waste manifest requirements adopted in new §335.54 and in amended

§335.112 and §335.152; change the titles of amended §335.10 and amended §335.11 in references to these sections by deleting the terms "Industrial" and "Solid" to conform to the use of the term “Class 1”; remove discontinued term “designated OECD member countries”; add a reference to import export requirements adopted in amended §335.152; and to remove import export requirements to conform with the adoption of these requirements under new §335.54 and amended §335.112. These changes are described further in the Section by Section Discussion for each section identified.

The commission adopts amendments to §335.241(b)(4) to incorporate federal revisions associated with the Imports and Exports of Hazardous Waste Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85696) by revising the language in §335.241(b)(4) to be consistent with the federal language in 40 CFR §266.70(b)(3). The Imports and Exports of Hazardous Waste Rule was adopted June 5, 2020 (45 TexReg 3773), however §335.241 was not opened and revised at that time. The commission adopts further amendments to §335.241(b)(4) to remove the reference to repealed §335.76 and clarify that new §335.58 applies to exports and imports of precious metals for recovery.

Division 4: Spent Lead-Acid Batteries Being Reclaimed

§335.251, Applicability and Requirements

The commission adopts amendments to §335.251(a) to adopt by reference the revisions associated with the Hazardous Waste Generator Improvements Rule

promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by updating the *Federal Register* citation for 40 CFR Part 266, Subpart G.

The commission adopts amendments to §335.251(c) and (e) - (g) to replace references to repealed §335.63 with new §335.53 as described in the Section by Section Discussion for those sections.

Division 5: Universal Waste Rule

§335.261, Universal Waste Rule

The commission adopts revisions to the universal waste regulations, as described in the Section by Section Discussion for this section, to add aerosol cans to the list of hazardous waste recognized as universal waste.

The commission adopts amendments to §335.261(a) to update the *Federal Register* citation for 40 CFR Part 273 to adopt by reference revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816), and the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202).

The commission adopts amendments to §335.261(b)(4) to replace the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission adopts amendments to §335.261(b)(8) to replace the reference to §335.77 with adopted new §335.57 as described in the Section by Section Discussion for those sections.

The commission adopts amendments to §335.261(b)(12) to replace the citation to §335.261(b)(16)(E) with §335.261(b)(19)(E) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission adopts amendments to §335.261(b)(14) - (16) to conform with revisions associated with the Aerosol Can Waste Rule by adding references to Chapter 335 instead of reference to 40 CFR Part 261, adding a reference to §335.41(f) instead of 40 CFR §261.7 and renumbering the subsequent paragraphs.

The commission adopts amendments to renumbered §335.261(b)(17) to replace the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission adopts further amendments to renumbered §335.261(b)(17) to add that 40 CFR §261.4(b)(1) is changed to both §335.1 and §335.402(5). The reference to §335.402(5) was mistakenly listed in renumbered §335.261(b)(18).

The commission adopts amendments to renumbered §335.261(b)(18) to replace the

reference to 40 CFR §261.5 with 40 CFR §262.14 to conform with revised 40 CFR §273.8 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). Additionally, the commission adopts amendments to renumbered §335.261(b)(18) by replacing the reference to repealed §335.78 with new §335.53 as described in the Section by Section Discussion for those sections, and by replacing the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule and the renumbering of paragraphs in this subsection.

The commission adopts further amendments to renumbered §335.261(b)(18) to remove the reference to §335.402(5).

The commission adopts §335.261(b)(19)(F)(vi) to implement revisions associated with the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202). This revision will add aerosol cans to the list of hazardous wastes recognized as a universal waste regulated under this division.

The commission adopts amendments to renumbered §335.261(b)(20) to replace the citation to §335.261(b)(16)(D) with §335.261(b)(19)(D) to conform with revisions associated with the Aerosol Can Waste Rule and the renumbering of paragraphs in this subsection.

The commission adopts amendments to renumbered §335.261(b)(23) to implement

revisions associated with the Aerosol Can Waste Rule by replacing the reference to "40 CFR §262.34" with "40 CFR parts 260 through 272" to correspond with revised 40 CFR §273.13, and by replacing the reference to repealed §335.69 with Chapter 335.

The commission adopts §335.261(b)(25) and (26) to conform with revisions associated with the Aerosol Can Waste Rule by adding references to §335.53 instead of the references to 40 CFR §§262.11 and 262.14 - 262.17; adding a reference to Chapter 335 instead of the reference to 40 CFR Parts 260 - 272; and renumbering the subsequent paragraphs.

The commission adopts amendments to renumbered §335.261(b)(28) to replace the citation to §335.261(b)(16)(C) with §335.261(b)(19)(C) to conform with revisions associated with the Aerosol Can Waste Rule and renumbering the subsequent paragraphs.

The commission adopts amendments to renumbered §335.261(b)(31) to implement revisions associated with the Aerosol Can Waste Rule by replacing the reference to "40 CFR §262.34" with "40 CFR parts 260 through 272" to correspond with revised 40 CFR §273.33, and by replacing the reference to repealed §335.69 with Chapter 335.

The commission adopts §335.261(b)(35) and (36) to conform with revisions associated with the Aerosol Can Waste Rule by adding references to §335.53 instead of the reference to 40 CFR §§262.11 or 262.14 - 262.17, and reference to Chapter 335 instead

of the reference to 40 CFR Parts 260 - 272, and renumbering the subsequent paragraphs.

The commission adopts amendments to renumbered §335.261(b)(41) to replace the citation to §335.261(b)(16)(A) with §335.261(b)(19)(A) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission adopts amendments to renumbered §335.261(b)(45) to replace the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission adopts amendments to §335.261(c) to implement revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts language consistent with 40 CFR §273.80(a).

The commission adopts §335.261(c)(4) to implement revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts language consistent with 40 CFR §273.80(d). Specifically, the EPA added 40 CFR §273.80(d) to exclude hazardous waste pharmaceuticals from being added as a universal waste category.

Division 6: Military Munitions

§335.272, Standards.

The commission adopts amendments to §335.272(b)(6) to replace the reference to repealed §335.61(h) with new §335.52 as described in the Section by Section Discussion for those sections.

The commission adopts amendments to §335.272(b)(7) to replace the section title for §335.91, which was incorrectly identified as "Standards Applicable to Transporters of Hazardous Waste", the title for Chapter 335, Subchapter D.

Since proposal, the commission adopts amendments to §335.272(b)(9) replacing a citation to §335.402 with a citation to §35.402 to correct a typographical error.

Subchapter O: Land Disposal Restrictions

§335.431, Purpose, Scope, and Applicability

The commission adopts amendments to §335.431(c)(1) to adopt by reference revisions to 40 CFR Part 268 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). Specifically, the EPA amended 40 CFR §§268.1, 268.7, and 268.50 in the Hazardous Waste Generator Improvements Rule.

The commission adopts further amendments to §335.431(c)(1) to adopt by reference revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these revisions by

amending the *Federal Register* citation for 40 CFR Part 268. Specifically, the EPA amended the section heading in 40 CFR §268.7 and the subject heading in 40 CFR §268.7(a) to include reverse distributors. The EPA also added 40 CFR §268.50(a)(4) and (5) to clarify that healthcare facilities and reverse distributors that meet certain conditions are not subject to the prohibition of storage of hazardous wastes restricted from land disposal under the RCRA.

The commission adopts amendments to §335.431(d)(5) to replace the federal citation for 40 CFR §262.34 with 40 CFR §262.16 and §262.17 consistent with the revised language in 40 CFR §268.50(a)(1), and replace the reference to repealed §335.69 with new §335.53 as described in the Section by Section Discussion for that section.

The commission adopts §335.431(d)(6) and (7) to conform with revisions associated with the Pharmaceutical Waste Rule by adding state replacement references for the new federal language.

Subchapter Q: Pollution Prevention: Source Reduction and Waste Minimization

§335.471, Definitions

The commission adopts amendments to §335.471(1) to remove the definition of “Acute hazardous waste” and renumber the subsequent paragraphs. A new definition of "Acute hazardous waste" is adopted in §335.1(6) as further described in the Section by Section Discussion for that section.

The commission adopts amendments to §335.471(3) to remove the definition of "Conditionally exempt small quantity generator" and renumber the subsequent paragraphs. The EPA renamed the generator classification "conditionally exempt small quantity generator" as "very small quantity generator" in the Hazardous Waste Generator Improvements Rule, and definitions for "conditionally exempt small quantity generator" and "very small quantity generator" are adopted in §335.1(38) and (193) respectively as further described in the Section by Section Discussions for that section.

The commission adopts amendments to §335.471(5) to remove the definition of "Environmental management system" and renumber the subsequent paragraphs. The definition for "Environmental management system" is no longer needed due to the adopted deletion of §335.477(3) as described in the Section by Section Discussion for that section.

The commission adopts amendments to §335.471(8) to remove the definition of "Large quantity generator" and renumber the subsequent paragraphs. The definition for "Large quantity generator" is adopted in §335.1(105) as further described in the Section by Section Discussion for that section.

The commission adopts amendments to §335.471(12) to remove the definition of " Small quantity generator" and renumber the subsequent paragraphs. The definition for "Small quantity generator" will no longer be needed in this subchapter due to the

expansion of the definition in §335.1(159) as further described in the Section by Section Discussion for that section.

§335.474, Pollution Prevention Plans

The commission adopts amendments to §335.474(1) to replace the citation for the definition of "Large quantity generators" in §335.471(8) with §335.1, and to remove the citation for the definition of "TRI Form R reporters" in §335.471(15).

The commission adopts amendments to §335.474(2) to replace the citation for the definition of "Small quantity generators" in §335.471(12) with §335.1, and to remove the citation for the definition of "TRI Form R reporters" in §335.471(15).

§335.477, Exemptions

The commission adopts amendments to §335.477(3) to delete the paragraph. The referenced section, 30 TAC §90.36, was repealed as published in the July 13, 2012 issue of the *Texas Register* (37 TexReg 5310).

Subchapter R: Waste Classification

§335.503, Waste Classification and Waste Coding Required

The commission adopts amendments to §335.503(a)(1) to clarify that hazardous waste and industrial solid waste are subject to this chapter.

The commission adopts amendments to §335.503(b) to clarify how an eight-digit waste

code number is assigned and the use of characters and digits in the waste code number.

The commission adopts amendments to §335.503(b)(1) to clarify that the first four characters of a waste code number which constitute the four-character sequence number may consist of numeric and or alpha characters.

The commission adopts amendments to §335.503(b)(2) to remove discontinued practice of assigning alphanumeric sequences codes for one-time shipments for registered generators. The executive director assigns alphanumeric sequences codes for one-time shipments for unregistered generators in accordance with §335.503(b)(3).

The commission adopts amendments to §335.503(b)(6) and (7) replacing references to CESQG with references to generators meeting the conditions for exemption for a VSQG in conformance with federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The definition for VSQG is adopted in §335.1 as described in the Section by Section Discussion for that definition.

The commission adopts amendments to §335.503(b)(6) and (7) to reflect changes to the first four characters of the waste code indicating that hazardous waste is generated by the lowest tier hazardous waste generator by replacing the four-character sequence number "CESQ" with the four-character sequence number "VSQG." The

commission intends to implement this change by allowing generators that are not required to transport waste with an accompanying hazardous waste manifest to use either the new four-character sequence number "VSQG" or to continue using the repealed four-character sequence number "CESQ" through December 31, 2024. The commission intends to require use of the sequence number "VSQG" beginning on January 1, 2025.

The commission adopts amendments to §335.503(b)(8) to implement plain language clarifications regarding the four-character sequence number “TSDF” as the first four characters of the waste code when shipping waste received from off-site, and to remove manifesting instructions adopted and reorganized under §335.54 and §335.12.

The commission adopts amendments to §335.503(b)(9) to add the requirement for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility to use the four-character sequence number "PHRM" as the first four characters of the waste code in conformance with changes associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816).

§335.504, Hazardous Waste Determination

The commission adopts amendments to §335.504 to label implied subsection (a) as subsection (a); add the catch line "Hazardous waste determination"; and add §335.504(a)(3)(A) and (B), (B)(i) and (ii), (b), and (c) to adopt certain requirements of 40

CFR §262.11 in narrative. These amendments adopt revisions to 40 CFR §262.11 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

The commission adopts amendments to §335.504(a)(1) to adopt by reference revisions to 40 CFR Part 261, Subpart A associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), the Definition of Solid Waste Rule promulgated in the *Federal Register* on May 30, 2018 (83 FR 24664), the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816), and the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202). The commission adopts these revisions by amending the *Federal Register* citation for 40 CFR Part 261, Subpart A.

The commission adopts amendments to §335.504(a)(1) to adopt by reference revisions to 40 CFR Part 261, Subpart E associated with the Export and Import Confidentiality Rule promulgated in the *Federal Register* on December 26, 2017 (82 FR 60894) and amended in the *Federal Register* on August 6, 2018 (83 FR 38262). The commission adopts these revisions by amending the *Federal Register* citation for 40 CFR Part 261, Subpart E.

The commission adopts amendments to §335.504(a)(2) to adopt revisions in the hazardous waste determination requirements of 40 CFR §262.11 and to adopt by

reference revisions to 40 CFR Part 261, Subpart D associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816), The commission adopts these revisions by amending the *Federal Register* citation for 40 CFR Part 261, Subpart D.

§335.510, Sampling Documentation

The commission adopts amendments to §335.510(a) to add the reference to 40 CFR §262.11(f) as adopted by reference at §335.53 to clarify the documentation required for generators to conform with revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

§335.511, Use of Process Knowledge

The commission adopts amendments to §335.511(a) to require generators to follow §335.504 when using process knowledge to classify hazardous waste and to add language specifying what constitutes acceptable process knowledge generators may use to classify nonhazardous industrial waste. These amendments will conform with revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

§335.513, Documentation Required

The commission adopts amendments to §335.513(a) to add the reference to 40 CFR

§262.11(f) as adopted by reference at §335.53 to the documentation required for generators to conform with revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

§335.521, Appendices

The commission adopts amendments to Figure 30 TAC §335.521(a)(2) to replace the word "non-hazardous" with "nonhazardous" for consistency with the rest of the chapter.

The commission adopts amendments to §335.521(b) to revise the name of the agency and the agency website.

Subchapter T: Permitting Standards for Owners and Operators of Commercial Industrial Nonhazardous Waste Landfill Facilities

§335.590, Operational and Design Standards

The commission adopts amendments to §335.590(25) to adopt revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission adopts these revisions by replacing references to CESQG with VSQG. The reference to repealed §335.78(a) is deleted.

Subchapter U: Standards for Owners and Operators of Hazardous Waste Facilities

Operating Under a Standard Permit

§335.602, Standards

The commission adopts amendments to §335.602(a)(4) to adopt by reference revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission adopts these revisions by amending the *Federal Register* citation for 40 CFR Part 267, Subpart E.

The commission adopts amendments to §335.602(b)(2)(I) to adopt by reference revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission adopts these revisions by replacing the reference to 40 CFR §262.34 with 40 CFR §262.16 or §262.17 in accordance with revisions to 40 CFR §267.71, and replacing the reference to repealed §335.69 with new §335.53, the section in which these federal regulations are adopted.

Subchapter V: Standards for Reclamation of Hazardous Secondary Materials

§335.702, Standards

The commission adopts amendments to §335.702(a)(3) to adopt by reference revisions to 40 CFR §261.420(g) associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), by adding a federal citation for 40 CFR Part 261, Subpart M.

§335.703, Financial Assurance Requirements

The commission adopts amendments to §335.703(c)(1) to adopt revisions associated with the Definition of Solid Waste Rule published in the May 30, 2018 issue of the *Federal Register* (83 FR 24664) by deleting the phrase "receiving a variance for."

Subchapter W: Management Standards for Hazardous Waste Pharmaceuticals

§335.751, Definitions

The commission adopts new §335.751 to adopt definitions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding definitions for the terms "Evaluated hazardous waste pharmaceutical", "Hazardous waste pharmaceutical", "Healthcare facility", "Household waste pharmaceutical", "Long-term care facility", "Non-creditable hazardous waste pharmaceutical", "Nonhazardous waste pharmaceutical", "Non-pharmaceutical hazardous waste", "Pharmaceutical", "Potentially creditable hazardous waste pharmaceutical", and "Reverse distributor", consistent with the definitions in 40 CFR §266.500.

§335.753, Applicability

The commission adopts new §335.753 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.501 to establish the applicability of Chapter 335, Subchapter W to healthcare facilities and reverse distributors for the management of

hazardous waste pharmaceuticals.

§335.755, Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The commission adopts new §335.755 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.502 to establish the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

§335.757, Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

The commission adopts new §335.757 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.503 to establish the standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

§335.759, Healthcare Facilities That are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste

The commission adopts new §335.759 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent

with language in 40 CFR §266.504 to establish the standards applicable to healthcare facilities that are also VSQGs.

§335.761, Prohibition of Sewering Hazardous Waste Pharmaceuticals

The commission adopts new §335.761 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.505 to establish the sewering prohibition applicable to all hazardous waste pharmaceuticals.

§335.763, Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program

The commission adopts new §335.763 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.506 to establish the conditional exemption from regulation under this subchapter for hazardous waste pharmaceuticals that are also subject to regulation by the federal Drug Enforcement Administration.

§335.765, Residues of Hazardous Waste Pharmaceuticals in Empty Containers

The commission adopts new §335.765 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019

(84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.507 to describe the requirements for containers with residues of hazardous waste pharmaceuticals to be considered empty.

§335.767, Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor

The commission adopts new §335.767 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.508 and adopting 40 CFR §266.508(a)(1)(iii)(b) by reference, to establish the shipping requirements for hazardous waste pharmaceuticals that are not eligible for a manufacturer's credit.

§335.769, Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor

The commission adopts new §335.769 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.509 to establish the shipping requirements for hazardous waste pharmaceuticals that are potentially eligible for a manufacturer's credit.

§335.771, Standards for the Management of Potentially Creditable and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors

The commission adopts new §335.771 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission adopts these regulations by adding language consistent with language in 40 CFR §266.510 to establish the standards applicable to reverse distributors for the management of hazardous waste pharmaceuticals. This section will also establish registration and reporting requirements for reverse distributors.

Final Regulatory Impact Determination

The commission reviewed the rulemaking adoption in light of the regulatory analysis requirements of the Texas Government Code, §2001.0225, and determined that the action is not subject to Texas Government Code, §2001.0225, because it does not meet the definition of a "Major environmental rule" as defined in that statute. A "Major environmental rule" is a rule the specific intent of which is to protect the environment or reduce risks to human health from environmental exposure, and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The rulemaking adoption is not a major environmental rule because it is not anticipated to adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state since the rulemaking adoption implements requirements already imposed on the regulated community under 42 United States

Code (USC), §6926(g). Likewise, there will be no adverse effect in a material way on the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state from those revisions outside 42 USC, §6926(g), because either the changes are not substantive, or the regulated community will benefit from the greater flexibility and reduced compliance burden.

Texas Government Code, §2001.0225, applies to a major environmental rule, the result of which is to: exceed a standard set by federal law, unless the rule is specifically required by state law; exceed an express requirement of state law, unless the rule is specifically required by federal law; exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; or adopt a rule solely under the general authority of the commission. The rulemaking adoption does not meet any of the four applicability requirements listed in Texas Government Code, §2001.0225.

First, the rulemaking will not exceed a standard set by federal law because the commission is adopting this rulemaking to implement revisions to the federal hazardous waste program. The commission must meet the minimum standards and mandatory requirements of the federal program to maintain authorization of the state hazardous waste program.

Second, although the rulemaking adopts some requirements that are more stringent

than existing state laws, federal law requires the commission to promulgate rules that are as stringent as federal law for the commission to maintain authorization of the state hazardous waste program.

Third, the rulemaking will not exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government, where the delegation agreement or contract is to implement a state and federal program. On the contrary, the commission is adopting rules that are required to maintain authorization of the state hazardous waste program.

And fourth, this rulemaking will not seek to adopt a rule solely under the general powers of the agency. Rather, this rulemaking is authorized by specific sections of the Texas Water Code and the Texas Health and Safety Code that are cited in the Statutory Authority section of this preamble.

The commission invited public comment regarding the draft regulatory impact analysis determination during the public comment period. No comments were received on the Draft Regulatory Impact Analysis Determination.

Takings Impact Assessment

The commission evaluated the rulemaking adoption and performed analysis of whether the adopted rules constitute a taking under Texas Government Code, Chapter 2007. The specific purpose of the adopted rules is to maintain state's authorization to

implement the RCRA hazardous waste program by adopting state hazardous waste rules that are equivalent to the federal regulations. The adopted rulemaking substantially advances these stated purposes by adopting rules that are equivalent to the federal regulations or incorporate the federal regulations.

The commission's analysis indicates that Texas Government Code, Chapter 2007 does not apply to the portions of the rulemaking adoption that adopts rules that meet the minimum standards of the federal hazardous waste program because Texas Government Code, §2007.003(b)(4), exempts an action reasonably taken, by a state agency, to fulfill an obligation mandated by federal law from the requirements of Texas Government Code, Chapter 2007. Under 42 USC, §6926(g), the state must adopt rules that meet the minimum standards of the federal hazardous waste program administered by the EPA in order to maintain authorization to administer the program. Therefore, the portions of the rulemaking adoption that are adopting rules that meet the minimum standards of the federal hazardous waste program are exempt from the requirements of Texas Government Code, Chapter 2007 because the rules are required by federal law.

Finally, to the extent that portions of the rulemaking adoption are not exempt under Texas of the adopted rules will be neither a statutory nor a constitutional taking of private real property. Specifically, the subject adopted regulations will not affect a landowner's rights in real property because the rulemaking adoption will not burden (constitutionally); nor restrict or limit the owner's right to property and reduce its

value by 25% or more beyond that which would otherwise exist in the absence of the regulations.

Consistency with the Coastal Management Program

The commission reviewed the rulemaking adoption and found that the adoption is subject to the Texas Coastal Management Program (CMP) in accordance with the Coastal Coordination Act, Texas Natural Resources Code, §§33.201 et seq., and therefore must be consistent with all applicable CMP goals and policies. The commission conducted a consistency determination for the adopted rules in accordance with Coastal Coordination Act implementation rules, 31 TAC §505.22 and found the rulemaking adoption is consistent with the applicable CMP goals and policies. The CMP goals applicable to the adopted rules include protect, preserve, restore, and enhance the diversity, quality, quantity, functions, and values of coastal natural resource areas (CNRAs); to ensure sound management of all coastal resources by allowing for compatible economic development and multiple human uses of the coastal zone; and to make agency and subdivision decision-making affecting CNRAs efficient by identifying and addressing duplication and conflicts among local, state, and federal regulatory and other programs for the management of CNRAs. CMP policies applicable to the adopted rules include to construction and operation of solid waste treatment, storage, and disposal facilities, such that new solid waste facilities and areal expansions of existing solid waste facilities shall be sited, designed, constructed, and operated to prevent releases of pollutants that may adversely affect CNRAs and, at a minimum, comply with standards established under the federal Solid

Waste Disposal Act, 42 United States Code, §§6901 et seq. Promulgation and enforcement of these rules will not violate or exceed any standards identified in the applicable CMP goals and policies because the adopted rules are consistent with these CMP goals and policies, because these rules do not create or have a direct or significant adverse effect on any coastal natural resource areas, and because the adopted rules will update and enhance the commission's rules concerning hazardous waste facilities.

The commission invited public comment regarding the consistency with the coastal management program during the public comment period. There were no comments received regarding the CMP.

Public Comment

The commission held a virtual public hearing on August 23, 2021. The comment period closed on August 30, 2021. The commission received comments from CVS Health (CVS), the Household & Commercial Products Association (HCPA), Texas Chemical Council (TCC), Texas Industry Project (TIP), Texas Molecular Holdings LLC (TM), and one individual. Four commenters supported the proposed rule revisions, two commenters were neither in support of nor against the proposed rule revisions, and three commenters suggested changes to the rule revisions.

Response to Comments

Comment

CVS commented in support of the adoption of the Pharmaceutical Waste Rule in full.

HCPA commented in support of the addition of aerosol cans to the list of hazardous wastes that may be managed under the universal waste program. TCC and TM commented in support of the rulemaking, and TM commented in support of adoption of 40 CFR §260.5.

Response

The commission acknowledges these comments.

Comment

TM recommended that the commission hold stakeholder meetings to facilitate compliance with the new and amended rules.

Response

The commission intends to provide guidance and conduct outreach to facilitate compliance with the adopted provisions. No changes have been made in response to this comment.

Comment

TM commented that use of the term "unpermitted" in the heading of §335.6(a) is confusing and recommended using the term "permit-exempt."

Response

The commission agrees with this comment and changed the catch line of §335.6(a)

from "Notification of unpermitted industrial solid waste activities" to "Notification of industrial solid waste and municipal hazardous waste activities not authorized by a permit."

Comment

TCC and TIP asked the commission to elaborate on the small quantity generator (SQG) renotification required by §335.6, asked whether a SQG will use the EPA 8700-12 form or a different form to renotify and asked what additional information a SQG would be required to submit.

Response

The commission intends to provide guidance to inform generators how to comply with the state SQG renotification requirements. The commission's intent is to provide flexibility for the executive director to approve a variety of methods of re-notification such as updates to solid waste registrations via either federal or state forms and submittal of annual waste summaries. The commission's implementation of SQG renotification will include, at a minimum, the information required by the 8700-12 form. No changes have been made in response to this comment.

Comment

TIP recommends requiring one collective SQG renotification for multiple SQGs associated with a common central facility.

Response

The commission's implementation of the SQG renotification requirement must be at least as stringent as the EPA's requirements. Hazardous waste generator categories and generator conditional exemptions are dependent on the individual site where hazardous waste is generated and each SQG is required to have a unique EPA identification number. Thus, it is not clear that combining renotifications of multiple SQGs is practical or would satisfy the requirement. No changes have been made in response to this comment.

Comment

TM requested clarification of the annual waste summary (AWS) requirements in §335.9(a)(2)(C)(ii).

Response

The requirement in §335.9(a)(2)(C)(ii) is applicable to the receipt of off-site generated Class 1 waste by an owner or operator in compliance with §335.10(e) and to the receipt of off-site generated hazardous waste from a very small quantity generator (VSQG) in compliance with 40 CFR §262.17(f) as adopted under §335.53(f). The owner or operator or large quantity generator consolidating waste from off-site must report the waste received from off-site as their own on their AWS. The Class 1 waste generator and the VSQG shipping wastes off-site are not required to submit an AWS under §335.9(a)(4) for these wastes under these scenarios. No changes have been made in response to this comment.

Comment

TM requested that the commission revise §335.10(c)(1) to require the EPA ID number to be included on a manifest for shipments of Class 1 industrial waste, and allow use of a solid waste registration number only if the generator does not have an EPA ID number.

Response

Because Class 1 industrial waste generators are not required to obtain an EPA ID number, the commission declines to require a manifest prepared for a shipment of Class 1 industrial waste to include an EPA ID number. No changes have been made in response to this comment.

Comment

TM requested clarification of the annual waste summary requirements in §335.10(e)(3) for generators receiving waste from off-site.

Response

The owner or operator of the receiving facility must report the Class 1 industrial solid waste received from off-site on the annual waste summary per §335.10(e)(3). No changes have been made in response to this comment.

Comment

TM recommended using data from the e-manifest system instead of requiring a separate annual waste summary and waste receipt summaries.

Response

The commission is required by state law to collect and record information about industrial and hazardous waste. Until or unless the commission transitions to importing, converting, and uploading data from the e-manifest system into commission databases, receivers may download data from the e-manifest system and convert the data to a file format that may be imported into TCEQ's monthly waste receipt summary. No changes have been made in response to this comment.

Comment

TM commented that §335.13(e)(2) conflicts with §335.6(c).

Response

Paragraph §335.13(e)(2) describes one of three conjunctive elements that define an unregistered generator, specifically the amount of hazardous or Class 1 waste that the generator generates in a calendar month. This section does not create an exception to the requirement to register under §335.6(c). The executive director may assign a temporary solid waste registration number (SWR) to facilitate the management and transportation of hazardous waste and/or Class 1 waste by an unregistered generator because the generator does not have an active registration. The executive director may assign a four-digit sequence number to be used as the

first four digits of the Texas waste code as required by §335.503, to facilitate the management and transportation of hazardous waste and/or Class 1 waste by an unregistered generator because the generator does not have an active registration and as such does not assign Texas waste codes to waste generated on-site. Assignment of a temporary SWR, the first four digits of a Texas waste code, and/or a temporary EPA ID number is currently known as the commission's one-time shipment program. A temporary SWR or use of a temporary Texas waste code does not conflict with or waive the registration requirements of §335.6(c). This is reenforced by §335.6(c)(3) which states that notifications under §335.6 are in addition to any information required by §335.13.

Comment

TM asked whether §335.13(e) is only applicable to a VSQG during an episodic event.

Response

An unregistered generator of hazardous waste or an unregistered generator of Class 1 industrial waste may request that the executive director assign a temporary SWR and/or the first four digits of a temporary Texas waste code to facilitate the management and immediate transportation of waste if the generator does not have an active registration and as such does not assign Texas waste codes to waste generated on-site. The commission is adopting a new conditional exclusion under the Generator Improvements Rule that is applicable to certain hazardous waste generated during episodic events. The commission's established one-time shipment

program as described under the previous response is independent from the new conditional exclusion regarding hazardous waste. No changes have been made in response to this comment.

Comment

TM asked how long a temporary solid waste registration number (SWR) or Texas waste code may be used before registration is required under 335.6.

Response

As explained in the previous two responses, the executive director providing an unregistered generator a temporary SWR or a four-digit sequence number to be used as the first four digits of a Texas waste code in accordance with §335.503 and §335.13 does not waive or create an exception to the registration requirements of §335.6(c). Owners and operators and unregistered generators using a temporary SWR or a four-digit sequence number as the first four digits of a Texas waste code must renew its one-time shipment requests on a yearly basis. A Texas waste code that uses a four-digit sequence number assigned by the executive director is no longer considered valid one year after it was requested. In response to this comment the commission has further amended §335.13(d)(3) to clarify that the executive director assigns the four-digit sequence used as the first four digits of the Texas waste code.

Comment

TCC and TIP encouraged the commission to exclude temporary waste accumulation areas used for one-time events from closure requirements in §335.53(f), and to mirror Louisiana Department of Environmental Quality (LDEQ) regulations that allow documentation of closure of these units using existing recordkeeping practices.

Response

The Commission's implementation of Texas' hazardous waste program must be at least as stringent as the EPA's hazardous waste regulations. The EPA promulgated a definition of central accumulation area (CAA) to include an on-site hazardous waste accumulation area that is subject to conditions for exemption for a small quantity generator or a large quantity generator (LQG). The EPA expressly included CAA among hazardous waste units that an LQG is required to demonstrate closure of in accordance with the closure performance standards. No changes have been made in response to this comment.

Comment

TCC and TIP requested additional information about how the commission will implement pre-transport requirements of §335.55 which implement extensive Department of Transportation requirements. TIP raised concerns that improperly labelling containers is a common RCRA violation, and that large complex facilities contain hundreds of drums and containers that require labeling. TIP and TCC recommended that the commission provide guidance and TCC recommended that the commission utilize a logical and realistic approach to implementation and

enforcement of the new requirements.

Response

The commission may issue guidance on the pre-transportation requirements. The EPA committed to issuing additional guidance and to conducting training on the Generator Improvements Rule in the Generator Improvements Rule adoption preamble. The commission's implementation is informed by the floor of the EPA's requirements as identified in EPA guidance. No changes have been made in response to this comment.

Comment

TCC and TIP expressed concerns that the EPA large quantity generator (LQG) Quick Reference Guide guidance is not relevant to large complex facilities and encouraged the commission to provide an example Quick Reference Guide that would be appropriate for these facilities.

Response

The commission acknowledges this comment. No changes have been made in response to this comment.

Comment

TCC and TIP encouraged the commission to revise the Quick Reference Guide requirements in §335.61 to mirror LDEQ regulations that allow satellite accumulation

area (SAA) locations to be generally identified on the Quick Reference Guide facility map and to exclude short-term, temporary storage central accumulation areas, such as RCRA 90-day units, from Quick Reference Guide and contingency plan requirements.

Response

The commission declines to limit the scope of the federal hazardous regulations being adopted by reference. The commission's implementation of Texas' hazardous waste program must be at least as stringent as the EPA's hazardous waste regulations. The EPA introduced the term "quick reference guide" to replace the term "contingency plan executive summary." The EPA promulgated a definition of central accumulation area (CAA) to include an on-site hazardous waste accumulation area that is subject to conditions for exemption for a SQG or a LQG. The EPA did not exclude CAA or less than 90-day units from Quick Reference Guide and contingency planning requirements. The commission acknowledges that the general location of a SAA location may satisfy the intent and purpose of depicting locations of and routes of access to hazardous wastes in the quick reference guide facility map. The commission's implementation is informed by the floor of the EPA's requirements as identified in EPA guidance. No changes have been made in response to this comment.

Comment

TCC and TIP commented that under the verified recycler exclusion (VRE), which was proposed to be repealed and replaced by the transfer based exclusion (TBE), that the

facility owner operator and the commission are responsible for assuring that off-site facilities for the recycling of hazardous secondary materials (HSM) are in compliance with legitimate HSM recycling criteria and that under the TBE the burden of assuring compliance falls to the owner operator and generators that send HSM to off-site recycling facilities. TIP commented that the commission is more experienced and better situated to review and certify compliance with HSM legitimate recycling criteria than generators that may be influenced by costs associated with compliance and asserted that TBE also imposes additional costs on generators when sending HSM off-site for recycling. TCC and TIP urged that the commission retain VRE, not replace VRE with TBE and that the commission enhance implementation of VRE with a formal application and approval process.

Response

While the commission agrees that EPA allows state hazardous waste programs to be broader in scope than the federal program, the management standards applicable to the recycling of HSM at an off-site facility under Verified Recycler Exclusion and Transfer Based Exclusion are equivalent. Additionally, the commission acknowledges that HSM generators will assume additional costs of conducting and documenting due diligence and certifying that off-site HSM recycling facilities conduct legitimate recycling in compliance with the regulations. However, the commission has determined that repealing the Verified Recycler Exclusion and adopting the Transfer Based Exclusion would provide consistency with the federal program and offer the greatest amount of flexibility for the recycling of HSM in-

state and across state lines while still being protective of human health and the environment. No changes have been made in response to this comment.

Comment

An individual requested that the commission clarify in the final rule or in the Response to Comments that hazardous secondary materials (HSM) originating in Texas are authorized to be transported to and managed at an out-of-state verified reclamation facility operating under a state-only verified recycling exclusion.

Response

A statement in the adoption preamble would not have the legal effect of authorizing HSM that is managed in compliance with the Transfer Based Exclusion to be transported to and managed at an out-of-state facility under a state-only verified recycler exclusion. The requirements of each federal HSM exclusion, as promulgated by the EPA, are not interchangeable. Because states have adopted the Verified Recycler Exclusion with changes to the vacated federal exclusion, whether HSM managed in compliance with Texas' Transfer Based Exclusion is authorized to be consigned for transportation to an out-of-state facility in compliance with a state-only Verified Recycler Exclusion necessitates a case-by-case analysis. No changes have been made in response to this comment.

Comment

TM requested sufficient notice for customers to transition from CESQ sequence

numbers to VSQG sequence numbers, and to confirm that the state STEERS system will accept VSQG IDs for WRS submittals.

Response

The commission described the implementation of this requirement in the proposal preamble Section by Section Discussion for §335.503(b)(6) and (7) with a deadline to begin requiring the VSQG sequence number after January 1, 2025. The commission's implementation of Texas' hazardous waste program is informed by the floor of EPA's requirements as iterated in EPA guidance, including the use of TXCESQG and TXVSQG for the EPA ID, and thus the commission intends to allow for TXVSQG as a valid EPA ID for unregistered VQSGs in the WRS reporting. No changes have been made in response to this comment.

Comment

TM requested clarification of the applicability of the Pharmaceutical Waste Rule to their commercial hazardous and nonhazardous waste treatment, storage, and disposal facilities that stock and provide first aid supplies and over the counter medications for employees.

Response

A waste management facility maintaining first aid supplies and over the counter medications for employees does not trigger applicability of 40 CFR Part 266, Subpart P, as adopted under Chapter 335, Subchapter W. The sewerage ban

prohibiting the disposal of over the counter and prescription medications by introducing those materials to the sewer is broadly applicable to all types of facilities and sewer systems. The commission's implementation of the Pharmaceutical Waste Rule is informed by the floor of the EPA's requirements as identified in EPA guidance. In the February 22, 2019 *Federal Register*, EPA's adoption preamble for the hazardous waste pharmaceutical requirements states that "this final rule does not affect how RCRA-permitted or interim status TSDFs manage hazardous waste pharmaceuticals at their facilities, except indirectly when they treat hazardous waste pharmaceuticals to meet the land disposal restrictions" (84 FR 5836). No changes have been made in response to this comment.

Comment

TM requested guidance on how pharmaceuticals will be considered legitimately used/reused or reclaimed for exclusion from the definition of solid waste.

Response

The commission's implementation of the Pharmaceutical Waste Rule is informed by the floor of EPA's requirements as iterated in EPA guidance, including the preamble of the federal promulgation of the hazardous waste pharmaceutical requirements applicable to exclusions for legitimately used/reused or reclaimed pharmaceuticals. No changes have been made in response to this comment.

SUBCHAPTER A: INDUSTRIAL SOLID WASTE AND MUNICIPAL HAZARDOUS WASTE IN GENERAL

§§335.1, 335.2, 335.6, 335.9, 335.10, 335.11, 335.12, 335.13, 335.14, 335.15, 335.18, 335.19, 335.24, 335.26 - 335.27, 335.31

Statutory Authority

The amendments and new sections are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments and new sections are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendments and new sections implement THSC, Chapter 361.

§335.1. Definitions.

In addition to the terms defined in Chapter 3 of this title (relating to Definitions), the following words and terms, when used in this chapter, have the following meanings.

(1) Aboveground tank--A device meeting the definition of "Tank" in this section and that is situated in such a way that the entire surface area of the tank is completely above the plane of the adjacent surrounding surface and the entire surface area of the tank (including the tank bottom) is able to be visually inspected.

(2) Act--Texas Health and Safety Code, Chapter 361.

(3) Active life--The period from the initial receipt of hazardous waste at the facility until the executive director receives certification of final closure.

(4) Active portion--That portion of a facility where processing, storage, or disposal operations are being or have been conducted after November 19, 1980, and which is not a closed portion. (See also "Closed portion" and "Inactive portion.")

(5) Activities associated with the exploration, development, and production of oil or gas or geothermal resources--Activities associated with:

(A) the drilling of exploratory wells, oil wells, gas wells, or geothermal resource wells;

(B) the production of oil or gas or geothermal resources, including:

(i) activities associated with the drilling of injection water source wells that penetrate the base of usable quality water;

(ii) activities associated with the drilling of cathodic protection holes associated with the cathodic protection of wells and pipelines subject to the jurisdiction of the commission to regulate the production of oil or gas or geothermal resources;

(iii) activities associated with gasoline plants, natural gas or natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants;

(iv) activities associated with any underground natural gas storage facility, provided the terms "Natural gas" and "Storage facility" shall have the meanings set out in the Texas Natural Resources Code, §91.173;

(v) activities associated with any underground hydrocarbon storage facility, provided the terms "Hydrocarbons" and "Underground hydrocarbon storage facility" shall have the meanings set out in the Texas Natural Resources Code, §91.201; and

(vi) activities associated with the storage, handling, reclamation, gathering, transportation, or distribution of oil or gas prior to the refining of such oil or prior to the use of such gas in any manufacturing process or as a residential or industrial fuel;

(C) the operation, abandonment, and proper plugging of wells subject to the jurisdiction of the commission to regulate the exploration, development, and production of oil or gas or geothermal resources; and

(D) the discharge, storage, handling, transportation, reclamation, or disposal of waste or any other substance or material associated with any activity listed in subparagraphs (A) - (C) of this paragraph, except for waste generated in connection with activities associated with gasoline plants, natural gas or natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants if that waste is a hazardous waste as defined by the administrator of the United States Environmental Protection Agency in accordance with the Federal Solid Waste Disposal Act, as amended (42 United States Code, §§6901 et seq.).

(6) Acute hazardous waste--Hazardous wastes that meet the listing criteria in 40 Code of Federal Regulations (CFR) §261.11(a)(2) and therefore are either listed in 40 CFR §261.31 with the assigned hazard code of (H) or are listed in 40 CFR §261.33(e).

(7) [(6)] Administrator--The administrator of the United States Environmental Protection Agency or his designee.

(8) Aerosol can--A non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

(9) [(7)] AES filing compliance date--The date that the United States Environmental Protection Agency (EPA) announces in the *Federal Register*[ ], on or after which exporters of hazardous waste and exporters of cathode ray tubes for recycling are required to file EPA information in the Automated Export System or its successor system, under the International Trade Data System platform.

(10) [(8)] Airbag waste--Any hazardous waste airbag modules or hazardous waste airbag inflators.

(11) [(9)] Airbag waste collection facility--Any facility that receives airbag waste from airbag handlers subject to regulation under §335.281 of this title (relating to Airbag Waste) and accumulates the waste for more than ten days.

(12) [(10)] Airbag waste handler--Any person, by site, who generates airbag waste that is subject to regulation under this chapter.

(13) [(11)] Ancillary equipment--Any device that is used to distribute, meter, or control the flow of solid waste or hazardous waste from its point of generation to a storage or processing tank(s), between solid waste or hazardous waste storage and processing tanks to a point of disposal on site, or to a point of shipment for disposal off site. Such devices include, but are not limited to, piping, fittings, flanges, valves, and pumps.

(14) [(12)] Aquifer--A geologic formation, group of formations, or part of a formation capable of yielding a significant amount of groundwater to wells or springs.

(15) [(13)] Area of concern--Any area of a facility under the control or ownership of an owner or operator where a release to the environment of hazardous wastes or hazardous constituents has occurred, is suspected to have occurred, or may occur, regardless of the frequency or duration.

(16) [(14)] Authorized representative--The person responsible for the overall operation of a facility or an operation unit (i.e., part of a facility), e.g., the plant manager, superintendent, or person of equivalent responsibility.

(17) [(15)] Battery--As defined in §335.261 of this title (relating to Universal Waste Rule).

(18) [(16)] Boiler--An enclosed device using controlled flame combustion and having the following characteristics:

(A) the unit must have physical provisions for recovering and exporting thermal energy in the form of steam, heated fluids, or heated gases;

(B) the unit's combustion chamber and primary energy recovery section(s) must be of integral design. To be of integral design, the combustion chamber and the primary energy recovery section(s) (such as waterwalls and superheaters) must be physically formed into one manufactured or assembled unit. A unit in which the combustion chamber and the primary energy recovery section(s) are joined only by ducts or connections carrying flue gas is not integrally designed; however, secondary energy recovery equipment (such as economizers or air preheaters) need not be physically formed into the same unit as the combustion chamber and the primary energy recovery section. The following units are not precluded from being boilers solely because they are not of integral design:

(i) process heaters (units that transfer energy directly to a process stream); and

(ii) fluidized bed combustion units;

(C) while in operation, the unit must maintain a thermal energy recovery efficiency of at least 60%, calculated in terms of the recovered energy compared with the thermal value of the fuel; and

(D) the unit must export and utilize at least 75% of the recovered energy, calculated on an annual basis. In this calculation, no credit shall be given for recovered heat used internally in the same unit. (Examples of internal use are the preheating of fuel or combustion air, and the driving of induced or forced draft fans or feedwater pumps); or

(E) the unit is one which the executive director has determined, on a case-by-case basis, to be a boiler, after considering the standards in §335.20 of this title (relating to Variance To Be Classified as a Boiler).

(19) [(17)] Captive facility--A facility that accepts wastes from only related (within the same corporation) off-site generators.

(20) [(18)] Captured facility--A manufacturing or production facility that generates an industrial solid waste or hazardous waste that is routinely stored, processed, or disposed of on a shared basis in an integrated waste management unit owned, operated by, and located within a contiguous manufacturing complex.

(21) [(19)] Captured receiver--A receiver that is located within the property boundaries of the generators from which it receives waste.

(22) [(20)] Carbon dioxide stream--Carbon dioxide that has been captured from an emission source (e.g., power plant), plus incidental associated substances derived from the source materials and the capture process, and any substances added to the stream to enable or improve the injection process.

(23) [(21)] Carbon regeneration unit--Any enclosed thermal treatment device used to regenerate spent activated carbon.

(24) [(22)] Cathode ray tube (CRT)--A vacuum tube, composed primarily of glass, which is the visual or video display component of an electronic device. A used, intact CRT means a CRT whose vacuum has not been released. A used, broken CRT means its glass has been removed from its housing, or casing whose vacuum has been released.

(25) [(23)] Cathode ray tube (CRT) collector--A person who receives used, intact CRTs for recycling, repair, resale, or donation.

(26) [(24)] Cathode ray tube (CRT) exporter--Any person in the United States who initiates a transaction to send used CRTs outside the United States or its territories for recycling or reuse, or any intermediary in the United States arranging for such export.

(27) [(25)] Cathode ray tube (CRT) glass manufacturer--An operation or part of an operation that uses a furnace to manufacture CRT glass.

(28) [(26)] Cathode ray tube (CRT) processing--Conducting all of the following activities:

(A) receiving broken or intact CRTs;

(B) intentionally breaking intact CRTs or further breaking or separating broken CRTs; and

(C) sorting or otherwise managing glass removed from CRT monitors.

(29) Central accumulation area--Any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either 40 Code of Federal Regulations (CFR) §262.16 or §262.17, as these sections are adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste). In accordance with 40 CFR Part 262, Subpart K, as adopted by reference under §335.59 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities), a central accumulation area at an eligible academic entity that chooses to operate under 40 CFR Part 262, Subpart K, is also subject to 40 CFR §262.211 as adopted by reference under §335.59 of this title when accumulating unwanted material and/or hazardous waste.

(30) [(27)] Certification--A statement of professional opinion based upon knowledge and belief.

(31) [(28)] Class 1 wastes--Any industrial solid waste or mixture of industrial solid wastes which because of its concentration, or physical or chemical characteristics, is toxic, corrosive, flammable, a strong sensitizer or irritant, a generator of sudden pressure by decomposition, heat, or other means, or may pose a substantial present or potential danger to human health or the environment when improperly processed, stored, transported, or disposed of or otherwise managed, as further defined in §335.505 of this title (relating to Class 1 Waste Determination).

(32) [(29)] Class 2 wastes--Any individual solid waste or combination of industrial solid waste which cannot be described as hazardous, Class 1, or Class 3 as defined in §335.506 of this title (relating to Class 2 Waste Determination).

(33) [(30)] Class 3 wastes--Inert and essentially insoluble industrial solid waste, usually including, but not limited to, materials such as rock, brick, glass, dirt, and certain plastics and rubber, etc., that are not readily decomposable, as further defined in §335.507 of this title (relating to Class 3 Waste Determination).

(34) [(31)] Closed portion--That portion of a facility which an owner or operator has closed in accordance with the approved facility closure plan and all applicable closure requirements. *(See* also "Active portion" and "Inactive portion.")

(35) [(32)] Closure--The act of permanently taking a waste management unit or facility out of service.

(36) [(33)] Commercial hazardous waste management facility--Any hazardous waste management facility that accepts hazardous waste or polychlorinated biphenyl compounds for a charge, except a captured facility or a facility that accepts waste only from other facilities owned or effectively controlled by the same person.

(37) [(34)] Component--Either the tank or ancillary equipment of a tank system.

(38) Conditionally exempt small quantity generator--A conditionally exempt small quantity generator (CESQG) is a very small quantity generator as defined in this section that meets the independent requirements and the conditions for exemption for a very small quantity generator under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste). A reference to a conditionally exempt small quantity generator, "CESQG", or a person who generates no more than 100 kilograms of hazardous waste in a calendar month is a reference to a very small quantity generator.

(39) [(35)] Confined aquifer--An aquifer bounded above and below by impermeable beds or by beds of distinctly lower permeability than that of the aquifer itself; an aquifer containing confined groundwater.

(40) [(36)] Contained--Hazardous secondary materials held in a unit (including a "Land-based unit" as defined in this section) that meets the following criteria:

(A) the unit is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the hazardous secondary materials to the environment, and is designed, as appropriate for the hazardous secondary materials, to prevent releases of hazardous secondary materials to the environment. Unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to

water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures;

(B) the unit is properly labeled or otherwise has a system (such as a log) to immediately identify the hazardous secondary materials in the unit;

(C) the unit holds hazardous secondary materials that are compatible with other hazardous secondary materials placed in the unit and is compatible with the materials used to construct the unit and addresses any potential risks of fires or explosions; and

(D) hazardous secondary materials in units that meet the requirements of 40 Code of Federal Regulations Parts 264 and 265 are presumptively contained.

(41) [(37)] Container--Any portable device in which a material is stored, transported, processed, or disposed of, or otherwise handled.

(42) [(38)] Containment building--A hazardous waste management unit that is used to store or treat hazardous waste under the provisions of §335.112(a)(21) or §335.152(a)(19) of this title (relating to Standards).

(43) [(39)] Contaminant--Includes, but is not limited to, "Solid waste," "Hazardous waste," and "Hazardous waste constituent" as defined in this section; "Pollutant" as defined in Texas Water Code (TWC), §26.001, and Texas Health and Safety Code (THSC), §361.401; "Hazardous substance" as defined in THSC, §361.003; and other substances that are subject to the Texas Hazardous Substances Spill Prevention and Control Act, TWC, §§26.261 - 26.267.

(44) [(40)] Contaminated medium/media--A portion or portions of the physical environment to include soil, sediment, surface water, groundwater or air, that contain contaminants at levels that pose a substantial present or future threat to human health and the environment.

(45) [(41)] Contingency plan--A document setting out an organized, planned, and coordinated course of action to be followed in case of a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.

(46) [(42)] Control--To apply engineering measures such as capping or reversible treatment methods and/or institutional measures such as deed restrictions to facilities or areas with wastes or contaminated media which result in remedies that are protective of human health and the environment when combined with appropriate maintenance, monitoring, and any necessary further corrective action.

(47) [(43)] Corrosion expert--A person who, by reason of his knowledge of the physical sciences and the principles of engineering and mathematics, acquired by a professional education and related practical experience, is qualified to engage in the practice of corrosion control on buried or submerged metal piping systems and metal tanks. Such a person must be certified as being qualified by the National Association of Corrosion Engineers or be a registered professional engineer who has certification or licensing that includes education and experience in corrosion control on buried or submerged metal piping systems and metal tanks.

(48) [(44)] Decontaminate--To apply a treatment process(es) to wastes or contaminated media whereby the substantial present or future threat to human health and the environment is eliminated.

(49) [(45)] Designated facility--A hazardous waste treatment, storage, or disposal facility which: has received a permit (or interim status) in accordance with the requirements of 40 Code of Federal Regulations (CFR) Parts 124 and 270; has received a permit (or interim status) from a state authorized in accordance with 40 CFR Part 271; or is regulated under 40 CFR §261.6(c)(2) or 40 CFR Part 266, Subpart F and has been designated on the manifest by the generator pursuant to 40 CFR §262.20. For hazardous wastes, if a waste is destined to a facility in an authorized state which has not yet obtained authorization to regulate that particular waste as hazardous, then the designated facility must be a facility allowed by the receiving state to accept such waste. For Class 1 wastes, a designated facility is any treatment, storage, or disposal

facility authorized to receive the Class 1 waste that has been designated on the manifest by the generator. Designated facility also means a generator site designated on the manifest to receive its waste as a return shipment from a facility that has rejected the waste in accordance with 40 CFR §264.72(f) as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.72(f) as adopted under §335.112 of this title (relating to Standards) [§335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities)].

(50) [(46)] Destination facility--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(51) [(47)] Dike--An embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids, or other materials.

(52) [(48)] Dioxins and furans (D/F)--Tetra, penta, hexa, hepta, and octa-chlorinated dibenzo dioxins and furans.

(53) [(49)] Discharge or hazardous waste discharge--The accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of waste into or on any land or water.

(54) [(50)] Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwaters.

(55) [(51)] Disposal facility--A facility or part of a facility at which solid waste is intentionally placed into or on any land or water, and at which waste will remain after closure. The term "Disposal facility" does not include a corrective action management unit into which remediation wastes are placed.

(56) [(52)] Drip pad--An engineered structure consisting of a curbed, free-draining base, constructed of non-earthen materials and designed to convey preservative kick-back or drippage from treated wood, precipitation, and surface water run-on to an associated collection system at wood preserving plants.

(57) [(53)] Electronic import-export reporting compliance date--The date that the United States Environmental Protection Agency (EPA) announces in the *Federal Register*, on or after which exporters, importers, and receiving facilities are required to submit certain export and import related documents to EPA using EPA's waste Import Export Tracking System, or its successor system.

(58) [(54)] Electronic manifest or e-Manifest--The electronic format of the hazardous waste manifest that is obtained from the United States Environmental Protection Agency's (EPA's) national e-Manifest system and transmitted electronically to the system, and that is the legal equivalent of EPA Forms 8700-22 (Manifest) and 8700-22A (Continuation Sheet).

(59) [(55)] Electronic manifest system or e-Manifest system--The United States Environmental Protection Agency's national information technology system through which the electronic manifest may be obtained, completed, transmitted, and distributed to users of the electronic manifest and to regulatory agencies.

(60) [(56)] Elementary neutralization unit--A device which:

(A) is used for neutralizing wastes which are hazardous only because they exhibit the corrosivity characteristic defined in 40 Code of Federal Regulations (CFR) §261.22, or are listed in 40 CFR Part 261, Subpart D, only for this reason; or is used for neutralizing the pH of nonhazardous industrial solid waste; and

(B) meets the definition of "Tank," "Tank system," "Container," or "Transport vehicle," as defined in this section; or "Vessel" as defined in 40 CFR §260.10.

(61) [(57)] Essentially insoluble--Any material, which if representatively sampled and placed in static or dynamic contact with deionized water at ambient temperature for seven days, will not leach any quantity of any constituent of the material into the water in excess of current United States Public Health Service or United States Environmental Protection Agency limits for drinking water as published in the *Federal Register.*

(62) [(58)] Equivalent method--Any testing or analytical method approved by the administrator under 40 Code of Federal Regulations §260.20 and §260.21.

(63) [(59)] Existing portion--That land surface area of an existing waste management unit, included in the original Part A permit application, on which wastes have been placed prior to the issuance of a permit.

(64) [(60)] Existing tank system or existing component--A tank system or component that is used for the storage or processing of hazardous waste and that is in operation, or for which installation has commenced on or prior to July 14, 1986. Installation will be considered to have commenced if the owner or operator has obtained all federal, state, and local approvals or permits necessary to begin physical construction of the site or installation of the tank system and if either:

(A) a continuous on-site physical construction or installation program has begun; or

(B) the owner or operator has entered into contractual obligations--which cannot be canceled or modified without substantial loss--for physical construction of the site or installation of the tank system to be completed within a reasonable time.

(65) [(61)] Explosives or munitions emergency--A situation involving the suspected or detected presence of unexploded ordnance, damaged or deteriorated explosives or munitions, an improvised explosive device, other potentially explosive material or device, or other potentially harmful military chemical munitions or device, that creates an actual or potential imminent threat to human health, including safety, or the environment, including property, as determined by an explosives or munitions emergency response specialist. These situations may require immediate and expeditious action by an explosives or munitions emergency response specialist to control, mitigate, or eliminate the threat.

(66) [(62)] Explosives or munitions emergency response--All immediate response activities by an explosives and munitions emergency response specialist to control, mitigate, or eliminate the actual or potential threat encountered during an explosives or munitions emergency, subject to the following:

(A) an explosives or munitions emergency response includes in-place render-safe procedures, treatment or destruction of the explosives or munitions

and/or transporting those items to another location to be rendered safe, treated, or destroyed;

(B) any reasonable delay in the completion of an explosives or munitions emergency response caused by a necessary, unforeseen, or uncontrollable circumstance will not terminate the explosives or munitions emergency; and

(C) explosives and munitions emergency responses can occur on either public or private lands and are not limited to responses at hazardous waste facilities.

(67) [(63)] Explosives or munitions emergency response specialist--An individual trained in chemical or conventional munitions or explosives handling, transportation, render-safe procedures, or destruction techniques, including United States Department of Defense (DOD) emergency explosive ordnance disposal, technical escort unit, and DOD-certified civilian or contractor personnel; and, other federal, state, or local government, or civilian personnel similarly trained in explosives or munitions emergency responses.

(68) [(64)] Extrusion--A process using pressure to force ground poultry carcasses through a decreasing-diameter barrel or nozzle, causing the generation of heat sufficient to kill pathogens, and resulting in an extruded product acceptable as a feed ingredient.

(69) [(65)] Facility--Includes:

(A) all contiguous land, and structures, other appurtenances, and improvements on the land, used for storing, processing, or disposing of municipal hazardous waste or industrial solid waste, or for the management of hazardous secondary materials prior to reclamation. A facility may consist of several treatment, storage, or disposal operational units (e.g., one or more landfills, surface impoundments, or combinations of them);

(B) for the purpose of implementing corrective action under §335.167 of this title (relating to Corrective Action for Solid Waste Management Units) or §335.602(a)(5) of this title (relating to Standards), all contiguous property under the control of the owner or operator seeking a permit for the treatment, storage, and/or disposal of hazardous waste. This definition also applies to facilities implementing corrective action under Texas Water Code, §7.031 (Corrective Action Relating to Hazardous Waste);

(C) regardless of subparagraph (B) of this paragraph, a "Remediation waste management site," as defined in 40 Code of Federal Regulations §260.10, is not a facility that is subject to §335.167 of this title, but is subject to corrective action requirements if the site is located within such a facility.

(70) [(66)] Final closure--The closure of all hazardous waste management units at the facility in accordance with all applicable closure requirements so that hazardous waste management activities under Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) and Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) are no longer conducted at the facility unless subject to the provisions in Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste) [§335.69 of this title (relating to Accumulation Time)].

(71) [(67)] Food-chain crops--Tobacco, crops grown for human consumption, and crops grown for feed for animals whose products are consumed by humans.

(72) [(68)] Freeboard--The vertical distance between the top of a tank or surface impoundment dike, and the surface of the waste contained therein.

(73) [(69)] Free liquids--Liquids which readily separate from the solid portion of a waste under ambient temperature and pressure.

(74) [(70)] Gasification--A process through which recoverable feedstocks are heated and converted into a fuel-gas mixture in an oxygen-deficient atmosphere and the mixture is converted into a valuable raw, intermediate, or final product,

including a plastic, monomer, chemical, wax, lubricant, or chemical feedstock or crude oil, diesel, gasoline, diesel and gasoline blendstock, home heating oil, ethanol, or another fuel.

(75) [(71)] Gasification facility--A facility that receives, separates, stores, and converts post-use polymers and recoverable feedstocks using gasification.

(76) [(72)] Generator--Any person, by site, who produces municipal hazardous waste or industrial solid waste; any person who possesses municipal hazardous waste or industrial solid waste to be shipped to any other person; or any person whose act first causes the solid waste to become subject to regulation under this chapter. For the purposes of this regulation, a person who generates or possesses Class 3 wastes only shall not be considered a generator.

(77) [(73)] Groundwater--Water below the land surface in a zone of saturation.

(78) [(74)] Hazardous industrial waste--Any industrial solid waste or combination of industrial solid wastes identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency in accordance with the Resource Conservation and Recovery Act of 1976, §3001 (42 United States Code, §6921). The administrator has identified the characteristics of hazardous wastes and listed certain wastes as hazardous in 40 Code of Federal Regulations Part 261. The

executive director will maintain in the offices of the commission a current list of hazardous wastes, a current set of characteristics of hazardous waste, and applicable appendices, as promulgated by the administrator.

(79) [(75)] Hazardous secondary material--A secondary material (e.g., spent material, by-product, or sludge) that, when discarded, would be identified as "Hazardous waste" as defined in this section.

(80) [(76)] Hazardous secondary material generator--Any person whose act or process produces hazardous secondary materials at the generating facility. For purposes of this paragraph, "generating facility" means all contiguous property owned, leased, or otherwise controlled by the hazardous secondary material generator. For the purposes of 40 Code of Federal Regulations §261.4(a)(23), a facility that collects hazardous secondary materials from other persons is not the hazardous secondary material generator.

(81) [(77)] Hazardous substance--Any substance designated as a hazardous substance under 40 Code of Federal Regulations Part 302.

(82) [(78)] Hazardous waste--Any solid waste identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency in accordance with the federal Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, 42 United States Code, §§6901 *et seq.*

(83) [(79)] Hazardous waste constituent--A constituent that caused the administrator to list the hazardous waste in 40 Code of Federal Regulations (CFR) Part 261, Subpart D or a constituent listed in Table 1 of 40 CFR §261.24.

(84) [(80)] Hazardous waste management facility--All contiguous land, including structures, appurtenances, and other improvements on the land, used for processing, storing, or disposing of hazardous waste. The term includes a publicly- or privately-owned hazardous waste management facility consisting of processing, storage, or disposal operational hazardous waste management units such as one or more landfills, surface impoundments, waste piles, incinerators, boilers, and industrial furnaces, including cement kilns, injection wells, salt dome waste containment caverns, land treatment facilities, or a combination of units.

(85) [(81)] Hazardous waste management unit--A landfill, surface impoundment, waste pile, industrial furnace, incinerator, cement kiln, injection well, container, drum, salt dome waste containment cavern, or land treatment unit, or any other structure, vessel, appurtenance, or other improvement on land used to manage hazardous waste.

(86) [(82)] In operation--Refers to a facility which is processing, storing, or disposing of solid waste or hazardous waste.

(87) [(83)] Inactive portion--That portion of a facility which is not operated after November 19, 1980. (*See* also "Active portion" and "Closed portion.")

(88) [(84)] Incinerator--

(A) Any enclosed device that:

(i) uses controlled flame combustion and neither meets the criteria for classification as a boiler, sludge dryer, or carbon regeneration unit, nor is listed as an industrial furnace; or

(ii) meets the definition of "Infrared incinerator" or "Plasma arc incinerator."

(B) Does not include a "Gasification facility" or "Pyrolysis facility[,]" managing "Recoverable feedstock[,]" as defined in this section.

(89) [(85)] Incompatible waste--A hazardous waste which is unsuitable for:

(A) placement in a particular device or facility because it may cause corrosion or decay of containment materials (e.g., container inner liners or tank walls); or

(B) commingling with another waste or material under uncontrolled conditions because the commingling might produce heat or pressure, fire or explosion, violent reaction, toxic dusts, mists, fumes, or gases, or flammable fumes or gases.

(90) [(86)] Individual generation site--The contiguous site at or on which one or more solid waste or hazardous wastes are generated. An individual generation site, such as a large manufacturing plant, may have one or more sources of solid waste or hazardous waste, but is considered a single or individual generation site if the site or property is contiguous.

(91) [(87)] Industrial furnace--Includes any of the following enclosed devices that use thermal treatment to accomplish recovery of materials or energy:

(A) cement kilns;

(B) lime kilns;

(C) aggregate kilns;

(D) phosphate kilns;

(E) coke ovens;

(F) blast furnaces;

(G) smelting, melting, and refining furnaces (including pyrometallurgical devices such as cupolas, reverberator furnaces, sintering machines, roasters, and foundry furnaces);

(H) titanium dioxide chloride process oxidation reactors;

(I) methane reforming furnaces;

(J) pulping liquor recovery furnaces;

(K) combustion devices used in the recovery of sulfur values from spent sulfuric acid;

(L) halogen acid furnaces for the production of acid from halogenated hazardous waste generated by chemical production facilities where the furnace is located on the site of a chemical production facility, the acid product has a halogen acid content of at least 3.0%, the acid product is used in a manufacturing process, and, except for "Hazardous waste" burned as fuel, hazardous waste fed to the furnace has a minimum halogen content of 20% as generated; and

(M) other devices the commission may list, after the opportunity for notice and comment is afforded to the public.

(92) [(88)] Industrial solid waste--Solid waste resulting from or incidental to any process of industry or manufacturing, or mining or agricultural operation, which may include "Hazardous waste" as defined in this section.

(93) [(89)] Infrared incinerator--Any enclosed device that uses electric powered resistance heaters as a source of radiant heat followed by an afterburner using controlled flame combustion and which is not listed as an industrial furnace.

(94) [(90)] Inground tank--A device meeting the definition of "Tank" in this section whereby a portion of the tank wall is situated to any degree within the ground, thereby preventing visual inspection of that external surface area of the tank that is in the ground.

(95) [(91)] Injection well--A well into which fluids are injected. *(See* also "Underground injection.")

(96) [(92)] Inner liner--A continuous layer of material placed inside a tank or container which protects the construction materials of the tank or container from the contained waste or reagents used to treat the waste.

(97) [(93)] Installation inspector--A person who, by reason of his knowledge of the physical sciences and the principles of engineering, acquired by a professional education and related practical experience, is qualified to supervise the installation of tank systems.

(98) [(94)] Intermediate facility--Any facility that stores hazardous secondary materials for more than ten days, other than a hazardous secondary material generator or reclaimer of such material.

(99) [(95)] International shipment--The transportation of hazardous waste into or out of the jurisdiction of the United States.

(100) [(96)] Lamp--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(101) [(97)] Land-based unit--When used to describe recycling of hazardous secondary materials, an area where hazardous secondary materials are placed in or on the land before recycling. This definition does not include land-based production units.

(102) [(98)] Land treatment facility--A facility or part of a facility at which solid waste or hazardous waste is applied onto or incorporated into the soil surface

and that is not a corrective action management unit; such facilities are disposal facilities if the waste will remain after closure.

(103) [(99)] Landfill--A disposal facility or part of a facility where solid waste or hazardous waste is placed in or on land and which is not a pile, a land treatment facility, a surface impoundment, an injection well, a salt dome formation, a salt bed formation, an underground mine, a cave, or a corrective action management unit.

(104) [(100)] Landfill cell--A discrete volume of a solid waste or hazardous waste landfill which uses a liner to provide isolation of wastes from adjacent cells or wastes. Examples of landfill cells are trenches and pits.

(105) Large quantity generator--A generator who generates any of the following amounts in a calendar month:

(A) greater than or equal to 1,000 kilograms (2,200 pounds) of non-acute hazardous waste; or

(B) greater than 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 Code of Federal Regulations (CFR) §261.31 or §261.33(e); or

(C) greater than 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR §261.31 or §261.33(e).

(106) [(101)] Leachate--Any liquid, including any suspended components in the liquid, that has percolated through or drained from solid waste or hazardous waste.

(107) [(102)] Leak-detection system--A system capable of detecting the failure of either the primary or secondary containment structure or the presence of a release of solid waste or hazardous waste or accumulated liquid in the secondary containment structure. Such a system must employ operational controls (e.g., daily visual inspections for releases into the secondary containment system of aboveground tanks) or consist of an interstitial monitoring device designed to detect continuously and automatically the failure of the primary or secondary containment structure or the presence of a release of solid waste or hazardous waste into the secondary containment structure.

(108) [(103)] Licensed professional geoscientist--A geoscientist who maintains a current license through the Texas Board of Professional Geoscientists in accordance with its requirements for professional practice.

(109) [(104)] Liner--A continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment, landfill, or landfill cell, which restricts the downward or lateral escape of solid waste or hazardous waste, hazardous waste constituents, or leachate.

(110) [(105)] Management or hazardous waste management--The systematic control of the collection, source separation, storage, transportation, processing, treatment, recovery, and disposal of solid waste or hazardous waste.

(111) [(106)] Manifest--The waste shipping document, United States Environmental Protection Agency (EPA) Form 8700-22 (including, if necessary, EPA Form 8700-22A), or the electronic manifest, originated and signed by the generator or offeror in accordance with [the instructions in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste) and] the applicable requirements of this chapter and 40 Code of Federal Regulations Parts 262 - 265.

(112) [(107)] Manifest tracking number--The alphanumeric identification number (i.e., a unique three-letter suffix preceded by nine numerical digits), which is pre-printed in Item 4 of the manifest by a registered source.

(113) [(108)] Military munitions--All ammunition products and components produced or used by or for the Department of Defense (DOD) or the

United States Armed Services for national defense and security, including military munitions under the control of the DOD, the United States Coast Guard, the United States Department of Energy (DOE), and National Guard personnel. The term "military munitions":

(A) includes confined gaseous, liquid, and solid propellants, explosives, pyrotechnics, chemical and riot control agents, smokes, and incendiaries used by DOD components, including bulk explosives and chemical warfare agents, chemical munitions, rockets, guided and ballistic missiles, bombs, warheads, mortar rounds, artillery ammunition, small arms ammunition, grenades, mines, torpedoes, depth charges, cluster munitions and dispensers, demolition charges, and devices and components thereof; and

(B) includes non-nuclear components of nuclear devices, managed under DOE's nuclear weapons program after all required sanitization operations under the Atomic Energy Act of 1954, as amended, have been completed; but

(C) does not include wholly inert items, improvised explosive devices, and nuclear weapons, nuclear devices, and nuclear components thereof.

(114) [(109)] Miscellaneous unit--A hazardous waste management unit where hazardous waste is stored, processed, or disposed of and that is not a container, tank, surface impoundment, pile, land treatment unit, landfill, incinerator, boiler,

industrial furnace, underground injection well with appropriate technical standards under Chapter 331 of this title (relating to Underground Injection Control), corrective action management unit, containment building, staging pile, or unit eligible for a research, development, and demonstration permit or under Chapter 305, Subchapter K of this title (relating to Research, Development, and Demonstration Permits).

(115) [(110)] Movement--That solid waste or hazardous waste transported to a facility in an individual vehicle.

(116) [(111)] Municipal hazardous waste--A municipal solid waste or mixture of municipal solid wastes which has been identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency.

(117) [(112)] Municipal solid waste--Solid waste resulting from or incidental to municipal, community, commercial, institutional, and recreational activities; including garbage, rubbish, ashes, street cleanings, dead animals, abandoned automobiles, and all other solid waste other than industrial waste.

(118) [(113)] New tank system or new tank component--A tank system or component that will be used for the storage or processing of hazardous waste and for which installation has commenced after July 14, 1986; except, however, for purposes of 40 Code of Federal Regulations (CFR) §264.193(g)(2) (incorporated by reference at §335.152(a)(8) of this title (relating to Standards)) and 40 CFR §265.193(g)(2)

(incorporated by reference at §335.112(a)(9) of this title (relating to Standards)), a new tank system is one for which construction commences after July 14, 1986. *(See* also "Existing tank system.")

(119) [(114)] No free liquids--As used in 40 Code of Federal Regulations §261.4(a)(26) and (b)(18), means that solvent-contaminated wipes may not contain free liquids as determined by Method 9095B (Paint Filter Liquids Test), included in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication SW-846), which is incorporated by reference at §335.31 of this title (relating to Incorporation of References), and that there is no free liquid in the container holding the wipes.

(120) Non-acute hazardous waste--All hazardous wastes that are not acute hazardous waste, as defined in this section.

(121) [(115)] Off-site--Property which cannot be characterized as on-site.

(122) [(116)] Onground tank--A device meeting the definition of "Tank" in this section and that is situated in such a way that the bottom of the tank is on the same level as the adjacent surrounding surface so that the external tank bottom cannot be visually inspected.

(123) [(117)] On-Site--The same or geographically contiguous property which may be divided by public or private rights-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing, as opposed to going along, the right-of-way. Noncontiguous properties owned by the same person but connected by a right-of-way which he controls and to which the public does not have access, is also considered on-site property.

(124) [(118)] Open burning--The combustion of any material without the following characteristics:

(A) control of combustion air to maintain adequate temperature for efficient combustion;

(B) containment of the combustion-reaction in an enclosed device to provide sufficient residence time and mixing for complete combustion; and

(C) control of emission of the gaseous combustion products. *(See* also "Incinerator" and "Thermal processing.")

(125) [(119)] Operator--The person responsible for the overall operation of a facility.

(126) [(120)] Owner--The person who owns a facility or part of a facility.

(127) [(121)] Partial closure--The closure of a hazardous waste management unit in accordance with the applicable closure requirements of Subchapters E and F of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; and Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) at a facility that contains other active hazardous waste management units. For example, partial closure may include the closure of a tank (including its associated piping and underlying containment systems), landfill cell, surface impoundment, waste pile, or other hazardous waste management unit, while other units of the same facility continue to operate.

(128) [(122)] PCBs or polychlorinated biphenyl compounds--Compounds subject to 40 Code of Federal Regulations Part 761.

(129) [(123)] Permit--A written permit issued by the commission which, by its conditions, may authorize the permittee to construct, install, modify, or operate a specified municipal hazardous waste or industrial solid waste treatment, storage, or disposal facility in accordance with specified limitations.

(130) [(124)] Personnel or facility personnel--All persons who work at, or oversee the operations of, a solid waste or hazardous waste facility, and whose actions or failure to act may result in noncompliance with the requirements of this chapter.

(131) [(125)] Pesticide--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(132) [(126)] Petroleum substance--A crude oil or any refined or unrefined fraction or derivative of crude oil which is a liquid at standard conditions of temperature and pressure.

(A) Except as provided in subparagraph (C) of this paragraph for the purposes of this chapter, a "Petroleum substance" shall be limited to a substance in or a combination or mixture of substances within the following list (except for any listed substance regulated as a hazardous waste under the federal Solid Waste Disposal Act, Subtitle C (42 United States Code (USC), §§6921, *et seq.))* and which is liquid at standard conditions of temperature (20 degrees Centigrade) and pressure (1 atmosphere):

(i) basic petroleum substances--i.e., crude oils, crude oil fractions, petroleum feedstocks, and petroleum fractions;

(ii) motor fuels--a petroleum substance which is typically used for the operation of internal combustion engines and/or motors (which includes, but is not limited to, stationary engines and engines used in transportation vehicles and marine vessels);

(iii) aviation gasolines--i.e., Grade 80, Grade 100, and Grade 100-LL;

(iv) aviation jet fuels--i.e., Jet A, Jet A-1, Jet B, JP-4, JP-5, and JP-8;

(v) distillate fuel oils--i.e., Number 1-D, Number 1, Number 2-D, and Number 2;

(vi) residual fuel oils--i.e., Number 4-D, Number 4-light, Number 4, Number 5-light, Number 5-heavy, and Number 6;

(vii) gas-turbine fuel oils--i.e., Grade O-GT, Grade 1-GT, Grade 2-GT, Grade 3-GT, and Grade 4-GT;

(viii) illuminating oils--i.e., kerosene, mineral seal oil, long-time burning oils, 300 oil, and mineral colza oil;

(ix) lubricants--i.e., automotive and industrial lubricants;

(x) building materials--i.e., liquid asphalt and dust-laying oils;

(xi) insulating and waterproofing materials--i.e., transformer oils and cable oils; and

(xii) used oils--See definition for "Used oil" in this section.

(B) For the purposes of this chapter, a "Petroleum substance" shall include solvents or a combination or mixture of solvents (except for any listed substance regulated as a hazardous waste under the federal Solid Waste Disposal Act, Subtitle C (42 USC, §§6921, *et seq.))* and which is liquid at standard conditions of temperature (20 degrees Centigrade) and pressure (1 atmosphere) i.e., Stoddard solvent, petroleum spirits, mineral spirits, petroleum ether, varnish makers' and painters' naphthas, petroleum extender oils, and commercial hexane.

(C) The following materials are not considered petroleum substances:

(i) polymerized materials, i.e., plastics, synthetic rubber, polystyrene, high and low density polyethylene;

(ii) animal, microbial, and vegetable fats;

(iii) food grade oils;

(iv) hardened asphalt and solid asphaltic materials--i.e., roofing shingles, roofing felt, hot mix (and cold mix); and

(v) cosmetics.

(133) [(127)] Pile--Any noncontainerized accumulation of solid, nonflowing solid waste or hazardous waste that is used for processing or storage, and that is not a corrective action management unit or a containment building.

(134) [(128)] Plasma arc incinerator--Any enclosed device using a high intensity electrical discharge or arc as a source of heat followed by an afterburner using controlled flame combustion and which is not listed as an industrial furnace.

(135) [(129)] Post-closure order--An order issued by the commission for post-closure care of interim status units, a corrective action management unit unless authorized by permit, or alternative corrective action requirements for contamination commingled from Resource Conservation and Recovery Act and solid waste management units.

(136) [(130)] Post-use polymers--Plastic polymers that derive from industrial sources or activities that would be classified as a nonhazardous industrial solid waste if not converted into a valuable raw, intermediate, or final product. Post-

use polymers include used polymers that contain incidental contaminants or impurities such as paper labels or metal rings but do not include used polymers mixed with solid waste, medical waste, hazardous waste, electronic waste, tires, or construction or demolition debris.

(137) [(131)] Poultry--Chickens or ducks being raised or kept on any premises in the state for profit.

(138) [(132)] Poultry carcass--The carcass, or part of a carcass, of poultry that died as a result of a cause other than intentional slaughter for use for human consumption.

(139) [(133)] Poultry facility--A facility that:

(A) is used to raise, grow, feed, or otherwise produce poultry for commercial purposes; or

(B) is a commercial poultry hatchery that is used to produce chicks or ducklings.

(140) [(134)] Processing--The extraction of materials, transfer, volume reduction, conversion to energy, or other separation and preparation of solid waste for reuse or disposal, including the treatment or neutralization of solid waste or

hazardous waste, designed to change the physical, chemical, or biological character or composition of any solid waste or hazardous waste so as to neutralize such waste, or so as to recover energy or material from the waste or so as to render such waste nonhazardous, or less hazardous; safer to transport, store or dispose of; or amenable for recovery, amenable for storage, or reduced in volume. The transfer of solid waste for reuse or disposal as used in this definition does not include the actions of a transporter in conveying or transporting solid waste by truck, ship, pipeline, or other means. Unless the executive director determines that regulation of such activity is necessary to protect human health or the environment, the definition of "Processing" does not include activities relating to those materials exempted by the administrator of the United States Environmental Protection Agency in accordance with the federal Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, 42 United States Code, §§6901 *et seq.,* as amended.

(141) [(135)] Publicly-owned treatment works (POTW)--Any device or system used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature which is owned by a state or municipality (as defined by the federal Clean Water Act, §502(4)). The definition includes sewers, pipes, or other conveyances only if they convey wastewater to a POTW providing treatment.

(142) [(136)] Pyrolysis--A manufacturing process through which post-use polymers are heated in an oxygen-deficient atmosphere until melted and thermally

decomposed and then cooled, condensed, and converted into a valuable raw, intermediate, or final product, including a plastic, monomer, chemical, wax, lubricant, or chemical feedstock or crude oil, diesel, gasoline, diesel and gasoline blendstock, home heating oil, ethanol, or another fuel.

(143) [(137)] Pyrolysis facility--A manufacturing facility that receives, separates, stores, and converts post-use polymers using pyrolysis.

(144) [(138)] Qualified groundwater scientist--A scientist or engineer who has received a baccalaureate or post-graduate degree in the natural sciences or engineering, and has sufficient training and experience in groundwater hydrology and related fields as may be demonstrated by state registration, professional certifications, or completion of accredited university courses that enable that individual to make sound professional judgments regarding groundwater monitoring and contaminant fate and transport.

(145) [(139)] Recognized trader--A person domiciled in the United States, by site of business, who acts to arrange and facilitate transboundary movements of wastes destined for recovery or disposal operations, either by purchasing from and subsequently selling to United States and foreign facilities, or by acting under arrangements with a United States waste facility to arrange for the export or import of the wastes.

(146) [(140)] Recoverable feedstock--One or more of the following materials, derived from nonhazardous industrial solid waste, other than coal refuse, that has been processed so that it may be used as feedstock in a "Gasification facility" or "Pyrolysis facility" as defined in this section:

(A) post-use polymers; and

(B) material, including municipal solid waste containing post-use polymers and other post-industrial waste containing post-use polymers, that has been processed into a fuel or feedstock for which the commission or the United States Environmental Protection Agency has made a non-waste determination under 40 Code of Federal Regulations §241.3(c), as amended through February 8, 2016 (81 FR 6742).

(147) [(141)] Regional administrator--The regional administrator for the United States Environmental Protection Agency region in which the facility is located, or his designee.

(148) [(142)] Remanufacturing--Processing a higher-value hazardous secondary material in order to manufacture a product that serves a similar functional purpose as the original commercial-grade material. For the purpose of this definition, a hazardous secondary material is considered higher-value if it was generated from the use of a commercial-grade material in a manufacturing process and can be remanufactured into a similar commercial-grade material.

(149) [(143)] Remediation--The act of eliminating or reducing the concentration of contaminants in contaminated media.

(150) [(144)] Remediation waste--All solid and hazardous wastes, and all media (including groundwater, surface water, soils, and sediments) and debris, which contain listed hazardous wastes or which themselves exhibit a hazardous waste characteristic, that are managed for the purpose of implementing corrective action requirements under §335.167 of this title (relating to Corrective Action for Solid Waste Management Units) and Texas Water Code, §7.031 (Corrective Action Relating to Hazardous Waste). For a given facility, remediation wastes may originate only from within the facility boundary, but may include waste managed in implementing corrective action for releases beyond the facility boundary under §335.166(5) of this title (relating to Corrective Action Program) or §335.167(c) of this title.

(151) [(145)] Remove--To take waste, contaminated design or operating system components, or contaminated media away from a waste management unit, facility, or area to another location for treatment, storage, or disposal.

(152) [(146)] Replacement unit--A landfill, surface impoundment, or waste pile unit:

(A) from which all or substantially all the waste is removed; and

(B) that is subsequently reused to treat, store, or dispose of hazardous waste. "Replacement unit" does not apply to a unit from which waste is removed during closure, if the subsequent reuse solely involves the disposal of waste from that unit and other closing units or corrective action areas at the facility, in accordance with an approved closure plan or United States Environmental Protection Agency or state approved corrective action.

(153) [(147)] Representative sample--A sample of a universe or whole (e.g., waste pile, lagoon, groundwater) which can be expected to exhibit the average properties of the universe or whole.

(154) [(148)] Run-off--Any rainwater, leachate, or other liquid that drains over land from any part of a facility.

(155) [(149)] Run-on--Any rainwater, leachate, or other liquid that drains over land onto any part of a facility.

(156) [(150)] Saturated zone or zone of saturation--That part of the earth's crust in which all voids are filled with water.

(157) [(151)] Shipment--Any action involving the conveyance of municipal hazardous waste or industrial solid waste by any means off-site.

(158) [(152)] Sludge dryer--Any enclosed thermal treatment device that is used to dehydrate sludge and that has a maximum total thermal input, excluding the heating valve of the sludge itself, of 2,500 British thermal units per pound of sludge treated on a wet-weight basis.

(159) [(153)] Small quantity generator--A generator who generates the following amounts in a calendar month: [less than 1,000 kilograms of hazardous waste in a calendar month.]

(A) greater than 100 kilograms (220 pounds) but less than 1,000 kilograms (2,200 pounds) of non-acute hazardous waste;

(B) less than or equal to 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 Code of Federal Regulations (CFR) §261.31 or §261.33(e); and

(C) less than or equal to 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR §261.31 or §261.33(e).

(160) [(154)] Solid waste--

(A) Any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant or air pollution control facility, and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, municipal, commercial, mining, and agricultural operations, and from community and institutional activities, but does not include:

(i) solid or dissolved material in domestic sewage, or solid or dissolved material in irrigation return flows, or industrial discharges subject to regulation by permit issued in accordance with Texas Water Code, Chapter 26 (an exclusion applicable only to the actual point source discharge that does not exclude industrial wastewaters while they are being collected, stored, or processed before discharge, nor does it exclude sludges that are generated by industrial wastewater treatment);

(ii) uncontaminated soil, dirt, rock, sand, and other natural or man-made inert solid materials used to fill land if the object of the fill is to make the land suitable for the construction of surface improvements. The material serving as fill may also serve as a surface improvement such as a structure foundation, a road, soil erosion control, and flood protection. Man-made materials exempted under this provision shall only be deposited at sites where the construction is in progress or imminent such that rights to the land are secured and engineering, architectural, or other necessary planning have been initiated. Waste disposal shall be considered to

have occurred on any land which has been filled with man-made inert materials under this provision if the land is sold, leased, or otherwise conveyed prior to the completion of construction of the surface improvement. Under such conditions, deed recordation shall be required. The deed recordation shall include the information required under §335.5(a) of this title (relating to Deed Recordation of Waste Disposal), prior to sale or other conveyance of the property;

(iii) waste materials which result from "Activities associated with the exploration, development, or production of oil or gas or geothermal resources," as those activities are defined in this section, and any other substance or material regulated by the Railroad Commission of Texas in accordance with the Texas Natural Resources Code, §91.101, unless such waste, substance, or material results from activities associated with gasoline plants, natural gas, or natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants and is a hazardous waste as defined by the administrator of the United States Environmental Protection Agency (EPA) in accordance with the federal Solid Waste Disposal Act, 42 United States Code, §§6901 *et seq.,* as amended;

(iv) a material excluded by 40 Code of Federal Regulations (CFR) §§261.4(a), 261.39, or 261.40, as adopted under §335.504 of this title (relating to Hazardous Waste Determination), [§261.40, as amended through January 13, 2015 (80 FR 1694), §261.4(a)(1) - (15), (17) - (24), (26), and (27), as amended through April 8, 2015 (80 FR 18777), or §261.39, as amended through November 28, 2016 (81 FR

85696),] subject to the changes in this clause, by variance, or by non-waste determination granted under §335.18 of this title (relating to Non-Waste Determinations and Variances from Classification as a Solid Waste), §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste), §335.21 of this title (relating to Procedures for Variances from Classification as a Solid Waste or To Be Classified as a Boiler or for Non-Waste Determinations), and §335.32 of this title (relating to Standards and Criteria for Non-Waste Determinations). For the purposes of the exclusions under 40 CFR §261.39 and §261.40, 40 CFR §261.41 is adopted by reference under §335.504 of this title [as amended through July 28, 2006 (71 FR 42928)]; or

(v) recoverable feedstocks that are processed through pyrolysis or gasification at a pyrolysis facility or gasification facility, where the primary function of the facility is to convert recoverable feedstocks into materials that have a resale value greater than the cost of processing the recoverable feedstock for subsequent beneficial use and where solid waste generated from converting recoverable feedstock is disposed of at an authorized solid waste management facility.

(B) A discarded material is any material which is:

(i) abandoned, as explained in subparagraph (C) of this paragraph;

(ii) recycled, as explained in subparagraph (D) of this paragraph;

(iii) considered inherently waste-like, as explained in subparagraph (E) of this paragraph; or

(iv) a military munition identified as a solid waste in 40 CFR §266.202.

(C) Materials are solid wastes if they are abandoned by being:

(i) disposed of;

(ii) burned or incinerated;

(iii) accumulated, stored, or processed (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated; or

(iv) sham recycling as explained in subparagraph (J) of this paragraph.

(D) Except for materials described in subparagraph (H) of this paragraph, materials are solid wastes if they are "recycled" or accumulated, stored, or

processed before recycling as specified in this subparagraph. The chart referred to as Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [§335.1(154)(D)(iv)] indicates only which materials are considered to be solid wastes when they are recycled and is not intended to supersede the definition of "Solid waste" provided in subparagraph (A) of this paragraph.

(i) Used in a manner constituting disposal. Materials noted with an asterisk in Column 1 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [§335.1(154)(D)(iv)] are solid wastes when they are:

(I) applied to or placed on the land in a manner that constitutes disposal; or

(II) used to produce products that are applied to or placed on the land or are otherwise contained in products that are applied to or placed on the land (in which cases the product itself remains a solid waste). However, commercial chemical products listed in 40 CFR §261.33 are not solid wastes if they are applied to the land and that is their ordinary manner of use.

(ii) Burning for energy recovery. Materials noted with an asterisk in Column 2 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [§335.1(154)(D)(iv)] are solid wastes when they are:

(I) burned to recover energy; or

(II) used to produce a fuel or are otherwise contained in fuels (in which cases the fuel itself remains a solid waste). However, commercial chemical products, which are listed in 40 CFR §261.33, not listed in §261.33, but that exhibit one or more of the hazardous waste characteristics, or will be considered nonhazardous waste if disposed, are not solid wastes if they are fuels themselves and burned for energy recovery.

(iii) Reclaimed. Materials noted with an asterisk in Column 3 of Table 1 are solid wastes when reclaimed (unless they meet the requirements of 40 CFR §261.4(a)(17), (23), (24), or (27)). Materials without an asterisk in Column 3 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [§335.1(154)(D)(iv)] are not solid wastes when reclaimed.

(iv) Accumulated speculatively. Materials noted with an asterisk in Column 4 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [§335.1(154)(D)(iv)] are solid wastes when accumulated speculatively.

Figure: 30 TAC §335.1(160)(D)(iv)

[Figure: 30 TAC §335.1(154)(D)(iv)]

TABLE 1

	Use Constituting Disposal S.W. Def. (D)(i)	**Energy Recovery/Fuel S.W. Def. (D)(ii)**	**Reclamation S.W. Def. (D)(iii)[2]**	**Speculative Accumulation S.W. Def. (D)(iv)**
Spent materials (listed hazardous and not listed characteristically hazardous)	*	*	*	*
Spent materials (nonhazardous)[1]	*	*	*	*
Sludges (listed hazardous in 40 CFR §261.31 or §261.32)	*	*	*	*
Sludges (not listed characteristically hazardous)	*	*		*
Sludges (nonhazardous)[1]	*	*		*
By-products (listed hazardous in 40 CFR §261.31 or §261.32)	*	*	*	*
By-products (not listed characteristically hazardous)	*	*		*
By-products (nonhazardous)[1]	*	*		*
Commercial chemical products (listed, not listed characteristically hazardous, and nonhazardous)	*	*		
Scrap metal that is not excluded under subparagraph (A)	*	*	*	*

of this paragraph (hazardous)				
Scrap metal other than excluded scrap metal (see §335.17(a)(9) of this title) (nonhazardous)[1]	*	*	*	*

NOTE: The terms "spent materials," "sludges," "by-products," "scrap metal," and "excluded scrap metal" are defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials).

[1] These materials are governed by the provisions of §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) only.

[2] Reclamation (40 CFR §261.2(c)(3)), except as provided in [Except as provided in 40 CFR §261.2(c)(3) and] §261.4(a)(17) for mineral processing secondary materials or as provided in 40 CFR §261.4(a)(23), (24), or (27) for hazardous secondary materials.

(E) Materials that are identified by the administrator of the EPA as inherently waste-like materials under 40 CFR §261.2(d) are solid wastes when they are recycled in any manner.

(F) Materials are not solid wastes when they can be shown to be recycled by being:

(i) used or reused as ingredients in an industrial process to make a product, provided the materials are not being reclaimed;

(ii) used or reused as effective substitutes for commercial products;

(iii) returned to the original process from which they were generated, without first being reclaimed or land disposed. The material must be returned as a substitute for feedstock materials. In cases where the original process to which the material is returned is a secondary process, the materials must be managed such that there is no placement on the land. In cases where the materials are generated and reclaimed within the primary mineral processing industry, the conditions of the exclusion found at 40 CFR §261.4(a)(17) apply rather than this provision; or

(iv) secondary materials that are reclaimed and returned to the original process or processes in which they were generated where they are reused in the production process provided:

(I) only tank storage is involved, and the entire process through completion of reclamation is closed by being entirely connected with pipes or other comparable enclosed means of conveyance;

(II) reclamation does not involve controlled flame combustion (such as occurs in boilers, industrial furnaces, or incinerators);

(III) the secondary materials are never accumulated in such tanks for over 12 months without being reclaimed; and

(IV) the reclaimed material is not used to produce a fuel, or used to produce products that are used in a manner constituting disposal.

(G) Except for materials described in subparagraph (H) of this paragraph, the following materials are solid wastes, even if the recycling involves use, reuse, or return to the original process, as described in subparagraph (F) of this paragraph:

(i) materials used in a manner constituting disposal, or used to produce products that are applied to the land;

(ii) materials burned for energy recovery, used to produce a fuel, or contained in fuels;

(iii) materials accumulated speculatively; or

(iv) materials deemed to be inherently waste-like by the administrator of the EPA, as described in 40 CFR §261.2(d)(1) and (2).

(H) With the exception of contaminated soils which are being relocated for use under §350.36 of this title (relating to Relocation of Soils Containing Chemicals of Concern for Reuse Purposes) and other contaminated media, materials that will otherwise be identified as nonhazardous solid wastes if disposed of are not

considered solid wastes when recycled by being applied to the land or used as ingredients in products that are applied to the land, provided these materials can be shown to meet all of the following criteria:

(i) a legitimate market exists for the recycling material as well as its products;

(ii) the recycling material is managed and protected from loss as will be raw materials or ingredients or products;

(iii) the quality of the product is not degraded by substitution of raw material/product with the recycling material;

(iv) the use of the recycling material is an ordinary use and it meets or exceeds the specifications of the product it is replacing without treatment or reclamation, or if the recycling material is not replacing a product, the recycling material is a legitimate ingredient in a production process and meets or exceeds raw material specifications without treatment or reclamation;

(v) the recycling material is not burned for energy recovery, used to produce a fuel, or contained in a fuel;

(vi) the recycling material can be used as a product itself or to produce products as it is generated without treatment or reclamation;

(vii) the recycling material must not present an increased risk to human health, the environment, or waters in the state when applied to the land or used in products which are applied to the land and the material, as generated:

(I) is a Class 3 waste under Subchapter R of this chapter (relating to Waste Classification), except for arsenic, cadmium, chromium, lead, mercury, nickel, selenium, and total dissolved solids; and

(II) for the metals listed in subclause (I) of this clause:

(-a-) is a Class 2 or Class 3 waste under Subchapter R of this chapter; and

(-b-) does not exceed a concentration limit under §312.43(b)(3), Table 3 of this title (relating to Metal Limits); and

(viii) with the exception of the requirements under §335.17(a)(8) of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials):

(I) at least 75% (by weight or volume) of the annual production of the recycling material must be recycled or transferred to a different site and recycled on an annual basis; and

(II) if the recycling material is placed in protective storage, such as a silo or other protective enclosure, at least 75% (by weight or volume) of the annual production of the recycling material must be recycled or transferred to a different site and recycled on a biennial basis.

(I) Respondents in actions to enforce the industrial solid waste regulations and facility operators who raise a claim that a certain material is not a solid waste, or is conditionally exempt from regulation, must demonstrate that there is a known market or disposition for the material, and that they meet the terms of the exclusion or exemption. In doing so, they must provide appropriate documentation (such as contracts showing that a second person uses the material as an ingredient in a production process) to demonstrate that the material is not a waste, or is exempt from regulation. In addition, owners or operators of facilities claiming that they actually are recycling materials must show that they have the necessary equipment to do so and that the recycling activity is legitimate and beneficial.

(J) A hazardous secondary material found to be sham recycled is considered discarded and a solid waste. Sham recycling is recycling that is not

legitimate recycling as defined in §335.27 of this title (relating to Legitimate Recycling of Hazardous Secondary Materials).

(K) Materials that are reclaimed from solid wastes and that are used beneficially are not solid wastes and hence are not hazardous wastes under 40 CFR §261.3(c) unless the reclaimed material is burned for energy recovery or used in a manner constituting disposal.

(L) Other portions of this chapter that relate to solid wastes that are recycled include §335.6 of this title (relating to Notification Requirements), §§335.17 - 335.19 of this title, §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), and Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities).

(M) Steel slag may not be considered as solid waste if the steel slag is an intended output or result of the use of an electric arc furnace to make steel, introduced into the stream of commerce, and managed as an item of commercial value, including through a controlled use in a manner constituting disposal, and not as discarded material.

(N) Foundry sand from the iron and steel casting industry may not be considered as solid waste if the sand is an intended output or result of the use of

an iron or steel casting process to make cast iron and steel products, introduced into the stream of commerce, and managed as an item of commercial value, including through a controlled use in a manner constituting disposal, and not as discarded material.

(161) [(155)] Solvent-contaminated wipe--A wipe that, after use or after cleaning up a spill, either:

(A) contains one or more of the F001 through F005 solvents listed in 40 Code of Federal Regulations (CFR) §261.31 or the corresponding P- or U-listed solvents found in 40 CFR §261.33;

(B) exhibits a hazardous characteristic found in 40 CFR Part 261, Subpart C, when that characteristic results from a solvent listed in 40 CFR Part 261; and/or

(C) exhibits only the hazardous waste characteristic of ignitability found in 40 CFR §261.21 due to the presence of one or more solvents that are not listed in 40 CFR Part 261. Solvent-contaminated wipes that contain listed hazardous waste other than solvents, or exhibit the characteristic of toxicity, corrosivity, or reactivity due to contaminants other than solvents, are not eligible for the exclusions at 40 CFR §261.4(a)(26) and (b)(18).

(162) [(156)] Sorbent--A material that is used to soak up free liquids by either adsorption or absorption, or both. Sorb means to either adsorb or absorb, or both.

(163) [(157)] Spill--The accidental spilling, leaking, pumping, emitting, emptying, or dumping of solid waste or hazardous wastes or materials which, when spilled, become solid waste or hazardous wastes into or on any land or water.

(164) [(158)] Staging pile--An accumulation of solid, non-flowing "Remediation waste," as defined in this section, that is not a containment building and that is used only during remedial operations for temporary storage at a facility. Staging piles must be designated by the executive director according to the requirements of 40 Code of Federal Regulations §264.554, as adopted by reference under §335.152(a) of this title (relating to Standards).

(165) [(159)] Standard permit--A Resource Conservation and Recovery Act permit authorizing management of hazardous waste issued under Chapter 305, Subchapter R of this title (relating to Resource Conservation and Recovery Act Standard Permits for Storage and Treatment Units) and Subchapter U of this chapter (relating to Standards for Owners and Operators of Hazardous Waste Facilities Operating Under a Standard Permit). The standard permit may have two parts, a uniform portion issued in all cases and a supplemental portion issued at the executive director's discretion.

(166) [(160)] Storage--The holding of solid waste for a temporary period, at the end of which the waste is processed, disposed of, recycled, or stored elsewhere.

(167) [(161)] Sump--Any pit or reservoir that meets the definition of "Tank" in this section and those troughs/trenches connected to it that serve to collect solid waste or hazardous waste for transport to solid waste or hazardous waste treatment, storage, or disposal facilities; except that as used in the landfill, surface impoundment, and waste pile rules, "sump" means any lined pit or reservoir that serves to collect liquids drained from a leachate collection and removal system or leak detection system for subsequent removal from the system.

(168) [(162)] Surface impoundment or impoundment--A facility or part of a facility which is a natural topographic depression, man-made excavation, or diked area formed primarily of earthen materials (although it may be lined with man-made materials), which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well or a corrective action management unit. Examples of surface impoundments are holding, storage, settling, and aeration pits, ponds, and lagoons.

(169) [(163)] Tank--A stationary device, designed to contain an accumulation of solid waste which is constructed primarily of non-earthen materials (e.g., wood, concrete, steel, plastic) which provide structural support.

(170) [(164)] Tank system--A solid waste or hazardous waste storage or processing tank and its associated ancillary equipment and containment system.

(171) [(165)] TEQ--Toxicity equivalence, the international method of relating the toxicity of various dioxin/furan congeners to the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin.

(172) [(166)] Thermal processing--The processing of solid waste or hazardous waste in a device which uses elevated temperatures as the primary means to change the chemical, physical, or biological character or composition of the solid waste or hazardous waste. Examples of thermal processing are incineration, molten salt, pyrolysis, calcination, wet air oxidation, and microwave discharge. *(See* also "Incinerator" and "Open burning.")

(173) [(167)] Thermostat--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(174) [(168)] Totally enclosed treatment facility--A facility for the processing of hazardous waste which is directly connected to an industrial production process and which is constructed and operated in a manner which prevents the release of any hazardous waste or any constituent thereof into the environment during processing. An example is a pipe in which acid waste is neutralized.

(175) [(169)] Transfer facility--Any transportation-related facility including loading docks, parking areas, storage areas, and other similar areas where shipments of hazardous or industrial solid waste or hazardous secondary materials are held during the normal course of transportation.

(176) [(170)] Transport vehicle--A motor vehicle or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (trailer, railroad freight car, etc.) is a separate transport vehicle. Vessel includes every description of watercraft, used or capable of being used as a means of transportation on the water.

(177) [(171)] Transporter--Any person who conveys or transports municipal hazardous waste or industrial solid waste by truck, ship, pipeline, or other means.

(178) [(172)] Treatability study--A study in which a hazardous or industrial solid waste is subjected to a treatment process to determine:

(A) whether the waste is amenable to the treatment process;

(B) what pretreatment (if any) is required;

(C) the optimal process conditions needed to achieve the desired treatment;

(D) the efficiency of a treatment process for a specific waste or wastes; or

(E) the characteristics and volumes of residuals from a particular treatment process. Also included in this definition for the purpose of the exemptions under 40 Code of Federal Regulations §261.4(e) and (f) and §335.2 of this title (relating to Permit Required) [(§§335.2, 335.69, and 335.78 of this title (relating to Permit Required; and Accumulation Time; and Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)) exemptions] are liner compatibility, corrosion, and other material compatibility studies and toxicological and health effects studies. A treatability study is not a means to commercially treat or dispose of hazardous or industrial solid waste.

(179) [(173)] Treatment--To apply a physical, biological, or chemical process(es) to wastes and contaminated media which significantly reduces the toxicity, volume, or mobility of contaminants and which, depending on the process(es) used, achieves varying degrees of long-term effectiveness.

(180) [(174)] Treatment zone--A soil area of the unsaturated zone of a land treatment unit within which hazardous constituents are degraded, transferred, or immobilized.

(181) [(175)] Underground injection--The subsurface emplacement of fluids through a bored, drilled, or driven well; or through a dug well, where the depth of the dug well is greater than the largest surface dimension. *(See* also "Injection well.")

(182) [(176)] Underground tank--A device meeting the definition of "Tank" in this section whose entire surface area is totally below the surface of and covered by the ground.

(183) [(177)] Unfit-for-use tank system--A tank system that has been determined through an integrity assessment or other inspection to be no longer capable of storing or processing solid waste or hazardous waste without posing a threat of release of solid waste or hazardous waste to the environment.

(184) [(178)] United States Environmental Protection Agency (EPA) hazardous waste number--The number assigned by the EPA to each hazardous waste listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D and to each characteristic identified in 40 CFR Part 261, Subpart C.

(185) [(179)] United States Environmental Protection Agency (EPA) identification number--The number assigned by the EPA or the commission to each generator, transporter, and processing, storage, or disposal facility.

(186) [(180)] Universal waste--Any of the hazardous wastes defined as universal waste under §335.261(b)(19)(F) [§335.261(b)(16)(F)] of this title (relating to Universal Waste Rule) that are managed under the universal waste requirements of Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule).

(187) [(181)] Universal waste handler--Has the definition adopted as "Large quantity handler of universal waste" and "Small quantity handler of universal waste" under §335.261 of this title (relating to Universal Waste Rule).

(188) [(182)] Universal waste transporter--Has the definition adopted under 40 Code of Federal Regulations §273.9.

(189) [(183)] Unsaturated zone or zone of aeration--The zone between the land surface and the water table.

(190) [(184)] Uppermost aquifer--The geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected within the facility's property boundary.

(191) [(185)] Used oil--Any oil that has been refined from crude oil, or any synthetic oil, that has been used, and, as a result of such use, is contaminated by physical or chemical impurities. Used oil fuel includes any fuel produced from used oil by processing, blending, or other treatment. Rules applicable to nonhazardous used oil, oil characteristically hazardous from use versus mixing, very [conditionally exempt] small quantity generator hazardous used oil, and household used oil after collection that will be recycled are found in Chapter 324 of this title (relating to Used Oil Standards) and 40 Code of Federal Regulations Part 279 (Standards for Management of Used Oil).

(192) [(186)] User of the electronic manifest system--A hazardous waste generator, a hazardous waste transporter, an owner or operator of a hazardous waste treatment, storage, recycling, or disposal facility, or any other person that:

(A) is required to use a manifest to comply with:

(i) any federal or state requirement to track the shipment, transportation, and receipt of hazardous waste or other waste material that is shipped from the site of generation to an off-site designated facility for treatment, storage, recycling, or disposal; or

(ii) any federal or state requirement to track the shipment, transportation, and receipt of rejected wastes or regulated container residues that are

shipped from a designated facility to an alternative facility, or returned to the generator; and

(B) elects to use the system to obtain, complete and transmit an electronic manifest format supplied by the United States Environmental Protection Agency electronic manifest system; or

(C) elects to use the paper manifest form and submits to the system for data processing purposes a paper copy of the manifest (or data from such a paper copy), in accordance with 40 Code of Federal Regulations (CFR) §264.71(a)(2)(v) as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.71(a)(2)(v) as adopted under §335.112 of this title (relating to Standards) [§335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste)]. These paper copies are submitted for data exchange purposes only and are not the official copies of record for legal purposes.

(193) Very small quantity generator--A generator who generates less than or equal to the following amounts in a calendar month:

(A) 100 kilograms (220 pounds) of non-acute hazardous waste; and

(B) 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 Code of Federal Regulations (CFR) §261.31 or §261.33(e); and

(C) 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR §261.31 or §261.33(e).

(194) [(187)] Wastewater treatment unit--A device which:

(A) is part of a wastewater treatment facility subject to regulation under either the Federal Water Pollution Control Act (federal Clean Water Act), 33 United States Code, §§466 *et seq.,* §402 or §307(b), as amended;

(B) receives and processes or stores an influent wastewater which is a hazardous or industrial solid waste, or generates and accumulates a wastewater treatment sludge which is a hazardous or industrial solid waste, or processes or stores a wastewater treatment sludge which is a hazardous or industrial solid waste; and

(C) meets the definition of "Tank" or "Tank system" as defined in this section.

(195) [(188)] Water (bulk shipment)--The bulk transportation of municipal hazardous waste or Class 1 industrial solid waste which is loaded or carried on board a vessel without containers or labels.

(196) [(189)] Well--Any shaft or pit dug or bored into the earth, generally of a cylindrical form, and often walled with bricks or tubing to prevent the earth from caving in.

(197) [(190)] Wipe--A woven or non-woven shop towel, rag, pad, or swab made of wood pulp, fabric, cotton, polyester blends, or other material.

(198) [(191)] Zone of engineering control--An area under the control of the owner/operator that, upon detection of a solid waste or hazardous waste release, can be readily cleaned up prior to the release of solid waste or hazardous waste or hazardous constituents to groundwater or surface water.

§335.2. Permit Required.

(a) Except with regard to storage, processing, or disposal to which subsections (c) - (h) of this section apply, and as provided in §335.45(b) of this title (relating to Effect on Existing Facilities), and in accordance with the requirements of §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) and §335.25 of this title (relating to Handling, Storing, Processing, Transporting, and Disposing of Poultry Carcasses), and as provided in §332.4 of this title (relating to General Requirements), no person may cause, suffer, allow, or permit any activity of storage, processing, or disposal of any industrial solid waste or municipal hazardous waste unless such activity is authorized by a permit,

amended permit, or other authorization from the Texas Commission on Environmental Quality (commission) or its predecessor agencies, the Texas Department of State Health Services (DSHS), or other valid authorization from a Texas state agency. No person may commence physical construction of a new hazardous waste management facility without first having submitted Part A and Part B of the permit application and received a finally effective permit.

(b) In accordance with the requirements of subsection (a) of this section, no generator, transporter, owner or operator of a facility, or any other person may cause, suffer, allow, or permit its wastes to be stored, processed, or disposed of at an unauthorized facility or in violation of a permit. In the event this requirement is violated, the executive director will seek recourse against not only the person who stored, processed, or disposed of the waste, but also against the generator, transporter, owner or operator, or other person who caused, suffered, allowed, or permitted its waste to be stored, processed, or disposed.

(c) Any owner or operator of a solid waste management facility that is in existence on the effective date of a statutory or regulatory change that subjects the owner or operator to a requirement to obtain a hazardous waste permit who has filed a hazardous waste permit application with the commission in accordance with the rules and regulations of the commission, may continue the storage, processing, or disposal of hazardous waste until such time as the commission approves or denies the application, or, if the owner or operator becomes subject to a requirement to obtain a

hazardous waste permit after November 8, 1984, except as provided by the United States Environmental Protection Agency (EPA) or commission rules relative to termination of interim status. If a solid waste facility which has become a commercial hazardous waste management facility as a result of the federal toxicity characteristic rule effective September 25, 1990, and is required to obtain a hazardous waste permit, such facility that qualifies for interim status is limited to those activities that qualify it for interim status until the facility obtains the hazardous waste permit. Owners or operators of municipal hazardous waste facilities that satisfied this requirement by filing an application on or before November 19, 1980, with the EPA are not required to submit a separate application with the DSHS. Applications filed under this section shall meet the requirements of §335.44 of this title (relating to Application for Existing On-Site Facilities). Owners and operators of solid waste management facilities that are in existence on the effective date of statutory or regulatory amendments under the Texas Solid Waste Disposal Act (Vernon's Supplement 1991), Texas Civil Statutes, Article 4477-7, or the Resource Conservation and Recovery Act (RCRA), 42 United States Code, §§6901 *et seq.,* that render the facilities subject to the requirement to obtain a hazardous waste permit, may continue to operate if Part A of their permit application is submitted no later than six months after the date of publication of regulations by the EPA under RCRA, which first require them to comply with the standards in Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities), or Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities); or 30 days after the date they first become subject to the

standards in these subchapters, whichever first occur; or for generators who generate greater than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month and who process, store, or dispose of these wastes on-site, a Part A permit application shall be submitted to the EPA by March 24, 1987, as required by 40 Code of Federal Regulations (CFR) §270.10(e)(1)(iii). This subsection shall not apply to a facility if it has been previously denied a hazardous waste permit or if authority to operate the facility has been previously terminated. Applications filed under this section shall meet the requirements of §335.44 of this title. For purposes of this subsection, a solid waste management facility is in existence if the owner or operator has obtained all necessary federal, state, and local preconstruction approvals or permits, as required by applicable federal, state, and local hazardous waste control statutes, regulations, or ordinances; and either:

(1) a continuous physical, on-site construction program has begun; or

(2) the owner or operator has entered into contractual obligations, which cannot be cancelled or modified without substantial loss, for construction of the facility to be completed within a reasonable time.

(d) No permit shall be required for:

(1) the processing or disposal of nonhazardous industrial solid waste, if the waste is processed or disposed on property owned or otherwise effectively

controlled by the owner or operator of the industrial plant, manufacturing plant, mining operation, or agricultural operation from which the waste results or is produced; the property is within 50 miles of the plant or operation; and the waste is not commingled with waste from any other source or sources (An industrial plant, manufacturing plant, mining operation, or agricultural operation owned by one person shall not be considered an "other source" with respect to other plants and operations owned by the same person.);

(2) the storage of nonhazardous industrial solid waste, if the waste is stored on property owned or otherwise effectively controlled by the owner or operator of the industrial plant, manufacturing plant, mining operation, or agricultural operation from which the waste results or is produced, and the waste is not commingled with waste from any other source or sources (An industrial plant, manufacturing plant, mining operation, or agricultural operation owned by one person shall not be considered an "other source" with respect to other plants and operations owned by the same person.);

(3) the storage or processing of nonhazardous industrial solid waste, if the waste is processed in an elementary neutralization unit;

(4) the collection, storage, or processing of nonhazardous industrial solid waste, if the waste is collected, stored, or processed as part of a treatability study;

(5) the storage of nonhazardous industrial solid waste, if the waste is stored in a transfer facility in containers for a period of ten days or less, unless the executive director determines that a permit should be required in order to protect human health and the environment;

(6) the storage or processing of nonhazardous industrial solid waste, if the waste is processed in a publicly owned treatment works with discharges subject to regulation under the federal Clean Waste Act, §402, as amended through October 4, 1996, if the owner or operator has a National Pollutant Discharge Elimination System permit and complies with the conditions of the permit;

(7) the storage or processing of nonhazardous industrial solid waste, if the waste is stored or processed in a wastewater unit and is discharged in accordance with a Texas Pollutant Discharge Elimination System authorization issued under Texas Water Code, Chapter 26;

(8) the storage or processing of nonhazardous industrial solid waste, if the waste is stored or processed in a wastewater treatment unit that discharges to a publicly owned treatment works and the units are located at a noncommercial solid waste management facility; or

(9) the storage or processing of nonhazardous industrial solid waste, if the waste is processed in a wastewater treatment unit that discharges to a publicly

owned treatment works liquid wastes that are incidental to the handling, processing, storage, or disposal of solid wastes at municipal solid waste facilities or commercial industrial solid waste landfill facilities.

(e) No permit shall be required for the on-site storage of hazardous waste by a person who meets the conditions for exemption for a very small quantity generator in 40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [is a conditionally exempt small quantity generator as described in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)].

(f) No permit under this chapter shall be required for the storage, processing, or disposal of hazardous waste by a person described in §335.41(b) - (d) of this title (relating to Purpose, Scope, and Applicability) or for the storage of hazardous waste under the provisions of 40 CFR §261.4(c) and (d) as adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(g) No permit under this chapter shall be required for the storage, processing, or disposal of hazardous industrial waste or municipal hazardous waste that is generated or collected for the purpose of conducting treatability studies. Such samples are subject to the requirements in 40 CFR §261.4(e) and (f) [, as amended through

November 28, 2016 (81 FR 83696), which are adopted by reference] as adopted under §335.504 of this title.

(h) A person may obtain authorization from the executive director for the storage, processing, or disposal of nonhazardous industrial solid waste in an interim status landfill that has qualified for interim status in accordance with 40 CFR Part 270, Subpart G, and that has complied with the standards in Subchapter E of this chapter, by complying with the notification and information requirements in §335.6 of this title (relating to Notification Requirements). The executive director may approve or deny the request for authorization or grant the request for authorization subject to conditions, which may include, without limitation, public notice and technical requirements. A request for authorization for the disposal of nonhazardous industrial solid waste under this subsection shall not be approved unless the executive director determines that the subject facility is suitable for disposal of such waste at the facility as requested. At a minimum, a determination of suitability by the executive director must include approval by the executive director of construction of a hazardous waste landfill meeting the design requirements of 40 CFR §265.301(a). In accordance with §335.6 of this title, such person shall not engage in the requested activities if denied by the executive director or unless 90 days' notice has been provided and the executive director approves the request except where express executive director approval has been obtained prior to the expiration of the 90 days. Authorization may not be obtained under this subsection for:

(1) nonhazardous industrial solid waste, the storage, processing, or disposal of which is expressly prohibited under an existing permit or site development plan applicable to the facility or a portion of the facility;

(2) polychlorinated biphenyl compounds wastes subject to regulation by 40 CFR Part 761;

(3) explosives and shock-sensitive materials;

(4) pyrophorics;

(5) infectious materials;

(6) liquid organic peroxides;

(7) radioactive or nuclear waste materials, receipt of which will require a license from the DSHS or the commission or any other successor agency; and

(8) friable asbestos waste unless authorization is obtained in compliance with the procedures established under §330.171(c)(3)(B) - (E) of this title (relating to Disposal of Special Wastes). Authorizations obtained under this subsection shall be effective during the pendency of the interim status and shall cease upon the termination of interim status, final administrative disposition of the subject permit

application, failure of the facility to operate the facility in compliance with the standards set forth in Subchapter E of this chapter, or as otherwise provided by law.

(i) Owners or operators of hazardous waste management units must have permits during the active life (including the closure period) of the unit. Owners or operators of surface impoundments, landfills, land treatment units, and waste pile units that received wastes after July 26, 1982, or that certified closure (according to 40 CFR §265.115) after January 26, 1983, must have post-closure permits, unless they demonstrate closure by removal or decontamination as provided under 40 CFR §270.1(c)(5) and (6), or obtain an order in lieu of a post-closure permit, as provided in subsection (m) of this section. If a post-closure permit is required, the permit must address applicable provisions of 40 CFR Part 264, and Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) provisions concerning groundwater monitoring, unsaturated zone monitoring, corrective action, and post-closure care requirements. The denial of a permit for the active life of a hazardous waste management facility or unit does not affect the requirement to obtain a post-closure permit under this section.

(j) Upon receipt of the federal Hazardous and Solid Waste Act (HSWA) authorization for the commission's Hazardous Waste Program, the commission shall be authorized to enforce the provisions that the EPA imposed in hazardous waste permits that were issued before the HSWA authorization was granted.

(k) Any person who intends to conduct an activity under subsection (d) of this section shall comply with the notification requirements of §335.6 of this title.

(l) No permit shall be required for the management of universal wastes by universal waste handlers or universal waste transporters, in accordance with the definitions and requirements of Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule).

(m) At the discretion of the commission, an owner or operator may obtain a post-closure order in lieu of a post-closure permit for interim status units, a corrective action management unit unless authorized by a permit, or alternative corrective action requirements for contamination commingled from RCRA and solid waste management units. The post-closure order must address the facility-wide corrective action requirements of §335.167 of this title (relating to Corrective Action for Solid Waste Management Units) and groundwater monitoring requirements of §335.156 of this title (relating to Applicability of Groundwater Monitoring and Response).

(n) Except as provided in subsection (d)(9) of this section, owners or operators of commercial industrial solid waste facilities that receive industrial solid waste for discharge to a publicly owned treatment works are required to obtain a permit under this subchapter. By June 1, 2006, owners or operators of existing commercial industrial solid waste facilities that receive industrial solid waste for discharge to a publicly

owned treatment works must have a permit issued under this subchapter or obtain a general permit issued under Chapter 205 of this title (relating to General Permits for Waste Discharges) to continue operating. A general permit issued under Chapter 205 of this title will authorize operations until a final decision is made on the application for an individual permit or 15 months, whichever is earlier. The general permit shall authorize operations for a maximum period of 15 months except that authorization may be extended on an individual basis in one-year increments at the discretion of the executive director. Should an application for a general permit issued under Chapter 205 of this title be submitted, the applicant shall also submit to the commission, by June 1, 2006, the appropriate information to demonstrate compliance with financial assurance requirements for closure of industrial solid waste facilities in accordance with Chapter 37, Subchapter P of this title (relating to Financial Assurance for Hazardous and Nonhazardous Industrial Solid Waste Facilities). Owners or operators of commercial industrial solid waste facilities that receive industrial solid waste for discharge to a publicly owned treatment works operating under a general permit issued under Chapter 205 of this title shall submit an application for a permit issued under this subchapter prior to September 1, 2006.

(o) Treatment, storage, and disposal facilities that are otherwise subject to permitting under RCRA and that meet the criteria in paragraphs (1) or paragraph (2) of this subsection, may be eligible for a standard permit under Subchapter U of this chapter (relating to Standards for Owners and Operators of Hazardous Waste Facilities Operating Under a Standard Permit) if they satisfy one of the two following criteria:

(1) facility generates hazardous waste and then non-thermally treats and/or stores hazardous waste on-site; or

(2) facility receives hazardous waste generated off-site by a generator under the same ownership as the receiving facility.

(p) No permit under this chapter shall be required for a reverse distributor accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in §335.751 of this title (relating to Definitions) in compliance with Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals). Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals in compliance with Subchapter W of this chapter shall notify the executive director in accordance with §335.6 of this title.

§335.6. Notification Requirements.

(a) Notification of industrial solid waste and municipal hazardous waste activities not authorized by a permit. ~~(a) Notification of unpermitted industrial solid waste activities.~~ Any person who intends to store, process, recycle, or dispose of industrial solid waste without a permit, as authorized by §335.2(d), (f), or (h) of this title (relating to Permit Required) or §335.24 of this title (relating to Requirements for

Recyclable Materials and Nonhazardous Recyclable Materials), shall notify the executive director using a method approved by the executive director, that storage, processing, recycling, or disposal activities are planned.

(1) A person required to notify of activities under this subsection shall notify at least 90 days before conducting an activity under this subsection.

(2) A person required to notify under this section shall submit additional information, upon request, to the executive director to demonstrate that storage, processing, recycling, or disposal is compliant with the terms of this chapter, including but not limited to information listed under subsection (b)(3) of this section.

(b) Duty to notify of changed and new information. Any person who stores, processes, or disposes of municipal hazardous waste or industrial solid waste shall promptly notify the executive director using a method approved by the executive director of:

(1) any new information concerning storage, processing, and disposal described in paragraph (3) of this subsection; and

(2) any changes to information previously submitted or reported under subsection (a) of this section:

(A) authorized in any permit issued by the commission; or

(B) submitted or reported to the commission in any application filed with the commission.

(3) Information concerning storage, processing, and disposal required to be submitted under this subsection includes and is not limited to:

(A) waste composition;

(B) waste management methods;

(C) facility engineering plans and specifications; and

(D) the geology where the facility is located.

(4) A person who notifies the executive director under this section shall immediately document and notify the executive director within 90 days of changes in information previously provided and additional information that was not provided.

(c) Generator registration.

(1) Any person, by site, that generates in any calendar month more than 100 kilograms of non-acute hazardous waste, more than 1 kilogram of acute hazardous waste, or more than 100 kilograms of industrial Class 1 waste shall register in a method approved by the executive director.

(2) Large quantity generators must meet the requirements of this subsection using the electronic interface provided by the executive director unless:

(A) the executive director has granted a written request to use paper forms or an alternative notification method; or

(B) the software does not have features capable of meeting the requirements.

(3) Notifications submitted pursuant to this section shall be in addition to information provided in any permit applications required by §335.2 of this title, or any reports required by §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), and §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste).

(4) If waste is recycled on-site or managed pursuant to §335.2(d)(1) - (4) or (6) - (9) of this title, the generator must also comply with the notification requirements specified in subsection (h) of this section.

(5) The information submitted pursuant to the notification requirements of this subchapter and to the additional requirements of §335.503 of this title (relating to Waste Classification and Waste Coding Required) shall include, but is not limited to:

(A) a description of the waste including:

(i) a description of the process generating the waste; and

(ii) the composition of the waste;

(B) a hazardous waste determination in accordance with §335.504 of this title (relating to Hazardous Waste Determination), which includes the appropriate United States Environmental Protection Agency (EPA) hazardous waste number(s) described in 40 Code of Federal Regulations (CFR) Part 261;

(C) the disposition of each solid waste generated, if subject to the notification requirement of this subsection, including:

(i) whether the waste is managed on-site and/or off-site;

(ii) a description of the type and use of each on-site waste management facility unit;

(iii) a listing of the wastes managed in each unit; and

(iv) whether each unit is permitted, or qualifies for an exemption, under §335.2 of this title.

(d) Transporter registration. Any person who transports hazardous waste or industrial Class 1 waste shall notify the executive director of such activity by registering using a method approved by the executive director. A person, by site, that generates in any calendar month less than 100 kilograms of non-acute hazardous waste, less than 1 kilogram of acute hazardous waste, and less than 100 kilograms of industrial Class 1 waste and only transports their own waste is not required to comply with this subsection.

(e) Transfer facility registration. A person that intends to operate a transfer facility in accordance with §335.94 of this title (relating to Transfer Facility Requirements) shall notify the executive director of such activity by registering using a method approved by the executive director.

(f) Waste analysis. Any person who ships, stores, processes, or disposes of

industrial solid waste or hazardous waste shall provide the chemical analysis of the solid waste performed in accordance with Subchapter R of this chapter (relating to Waste Classification) to the executive director upon written request.

(g) Notification prior to facility expansion. Any person who stores, processes, or disposes of industrial solid waste or municipal hazardous waste shall notify the executive director in writing of any activity or facility expansion not authorized by permit, at least 90 days prior to conducting such activity. Such person shall submit to the executive director upon request such information as may reasonably be required to enable the executive director to determine whether such activity is compliant with this chapter.

(h) Notification of recycling activities. Any person who intends to ship off-site or transfer to another person for recycling, or who conducts or intends to conduct the recycling of, industrial solid waste, municipal hazardous waste, recyclable materials, or nonhazardous recyclable materials as defined in §335.24 of this title or Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities) and who is required to notify under §335.24 of this title or Subchapter H of this chapter shall notify the executive director using a method approved by the executive director.

(1) A person that is required to notify under this subsection shall include, at a minimum, the following information:

(A) the type(s), classification(s), Texas waste code(s) and EPA hazardous waste number(s) described in 40 CFR Part 261, if any, of each industrial solid waste and municipal hazardous waste intended to be recycled;

(B) the method of storage prior to recycling; and

(C) the nature of the recycling activity.

(2) A person required to notify the executive director of the intent to recycle under this subsection may begin recycling activities 90 days after submitting notification of intent to recycle under this subsection if the executive director has not requested additional information in response to the notification or upon receipt of an acknowledgment from the executive director.

(i) Notification of operating under the small quantity burner exemption. The owner or operator of a facility qualifying for the small quantity burner exemption under 40 CFR §266.108 must provide a one-time signed, written notification to the EPA and to the executive director indicating the following:

(1) the combustion unit is operating as a small quantity burner of hazardous waste;

(2) the owner and operator are in compliance with the requirements of 40 CFR §266.108, §335.221(a)(19) of this title (relating to Applicability and Standards) and this subsection; and

(3) the maximum quantity of hazardous waste that the facility may burn as provided by 40 CFR §266.108(a)(1).

(j) Notification of used oil activities. Notification and regulation requirements on nonhazardous used oil, oil made characteristically hazardous by use (instead of mixing), used oil generated by a very small quantity generator, and household used oil after collection that will be recycled shall notify in accordance with Chapter 324 of this title (relating to Used Oil).

(k) Notification exemption for the disposal of animal carcasses. A landowner who disposes of domestic or exotic animal carcasses and who complies with a certified water quality management plan developed for their site under Texas Agriculture Code, §201.026(f) as added by Acts 2001, 77th Legislature, Chapter 1189, §1 (relating to Nonpoint Source Pollution) is exempt from the notification requirements of subsections (a) and (b) of this section.

(l) Healthcare facilities notification. A person required to notify the executive director under §335.755 of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals) shall notify using a

method approved by the executive director.

(m) Reverse distributor registration. A person required to notify the executive director under §335.771 of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors) shall register using a method approved by the executive director.

§335.9. Recordkeeping and Annual Reporting Procedures Applicable to Generators.

(a) A generator of hazardous or industrial solid waste shall comply with the recordkeeping and reporting requirements of this section. Nonhazardous recyclable materials regulated under §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), are not subject to the requirements of this section [Except with regard to nonhazardous recyclable materials regulated pursuant to §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), each generator of hazardous or industrial solid waste shall comply with the following].

(1) A [The] generator shall make and keep records of all hazardous and industrial solid waste activities regarding the quantities generated, received from off-site, stored, processed, and disposed of on-site or shipped off-site for storage, processing, recycling, or disposal. These records must [and which], at a minimum,

include [includes] the information described in subparagraphs (A) - (G) of this paragraph. These records must [may] be maintained in a readily retrievable format [any format, provided they are retrievable and easy to copy]. The required records must be sufficiently detailed and complete to support any contentions or claims made by the generator with respect to:

(A) the description, character, and classification of each waste, in accordance with Subchapter R of this chapter (relating to Waste Classification) and any changes and additional information required under §335.6(c) and (d) of this title (relating to Notification Requirements);

(B) the quantity generated;

(C) except generators that generate less than 100 kilograms of non-acute hazardous waste, less than 1 kilogram of acute hazardous waste, and less than 100 kilograms of industrial Class 1 waste per calendar month [for conditionally exempt small quantity generators regulated under §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated By Conditionally Exempt Small Quantity Generators)], the quantity held in on-site storage as of December 31 of each calendar year;

(D) the quantity processed or disposed of at each on-site facility unit during the calendar year;

(E) the method of storage, processing, or disposal as described by codes listed on the form or instructions;

(F) the quantity shipped off-site for storage, processing, or disposal each calendar year, including the transporter and the name, address, and location of each off-site facility [and transporter] receiving shipments; and

(G) the location of each [all] hazardous waste satellite accumulation area [areas, situated at or near any point of generation,] where hazardous wastes are temporarily accumulated in accordance with §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [under the control of the operator of the process generating the wastes are placed in containers and initially accumulated without a permit or interim status in accordance with §335.69(d) of this title (relating to Accumulation Time)].

(2) The generator shall submit to the executive director a complete and correct Annual Waste Summary using the electronic interface, paper forms, or other method approved by the executive director by the deadlines provided in, and in accordance with, this paragraph [detailing the management of each hazardous and Class 1 waste generated on-site during the reporting calendar year. The Annual Waste Summary shall also include the management of any hazardous or Class 1 waste generated in a year previous to the reporting year, but managed in the reporting

calendar year. The Annual Waste Summary shall be submitted using electronic software or paper forms provided or approved by the executive director. Upon written request by the generator, the executive director may authorize an extension to the report due date. Any registered generator who generates 1,000 kilograms or more of hazardous waste in any calendar month, must submit the Annual Waste Summary using software provided by the executive director unless the executive director has granted a written request to use paper forms or an alternative reporting method. Generators shall report as follows].

(A) Generators submitting their Annual Waste Summary on paper forms must do so on or before January 25 of the year following the reporting calendar year unless the executive director has approved a request for an extension.

(B) Generators submitting their Annual Waste Summary electronically must do so on or before March 1 of the year following the reporting calendar year unless the executive director has approved a request for an extension.

(C) The Annual Waste Summary shall include the information under paragraph (1) of this subsection and detailed information regarding:

(i) the management of each hazardous and industrial Class 1 waste generated on-site during the reporting calendar year;

(ii) the management of each hazardous and industrial Class 1 waste received from off-site during the reporting calendar year; and

(iii) the management of each hazardous and industrial Class 1 waste received from off-site or generated in a year prior to the reporting year and managed on-site during the reporting calendar year.

(D) A large quantity generator must submit the Annual Waste Summary using the electronic interface provided by the executive director unless the executive director has approved an alternative reporting method.

(3) A generator that certifies on the Annual Waste Summary that the generator met the conditions in this paragraph during the reporting calendar year is not required to submit the information in paragraph (2) of this subsection. [Generators are not required to submit the information required in paragraph (1) of this subsection if they certify on the annual summary that all of the following conditions have been met:]

(A) The volume of hazardous waste accumulated on-site did not exceed the volumes for a very small generator classification in 40 Code of Federal Regulations (CFR) §262.14(a)(3) and (4) as adopted under §335.53 of this title [during the year, total on-site accumulation of hazardous waste did not equal or exceed 1,000 kilograms].

(B) The generator generated less than: [no acute hazardous waste was generated or accumulated during the year exceeding the limits specified in §335.78(e)(1) and (2) of this title;]

(i) 1,200 kilograms of non-acute hazardous waste;

(ii) 1,200 kilograms of industrial Class 1 waste; and

(iii) 1 kilogram of acute hazardous waste.

[(C) a total of less than 1,200 kilograms of hazardous waste, and a total of less than 1,200 kilograms of Class 1 waste (2,400 kilograms or less of hazardous waste plus Class 1 waste combined) was generated during the year.]

(4) A generator is not required to submit an Annual Waste Summary if, during the entire calendar year, that generator: [Generators who are regulated under §335.78 of this title and also meet the requirements of paragraph (3) of this subsection are not required to submit an annual summary].

(A) meets the conditions for exemption for a very small quantity generator under §335.53 of this title;

(B) generates less than 100 kilograms of industrial class 1 waste per month; and

(C) meets the requirements of paragraph (3) of this subsection.

(b) A large quantity generator that ships hazardous waste off-site, treats, stores, or disposes of hazardous waste onsite, or receives hazardous waste from very small quantity generators must submit the biennial report information required by 40 CFR §262.41, adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators). Information submitted in accordance with Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste), and Subchapter R of this chapter (relating to Waste Classification) is not required to be resubmitted in a biennial report required by 40 CFR §262.41 [A generator who ships his hazardous waste off-site must also report the information specified in §335.71 of this title (relating to Biennial Reporting). Any waste related information that has already been submitted by generators under the requirements of this section or §335.71 of this title need not be included in the reports from permitted or interim status facilities under 40 CFR §264.75 or §265.75].

§335.10. Shipping and Reporting Procedures Applicable to Generators of Hazardous

Waste or Class 1 Waste.

(a) Except as provided in paragraph (2) of this subsection, no person who generates, transports, processes, stores, or disposes of hazardous waste shall cause, suffer, allow, or permit the shipment of hazardous waste unless the person complies with this subsection, §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste), §335.54 of this title (relating to Hazardous Waste Manifest), and §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal) [he complies with the requirements of paragraph (1) of this subsection, and the manifest requirements in 40 Code of Federal Regulations (CFR) §§262.20 - 262.25, 262.27, and 262.42, as these sections are amended through February 7, 2014 (79 FR 7518), and 40 CFR Part 262, Subpart H, and the Appendix to 40 CFR Part 262, as amended through November 28, 2016 (81 FR 85696)].

(1) In addition, generators and owners or operators of treatment, storage, or disposal facilities shall include a Texas waste code for each hazardous waste itemized on the manifest.

(2) The manifest required by this subsection is not required for the transportation of hazardous waste when all of the conditions of an applicable

exemption from manifesting have been met, including and not limited to the exemptions in this paragraph and subsection (b) of this section [No manifest is required for a hazardous waste generated by a generator that generates less than the quantity limits of hazardous waste specified in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators) or a municipal generator that generates less than the quantity limit of hazardous waste specified in §335.78 of this title].

(A) The manifesting requirements of this section are not applicable to the transportation of hazardous waste generated by a very small quantity generator (VSQG) that meets the conditions for exemption in 40 Code of Federal Regulations (CFR) §262.14 as adopted in §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(B) The manifesting requirements of this section are not applicable to the transportation of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor in compliance with §335.769 of this title (relating to Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor).

(b) The manifesting and marking requirements of §335.55 of this title (relating to Pre-Transport Requirements Applicable to Small and Large Quantity Generators) are

not applicable to the transportation of hazardous waste [No manifest and no marking in accordance with §335.67(b) of this title (relating to Marking) is required for hazardous waste transported] on a public or private right-of-way within or along the border of contiguous property under the control of the same person, even if such contiguous property is divided by a public or private right-of-way. However, in the event of a hazardous waste discharge on a public or private right-of-way, the generator or transporter must comply with the requirements of §335.93 of this title (relating to Hazardous Waste Discharges).

(c) Except as provided in subsections (d) and (e) of this section, persons who generate, transport, process, store, or dispose of Class 1 waste shall not cause, suffer, allow, or permit the shipment of Class 1 waste unless the person complies with the manifest requirements adopted in §335.54 of this title with the following changes and additions: [listed in subsection (a) of this section, with the following changes:]

(1) when Class 1 waste is itemized on the manifest, either [use] the Texas Commission on Environmental Quality solid waste registration (SWR) number or the United States Environmental Protection Agency (EPA) identification number must [to] identify the generator, transporter, and designated facility [receiver]; and [use] the Texas waste code, instead [in place] of the EPA waste code, must identify the waste; [and]

(2) when both hazardous and Class 1 waste are itemized on the same manifest, the [use] EPA identification numbers, not SWR numbers, must [to] identify the generator, transporter, and designated facility [receiver]; and [use] the Texas waste codes must identify [for] each waste itemized on the manifest; [.]

(3) the term "Designated facility" has the meaning in §335.1 of this title (relating to Definitions);

(4) the term "Hazardous waste" is replaced by the term "Class 1 waste";

(5) the exceptions for hazardous waste being reclaimed under 40 CFR §262.20(e) are not applicable to transportation of Class 1 waste;

(6) in the event of a discharge on a public right of way, the generator or transporter must comply with Chapter 327 of this title (relating to Spill Prevention and Control) and §335.93 of this title instead of complying with 40 CFR §263.30 and §263.31 as required by 40 CFR §262.20(f); and

(7) waste minimization certification required by 40 CFR §262.27 is not applicable to Class 1 waste.

(d) No manifest is required for the shipment of Class 1 waste generated by a person that generated less than 100 kilograms of Class 1 waste during the calendar

month in which the subject Class 1 waste was generated [where the generator is an industrial generator that generates less than the quantity limits of Class 1 waste specified in §335.78 of this title or is a municipal generator that generates less than the quantity limit of Class 1 waste specified in §335.78 of this title].

(e) No manifest is required for the shipment of Class 1 waste to property owned or otherwise effectively controlled by the owner or operator of an industrial plant, manufacturing plant, mining operation, or agricultural operation from which the waste results or is produced, provided that:

(1) the property is within 50 miles of the plant or operation; [and]

(2) the waste is not commingled with waste from any other source or sources. An industrial plant, manufacturing plant, mining operation, or agricultural operation owned by one person shall not be considered another source with respect to other plants or operations owned by the same person; and [.]

(3) the owner or operator of a facility that receives and stores, processes, or disposes Class 1 waste from off-site in compliance with an exception from permit required in §335.2(d)(1) or (2) of this title (relating to Permit Required) must report Class 1 industrial waste received from off-site in the Annual Waste Summary submitted for the receiving facility in accordance with §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators).

§335.11. Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste.

(a) Incorporation by reference. The commission adopts by reference 40 Code of Federal Regulations (CFR) Part 263, Subpart B (Compliance With the Manifest System and Recordkeeping), as amended through the January 3, 2018 issue of the *Federal Register* (83 FR 420).

(b) Hazardous waste transporters. Except as provided by §335.10(a)(2) of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), persons who transport hazardous waste must comply with:

(1) subsection (a) of this section;

(2) §335.4 of this title (relating to General Prohibitions);

(3) §335.6 of this title (relating to Notification Requirements);

(4) §335.10 of this title;

(5) §335.14 of this title (relating to Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste); and

(6) Subchapter D of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste).

(c) Class 1 industrial waste transporters. Except as provided by §335.10 of this title, a person who transports Class 1 waste shall comply with subsection (b)(1) - (5) of this section and the manifesting requirements adopted under subsection (a) of this section, with the changes and additions in this subsection.

(1) When only Class 1 waste is itemized on the manifest, a Texas Commission on Environmental Quality solid waste registration (SWR) number or a United States Environmental Protection Agency (EPA) identification number may be used for the generator, transporter, and designated facility.

(2) When both hazardous and Class 1 industrial waste are itemized on the same manifest, an EPA identification number must be used for the generator, transporter, and designated facility.

(3) A Texas waste code, instead of an EPA waste code, must identify each Class 1 waste itemized on the manifest.

(4) The term "Hazardous waste" is changed to the term "Class 1 waste."

(5) The import and export requirements of 40 CFR §263.20(a)(2), (c), and (g) are not applicable to the transportation of Class 1 waste.

(6) The exclusion from manifesting requirements for hazardous waste being transported pursuant to a reclamation agreement under 40 CFR §263.20(h) is not applicable to the transportation of Class 1 waste.

(7) In the event of a spill or discharge of Class 1 waste during transportation, the transporter shall notify the commission in accordance with Chapter 327 of this title (relating to Spill Prevention and Control), and Texas Water Code, §26.039, and take appropriate immediate action to protect human health and the environment (e.g., notify local authorities, dike the discharge).

(8) A transporter shall clean up any Class 1 waste spill or discharge that occurs during transportation or take such action as required in §327.5 of this title (relating to Actions Required) so that the Class 1 waste discharge no longer presents a hazard to human health or the environment.

§335.12. Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities.

(a) Except as provided by §335.10(a)(2) of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), persons who generate, process, store, or dispose of hazardous waste must comply with this subsection as well as subsections (c) and (d) of this section and 40 Code of Federal Regulations (CFR) Part 264, Subpart E (Manifest System, Recordkeeping, and Reporting), as adopted in §335.152 of this title (relating to Standards) or 40 CFR Part 265, Subpart E (Manifest System, Recordkeeping, and Reporting), as adopted in §335.112 of this title (relating to Standards) [40 Code of Federal Regulations (CFR) §264.72 or §265.72, depending on the status of the person, as these sections are amended through February 7, 2014 (79 FR 7518); and 40 CFR §264.71 or §265.71, depending on the status of the person, as these sections are amended through November 28, 2016 (81 FR 85696), and with the Appendix to 40 CFR Part 262, as amended through November 28, 2016 (81 FR 85696). The references in §335.112(b)(1) and (10) and §335.152(c)(1) and (10) of this title (relating to Standards) do not apply to this provision].

(b) Except as provided by §335.10(d) and (e) of this title, persons who generate, transport, process, store, or dispose of Class 1 waste must comply with this subsection as well as subsections (c) and (d) of this section and 40 CFR Part 264, Subpart E as adopted in §335.152 of this title with the changes in this subsection [40 CFR §264.72 and §264.76, as amended through February 7, 2014 (79 FR 7518), and §264.71 and the Appendix to 40 CFR Part 262, as amended through November 28, 2016 (81 FR 85696),

and a manifest or copy of e-Manifest must accompany the shipment which designates that facility to receive the waste].

(1) "Hazardous waste" is changed to "Class 1 waste."

(2) When only Class 1 waste is itemized on the manifest a Texas Commission on Environmental Quality solid waste registration number or a United States Environmental Protection Agency identification number may be used for the generator, transporter, and designated facility.

(3) "Regional Administrator" is changed to "Executive director."

(4) The requirements of 40 CFR Part 262, Subpart H (Transboundary Movements of Hazardous Waste for Recovery or Disposal) are not applicable to Class 1 waste imported from outside of the United States.

(c) The commission adopts by reference 40 CFR §260.4 (Manifest copy submission requirements for certain interstate waste shipments), as adopted in the *Federal Register* on January 3, 2018 (83 FR 420).

(d) The commission adopts by reference 40 CFR §260.5 (Applicability of electronic manifest system and user fee requirements to facilities receiving state-only regulated waste shipments) as adopted in the *Federal Register* on January 3, 2018 (83

FR 420).

§335.13. Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste.

(a) The requirements of this section do not apply to a generator that generates less than 100 kilograms of Class 1 waste, 100 kilograms of hazardous waste, and 1 kilogram of acute hazardous in a calendar month, by site [The requirements of this section do not apply to generators who generate hazardous waste or Class 1 waste in quantities less than 100 kilograms in a calendar month, or acute hazardous waste in quantities specified in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)].

(b) An unregistered generator that ships [Unregistered generators who ship] hazardous waste or Class 1 waste shall prepare a complete and correct Waste Shipment Summary from the manifests.

(c) The Waste Shipment Summary shall be prepared in a form provided or approved by the executive director and submitted to the executive director on or before the 25th of each month for shipments originating during the previous month. An [The] unregistered generator must keep a copy of each summary for a period of at least three years from the due date of the summary. An unregistered generator must

[These generators are required to] prepare and submit a Waste Shipment Summary only for those months in which shipments are actually made.

(d) A registered generator is defined as an in-state generator who has complied with §335.6 of this title (relating to Notification Requirements) and has an active [, and is assigned a] solid waste registration number.

(e) An unregistered generator is defined as an in-state generator that:

(1) does not have an active solid waste registration;

(2) in a calendar month generates more than 100 kilograms of non-acute hazardous waste, 1 kilogram of acute hazardous waste, or 100 kilograms of Class 1 waste; and [who is not a conditionally exempt small quantity generator, as defined in §335.78 of this title, that]

(3) ships hazardous waste and/or Class 1 industrial waste using a temporary solid waste registration number and a temporary Texas waste code that begins with a four-character sequence number assigned by the executive director.

(f) Both registered and unregistered generators shall comply with the manifest and recordkeeping requirements under §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste)

[The registered/unregistered generator shall retain a copy of each manifest required by §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste) for at least three years from the date of shipment by the registered/unregistered generator].

[(g) A registered/unregistered generator who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the waste was accepted by the initial transporter must contact the transporter and/or the owner or operator of the designated facility to determine the status of the hazardous waste or Class 1 waste.]

[(h) A registered/unregistered generator must submit an exception report to the executive director if he has not received a copy of the manifest with the handwritten signatures of the owner or operator of the designated facility within 45 days of the date that the waste was accepted by the initial transporter. The exception report must be retained by the registered/unregistered generator for at least three years from the date the waste was accepted by the initial transporter and must include:]

[(1) a legible copy of the manifest for which the generator does not have confirmation of delivery; and]

[(2) a copy of a letter signed by the generator or his authorized representative explaining the efforts taken to locate the hazardous waste or Class 1 waste and the results of those efforts.]

[(i) The periods of record retention required by this section are automatically extended during the course of any unresolved enforcement action regarding the regulated activity.]

[(j) Any person who exports or imports hazardous waste must comply with 40 CFR §262.12 and 40 CFR Part 262, Subpart H, as adopted by reference under §335.76(a) of this title (relating to Additional Requirements Applicable to International Shipments).]

§335.14. Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste.

A hazardous waste transporter and a Class 1 waste transporter shall comply with the manifesting and recordkeeping requirements of 40 Code of Federal Regulations (CFR) Part 263, Subpart B as adopted under §335.11 of this title (relating to Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste).

§335.15. Recordkeeping and Reporting Requirements Applicable to Owners or

Operators of Treatment, Storage, or Disposal Facilities.

This section applies to owners and operators of facilities that receive hazardous waste or Class 1 waste from off-site sources and owners and operators of facilities that have notified the executive director of the intent to receive hazardous waste or Class 1 waste from off-site sources. [who receive hazardous or Class 1 waste from off-site sources or who have notified that they intend to receive hazardous or Class 1 waste from off-site sources.]

(1) Manifest requirements. The owner or operator of the treatment, storage, or disposal facility designated on the manifest shall comply with the manifesting and recordkeeping requirements of 40 Code of Federal Regulations (CFR) Part 264, Subpart E as adopted under §335.152 of this title (relating to Standards) or 40 CFR Part 265, Subpart E as adopted under §335.112 of this title (relating to Standards), the manifest copy submission requirements for certain interstate waste shipments in 40 CFR §260.4 as adopted under §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), the electronic manifest system and user fees for facilities that receive state-only regulated waste shipments requirements in 40 CFR §260.5 as adopted under §335.12 of this title, and 40 CFR Part 262, Subpart B as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) [retain a copy of each manifest or, in the case of shipments by rail or water (bulk shipment), a copy of each

manifest and shipping paper, for a minimum of three years from the date of initial shipment by the generator or primary exporter where appropriate].

(2) Monthly Waste Receipt Summary. Except as provided in paragraph (6) of this section or as provided in §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), the owner or operator shall prepare a complete and correct Monthly Waste Receipt Summary in accordance with this paragraph. The owner or operator shall: [for all manifested and unmanifested hazardous or Class 1 waste shipments received. The Monthly Waste Receipt Summary shall be submitted electronically, using software provided by the executive director. Upon written request by the receiver, authorization may be given by the executive director to use paper forms or an alternative reporting method. The Monthly Waste Receipt Summary shall be submitted to the executive director on or before the 25th of each month for wastes or manifests received during the previous month. (The appropriate abbreviations for method of treatment, storage, and disposal of waste and for units of measure may be found on the form or accompanying instructions.) Any owner or operator of a treatment, storage, or disposal facility required to comply with this paragraph shall prepare and submit a Monthly Waste Receipt Summary each month even if no waste was received.]

(A) submit a Monthly Waste Receipt Summary on or before the 25th of every month;

(B) include all manifested and unmanifested hazardous and Class 1 waste shipments received during the previous month, if any;

(C) use the electronic interface provided by the executive director unless the executive director has approved an alternative reporting method; and

(D) identify the methods of treatment, storage, and disposal of waste and units of measure using abbreviations and codes provided by the executive director.

(3) Unmanifested waste report. An owner or operator shall comply with the unmanifested waste reporting requirements of this paragraph. [If a facility accepts for treatment, storage, or disposal any hazardous waste or Class 1 waste from an off-site source without an accompanying manifest, or without an accompanying shipping paper as described in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste), and if the waste is not excluded from the manifest requirement of this chapter, then the owner or operator must prepare and submit a letter to the executive director within 15 days after receiving the waste. The unmanifested waste report must contain the following information:]

(A) An owner or operator that accepts hazardous waste from an off-site source that is not excluded from the manifest requirements of this chapter and

is not accompanied by a manifest shall complete and submit an unmanifested waste report within 15 days after receiving the waste to the executive director that includes:

(i) the United States Environmental Protection Agency (EPA) identification (ID) number, solid waste registration (SWR) number, name, and address of the facility;

(ii) the date the facility received the waste;

(iii) the EPA ID number, SWR number, name, and address of the generator and the transporter, if available;

(iv) a description and the quantity of each unmanifested hazardous waste the facility received which was not accompanied by a manifest;

(v) the method of treatment, storage, or disposal for each hazardous waste;

(vi) the certification signed by the owner or operator of the facility or his authorized representative; and

(vii) a brief explanation of why the waste was unmanifested, if known.

(B) An owner or operator that accepts Class 1 waste, that is not excluded from the manifest requirements of this chapter, from an off-site source without an accompanying manifest shall complete and submit an unmanifested waste report to the executive director within 15 days after receiving the waste that contains:

(i) [(A)] the EPA ID number, SWR number, [United States Environmental Protection Agency (EPA) identification number] name, and address of the receiving facility;

(ii) [(B)] the date the facility received the waste;

(iii) [(C)] the EPA identification number, SWR number, name, and address of the generator and the transporter, if available;

(iv) [(D)] a description and the quantity of each unmanifested Class 1 [hazardous] waste the facility received which was not accompanied by a manifest;

(v) [(E)] the method of treatment, storage, or disposal for each Class 1 hazardous waste;

(vi) [(F)] the certification signed by the owner or operator of the facility or his authorized representative; and

(vii) [(G)] a brief explanation of why the waste was unmanifested, if known.

(4) Records retention. The owner or operator shall retain a copy of each summary required by paragraphs (2) and (3) of this section for a minimum of three years from the date of each summary.

(5) Extended records retention. The period of record retention required by this section is automatically extended during the course of any unresolved enforcement action regarding the regulated activity.

(6) Monthly Waste Receipt Summary for reclamation of hazardous waste generated by very small quantity generators. An owner or operator reclaiming hazardous wastes received from a very small quantity generator shall complete and submit a Monthly Waste Receipt Summary unless the executive director has approved an exception from reporting. [An owner or operator reclaiming hazardous wastes received from a conditionally exempt small quantity generators is subject to the requirements of this section requiring completion of a Monthly Waste Receipt Summary, from his copy of all manifests received during the month, unless he has requested in writing a modification in the reporting requirements. A modification

relieving the owner or operator of having to report each manifested shipment on the Monthly Waste Receipt Summary may be granted at the discretion of the executive director on a case-by-case basis.]

(7) Biennial report information provided in a Monthly Waste Receipt Summary. Information which has already been submitted by permitted or interim status facilities under the requirements of this section and of Subchapter A of this chapter need not be included in the reports required by 40 CFR §264.75 or §265.75 (relating to Biennial Reports), as adopted under §335.112 and §335.152 of this title; these biennial reports must be submitted to the executive director using a method approved by the executive director [in letter format] rather than by EPA form.

(8) Class 1 industrial waste received from off-site reported in Annual Waste Summary. The owner or operator of a facility that stores, processes or disposes Class 1 industrial waste received from off-site in accordance with an exception from permit required under §335.2(d)(1) or (2) of this title (relating to Permit Required), must report Class 1 industrial waste received from off-site on the Annual Waste Summary submitted for the receiving facility in accordance with §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators).

§335.18. Non-Waste Determinations and Variances from Classification as a Solid

Waste.

(a) In accordance with the standards and criteria in §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste) and §335.32 of this title (relating to Standards and Criteria for Non-Waste Determinations), and in accordance with the procedures in §335.21 of this title (relating to Procedures for Variances from Classification as a Solid Waste or To Be Classified as a Boiler or for Non-Waste Determinations) the executive director may determine on a case-by-case basis that the following recyclable materials and nonhazardous recyclable materials are not solid wastes:

(1) materials that are accumulated speculatively without sufficient amounts being recycled (as defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials));

(2) materials that are reclaimed and then reused within the original production process in which they were generated;

(3) materials that have been reclaimed but must be reclaimed further before the materials are completely recovered;

(4) hazardous secondary materials that are reclaimed in a continuous industrial process; or

(5) hazardous secondary materials that are indistinguishable in all relevant aspects from a product or intermediate. [; or]

[(6) hazardous secondary materials that are transferred for reclamation under 40 Code of Federal Regulations §261.4(a)(24) and are managed at a verified reclamation facility or intermediate facility where the management of the hazardous secondary materials is not addressed under a Resource Conservation and Recovery Act Part B permit or interim status standards.]

(b) Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid waste," §335.6 of this title (relating to Notification Requirements), §335.17 of this title, §335.19 of this title, §335.20 of this title (relating to Variance To Be Classified as a Boiler), §335.21 of this title, §335.22 of this title (relating to Additional Regulation of Certain Hazardous Waste Recycling Activities on a Case-by-Case Basis), §335.23 of this title (relating to Procedures for Case-by-Case Regulation of Hazardous Waste Recycling Activities), §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities), and Subchapter V of this title (relating to Standards for Reclamation of Hazardous Secondary Materials).

§335.19. Standards and Criteria for Variances from Classification as a Solid Waste.

(a) The executive director may grant requests for a variance from classifying as a solid waste those materials that are accumulated speculatively without sufficient amounts being recycled if the applicant demonstrates that sufficient amounts of the material will be recycled or transferred for recycling in the following year. If a variance is granted, it is valid only for the following year, but can be renewed, on an annual basis, by filing a new application. The executive director's decision will be based on the following criteria:

(1) the manner in which the material is expected to be recycled, when the material is expected to be recycled, and whether this expected disposition is likely to occur (for example, because of past practice, market factors, the nature of the material, or contractual arrangements for recycling);

(2) the reason that the applicant has accumulated the material for one or more years without recycling 75% of the weight or volume accumulated at the beginning of the year;

(3) the quantity of material already accumulated and the quantity expected to be generated and accumulated before the material is recycled;

(4) the extent to which the material is handled to minimize loss; and

(5) other relevant factors.

(b) The executive director may grant requests for a variance from classifying as a solid waste those materials that are reclaimed and then reused as feedstock within the original production process in which the materials were generated if the reclamation operation is an essential part of the production process. This determination will be based on the following criteria:

(1) how economically viable the production process would be if it were to use virgin materials, rather than reclaimed materials;

(2) the extent to which the material is handled before reclamation to minimize loss;

(3) the time periods between generating the material and its reclamation, and between reclamation and return to the original primary production process;

(4) the location of the reclamation operation in relation to the production process;

(5) whether the reclaimed material is used for the purpose for which it was originally produced when it is returned to the original process, and whether it is returned to the process in substantially its original form;

(6) whether the person who generates the material also reclaims it; and

(7) other relevant factors.

(c) The executive director may grant requests for a variance from classifying as a solid waste those hazardous secondary materials that have been partially reclaimed, but must be reclaimed further before recovery is completed, if the partial reclamation has produced a commodity-like material. A determination that a partially-reclaimed material for which the variance is sought is commodity-like material will be based on whether the hazardous secondary material is legitimately recycled as specified in §335.27 of this title (relating to Legitimate Recycling of Hazardous Secondary Materials) and on whether all of the following decision criteria are satisfied:

(1) whether the degree of partial reclamation the material has undergone is substantial as demonstrated by using a partial reclamation process other than the process that generated the hazardous waste;

(2) whether the partially reclaimed material has sufficient economic value that it will be purchased for further reclamation;

(3) whether the partially reclaimed material is a viable substitute for a product or intermediate produced from virgin or raw materials which is used in subsequent production steps;

(4) whether there is a market for the partially reclaimed material as demonstrated by known customer(s) who are further reclaiming the material (e.g., records of sales and/or contracts and evidence of subsequent use, such as bills of lading);

(5) whether the partially reclaimed material is handled to minimize loss; and

(6) other relevant factors.

[(d) The executive director may grant requests for a variance from classifying as a solid waste those hazardous secondary materials that are transferred for reclamation in accordance with the requirements of 40 Code of Federal Regulations (CFR) §261.4(a)(24) and are managed at a verified reclamation facility or intermediate facility where the management of the hazardous secondary materials is not addressed under a Resource Conservation and Recovery Act (RCRA) Part B permit or interim status standards. The executive director's decision will be based on the following criteria:]

[(1) the reclamation facility or intermediate facility must demonstrate that the reclamation process for the hazardous secondary materials is legitimate pursuant to §335.27 of this title;]

[(2) the reclamation facility or intermediate facility must satisfy the financial assurance requirements of §335.703 of this title (relating to Financial Assurance Requirements);]

[(3) the reclamation facility or intermediate facility must not be subject to a formal enforcement action in the previous three years and not be classified as a significant non-complier under RCRA, Subtitle C, or must provide credible evidence that the facility will manage the hazardous secondary materials properly. Credible evidence may include a demonstration that the facility has taken remedial steps to address the violations and prevent future violations, or that the violations are not relevant to the proper management of the hazardous secondary materials;]

[(4) the intermediate or reclamation facility must have the equipment and trained personnel needed to safely manage the hazardous secondary material and must meet emergency preparedness and response requirements under 40 CFR Part 261, Subpart M;]

[(5) if residuals are generated from the reclamation of the excluded hazardous secondary materials, the reclamation facility must have the permits

required (if any) to manage the residuals, have a contract with an appropriately permitted facility to dispose of the residuals or present credible evidence that the residuals will be managed in a manner that is protective of human health and the environment; and]

[(6) the intermediate or reclamation facility must address the potential for risk to proximate populations from unpermitted releases of the hazardous secondary material to the environment (i.e., releases that are not covered by a permit, such as a permit to discharge to water or air), which may include, but are not limited to, potential releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures), and must include consideration of potential cumulative risks from other nearby potential stressors.]

(d) [(e)] Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid waste," §335.6 of this title (relating to Notification Requirements), §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), §335.18 of this title (relating to Non-Waste Determinations and Variances from Classification as a Solid Waste), §335.20 of this title (relating to Variance To Be Classified as a Boiler), §335.21 of this title (relating to Procedures for Variances from Classification as a Solid Waste or To Be Classified as a Boiler or for Non-Waste Determinations), §335.22 of this title (relating to Additional Regulation of

Certain Hazardous Waste Recycling Activities on a Case-by-Case Basis), §335.23 of this title (relating to Procedures for Case-by-Case Regulation of Hazardous Waste Recycling Activities), §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities), and Subchapter V of this chapter (relating to Standards for Reclamation of Hazardous Secondary Materials).

§335.24. Requirements for Recyclable Materials and Nonhazardous Recyclable Materials.

(a) Hazardous wastes that are recycled are subject to the requirements for generators, transporters, and storage facilities of subsections (d) - (f) of this section, except for the materials listed in subsections (b) and (c) of this section. Hazardous wastes that are recycled will be known as recyclable materials. Nonhazardous industrial wastes that are recycled will be known as nonhazardous recyclable materials. Nonhazardous recyclable materials are subject to the requirements of subsections (h) - (l) of this section.

(b) The following recyclable materials are not subject to the requirements of this section, except as provided in subsections (g) and (h) of this section, but are regulated under the applicable provisions of Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter H of this chapter

(relating to Standards for the Management of Specific Wastes and Specific Types of Facilities) and all applicable provisions in Chapter 305 of this title (relating to Consolidated Permits); Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 17 of this title (relating to Tax Relief for Property Used for Environmental Protection); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution Procedure); Chapter 50 of this title (relating to Action on Applications and Other Authorizations); Chapter 55 of this title (relating to Requests for Reconsideration and Contested Case Hearings; Public Comment); Chapter 70 of this title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); and Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings).

(1) recyclable materials used in a manner constituting disposal;

(2) hazardous wastes burned for energy recovery in boilers and industrial furnaces that are not regulated under Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) or Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities);

(3) recyclable materials from which precious metals are reclaimed;

(4) spent lead-acid batteries that are being reclaimed.

(c) The following recyclable materials are not subject to regulation under Subchapters B - I or O of this chapter (relating to Hazardous Waste Management General Provisions; Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Location Standards for Hazardous Waste Storage, Processing, or Disposal; Standards for the Management of Specific Wastes and Specific Types of Facilities; Prohibition on Open Dumps; and Land Disposal Restrictions); Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 17 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; Chapter 86 of this title; or Chapter 305 of this title, except as provided in subsections (g) and (h) of this section:

(1) Industrial ethyl alcohol that is reclaimed except that exports and imports of such recyclable materials must comply with the requirements of 40 Code of Federal Regulations (CFR) Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal)

[amended though November 28, 2016 (81 FR 85696)]. Transporters transporting a shipment for export may not accept a shipment if they know the shipment does not conform to the United States Environmental Protection Agency (EPA) acknowledgment of consent, must ensure that a copy of the EPA acknowledgment of consent accompanies the shipment, and must ensure that it is delivered to the facility designated by the person initiating the shipment;

(2) scrap metal that is not already excluded under 40 CFR §261.4(a)(13) as adopted under §335.504 of this title (relating to Hazardous Waste Determination);

(3) fuels produced from the refining of oil-bearing hazardous waste along with normal process streams at a petroleum refining facility if such wastes result from normal petroleum refining, production, and transportation practices (this exemption does not apply to fuels produced from oil recovered from oil-bearing hazardous waste, where such recovered oil is already excluded under 40 CFR §261.4(a)(12), as adopted under §335.504 of this title [amended through April 8, 2015 (80 FR 18777))]; and

(4) the following hazardous waste fuels:

(A) Hazardous waste fuel produced from oil-bearing hazardous wastes from petroleum refining, production or transportation practices, or produced from oil reclaimed from such hazardous wastes where such hazardous wastes are reintroduced into a process that does not use distillation or does not produce

products from crude oil so long as the resulting fuel meets the used oil specification under 40 CFR §279.11 and so long as no other hazardous wastes are used to produce the hazardous waste fuel;

(B) Hazardous waste fuel produced from oil-bearing hazardous waste from petroleum refining production, and transportation practices, where such hazardous wastes are reintroduced into a refining process after a point at which contaminants are removed, so long as the fuel meets the used oil fuel specification under 40 CFR §279.11;

(C) Oil reclaimed from oil-bearing hazardous wastes from petroleum refining, production, and transportation practices, which reclaimed oil is burned as fuel without reintroduction to a refining process, so long as the reclaimed oil meets the used oil fuel specification under 40 CFR §279.11.

(d) Generators and transporters of recyclable materials are subject to the applicable requirements of Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter C of this chapter, Subchapter D of this chapter, and Subchapter R of this chapter [Subchapter C of this chapter and Subchapter D of this chapter], and the notification requirements of §335.6 of this title (relating to Notification Requirements), except as provided in subsections (a) - (c) of this section.

(e) Owners or operators of facilities that store recyclable materials before they are recycled are regulated under all applicable provisions of this chapter, and Chapter 305 of this title; Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 17 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; and the notification requirements under §335.6 of this title, except as provided in subsections (a) - (c) of this section. The recycling process itself is exempt from regulation.

(f) Owners or operators of facilities that recycle recyclable materials without storing them before they are recycled are subject to the following requirements, except as provided in subsections (a) - (c) of this section:

(1) notification requirements under §335.6 of this title; [and]

(2) Section 335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities)<u>;</u> [.]

<u>(3) Section 335.15 of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities); and</u>

(4) the biennial reporting requirements of 40 Code of Federal Regulations §264.75 or §265.75 as adopted under §335.112 or §335.152 of this title (relating to Standards; or Standards).

(g) Recyclable materials (excluding those listed in subsections (b)(4), and (c)(1) - (5) of this section) remain subject to the requirements of §§335.4, 335.6, and 335.9 - 335.15 of this title (relating to General Prohibitions; Notification Requirements; Recordkeeping and Annual Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste; Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste; Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities; Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste; Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste; and Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities, respectively), as applicable. Recyclable materials listed in subsections (b)(4) and (c)(2) of this section remain subject to the requirements of subsection (h) of this section.

(h) Industrial solid wastes that are nonhazardous recyclable materials and recyclable materials listed in subsections (b)(4) and (c)(2) of this section remain subject to the requirements of §335.4 of this title. In addition, industrial solid wastes that are nonhazardous recyclable materials and recyclable materials listed in subsection (c)(2)

of this section remain subject to the requirements of §335.6 of this title. Industrial solid wastes that are nonhazardous recyclable materials and recyclable materials listed in subsections (b)(4) and (c)(2) of this section may also be subject to the requirements of §§335.10 - 335.15 of this title, as applicable, if the executive director determines that such requirements are necessary to protect human health and the environment. In making the determination, the executive director shall consider the following criteria:

(1) the waste's toxicity, corrosivity, flammability, ability to sensitize or irritate, or propensity for decomposition and creation of sudden pressure;

(2) the potential for the objectionable constituent to migrate from the waste into the environment if improperly managed;

(3) the persistence of any objectionable constituent or any objectionable degradation product in the waste;

(4) the potential for the objectionable constituent to degrade into nonharmful constituents;

(5) the degree to which the objectionable constituent bioaccumulates in ecosystems;

(6) the plausible types of improper management to which the waste could be subjected;

(7) the nature and severity of potential damage to the public health and environment;

(8) whether subjecting the waste to additional regulation will provide additional protection for human health and the environment; and

(9) other relevant factors.

(i) Except as provided in Texas Health and Safety Code, §361.090, facilities managing recyclable materials that are required to obtain a permit under this section may also be permitted to manage nonhazardous recyclable materials at the same facility if the executive director determines that such regulation is necessary to protect human health and the environment. In making this determination, the executive director shall consider the following criteria:

(1) whether managing nonhazardous recyclable materials will create an additional risk of release of the hazardous recyclable materials into the environment;

(2) whether hazardous and nonhazardous wastes that are incompatible are stored and/or processed in the same or connected units;

(3) whether the management of recyclable materials and nonhazardous recyclable materials is segregated within the facility;

(4) the waste's toxicity, corrosivity, flammability, ability to sensitize or irritate, or propensity for decomposition and creation of sudden pressure;

(5) the potential for the objectionable constituent to migrate from the waste into the environment if improperly managed;

(6) the persistence of any objectionable constituent or any objectionable degradation product in the waste;

(7) the potential for the objectionable constituent to degrade into harmful constituents;

(8) the degree to which the objectionable constituent bioaccumulates in ecosystems;

(9) the plausible types of improper management to which the waste could be subjected;

(10) the nature and severity of potential damage to the public health and environment;

(11) whether subjecting the waste to additional regulation will provide additional protection for human health and the environment; and

(12) other relevant factors.

(j) Closure cost estimates.

(1) Except as otherwise approved by the executive director, an owner or operator of a recycling facility that stores combustible nonhazardous materials outdoors, or that poses a significant risk to public health and safety as determined by the executive director, shall provide a written cost estimate, in current dollars, showing the cost of hiring a third party to close the facility by disposition of all processed and unprocessed materials in accordance with all applicable regulations. The closure cost estimate for financial assurance must be submitted with any new notification in accordance with §335.6 within 60 days of the effective date of this rule for existing facilities or as otherwise requested by the executive director.

(2) The estimate must:

(A) equal the costs of closure of the facility, including disposition of the maximum inventories of all processed and unprocessed combustible materials stored outdoors on site during the life of the facility, in accordance with all applicable regulations;

(B) be based on the costs of hiring a third party that is not affiliated (as defined in §328.2 of this title (relating to Definitions)) with the owner or operator; and

(C) be based on a per cubic yard and/or short ton measure for collection and disposition costs.

(k) Financial assurance. An owner or operator of a recycling facility that stores nonhazardous combustible recyclable materials outdoors, or that poses a significant risk to public health and safety as determined by the executive director, shall establish and maintain financial assurance for closure of the facility in accordance with Chapter 37, Subchapter J of this title (relating to Financial Assurance for Recycling Facilities).

(l) Closure requirements.

(1) Closure must include collecting processed and unprocessed materials, and transporting the materials to an authorized facility for disposition unless otherwise approved or directed in writing by the executive director.

(2) Closure of the facility must be completed within 180 days following the most recent acceptance of processed or unprocessed materials unless otherwise approved or directed in writing by the executive director.

(m) Used oil that is recycled and is also a hazardous waste solely because it exhibits a hazardous characteristic is not subject to the requirements of Subchapters A - I or O of this chapter, but is regulated under Chapter 324 of this title (relating to Used Oil Standards). Used oil that is recycled includes any used oil which is reused, following its original use, for any purpose (including the purpose for which the oil was originally used). Such term includes, but is not limited to, oil which is re-refined, reclaimed, burned for energy recovery, or reprocessed.

(n) Owners or operators of facilities subject to hazardous waste permitting requirements with hazardous waste management units that recycle hazardous wastes are subject to the requirements of 40 CFR Part 264 or Part 265, Subparts AA and BB, as adopted by reference under §335.152(a)(17) and (18) and §335.112(a)(19) and (20) of this title (relating to Standards).

(o) Hazardous waste that is exported or imported for purpose of recovery is subject to the requirements of 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title [amended through November 28, 2016 (81 FR 85696)].

(p) Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid waste," §335.6 of this title, §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), §335.18 of this title (relating to Variances from Classification as a Solid Waste), §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste), §335.26 of this title (relating to Notification Requirement for Hazardous Secondary Materials, §335.27 of this title (relating to Legitimate Recycling of Hazardous Secondary Materials), [and] Subchapter H of this chapter, and Subchapter V of this chapter (relating to Standards for Reclamation of Hazardous Secondary Materials).

§335.26. Notification Requirement for Hazardous Secondary Materials.

Persons who generate, process, store or recycle hazardous secondary materials must comply with the requirements of 40 Code of Federal Regulations (CFR) §260.42 (Notification requirements for hazardous secondary materials) as adopted and amended through May 30, 2018 (83 FR 24664) [January 13, 2015 (80 FR 1694)]. For the purposes of this section and 40 CFR §260.42, the term "Regional Administrator" is changed to the term "executive director" of the Texas Commission on Environmental Quality.

§335.27. Legitimate Recycling of Hazardous Secondary Materials.

Persons who generate, process, store or recycle hazardous secondary materials must comply with the requirements of 40 Code of Federal Regulations (CFR) §260.43 (Legitimate recycling of hazardous secondary materials) as adopted and amended through May 30, 2018 (83 FR 24664) [January 13, 2015 (80 FR 1694)]. For the purposes of this section and 40 CFR §260.43, the term, "Regional Administrator" is changed to the term "executive director" of the Texas Commission on Environmental Quality.

§335.31. Incorporation of References.

When used in this chapter, the references contained in 40 Code of Federal Regulations (CFR) §260.11 are incorporated by reference as amended and adopted in the CFR through November 28, 2016 (81 FR 85732) [November 28, 2016 (81 FR 85696)].

SUBCHAPTER A: INDUSTRIAL SOLID WASTE AND MUNICIPAL HAZARDOUS WASTE IN GENERAL

[§§335.6, 335.11, 335.14]

Statutory Authority

The repealed rules are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The repealed rules are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted repealed rules implement THSC, Chapter 361.

[§335.6. Notification Requirements.]

[(a) Any person who intends to store, process, or dispose of industrial solid waste without a permit, as authorized by §335.2(d), (e), (f), or (h) of this title (relating to Permit Required) or §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), shall notify the executive director in writing or using electronic notification software provided by the executive director, that storage, processing, or disposal activities are planned, at least 90 days prior to engaging in such activities. Recycling operations may commence 90 days after the initial notification of the intent to recycle, or upon receipt of confirmation that the executive director has reviewed the information found in this section. The executive director may require submission of information necessary to determine whether storage, processing, or disposal is compliant with the terms of this chapter. Required information may include, but is not limited to, information concerning waste composition, waste management methods, facility engineering plans and specifications, or the geology where the facility is located. Any registered generator who generates 1,000 kilograms or more of hazardous waste in any calendar month, must meet the requirements of this subsection by electronic notification using software provided by the executive director unless the executive director has granted a written request to use paper forms or an alternative notification method or the software does not have features capable of meeting the requirements.]

[(b) Any person who stores, processes, or disposes of municipal hazardous waste or industrial solid waste shall have the continuing obligation to immediately provide notice to the executive director in writing or using electronic notification software provided by the executive director, of any changes or additional information concerning waste composition, waste management methods, facility engineering plans and specifications, or the geology where the facility is located to that reported in subsection (a) of this section, authorized in any permit, or stated in any application filed with the commission. Any registered generator who generates 1,000 kilograms or more of hazardous waste in any calendar month, must meet the requirements of this subsection by electronic notification using software provided by the executive director unless the executive director has granted a written request to use paper forms or an alternative notification method or the software does not have features capable of meeting the requirements.]

[(c) Any person who generates hazardous waste in a quantity greater than the limits specified in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators) in any calendar month or greater than 100 kilograms in any calendar month of industrial Class 1 waste shall notify the executive director of such activity using electronic notification software or paper forms provided by the executive director. Any registered generator who generates 1,000 kilograms or more of hazardous waste in any calendar month, must meet the requirements of this subsection by electronic notification using software provided by the executive director unless the executive director has granted a

written request to use paper forms or an alternative notification method or the software does not have features capable of meeting the requirements. The executive director may require submission of information necessary to determine whether the storage, processing, or disposal is compliant with the terms of this chapter. Notifications submitted pursuant to this section shall be in addition to information provided in any permit applications required by §335.2 of this title, or any reports required by §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste), and §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste). Any person who provides notification pursuant to this subsection shall have the continuing obligation to immediately document any changes or additional information with respect to such notification and within 90 days of the occurrence of such change or of becoming aware of such additional information, provide notice to the executive director in writing or using electronic notification software provided by the executive director, of any such changes or additional information to that reported previously. Any registered generator who generates 1,000 kilograms or more of hazardous waste in any calendar month, must meet the requirements of this subsection by electronic notification using software provided by the executive director unless the executive director has granted a written request to use paper forms or an alternative notification method or the software does not have features capable of meeting the requirements. If waste is

recycled on-site or managed pursuant to §335.2(d) of this title, the generator must also comply with the notification requirements specified in subsection (h) of this section. The information submitted pursuant to the notification requirements of this subchapter and to the additional requirements of §335.503 of this title (relating to Waste Classification and Waste Coding Required) shall include, but is not limited to:]

[(1) a description of the waste;]

[(2) a description of the process generating the waste;]

[(3) the composition of the waste;]

[(4) a proper hazardous waste determination which includes the appropriate EPA hazardous waste number(s) described in 40 Code of Federal Regulations (CFR) Part 261. Generators must determine whether such waste is hazardous as defined in 40 CFR Part 261 and submit the results of that hazardous waste determination to the executive director;]

[(5) the disposition of each solid waste generated, if subject to the notification requirement of this subsection, including the following information:]

[(A) whether the waste is managed on-site and/or off-site;]

[(B) a description of the type and use of each on-site waste management facility unit;]

[(C) a listing of the wastes managed in each unit; or]

[(D) whether each unit is permitted, or qualifies for an exemption, under §335.2 of this title.]

[(d) Any person who transports hazardous or Class 1 waste shall notify the executive director of such activity on forms furnished or approved by the executive director, except:]

[(1) industrial generators who generate less than 100 kilograms of Class 1 waste per month and less than the quantity limits of hazardous waste specified in §335.78 of this title and who only transport their own waste; and]

[(2) municipal generators who generate less than the quantity limits of hazardous waste specified in §335.78 of this title and who only transport their own waste.]

[(e) Persons operating transfer facilities in accordance with §335.94 of this title (relating to Transfer Facility Requirements) shall notify the executive director of such activity.]

[(f) Upon written request of the executive director, any person who ships, stores, processes, or disposes of industrial solid waste or hazardous waste, as defined in this subchapter, shall perform a chemical analysis of the solid waste and provide results of the analysis to the executive director.]

[(g) Any person who stores, processes, or disposes of industrial solid waste or municipal hazardous waste shall notify the executive director in writing of any activity of facility expansion not authorized by permit, at least 90 days prior to conducting such activity. Such person shall submit to the executive director upon request such information as may reasonably be required to enable the executive director to determine whether such activity is compliant with this chapter.]

[(h) Any person who conducts or intends to conduct the recycling of industrial solid waste or municipal hazardous waste as defined in §335.24 of this title or Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities) and who is required to notify under §335.24 of this title or Subchapter H of this chapter must submit in writing to the executive director, at a minimum, the following information: the type(s) of industrial solid waste or municipal hazardous waste to be recycled, the method of storage prior to recycling, and the nature of the recycling activity. New recycling activities require such notification a minimum of 90 days prior to engaging in such activities. Recycling operations may commence 90 days after the initial notification of the intent to recycle,

or upon receipt of confirmation that the executive director has reviewed the information found in this section. Persons engaged in recycling of industrial solid waste or municipal hazardous waste prior to the effective date of this section shall submit such notification within 60 days of the effective date of this subsection.]

[(i) The owner or operator of a facility qualifying for the small quantity burner exemption under 40 CFR §266.108 must provide a one-time signed, written notification to the EPA and to the executive director indicating the following:]

[(1) The combustion unit is operating as a small quantity burner of hazardous waste;]

[(2) The owner and operator are in compliance with the requirements of 40 CFR §266.108, §335.221(a)(19) of this title (relating to Applicability and Standards) and this subsection of this section; and]

[(3) The maximum quantity of hazardous waste that the facility may burn as provided by 40 CFR §266.108(a)(1).]

[(j) Notification and regulation requirements on nonhazardous used oil, oil made characteristically hazardous by use (instead of mixing), CESQG hazardous used oil, and household used oil after collection that will be recycled are found in Chapter 324 of this title (relating to Used Oil).]

[(k) Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid Waste," §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), §335.18 of this title (relating to Variances from Classification as a Solid Waste), §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste), §335.24 of this title, and Subchapter H of this chapter.]

[(l) A landowner who disposes of domestic or exotic animal carcasses and who complies with a certified water quality management plan developed for their site under Texas Agriculture Code, §201.026(f) as added by Acts 2001, 77th Legislature, Chapter 1189, §1 (relating to Nonpoint Source Pollution) is exempt from the notification requirements of subsections (a) and (b) of this section.]

[§335.11. Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste.]

[(a) Except as provided by §335.10(a)(2) of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), persons who transport hazardous waste must comply with the manifest requirements in 40 Code of Federal Regulations (CFR) §§263.21, 263.22, and 263.25, as these sections are amended through February 7, 2014 (79 FR 7518), and 40 CFR §263.20 and

the Appendix to 40 CFR Part 262, as these are amended through November 28, 2016 (81 FR 85696), as well as the following:]

[(1) the person must comply with §335.10 of this title; and]

[(2) in the case of hazardous waste exports, the person must ensure that the shipment conforms to the requirements set forth in the regulations contained in 40 CFR §263.20.]

[(b) Except as provided by §335.10(d) and (e) of this title, a person who transports Class 1 waste must comply with the requirements of subsection (a) of this section, except those requirements in 40 CFR §263.20(a)(2).]

[§335.14. Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste.]

[(a) A transporter of hazardous waste or Class 1 waste shall retain a copy of each manifest signed by the generator or, in the case of exports of hazardous waste, the primary exporter; the transporter; and the next designated transporter, or the owner or operator of the facility designated on the manifest for a minimum of at least three years from the date of initial shipment.]

[(b) For shipments delivered to the facility designated on the manifest by water (bulk shipment), each water (bulk shipment) transporter must retain a copy of a shipping paper containing all the information required by §335.11(e) of this title (relating to Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste) for a minimum of three years from the date of initial shipment.]

[(c) For shipments of hazardous waste or Class 1 waste by rail within the United States:]

[(1) the initial rail transporter must keep a copy of the manifest and shipping paper with all of the information required in §335.11(f)(2) of this title for a period of three years from the date the hazardous waste or Class 1 waste was accepted by the initial transporter; and]

[(2) the final rail transporter must keep a copy of the signed manifest (or the shipping paper if signed by the designated facility in lieu of the manifest) for a period of three years from the date the hazardous waste or Class 1 waste was accepted by the initial transporter.]

[(d) A transporter who transports waste out of the United States must retain a copy of the manifest indicating that the hazardous waste or waste left the United States for a minimum of three years from the date of initial shipment.]

[(e) The periods of record retention required by this section are automatically extended during the course of any unresolved enforcement action regarding the regulated activity.]

SUBCHAPTER B: HAZARDOUS WASTE MANAGEMENT GENERAL PROVISIONS

§335.41, §335.46

Statutory Authority

The amendments are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendments implement THSC, Chapter 361.

§335.41. Purpose, Scope and Applicability.

(a) The purpose of this chapter is to implement a state hazardous waste program which controls from point of generation to ultimate disposal those wastes which have been identified by the administrator of the United States Environmental Protection Agency (EPA) in 40 Code of Federal Regulations (CFR) Part 261.

(b) Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities); Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste, Treatment, Storage, or Disposal Facilities); §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities); and §335.15 of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities) do not apply to an owner or operator of a totally enclosed treatment facility, as defined in §335.1 of this title (relating to Definitions).

(c) Except as provided in §335.47 of this title (relating to Special Requirements for Persons Eligible for a Federal Permit by Rule), Subchapters E and F of this chapter do not apply to the owner or operator of a publicly owned treatment works (POTW) that processes, stores, or disposes of hazardous waste.

(d) Subchapters E and F of this chapter do not apply to:

(1) the owner or operator of an elementary neutralization unit provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40, Table Treatment Standards for Hazardous Wastes), or reactive (D003) waste, to remove the characteristic before land disposal, the owner/operator must comply with the requirements in 40 CFR §264.17(b);

(2) persons engaged in processing or containment activities during immediate response to a discharge of a hazardous waste; an imminent and substantial threat of discharge of hazardous waste; a discharge of a material which, when discharged, becomes a hazardous waste; or an immediate threat to human health, public safety, property, or the environment, from the known or suspected presence of military munitions, other explosive material, or an explosive device, as determined by an explosive or munitions emergency response specialist as defined in §335.1 of this title, except that:

(A) an owner or operator of a facility otherwise regulated under Subchapter E of this chapter must comply with all applicable requirements of §335.112(a)(2) and (3) of this title (relating to Standards) and §335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator);

(B) an owner or operator of a facility otherwise regulated under Subchapter F of this chapter must comply with all applicable requirements of §335.152(a)(2) and (3) of this title (relating to Standards) and §335.153 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator);

(C) any person who continues or initiates hazardous waste processing or containment activities after the immediate response is over is subject to all applicable requirements of Subchapters E and F of this chapter and Chapter 305 of this title (relating to Consolidated Permits); and

(D) in the case of an explosives or munitions emergency response, if a federal, state, tribal, or local official acting within the scope of his or her official responsibilities, or an explosives or emergency response specialist, determines that immediate removal of the material is necessary to protect human health or the environment, that official or specialist may authorize the removal of the material or waste by transporters who do not have EPA identification numbers and without the preparation of a manifest. In the case of emergencies involving military munitions, the responding military emergency response specialist's organizational unit must retain records for three years identifying the dates of the response, the responsible persons responding, the type and description of material addressed, and its disposition;

(3) persons adding absorbent material to waste in a container, as defined in §335.1 of this title and persons adding waste to absorbent material in a container,

provided that these actions occur at the time that waste is first placed in the container, and that in the case of permitted facilities, 40 CFR §§264.17(b), 264.171, and 264.172 are complied with, and for all other facilities, 40 CFR §§265.17(b), 265.171, and 265.172 are complied with;

(4) a farmer disposing of waste pesticides from the farmer's own use in compliance with 40 CFR §262.70 as adopted under §335.57 [§335.77] of this title (relating to Farmers);

(5) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, provided that the wastewater is discharged in accordance with a Texas Pollutant Discharge Elimination System authorization issued under Texas Water Code, Chapter 26, and if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b);

(6) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, located at a noncommercial solid waste management facility that discharges to a publicly owned treatment works, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the

characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b);

(7) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, located at a municipal solid waste facility or commercial industrial solid waste landfill disposal facility that discharges to a publicly owned treatment works liquid wastes that are incidental to the handling, processing, storage, or disposal of solid wastes, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b); [or]

(8) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, located at a commercial industrial solid waste facility that receives waste for discharge to a publicly owned treatment works, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b), but is subject to the permitting requirements of §335.2(n) of this title (relating to Permit Required); [.]

(9) the owner or operator of a facility permitted, licensed, or registered by a state to manage municipal or industrial solid waste, if the only hazardous waste the

facility treats, stores, or disposes of is excluded from regulation under this chapter by 40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste);

(10) a generator accumulating waste on-site in compliance with applicable conditions for exemption in 40 CFR §§262.14, 262.15, 262.16, or 262.17 as adopted under §335.53 of this title except to the extent the requirements of Subchapter E or F of this chapter are included in 40 CFR §§262.14 - 262.17; or

(11) a reverse distributor accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, in compliance with Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals).

(e) Subchapter E of this chapter does not apply to:

(1) a very small quantity generator that meets the conditions for exemption for a very small quantity generator in 40 CFR §262.14 as adopted under §335.53 of this title that [person who] stores, processes, or disposes of hazardous waste on-site [and meets the requirements of §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)]; or

(2) A generator accumulating waste on-site in compliance with applicable conditions for exemption in and 40 CFR Part 262, Subparts K and L as adopted under §335.59 and §335.60 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities; and Alternative Standards for Episodic Generation), except to the extent the requirements of Subchapter E of this chapter are included in 40 CFR Part 262, Subparts K and L [the owner or operator of a solid waste facility who stores, processes, or disposes of hazardous waste received from a conditionally exempt small quantity generator].

(f) The following requirements apply to residues of hazardous waste in containers.

(1) Subchapters B - F and O of this chapter (relating to Hazardous Waste Management General Provisions; Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for Owners and Operators of Hazardous Waste, Treatment, Storage, or Disposal Facilities; and Land Disposal Restrictions) do not apply to any hazardous waste remaining in either an empty container or an inner liner removed from an empty container, as defined in paragraph (2) of this subsection. This exemption does not apply to any hazardous waste in either a container that is not empty or an inner liner removed from a container that is not empty.

(2) For purposes of determining whether a container is empty under this subsection, the following provisions apply:

(A) a container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in 40 CFR §§261.31, 261.32, or 261.33(e) is empty if:

(i) all wastes have been removed that can be using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, and aspirating; and

(ii) no more than 2.5 centimeters (one inch) of residue remains on the bottom of the container or inner liner; or

(iii) no more than 3.0% by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size, or no more than 0.3% by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size;

(B) a container that has held a hazardous waste that is a compressed gas is empty when the pressure in the container approaches atmosphere; [or]

(C) a container or an inner liner removed from a container that has held an acute hazardous waste listed in 40 CFR §§261.31, 261.32, or 261.33(e) is empty if:

(i) the container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) the container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) in the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container has been removed.

(D) A container of hazardous waste pharmaceuticals is subject to §335.765 of this title (relating to Residues of Hazardous Waste Pharmaceuticals in

Empty Containers) instead of this section for determining when it is considered empty, except as provided by §335.765(c) and (d) of this title.

(g) Subchapters B - F and O of this chapter do not apply to hazardous waste that is managed as a recyclable material described in §335.24(b) and (c) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), except to the extent that requirements of these subchapters are referred to in Subchapter H of this chapter and Chapter 324 of this title (relating to Used Oil Standards).

(h) Subchapters E and F of this chapter apply to owners or operators of all facilities that treat, store, or dispose of hazardous waste referred to in Subchapter O of this chapter.

(i) Except as provided in §335.47 of this title, Subchapter F of this chapter does not apply to persons disposing of hazardous waste by means of underground injection. However, Subchapter F of this chapter does apply to the aboveground storage or processing of hazardous waste before it is injected underground.

(j) Except as specified in Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule), Subchapters B - F and O of this chapter and Chapter 305 of this title do not apply to universal wastes, universal waste handlers, or universal waste transporters as defined in §335.261 of this title (relating to Universal Waste Rule).

Universal wastes are not fully regulated hazardous wastes, but are subject to regulation under Subchapter H, Division 5 of this chapter.

§335.46. Sharing of Information.

(a) Any information obtained or used by the commission in the administration of a hazardous waste program authorized under the Resource Conservation and Recovery Act of 1976, §3006 and 40 Code of Federal Regulations (CFR) Part 271 shall be available to the Environmental Protection Agency upon request without restriction. If the information has been submitted to the commission under a claim of confidentiality, the commission shall submit that claim to the Environmental Protection Agency when providing information under this section. Any information obtained from the commission and subject to a claim of confidentiality will be treated by the Environmental Protection Agency in accordance with 40 CFR Part 2. If the Environmental Protection Agency obtains information that is not claimed to be confidential, the Environmental Protection Agency may make that information available to the public without further notice.

(b) The commission adopts by reference 40 CFR §260.2(c) as amended through February 7, 2014 in the *Federal Register* (79 FR 7518).

(c) The commission adopts by reference 40 CFR §260.2(d) as amended through December 26, 2017 in the *Federal Register* (82 FR 60894).

SUBCHAPTER C: STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

§§335.51 - 335.61

Statutory Authority

The new rules are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The new rules are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted new rules implement THSC, Chapter 361.

§335.51. Definitions.

The following terms have the following meanings when used in this subchapter.

(1) Condition for exemption--Any requirement in 40 Code of Federal Regulations (CFR) §262.14 (Conditions for exemption for a very small quantity generator), §262.15 (Satellite accumulation area regulations for small and large quantity generators), §262.16 (Conditions for exemption for a small quantity generator that accumulates hazardous waste), §262.17 (Conditions for exemption for a large quantity generator that accumulates hazardous waste), §262.70 (Farmers), or 40 CFR Part 262, Subpart K (Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities), or 40 CFR Part 262, Subpart L (Alternative Standards for Episodic Generation), as adopted under this subchapter, that states an event, action, or standard that must occur or be met in order to obtain an exemption from any applicable requirement in Chapter 37 of this title (relating to Financial Assurance), Chapter 39 of this title (relating to Public Notice), and Chapter 305 of this title (relating to Consolidated Permits), Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste), or from any requirement for notification under Resource Conservation and Recovery Act, §3010.

(2) Independent requirement--A requirement of 40 Code of Federal Regulations (CFR) Part 262 (Standards Applicable to Generators of Hazardous Waste),

as adopted under this chapter, that states an event, action, or standard that must occur or be met; and that applies without relation to, or irrespective of, the purpose of obtaining a conditional exemption from storage facility permit, interim status, and operating requirements under 40 CFR §§262.14 - 262.17, or 40 CFR Part 262, Subpart K (Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities), or 40 CFR Part 262, Subpart L (Alternative Standards for Episodic Generation), as adopted in this subchapter.

§335.52. Purpose, Scope, and Applicability.

(a) The regulations in this subchapter establish standards for generators of hazardous waste. These standards are in addition to any applicable provisions contained in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General).

(1) A person who generates a hazardous waste as defined by 40 Code of Federal Regulations (CFR) §261.3, as adopted under §335.504 of this title (relating to Hazardous Waste Determination), is subject to all applicable independent requirements listed in this section.

(A) Independent requirements of a very small quantity generator:

(i) §335.504 of this title; and

(ii) 40 CFR §262.13 (Generator category determination) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(B) Independent requirements of a small quantity generator:

(i) §335.504 of this title;

(ii) 40 CFR §262.11(e) and (f) (Hazardous waste determination and recordkeeping), as adopted under §335.53 of this title;

(iii) 40 CFR §262.13, as adopted under §335.53 of this title;

(iv) 40 CFR §262.18 (EPA identification numbers and re-notification for small quantity generators and large quantity generators), as adopted under §335.53 of this title;

(v) 40 CFR Part 262, Subpart B (Manifest Requirements Applicable to Small and Large Quantity Generators), as adopted under §335.54 of this title (relating to Hazardous Waste Manifest);

(vi) 40 CFR Part 262, Subpart C (Pre-Transport Requirements Applicable to Small and Large Quantity Generators) as adopted under §335.55 of this title (relating to Pre-Transport Requirements Applicable to Large and Small Quantity Generators);

(vii) 40 CFR §262.40 (Recordkeeping) as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Large and Small Quantity Generators);

(viii) 40 CFR §262.44 (Recordkeeping for small quantity generators) as adopted under §335.56 of this title;

(ix) §§335.6(b), (c) and (f), 335.9, 335.10(a) and 335.13 of this title (relating to Notification Requirements; Recordkeeping and Annual Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste; and Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste); and

(x) 40 CFR Part 262, Subpart H (Transboundary Movements of Hazardous Waste for Recovery or Disposal), as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal).

(C) Independent requirements of a large quantity generator:

(i) §335.504 of this title;

(ii) 40 CFR §262.11(e) and (f) as adopted under §335.53 of this title;

(iii) 40 CFR §262.13 as adopted under §335.53 of this title;

(iv) 40 CFR §262.18 as adopted under §335.53 of this title;

(v) 40 CFR Part 262, Subpart B as adopted under §335.54 of this title;

(vi) 40 CFR Part 262, Subpart C as adopted under §335.55 of this title;

(vii) 40 CFR Part 262, Subpart D (Recordkeeping and Reporting Applicable to Small and Large Quantity Generators), as adopted under §335.56 of this title except 40 CFR §262.44;

(viii) §§335.6(b), (c) and (f), 335.9, 335.10(a) and 335.13 of this title; and

(ix) 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title.

(2) A generator that accumulates hazardous waste on-site is a person that stores hazardous waste and is subject to the applicable requirements of Chapter 37 of this title (relating to Financial Assurance), Chapter 39 of this title (relating to Public Notice), Chapter 305 of this title (relating to General Provisions), Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste), and Section 3010 of Resource Conservation and Recovery Act (RCRA) unless it is one of the following:

(A) a very small quantity generator that meets the conditions for exemption in 40 CFR §262.14 (Conditions for exemption for a very small quantity generator), as adopted under §335.53 of this title;

(B) a small quantity generator that meets the conditions for exemption in 40 CFR §262.16 (Conditions for exemption for a small quantity generator that accumulates hazardous waste) and meets the requirements of 40 CFR §262.15 (Satellite accumulation area regulations for small and large quantity generators), as 40 CFR §262.15 and §262.16 are adopted under §335.53 of this title; and

(C) a large quantity generator that meets the conditions for exemption in 40 CFR §262.17 (Conditions for exemption for a large quantity generator

that accumulates hazardous waste) and meets the requirements of 40 CFR §262.15, as 40 CFR §262.15 and §262.17 are adopted under §335.53 of this title.

(3) A generator shall not transport, offer its hazardous waste for transport, or otherwise cause its hazardous waste to be sent to a facility that is not a designated facility, as defined in §335.1 of this title (relating to Definitions), or not otherwise authorized to receive the generator's hazardous waste.

(b) A generator must use 40 CFR §262.13 as adopted under §335.53 of this title to determine their generator category and which provisions of this subchapter are applicable to the generator based on the quantity of hazardous waste generated per calendar month.

(c) Any person who exports or imports hazardous wastes must comply with 40 CFR §262.18 as adopted under §335.53 of this title and 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title.

(d) Any person who imports hazardous waste into the United States must comply with the standards applicable to generators established in 40 CFR Part 262.

(e) A farmer who generates waste pesticides which are hazardous waste and who complies with all of the requirements of 40 CFR §262.70 (Farmers), as adopted under §335.57 of this title (relating to Farmers), is not required to comply with other

standards in this subchapter or this chapter with respect to such pesticides.

(f) This subsection describes the consequences of violating of an independent requirement and not complying with a condition for exemption.

(1) A generator's violation of an independent requirement is subject to penalty and injunctive relief under Texas Health and Safety Code, Chapter 361, Texas Water Code, Chapter 7, and Section 3008 of RCRA.

(2) A generator's noncompliance with a condition for exemption in this part is not subject to penalty or injunctive relief under Texas Health and Safety Code, Chapter 361, Texas Water Code, Chapter 7, or Section 3008 of RCRA as a violation of a Texas Administrative Code section adopting a 40 CFR Part 262 condition for exemption. Noncompliance by any generator with an applicable condition for exemption from storage permit and operations requirements means that the facility is a storage facility operating without an exemption from the permit, interim status, operations, and notification requirements in this chapter, and in Chapters 37, 39, and 305 of this title. Without an exemption, any violations of such storage requirements are subject to penalty and injunctive relief under Texas Health and Safety Code, Chapter 361, Texas Water Code, Chapter 7, and Section 3008 of RCRA.

(g) An owner or operator who initiates a shipment of hazardous waste from a treatment, storage, or disposal facility must comply with the generator standards

established in this subchapter.

(h) Persons responding to an explosives or munitions emergency in accordance with §335.41(d)(2) of this title (relating to Purpose, Scope and Applicability) are not required to comply with the standards of this subchapter.

(i) The laboratories owned by an eligible academic entity (for purposes of this paragraph, the terms "laboratory" and "eligible academic entity" shall have the meaning defined in 40 CFR §262.200, as adopted under §335.59 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities) that elect to be subject to the requirements of 40 CFR Part 262, Subpart K, as adopted by reference under §335.59 of this title are not subject to:

(1) the independent requirements of §335.504 of this title or 40 CFR §262.11 as adopted under §335.53 of this title;

(2) the regulations in 40 CFR §262.15 as adopted under §335.53 of this title for large quantity generators and small quantity generators, except as provided in 40 CFR Part 262, Subpart K, as adopted under §335.59 of this title; or

(3) the conditions of 40 CFR §262.14 as adopted under §335.53 of this title, except as provided in 40 CFR Part 262, Subpart K, as adopted by reference under §335.59 of this title.

(j) A reverse distributor as defined in §335.751 of this title (relating to Definitions) is subject to Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals) for the management of hazardous waste pharmaceuticals instead of this subchapter.

(k) A healthcare facility, as defined in §335.751 of this title, must determine whether it is subject to Subchapter W of this chapter for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kilograms (kg) (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in 40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title (relating to Hazardous Waste Determination), is subject to Subchapter W of this chapter for the management of hazardous waste pharmaceuticals in lieu of this subchapter. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its

non-pharmaceutical hazardous waste, remains subject to 40 CFR §262.14 as adopted in §335.53 of this title, and is not subject to Subchapter W of this chapter, except for §335.761 and §335.765 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; and Residues of Hazardous Waste Pharmaceuticals in Empty Containers), and the optional provisions of §335.759 of this title (relating to Healthcare Facilities That are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste).

§335.53. General Standards Applicable to Generators of Hazardous Waste.

(a) The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) §262.11(e) - (g) (Hazardous waste determination and record keeping) as adopted and amended in the *Federal Register* through November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In 40 CFR §262.11(e), "parts 261, 264, 265, 266, 267, 268, and 273 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(2) In 40 CFR §262.11(f), "40 CFR 261.3" means as this section is adopted under §335.504 of this title (relating to Hazardous Waste Determination); "paragraphs (c) and (d) of this section" are changed to "§335.504(a)(2) and (3) of this title";

"paragraph (d)(1)" is changed to "§335.504(a)(3)(A) of this title"; and the term "Administrator" is changed to the term "executive director."

(3) In 40 CFR §262.11(g), "subparts C and D of part 261 of this chapter" is changed to "40 CFR Part 261, Subparts C and D, as adopted by reference under §335.504 of this title"; and "§262.32" is changed to "40 CFR §262.32 as adopted by reference under §335.55 of this title (relating to Pre-Transport Requirements Applicable to Small and Large Quantity Generators)."

(b) The commission adopts by reference the regulations contained in 40 CFR §262.13 (Generator category determination), including Table 1, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), and amended in the *Federal Register* through February 22, 2019 (84 FR 5816) subject to the changes in this subsection.

(1) In the introductory text to 40 CFR §262.13, "§260.10 of this chapter" is changed to "§335.1 of this title (relating to Definitions)."

(2) In 40 CFR §262.13(c), "this part" is changed to "this chapter."

(3) In 40 CFR §262.13(c)(1), "40 CFR 261.4(c) through (f), 261.6(a)(3), or 261.7(a)(1)" is changed to "§335.2(f) and (g) of this title (relating to Permit Required), §335.24(c)(1) - (4) of this title (relating to Requirements for Recyclable Materials and

Nonhazardous Recyclable Materials), and §335.41(f) of this title (relating to Purpose, Scope and Applicability)."

(4) In 40 CFR §262.13(c)(2), "40 CFR 260.10" is changed to "§335.1 of this title."

(5) In 40 CFR §262.13(c)(3), "40 CFR 261.6(c)(2)" is changed to "§335.24(g) of this title."

(6) In 40 CFR §262.13(c)(4), "40 CFR 261.6(a)(4) and 40 CFR part 279" is changed to "§335.24(m) of this title and Chapter 324 of this title (relating to Used Oil Standards)."

(7) In 40 CFR §262.13(c)(5), "40 CFR part 266 subpart G" is changed to "Subchapter H, Division 4 of this chapter (relating to Spent Lead-Acid Batteries Being Reclaimed)."

(8) In 40 CFR §262.13(c)(6), "40 CFR 261.9 and 40 CFR part 273" is changed to "40 CFR §261.9 as adopted under §335.504(a)(1) of this title and Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule)."

(9) In 40 CFR §262.13(c)(7), "listed in 40 CFR part 261 subpart D or exhibiting one or more characteristics in 40 CFR part 261 subpart C" is changed to

"listed in 40 CFR Part 261, Subpart D or exhibiting one or more characteristics in 40 CFR Part 261, Subpart C as adopted under §335.504 of this title"; "§262.213" is changed to "§335.59 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities)"; and "§262.200" is changed to "40 CFR §262.200 as adopted under §335.59 of this title."

(10) In 40 CFR §262.13(c)(8), "subpart L of this part" is changed to "§335.60 of this title (relating to Alternative Standards for Episodic Generation)."

(11) In 40 CFR §262.13(c)(9), "§266.500" is changed to "§335.751 of this title (relating to Definitions); "40 CFR part 266 subpart P" is changed to "Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals)"; and "§266.506" is changed to "§335.763 of this title (relating to Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program)."

(12) In 40 CFR §262.13(e), "§262.10" is changed to "§335.52 of this title (relating to Purpose, Scope, and Applicability)"; and "§§262.14, 262.15, 262.16 or 262.17" is changed to "40 CFR §§262.14, 262.15, 262.16 or 262.17 as adopted under subsections (c) - (f) of this section."

(13) In 40 CFR §262.13(f)(1)(i):

(A) "§262.14" is changed to "40 CFR §262.14 as adopted in subsection (c) of this section";

(B) "§260.10 of this chapter" is changed to "§335.1 of this title"; and

(C) "part 261 subpart C of this chapter" is changed to "40 CFR Part 261, Subpart C as adopted under §335.504 of this title."

(14) In 40 CFR §262.13(f)(1)(ii), "40 CFR 260.10 of this chapter" is changed to "§335.1 of this title."

(15) In 40 CFR §262.13(f)(1)(iii), "40 CFR part 279" is changed to "Chapter 324 of this title."

(16) In 40 CFR §262.13(f)(2)(i):

(A) "§§261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i)" are changed to "40 CFR §§261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i) as adopted under §335.504 of this title";

(B) "§268.3(a)" is changed to "40 CFR §268.3(a), as adopted under §335.431(c) of this title (relating to Purpose, Scope, and Applicability)";

(C) "§268.40" is changed to "40 CFR §268.40 as adopted under §335.431(c) of this title"; and

(D) "§262.11" is changed to "§335.504 of this title and 40 CFR §262.11(e) - (g) as adopted under subsection (a) of this section."

(17) In 40 CFR §262.13(f)(2)(ii), "§260.10 of this chapter" is changed to "§335.1 of this title."

(c) The commission adopts by reference the regulations contained in 40 CFR §262.14, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), and amended in the *Federal Register* through February 22, 2019 (84 FR 5816) subject to the changes in this subsection.

(1) In 40 CFR §262.14(a), "parts 124, 262 (except §§262.10 - 262.14) through 268 and 270 of this chapter" is changed to "40 CFR Part 262, except §§262.10 - 262.14, as adopted in this subchapter; §335.2 of this title (relating to Permit Required); Subchapters D - H and O of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for

Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Location Standards for Hazardous Waste Storage, Processing, or Disposal; Standards for the Management of Specific Wastes and Specific Types of Facilities; and Land Disposal Restrictions); and Chapters 37, 39, and 305 of this title (relating to Financial Assurance; Public Notice; and Consolidated Permits)."

(2) In 40 CFR §262.14(a)(1), "§260.10 of this chapter" is changed to "§335.1 of this title (relating to Definitions)."

(3) In 40 CFR §262.14(a)(2), "§262.11(a) through (d)" is changed to "§335.504 of this title."

(4) In 40 CFR §262.14(a)(3), "§§261.31 or 261.33(e) of this chapter" is changed to "40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title."

(5) In 40 CFR §262.14(a)(3)(ii), "§262.17(a) through (g)" is changed to "40 CFR §262.17(a) - (g) as adopted under subsection (f) of this section."

(6) In 40 CFR §262.14(a)(4)(iii), "§262.16(b)(2) through (f)" is changed to "40 CFR §262.16(b)(2) - (f) as adopted under subsection (e) of this section."

(7) In 40 CFR §262.14(a)(5)(i), "part 270 of this chapter" is changed to "40 CFR Part 270 or Chapter 335 of this title";

(8) In 40 CFR §262.14(a)(5)(ii), "parts 265 and 270 of this chapter" is changed to "40 CFR Parts 265 and 270 or Chapter 335 of this title;"

(9) In 40 CFR §262.14 (a)(5)(vii), after "part 273 of this chapter" is changed to "40 CFR Part 273 or Chapter 335, Subchapter H, Division 5 of this title (relating to Universal Waste Rule)."

(10) In 40 CFR §262.14(a)(5)(viii)(A), "§260.10 of this chapter" is changed to "§3.2 of this title (relating to Definitions)."

(11) In 40 CFR §262.14(a)(5)(ix), "§266.500" is changed to "§335.751 of this title (relating to Definitions)."

(12) In 40 CFR §262.14(a)(5)(x), "§266.500" is changed to "§335.751 of this title"; and "§§266.502(l) and 266.503(b)" is changed to "§335.755(l) and §335.757(b) of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals; and Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals)."

(13) In 40 CFR §262.14(a)(5)(xi), "§261.4(j) of this chapter" is changed to "§335.281 of this title (relating to Airbag Waste)."

(14) In 40 CFR §262.14(c), "subpart L of this part" is changed to "§335.60 of this title (relating to Alternative Standards for Episodic Generation))"; and "§§262.15, 262.16, and 262.17" is changed to "40 CFR §§262.15, 262.16 and 262.17 as adopted under subsections (d) - (f) of this section."

(d) The commission adopts by reference the regulations contained in 40 CFR §262.15, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In 40 CFR §262.15(a):

(A) "§261.31 or §261.33(e) of this chapter" is changed to "40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title";

(B) "parts 124, 264 through 267, and 270 of this chapter" is changed to "§335.2 of this title; Subchapters E - H of this chapter; Chapters 37, 39, and 305 of this title; and Chapter 281 of this title (relating to Consolidated Permits); and

(C) "§262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8)" is changed to "40 CFR §262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8) as adopted under subsections (d) - (f) of this section."

(2) In 40 CFR §262.15(a)(1), "§262.16(b) or §262.17(a)" is changed to "40 CFR §262.16(b) or §262.17(a)" as adopted under subsections (e) and (f) of this section.

(3) In 40 CFR §262.15(a)(3)(i), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(a)(25)(D) of this title (relating to Standards)"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(4) In 40 CFR §262.15(a)(3)(ii), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(a)(24)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(5) In 40 CFR §262.15(a)(6), "§261.31 or §261.33(e) of this chapter" is changed to "40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title."

(6) In 40 CFR §262.15(a)(6)(i), "§262.16(b) or §262.17(a)" is changed to "40 CFR §262.16(b) or §262.17(a) as adopted under subsections (e) and (f) of this section."

(7) In 40 CFR §262.15(a)(6)(ii)(A), "§262.16(b) or §262.17(a)" is changed to "40 CFR §262.16(b) or §262.17(a) as adopted under subsections (e) and (f) of this section."

(8) In 40 CFR §262.15(a)(7), "§262.16(b)(8)" is changed to "40 CFR §262.16(b)(8) as adopted under subsection (e) of this section"; and "§262.16(b)(9)" is changed to "40 CFR §262.16(b)(9) as adopted under subsection (e) of this section."

(9) In 40 CFR §262.15(a)(8), "subpart M of this part" is changed to "40 CFR Part 262, Subpart M as adopted under §335.61 of this title (relating to Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators)."

(e) The commission adopts by reference the regulations contained in 40 CFR §262.16, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In the introductory text to 40 CFR §262.16, "parts 124, 264 through 267, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E – H of this chapter."

(2) In 40 CFR §262.16(a), "§260.10 of this chapter" is changed to "§335.1 of this title."

(3) In 40 CFR §262.16(b), "paragraphs (d) and (e)" is changed to "paragraphs (c) and (d)";

(4) In 40 CFR §262.16(b)(2)(v)(A), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(25)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(5) In 40 CFR §262.16(b)(2)(v)(B), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(25)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(6) In 40 CFR §262.16(b)(3)(ii)(A), "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(7) In 40 CFR §262.16(b)(3)(vi), "§261.3(c) or (d) of this chapter" is changed to "40 CFR §261.3(c) or (d) as adopted under 335.504"; and "parts 262, 263, 265 and 268 of this chapter" is changed to "Chapter 335 of this title and all applicable chapters of this title."

(8) In 40 CFR §262.16(b)(3)(vii)(A)(1), "§261.21 or §261.23 of this chapter" is changed to "40 CFR §261.21 or §261.23 as adopted under §335.504 of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(9) In 40 CFR §262.16(b)(3)(vii)(B), "§260.11" is changed to "40 CFR §260.11, which is incorporated by reference under §335.31 of this title (relating to Incorporation of References)."

(10) In 40 CFR §262.16(b)(3)(vii)(C)(1), "part 265 appendix V " is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(24)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(11) In 40 CFR §262.16(b)(3)(vii)(C)(2), "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(12) In 40 CFR §262.16(b)(4)(i), "Subpart W of 40 CFR part 265 (except §265.445 (c))" is changed to "40 CFR Part 265, Subpart W (except §265.445(c)) as adopted under §335.112(a)(18) of this title."

(13) In 40 CFR §262.16(b)(4)(ii), "§262.15" is changed to "40 CFR §262.15 as adopted under subsection (d) of this section."

(14) In 40 CFR §262.16(b)(5), "40 CFR part 265 subpart DD" is changed to "40 CFR Part 265, Subpart DD as adopted under §335.112(a)(22) of this title."

(15) In 40 CFR §262.16(b)(5)(i), "40 CFR 265.1101" is changed to "40 CFR §265.1101 as adopted under §335.112(a)(22) of this title."

(16) In 40 CFR §262.16(b)(7), "40 CFR part 268" is changed to "40 CFR Part 268 as adopted under Subchapter O of this title."

(17) In 40 CFR §262.16(b)(8)(iv)(A) and (B), "(a)(8)(ii)" is changed to "(b)(8)(ii)."

(18) In 40 CFR §262.16(d), "40 CFR parts 264, 265, 267, 268, and 270 of this chapter" is changed to "Chapter 335 of this title and the applicable chapters of this title" and the terms "EPA" and "Regional Administrator" are changed to the term "executive director."

(19) In 40 CFR §262.16(e), "§264.72 or §265.72 of this chapter" is changed to "40 CFR §264.72 or §265.72 as adopted under §§335.112 or 335.152 of this title (relating to Standards and Standards)."

(20) In 40 CFR §262.16(f), "subpart L of this part" is changed to "§335.60 of this title (relating to Alternative Standards for Episodic Generation)"; and "§262.17" is changed to "40 CFR §262.17 as adopted under subsection (f) of this section."

(f) The commission adopts by reference the regulations contained in 40 CFR

§262.17, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In the introductory text to 40 CFR §262.17, "parts 124, 264 through 267, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title, and Subchapters E - H of this chapter."

(2) In 40 CFR §262.17(a)(1)(i), "subparts AA, BB, and CC of 40 CFR part 265" is changed to "40 CFR Part 265, Subparts AA, BB, and CC as adopted under §335.112(a)(19) - (21) of this title (relating to Standards)."

(3) In 40 CFR §262.17(a)(1)(vii)(A), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(25)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(4) In 40 CFR §262.17(a)(1)(vii)(B), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(24)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(5) In 40 CFR §262.17(a)(2), "subparts J, except §265.197(c) of Closure and post-closure care and §265.200" is changed to "40 CFR Part 265, Subpart J, except

§265.197(c) of Closure and post-closure care and §265.200 as adopted under §335.112(a)(9) of this title"; and "AA, BB, and CC of 40 CFR part 265" is changed to "40 CFR Part 265, Subparts AA, BB, and CC as adopted under §335.112(a)(19) - (21) of this title."

(6) In 40 CFR §262.17(a)(3)(i), "Subpart W of 40 CFR part 265 " is changed to "40 CFR Part 265, Subpart W as adopted under §335.112(a)(18) of this title."

(7) In 40 CFR §262.17(a)(3)(ii), "§262.15" is changed to "40 CFR §262.15 as adopted under subsection (d) of this section."

(8) In 40 CFR §262.17(a)(4), "40 CFR part 265 subpart DD" is changed to "40 CFR Part 265, Subpart DD as adopted under §335.112(a)(22) of this title."

(9) In 40 CFR §262.17(a)(4)(i), "40 CFR 265.1101" is changed to "40 CFR §265.1101 as adopted under §335.112(a)(22) of this title."

(10) In 40 CFR §262.17(a)(6), "subpart M of this part" is changed to "40 CFR Part 262, Subpart M as adopted under §335.61."

(11) In 40 CFR §262.17(a)(7)(i)(A), "(a)(7)(iv)" is changed to "(a)(7)(iv)(C)."

(12) In 40 CFR §262.17(a)(8)(ii)(B), "§265.310 of this chapter" is changed to "40 CFR §265.310 as adopted under §335.112(a)(13) of this title"; and "§265.445(b)" is changed to "40 CFR §265.445(b) as adopted under §335.112(a)(18) of this title."

(13) In 40 CFR §262.17(a)(8)(iii)(A)(2), "§261.3(d) of this chapter" is changed to "40 CFR §261.3(d) as adopted under §335.504 of this title."

(14) In 40 CFR §262.17(a)(8)(iii)(A)(3), "parts 262, 263, 265 and 268 of this chapter" is changed to "Chapter 335 of this title, and all applicable chapters of this title."

(15) In 40 CFR §262.17(a)(8)(iii)(A)(4), "(a)(8)(ii)(A)(2)" is changed to "(a)(8)(iii)(A)(2)"; "§265.310 of this chapter" is changed to "40 CFR §265.310 as adopted under §335.112(a)(13) of this title"; and "subparts G and H of part 265 of this chapter" is changed to "40 CFR Part 265, Subparts G and H as adopted under §335.112(a)(6) and (7) of this title."

(16) In 40 CFR §262.17(a)(8)(iv), "§265.445(a) and (b) of this chapter" is changed to "40 CFR §265.445(a) and (b) as adopted under §335.112(a)(18) of this title."

(17) In 40 CFR §262.17(a)(9), "40 CFR part 268" is changed to "40 CFR Part 268 as adopted under Subchapter O of this title."

(18) In 40 CFR §262.17(b), "40 CFR parts 124, 264 through 268, and part 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter" and the terms "EPA" and "Regional Administrator" are changed to the term "executive director."

(19) In 40 CFR §262.17(c), "parts 124, 264 through 267 and part 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter."

(20) In 40 CFR §262.17(c)(4)(i)(C), "subpart DD of 40 CFR part 265" is changed to "40 CFR Part 265, Subpart DD as adopted under §335.112(a)(22) of this title"; and "40 CFR 265.1101" is changed to "40 CFR §265.1101 as adopted under §335.112(a)(22) of this title."

(21) In 40 CFR §262.17(c)(4)(ii), "subparts G and H of part 265" is changed to "40 CFR Part 265, Subparts G and H as adopted under §335.112(a)(6) and (7) of this title."

(22) In 40 CFR §262.17(d), "parts 124, 264 through 267, 270" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H of this chapter."

(23) In 40 CFR §262.17(e), "40 CFR parts 124, 264 through 268, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter"; and the terms "EPA" and "Regional Administrator" are changed to the term "executive director."

(24) In 40 CFR §262.17(f), "§260.10 of this chapter" is changed to "§3.2 of this title (relating to Definitions)" and "parts 124, 264 through 268, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter."

(25) In 40 CFR §262.17(f)(1), "EPA" is changed to "TCEQ"; and "EPA Form 8700-12" is changed to "a method approved by the executive director."

(26) In 40 CFR §262.17(f)(1)(ii), "Site ID form (EPA Form 8700-12)" is changed to "notification using a method approved by the executive director."

(27) In 40 CFR §262.17(f)(3), "§262.10(a)(1)(iii)" is changed to "§335.52(a)(1)(C) of this title (relating to Purpose, Scope, and Applicability)."

(28) In 40 CFR §262.17(g), "§264.72 or §265.72 of this chapter" is changed to "40 CFR §264.72 or §265.72 as adopted under §§335.112 or 335.152 of this title."

(g) The commission adopts by reference the regulations contained in 40 CFR §262.18 (EPA identification numbers and re-notification for small quantity generators and large quantity generators), as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) The term "Administrator" is changed to the term "executive director."

(2) The generator shall provide the information required by the RCRA Site Identification Form (EPA Form 8700-12) using a method approved by the executive director.

(3) In 40 CFR §262.18(d)(1), the re-notification required of a small and large quantity generator must be made to the executive director instead of the EPA.

(4) In 40 CFR §262.18(d)(2), "Biennial Report required under §262.41" is changed to "Biennial Report required under 40 CFR §262.41 as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators).

§335.54. Hazardous Waste Manifest.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart B, §§262.20 (General requirements),

262.21(a) - (f)(4) - (8) and (g) - (m) (Manifest tracking numbers, manifest printing, and obtaining manifests), 262.22 (Number of copies), 262.23 (Use of the manifest), 262.24 (Use of the electronic manifest), 262.25 (Electronic manifest signatures), and 262.27 (Waste minimization certification), as amended in the *Federal Register* through January 3, 2018 (83 FR 420), subject to the changes in this subsection.

(1) In the event of a discharge of hazardous waste on a public or private right-of-way during the transportation of hazardous wastes the generator or transporter must also comply with the requirements of §335.93 of this title (relating to Hazardous Waste Discharges) and Chapter 327 of this title (relating to Spill Prevention and Control).

(2) The reference to §262.40(a)(Recordkeeping) means 40 CFR §262.40(a) as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators).

(3) References to 40 CFR §§264.71, 264.72, or 265.72 mean as the section is adopted under §335.112 or §335.152 of this title (relating to Standards).

(4) Generators shall comply with §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste).

(5) Users of the manifest are subject to 40 CFR §260.2(c) as adopted under §335.46(b) of this title (relating to Sharing of Information).

§335.55. Pre-Transport Requirements Applicable to Small and Large Quantity Generators.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart C, §§262.30 - 262.35 as amended in the *Federal Register* through November 28, 2016 (81 FR 85732), with the reference to §268.42(c) changed to "40 CFR §268.42(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability)."

§335.56. Recordkeeping and Reporting Applicable to Small and Large Quantity Generators.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart D, §§262.40 - 262.44 as amended in the *Federal Register* through November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) The term "Administrator" is changed to the term "executive director."

(2) The terms "Regional Administrator" and "EPA Regional Administrator for the Region" are changed to the term "executive director."

(3) Under 40 CFR §262.41:

(A) a large quantity generator shall submit the information in United States Environmental Protection Agency (EPA) Form 8700-13 A/B required by 40 CFR §262.41 (Biennial report for large quantity generators), using the method approved by the executive director; and

(B) "in accordance with the provisions of 40 CFR parts 264, 265, 266, 267 and 270" means in accordance with Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste) and the applicable chapters of this title.

(4) References to "§261.31" or "§261.33(e)" mean as these sections are adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(5) References to "§262.11(f)" or "§262.17(f)" mean as these sections are adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(6) Reference to "§262.23(a)" means 40 CFR §262.23(a) as that section is adopted under §335.54 of this title (relating to Hazardous Waste Manifest).

(7) Reference to §262.83(g) means 40 CFR §262.83(g) as that section is adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal)."

(8) References to "40 CFR §264.72(e)(1) through (6)" or "40 CFR §265.72(e)(1) through (6)" mean as these sections are adopted under §335.112 and §335.152 of this title (relating to Standards).

§335.57. Farmers.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart G, §262.70 as amended in the *Federal Register* through July 14, 2006 (71 FR 40254), subject to the clarifications in this subsection.

(1) Reference to "§261.7(b)(3)" is changed to "40 CFR §261.7(b)(3) as adopted under §335.504 of this title (relating to Hazardous Waste Determination)."

(2) Reference to "40 CFR parts 264, 265, 268, or 270" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Solid Waste), or the applicable chapters of this title."

§335.58. Transboundary Movements of Hazardous Waste for Recovery or Disposal.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations Part 262, Subpart H, §§262.80 - 262.84 as amended in the *Federal Register* through August 6, 2018 (83 FR 38262). Availability and confidentiality of hazardous waste export, import, and transit information is subject to 40 CFR §260.2(d) as adopted under §335.46(c) of this title (relating to Sharing of Information).

§335.59. Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart K, §§262.200 - 262.216 as amended in the *Federal Register* through November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) "Operating under this subpart" is changed to "operating under 40 CFR Part 262, Subpart K as adopted under this section."

(2) "Provisions of this subpart" is changed to "provisions of 40 CFR Part 262, Subpart K as adopted under this section."

(3) "Requirements of this subpart" is changed to "requirements of 40 CFR Part 262, Subpart K as adopted under this section."

(4) An eligible academic entity notifying in accordance with 40 CFR §262.201 and §262.203 shall notify using a method approved by the executive director.

(5) References to "§260.10" are changed to "§335.1 of this title (relating to Definitions)."

(6) References to 40 CFR §§261.2, 261.3 and 261.5 mean as these sections are adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(7) References to "40 CFR part 261, subpart D", "40 CFR part 261, subpart C", and "§261.33(e)" mean as these parts and this section are adopted under §335.504 of this title.

(8) Reference to "40 CFR part 262" means "40 CFR Part 262 as adopted under this subchapter."

(9) References to 40 CFR §§262.11, 262.13, 262.14, 262.15, 262.16, and 262.17 mean as these sections are adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(10) References to 40 CFR §§262.203 and 262.206 - 262.214 mean as these sections are adopted under this section.

(11) Reference to "§265.16(e)" is changed to "40 CFR §265.16(e) as adopted under §335.112 of this title (relating to Standards)."

(12) In 40 CFR §262.213(a)(1), "1 kg or solid reactive acutely hazardous unwanted material" is changed to "1 kg of solid reactive acutely hazardous unwanted material."

(13) Eligible academic entities who are also registered generators as defined in §335.13(d) of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste) must report any laboratory waste in accordance with §335.9(a)(2) of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators). Such generators must report the management of the laboratory waste but are not required to report the quantities generated.

§335.60. Alternative Standards for Episodic Generation.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart L, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) Reference to "subpart B of this part" is changed to "40 CFR Part 262, Subpart B as adopted under §335.54 of this title (relating to Hazardous Waste Manifest)."

(2) Reference to "§260.10 of this chapter" is changed to "§335.1 of this title (relating to Definitions)."

(3) The term "EPA" is changed to the term "executive director."

(4) The term "Regional Administrator" is changed to the term "executive director."

(5) References to 40 CFR "§262.16(b)(2) of this chapter", "§262.16(b)(3)", and "§262.16(b)(9)(i)" mean as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(6) Under 40 CFR §262.232(a)(1), the reference to "§262.233" means as 40 CFR §262.233 is adopted under this section.

(7) Under 40 CFR §262.232(a)(2) the very small quantity generator shall:

(A) notify the executive director 30 days prior to initiating a planned episodic event by submitting the information required in United States Environmental Protection Agency (EPA) Form 8700-12 using a method approved by the executive director;

(B) notify the executive director within 72 hours of an unplanned event in a manner approved by the executive director;

(C) notify the executive director of an unplanned episodic event by submitting the information required in EPA Form 8700-12 using a method approved by the executive director.

(D) When complying with the emergency procedures for a very small quantity generator under 40 CFR §262.16(b)(9)(i) referenced in 40 CFR §262.232(a)(2) or for a small quantity generator referred to in 40 CFR §262.232(b)(2), very small and small quantity generators shall also notify in accordance with and comply with §335.93 of this title (relating to Hazardous Waste Discharges), and Chapter 327 of this title (relating to Spill Prevention and Control).

(8) Under 40 CFR §262.232(a)(3), the very small quantity generator that has not been issued an EPA identification (ID) number must obtain an EPA ID number by submitting the information required in EPA Form 8700-12 to the executive director using a method approved by the executive director.

(9) In 40 CFR §262.232(b)(4), "from an episodic event waste on drip pads" is changed to "from an episodic event on drip pads."

(10) In 40 CFR §262.232(b)(4)(ii)(C), "the date upon which each period of accumulation begins and ends" is changed to "the date upon which each episodic event begins."

§335.61. Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart M, §§262.250 - 262.256 and §§262.260 - 262.265, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) "Regulations of this subpart" means regulations of 40 CFR Part 262, Subpart M as adopted under this section.

(2) "Standards of this part" means standards of 40 CFR Part 262 as adopted under this subchapter.

(3) Reference to "§261.3(c) or (d) of this chapter" is changed to "40 CFR §261.3(c) or (d) as adopted under §335.504 of this title (relating to Hazardous Waste Determination)."

(4) References to 40 CFR §§262.250, 262.252, 262.256, 262.260, 262.264, and 262.265 mean as these sections are adopted by reference under this section.

(5) Reference to "part 262 of this chapter" mean "40 CFR Part 262 as adopted under this subchapter."

(6) Reference to "part 263 of this chapter" is changed to "§335.11 and §335.14 of this title and Subchapter D of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste)."

(7) Reference to "the applicable requirements and conditions for exemption in Parts 262, 263, and 265 of this chapter" is changed to "the applicable requirements and conditions for exemption in this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

SUBCHAPTER C: STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

[§§335.61 - 335.63, 335.65 - 335.71, 335.73 - 335.79]

Statutory Authority

The repealed rules are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The repealed rules are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted repealed rules implement THSC, Chapter 361.

[§335.61. Purpose, Scope and Applicability.]

[(a) Except as provided in subsection (b) of this section, this subchapter establishes standards for generators of hazardous waste. These standards are in addition to any applicable provisions contained in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General).]

[(b) The provisions of this subchapter with which a generator who stores, processes or disposes of hazardous waste on-site must comply are §335.62 of this title (relating to Hazardous Waste Determination and Waste Classification), §335.63 of this title (relating to EPA Identification Numbers), §335.70 of this title (relating to Recordkeeping), §335.73 of this title (relating to Additional Reporting), and, if applicable, §335.77 of this title (relating to Farmers), and §335.69 of this title (relating to Accumulation Time).]

[(c) Any person who imports hazardous waste into the state from a foreign country shall comply with standards applicable to generators.]

[(d) An owner or operator who initiates a shipment of hazardous waste from a processing, storage or disposal facility must comply with the generator standards contained in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste) and §335.13 of this title (relating to Recordkeeping and Reporting

Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste), and this subchapter. The provisions of §335.69 of this title are applicable to on-site accumulation of hazardous wastes by generators. Therefore, the provisions of §335.69 of this title only apply to owners or operators who are shipping hazardous waste which they generate at that facility.]

[(e) A farmer who generates waste pesticides which are hazardous waste and who complies with §335.77 of this title is not required to comply with this chapter with respect to those pesticides.]

[(f) A generator who treats, stores, or disposes of hazardous waste on-site must comply with the applicable standards and permit requirements set forth in Subchapters E, F, H, and O of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste) and with Chapter 305 of this title (relating to Consolidated Permits).]

[(g) Section 335.78(c) and (d) of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators) must be used to determine the applicability of provisions of this subchapter that are dependent on calculations of the quantity of hazardous waste generated per month.]

[(h) The requirements of this subchapter do not apply to persons responding to an explosives or munitions emergency in accordance with §335.41(d)(2) of this title (relating to Purpose, Scope and Applicability).]

[(i) For purposes of this subsection, the terms "laboratory" and "eligible academic entity" shall have the meaning as defined in 40 Code of Federal Regulations §262.200. The laboratories owned by an eligible academic entity that chooses to be subject to the requirements of §335.79 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities) are not subject to:]

[(1) for large and small quantity generators, the requirements of §335.504 of this title (relating to Hazardous Waste Determination) and §335.69 of this title, except as provided in §335.79 of this title; and]

[(2) for conditionally exempt small quantity generators, the conditions of §335.78 of this title, except as provided in §335.79 of this title.]

[§335.62. Hazardous Waste Determination and Waste Classification.]

[A person who generates a solid waste must determine if that waste is hazardous pursuant to §335.504 of this title (relating to Hazardous Waste Determination) and must classify any nonhazardous waste under the provisions of

Subchapter R of this chapter (relating to Waste Classification). If the waste is determined to be hazardous, the generator must refer to this chapter and to 40 Code of Federal Regulations Parts 261, 264, 265, 266, 267, 268, and 273 for any possible applicable exclusions or restrictions pertaining to management of the specific waste.]

[§335.63. EPA Identification Numbers.]

[(a) A generator must not store, process, dispose of, transport, or offer for transportation, hazardous waste without having received an Environmental Protection Agency (EPA) identification number.]

[(b) A generator must not offer hazardous waste to transporters or to storage, processing or disposal facilities that have not received an EPA identification number.]

[(c) A recognized trader must not arrange for import or export of hazardous waste without having received an EPA identification number from the EPA Administrator.]

[§335.65. Packaging.]

[Before transporting hazardous waste or offering hazardous waste for transportation off-site, a generator must package the waste in accordance with the

applicable Department of Transportation regulations on packaging under 49 Code of Federal Regulations Parts 173, 178, and 179.]

[§335.66. Labeling.]

[Before transporting or offering hazardous waste for transportation off-site, a generator must label each package in accordance with applicable Department of Transportation regulations on hazardous materials under 49 Code of Federal Regulations Part 172.]

[§335.67. Marking.]

[(a) Before transporting or offering hazardous waste for transportation off-site, a generator must mark each package of hazardous waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 Code of Federal Regulations (CFR) Part 172.]

[(b) Before transporting or offering hazardous waste for transportation off-site, a generator must mark each container of 119 gallons or less used in such transportation with the following words and information displayed in accordance with the requirements of 49 CFR §172.304: HAZARDOUS WASTE - Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency (EPA).]

[Figure: 30 TAC §335.67(b)]

[Generator's Name and Address _____

Generator EPA Identification Number _____

Manifest Tracking Number _____]

[§335.68. Placarding.]

[Before transporting or offering hazardous waste for transportation off-site, a generator must placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 Code of Federal Regulations (CFR) Part 172, Subpart F. If placards are not required, a generator must mark each motor vehicle according to 49 CFR §171.3(b)(1), which states that no person may accept for transportation, transport, or deliver a hazardous waste for which a manifest is required unless that person has marked each motor vehicle used to transport hazardous waste in accordance with §390.21 or §1058.2 even though placards may not be required.]

[§335.69. Accumulation Time.]

[(a) Generators that comply with the requirements of paragraph (1) of this subsection are exempt from all requirements adopted by reference in §335.112(a)(6)

and (7) of this title (relating to Standards), except 40 Code of Federal Regulations (CFR) §265.111 and §265.114. Except as provided in subsections (f) - (h) and (n) of this section, a generator may accumulate hazardous waste on-site for 90 days without a permit or interim status provided that:]

[(1) the waste is placed:]

[(A) in containers and the generator complies with the applicable requirements of 40 CFR Part 265, Subparts I, AA, BB, and CC, as adopted by reference under §335.112(a) of this title; and/or]

[(B) in tanks and the generator complies with the applicable requirements of 40 CFR Part 265, Subparts J, AA, BB, and CC, except 40 CFR §265.197(c) and §265.200, as adopted by reference under §335.112(a) of this title; and/or]

[(C) on drip pads and the generator complies with §335.112(a)(18) of this title and maintains the following records at the facility: a description of procedures that will be followed to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal; and/or]

[(D) in containment buildings and the generator complies with 40 CFR Part 265, Subpart DD, as adopted by reference under §335.112(a) of this title and has placed its professional engineer certification that the building complies with the design standards specified in 40 CFR §265.1101 in the facility's operating record prior to operation of the unit. The owner or operator shall maintain the following records at the facility:]

[(i) a written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the facility showing that they are consistent with respecting the 90-day limit, and documentation that the procedures are complied with; or]

[(ii) documentation that the unit is emptied at least once every 90 days;]

[(2) the date upon which each period of accumulation begins is clearly marked and visible for inspection on each container; and]

[(3) while being accumulated on-site, each container and tank is labeled or marked clearly with the words, "Hazardous Waste"; and]

[(4) the generator complies with the following:]

[(A) the requirements for owners or operators in 40 CFR Part 265, Subparts C and D and with 40 CFR §265.16, as adopted by reference in §335.112(a) of this title;]

[(B) all applicable requirements under 40 CFR Part 268, as adopted by reference under §335.431 of this title (relating to Purpose, Scope, and Applicability); and]

[(C) Section 335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator).]

[(b) A generator of 1,000 kilograms or greater of hazardous waste in a calendar month, or greater than 1 kilogram of acute hazardous waste listed in 40 CFR §261.31 or §261.33(e) in a calendar month, who accumulates hazardous waste or acute hazardous waste for more than 90 days is an operator of a storage facility and is subject to the requirements of 40 CFR Parts 264, 265, and 267 and the permit requirements of 40 CFR Part 270 unless he has been granted an extension to the 90-day period. Such extension may be granted by the executive director if hazardous wastes must remain on-site for longer than 90 days due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the executive director on a case-by-case basis.]

[(c) Persons exempted under this provision, who generate hazardous waste, are still subject to the requirements in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General) applicable to generators of Class 1 waste.]

[(d) A generator, other than a conditionally exempt small quantity generator regulated under §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators), may accumulate as much as 55 gallons of hazardous waste or one quart of acutely hazardous waste listed in 40 CFR §261.31 or §261.33(e) in containers at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste, without a permit or interim status and without complying with subsection (a) or (f) of this section provided he:]

[(1) complies with 40 CFR §§265.171, 265.172, and 265.173(a), as adopted by reference under §335.112(a) of this title; and]

[(2) marks his containers either with the words "Hazardous Waste" or with other words that identify the contents of the containers.]

[(e) A generator who accumulates either hazardous waste or acutely hazardous waste listed in 40 CFR §261.31 or §261.33(e) in excess of the amounts listed in subsection (d) of this section at or near any point of generation must, with respect to

that amount of excess waste, comply within three days with subsection (a) of this section or other applicable provisions of this chapter. During the three-day period, the generator must continue to comply with subsection (d) of this section. The generator must mark the container holding the excess accumulation of hazardous waste with the date the excess amount began accumulating.]

[(f) A generator who generates greater than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status provided that:]

[(1) the quantity of waste accumulated on-site never exceeds 6,000 kilograms;]

[(2) the generator complies with the requirements of 40 CFR Part 265, Subpart I, as adopted by reference under §335.112(a) of this title, except 40 CFR §265.176 and §265.178;]

[(3) the generator complies with the requirements of 40 CFR §265.201, as adopted by reference under §335.112(a) of this title;]

[(4) the generator complies with the requirements of:]

[(A) subsection (a)(2) and (3) of this section;]

[(B) 40 CFR Part 265, Subpart C, as adopted by reference under §335.112(a) of this title;]

[(C) all applicable requirements under 40 CFR Part 267, as adopted by reference under §335.601 and §335.602 of this title (relating to Purpose, Scope, and Applicability; and Standards); and]

[(D) all applicable requirements under 40 CFR Part 268, as adopted by reference under §335.431 of this title; and]

[(5) the generator complies with the following requirements.]

[(A) At all times there must be at least one employee either on the premises or on call (i.e., available to respond to an emergency by reaching the facility within a short period of time) with the responsibility for coordinating all emergency response measures specified in subparagraph (D) of this paragraph. This employee is the emergency coordinator.]

[(B) The generator must post the following information next to telephones that may be used to summon emergency assistance:]

[(i) the name and telephone number of the emergency coordinator;]

[(ii) location of fire extinguishers and spill control material, and, if present, fire alarm; and]

[(iii) the telephone number of the fire department, unless the facility has a direct alarm.]

[(C) The generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies;]

[(D) The emergency coordinator or his designee must respond to any emergencies that arise. The applicable responses are as follows.]

[(i) In the event of a fire, call the fire department or attempt to extinguish it using a fire extinguisher.]

[(ii) In the event of a spill, contain the flow of hazardous waste to the extent possible, and as soon as is practicable, clean up the hazardous waste and any contaminated materials or soil.]

[(iii) In the event of a fire, explosion, or other release which could threaten human health outside the facility or when the generator has knowledge that a spill has reached surface water, the generator must immediately notify the National Response Center (using its 24-hour toll free number (800) 424-8802) and the commission according to the procedures set out in the State of Texas oil and hazardous substances spill contingency plan. The reports must include the following information:]

[(I) the name, address, and United States Environmental Protection Agency (EPA) identification number of the generator;]

[(II) date, time, and type of incident (e.g., spill or fire);]

[(III) quantity and type of hazardous waste involved in the incident;]

[(IV) extent of injuries, if any; and]

[(V) estimated quantity and disposition of recovered materials, if any.]

[(g) A generator who generates greater than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month and who must transport his waste, or offer his waste for transportation, over a distance of 200 miles or more for off-site processing, storage, or disposal may accumulate hazardous waste on-site for 270 days or less without a permit or without having interim status, provided that he complies with the requirements of subsection (f) of this section.]

[(h) A generator who generates greater than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month and who accumulates hazardous waste in quantities exceeding 6,000 kilograms or accumulates hazardous waste for more than 180 days (or for more than 270 days if he must transport his waste, or offer his waste for transportation, over a distance of 200 miles or more) is an operator of a storage facility and is subject to the requirements of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste), and Subchapters E and F of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; and Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) and the permit requirements of Chapter 305 of this title (relating to Consolidated Permits), unless he has been granted an extension to the 180-day (or 270-day, if applicable) period. Such extension may be granted by the executive director if hazardous wastes must remain on-site for longer than 180 days (or 270 days, if applicable) due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30

days may be granted at the discretion of the executive director on a case-by-case basis.]

[(i) A generator who generates or collects hazardous waste for the purpose of treatability studies is not subject to this section.]

[(j) A generator of 1,000 kilograms or greater of hazardous waste per calendar month who also generates wastewater treatment sludges from electroplating operations that meet the listing description for EPA hazardous waste number F006, may accumulate F006 waste on-site for more than 90 days, but not more than 180 days without a permit or without having interim status provided that:]

[(1) the generator has implemented pollution prevention practices that reduce the amount of any hazardous substances, pollutants, or contaminants entering the F006 waste or otherwise released to the environment prior to its recycling;]

[(2) the F006 waste is legitimately recycled through metals recovery;]

[(3) no more than 20,000 kilograms of F006 waste is accumulated on-site at any one time; and]

[(4) the F006 waste is managed in accordance with the following:]

[(A) the F006 waste is placed:]

[(i) in containers and the generator complies with the applicable requirements of 40 CFR Part 265, Subparts I, AA, and BB, as adopted by reference under §335.112(a) of this title, and 40 CFR Part 265, Subpart CC; and/or]

[(ii) in tanks and the generator complies with the applicable requirements of 40 CFR Part 265, Subparts J, AA, BB, as adopted by reference under §335.112(a) of this title, and 40 CFR Part 265, Subpart CC, except 40 CFR §265.197(c) and §265.200; and/or]

[(iii) in containment buildings and the generator complies with 40 CFR Part 265, Subpart DD, as adopted by reference under §335.112(a) of this title, and has placed its professional engineer certification that the building complies with the design standards specified in 40 CFR §265.1101 in the facility's operating record prior to operation of the unit. The owner or operator shall maintain the following records at the facility:]

[(I) a written description of procedures to ensure that the F006 waste remains in the unit for no more than 180 days, a written description of the waste generation and management practices for the facility showing that they are consistent with the 180-day limit, and documentation that the generator is complying with the procedures; or]

[(II) documentation that the unit is emptied at least once every 180 days;]

[(B) the generator complies with 40 CFR §265.111 and §265.114, as adopted by reference under §335.112(a)(6) of this title;[

[(C) the date upon which each period of accumulation begins is clearly marked and visible for inspection on each container;]

[(D) while being accumulated on-site, each container and tank is labeled or marked clearly with the words "Hazardous Waste"; and]

[(E) the generator complies with the following:]

[(i) the requirements for owners or operators in 40 CFR Part 265, Subparts C and D, and 40 CFR §265.16, as adopted by reference under §335.112(a) of this title;]

[(ii) 40 CFR §268.7(a)(5), as adopted by reference under §335.431(c) of this title; and]

[(iii) Section 335.113 of this title.]

[(k) A generator of 1,000 kilograms or greater of hazardous waste per calendar month who also generates wastewater treatment sludges from electroplating operations that meet the listing description for EPA hazardous waste number F006, and who must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more for off-site metals recovery, may accumulate F006 waste on-site for more than 90 days, but not more than 270 days without a permit or without having interim status if the generator complies with the requirements of subsection (j)(1) - (4) of this section.]

[(l) A generator accumulating F006 waste in accordance with subsection (j) or (k) of this section who accumulates F006 waste on-site for more than 180 days (or for more than 270 days if the generator must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more), or who accumulates more than 20,000 kilograms of F006 waste on-site is an operator of a hazardous waste storage facility and is subject to the requirements of this chapter and Chapter 305 of this title applicable to such owners and operators, unless the generator has been granted an extension to the 180-day (or 270-day if applicable) period or an exception to the 20,000 kilogram accumulation limit. Such extensions and exceptions may be granted by the executive director if F006 waste must remain on-site for longer than 180 days (or 270 days if applicable) or if more than 20,000 kilograms of F006 waste must remain on-site due to unforeseen, temporary, and uncontrollable circumstances. An extension of up

to 30 days or an exception to the accumulation limit may be granted at the discretion of the executive director on a case-by-case basis.]

[(m) A generator who sends a shipment of hazardous waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste) may accumulate the returned waste on-site in accordance with subsections (a) and (b) of this section or subsections (f) - (h) of this section depending on the amount of hazardous waste on-site in that calendar month. Upon receipt of the returned shipment, the generator must:]

[(1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or]

[(2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.]

[(n) A generator who sends a shipment of Class 1 waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with

the manifest discrepancy provisions of §335.10 of this title may accumulate the returned waste on-site. Upon receipt of the returned shipment, the generator must:]

[(1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or]

[(2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.]

[§335.70. Recordkeeping.]

[(a) A generator of hazardous waste must keep records of any test results, waste analyses, or other determinations made in accordance with §335.62 of this title (relating to Hazardous Waste Determination) for at least three years from the date that the waste was last sent to an on-site or off-site storage, processing or disposal facility.]

[(b) The generator shall keep a copy of each annual report and exception report required by this title for a period of at least three years from the due date of the report.]

[(c) The periods of record retention required by subsections (a) and (b) of this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the executive director.]

[§335.71. Biennial Reporting.]

[In addition to annual reporting which is required under §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), in every even-numbered year facilities subject to the United States Environmental Protection Agency biennial reporting requirements shall submit to the commission information as required by 40 Code of Federal Regulations §262.41, as amended through November 28, 2016 (81 FR 85696). Upon request, this supplemental information shall be prepared in a form provided or approved by the executive director and submitted within the specified timeframe. Activities covered in the report shall be for the previous odd-numbered report year. Facilities subject to the United States Environmental Protection Agency biennial reporting requirements include all large quantity generators of hazardous waste for any month during the previous odd-numbered report year.]

[§335.73. Additional Reporting.]

[The executive director may require generators to furnish additional reports concerning the quantities and disposition of wastes identified or listed in 40 Code of Federal Regulations Part 261, Subparts C and D.]

[§335.74. Special Requirements for Generators of Between 100 and 1,000 Kilograms

per Month.]

[A generator who generates greater than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month is exempt from the recordkeeping and reporting requirements of this subchapter, except for §335.70(a) and (c) of this title (relating to Recordkeeping); and §335.73 of this title (relating to Additional Reporting); and §335.13(a) and (g) of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste and Primary Exporters of Hazardous Waste). Such generators are subject to the requirements of §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators).]

[§335.75. Notification Requirements for Interstate Shipments.]

[In the case of interstate shipments of hazardous waste for which a manifest has not been returned within 45 days of acceptance of the waste by the initial transporter, the generator shall notify the appropriate regulatory agency of the state in which the designated facility is located and the appropriate regulatory agency of the state in which the shipment may have been delivered. If a state required to be notified under this section has not received interim or final authorization pursuant to the Resource Conservation and Recovery Act of the 1976, §3006, the generator shall notify the administrator that the manifest has not been returned.]

[§335.76. Additional Requirements Applicable to international Shipments.]

[(a) Transboundary movements of hazardous waste shall comply with 40 Code of Federal Regulations (CFR) §262.12, and 40 CFR Part 262, Subpart H, as amended through November 28, 2016 (81 FR 85696).]

[(b) Imports of industrial solid waste shall comply with all applicable requirements of this chapter.]

[(c) Reporting for exports of hazardous waste is not required on the Biennial Report form. A separate annual report requirement is set forth at 40 CFR §262.83(g), as amended through November 28, 2016 (81 FR 85696), for hazardous waste exporters.]

[§335.77. Farmers.]

[A farmer disposing of waste pesticides from his own use which are hazardous wastes is not required to comply with this chapter for those wastes provided that he triple rinses each emptied pesticide container in accordance with §335.41(f)(2)(C) of this title (relating to Purpose, Scope, and Applicability) and disposes of the pesticide residues on his own farm in a manner consistent with the disposal instructions on the pesticide label.]

[§335.78. Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators.]

[(a) A generator is a conditionally exempt small quantity generator in a calendar month if he generates no more than 100 kilograms of hazardous waste in that month.]

[(b) Except for those wastes identified in subsections (e) - (g) and (j) of this section, a conditionally exempt small quantity generator's hazardous wastes are not subject to regulation under Subchapters C - H and O of this chapter (relating to Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Location Standards for Hazardous Waste Storage, Processing, or Disposal; Standards for the Management of Specific Wastes and Specific Types of Facilities; and Land Disposal Restrictions); Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution Procedure); Chapter 50 of this title (relating to Action on Applications and Other Authorizations); Chapter 55 of this title (relating to Requests for Reconsideration and Contested Case Hearings; Public Comment); Chapter 70 of this

title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings; Chapter 305 of this title (relating to Consolidated Permits); or the notification requirements of the Resource Conservation and Recovery Act, §3010, provided the generator complies with the requirements of subsections (f), (g), and (j) of this section.]

[(c) When making the quantity determinations of Subchapters A - C of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General; Hazardous Waste Management General Provisions; and Standards Applicable to Generators of Hazardous Waste), the generator must include all hazardous waste it generates, except hazardous waste that:]

[(1) is exempt from regulation under 40 Code of Federal Regulations (CFR) §261.4(c) - (f), as amended through November 28, 2016 (81 FR 85696), §335.24(c) of this title (relating to Requirements For Recyclable Materials and Nonhazardous Recyclable Materials), §335.41(f)(1) of this title (relating to Purpose, Scope and Applicability), or 40 CFR §261.8;]

[(2) is managed immediately upon generation only in on-site elementary neutralization units, wastewater treatment units, or totally enclosed treatment facilities as defined in §335.1 of this title (relating to Definitions);]

[(3) is recycled, without prior storage or accumulation, only in an on-site process subject to regulation under §335.24(f) of this title;]

[(4) is used oil managed under the requirements of §335.24(j) of this title and Chapter 324 of this title (relating to Used Oil);]

[(5) are spent lead-acid batteries managed under the requirements of §335.251 of this title (relating to Applicability and Requirements);]

[(6) is universal waste managed under §335.41(j) of this title and Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule); or]

[(7) is an unused commercial chemical product (listed in 40 CFR Part 261, Subpart D or exhibiting one or more characteristics in 40 CFR Part 261, Subpart C) that is generated solely as a result of a laboratory clean-out conducted at an eligible academic entity consistent with 40 CFR §262.213. For purposes of this provision, the phrase "eligible academic entity" shall have the meaning as defined in 40 CFR §262.200.]

[(d) In determining the quantity of hazardous waste generated, a generator need not include:]

[(1) hazardous waste when it is removed from on-site storage provided that the waste was counted at the time it was generated;]

[(2) hazardous waste which is generated or collected for the purpose of treatability studies;]

[(3) hazardous waste produced by on-site processing (including reclamation) of his hazardous waste, so long as the hazardous waste that is processed was counted once; or]

[(4) spent materials that are generated, reclaimed, and subsequently reused on-site, so long as such spent materials have been counted once.]

[(e) If a generator generates acute hazardous waste in a calendar month in quantities greater than set forth in paragraphs (1) or (2) of this subsection, all quantities of that acute hazardous waste are subject to full regulation under Subchapters C - H and O of this chapter; Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; Chapter 86 of this title; Chapter 305 of this title; and the notification requirements of the Resource Conservation and Recovery Act, §3010:]

[(1) a total of one kilogram of acute hazardous waste listed in 40 CFR §§261.31, 261.32, or 261.33(e); or]

[(2) a total of 100 kilograms of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in 40 CFR §§261.31, 261.32, or 261.33(e).]

[(f) In order for acute hazardous wastes generated by a generator of acute hazardous wastes in quantities equal to or less than those set forth in subsection (e)(1) or (2) of this section to be excluded from full regulation under this section, the generator must comply with the following requirements:]

[(1) The generator must comply with the requirements in §335.62 of this title (relating to Hazardous Waste Determination and Waste Classification).]

[(2) The generator may accumulate acute hazardous waste on-site. If the generator accumulates at any time acute hazardous wastes in quantities greater than those set forth in subsection (e)(1) or (2) of this section, all of those accumulated wastes are subject to regulation under Subchapters C - H and O of this chapter; Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; Chapter 86 of this title; Chapter 305 of this title; and the notification

requirements of the Resource Conservation and Recovery Act, §3010. The time period of §335.69(f) of this title (relating to Accumulation Time) for accumulation of wastes on-site begins when the accumulated wastes exceed the applicable exclusion limit.]

[(3) A conditionally exempt small quantity generator may either process or dispose of its acute hazardous waste in an on-site facility, or ensure delivery to an off-site storage, processing or disposal facility, either of which, if located in the United States, is:]

[(A) permitted by the United States Environmental Protection Agency (EPA) under 40 CFR Part 270;]

[(B) in interim status under 40 CFR Parts 270 and 265;]

[(C) authorized to manage hazardous waste by a state with a hazardous waste management program approved under 40 CFR Part 271;]

[(D) permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill, is subject to 40 CFR Part 258;]

[(E) permitted, licensed, or registered by a state to manage non-municipal nonhazardous waste and, if managed in a non-municipal nonhazardous

waste disposal unit after January 1, 1998, is subject to the requirements in 40 CFR §§257.5 - 257.30;]

[(F) a facility which:]

[(i) beneficially uses or reuses, or legitimately recycles or reclaims its waste; or]

[(ii) processes its waste prior to beneficial use or reuse, or legitimate recycling or reclamation; or]

[(G) for universal waste managed under Subchapter H, Division 5 of this chapter, a universal waste handler or destination facility subject to the requirements of Subchapter H, Division 5 of this chapter.]

[(g) In order for hazardous waste generated by a conditionally exempt small quantity generator in quantities of less than 100 kilograms of hazardous waste during a calendar month to be excluded from full regulation under this section, the generator must comply with the following requirements:]

[(1) The conditionally exempt small quantity generator must comply with §335.62 of this title.]

[(2) The conditionally exempt small quantity generator may accumulate hazardous waste on-site. If such generator accumulates at any time more than a total of 1000 kilograms of its hazardous wastes, all of those accumulated wastes are subject to regulation under the special provisions of this subchapter applicable to generators of between 100 kilograms and 1000 kilograms of hazardous waste in a calendar month as well as the requirements of Subchapters D - H and O of this chapter; Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; Chapter 86 of this title; Chapter 305 of this title; and the notification requirements of the Resource Conservation and Recovery Act, §3010. The time period of §335.69(f) of this title for accumulation of wastes on-site begins for a conditionally exempt small quantity generator when the accumulated wastes exceed 1,000 kilograms;]

[(3) A conditionally exempt small quantity generator may either process or dispose of its hazardous waste in an on-site facility, or ensure delivery to an off-site storage, processing or disposal facility, either of which, if located in the United States, is:]

[(A) permitted by the EPA under 40 CFR Part 270;]

[(B) in interim status under 40 CFR Parts 270 and 265;]

[(C) authorized to manage hazardous waste by a state with a hazardous waste management program approved under 40 CFR Part 271;]

[(D) permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill, is subject to 40 CFR Part 258 or equivalent or more stringent rules under Chapter 330 of this title (relating to Municipal Solid Waste);]

[(E) permitted, licensed, or registered by a state to manage non-municipal or industrial nonhazardous waste and, if managed in a non-municipal or industrial nonhazardous waste disposal unit after January 1, 1998, is subject to the requirements in 40 CFR §§257.5 - 257.30 or equivalent or more stringent counterpart rules that may be adopted by the commission relating to additional requirements for industrial nonhazardous waste disposal units that may receive hazardous waste from conditionally exempt small quantity generators;]

[(F) a facility which:]

[(i) beneficially uses or reuses, or legitimately recycles or reclaims its waste;]

[(ii) processes its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;]

[(G) for universal waste managed under Subchapter H, Division 5 of this chapter, a universal waste handler or destination facility subject to the requirements of Subchapter H, Division 5 of this chapter; or]

[(H) for airbag waste, an airbag waste collection facility or a designated facility subject to the requirements of 40 CFR §261.4(j).]

[(h) Hazardous waste subject to the reduced requirements of this section may be mixed with nonhazardous waste and remain subject to these reduced requirements even though the resultant mixture exceeds the quantity limitations identified in this section, unless the mixture meets any of the characteristics of hazardous waste identified in 40 CFR Part 261, Subpart C.]

[(i) If any person mixes a solid waste with a hazardous waste that exceeds a quantity exclusion level of this section, the mixture is subject to full regulation under this chapter.]

[(j) If a conditionally exempt small quantity generator's wastes are mixed with used oil, the mixture is subject to Chapter 324 of this title (relating to Used Oil Standards) and 40 CFR Part 279. Any material produced from such a mixture by processing, blending, or other treatment is also so regulated.]

[§335.79. Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities.]

[This section incorporates by reference the federal Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities in 40 Code of Federal Regulations Part 262, Subpart K, §§262.200 - 262.216 (known as the "Academic Laboratories rule"), as amended through December 20, 2010 (75 FR 79304).]

SUBCHAPTER D: STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

§335.91 and §335.94

Statutory Authority

The amendments are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendments implement THSC, Chapter 361.

§335.91. Scope.

(a) This subchapter establishes standards for persons [transporters] transporting hazardous waste to off-site storage, processing, or disposal facilities. These standards are in addition to any applicable provisions contained in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste Management in General).

(b) This subchapter does not apply to on-site transportation of hazardous waste by generators or by owners or operators of storage, processing or disposal facilities.

(c) A hazardous waste transporter must also comply with the standards applicable to generators of hazardous waste found in §§335.6, 335.9, 335.10, and 335.13 of this title (relating to Notification Requirements; Recordkeeping and Annual Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste; and Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste), Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste) including §335.52(d) of this title (relating to Purpose, Scope, and Applicability), and Subchapter R of this chapter (relating to Waste Classification) if the transporter [A transporter of hazardous waste must also comply with any standards applicable to generators of hazardous waste if he]:

(1) transports hazardous waste into the state from a foreign country; or

(2) mixes hazardous waste of different Department of Transportation shipping descriptions by placing them into a single container.

(d) Transporters who store hazardous waste are owners or operators of storage facilities and, as such, are also subject to the permit requirements and storage standards contained in this chapter.

(e) A transporter of hazardous waste that is being imported from or exported to any other country for purposes of recovery or disposal is subject to all relevant requirements of 40 Code of Federal Regulations (CFR), Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal), including, but not limited to, 40 CFR §262.83(d) and §262.84(d) for movement documents [, as amended through November 28, 2016 (81 FR 85696)].

(f) The regulations in this chapter do not apply to transportation during an explosives or munitions emergency response conducted in accordance with §335.41(d)(2) of this title (relating to Purpose, Scope and Applicability).

(g) 40 CFR §266.203, as adopted by reference under Subchapter H, Division 6 of this chapter (relating to Military Munitions), identifies how the requirements of this

subchapter apply to military munitions classified as solid waste under 40 CFR §266.202.

§335.94. Transfer Facility Requirements.

(a) Unless the executive director determines that a permit should be required in order to protect human health and the environment, a transporter who stores manifested shipments of hazardous waste in containers meeting the independent requirements of 40 Code of Federal Regulations (CFR) §262.30 (Packaging) as adopted under §335.55 of this title (relating to Pre-Transport Requirements Applicable to Small and Large Quantity Generators), [§335.65 of this title (relating to Packaging)] at a transfer facility owned or operated by a registered transporter for a period of ten days or less is not subject to the requirement for a permit under §335.2 of this title (relating to Permit Required), with respect to the storage of those wastes provided that the transporter complies with the following sections:

(1) 40 CFR [Code of Federal Regulations (CFR)] §265.14 ([relating to] Security);

(2) 40 CFR §265.15 ([relating to] General Inspection Requirements);

(3) 40 CFR §265.16 ([relating to] Personnel Training);

(4) 40 CFR Part 265, Subpart C;

(5) 40 CFR Part 265, Subpart D (except §265.56(j)) and §335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator); and

(6) 40 CFR Part 265, Subpart I.

(b) The executive director may require a permit for that portion of a facility otherwise exempted from that requirement under subsection (a) of this section, with respect to the storage of hazardous waste in containers, if the facility's operation also includes other storage and processing of hazardous waste which is not exempt under subsection (a) of this section.

(c) When consolidating the contents of two or more containers with the same hazardous waste into a new container, or when combining and consolidating two different hazardous wastes that are compatible with each other, the transporter must mark its containers of 119 gallons or less with the following information:

(1) The words "Hazardous Waste"; and

(2) The applicable United States Environmental Protection Agency hazardous waste number(s) in 40 CFR Part 261, Subparts C and D, as adopted under

§335.504 of this title (relating to Hazardous Waste Determination) or in compliance with 40 CFR §262.32(c), as adopted under §335.55 of this title.

SUBCHAPTER E: INTERIM STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, OR DISPOSAL FACILITIES

§335.112

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.112. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 265 (including all appendices to 40 CFR Part 265) (except as otherwise specified in this section) are adopted by reference as amended in the *Federal Register* through June 1, 1990 (55 FR 22685) and as further amended as indicated in each paragraph of this subsection:

(1) Subpart B - General Facility Standards (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [(81 FR 85696)]);

(2) Subpart C - Preparedness and Prevention;

(3) Subpart D - Contingency Plan and Emergency Procedures (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §265.56(d);

(4) Subpart E - Manifest System, Recordkeeping, and Reporting (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [November 28, 2016 (81 FR 85696)]), except 40 CFR §265.76 and §265.77 [§§265.71, 265.72, and 265.75 - 265.77];

(5) Subpart F - Groundwater Monitoring (as amended in the *Federal Register* through April 4, 2006 (71 FR 16862)), except 40 CFR §265.90 and §265.94;

(6) Subpart G - Closure and Post-Closure (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)); except 40 CFR §265.112(d)(3) and (4) and §265.118(e) and (f);

(7) Subpart H - Financial Requirements (as amended in the *Federal Register* through September 16, 1992 (57 FR 42832)); except 40 CFR §§265.140, 265.141, 265.142(a)(2), (b) and (c), 265.143(a) - (g), 265.144(b) and (c), 265.145(a) - (g), 265.146 [264.146], 265.147(a) - (d), and (f) - (k), and 265.148 - 265.150;

(8) Subpart I - Use and Management of Containers (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(9) Subpart J - Tank Systems (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(10) Subpart K - Surface Impoundments (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(11) Subpart L - Waste Piles (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §265.253;

(12) Subpart M - Land Treatment (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)) except, 40 CFR §§265.272, 265.279, and 265.280;

(13) Subpart N - Landfills (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §§265.301(f) - (i), 265.314, and 265.315;

(14) Subpart O - Incinerators (as amended in the *Federal Register* through October 12, 2005 (70 FR 59402));

(15) Subpart P - Thermal Treatment (as amended in the *Federal Register* through July 17, 1991 (56 FR 32692));

(16) Subpart Q - Chemical, Physical, and Biological Treatment (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(17) Subpart R - Underground Injection;

(18) Subpart W - Drip Pads (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(19) Subpart AA - Air Emission Standards for Process Vents (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(20) Subpart BB - Air Emission Standards for Equipment Leaks (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [April 4, 2006 (71 FR 16862)]);

(21) Subpart CC - Air Emission Standards for Tanks, Surface Impoundments, and Containers (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [July 14, 2006 (71 FR 40254)]);

(22) Subpart DD - Containment Buildings (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(23) Subpart EE - Hazardous Waste Munitions and Explosives Storage (as amended in the *Federal Register* through February 12, 1997 (62 FR 6622)); [and]

(24) Subpart FF - Fees for the Electronic Hazardous Waste Manifest Program (as amended in the *Federal Register* through January 3, 2018 (83 FR 420); and

(25) [(24)] the following appendices contained in 40 CFR Part 265:

(A) Appendix I - Recordkeeping Instructions (as amended in the *Federal Register* through March 24, 1994 (59 FR 13891));

(B) Appendix III - EPA Interim Primary Drinking Water Standards;

(C) Appendix IV - Tests for Significance;

(D) Appendix V - Examples of Potentially Incompatible Waste; and

(E) Appendix VI - Compounds With Henry's Law Constant Less Than 0.1 Y/X.

(b) Except in 40 CFR §265.71 adopted under subsection (a)(4) of this section and 40 CFR Part 265, Subpart FF adopted under subsection (a)(24) of this section, the [The] regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality or to the commission, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B.

(2) The term "treatment" is changed to "processing."

(3) Reference to Resource Conservation and Recovery Act, §3008(h) is changed to Texas Water Code, §7.031(c) - (e) (Corrective Action Relating to Hazardous Waste).

(4) Reference to:

(A) 40 CFR §260.10 is changed to §335.1 of this title (relating to Definitions);

(B) 40 CFR §264.90 is changed to §335.156 of this title (relating to Applicability of Groundwater Monitoring and Response);

(C) 40 CFR §264.101 is changed to §335.167 of this title (relating to Corrective Action for Solid Waste Management Units);

(D) 40 CFR §264.310 is changed to §335.174 of this title (relating to Closure and Post-Closure Care (Landfills));

(E) 40 CFR §265.1 is changed to §335.111 of this title (relating to Purpose, Scope, and Applicability);

(F) 40 CFR §265.90 is changed to §335.116 of this title (relating to Applicability of Groundwater Monitoring Requirements);

(G) 40 CFR §265.94 is changed to §335.117 of this title (relating to Recordkeeping and Reporting);

(H) 40 CFR §265.314 is changed to §335.125 of this title (relating to Special Requirements for Bulk and Containerized Waste);

(I) 40 CFR §270.1 is changed to §335.2 of this title (relating to Permit Required);

(J) 40 CFR §270.28 is changed to §305.50 of this title (relating to Additional Requirements for an Application for a Hazardous or Industrial Solid Waste Permit and for a Post-Closure Order);

(K) 40 CFR §270.41 is changed to §305.62 of this title (relating to Amendments);

(L) 40 CFR §270.42 is changed to §305.69 of this title (relating to Solid Waste Permit Modification at the Request of the Permittee); and

(M) Qualified professional engineer is changed to Texas licensed professional engineer.

(5) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapters 50, 305, and 335 of this title (relating to Action on Applications and Other Authorizations; Consolidated Permits; and Industrial Solid Waste and Municipal Hazardous Waste), as applicable.

(6) Reference to 40 CFR Part 265, Subpart D (Contingency Plan and Emergency Procedures) is changed to §335.112(a)(3) of this title (relating to Standards) and §335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator).

(7) References to 40 CFR §265.76 and §265.77 are changed to [Reference to 40 CFR §§265.71, 265.72, 265.76, and 265.77 is changed to §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), §335.12(a) of this title,] §335.15(3) of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), and §335.115 of this title (relating to Additional Reports), respectively.

(8) Reference to 40 CFR Part 264, Subpart F is changed to §335.156 of this title, §335.157 of this title (relating to Required Programs), §335.158 of this title

(relating to Groundwater Protection Standard), §335.159 of this title (relating to Hazardous Constituents), §335.160 of this title (relating to Concentration Limits), §335.161 of this title (relating to Point of Compliance), §335.162 of this title (relating to Compliance Period), §335.163 of this title (relating to General Groundwater Monitoring Requirements), §335.164 of this title (relating to Detection Monitoring Program), §335.165 of this title (relating to Compliance Monitoring Program), §335.166 of this title (relating to Corrective Action Program), and §335.167 of this title.

(9) Reference to 40 CFR Part 265, Subpart F is changed to include §335.116 and §335.117 of this title, in addition to the reference to 40 CFR Part 265, Subpart F, except §265.90 and §265.94.

(10) Reference to the EPA is changed to the Texas Commission on Environmental Quality.

[(c) A copy of 40 CFR Part 265 is available for inspection at the library of the Texas Commission on Environmental Quality, located on the first floor of Building A at 12100 Park 35 Circle, Austin, Texas.]

SUBCHAPTER F: PERMITTING STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, OR DISPOSAL FACILITIES

§335.152

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.152. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 264 (including all appendices to Part 264) are adopted by reference as amended in the *Federal Register* through June 1, 1990 (55 FR 22685) and as further amended and adopted as indicated in each paragraph of this subsection:

(1) Subpart B--General Facility Standards (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [(81 FR 85696)]); in addition, the facilities which are subject to 40 CFR Part 264, Subpart X, are subject to regulation under 40 CFR §264.15(b)(4) and §264.18(b)(1)(ii);

(2) Subpart C--Preparedness and Prevention;

(3) Subpart D--Contingency Plan and Emergency Procedures (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §264.56(d);

(4) Subpart E--Manifest System, Recordkeeping and Reporting (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [November 28, 2016 (81 FR 85696)]), except 40 CFR §264.76 and §264.77 [40 CFR §§264.71, 264.72, 264.76, and 264.77]; facilities which are subject to 40 CFR Part 264, Subpart X, are subject to 40 CFR §264.73(b)(6);

(5) Subpart G--Closure and Post-Closure (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)); facilities which are subject to 40 CFR Part 264, Subpart X, are subject to 40 CFR §§264.90(d), 264.111(c), 264.112(a)(2), 264.114, 264.117(a)(1)(i) and (ii), and 264.118(b)(1) and (2)(i) and (ii);

(6) Subpart H--Financial Requirements (as amended in the *Federal Register* through April 4, 2006 (71 FR 16862)); except 40 CFR §§264.140, 264.141, 264.142(a)(2), (b) and (c), 264.143(a) - (h), 264.144(b) and (c), 264.145(a) - (h), 264.146, 264.147(a) - (d), and (f) - (k), and 264.148 - 264.151; and subject to the following limitations: facilities which are subject to 40 CFR Part 264, Subpart X, are subject to 40 CFR§264.142(a) and §264.144(a), and §37.6031(c) of this title (relating to Financial Assurance Requirements for Liability);

(7) Subpart I--Use and Management of Containers (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(8) Subpart J--Tank Systems (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(9) Subpart K--Surface Impoundments (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §264.221 and §264.228:

(A) reference to 40 CFR §264.221 is changed to §335.168 of this title (relating to Design and Operating Requirements (Surface Impoundments));

(B) reference to 40 CFR §264.228 is changed to §335.169 of this title (relating to Closure and Post-Closure Care (Surface Impoundments));

(10) Subpart L--Waste Piles (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §264.251;

(11) Subpart M--Land Treatment (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §264.273 and §264.280;

(12) Subpart N--Landfills (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §§264.301, 264.310, 264.314, and 264.315;

(13) Subpart O--Incinerators (as amended in the *Federal Register* through April 8, 2008 (73 FR 18970));

(14) Subpart S--Special Provisions for Cleanup (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989));

(15) Subpart W--Drip Pads (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(16) Subpart X--Miscellaneous Units (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(17) Subpart AA--Air Emission Standards for Process Vents (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) with the reference to "40 CFR 262.34(a)" replaced with "40 CFR §262.17 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" [July 14, 2006 (71 FR 40254)]);

(18) Subpart BB--Air Emission Standards for Equipment Leaks (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) with the reference to "40 CFR 262.34(a)" replaced with "40 CFR §262.17 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" [July 14, 2006 (71 FR 40254)]);

(19) Subpart CC--Air Emission Standards for Tanks, Surface Impoundments, and Containers (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [July 14, 2006 (71 FR 40254)]);

(20) Subpart DD--Containment Buildings (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [July 14, 2006 (71 FR 40254)]);

(21) Subpart EE--Hazardous Waste Munitions and Explosives Storage (as amended in the *Federal Register* through August 1, 2005 (70 FR 44150)); [and]

(22) Subpart FF--Fees for the Electronic Hazardous Waste Manifest Program (as amended in the *Federal Register* through January 3, 2018 (83 FR 420); and

(23) [(22)] the following appendices contained in 40 CFR Part 264:

(A) Appendix I--Recordkeeping Instructions (as amended in the *Federal Register* through March 24, 1994 (59 FR 13891));

(B) Appendix IV--Cochron's Approximation to the Behrens-Fisher Students' T-Test;

(C) Appendix V--Examples of Potentially Incompatible Waste;

(D) Appendix VI--Political Jurisdictions in Which Compliance With §264.18(a) Must Be Demonstrated; and

(E) Appendix IX--Ground-Water Monitoring List (as amended in the *Federal Register* through June 13, 1997 (62 FR 32451)).

(b) The provisions of 40 CFR §264.18(b) are applicable to owners and operators of hazardous waste management facilities, for which a permit is being sought, which are not subject to the requirements of §§335.201 - 335.206 of this title (relating to Purpose, Scope, and Applicability; Definitions; Site Selection to Protect Groundwater or Surface Water; Unsuitable Site Characteristics; Prohibition of Permit Issuance; and Petitions for Rulemaking). [A copy of 40 CFR §264.18(b) is available for inspection at the library of the Texas Commission on Environmental Quality, located on the first floor of Building A at 12100 Park 35 Circle, Austin, Texas.]

(c) Except in 40 CFR §264.71 adopted under subsection (a)(4) of this section and 40 CFR Part 264, Subpart FF adopted under subsection (a)(22) of this section, the [The] regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality or to the commission, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B.

(2) The term "treatment" is changed to "processing."

(3) Reference to Resource Conservation and Recovery Act, §3008(h) is changed to Texas Water Code, §7.031(c) - (e) (Corrective Action Relating to Hazardous Waste).

(4) Reference to:

(A) 40 CFR §260.10 is changed to §335.1 of this title (relating to Definitions);

(B) 40 CFR §264.1 is changed to §335.151 of this title (relating to Purpose, Scope, and Applicability);

(C) 40 CFR §264.280 is changed to §335.172 of this title (relating to Closure and Post-Closure Care (Land Treatment Units));

(D) 40 CFR §264.90 is changed to §335.156 of this title (relating to Applicability of Groundwater Monitoring and Response);

(E) 40 CFR §264.101 is changed to §335.167 of this title (relating to Corrective Action for Solid Waste Management Units);

(F) 40 CFR §264.310 is changed to §335.174 of this title (relating to Closure and Post-Closure Care (Landfills));

(G) 40 CFR §270.41 is changed to §305.62 of this title (relating to Amendments); and

(H) 40 CFR §270.42 is changed to §305.69 of this title (relating to Solid Waste Permit Modification at the Request of the Permittee).

(5) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapters 50, 305, and 335 of this title (relating to Action on Applications and Other Authorizations; Consolidated Permits; and Industrial Solid Waste and Municipal Hazardous Waste), as applicable.

(6) Reference to 40 CFR Part 264, Subpart D is changed to §335.152(a)(3) of this title (relating to Standards) and §335.153 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator).

(7) References [Reference] to 40 CFR §264.76 and §264.77 are changed to [§§264.71, 264.72, 264.76, and 264.77 is changed to §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), §335.12(a) of this title,] §335.15(3) of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of

Treatment, Storage, or Disposal Facilities), and §335.155 of this title (relating to Additional Reports), respectively.

(8) Reference to 40 CFR Part 264, Subpart F is changed to §335.156 of this title, §335.157 of this title (relating to Required Programs), §335.158 of this title (relating to Groundwater Protection Standard), §335.159 of this title (relating to Hazardous Constituents), §335.160 of this title (relating to Concentration Limits), §335.161 of this title (relating to Point of Compliance), §335.162 of this title (relating to Compliance Period), §335.163 of this title (relating to General Groundwater Monitoring Requirements), §335.164 of this title (relating to Detection Monitoring Program), §335.165 of this title (relating to Compliance Monitoring Program), §335.166 of this title (relating to Corrective Action Program), and §335.167 of this title.

(9) Reference to 40 CFR Part 265, Subpart F is changed to include §335.116 of this title (relating to Applicability of Groundwater Monitoring Requirements) and §335.117 of this title (relating to Recordkeeping and Reporting), in addition to the reference to 40 CFR Part 265, Subpart F, except §265.90 and §265.94.

(10) Reference to the EPA is changed to the Texas Commission on Environmental Quality.

(11) Reference to qualified professional engineer is changed to Texas licensed professional engineer.

[(d) A copy of 40 CFR Part 264 is available for inspection at the library of the Texas Commission on Environmental Quality, located on the first floor of Building A at 12100 Park 35 Circle, Austin, Texas.]

SUBCHAPTER H: STANDARDS FOR THE MANAGEMENT OF SPECIFIC WASTES AND SPECIFIC TYPES OF FACILITIES

DIVISION 2: HAZARDOUS WASTE BURNED FOR ENERGY RECOVERY

§335.221

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.221. Applicability and Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 266 (including all appendices to 40 CFR Part 266) are adopted by reference, as amended and adopted in the CFR through April 8, 2008 (73 FR 18970), except as noted in this section:

(1) 40 CFR §266.100--Applicability (as amended through July 14, 2006 (71 FR 40254)), except 40 CFR §266.100(c); and reference to "the applicable requirements of subparts A through H, BB, and CC of parts 264 and 265 of this chapter" is changed to "the applicable requirements of §§335.111 of this title (relating to Purpose, Scope, and Applicability), 335.112(a)(1) - (7), (20), and (21) of this title (relating to Standards), 335.151 of this title (relating to Purpose, Scope, and Applicability), and 335.152(a)(1) - (6), (18), and (19) of this title (relating to Standards)";

(2) 40 CFR §266.102(a)--Permit Standards for Burners - Applicability, excepting those portions of 40 CFR §266.102(a) containing references to 40 CFR §§264.56(d), 264.71 - 264.72, 264.75 - 264.77, 264.90, 264.101, and 264.142(a)(2);

(3) 40 CFR §266.102(b)--Permit Standards for Burners - Hazardous Waste Analysis;

(4) 40 CFR §266.102(c)--Permit Standards for Burners - Emission Standards;

(5) 40 CFR §266.102(d)--Permit Standards for Burners - Permits;

(6) 40 CFR §266.102(e)--Permit Standards for Burners - Operating Requirements (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(7) 40 CFR §266.103 (a)(1) - (3)--Interim Status Standards for Burners - Purpose, Scope, and Applicability--General; Exemptions; and Prohibition on Burning Dioxin-Listed Wastes, respectively, except 40 CFR §266.103(a)(1)(iii) and §266.103(a)(2);

(8) 40 CFR §266.103(a)(4)--Interim Status Standards for Burners--Purpose, Scope, and Applicability--Applicability of Part 265 Standards (as amended in the *Federal Register* through (July 14, 2006 (71 FR 40254))), excepting those portions of 40 CFR §266.103(a)(4) containing references to 40 CFR §§265.56(d), 265.71 - 265.72, 265.75 - 265.77, 265.142(a)(2); facilities qualifying for a corporate guarantee for liability are subject to 40 CFR §265.147(g)(2) and §264.151(h)(2), as amended;

(9) 40 CFR §266.103(a)(5) - (6)--Interim Status Standards for Burners - Purpose, Scope, and Applicability: Special Requirements for Furnaces; and Restrictions on Burning Hazardous Waste That Is Not a Fuel;

(10) 40 CFR §266.103(b)--Interim Status Standards for Burners - Certification of Precompliance (as amended through (July 14, 2006 (71 FR 40254))), except 40 CFR §266.103(b)(1) and (6);

(11) 40 CFR §266.103(c)--Interim Status Standards for Burners - Certification of Compliance (as amended through (July 14, 2006 (71 FR 40254))), except 40 CFR §266.103(c)(3)(i);

(12) 40 CFR §266.103(f)--Interim Status Standards for Burners - Start-Up and Shut-Down;

(13) 40 CFR §266.103(g)(1) - (2)--Interim Status Standards for Burners - Automatic Waste Feed Cutoff (as amended in the *Federal Register* through [(]July 14, 2006 (71 FR 40254))[)];

(14) 40 CFR §266.103(h) - (l)--Interim Status Standards for Burners: Fugitive Emissions; Changes; Monitoring and Inspections; Recordkeeping; and Closure, respectively, as amended in the *Federal Register* through April 4, 2006 (71 FR 16862);

(15) 40 CFR §266.104--Standards to Control Organic Emissions, except 40 CFR §266.104(h);

(16) 40 CFR §266.105--Standards to Control Particulate Matter, except 40 CFR §266.105(d);

(17) 40 CFR §266.106--Standards to Control Metals Emissions (as amended in the *Federal Register* through (July 14, 2006 (71 FR 40254))), except 40 CFR §266.106(i);

(18) §266.107--Standards to Control Hydrogen Chloride (HCl) and Chlorine Gas ($C1_2$) Emissions, except 40 CFR §266.107(h);

(19) 40 CFR §266.108--Small Quantity On-Site Burner Exemption, except §266.108(d), and except that hazardous wastes generated by a very small quantity generator [subject to §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)] may not be burned in an off-site device under the exemption provided by 40 CFR §266.108;

(20) 40 CFR §266.109--Low-Risk Waste Exemption (as amended in the *Federal Register* through (July 14, 2006 (71 FR 40254)));

(21) 40 CFR §266.110--Waiver of DRE Trial Burn for Boilers;

(22) 40 CFR §266.111--Standards for Direct Transfer; and

(23) 40 CFR §266.112--Regulation of Residues.

(b) The following hazardous wastes and facilities are not regulated under this division:

(1) used oil burned for energy recovery that is also a hazardous waste solely because it exhibits a characteristic of hazardous waste identified in 40 CFR Part 261, Subpart C, from use versus mixing. Such used oil is subject to regulation by the United States Environmental Protection Agency (EPA) under 40 CFR Part 279 and Chapter 324 of this title (relating to Used Oil Standards). This exception does not apply if the used oil has been made hazardous by mixing with characteristic or listed hazardous waste other than by a generator that meets the conditions for exemption for a very [conditionally exempt] small quantity generator or household generator;

(2) hazardous wastes that are exempt from regulation under [the provisions of] 40 CFR §261.4 [,] and §335.24(c)(3) - (4) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) [, and hazardous wastes that are subject to the special requirements for conditionally exempt small quantity generators under the provisions of §335.78 of this title];

(3) hazardous wastes generated by a very small quantity generator that meets the conditions for exemption of a very small quantity generator;

(4) [(3)] gas recovered from hazardous or solid waste landfills when such gas is burned for energy recovery; and

(5) [(4)] coke ovens, if the only hazardous waste burned is EPA Hazardous Waste No. K087, decanter tank tar sludge from coking operations.

SUBCHAPTER H: STANDARDS FOR THE MANAGEMENT OF SPECIFIC WASTES AND SPECIFIC TYPES OF FACILITIES

DIVISION 3: RECYCLABLE MATERIALS UTILIZED FOR PRECIOUS METAL RECOVERY

§335.241

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.241. Applicability and Requirements.

(a) The regulations of this section apply to recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, platinum, palladium, iridium, osmium, rhodium, ruthenium, or any combination of these.

(b) Persons who generate, transport, or store recyclable materials that are regulated under this section are subject to the following requirements:

(1) §335.4 of this title (relating to General Prohibitions);

(2) §335.6 of this title (relating to Notification Requirements);

(3) §§335.9 - 335.12 of this title (relating to Shipping and Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Municipal Hazardous Waste or Class 1 [Industrial Solid] Waste; Shipping Requirements for Transporters of Municipal Hazardous Waste or Class 1 [Industrial Solid] Waste; Shipping Requirements Applicable to Owners or Operators of Storage, Processing, or Disposal Facilities), §335.54 of this title (relating to Hazardous Waste Manifest), 40 Code of Federal Regulations (CFR) §265.71 and §265.72 as adopted by reference under §335.112(a)(4) of this title (relating to Standards), and 40 CFR §264.71

and §264.72 as adopted by reference under §335.152(a)(4) of this title (relating to Standards), for generators, transporters, or persons who store, as applicable; and

(4) For precious metals exported to or imported from other countries for recovery [designated OECD member countries for recovery], 40 Code of Federal Regulations (CFR) Part 262, Subpart H[,] and §265.12 adopted by reference under §335.112 of this title (relating to Standards) [§265.12(a). For precious metals exported to or imported from non-OECD countries for recovery, §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste and §335.76 of this title (relating to Additional Requirements Applicable to International Shipments)].

(c) Persons who store recyclable materials that are regulated under this section shall keep the following records to document that they are not accumulating these materials speculatively, as defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials):

(1) records showing the volume of these materials stored at the beginning of the calendar year;

(2) the amount of these materials generated or received during the calendar year; and

(3) the amount of materials remaining at the end of the calendar year.

(d) Recyclable materials that are regulated under this section that are accumulated speculatively, as defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), are subject to all applicable provisions of this chapter (excluding this subchapter), Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution); Chapter 50 of this title (relating to Actions on Applications); Chapter 55 of this title (relating to Request for Contested Case Hearings); Chapter 70 of this title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings; Chapter 261 of this title (relating to Introductory Provisions); Chapter 277 of this title (relating to Use Determinations for Tax Exemption for Pollution Control Property); and Chapter 305 of this title (relating to Consolidated Permits).

SUBCHAPTER H: STANDARDS FOR THE MANAGEMENT OF SPECIFIC WASTES AND SPECIFIC TYPES OF FACILITIES

DIVISION 4: SPENT LEAD-ACID BATTERIES BEING RECLAIMED

§335.251

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.251. Applicability and Requirements.

(a) The regulations of this section adopt by reference 40 Code of Federal Regulations (CFR) Part 266, Subpart G as amended in the *Federal Register* through November 28, 2016 (81 FR 85732 [85696]). This section applies to persons who reclaim (including regeneration) spent lead-acid batteries that are recyclable materials (spent batteries). Persons who generate, transport, or collect spent batteries, who regenerate spent batteries, who store spent batteries that are to be regenerated, or who store spent batteries but do not reclaim them (other than spent batteries that are to be regenerated), are not subject to regulation under this chapter, except that §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) applies; and are not subject to regulation under Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution Procedure); Chapter 50 of this title (relating to Action on Applications and Other Authorizations); Chapter 55 of this title (relating to Requests for Contested Case Hearings; Public Comment); Chapter 70 of this title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings); or

Chapter 305 of this title (relating to Consolidated Permits). Such persons, however, remain subject to the requirements of the Texas Water Code, Chapter 26.

(b) Owners or operators of facilities that store spent lead-acid batteries before reclaiming them (other than spent batteries that are to be regenerated) are subject to the following requirements:

(1) all applicable provisions in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter B of this chapter (relating to Hazardous Waste Management General Provisions), Subchapter E of this chapter (relating to Interim Standards of Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities), Subchapter F of this chapter (relating to Permitting Standards of Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities), and Subchapter U of this chapter (relating to Standards for Owners and Operators of Hazardous Waste Facilities Operating under a Standard Permit), except for the requirements in §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities) and 40 CFR §265.13; and

(2) all applicable provisions in Chapters 1, 3, 10, 20, 37, 39, 40, 50, 55, 70, 80, and 305 of this title.

(c) Persons who export spent batteries for reclamation in a foreign country where they will be reclaimed through regeneration or any other means are not subject to the requirements of Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste), except for §335.53(a) and (g) of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [§335.63 of this title (relating to EPA Identification Numbers)]; Subchapter D of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste), except for §335.91(e) of this title (relating to Scope); Subchapter E of this chapter (relating to Interim Standards of Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities); Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities); or Subchapter O of this chapter (relating to Land Disposal Restrictions), or Chapter 1, 3, 10, 20, 37, 39, 40, 50, 55, 70, 80, 86, or 305 of this title. Such persons must comply with [, however, remain subject to the requirements of §§335.63, 335.91(e), and] §335.504 of this title (relating to Hazardous Waste Determination).

(d) Persons who transport spent batteries in the United States to export them for reclamation in a foreign country where they will be reclaimed through regeneration or any other means are not subject to the requirements of Subchapter C of this chapter; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter; or Subchapter O of this chapter, or Chapter 1, 3, 10, 20, 37, 39, 40, 50, 55, 70, 80, 86, or 305 of this title. Such persons, however, remain subject to the requirements of §335.91(e) of this title.

(e) Persons who import spent batteries from a foreign country and store these spent batteries, but are not the reclaimer, and where the spent battery will be reclaimed other than through regeneration, are not subject to the requirements of Subchapter C of this chapter, except for §335.53(a) and (g) [§335.63] of this title; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter, or Chapter 1, 3, 10, 37, 39, 40, 50, 55, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504] of this title, and applicable provisions of Subchapter O of this chapter.

(f) Persons who import spent batteries from a foreign country and store these spent batteries before reclaiming them, and where the spent battery will be reclaimed other than through regeneration, are not subject to the requirements of Subchapter C of this chapter, except for §335.53(a) and (g) [§335.63] of this title; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter, or Chapter 1, 3, 10, 37, 39, 40, 50, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504] of this title, and applicable provisions of Subchapter O of this chapter.

(g) Persons who import spent batteries from a foreign country and do not store these spent before reclaiming them, and where they will be reclaimed other than

through regeneration, are not subject to the requirements of Subchapter C of this chapter, except for §335.53(a) and (g) of this title [§335.63 of this title]; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter, or Chapter 1, 3, 10, 37, 39, 40, 50, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504] of this title, and applicable provisions of Subchapter O of this chapter.

SUBCHAPTER H: STANDARDS FOR THE MANAGEMENT OF SPECIFIC WASTES AND SPECIFIC TYPES OF FACILITIES

DIVISION 5: UNIVERSAL WASTE RULE

§335.261

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.261. Universal Waste Rule.

(a) This section establishes requirements for managing universal wastes as defined in this section, and provides an alternative set of management standards in lieu of regulation, except as provided in this section, under all otherwise applicable chapters under 30 Texas Administrative Code. Except as provided in subsection (b) of this section, 40 Code of Federal Regulations (CFR) Part 273 is adopted by reference as amended in the *Federal Register* through December 9, 2019 (84 FR 67202) [November 28, 2016 (81 FR 85696)].

(b) 40 CFR Part 273, except 40 CFR §§273.1, 273.20, 273.39(a) and (b), 273.40, 273.56, 273.62(a), and 273.70, is adopted subject to the following changes:

(1) The term "regional administrator" is changed to "executive director" or "commission" consistent with the organization of the commission as set out in the Texas Water Code, Chapter 5.

(2) The terms "U.S. Environmental Protection Agency" and "EPA" are changed to "the Texas Commission on Environmental Quality," "the agency," or "the commission" consistent with the organization of the commission as set out in Texas Water Code, Chapter 5. This paragraph does not apply to 40 CFR §273.32(a)(3) or

§273.52 or to references to the following: "EPA Acknowledgment of Consent" or "EPA Identification Number."

(3) The term "treatment" is changed to "processing."

(4) The term "universal waste" is changed to "universal waste as defined under §335.261(b)(19)(F) [§335.261(b)(16)(F)] of this title (relating to Universal Waste Rule)."

(5) The term "this part" is changed to "Chapter 335, Subchapter H, Division 5 of this title (relating to Universal Waste Rule)."

(6) In 40 CFR §273.2(a) and (b), references to "40 CFR Part 266, Subpart G," are changed to "§335.251 of this title (relating to Applicability and Requirements)."

(7) In 40 CFR §273.2(b)(2), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(8) In 40 CFR §273.3(b)(1), the reference to "40 CFR §262.70" is changed to "§335.57 [§335.77] of this title (relating to Farmers)." Also, the phrase "(40 CFR §262.70 addresses pesticides disposed of on the farmer's own farm in a manner

consistent with the disposal instructions on the pesticide label, providing the container is triple rinsed in accordance with 40 CFR §261.7(b)(3))" is deleted.

(9) In 40 CFR §273.3(b)(2), the reference to "40 CFR parts 260 through 272" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(10) In 40 CFR §273.3(b)(3), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(11) In 40 CFR §273.3(d)(1)(i) and (ii), references to "40 CFR §261.2" are changed to "§335.1 of this title (relating to Definitions)."

(12) In 40 CFR §273.4(a), the reference to "§273.9" as it relates to the definition of "mercury-containing equipment" is amended to include the commission definition of "thermostats" as contained in §335.261(b)(19)(E) [§335.261(b)(16)(E)] of this title (relating to Universal Waste Rule) and in 40 CFR §273.4(b)(1), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(13) In 40 CFR §273.5(b)(1), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(14) In 40 CFR §273.6(b)(1), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(15) In 40 CFR §273.6(b)(2), the references to "part 261, subpart C, of this chapter" and "part 261, subpart D, of this chapter" are changed to "Chapter 335, Subchapter R of this title (relating to Waste Classification)."

(16) In 40 CFR §273.6(b)(3), the reference to "§261.7 of this chapter" is changed to "§335.41(f) of this title (relating to Purpose, Scope and Applicability)."

(17) [(14)] In 40 CFR §273.8(a)(1), the reference to "40 CFR §261.4(b)(1)" is changed to "§335.1 and §335.402(5) of this title (relating to Definitions; and Definitions)" and the reference to "§273.9" is changed to "§335.261(b)(19)(F) [§335.261(b)(16)(F)] of this title (relating to Universal Waste Rule)."

(18) [(15)] In 40 CFR §273.8(a)(2), the reference to "40 CFR §262.14 [§261.5]" is changed to "40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [§335.78 of this

title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)]" [and to "§335.402(5) of this title (relating to Definitions)"] and the reference to "§273.9" is changed to "§335.261(b)(19)(F) [§335.261(b)(16)(F)] of this title (relating to Universal Waste Rule)."

(19) [(16)] In 40 CFR §273.9, the following definitions are changed to the meanings described in this paragraph.

(A) Destination facility--A facility that treats, disposes, or recycles a particular category of universal waste, except those management activities described in 40 CFR §273.13(a) and (c) and 40 CFR §273.33(a) and (c), as adopted by reference in this section. A facility at which a particular category of universal waste is only accumulated is not a destination facility for purposes of managing that category of universal waste.

(B) Generator--Any person, by site, whose act or process produces hazardous waste identified or listed in 40 CFR Part 261 or whose act first causes a hazardous waste to become subject to regulation.

(C) Large quantity handler of universal waste--A universal waste handler (as defined in this section) who accumulates at any time 5,000 kilograms or more total of universal waste (as defined in this section), calculated collectively. This designation as a large quantity handler of universal waste is retained through the end

of the calendar year in which 5,000 kilograms or more total universal waste is accumulated.

(D) Small quantity handler of universal waste--A universal waste handler (as defined in this section) who does not accumulate at any time 5,000 kilograms or more total of universal waste (as defined in this section), calculated collectively.

(E) Thermostat--A temperature control device that contains metallic mercury in an ampule attached to a bimetal sensing element, and mercury-containing ampules that have been removed from these temperature control devices in compliance with the requirements of 40 CFR §273.13(c)(2) or §273.33(c)(2) as adopted by reference in this section.

(F) Universal waste--Any of the following hazardous wastes that are subject to the universal waste requirements of this section:

(i) batteries, as described in 40 CFR §273.2;

(ii) pesticides, as described in 40 CFR §273.3;

(iii) mercury-containing equipment, including thermostats, as described in 40 CFR §273.4;

(iv) paint and paint-related waste, as described in §335.262(b) of this title (relating to Standards for Management of Paint and Paint-Related Waste); [and]

(v) lamps, as described in 40 CFR §273.5; and [.]

(vi) aerosol cans, as described in 40 CFR §273.6.

(20) [(17)] In 40 CFR §273.10, the reference to "40 CFR §273.9" is changed to "§335.261(b)(19)(D) [§335.261(b)(16)(D)] of this title (relating to Universal Waste Rule)."

(21) [(18)] 40 CFR §273.11(b) is changed to read as follows: "Prohibited from diluting or treating universal waste, except when responding to releases as provided in 40 CFR §273.17; managing specific wastes as provided in 40 CFR §273.13; or crushing lamps under the control conditions of §335.261(e) of this title (relating to Universal Waste Rule)."

(22) [(19)] In 40 CFR §273.13(a)(3)(i), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(23) [(20)] In 40 CFR §273.13(c)(2)(iii) and (iv), references to "40 CFR parts 260 through 272 [§262.34]" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste) [§335.69 of this title (relating to Accumulation Time)]."

(24) [(21)] In 40 CFR §273.13(d)(1), the phrase "adequate to prevent breakage" is changed to "adequate to prevent breakage, except as specified in §335.261(e) of this title (relating to Universal Waste Rule)."

(25) In 40 CFR §273.13(e)(4)(iv), the reference to "40 CFR 262.14, 262.15, 262.16, or 262.17" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)."

(26) In 40 CFR §273.13(e)(4)(v), the reference to "40 CFR 262.11" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" and the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(27) [(22)] In 40 CFR §273.17(b), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(28) [(23)] In 40 CFR §273.30, the reference to "§273.9" is changed to "§335.261(b)(19)(C) [§335.261(b)(16)(C)] of this title (relating to Universal Waste Rule)."

(29) [(24)] 40 CFR §273.31(b) is changed to read as follows: "Prohibited from diluting or treating universal waste, except when responding to releases as provided in 40 CFR §273.37; managing specific wastes as provided in 40 CFR §273.33; or crushing lamps under the control conditions of §335.261(e) of this title (relating to Universal Waste Rule)."

(30) [(25)] In 40 CFR §273.33(a)(3)(i), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(31) [(26)] In 40 CFR §273.33(c)(2)(iii) and (iv), the references to "40 CFR parts 260 through 272 [§262.34]" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste) [§335.69 of this title (relating to Accumulation Time)]."

(32) [(27)] In 40 CFR §273.33(c)(4)(i), the reference, "40 CFR part 261, subpart C," is changed to "Chapter 335, Subchapter R of this title (relating to Waste Classification)."

(33) [(28)] In 40 CFR §273.33(c)(3)(ii), the reference, "40 CFR parts 260 through 272," is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(34) [(29)] In 40 CFR §273.33(d)(1), the phrase "adequate to prevent breakage" is changed to "adequate to prevent breakage, except as specified in §335.261(e) of this title (relating to Universal Waste Rule)."

(35) In 40 CFR §273.33(e)(4)(iv), the reference to "40 CFR 262.14, 262.15, 262.16, or §262.17" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)."

(36) In 40 CFR §273.33(e)(4)(v), the reference to "40 CFR 262.11" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" and the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(37) [(30)] In 40 CFR §273.37(b), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(38) [(31)] In 40 CFR §273.52(a), the reference to "40 CFR part 262" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(39) [(32)] In 40 CFR §273.52(b), the reference to "40 CFR part 262" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(40) [(33)] In 40 CFR §273.54(b), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(41) [(34)] In 40 CFR §273.60(a), the reference to "§273.9" is changed to "§335.261(b)(19)(A) [§335.261(b)(16)(A)] of this title (relating to Universal Waste Rule)" and the reference to "parts 264, 265, 266, 268, 270, and 124 of this chapter" is changed to " 30 Texas Administrative Code (relating to Environmental Quality)."

(42) [(35)] In 40 CFR §273.60(b), the reference to "40 CFR §261.6(c)(2)" is changed to "§335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials)."

(43) [(36)] In 40 CFR §273.80(a), the reference to "40 CFR §260.20 and §260.23" is changed to "§20.15 of this title (relating to Petition for Adoption of Rules) and §335.261(c) of this title (relating to Universal Waste Rule)."

(44) [(37)] In 40 CFR §273.80(b), the reference to "40 CFR §260.20(b)" is changed to "§20.15 of this title (relating to Petition for Adoption of Rules)."

(45) [(38)] In 40 CFR §273.81(a), the reference to "40 CFR §260.10" is changed to "§335.1 of this title (relating to Definitions) and the reference to "§273.9" is changed to "§335.261(b)(19)(F) [§335.261(b)(16)(F)] of this title (relating to Universal Waste Rule)."

(c) Except as provided in paragraph (4) of this subsection, any [Any] person seeking to add a hazardous waste or a category of hazardous waste to the universal waste rule may file a petition for rulemaking under this section, §20.15 of this title, and 40 CFR Part 273, Subpart G as adopted by reference in this section.

(1) To be successful, the petitioner must demonstrate to the satisfaction of the commission that regulation under the universal waste rule: is appropriate for the waste or category of waste; will improve management practices for the waste or category of waste; and will improve implementation of the hazardous waste program. The petition must include the information required by §20.15 of this title. The petition

should also address as many of the factors listed in 40 CFR §273.81 as are appropriate for the waste or category of waste addressed in the petition.

(2) The commission will grant or deny a petition using the factors listed in 40 CFR §273.81. The decision will be based on the commission's determinations that regulation under the universal waste rule is appropriate for the waste or category of waste, will improve management practices for the waste or category of waste, and will improve implementation of the hazardous waste program.

(3) The commission may request additional information needed to evaluate the merits of the petition.

(4) Hazardous waste pharmaceuticals are regulated under Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals) and may not be added as a category of hazardous waste for management under this section.

(d) Any waste not qualifying for management under this section must be managed in accordance with applicable state regulations.

(e) Crushing lamps is permissible only in a crushing system for which the following control conditions are met:

(1) an exposure limit of no more than 0.05 milligrams of mercury per cubic meter is demonstrated through sampling and analysis using Occupational Safety and Health Administration (OSHA) Method ID-140 or National Institute for Occupational Safety and Health Method Number 6009, based on an eight-hour time-weighted average of samples taken at the breathing zone height near the crushing system operating at the maximum expected level of activity;

(2) compliance with the notification requirements of §106.262 of this title (relating to Facilities (Emission and Distance Limitations) (Previously SE 118)) is demonstrated;

(3) documentation of the demonstrations under paragraphs (1) and (2) of this subsection is provided in a written report to the executive director; and

(4) the executive director approves the crushing system in writing.

SUBCHAPTER H: STANDARDS FOR THE MANAGEMENT OF SPECIFIC WASTES AND SPECIFIC TYPES OF FACILITIES

DIVISION 6: MILITARY MUNITIONS

§335.272

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.272. Standards.

(a) The regulations contained in 40 Code of Federal Regulations (CFR) Part 266 Subpart M, as amended in the *Federal Register* through February 12, 1997[,] (at 62 FR [FedReg] 6622) are adopted by reference, subject to the changes indicated in subsection (b) of this section.

(b) Reference to:

(1) August 12, 1997 is changed to the effective date of this rule;

(2) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapter 50 of this title (relating to Action on Applications and Other Authorizations), Chapter 305 of this title (relating to Consolidated Permits), and Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste), as applicable;

(3) 40 CFR Parts 260 - 279 means the commission's rules including, but not limited, to Chapter 50 of this title, Chapter 305 of this title, Chapter 328 of this title (relating to Waste Minimization and Recycling), and Chapter 335 of this title, as applicable;

(4) 40 CFR §260.10 is changed to §335.1 of this title (relating to Definitions);

(5) 40 CFR §261.2 is changed to the definition of "solid waste" in §335.1 of this title);

(6) 40 CFR §262.10(i) means as this section is adopted by reference under §335.52 of this title (relating to Purpose, Scope, and Applicability) [is changed to §335.61(h) of this title (relating to Standards Applicable to Generators of Hazardous Waste)];

(7) 40 CFR §263.10(e) means as this section is adopted under [is changed to] §335.91(f) of this title (relating to Scope [Standards Applicable to Transporters of Hazardous Waste]);

(8) 40 CFR §§264.1(g)(8), 265.1(c)(11), and 270.1(c)(3) are changed to §335.41(d)(2) of this title (relating to Hazardous Waste Management General Provisions);

(9) 40 CFR §270.61 is changed to §35.402 ~~§335.402~~ of this title (related to Emergency Actions Concerning Hazardous Waste);

(10) Resource Conservation and Recovery Act (RCRA) §1004(27) is changed to Texas Health and Safety Code (THSC), §361.003(34) (related to the definition of Solid Waste);

(11) RCRA §3004(u) is changed to Texas Water Code (TWC), §7.031(a) and (b) (relating to Corrective Action Relating to Hazardous Waste);

(12) RCRA §3008(h) is changed to TWC, §7.031(c) - (e) (relating to Corrective Action Relating to Hazardous Waste);

(13) RCRA §7003 is changed to THSC, §361.272 (relating to Administrative Orders Concerning Imminent and Substantial Endangerment), THSC, §361.273 (relating to Injunction as Alternative to Administrative Order), THSC, §361.301 (relating to Emergency Order), TWC, §26.121, (relating to Unauthorized Discharges Prohibited.)

SUBCHAPTER O: LAND DISPOSAL RESTRICTIONS

§335.431

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.431. Purpose, Scope, and Applicability.

(a) Purpose. The purpose of this subchapter is to identify hazardous wastes that are restricted from land disposal and define those limited circumstances under which an otherwise prohibited waste may continue to be land disposed.

(b) Scope and Applicability.

(1) Except as provided in paragraph (2) of this subsection, the requirements of this subchapter apply to persons who generate or transport hazardous waste and owners and operators of hazardous waste treatment, storage, and disposal facilities.

(2) The requirements of this subchapter do not apply to any entity that is either specifically excluded from coverage by this subchapter or would be excluded from the coverage of 40 Code of Federal Regulations (CFR) Part 268 by 40 CFR Part 261, if those parts applied.

(3) Universal waste handlers and universal waste transporters, as defined in and subject to regulation under Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule) are exempt from 40 CFR §268.7 and §268.50.

(c) Adoption by Reference.

(1) Except as provided in paragraph (2) of this subsection, and subject to the changes indicated in subsection (d) of this section, the regulations contained in 40 CFR Part 268, as amended in the *Federal Register* through February 22, 2019 (84 FR 5816) [June 13, 2011 (76 FR 34147)] are adopted by reference.

(2) The following sections of 40 CFR Part 268 are excluded from the sections adopted in paragraph (1) of this subsection: 40 CFR §§268.1(f), 268.5, 268.6, 268.7(a)(10), 268.13, 268.42(b), and 268.44.

(3) Appendices IV, VI - IX, and XI of 40 CFR Part 268 are adopted by reference as amended through July 14, 2006 (71 FR 40254).

(d) Changes to Adopted Parts. The parts of the CFR that are adopted by reference in subsection (c) of this section are changed as follows:

(1) The words "Administrator" or "Regional Administrator" are changed to "Executive Director;"

(2) The word "treatment" is changed to "processing;"

(3) The words *"Federal Register,"* when they appear in the text of the regulation, are changed to *"Texas Register;"*

(4) In 40 CFR §268.7(a)(6) and (7) [(a)(7)], the applicable definition of hazardous waste and solid waste is the one that is set out in this chapter rather than the definition of hazardous waste and solid waste that is set out in 40 CFR Part 261.

(5) In 40 CFR §268.50(a)(1), the reference to "§§262.16 and 262.17 [the citation to §262.34]" is changed to "40 CFR §262.16 and §262.17 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)." ["§335.69."]

(6) In 40 CFR §268.50(a)(4), the reference to "§§266.502 and 266.503 of this chapter" is changed to "§335.755 of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals) and §335.757 of this title (relating to Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals)."

(7) In 40 CFR §268.50(a)(5), the reference to "§266.510 of this chapter" is changed to "§335.771 of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors)."

SUBCHAPTER Q: POLLUTION PREVENTION: SOURCE REDUCTION AND WASTE MINIMIZATION

§§335.471, 335.474, 335.477

Statutory Authority

The amendments are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendments implement THSC, Chapter 361.

§335.471. Definitions.

The words and terms used in this subchapter have the meanings given in the Waste Reduction Policy Act of 1991, or the regulations promulgated thereunder. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Further, the following words and terms, as defined herein, shall only have application to this subchapter.

[(1) Acute hazardous waste--Hazardous waste listed by the administrator of the EPA under the federal Solid Waste Disposal Act, as amended by RCRA, because the waste meets the criteria for listing hazardous waste identified in 40 Code of Federal Regulations §261.11(a)(2).]

(1) [(2)] Base year--The year preceding the first year of the plan.

[(3) Conditionally exempt small quantity generator--A generator that does not accumulate more than 1,000 kilograms of hazardous waste at any one time at his facility and who generates less than 100 kilograms of hazardous waste in any given month.]

(2) [(4)] Environment--Water, air, and land and the interrelationship that exists among and between water, air, land, and all living things.

[(5) Environmental management system--As defined in §90.30(3) of this title (relating to Definitions). A documented management system to address applicable environmental regulatory requirements that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining an environmental policy directed toward continuous improvement.]

(3) [(6)] Facility--All buildings, equipment, structures, and other stationary items located on a single site or on contiguous or adjacent sites that are owned or operated by a person who is subject to this subchapter or by a person who controls, is controlled by, or is under common control with a person subject to this subchapter.

(4) [(7)] Generator and generator of hazardous waste--Has the meaning assigned by Texas Health and Safety Code, §361.131. A person whose act or process produces industrial solid waste or hazardous waste or whose act first causes an industrial solid waste or a hazardous waste to be regulated by the commission.

[(8) Large quantity generator--A generator that generates, through ongoing processes and operations at a facility:]

[(A) more than 1,000 kilograms of hazardous waste in a month; or]

[(B) more than one kilogram of acute hazardous waste in a month.]

(5) [(9)] Media and medium--Air, water, and land into which waste is emitted, released, discharged, or disposed.

(6) [(10)] Pollutant or contaminant--Includes any element, substance, compound, disease-causing agent, or mixture that after release into the environment and on exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions, including malfunctions in reproduction, or physical deformations in the organism or its offspring. The term does not include petroleum, crude oil, or any fraction of crude oil that is not otherwise specifically listed or designated as a hazardous substance under §101(14)(A) - (F) of the environmental response law, nor does it include natural gas, natural gas liquids, liquefied natural gas, synthetic gas of pipeline quality, or mixtures of natural gas and synthetic gas.

(7) [(11)] Release--Any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment. The term does not include:

(A) a release that results in an exposure to a person solely within a workplace, concerning a claim that the person may assert against the person's employer;

(B) an emission from the engine exhaust of a motor vehicle, rolling stock, aircraft, vessel, or pipeline pumping station engine;

(C) a release of source, by-product, or special nuclear material from a nuclear incident, as those terms are defined by the Atomic Energy Act of 1954, as amended ((42 United States Code, §§2011 *et seq.),* if the release is subject to requirements concerning financial protection established by the United States Nuclear Regulatory Commission under that Act, §170;

(D) for the purposes of the federal Comprehensive Environmental Responsibility, Compensation and Liability Act [CERCLA] (Superfund), §104, or other response action, a release of source, by-product, or special nuclear material from a processing site designated under the Uranium Mill Tailings Radiation Control Act of 1978 (42 United States Code, §7912 and §7942), §102(a)(1), or §302(a)); and

(E) the normal application of fertilizer.

[(12) Small quantity generator--A generator that generates through ongoing processes and operation at a facility:]

[(A) equal to or less than 1,000 kilograms but more than or equal to 100 kilograms of hazardous waste in a month; or]

[(B) equal to or less than one kilogram of acute hazardous waste in a month.]

(8) [(13)] Source reduction--Has the meaning assigned by the federal Pollution Prevention Act of 1990, Publication Law 101-508, §6603, 104 Stat. 1388. The term "source reduction" means any practice which:

(A) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and

(B) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants. The term includes equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control.

(9) [(14)] Tons--2,000 pounds, also referred to as short tons.

(10) [(15)] Toxic release inventory--A program which includes those chemicals on the list in Committee Print Number 99-169 of the United States Senate Committee on Environment and Public Works, titled "Toxic Chemicals Subject to the Emergency Planning and Community Right-To-Know Act of 1986 (EPCRA, 42 United States Code, §11023), 313" including any revised version of the list as may be made by the administrator of the EPA.

(11) [(16)] Waste minimization--A practice that reduces the environmental or health hazards associated with hazardous wastes, pollutants, or contaminants. Examples may include reuse, recycling, neutralization, and detoxification.

§335.474. Pollution Prevention Plans.

All persons identified under §335.473 of this title (relating to Applicability) shall prepare a five-year pollution prevention plan that shall be updated as necessary. Plans shall be maintained on-site and available to commission personnel for inspection. Prior to expiration of the initial plan and each succeeding five-year plan, a new five-year plan shall be prepared. Plans prepared under paragraphs (1) - (3) of this section shall contain a separate component addressing source reduction activities and a separate component addressing waste minimization activities.

(1) Large quantity generators or toxic release inventory (TRI) Form R reporters. For facilities that are large quantity generators as defined in §335.1

[§335.471(8)] of this title (relating to Definitions) or TRI Form R reporters [defined in §335.471(15) of this title], the plan shall include, at a minimum:

(A) an initial survey that identifies:

(i) for facilities described in §335.473(1) of this title, all activities that generate hazardous waste; and

(ii) for facilities described in §335.473(3), all activities that result in a release of TRI reportable chemicals;

(B) based on the initial survey, a prioritized list of economically and technologically feasible source reduction and waste minimization projects;

(C) an explanation of source reduction or waste minimization projects to be undertaken, with a discussion of technical and economic considerations, and environmental and human health risks considered in selecting each project to be undertaken;

(D) an estimate of the type and amount of reduction anticipated;

(E) a schedule for the implementation of each source reduction and waste minimization project;

(F) measurable source reduction and waste minimization goals for the entire facility, including incremental goals to aid in evaluating progress;

(G) an explanation of employee awareness and training programs to aid in accomplishing source reduction and waste minimization goals;

(H) identification of cases where the implementation of a source reduction or waste minimization activity designed to reduce risk to human health or the environment may result in the release of a different pollutant or contaminant or may shift the release to another medium;

(I) certification that the plan is complete and correct by the owner of the facility, or, if the facility is owned by a corporation, by an officer of the corporation that owns the facility who has the authority to commit the corporation's resources to implement the plan. A copy of the certification is to be submitted to the commission; and

(J) an executive summary of the plan submitted to the commission that shall include at a minimum:

(i) a description of the facility that shall include:

(I) name of facility;

(II) mailing and physical address;

(III) point-of-contact, including phone number and electronic mail (e-mail) address, if available;

(IV) a general description of the facility;

(V) applicable identification numbers, including: Texas Commission on Environmental Quality (TCEQ) solid waste registration number, EPA identification number, and TRI identification number;

(VI) primary standard industrial classification (SIC) code and, if applicable, North American Industry Classification System (NAICS); and

(VII) the specific time period the five-year plan is in effect;

(ii) a list of all hazardous wastes generated and the volume of each;

(iii) a list of all reportable TRI releases and transfers and the volume of each;

(iv) a prioritized list of pollutants and contaminants to be reduced;

(v) a statement of measurable reduction goals;

(vi) an explanation of environmental and human health risks considered in determining reduction goals;

(vii) a list of source reduction and waste minimization projects with an associated schedule toward implementation;

(viii) an implementation schedule for future reduction goals; and

(ix) identification and description of cases where the implementation of source reduction or waste minimization activity designed to reduce risk to human health or the environment may result in the release of a different pollutant or contaminant or may shift the release to another medium. Included in this description shall be a discussion of the change in characteristic of the normal waste stream or release and how it will be managed in the affected medium.

(K) The executive summary of the plan may include:

(i) a discussion of the person's previous efforts at the facility to reduce risk to human health and the environment or to reduce the generation of hazardous waste or the release of pollutants or contaminants;

(ii) a discussion of the effect changes in environmental regulations have had on the achievement of the source reduction and waste minimization goals;

(iii) the effect that events the person could not control have had on the achievement of the source reduction and waste minimization goals;

(iv) a description of projects that have reduced the generation of hazardous waste or the release of pollutants or contaminants; and

(v) a discussion of the operational decisions made at the facility that have affected the achievement of the source reduction or waste minimization goals or other risk reduction efforts.

(2) Small quantity generators/non-TRI Form R reporters. For facilities that are small quantity generators as defined in §335.1 [§335.471(12)] of this title and are

not TRI Form R reporters [as defined in §335.471(15) of this title], the plan shall include, at a minimum:

(A) a description of the facility which shall include:

(i) name of the facility;

(ii) mailing and physical address;

(iii) point-of-contact, including phone numbers and electronic mail (e-mail) address, if available;

(iv) general description of the facility; and

(v) applicable identification numbers, including: TCEQ solid waste registration number and EPA identification number;

(B) a list of all hazardous wastes generated and the volume of each;

(C) a prioritized list of pollutants and contaminants to be reduced;

(D) a statement of measurable reduction goals;

(E) information on environmental and human health risks, such as material safety data sheets or other available documentation, considered in determining reduction goals;

(F) A list of source reduction and waste minimization projects with an associated schedule of implementation;

(G) an implementation schedule for future reduction goals;

(H) certification that the plan is complete and correct by the owner of the facility or if the facility is owned by a corporation, by an officer of the corporation that owns the facility who has the authority to commit the corporation's resources to implement the plan. A copy of the certification must be submitted to the commission; and

(I) an executive summary of the plan submitted to the commission that shall include at a minimum:

(i) a description of the facility that shall include:

(I) name of facility;

(II) mailing and physical address;

(III) point-of-contact, including a phone number and email, if available;

(IV) EPA identification number and TCEQ solid waste registration number;

(V) primary SIC code; and if applicable, NAICS;

(VI) the specific time period the five-year plan is in effect;

(ii) a projection of the amount of hazardous waste that the facility will generate (based on what is reported as hazardous waste under §335.9 of this title (relating to Record Keeping and Annual Reporting Procedures Applicable to Generators)) at the end of the five-year period that the plan is in place;

(iii) prioritized list of pollutants and contaminants to be reduced;

(iv) a list of source reduction activities associated with reductions of pollutants and contaminants identified under subparagraph (C) of this paragraph.

(J) The executive summary of the plan may include:

(i) a discussion of the person's previous effort at the facility to reduce hazardous waste or the release of pollutants or contaminants through the pollution prevention plan;

(ii) a discussion of the effect that changes in environmental regulations have had on the achievement of the source reduction and waste minimization goals;

(iii) the effects that events the person could not control have had on the achievement of the source reduction and waste minimization goals;

(iv) a discussion of the operational decisions the person has made that have affected the achievement of the source reduction and waste minimization goals; and

(v) identification and description of cases where the implementation of source reduction and waste minimization activities designed to

reduce risk to human health or the environment may result in the release of a different pollutant or contaminant or may shift the release to another medium. Included in this description shall be a discussion of the change in characteristic of the normal waste stream or release and how it will be managed in the affected medium.

§335.477. Exemptions.

This subchapter does not apply to:

(1) facilities regulated by the Railroad Commission of Texas under the Natural Resources Code, §91.101 or §141.012;

(2) owners and operators of facilities listed in §335.473 of this title (relating to Applicability) who may apply on a case-by-case basis to the executive director for an exemption from this subchapter. The executive director may grant an exemption if the applicant demonstrates that sufficient reductions have been achieved. If an exemption is granted, it is valid only for the following year, but can be renewed, on an annual basis, by filing a new application. The executive director's decision will be based upon the following standards and criteria for determining practical economic and technical completion of the plan:

(A) the facility has reduced the amount of pollutants and contaminants being generated or released by 90% since the base year;

(B) potential impact on human health and the environment of any remaining hazardous waste generated, or pollutant or contaminant released; and

(C) a demonstration that additional reductions are not economically and technically feasible.

[(3) facilities that have an environmental management system (EMS) that meets the requirements and is approved by the executive director, as described in §90.36 of this title (relating to Evaluation of an Environmental Management System by the Executive Director) and report annually under the EMS program.]

SUBCHAPTER R: WASTE CLASSIFICATION

§§335.503, 335.504, 335.510, 335.511, 335.513, 335.521

Statutory Authority

The amendments are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendments implement THSC, Chapter 361.

§335.503. Waste Classification and Waste Coding Required.

(a) All industrial solid and municipal hazardous waste generated, stored, processed, transported, or disposed of in the state shall be classified according to the provisions of this subchapter.

(1) All solid waste shall be classified at the point of generation of the waste. A generator may not dilute a waste to avoid a Class 1 classification; however, combining nonhazardous waste streams for subsequent legitimate processing, storage, or disposal does not constitute dilution and is acceptable. Wastes shall be classified prior to, and following any type of processing or mixing of the waste. Hazardous waste and industrial solid waste are subject to the waste management requirements of this chapter.

(2) All industrial solid and municipal hazardous waste shall be classified as either:

(A) hazardous;

(B) Class 1;

(C) Class 2; or

(D) Class 3.

(3) A person who generates a solid waste shall first determine if that waste is hazardous pursuant to §335.504 of this title (relating to Hazardous Waste Determination).

(4) After making the hazardous waste determination as required in paragraph (3) of this subsection, if the waste is determined to be nonhazardous, the generator shall then classify the waste as Class 1, Class 2, or Class 3, pursuant to §§335.505 - 335.507 of this title (relating to Class 1 Waste Determination, Class 2 Waste Determination, and Class 3 Waste Determination) using one or more of the following methods:

(A) use the criteria for waste classification as provided in §§335.505 - 335.507 of this title;

(B) use process knowledge as provided in §335.511 of this title (relating to Use of Process Knowledge);

(C) classify the waste as directed under §335.508 of this title (relating to Classification of Specific Industrial Wastes); or

(D) choose to classify a nonhazardous waste as Class 1 without any analysis to support that classification. However, documentation (analytical data and/or process knowledge) is necessary to classify a waste as Class 2 or Class 3, pursuant to §335.513 of this title (relating to Documentation Required).

(b) All industrial solid waste and municipal hazardous waste generated, stored, processed, transported or disposed of in the state shall be coded with an eight-digit waste code number that consists of a four-character sequence number followed by a three-digit form code provided in §335.521(c) of this title (relating to Appendix 3) followed by one-character, H, 1, 2, or 3, depicting the waste classification identified in subsection (a)(2) of this section. Procedures for assigning sequence numbers are outlined as follows [which shall include a four-digit waste sequence number, a three-digit form code, and a one-character classification (either H, 1, 2, or 3). Form codes are provided in §335.521(c) of this title (relating to Appendix 3). Procedures for assigning waste code numbers and sequence numbers are outlined as follows and available from the agency at the address listed in §335.521(b) of this title (relating to Appendix 2)].

(1) The four-character sequence number consists of alpha and/or numeric characters [A waste code is represented by the following 8-digit character string: sequence number + form code + classification code (H, 1, 2, or 3)].

(2) Registered generators must assign a unique numeric sequence number between 0001 to 9999 to each individual waste. Sequence numbers need not be

assigned in sequential order [In-state generators will assign a unique four-digit sequence number to each individual waste. These sequence numbers will range from 0001 to 9999. They need not be assigned in sequential order. An in-state registered generator may choose to request the executive director assign a sequence number to a specific waste which is not regularly generated by a facility and is being shipped as a one-time shipment or choose to add that waste to the regular sequence numbers on a notice of registration. Sequence numbers provided by the executive director may be a combination of alpha and numeric characters].

(3) The executive director will provide [in-state] unregistered generators a [four-digit] sequence number for each regulated waste it generates, which may be a combination of alpha and numeric characters.

(4) Generators of wastes resulting from a spill may obtain a sequence number for the spill related wastes from the agency's Emergency Response Section.

(5) Out-of-state generators must use the sequence number "OUTS" as the first four characters of the waste code [will use the sequence code "OUTS" in the first four digits of the waste code].

(6) A generator that meets the conditions of an applicable exemption from manifesting requirements that manifests their hazardous and/or Class 1 nonhazardous waste must use the sequence number "VSQG" as the first four

characters of the waste code [CESQGs or industrial Class 1 non-hazardous waste generators that are exempt from manifesting as specified in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste) who voluntarily manifest their hazardous and or Class 1 nonhazardous waste may use "CESQ" as the first four digits of the waste code].

(7) A facility which receives and consolidates like waste from a person who meets the conditions for exemption for a very small quantity generator and generated less than 100 kilograms of non-acute hazardous waste, 1 kilogram of acute hazardous waste, and 100 kilograms of Class 1 industrial waste in the calendar month during which the waste was generated must use the sequence number "VSQG" as the first four characters of the waste code for any manifesting and/or reporting associated with that waste [Municipal Conditionally Exempt Small Quantity Generators should use "CESQ" in the first four positions of the waste code for any manifesting and/or reporting associated with that waste].

(8) A facility which receives a waste from off-site and consolidates that waste with other like waste received from off-site, other than its own (thus not changing the form code of the waste stream or its composition, hazardous waste classification, or Texas waste class), or stores a waste without treating, processing (as defined in §335.1 of this title (relating to Definitions), and without changing the form or composition of that waste may use the sequence number "TSDF" as the first four

characters of the waste code. The sequence number TSDF may not be used to identify wastes which are treated or altered or combined with unlike wastes. The sequence number TSDF is only to be used by facilities that store and/or accumulate a quantity of wastes from more than one site for subsequent shipment to a treatment or disposal facility. [A facility which receives a waste and consolidates that waste with other like waste, other than its own, (thus not changing the form code of the waste stream or its composition, hazardous, or Texas waste class), or stores a waste without treating, processing (as defined in §335.1 of this title (relating to Definitions)), or changing the form or composition of that waste may ship that waste to a storage, treatment, or disposal facility using the sequence code "TSDF" in the first four positions of the waste code. This does not pertain to wastes which are treated or altered or combined with unlike wastes. This "TSDF" designation is only to be used by facilities that store and/or accumulate a quantity of wastes from more than one site for subsequent shipment to a treatment or disposal facility. Manifest documents must note a final destination designated to receive a consolidated waste. The designated "final destination" receiving facility noted on the manifest must be a permitted facility in order to terminate the manifest, unless the waste is nonhazardous and does not require manifesting in accordance with §335.10(e) of this title and is going to a facility described in §335.10(e) of this title. A consolidated waste shipped to a non-permitted facility prior to being shipped to the final destination must proceed with the original manifests (noted with any appropriate changes) to the facility designated on the manifest for final handling.]

(9) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a designated facility must use the sequence number "PHRM" as the first four characters of the waste code.

§335.504. Hazardous Waste Determination

(a) Hazardous waste determination. A person who generates a solid waste, as defined in §335.1 of this title (relating to Definitions), must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to applicable Resource Conservation and Recovery Act (RCRA) and Texas Administrative Code regulations. The hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste such that the RCRA classification of the waste may change. A hazardous waste determination is made using the following steps: [must determine if that waste is hazardous using the following method:]

(1) A person must determine whether the material is excluded or exempted from regulation as a solid waste or as hazardous waste under the definition of solid waste in §335.1 of this title or identified in 40 Code of Federal Regulations (CFR) Part 261, Subpart A as amended in the *Federal Register* through February 22,

2019 (84 FR 5816), or Subpart E as amended in the *Federal Register* through August 6, 2018 (83 FR 38262) [Determine if the material is excluded or exempted from being a solid waste or hazardous waste per §335.1 of this title (relating to Definitions)] or identified in 40 Code of Federal Regulations (CFR) Part 261, Subpart A or E, as amended through November 28, 2016 (81 FR 85696)].

(2) If the waste is not excluded from regulation as a solid waste, the person must then use knowledge of the waste to determine whether the waste is a hazardous waste because it meets any of the listing descriptions, or is mixed with or derived from a waste that meets any of the listing descriptions identified in 40 CFR Part 261, Subpart D, as amended in the *Federal Register* through February 22, 2019 (84 FR 5816). Acceptable knowledge that may be used in making an accurate determination as to whether the waste is listed may include waste origin, composition, the process producing the waste, feedstock, and other reliable and relevant information [If the material is a solid waste, determine if the waste is listed as, or mixed with, or derived from a listed hazardous waste identified in 40 CFR Part 261, Subpart D, as amended through April 13, 2012 (77 FR 22229)].

(3) The person must also determine whether the waste exhibits one or more hazardous characteristics as identified in 40 CFR Part 261, Subpart C, as amended in the *Federal Register* through March 18, 2010 (75 FR 12989) by following the procedures in subparagraph (A) or (B) of this paragraph or a combination of both [If the material is a solid waste, determine whether the waste exhibits any

characteristics of a hazardous waste as identified in 40 CFR Part 261, Subpart C, as amended through March 18, 2010 (75 FR 12989)].

(A) The person must apply knowledge of the hazard characteristic of the waste in light of the materials or the processes used to generate the waste. Acceptable knowledge may include process knowledge (e.g., information about chemical feedstocks and other inputs to the production process); knowledge of products, by-products, and intermediates produced by the manufacturing process; chemical or physical characterization of wastes; information on the chemical and physical properties of the chemicals used or produced by the process or otherwise contained in the waste; testing that illustrates the properties of the waste; or other reliable and relevant information about the properties of the waste or its constituents. A test other than a test method set forth in 40 CFR Part 261, Subpart C or an equivalent test method approved by the United States Environmental Protection Agency (EPA) Administrator under 40 CFR §260.21, or by the executive director under §335.509 of this title (relating to Waste Analysis), may be used as part of a person's knowledge to determine whether a solid waste exhibits a characteristic of hazardous waste. However, such tests do not, by themselves, provide definitive results. Persons testing their waste must obtain a representative sample, as defined in §335.1 of this title, of the waste for the testing,

(B) When available knowledge is inadequate to make an accurate determination, the person must test the waste according to the applicable methods set

forth in 40 CFR Part 261, Subpart C or according to an equivalent method approved by the EPA Administrator under 40 CFR §260.21, or approved by the executive director under §335.509 of this title, and in accordance with the following:

(i) Persons testing their waste must obtain a representative sample, as defined in §335.1 of this title, of the waste for the testing.

(ii) Where a test method is specified in 40 CFR Part 261, Subpart C, the results of the regulatory test, when properly performed, are definitive for determining the regulatory status of the waste.

(b) Recordkeeping for small or large quantity generators. A large quantity generator and a small quantity generator shall maintain records supporting its hazardous waste determinations in accordance with 40 CFR §262.11(f) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(c) Recordkeeping for hazardous waste and Class 1 waste generators. Generators shall make and maintain records of a hazardous waste determination in accordance with §335.513 of this title (relating to Documentation Required), and 40 CFR §262.11(f) as adopted under §335.53 of this title.

§335.510. Sampling Documentation.

(a) Generators who use analytical data to classify their waste pursuant to §335.509 of this title (relating to Waste Analysis) must maintain documentation of their sampling procedures in accordance with this section and 40 Code of Federal Regulations §262.11(f) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(b) The sampling documentation must, at a minimum, include the following:

(1) dates samples were collected;

(2) a description of the site or unit from which the sample is taken and sampling location(s) at the site unit;

(3) sample methods and sample equipment utilized; and

(4) description of sample handling techniques, including containerization, preservation, and chain of custody.

(c) Generators shall document all the information listed in subsection (b) of this section, and shall retain copies on-site in accordance with §335.513 of this title (relating to Documentation Required).

(d) Generators who have existing sampling documentation, which includes the information listed in subsection (b) of this section, do not need to prepare any new documentation specifically for this section.

§335.511. Use of Process Knowledge.

(a) Generators using knowledge of the waste and the process producing the waste to classify or assist in classifying a waste as hazardous shall comply with §335.504 of this title (relating to Hazardous Waste Determination). Generators using knowledge of the waste to classify or assist in classifying a waste as Class 1, Class 2, or Class 3 shall comply with this section and consider the waste origin, composition, the process producing the waste, feedstock, and other reliable and relevant information [Generators may use their existing knowledge about the process to classify or assist in classifying a waste as hazardous, Class 1, Class 2, or Class 3]. Process knowledge must be documented and maintained on-site pursuant to §335.513 of this title (relating to Documentation Required), and 40 CFR §262.11(f) as adopted by reference under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste). Material safety data sheets, manufacturers' literature, and other documentation generated in conjunction with a particular process may be used to classify a waste provided that the literature provides reliable and relevant [sufficient] information about the waste and addresses the criteria set forth in §§335.504 - 335.508 of this title (relating to Hazardous Waste Determination, Class 1 Waste

Determination, Class 2 Waste Determination, Class 3 Waste Determination, and Classification of Specific Industrial Solid Wastes). For classes other than hazardous or Class 1, a generator must be able to demonstrate requisite knowledge of his or her process by satisfying all of the following.

(1) The generator must have a full description of the process, including a list of chemical constituents that enter the process. Constituents listed in Appendix 1 in §335.521 of this title (relating to Appendices) [of this subchapter] must be addressed in this description.

(2) The generator must have a full description of the waste, including a list of chemical constituents likely to be in the waste. This list should be based on paragraph (1) of this subsection.

(3) The generator may develop a subset of Appendix 1 of §335.521 of this title constituents by which to evaluate the waste utilizing the information from paragraphs (1) and (2) of this subsection.

(4) Documentation of the waste classification must be maintained and, if requested or required, provided to the executive director pursuant to §335.513 of this title.

(b) If the total concentration of the constituents demonstrates that individual analytes are not present in the waste, or that they are present but at such low concentrations that the appropriate maximum leachable concentrations could not possibly be exceeded, the Toxicity Characteristic Leaching Procedure (TCLP) [TCLP] extraction procedure discussed in §335.505(1) of this title need not be run. If an analysis of any one of the liquid fractions of the TCLP extract indicates that a regulated constituent is present at such high concentrations that, even after accounting for dilution from the other fractions of the extract, the concentration would be equal to or greater than the maximum leachable concentration for that constituent, then the waste is Class 1, and it is not necessary to analyze the remaining fractions of the extract.

§335.513. Documentation Required.

(a) Documentation on each waste stream is required to be maintained by the generator in accordance with the requirements of this subchapter, [and in accordance with] §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), and 40 Code of Federal Regulations §262.11(f) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(b) The following documentation shall be submitted by the generator to the executive director prior to waste shipment or disposal and not later than 90 days of initial waste generation:

(1) description of waste;

(2) date of initial waste generation;

(3) description of process that generated the waste;

(4) hazardous waste determination;

(5) all analytical data and/or process knowledge allowed under §335.511 of this title (relating to Use of Process Knowledge) used to characterize Class 3 wastes, including quality control data; and

(6) waste classification determination.

(c) The following documentation shall be maintained by the generator on site immediately upon waste generation and for a minimum of three years after the waste is no longer generated or stored or until site closure:

(1) all information required under subsection (b) of this section;

(2) all analytical data and/or process knowledge allowed under §335.511 of this title used to characterize hazardous, Class 1, Class 2, and Class 3 wastes, including quality control data.

(d) The executive director may request that a generator submit all documentation listed in subsections (b) and (c) of this section for auditing the classification assigned. Documentation requested under this section shall be submitted within ten working days of receipt of the request.

(e) Any changes to the information required in sections (b) and (c) of this subsection shall be maintained or submitted according to the timing requirements of this section.

(f) A generator may request information provided to the agency remain confidential in accordance with the Texas Open Records Act, the Texas Government Code, Chapter 552.

§335.521. Appendices.

(a) Appendix 1.

(1) Table 1.

Figure: 30 TAC §335.521(a)(1) (No change to the figure as it currently exists in TAC.)

Constituents of Concern and
Their Maximum Leachable Concentrations.

Values are based on information contained in Federal Registers Vol. 55 / Friday, July 27, 1990; Vol. 56 / June 7, 1991; and Integrated Risk Information Systems, U.S. Environmental Protection Agency, and 40 CFR 264 Appendix 9.

Compound	CAS No.	Concentration (mg/l)
Acenaphthene	83-32-9	210
Acetone	67-64-1	400
Acetonitrile	75-05-8	20
Acetophenone	98-86-2	400
Acrylamide	79-06-1	0.08
Acrylonitrile	107-13-1	0.6
Aniline	62-53-3	60
#Anthracene	120-12-7	1050
Antimony	7440-36-0	1
Arsenic	7440-38-2	1.8
Barium	7440-39-3	100.0
Benzene	71-43-2	0.50
Benzidine	92-87-5	0.002
Beryllium	7440-41-7	0.08
Bis(2-chloroethyl)ether	111-44-4	0.3
Bis(2-ethylhexyl) phthalate	117-81-7	30
	--	--
Bromodichloromethane	75-27-4	0.3
Bromomethane	74-83-9	5
Butylbenzyl phthalate	85-68-7	700
Cadmium	7440-43-9	0.5
Carbon disulfide	75-15-0	400
Carbon tetrachloride	56-23-5	0.50
Chlordane	57-74-9	0.03
Chlorobenzene	08-90-7	70
Chloroform	67-66-3	6.0
#Chloro-m-cresol, p	59-50-7	7000
2-Chlorophenol	95-57-8	20
Chromium	7440-47-3	5.0
m-Cresol	108-39-4	200.0*
o-Cresol	95-48-7	200.0*
p-Cresol	106-44-5	200.0*
DDD	72-54-8	1
DDE	72-55-9	1
DDT	50-29-3	1
Dibutyl phthalate	84-74-2	400

1,4-Dichlorobenzene	106-46-7	7.5
3,3-Dichlorobenzidine	91-94-1	0.8
1,2-Dichloroethane	107-06-2	0.50
Dichlorodifluoromethane	75-71-8	700
1,1-Dichloroethylene	75-35-4	0.6
1,3-Dichloropropene	542-75-6	1
2,4-Dichlorophenol	120-83-2	10
2,4-Dichlorophenoxy-	94-75-7	10.0
acetic acid (2,4-D)	--	--
Dieldrin	60-57-1	0.02
Diethyl phthalate	84-66-2	3000
Dimethoate	60-51-5	70
#2,4-Dimethylphenol	105-67-9	70
#2,6-Dimethylphenol	576-26-1	21
m-Dinitrobenzene	99-65-0	0.4
2,4-Dinitrophenol	51-28-5	7
2,4 -Dinitrotoluene	602-01-7	0.13
(and 2,6-, mixture)	--	--
#Dinoseb	88-85-7	3.5
1,4-Dioxane	123-91-1	30
Dioxins (Poly chlorinated dibenzo-p-dioxins)		
2,3,7,8-TCDD	1746-01-6	0.005
1,2,3,7,8-PeCDD	0321-76-4	0.010
1,2,3,4,7,8-HxCDD	57653-85-7	0.050
1,2,3,6,7,8-HxCDD	34465-46-8	0.050
1,2,3,7,8,9-HxCDD		0.050
Diphenylamine	122-39-4	90
1,2-Diphenylhydrazine	122-66-7	0.4
Disulfoton	298-04-4	0.1
Endosulfan	959-98-8	0.2
Endrin	72-20-8	0.02
#2-Ethoxyethanol	110-80-5	1400
Ethylbenzene	100-41-4	400
Ethylene dibromide	106-93-4	0.004
#Ethylene Glycol	107-21-1	7000
#Fluoranthene	206-44-0	140
#Fluorene	86-73-7	140
Furans (Polychlorinated dibenzo furans)		
2,3,7,8-TCDF	51207-31-9	0.050
1,2,3,7,8-PeCDF		0.100
2,3,4,7,8-PeCDF		0.010
1,2,3,4,7,8-HxCDF		0.050
1,2,3,6,7,8-HxCDF		0.050
1,2,3,7,8,9-HxCDF		0.050
Heptachlor	76-44-8	0.008
(and its hydroxide)	--	--
Heptachlor epoxide	1024-57-3	0.04
Hexachlorobenzene	118-74-1	0.13
Hexachloro-1,3-butadiene	87-68-3	0.4

Hexachlorocyclopentadiene	77-47-4	20
Hexachloroethane	67-72-1	3.0
Hexachlorophene	70-30-4	1
Isobutyl alcohol	78-83-1	1000
Isophorone	78-59-1	90
Lead	7439-92-1	1.5
Lindane	58-89-9	0.3
Mercury	7439-97-6	0.2
Methacrylonitrile	126-98-7	0.4
Methomyl	16752-77-5	90
Methoxychlor	72-43-5	10.0
#2-Methoxyethanol	109-86-4	14.0
Methyl ethyl ketone	78-93-3	200.0
Methyl isobutyl ketone	108-10-1	200
Methylene chloride	75-09-2	50
Methyl parathion	298-00-0	0.9
#Mirex	2385-85-5	0.7
Nickel	7440-02-0	70
Nitrobenzene	98-95-3	2.0
N-Nitroso-di-n-butylamine	924-16-3	0.06
N-Nitrosodiphenylamine	86-30-6	70
N-Nitrosomethylethylamine	10595-95-6	0.02
N-Nitroso-n-propylamine	621-64-7	0.05
N-Nitrosopyrrolidine	930-55-2	0.2
p-Phenylene diamine	106-50-3	20
Parathion	56-38-2	20
Pentachlorobenzene	608-93-5	3
Pentachloronitrobenzene	82-68-8	10
Pentachlorophenol	87-86-5	100.0
Phenol	108-95-2	2000
Pronamide	23950-58-5	300
#Pyrene	129-00-0	5.9
Pyridine	110-86-1	4
Selenium	7782-49-2	1.0
Silver	7440-22-4	5.0
Styrene	100-42-5	700
1,1,1,2-Tetrachloroethane	630-20-6	10
1,1,2,2-Tetrachloroethane	79-34-5	2
Tetrachloroethylene	127-18-4	0.7
2,3,4,6-Tetrachlorophenol	58-90-2	100
Toluene	108-88-3	1000
Toxaphene	8001-35-2	0.3
trans-1,3-Dichloro-propene	542-75-6	1
Tribromomethane (Bromoform)	75-25-2	70
1,2,4-Trichlorobenzene	120-82-1	70
1,1,1-Trichloroethane	71-55-6	300
Trichloroethylene	79-01-6	0.5

1,1,2-Trichloroethane	79-00-5	6
Trichlorofluoromethane	75-69-4	1000
2,4,5-Trichlorophenoxy-propionic acid (2,4,5 TP or Silvex)	93-72-1 --	1.0 --
1,2,3-Trichloropropane	96-18-4	20
2,4,5-Trichlorophenol	95-95-4	400.0
2,4,6-Trichlorophenol	88-06-2	2
Vanadium Pentoxide	1314-62-1	30
Vinyl chloride	75-01-4	0.2
Xylenes (all isomers)	1330-82-1	7000

Constituent added since original rule publication.
* If o-, m-, and p-Cresol concentrations cannot be differentiated, the total cresol concentration is used. The Maximum Concentration for total cresol is 200.0 mg/l.

(2) Table 2.

Figure: 30 TAC §335.521(a)(2)

[Figure: 30 TAC §335.521(a)(2)]

Appendix 1, Table 2.

Examples of Ignitable Solids.
Constituents listed from Department of Transportation Regulations, 49 CFR Part 173 Subpart E, October 1, 1993. (Note: The presence of a constituent on this table in a nonhazardous [non-hazardous] waste does not automatically identify that waste as a Class 1 ignitable waste. The constituents on this table are examples of materials which could be considered Class 1 ignitable waste. The physical characteristics of the waste will be the determining factor as to whether or not a waste is ignitable. Refer to §335.505(2) of this title (relating to Class 1 Waste Determination) for the Class 1 ignitable criteria.)
Compound or Material
Aluminum, metallic, powder
Alkali metal amalgams
Alkali metal amides
Aluminum alkyl halides
Aluminum alkyl hydrides

Aluminum alkyls
Aluminum borohydrides
Aluminum carbide
Aluminum ferrosilicon powder
Aluminum hydride
Aluminum phosphide
Aluminum resinate
Aluminum silicon powder
Ammonium picrate
2, 2'-Azodi-(2,4-dimethyl-4-methoxyvaleronitrile)
2, 2'-Azodi-(2,4-dimethylvaleronitrile)
1, 1' Azodi-(hexahydrobenzonitrile)
2,2'-Azodi (2-methyl-butryronitrile)
Azodiisobutryonitrile
Barium, metallic
Barium alloys, pyrophoric
Barium azide
Benzene-1,3-disulfohydrazide
Benzene sulfohydrazide
4-(Benzyl(ethyl)amino)-3-ethoxybenzenediazonium zinc chloride
4-(Benzyl(methyl)amino)-3-ethoxybenzenediazonium zinc chloride
Borneol
Boron trifluoride dimethyl etherate
5-tert-Butyl-2,4,6-trinitro-m-xylene
Calcium, metallic
Calcium carbide
Calcium chlorite
Calcium cyanamide
Calcium dithionite
Calcium hypochlorite
Calcium manganese silicon
Calcium silicon powder
Calcium phosphide
Calcium pyrophoric
Calcium resinate
Calcium silicide
Camphor, synthetic
Carbon, activated
Celluloid
Cerium
Cesium metal
Chromic acid or chromic acid mixture, dry
Cobalt naphthenates, powder

Cobalt resinate
Decaborane
2-Diazo-1-naphthol-4-sulpho-chloride
2-Diazo-1-naphthol-5-sulpho-chloride
2,5-Diethoxy-4-morpholinobenzenediazonium zinc chloride
Diethylzinc
4-Dimethylamino-6-(2-dimethyaminoethoxy) toluene-2-diazonium zinc chloride
Dimethylzinc
Dinitrophenolates
Dinitroresorcinol
N,N'-Dinitroso-N,N'-dimethyl terephthalamide
N,N'-Dinitrosopentamethylenetetramine
Diphenyloxide-4,4'disulfohydrazide
Dipicryl sulfide
4-Dipropylaminobenzenediazonium zinc chloride
Ferrocerium
Ferrosilicon
Ferrous metal
Hafnium powder
Hexamine
Hydrides, metal
3-(2-Hydroxyethoxy)-4-pyrrolidin-1-ylbenzenediazonium zinc chloride
Iron oxide, spent
Isosorbide dinitrate mixture
Lead phosphite, dibasic
Lithium acetylide-ethylene diamine complex
Lithium alkyls
Lithium aluminum hydride
Lithium amide, powdered
Lithium borohydride
Lithium ferro silicon
Lithium hydride
Lithium metal
Lithium nitride
Lithium silicon
Magnesium granules
Magnesium aluminum phosphide
Magnesium diamide
Magnesium phosphide
Magnesium silicide
Maneb
Manganese resinate
Methyl magnesium bromide

Methyldichlorosilane
Mono-(trichloro) tetra-(monopotassium dichloro)-penta-s-triazinetrione
N-methyl-N'-nitro-Nitrosoguanidine
Naphthalene
Nitrocellulose mixtures
Nitroguanidine
p-Nitrosodimethylaniline
Paraformaldehyde
Pentaborane
Peratic acid
Phosphorous, amorphous, red
Phosphorous, white or yellow
Phosphoric anhydride
Phosphorous pentachloride
Phosphorus pentasulfide
Phosphorus sesquisulfide
Phosphorus trisulfide
Picric acid
Potassium, metallic
Potassium dichloro-s-triazine-trione
Potassium borohydride
Potassium dithionite
Potassium phosphide
Potassium sulfide, anhydrous
Rubidium metal
Silicon powder, amorphous
Silver picrate
Sodium, metallic
Sodium aluminum hydride
Sodium amide
Sodium borohydride
Sodium chlorite
Sodium 2-diazo-1-naphthol-4-sulphonate
Sodium 2-diazo-1-naphthol-5-sulphonate
Sodium dichloro-s-triazine-trione
Sodium dinitro-ortho-cresolate
Sodium hydride
Sodium hydrosulfite
Sodium methylate
Sodium nitrite and mixtures
Sodium picramate, wet
Sodium potassium alloys
Sodium sulfide, anhydrous

Stannic phosphide
Strontium phosphide
Sulfur
Titanium metal powder
Titanium hydride
Trichloroisocyanuric acid
Trichlorosilane
Trichloro-s-triazinetrione
Trinitrobenzoic acid
Trinitrophenol
Trinitrotoluene
Urea nitrate
Zinc ammonium nitrite
Zinc phosphide
Zinc powder
Zinc resinate
Zirconium hydride, powdered
Zirconium picramate
Zirconium powder
Zirconium scrap

(3) Table 3.

Figure: 30 TAC §335.521(a)(3) (No change to the figure as it currently exists in TAC.)

Maximum Contaminant Levels (MCLs).

Values obtained from 40 CFR Part 141, Subparts B and G, Maximum Contaminant Levels and 40 CFR Part 143, Total Dissolved Solids.

Constituent	MCL (mg/l)
Arsenic	0.05
Barium	1
*Benzene	0.005
Cadmium	0.005
*Carbon tetrachloride	0.005
Chlordane	0.002

*Chlorobenzene	0.1
Chromium	0.1
2,4-D	0.07
*Dibromochloropropane	0.0002
*ortho-Dichlorobenzene	0.6
*para-Dichlorobenzene	0.075
*1,2-Dichloroethane	0.005
*1,1-Dichloroethylene	0.007
*trans-1,2-Dichloroethylene	0.1
*1,2-Dichloropropane	0.005
*Ethylbenzene	0.7
Heptachlor	.0004
Heptachlor epoxide	0.0002
Lead	0.05
Mercury	0.002
Methoxychlor	0.04
Pentachlorophenol	0.001
Selenium	0.05
Silver	0.05
*Styrene	0.1
*Tetrachloroethylene	0.005
*1,1,1-Trichloroethane	0.20
*Trichloroethylene	0.005
*Toluene	1
Toxaphene	0.003
2,4,5-TP (Silvex)	0.05
*Vinyl chloride	0.002
*Xylenes (total)	10
Total Dissolved Solids	500

* For a class 3 waste classification, these constituents must also be evaluated using the test methods described in 40 Code of Federal Regulations Part 261, Appendix II. See 335.507(4)(A)(ii) for additional information.

(b) Appendix 2.

Figure: 30 TAC §335.521(b)

[Figure: 30 TAC §335.521(b)]Appendix 2. TCEQ Mailing Information.

Texas Commission on Environmental Quality [Texas Natural Resource Conservation Commission]
Waste Permits Division
Industrial and Hazardous Waste Permits Section
MC 130

P.O.Box 13087
Austin, Texas 78711-3087

https://www.tceq.texas.gov/ [http://home.tnrcc.state.tx.us/]

(c) Appendix 3.

Figure: 30 TAC §335.521(c)

[Figure: 30 TAC §335.521(c)]

Appendix 3.

FORM CODES
_____
Code Waste description
_____
LAB PACKS
LAB PACKS - Lab packs of mixed wastes, chemicals, lab wastes
001 Lab packs of old chemicals only
002 Lab packs of debris only
003 Mixed lab packs
004 Lab packs containing acute hazardous wastes
005 Waste pharmaceuticals managed as hazardous waste
006 Airbag waste (airbag modules or airbag inflators managed as hazardous waste
009 Other lab packs (Specify in Comments)
LIQUIDS
INORGANIC LIQUIDS - Waste that is primarily inorganic and highly fluid (e.g., aqueous), with low suspended inorganic solids and low organic content
101 Aqueous waste with low solvents
102 Aqueous waste with low other toxic organics
103 Spent acid with metals
104 Spent acid without metals
105 Acidic aqueous waste
106 Caustic solution with metals but no cyanides
107 Caustic solution with metals and cyanides
108 Caustic solution with cyanides but no metals

109 Spent caustic
110 Caustic aqueous waste
111 Aqueous waste with reactive sulfides
112 Aqueous waste with other reactives (e.g., explosives)
113 Other aqueous waste with high dissolved solids
114 Other aqueous waste with low dissolved solids
115 Scrubber water
116 Leachate
117 Waste liquid mercury
119 Other inorganic liquids (Specify in Comments)
198 Nonhazardous photographic chemical wastes (inorganic)
199 Brine solution that could also bear the form code 113
ORGANIC LIQUIDS - Waste that is primarily organic and is highly fluid, with low inorganic solids content and low-to-moderate water content
201 Concentrated solvent-water solution
202 Halogenated (e.g., chlorinated) solvent
203 Non-halogenated solvent
204 Halogenated/non-halogenated solvent mixture
205 Oil-water emulsion or mixture
206 Waste oil
207 Concentrated aqueous solution of other organics
208 Concentrated phenolics
209 Organic paint, ink, lacquer, or varnish
210 Adhesives or epoxies
211 Paint thinner or petroleum distillates
212 Reactive or polymerizable organic liquids
219 Other organic liquids (Specify in Comments)
296 Ethylene glycol based antifreeze
297 Nonhazardous liquids containing greater than or equal to ( ) 50 and less than ( ) 500 ppm PCBs
298 Nonhazardous liquids containing greater than or equal to ( ) 500 ppm PCBs
299 Nonhazardous photographic chemical waste (organic)
SOLIDS
INORGANIC SOLIDS - Waste that is primarily inorganic and solid, with low organic content and low-to-moderate water content; not pumpable
301 Soil Contaminated with organics
302 Soil contaminated with inorganics only
303 Ash, slag, or other residue from incineration of wastes
304 Other "dry" ash, slag, or thermal residue
305 "Dry" lime or metal hydroxide solids chemically "fixed"

306 "Dry" lime or metal hydroxide solids not "fixed"
307 Metal scale, filings, or scrap
308 Empty or crushed metal drums or containers
309 Batteries or battery parts, casings, cores
310 Spent solid filters or adsorbents
311 Asbestos solids and debris
312 Metal-cyanide salts/chemicals
313 Reactive cyanide salts/chemicals
314 Reactive sulfide salts/chemicals
315 Other reactive salts/chemicals
316 Other metal salts/chemicals
319 Other waste inorganic solids (Specify in Comments)
388 Empty or crushed glass containers
389 Nonhazardous sandblasting waste
390 Nonhazardous concrete/cement/construction debris
391 Nonhazardous dewatered wastewater treatment sludge
392 Nonhazardous dewatered air pollution control device sludge
393 Catalyst waste
394 Nonhazardous solids containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
395 Nonhazardous solids containing greater than or equal to ( ) 500 ppm PCBs
396 Nonhazardous electrical equipment/devices containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs.
397 Nonhazardous electrical equipment/devices containing greater than or equal to ( ) 500 ppm PCBs
398 Nonhazardous soils containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
399 Nonhazardous soils containing greater than or equal to ( ) 500 ppm PCBs
ORGANIC SOLIDS - Waste that is primarily organic and solid, with low-to-moderate inorganic content and water content; not pumpable
401 Halogenated pesticide solid
402 Non-halogenated pesticide solid
403 Solids resins or polymerized organics
404 Spent carbon
405 Reactive organic solid
406 Empty fiber or plastic containers
407 Other halogenated organic solids (Specify in Comments)
409 Other non-halogenated organic solids (Specify in Comments)
488 Wood debris
489 Petroleum contaminated solids
490 Sand blasting waste
491 Dewatered biological treatment sludge

492 Dewatered sewage or other untreated biological sludge
493 Catalyst waste
494 Solids containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
495 Solids containing greater than or equal to ( ) 500 ppm PCBs
496 Electrical equipment/devices containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs.
497 Electrical equipment/devices containing greater than or equal to ( ) 500 ppm PCBs
498 Soils containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
499 Soils containing greater than or equal to ( ) 500 ppm PCBs
SLUDGES
INORGANIC SLUDGES - Waste that is primarily inorganic, with moderate-to-high water content and low organic content, and pumpable
501 Lime sludge without metals
502 Lime sludge with metals/metal hydroxide sludge
503 Wastewater treatment sludge with toxic organics
504 Other wastewater treatment sludge
505 Untreated plating sludge without cyanides
506 Untreated plating sludge with cyanides
507 Other sludge with cyanides
508 Sludge with reactive sulfides
509 Sludge with other reactives
510 Degreasing sludge with metal scale or filings
511 Air pollution control device sludge (e.g., fly ash, wet scrubber sludge)
512 Sediment or lagoon dragout contaminated with organics
513 Sediment or lagoon dragout contaminated with inorganics only
514 Drilling mud
515 Asbestos slurry or sludge
516 Chloride or other brine sludge
519 Other inorganic sludges (Specify in Comments)
597 Catalyst waste
598 Nonhazardous sludges containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
599 Nonhazardous sludges containing greater than or equal to ( ) 500 ppm PCBs
ORGANIC SLUDGES - Waste that is primarily organic with low-to-
moderate inorganic solids content and water content, and pumpable
601 Still bottoms of halogenated (e.g., chlorinated) solvents or other organic liquids
602 Still bottoms of non-halogenated solvents or other organic liquids

603 Oily sludge
604 Organic paint or ink sludge
605 Reactive or polymerizable organics
606 Resins, tars, or tarry sludge
607 Biological treatment sludge
608 Sewage or other untreated biological sludge
609 Other organic sludges (Specify in Comments)
695 Petroleum contaminated sludges other than still bottoms and oily sludges
696 Grease
697 Catalyst waste
698 Nonhazardous sludges containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
699 Nonhazardous sludges containing greater than or equal to ( ) 500 ppm PCBs
GASES
INORGANIC GASES - Waste that is primarily inorganic with a low organic content and is a gas at atmospheric pressure
701 Inorganic gases
ORGANIC GASES - Waste that is primarily organic with low-to-moderate inorganic content and is a gas at atmospheric pressure
801 Organic gases
PLANT TRASH
902 Supplemental plant production refuse - Class 2 waste from production, manufacturing, or laboratory operations. The total amount of the supplemental plant production refuse shall not exceed 20% of the annual average of the total plant refuse (form code 999) volume or weight, whichever is less.
999 Plant Trash - Class 2 waste originating in the facility offices or plant production area that is composed of paper, cardboard, linings, wrappings, paper and/or wooden packaging materials, food wastes, cafeteria waste, glass, aluminum foil, aluminum cans, aluminum scrap, stainless steel, steel, iron scrap, plastics, styrofoam, rope, twine, uncontaminated rubber, uncontaminated wooden materials, equipment belts, wirings, uncontaminated cloth, metal bindings, empty containers with a holding capacity of five gallons or less, uncontaminated floor sweepings, and/or food packaging, that are produced as a result of plant production, manufacturing, laboratory, general office, cafeteria, or food services operations. Personal cosmetics generated by facility personnel, excluding those cosmetics generated as a result of manufacturing or plant production operations.

(d) Appendix 4.

Figure: 30 TAC §335.521(d) (No change to the figure as it currently exists in TAC.)

Appendix 4. Seven-Day Distilled Water Leachate Test

This test is intended only for dry, solid wastes, i.e., waste materials without any free liquids.

1. Place a 250 gm. (dry weight) representative sample of the waste material in a 1,500 ml. Erlenmayer flask.

2. Add one liter of deionized or distilled water into the flask and mechanically stir the material at a low speed for five minutes.

3. Stopper the flask and allow to stand for seven days.

4. At the end of seven days, filter the supernatant solution through a .45-micron filter, collecting the supernatant into a separate flask.

5. Subject the filtered leachate to the appropriate analysis.

SUBCHAPTER T: PERMITTING STANDARDS FOR OWNERS AND OPERATORS OF COMMERCIAL INDUSTRIAL NONHAZARDOUS WASTE LANDFILL FACILITIES

§335.590

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.590. Operational and Design Standards.

The following requirements, including those applicable to municipal solid waste facilities, apply to owners and operators of facilities subject to this subchapter:

(1) §330.121 of this title (relating to General);

(2) §330.123 of this title (relating to Pre-operation Notice);

(3) §330.125 of this title (relating to Recordkeeping Requirements), except that the requirements under §330.125(b)(3) of this title concerning recordkeeping for gas monitoring and remediation plans relating to explosive and other gases do not apply, except as determined necessary by the executive director;

(4) §330.127 of this title (relating to Site Operating Plan);

(5) §330.129 of this title (relating to Fire Protection);

(6) §330.131 of this title (relating to Access Control);

(7) §330.133(a) - (c) of this title (relating to Unloading of Waste);

(8) §330.137 of this title (relating to Site Sign);

(9) §330.139 of this title (relating to Control of Windblown Waste and Litter);

(10) §330.141 of this title (relating to Easements and Buffer Zones);

(11) §330.143(a) of this title (relating to Landfill Markers and Benchmark);

(12) §330.149 of this title (relating to Odor Management Plan);

(13) §330.153 of this title (relating to Site Access Roads);

(14) §330.155 of this title (relating to Salvaging and Scavenging);

(15) §330.157 of this title (relating to Endangered Species Protection);

(16) §330.159 of this title (relating to Landfill Gas Control) as determined necessary by the executive director;

(17) §330.161 of this title (relating to Oil, Gas, and Water Wells);

(18) §330.163 of this title (relating to Compaction);

(19) §330.165 of this title (relating to Landfill Cover);

(20) §330.167 of this title (relating to Ponded Water);

(21) §330.175 of this title (relating to Visual Screening of Deposited Waste);

(22) §330.207 of this title (relating to Contaminated Water Management);

(23) the owner or operator shall have and follow procedures for the suppression and control of dust; and

(24) the owner or operator shall ensure that each commercial industrial nonhazardous waste landfill unit meets the requirements of subparagraphs (A) - (F) of this paragraph.

(A) Design criteria.

(i) Landfill cells shall be designed and constructed in accordance with subclause (I) or (II) of this clause, and shall also be constructed in accordance with subclause (III) of this clause.

(I) a design that ensures that the concentration values for constituents listed in §330.419(a) of this title (relating to Constituents for Detection Monitoring) will not be exceeded in the uppermost aquifer at the point of compliance, as specified by the executive director under clause (iv) of this subparagraph; or

(II) a composite liner, as defined in clause (ii) of this subparagraph, and a leachate collection system that is designed and constructed in accordance with subparagraph (B) of this paragraph; and

(III) unless the executive director approves an engineered design that the applicant has demonstrated will provide equal or greater protection to human health and the environment, a landfill cell must be constructed where the base of the containment structure, which includes the sides and bottom of the containment structure, is at least five feet above the uppermost saturated soil unit having a Unified Soil Classification of GW (well-graded gravel), GP (poorly-graded gravel), GM (silty gravel), GC (clayey gravel), SW (well-graded sand), SP (poorly-graded sand), or SM (silty sand), or a hydraulic conductivity greater than 1×10^{-5} cm/sec, unless such saturated soil unit is not sufficiently thick and laterally continuous to provide a significant pathway for waste migration.

(ii) For purposes of this section, "composite liner" means a system consisting of two components. The upper component shall consist of a

minimum 30-mil (0.75 mm) geomembrane liner and the lower component shall consist of at least a three-foot layer of compacted soil with a hydraulic conductivity of no more than 1 x 10-7 cm/sec. Geomembrane liner components consisting of high density polyethylene shall be at least 60-mil thick. The geomembrane liner component must be installed in direct and uniform contact with the compacted soil component.

(iii) When approving a design that complies with clause (i)(I) of this subparagraph, the executive director may consider at least the following factors:

(I) the hydrogeologic characteristics of the facility and surrounding land;

(II) the climatic factors of the area; and

(III) the volume and physical and chemical characteristics of the leachate.

(iv) For purposes of this paragraph, the point of compliance is defined in §330.3 of this title (relating to Definitions). In determining the point of compliance, the executive director may consider at least the following factors:

(I) the hydrogeologic characteristics of the facility and surrounding land;

(II) the volume and physical and chemical characteristics of the leachate;

(III) the quantity, quality, and direction of flow of groundwater;

(IV) the proximity and withdrawal rate of the groundwater users;

(V) the availability of alternative drinking water supplies;

(VI) the existing quality of the groundwater, including other sources of contamination and their cumulative impacts on the groundwater and whether groundwater is currently used or reasonably expected to be used for drinking water;

(VII) public health, safety, and welfare effects; and

(VIII) practicable capability of the owner or operator.

(B) Landfill cells shall have a leachate-collection system designed and constructed to maintain less than a 30-cm depth of leachate over the liner. The leachate-collection and leachate-removal system shall be:

(i) constructed of materials that are chemically resistant to the leachate expected to be generated;

(ii) of sufficient strength and thickness to prevent collapse under the pressures exerted by overlying wastes, waste cover materials, and by any equipment used at the landfill; and

(iii) designed and operated to function through the scheduled closure and post-closure period of the landfill.

(C) Storm water run-on/run-off facilities such as berms and ditches shall be provided in accordance with §330.63 of this title (relating to Contents of Part III of the Application).

(D) The site shall have a groundwater monitoring system installed that is capable of detecting the migration of pollutants from the landfill and is sampled semiannually for the parameters specified in Chapter 330, Subchapter J of this title (relating to Groundwater Monitoring and Corrective Action).

(E) The final cover placed over the commercial industrial nonhazardous waste landfill unit shall consist of a minimum of 18 inches of uncontaminated topsoil overlying four feet of compacted clay-rich soil material meeting the requirements of §330.457 of this title (relating to Closure Requirements for Municipal Solid Waste Landfill Units That Receive Waste on or after October 9, 1993). The final cover over the aerial fill shall meet the requirements of §330.457 of this title and shall include a flexible membrane component.

(F) Nonhazardous waste may be placed above natural grade in commercial industrial nonhazardous waste landfill units provided the conditions in clauses (i) - (vi) of this subparagraph are met, except as provided in clause (vii) of this subparagraph:

(i) waste placed above grade shall be laterally contained by dikes that are constructed to:

(I) prevent washout, release, or exposure of waste;

(II) be physically stable against slope failure, with a minimum safety factor of 1.5;

(III) prevent washout from hydrostatic and hydrodynamic forces from storms and floods;

(IV) prevent storm water from reaching the waste;

(V) minimize release of leachate; and

(VI) minimize long-term maintenance;

(ii) the liner required in paragraph (22) of this section shall extend to the crest of the dike;

(iii) waste placed against the dike is placed no higher that three feet below the crest of the dike;

(iv) the slope of the wastes placed in the commercial industrial nonhazardous waste landfill units does not exceed 3% to the center of the unit;

(v) no waste is placed higher than the lowest elevation of the dike crest; and

(vi) a dike certification report is submitted with Attachment 10 of Part III of the permit application. The certification shall be in the following form:

Figure: 30 TAC §335.590(24)(F)(vi) (No change to the figure as it currently exists in TAC.)

"I (Texas Licensed Professional Engineer), Texas P.E. Registration Number _____, certify under penalty of law that I have personally examined and am familiar with the design and construction of the dikes that are a portion of (unit name).
I further certify that I have evaluated the dike design and materials of construction using accepted engineering procedures, and have determined that the dike has structural integrity, and:

(I) Will withstand the stress of the pressure exerted by the types and amounts of wastes to be placed in the unit; and

(II) Will not fail due to scouring or piping, without dependence on any liner system included in the unit construction.

(Signature) Date: _____

(SEAL)"

(vii) a commercial industrial nonhazardous waste landfill is not subject to the requirements of clauses (ii) - (v) of this subparagraph provided that the owner or operator submits a demonstration that the standards of clause (i) of this subparagraph can be met without meeting the requirements of clauses (ii) - (v) of this subparagraph, the demonstration is approved in writing by the executive director, and the owner or operator enters the approval into the facility operating record.

(25) Hazardous waste generated by a very small quantity generator that meets the conditions for exemption for a very small quantity generator [from a conditionally exempt small quantity generator as defined in §335.78(a) of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators),] may be accepted for disposal in a [any] commercial industrial nonhazardous waste landfill facility provided the amount of hazardous waste accepted from each very [conditionally exempt] small quantity generator does not exceed 220 pounds (100 kilograms) a calendar month, and provided the landfill owner or operator is willing to accept the hazardous waste.

SUBCHAPTER U: STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE FACILITIES OPERATING UNDER A STANDARD PERMIT

§335.602

Statutory Authority

The amendment is adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendment implements THSC, Chapter 361.

§335.602. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 267 (including all appendices to 40 CFR Part 267) are adopted by reference as amended in the *Federal Register* through September 8, 2005 (70 FR 53420) and as further amended and adopted as indicated in each paragraph of this subsection:

(1) 40 CFR Part 267, Subpart B--General Facility Standards;

(2) 40 CFR Part 267, Subpart C--Preparedness and Prevention:

(3) 40 CFR Part 267, Subpart D--Contingency Plan and Emergency Procedures;

(4) 40 CFR Part 267, Subpart E--Recordkeeping, Reporting, and Notifying (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732 [85696]);

(5) 40 CFR Part 267, Subpart F--Releases from Solid Waste Management Units;

(6) 40 CFR Part 267, Subpart G--Closure;

(7) 40 CFR Part 267, Subpart I--Use and Management of Containers;

(8) 40 CFR Part 267, Subpart J--Tank Systems;

(9) 40 CFR Part 267, Subpart DD--Containment buildings; and

(10) 40 CFR §267.142, concerning Cost estimate for closure.

(b) The regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality or to the commission, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B.

(2) Reference to:

(A) 40 CFR Part 261 is changed to §335.504 of this title (relating to Hazardous Waste Determination);

(B) 40 CFR Part 262 is changed to Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste):

(C) 40 CFR §264.1 is changed to §335.151 of this title (relating to Purpose, Scope, and Applicability);

(D) Reference to 40 CFR Part 264, Subpart D is changed to §335.152(a)(3) of this title (relating to Standards) and §335.153 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator);

(E) 40 CFR Part 264, Subpart S is changed to §335.152(a)(14) of this title;

(F) 40 CFR Part 265 is changed to Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities);

(G) 40 CFR Part 268 is changed to Subchapter O of this chapter (relating to Land Disposal Restrictions);

(H) 40 CFR Part 270, Subpart J is changed to Chapter 305, Subchapter R of this title (relating to Resource Conservation and Recovery Act Standard Permits for Storage and Treatment Units);

(I) 40 CFR §262.16 or §262.17 are [§262.34 is] changed to §335.53 [§335.69] of this title (relating to General Standards Applicable to Generators of Hazardous Waste [Accumulation Time]);

(J) 40 CFR §264.101 is changed to §335.167 of this title (relating to Corrective Action for Solid Waste Management Units); and

(K) Reference to "standardized permit" is changed to "standard permit".

(3) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapters 50, 305, and 335 of this title (relating to Action on Applications and Other Authorizations; Consolidated Permits; and Industrial Solid Waste and Municipal Hazardous Waste, respectively), as applicable.

(c) An owner or operator of a unit that treats, stores, or disposes of hazardous waste in tanks, containers, and containment buildings authorized by a standard permit as specified in this section shall establish and maintain financial assurance in accordance with Chapter 37, Subchapter P of this title (relating to Financial Assurance for Hazardous and Nonhazardous Industrial Solid Waste Facilities).

SUBCHAPTER V: STANDARDS FOR RECLAMATION OF HAZARDOUS SECONDARY MATERIALS

§335.702, §335.703

Statutory Authority

The amendments are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted amendments implement THSC, Chapter 361.

§335.702. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 261 (including all appendices to 40 CFR Part 261) are adopted by reference as amended and adopted in the CFR through January 13, 2015 (80 FR 1694) and as further amended and adopted as indicated in each paragraph of this subsection:

(1) 40 CFR Part 261, Subpart I--Use and Management of Containers;

(2) 40 CFR Part 261, Subpart J--Tank Systems:

(3) 40 CFR Part 261, Subpart M--Emergency Preparedness and Response for Management of Excluded Hazardous Secondary Materials as amended through November 28, 2016 (81 FR 85732), except all references to "operating under a verified recycler variance under 40 CFR §260.31(d)";

(4) 40 CFR Part 261, Subpart AA--Air Emission Standards for Process Vents;

(5) 40 CFR Part 261, Subpart BB--Air Emission Standards for Equipment Leaks; and

(6) 40 CFR Part 261, Subpart CC--Air Emission Standards for Tanks and Containers.

(b) The regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B;

(2) 40 CFR §260.10 is changed to §335.1 of this title [chapter] (relating to Definitions);

(3) The terms "EPA" and "Environmental Protection Agency" are changed to "Texas Commission on Environmental Quality."

§335.703. Financial Assurance Requirements.

(a) Applicability.

(1) The requirements of this section apply to owners or operators of reclamation facilities and intermediate facilities managing hazardous secondary materials excluded under 40 Code of Federal Regulations (CFR) §261.4(a)(24), except:

(2) States and the Federal government are exempt from the financial assurance requirements of this section.

(b) When used in this section, the following words and terms shall have the same meanings as the definitions in §37.11 and §335.1 of this title (relating to Definitions) except:

(1) Closure--Includes the activities under §335.8 of this title (relating to Closure and Remediation) and applicable closure requirements of 40 CFR Parts 264 and 265.

(2) Closure plan--Includes the removal and decontamination plan for release as set out in §335.705 of this title (relating to Removal and Decontamination Plan for Release).

(c) Owners and operators of a reclamation facility or an intermediate facility required by 40 CFR §261.4(a)(24) to provide financial assurance, shall establish and maintain financial assurance for removal and decontamination and corrective action as a condition of the exclusion under 40 CFR §261.4(a)(24) and comply with Chapter 37,

Subchapters A and B of this title (relating to General Financial Assurance Requirements; and Financial Assurance Requirements for Closure, Post Closure, and Corrective Action) except:

(1) an owner or operator must submit an acceptable originally signed mechanism to the executive director prior to [receiving a variance for] the management of hazardous secondary materials under the exclusion in 40 CFR §261.4(a)(24);

(2) in addition to the reasons to draw specified in §37.101 of this title (relating to Drawing on the Financial Assurance Mechanisms), the executive director may draw on the financial assurance mechanism(s) following a determination by the executive director that the hazardous secondary materials do not meet the conditions of the exclusion under 40 CFR §261.4(a)(24).

(d) Owners or operators of a reclamation facility or intermediate facility required by 40 CFR §261.4(a)(24) to provide financial assurance must comply with Chapter 37, Subchapter C of this title (relating to Financial Assurance Mechanisms for Closure, Post Closure, and Corrective Action), by establishing financial assurance for removal and decontamination and corrective action using any of the following mechanisms as specified in Chapter 37, Subchapter C of this title:

(1) Trust fund (fully funded), except reimbursements to the owner or operator as specified under §37.201(j) of this title (relating to Trust Fund) may only be

made if the owner or operator begins final closure under the applicable requirements of 40 CFR Part 264 or 265;

(2) Surety bond guaranteeing payment, except:

(A) the bond must guarantee that the owner or operator will fund the standby trust fund in an amount equal to the penal sum of the bond before the loss of the exclusion under 40 CFR §261.4(a)(24) rather than the criteria set out in §37.211(d) of this title (relating to Surety Bond Guaranteeing Payment); and

(B) the alternate financial assurance to be provided by the Principal must meet the requirements specified in this section;

(3) Irrevocable standby letter of credit, except:

(A) the executive director may draw pursuant to subsection (c)(2) of this section in addition to §37.231 of this title (relating to Irrevocable Standby Letter of Credit); and

(B) alternate financial assurance must meet the requirements specified in this section;

(4) Financial test, except:

(A) the financial assurance amounts required by this section, for hazardous secondary materials must be included as an additional environmental obligation when determining eligibility for the financial test in accordance with §37.251 of this title (relating to Financial Test); and

(B) alternate financial assurance must meet the requirements of this section;

(5) Corporate guarantee except:

(A) the terms of the guarantee specified in §37.261(e)(1) of this title (relating to Corporate Guarantee), shall provide that following a determination by the executive director that the hazardous secondary materials at the owner or operator's facility covered by this guarantee do not meet the requirements of the exclusion under 40 CFR §261.4(a)(24) the guarantor will dispose of any hazardous secondary material as hazardous waste and close the facility in accordance with the applicable closure requirements of 40 CFR Part 264 or 265, or establish a trust fund as specified in this section, in the name of the owner or operator in the amount of the current cost estimate; and

(B) the terms of the guarantee requiring alternate financial assurance in §37.261(e)(3) of this title must meet the requirements of this section.

(e) Owners or operators of a reclamation facility or intermediate facility required by 40 CFR §261.4(a)(24) to provide financial assurance for removal and decontamination and corrective action shall comply with the wording requirements of Chapter 37, Subchapter D of this title (relating to Wording of the Mechanisms for Closure, Post Closure and Corrective Action) for the mechanisms indicated in subsection (d) of this section except:

(1) the phrases in the Payment Bond under §37.311 of this title (relating to Payment Bond) shall be revised by:

(A) replacing the following language identified here by quotation marks "Now, therefore, the conditions of the obligation are such that if the Principal shall faithfully, before the beginning of final closure of, or corrective action at, each facility identified above, fund into the standby trust fund the amount(s) identified above for the facility," with the following language identified here by quotation marks "Now, therefore, the conditions of the obligation are such that if the Principal shall faithfully, before the beginning of final closure of, or corrective action at, each facility identified above, fund into the standby trust fund the amount(s) identified above for the facility; or, if the Principal shall satisfy all the requirements for exclusion of hazardous secondary materials from classification as solid waste under 40 CFR §261.4(a)(24) and be released from the financial assurance requirements by the executive director"; and

(B) replacing the following language identified here by quotation marks "Or, if the Principal shall provide alternate financial assurance, as specified in 30 Texas Administrative Code, Chapter 37 (relating to Financial Assurance)" with the following language set off here by quotation marks "Or, if the Principal shall provide alternate financial assurance, as specified in 30 Texas Administrative Code, §335.703 (relating to Financial Assurance Requirements)"; and

(C) replacing the certification statement at the end of the Payment Bond with the following statement identified by quotation marks "The persons whose signatures appear below hereby certify that they are authorized to execute this surety bond on behalf of the Principal and Surety(ies) and that the wording of this surety bond is identical to the wording specified in 30 Texas Administrative Code §37.311 (relating to Payment Bond), as modified by 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements), as such regulations were constituted on the date the bond was executed.";

(2) The Chief Financial Officer's letter associated with the financial test specified in §37.351 of this title (relating to Financial Test), shall include the environmental obligations associated with the exclusion in paragraph 5(f) of the Chief Financial Officer's Letter in Figure: 30 TAC §37.351;

(3) The wording of the Corporate Guarantee required by §37.361 of this title (relating to Corporate Guarantee) shall be revised by:

(A) replacing Recital number 4 with "For value received from (owner or operator) (describe consideration and dollar amount), guarantor guarantees to the TCEQ that in the event of a determination by the executive director that the hazardous secondary materials at the owner or operator's facility covered by this guarantee do not meet the conditions of the exclusion under 40 CFR §261.4(a)(24), the guarantor will dispose of any hazardous secondary material as hazardous waste, and close the facility in accordance with the applicable closure requirements of 40 CFR Part 264 or 265, or establish a trust fund as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements) in the name of the (owner or operator) in the amount of the current cost estimate";

(B) replacing Recital number 5 with "Guarantor agrees that if, at the end of any fiscal year before termination of this guarantee, the guarantor fails to meet the financial test criteria, guarantor shall send within 90 days, by certified mail, notice to the TCEQ executive director and to (owner or operator) that the guarantor intends to provide alternate financial assurance as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements), as applicable, in the name of (owner or operator). Within 120 days after the end of such fiscal year, the guarantor shall establish such financial assurance unless (owner or operator) has done so";

(C) replacing Recital number 7 with "Guarantor agrees that within 30 days after being notified by the TCEQ executive director of a determination that guarantor no longer meets the financial test criteria or is disallowed from continuing as a guarantor of (closure, post closure, or corrective action), guarantor shall establish alternate financial assurance as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements) in the name of (owner or operator) unless (owner or operator) has done so";

(D) replacing Recital number 11 with "Guarantor agrees that if (owner or operator) fails to provide alternate financial assurance as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements), and obtain written approval of alternate financial assurance from the TCEQ executive director within 90 days after a notice of termination by the guarantor is received by the TCEQ executive director from guarantor, guarantor shall provide such alternate financial assurance in the name of the (owner or operator)"; and

(E) The wording of the certification statement at the end of the Corporate Guarantee shall be replaced with the following language identified by quotation marks "I hereby certify that the wording of this guarantee is identical to the wording specified in 30 Texas Administrative Code §37.361 (relating to Corporate Guarantee) as modified by 30 Texas Administrative Code §335.703 (relating to

Financial Assurance Requirements) as such regulations were constituted on the date first above written."

(f) An owner or operator of a reclamation or intermediate facility, or a group of facilities, subject to financial assurance requirements under 40 CFR §261.4(a)(24) shall establish and maintain financial assurance for bodily injury and property damage to third parties caused by sudden accidental occurrences arising from operations of the facility or group of facilities. The owner or operator must have and maintain liability coverage for sudden accidental occurrences in the amount of at least $1 million per occurrence with an annual aggregate of at least $2 million, exclusive of legal defense costs.

(g) An owner or operator of a reclamation or intermediate facility, or group of facilities, with a land-based unit as defined in §335.1 of this title shall establish and maintain financial assurance for bodily injury and property damage to third parties caused by nonsudden accidental occurrences arising from operations of the facility or group of facilities. The owner or operator must have and maintain liability coverage for nonsudden accidental occurrences in the amount of at least $3 million per occurrence with an annual aggregate of at least $6 million, exclusive of legal defense costs.

(h) An owner or operator who must meet the requirements of subsections (f) and (g) of this section may combine the required per-occurrence coverage levels for sudden and nonsudden [non-sudden] accidental occurrences into a single per-

occurrence level, and combine the required annual aggregate level. Owners or operators who combine coverage levels for sudden and nonsudden [non-sudden] accidental occurrences must maintain liability coverage in the amount of $4 million per occurrence and $8 million annual aggregate.

(i) Owners or operators of a reclamation facility or intermediate facility, or a group of facilities, subject to financial assurance requirements under 40 CFR §261.4(a)(24) must also comply with Chapter 37, Subchapters A and E of this title (relating to General Financial Assurance Requirements; and Financial Assurance Requirements for Liability Coverage) and shall use any of the mechanisms specified in Chapter 37, Subchapter F of this title (relating to Financial Assurance Mechanisms for Liability) to meet the liability requirements of this section except:

(1) liability insurance may only be demonstrated by providing an Endorsement for Liability as specified in §37.641 of this title (relating to Endorsement for Liability); and

(2) when using the financial test in accordance with §37.541 of this title (relating to Financial Test for Liability) the financial assurance amounts required by of this section, for hazardous secondary materials excluded under 40 CFR §261.4(a)(24) must be included as an additional environmental obligation.

(j) An owner or operator of a reclamation facility, an intermediate facility, or a group of facilities required by 40 CFR §261.4(a)(24) to provide financial assurance demonstrating liability coverage shall comply with the requirements of Chapter 37, Subchapter G of this title (relating to Wording of the Mechanisms for Liability) for the mechanisms required by subsection (i) of this section except The Chief Financial Officer's letter associated with the financial test for liability specified in §37.651 of this title (relating to Financial Test for Liability), must include the financial assurance amounts required by this section, for hazardous secondary materials excluded under 40 CFR §261.4(a)(24) as an additional environmental obligation in paragraph 5(f) of the Chief Financial Officer's Letter in Figure: 30 TAC §37.351.

(k) If the state of Texas either assumes legal responsibility for an owner's or operator's compliance with the closure, post closure, corrective action, or liability requirements of this chapter, or assures that funds will be available from state sources to cover those requirements, the owner or operator will be in compliance with the requirements of this chapter if the executive director determines that the state's assumption of responsibility is at least equivalent to the financial mechanisms specified in this chapter. The executive director will evaluate the equivalency of state guarantees principally in terms of certainty of the availability of funds for the required closure, post closure, or corrective action activities, or liability coverage; and the amount of funds that will be made available. The executive director may also consider other factors as the executive director deems appropriate. The owner or operator must submit to the executive director a letter from the State of Texas describing the nature

of the state's assumption of responsibility together with a letter from the owner or operator requesting that the state's assumption of responsibility be considered acceptable for meeting the requirements of this chapter. The letter from the state must include the following information: the facility's permit number and/or solid waste registration number, name, physical and mailing addresses, and the amount of funds for closure, post closure, or corrective action or liability coverage that are guaranteed by the state. The executive director will notify the owner or operator of the determination regarding the acceptability of the state's guarantee in lieu of financial mechanisms specified in this chapter. The executive director may require the owner or operator to submit additional information as is deemed necessary to make this determination. Upon approval by the executive director, the owner or operator will be deemed to be in compliance with the requirements of this chapter. If the State of Texas' assumption of responsibility is found acceptable as specified in this section except for the amount of funds available, the owner or operator may satisfy the requirements of this chapter by use of both the state's assurance and additional financial mechanisms as specified in this chapter. The amount of funds available through the state and the owner or operator's mechanisms shall equal at least the required amount.

SUBCHAPTER W: MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

§§335.751, 335.753, 335.755, 335.757, 335.759, 335.761, 335.763, 335.765, 335.767, 335.769, 335.771

Statutory Authority

The new rules are adopted under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The new rules are also adopted under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The adopted new rules implement THSC, Chapter 361.

§335.751. Definitions.

The following definitions apply to this subchapter:

(1) Evaluated hazardous waste pharmaceutical--A prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with §335.771(a)(3) of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

(2) Hazardous waste pharmaceutical--A pharmaceutical that is a solid waste, as defined in §335.1 of this title (relating to Definitions), and exhibits one or more characteristics identified in 40 Code of Federal Regulations (CFR) Part 261, Subpart C, or is listed in 40 CFR Part 261, Subpart D as these subparts are adopted by reference under §335.504 of this title (relating to Hazardous Waste Determination). A pharmaceutical is not a solid waste, as defined in §335.1 of this title, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in §335.1 of this title, and therefore not a hazardous waste pharmaceutical, if it has a reasonable

expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

(3) Healthcare facility--Any person that is lawfully authorized to:

(A) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure for the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(B) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

(4) Household waste pharmaceutical--A pharmaceutical that is a solid waste, as defined in §335.1 of this title (relating to Definitions), but is excluded from

being a hazardous waste under 40 Code of Federal Regulations §261.4(b)(1) as adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(5) Long-term care facility--A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

(6) Non-creditable hazardous waste pharmaceutical--A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

(7) Nonhazardous waste pharmaceutical--A pharmaceutical that is a solid waste, as defined in §335.1 of this title (relating to Definitions), and is not listed in 40

Code of Federal Regulations (CFR) Part 261, Subpart D, and does not exhibit a characteristic identified in 40 CFR Part 261, Subpart C.

(8) Non-pharmaceutical hazardous waste--A solid waste, as defined in §335.1 of this title (relating to Definitions), that is listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D or exhibits one or more characteristics identified in 40 CFR Part 261, Subpart C, but is not a pharmaceutical, as defined in this section.

(9) Pharmaceutical--Any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 Code of Federal Regulations §203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

(10) Potentially creditable hazardous waste pharmaceutical--A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and:

(A) is in original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(B) is undispensed;

(C) is unexpired or less than one year past expiration date; and

(D) is not an evaluated hazardous waste pharmaceutical.

(11) Reverse distributor--Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

§335.753. Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 40 Code of Federal Regulations (CFR) §262.14 as adopted under §335.53 of this title (relating to General

Standards Applicable to Generators of Hazardous Waste) and is not subject to this subchapter, except for §335.761 and §335.765 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; and Residues of Hazardous Waste Pharmaceuticals in Empty Containers) and the optional provisions of §335.759 of this title (relating to Healthcare Facilities That Are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste).

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with subsection (d) of this section for the management of its hazardous waste pharmaceuticals as an alternative to complying with 40 CFR §262.14 as adopted in §335.53 of this title and the optional provisions of §335.759 of this title.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations for the management of its non-pharmaceutical hazardous waste.

(d) Unless a healthcare facility is managing waste in compliance with subsection (a) of this section, a healthcare facility is subject to this subsection instead of Subchapters C, D, E, and F of this chapter (relating to Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment,

Storage, or Disposal Facilities; and Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) except as provided in this subchapter.

(1) A healthcare facility managing potentially creditable hazardous waste pharmaceuticals that are not destined for a reverse distributor or non-creditable hazardous waste pharmaceuticals must comply with §335.755 of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals) and §§335.761, 335.763, 335.765, and 335.767 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program; Residues of Hazardous Waste Pharmaceuticals in Empty Containers; and Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor).

(2) A healthcare facility managing potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor must comply with §335.755(a) and §335.757 (relating to Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals), §§335.761, 335.763, 335.765, and 335.769 of this title (relating to Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor).

(e) A reverse distributor is subject to §§335.761, 335.763, 335.765, 335.767, 335.769, and 335.771 of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors) of this title in lieu of Subchapters C, D, E or F of this chapter for the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this subchapter. Other generators are subject to Subchapter C of this chapter for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) Except as specified in this subsection and §335.4 of this title (relating to General Prohibitions), and unless the Commission finds or the executive director determines that industrial solid waste or recycling requirements are necessary to protect human health, the environment, or property, the following are not subject to this chapter:

(1) pharmaceuticals that are not solid waste, as defined by §335.1 of this title (relating to Definitions), because they are legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed;

(2) over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined in §335.1 of this title, because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed;

(3) pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration (FDA) in accordance with 21 CFR Part 7, Subpart C, until the FDA approves the destruction of the pharmaceuticals or the pharmaceuticals are discarded;

(4) pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR Part 1115, until the Consumer Product Safety Commission approves the destruction of the recalled pharmaceuticals;

(5) pharmaceuticals stored according to a preservation order, or stored in accordance with a litigation hold pursuant to an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded or the pharmaceuticals are discarded;

(6) investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR Part 312, until the decision is made to discard the investigational

new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste; and

(7) household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §335.763(a)(2) and §335.763(b) of this title.

(h) Healthcare facilities and reverse distributors regulated under this subchapter remain subject to Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter B of this chapter (relating to Hazardous Waste Management General Provisions), Subchapter O of this chapter (relating to Land Disposal Restrictions), and Subchapter R of this chapter (relating to Waste Classification), except as provided under this subchapter.

§335.755. Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals.

(a) Notification and withdrawal from this subchapter for healthcare facilities managing hazardous waste pharmaceuticals. A healthcare facility must notify the executive director that it is either subject to this subchapter, or is withdrawing from regulation under this subchapter, using the following procedures.

(1) Notification. A healthcare facility must notify the executive director that it is a healthcare facility operating under this subchapter using a method approved by the executive director within 60 days of becoming subject to this chapter. The method approved by the executive director collects the information required by the United States Environmental Protection Agency (EPA) Site Identification Form.

(A) A healthcare facility must submit a separate notification for each site or EPA identification number.

(B) A healthcare facility is not required to submit EPA hazardous waste numbers with this notification.

(C) A healthcare facility must retain a copy of a notification as long as the healthcare facility is subject to this subchapter.

(2) Withdrawal. A healthcare facility that elects to withdraw from this subchapter because it is a very small quantity generator that meets the conditions for exemption for a very small quantity generator under 40 Code of Federal Regulations (CFR) §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) must notify the executive director that it elects to withdraw from this subchapter using a method approved by the executive director. A healthcare facility is not required to submit any EPA hazardous waste

numbers with this notification. A healthcare facility must submit a separate notification for each site or EPA identification number.

(A) A healthcare facility must submit the notification that it is withdrawing from this subchapter in accordance with this paragraph before it begins operating under the conditions for exemption of a very small quantity generator in 40 CFR §262.14 as adopted under §335.53 of this title.

(B) A healthcare facility must retain a copy of a notification of withdrawal for three years from the date of the signature on the notification of withdrawal.

(b) Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Hazardous waste determination for non-creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical by determining if it exhibits a characteristic identified in 40 CFR Part 261, Subpart C or is listed in 40 CFR Part 261, Subpart D as adopted under §335.504 of this title (relating to

Hazardous Waste Determination) in order to determine whether the waste is subject to this subchapter. A healthcare facility may elect to manage its nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subchapter.

(d) Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must store containers containing non-creditable hazardous waste pharmaceuticals in accordance with the following container management standards.

(1) Container requirements. A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) Ignitable, reactive, or incompatible wastes. A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(E) through other like means threaten human health or the environment.

(3) Container security. A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) Accumulating non-creditable waste pharmaceuticals in the same container. A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and nonhazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of 40 CFR §268.3(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability)

must be accumulated in separate containers and labeled with all applicable EPA hazardous waste numbers.

(e) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must observe the following standards for on-site accumulation time of non-creditable hazardous waste pharmaceuticals.

(1) Maximum accumulation time. A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for one year or less without a permit or having interim status.

(2) Accumulation start date. A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(A) marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(B) maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(C) placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) Land disposal restrictions for non-creditable hazardous waste pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR Part 268 as adopted under Subchapter O of this chapter (relating to Land Disposal Restrictions). A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with 40 CFR §268.7(a) requirements as adopted under §335.431 of this title, except that it is not required to include the EPA hazardous waste numbers on the land disposal restrictions notification.

(h) Procedures for healthcare facilities for managing rejected shipments of non-

creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 40 CFR §264.72 as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.72 as adopted under §335.112 of this title (relating to Standards) may accumulate the returned non-creditable hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with subsections (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must complete the following.

(1) Healthcare facility manifest signature. The healthcare facility must sign either:

(A) item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) item 20 of the new manifest, if a new manifest was used for the returned shipment.

(2) Transporter manifest copy. The healthcare facility must provide the transporter a copy of the manifest used for the returned shipment.

(3) Designated facility manifest copy. Within 30 days of receipt of the rejected shipment, the healthcare facility must send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Maximum time to re-ship a rejected shipment. Within 90 days of receipt of the rejected shipment, the healthcare facility must transport or offer for transport the returned shipment in accordance with the shipping standards of §335.767(a) of this title (relating to Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor).

(i) Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals. A healthcare facility must comply with the following reporting requirements.

(1) Biennial and annual waste reporting by healthcare facilities. A healthcare facility is not subject to the Annual Waste Summary reporting requirements under §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators) or the biennial reporting requirements under 40 CFR §262.41 as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators) for non-creditable hazardous waste pharmaceuticals managed under this subchapter.

(2) Exception reporting by healthcare facilities for a missing copy of the manifest. A healthcare facility must submit an exception report to the executive director in the following situations.

(A) For shipments from a healthcare facility to a designated facility, if a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(i) a legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the executive director; and

(ii) a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility, if a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is

forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(i) a legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the executive director; and

(ii) a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(3) Additional reports. The executive director may require a healthcare facility to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals. A healthcare facility is subject to the following recordkeeping requirements.

(1) Signed manifest retention. A healthcare facility must keep a copy of each manifest signed in accordance with 40 CFR §262.23(a) as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) Exception report retention. A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) Waste determination documentation retention. A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with 40 CFR §262.11(f) as adopted under §335.53 of this title, for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all its non-creditable nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) Documentation retention extension. The periods of retention referred to in this section are extended automatically during the course of any unresolved

enforcement action regarding the regulated activity, or as requested by the executive director.

(5) Record inspections. All records must be readily available upon request by an inspector.

(k) Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subchapter.

(l) Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under 40 CFR §262.14 as adopted under §335.53 of this title, without a permit or without having interim status, if the receiving healthcare facility complies with the following.

(1) Consolidating waste pharmaceuticals at another healthcare facility under the control of the same person. The healthcare facility must be under the control of the same person as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site or has a

contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility. "Control," for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person shall not be deemed to "control" such healthcare facilities.

(2) Operating under this subchapter. The healthcare facility must be operating under this subchapter for the management of its non-creditable hazardous waste pharmaceuticals.

(3) Compliance with this subchapter. The healthcare facility must manage the non-creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subchapter.

(4) Recordkeeping requirements. The healthcare facility must keep records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off-site for three years from the date that the shipment is received.

§335.757. Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals.

(a) Hazardous waste determination for potentially creditable pharmaceuticals. A

healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical by determining if it is listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D or exhibits a characteristic identified in 40 CFR Part 261, Subpart C as adopted under §335.504 of this title (relating to Hazardous Waste Determination). A healthcare facility may choose to manage its potentially creditable nonhazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subchapter.

(b) Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under 40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) without a permit or without having interim status, provided the receiving healthcare facility:

(1) is under the control of the same person as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off-site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) is operating under this subchapter for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) manages the potentially creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subchapter; and

(4) keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off-site for three years from the date that the shipment is received.

(c) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) Biennial and Annual Waste Summary reporting by healthcare facilities. A healthcare facility is not subject to the Annual Waste Summary reporting requirements under §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators) or the biennial reporting requirements in 40 CFR §262.41 as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators) for potentially creditable hazardous waste pharmaceuticals managed under this subchapter.

(e) Recordkeeping by healthcare facilities. Healthcare facilities are subject to the

following recordkeeping requirements for managing potentially creditable hazardous waste pharmaceuticals.

(1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(A) the confirmation of delivery; and

(B) the shipping papers prepared in accordance with 49 CFR Part 172, Subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(3) All records must be readily available upon request by an inspector.

(f) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this

subchapter.

§335.759. Healthcare Facilities That are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste.

(a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) the receiving healthcare facility meets the conditions in §335.755(l) and §335.757(b) of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals; Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals), as applicable; or

(2) the very small quantity generator healthcare facility meets the conditions in 40 Code of Federal Regulations (CFR) §262.14(a)(5)(viii) and the receiving

large quantity generator meets the conditions in 40 CFR §262.17(f), both as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(c) Long-term care facilities that are very small quantity generators. A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) Long-term care facilities with 20 beds or fewer. A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to 40 CFR §262.14 as adopted under §335.53 of this title for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this subchapter, except for §335.761 and §335.765 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; and Residues of Hazardous Waste Pharmaceuticals in Empty Containers) and the other optional provisions of this section. A long-term care facility with 20 beds or fewer is subject to this subchapter if the executive director determines that the facility generates quantities of hazardous

waste in excess of the very small quantity generator limits as defined in §335.1 of this title (relating to Definitions). A long-term care facility with more than 20 beds that operates as a very small quantity generator under 40 CFR §262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by §335.1 of this title.

§335.761. Prohibition of Sewering Hazardous Waste Pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under 40 Code of Federal Regulations (CFR) §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) in lieu of this subchapter —and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR §403.5(b)(1).

§335.763. Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program.

(a) Conditional exemptions. Provided the conditions of subsection (b) of this section are met, the following are exempted from the requirements of this chapter:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 Code of Federal Regulations (CFR) Part 1308; and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) Conditions for exemption. The hazardous waste pharmaceuticals must be:

(1) managed in compliance with the sewer prohibition of §335.761 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals);

(2) collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(A) a permitted large municipal waste combustor, subject to 40 CFR Part 62, Subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR Part 60, Subpart Eb for new large municipal waste combustors;

(B) a permitted small municipal waste combustor, subject to 40 CFR Part 62, Subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR Part 60, Subpart AAAA for new small municipal waste combustors;

(C) a permitted hospital, medical and infectious waste incinerator, subject to 40 CFR Part 62, Subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR Part 60, Subpart Ec for new hospital, medical and infectious waste incinerators;

(D) a permitted commercial and industrial solid waste incinerator, subject to 40 CFR Part 62, Subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR Part 60, Subpart CCCC for new commercial and industrial solid waste incinerators; or

(E) a permitted hazardous waste combustor subject to 40 CFR Part 63, Subpart EEE.

§335.765. Residues of Hazardous Waste Pharmaceuticals in Empty Containers.

(a) Stock, dispensing and unit-dose containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under this subchapter provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subchapter and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) Intravenous (IV) bags. An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this

subchapter, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as described in §335.41(f) of this title (relating to Purpose, Scope, and Applicability).

(d) Other containers, including delivery devices. Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subchapter, unless the container held non-acute hazardous waste pharmaceuticals and is empty as described in §335.41(f) of this title. This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§335.767. Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor.

(a) Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with this subsection.

(1) The healthcare facility and reverse distributor must comply with the pre-transport requirements in this paragraph before transporting or offering non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals for transport off-site.

(A) Packaging. Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 Code of Federal Regulations (CFR) Parts 173, 178, and 180.

(B) Labeling. Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR Part 172, Subpart E.

(C) Marking. Mark hazardous waste pharmaceuticals in accordance with this subparagraph.

(i) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable federal Department of Transportation (DOT) regulations on hazardous materials under 49 CFR Part 172, Subpart D.

(ii) Mark each container of 119 gallons or less used in such transportation in accordance with 40 CFR §266.508(a)(1)(iii)(B) which is adopted by reference as adopted in the *Federal Register* on February 22, 2019 (84 FR 5940).

(iii) Lab packs that will be incinerated in compliance with 40 CFR §268.42(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste number(s).

(D) Placarding. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR Part 172, Subpart F.

(2) The healthcare facility and reverse distributor must comply with the manifest requirements of 40 CFR Part 262, Subpart B as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) and list a complete Texas waste code in Item 13 of the manifest), except:

(A) a healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable EPA hazardous waste numbers in Item 13 of the manifest; and

(B) a healthcare facility shipping non-creditable hazardous waste pharmaceuticals must use the four-letter sequence code "PHRM" in addition to the applicable Texas form code and classification code in Item 13 of the manifest.

(b) Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal).

(c) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR Part 262, Subpart H, as adopted by reference under §335.58 of this title, Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter B of this chapter (relating to Hazardous Waste Management General Provisions), Subchapter O of this chapter (relating to Land Disposal Restrictions), and Subchapter R of this chapter (relating to Waste Classification), except as provided under this subchapter. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that authorizes the owner or operator of the facility to accept

hazardous waste from off-site.

§335.769. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor.

(a) Shipping potentially creditable hazardous waste pharmaceuticals. A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable United States Department of Transportation regulations in 49 Code of Federal Regulations (CFR) Parts 171 - 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR §171.8. For purposes of the federal Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the United States Environmental Protection Agency specified in 40 CFR Part 262 as adopted under Subchapter C of this title (relating to Standards Applicable to Generators of Hazardous Waste). Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) Delivery confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse

distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) Procedures for when delivery confirmation is not received within 35 days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) Exporting potentially creditable hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal), except the manifesting requirement of 40 CFR §262.83(c), in addition to subsections (a) - (c) of this section.

(e) Importing potentially creditable hazardous waste pharmaceuticals. Any

person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to subsections (a) - (c) of this section instead of 40 CFR Part 262, Subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subchapter.

§335.771. Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors.

(a) A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a hazardous waste permit or without having interim status, provided that it complies with the conditions in this section. The following standards apply to reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(1) Registration. A reverse distributor must register with the executive director in accordance with §335.6 of this title (relating to Notification Requirements) using a method approved by the executive director within 60 days of becoming subject to this chapter.

(2) Inventory by the reverse distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(A) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(B) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(C) A reverse distributor that meets the inventory requirements of this paragraph by complying with other regulatory requirements, such as the Texas State Board of Pharmacy regulations, is not required to provide a separate inventory pursuant to this section.

(3) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another

reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(A) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with subsection (b) of this section.

(B) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with subsection (c) of this section.

(4) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility. Following the evaluation, the reverse distributor must manage the evaluated hazardous waste pharmaceuticals in accordance with subsection (c) of this section.

(5) Maximum accumulation time. The maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor is outlined in subparagraphs (A) and (B) of this paragraph.

(A) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(B) Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with subsection (a) of this section and the container labeling and management standards in §335.771(c)(4)(A) - (F).

(6) Security at the reverse distributor facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(A) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(i) a 24-hour continuous monitoring surveillance system;

(ii) an artificial barrier such as a fence; or

(iii) a means to control entry, such as keycard access.

(B) If the reverse distributor already meets the security requirements of this subsection because of other regulatory requirements, such as Drug Enforcement Administration or Texas State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 Code of Federal Regulations (CFR) Part 262, Subpart M as adopted under §335.61 of this title (relating to Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators).

(8) Closure of a reverse distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with §335.8 of this title (relating to Closure and Remediation) and 40 CFR §262.17(a)(8)(ii) and (iii) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(9) Reporting. Reverse distributors are subject to the following reporting requirements.

(A) A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off-site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the executive director within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(i) the United States Environmental Protection Agency (EPA) identification number, name and address of the reverse distributor;

(ii) the date the reverse distributor received the unauthorized waste;

(iii) the EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(iv) a description and the quantity of each unauthorized waste the reverse distributor received;

(v) the method of treatment, storage, or disposal for each unauthorized waste; and

(vi) a brief explanation of why the waste was unauthorized, if known.

(B) The executive director may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(A) A copy of its notification on file for as long as the facility is subject to this subchapter;

(B) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(C) A copy of its current inventory for as long as the facility is subject to this subchapter.

(b) Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in subsection (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of

manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow subsection (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow subsection (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with §335.769 of this title (relating to Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor).

(4) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(A) The confirmation of delivery; and

(B) The DOT shipping papers prepared in accordance with 49 CFR Part 172, Subpart C, if applicable.

(c) Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of subsection (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) Accumulation area at the reverse distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) Inspections of on-site accumulation area. A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of 40 CFR §262.17(a)(7) as adopted under §335.53 of this title.

(4) Labeling and management of containers at on-site accumulation areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(A) label the containers with the words, "hazardous waste pharmaceuticals";

(B) ensure the containers are in good condition and managed to prevent leaks;

(C) use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(D) keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(E) manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(i) generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(v) through other like means threaten human health or the environment; and

(F) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 40 CFR §268.3(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) United States Environmental Protection Agency (EPA) hazardous waste numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off-site, all containers must be marked with the applicable EPA hazardous waste numbers. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste number(s).

(6) Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in §335.767(a) or (b) of this title (relating to Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor).

(7) Procedures for a reverse distributor for managing rejected shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 40 CFR §264.72 as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.72 as adopted under §335.112 of this title (relating to Standards) may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with subsection (a) or (c) of this section. Upon receipt of the returned shipment, the reverse distributor must:

(A) Sign either:

(i) item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) item 20 of the new manifest, if a new manifest was used for the returned shipment;

(B) Provide the transporter a copy of the manifest;

(C) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(D) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of §335.767(a) or (b) of this title.

(8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR Part 268 as adopted under Subchapter O of this chapter (relating to Land Disposal Restrictions). A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 40 CFR §268.7(a) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability).

(9) Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals. Reverse distributors are subject to the following reporting requirements.

(A) A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must:

(i) comply with the reporting requirements of §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), and

(ii) in every even-numbered year, submit supplemental biennial reporting information for the previous odd-numbered report year required by 40 CFR §262.41 as adopted by reference under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators), upon request, in a method approved by the executive director within the specified timeframe. Information submitted to the executive director in accordance with Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste), and Subchapter R of this chapter (relating to Waste Classification) is not required to be resubmitted in a biennial report.

(B) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(C) A reverse distributor must submit an exception report to the executive director if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(i) a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(ii) a cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(D) For shipments rejected by the designated facility and shipped to an alternate facility, a reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(E) For shipments rejected by the designated facility and shipped to an alternate facility, a reverse distributor must submit an exception report to the executive director if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The exception report must include:

(i) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(ii) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals. Reverse distributors are subject to the following recordkeeping requirements.

(A) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by subsection (c)(2) of this

section. This log must be retained as a record for at least three years from the date of the inspection.

(B) A reverse distributor must keep a copy of each manifest signed in accordance with 40 CFR §262.23(a) as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(C) A reverse distributor must keep a copy of each report required by subparagraph (9)(A) of this subsection for at least three years from the due date of the report.

(D) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(E) A reverse distributor must keep records to document personnel training, in accordance with 40 CFR §262.17(a)(7)(iv) as adopted under §335.53 of this title.

(F) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended

automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(d) When a reverse distributor must have a permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the permitting and other requirements of this chapter if the reverse distributor:

(1) does not meet the conditions of this section;

(2) accepts manifested hazardous waste from off-site; or

(3) treats or disposes of hazardous waste pharmaceuticals on-site.

criteria for a cured compost as described in Table 2, "Maturity and Stability Standards."

(f) Waste grade final product. Any material that [~~which~~] does not meet the final product standards shall be appropriately disposed at a permitted municipal solid waste facility.

§332.75. Out of State Production.

Any compost produced outside of the State of Texas, which is distributed within Texas, shall be labelled pursuant to §332.74 of this title (relating to Compost [~~Final Product~~] Labelling Requirements).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Deputy Director, Environmental Law Division
Texas Commission on Environmental Quality
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CHAPTER 335. INDUSTRIAL SOLID WASTE AND MUNICIPAL HAZARDOUS WASTE

The Texas Commission on Environmental Quality (TCEQ, agency, or commission) proposes amendments to §§335.1, 335.2, 335.9, 335.10, 335.12, 335.13, 335.15, 335.18, 335.19, 335.24, 335.26, 335.27, 335.31, 335.41, 335.46, 335.91, 335.94, 335.112, 335.152, 335.221, 335.241, 335.251, 335.261, 335.272, 335.431, 335.471, 335.474, 335.477, 335.503, 335.504, 335.510, 335.511, 335.513, 335.521, 335.590, 335.602, 335.702, and 335.703. The commission also proposes to repeal §§335.6, 335.11, 335.14, 335.61 - 335.63, 335.65 - 335.71, and 335.73 - 335.79. The commission further proposes new §§335.6, 335.11, 335.14, 335.51 - 335.61, 335.751, 335.753, 335.755, 335.757, 335.759, 335.761, 335.763, 335.765, 335.767, 335.769, and 335.771.

Background and Summary of the Factual Basis for the Proposed Rules

The federal hazardous waste program is authorized under the federal Resource Conservation and Recovery Act of 1976 (RCRA), §3006. States may obtain authorization from the United States Environmental Protection Agency (EPA) to administer the hazardous waste program. State authorization is a rulemaking process through which the EPA delegates the primary responsibility of implementing the RCRA hazardous waste program to individual states. This process ensures national consistency and minimum standards while providing flexibility to states in implementing rules. State RCRA programs must always be at least as stringent as the federal requirements.

Texas received authorization of its hazardous waste "base program" under RCRA on December 26, 1984 and has continuously participated in the EPA's authorization program. To maintain the RCRA authorization, the commission must adopt regulations to meet the minimum standards of federal programs administered by the EPA. Because the federal regulations undergo regular revision, the commission must adopt new regulations regularly to meet the changing federal regulations.

The commission proposes in this rulemaking parts of the RCRA Rule Clusters XXIV - XXVIII that implement revisions to the federal hazardous waste program which were made by EPA between November 30, 2018 and December 9, 2019. Both mandatory and optional federal rule changes in these clusters are proposed to be adopted. Although not necessary to maintain authorization, the EPA also recommends that the optional federal rule changes be incorporated into the state rules. Maintaining equivalency with federal regulations would enable Texas to continue operating all delegated aspects of the federal hazardous waste program in lieu of the EPA.

Hazardous Waste Generator Improvements Rule

In the November 28, 2016 issue of the *Federal Register* (81 FR 85732), the EPA amended existing regulations applicable to generators of hazardous waste. The EPA's objectives for the revisions included: 1) reorganizing the hazardous waste generator regulations to make them more user-friendly and to improve their usability; 2) addressing gaps in the existing regulations; 3) providing greater flexibility for management of hazardous waste in a cost-effective and protective manner; and 4) making technical corrections to address errors and removing obsolete references.

The commission proposes adoption of the federal Hazardous Waste Generator Improvements Rule by repealing and replacing the standards applicable to generators of hazardous waste in Subchapter C (Standards Applicable to Generators of Hazardous Waste) and by amending sections of Subchapter R (Waste Classification). Because the generator standards are referenced throughout the chapter, the commission proposes multiple conforming amendments.

Export and Import Confidentiality Rule

In the December 26, 2017 issue of the *Federal Register* (82 FR 60894), the EPA further revised existing regulations regarding the export and import of hazardous wastes from and into the United States. Specifically, the EPA applied a confidentiality determination such that no person can assert confidential business information claims for documents related to the export, import, and transit of hazardous waste and export of excluded cathode ray tubes. The import and export confidentiality determination regulations were promulgated under the Hazardous and Solid Waste Amendments and are administered by the EPA.

Electronic Manifest Fee Rule

In the January 3, 2018 issue of the *Federal Register* (83 FR 420), the EPA established the methodology for determining and revising the user fees applicable to the electronic and paper manifests submitted to the national electronic manifest (e-Manifest) system developed under the Hazardous Waste Electronic Manifest Establishment Act (e-Manifest Act). Certain users of the hazardous waste manifest are required to pay a prescribed fee to the EPA for each electronic and paper manifest they use and submit to the national system. Regulations promulgated under the e-Manifest Act took effect in all states on the effective date of the federal rule.

The commission adopted the federal Hazardous Waste Electronic Manifest Rule promulgated in the *Federal Register* February 7, 2014 (79 FR 7518) on June 10, 2016 (41 TexReg 4259). The EPA issued a Special Consolidated Checklist for the two e-manifest rulemakings which contains additional guidance and revisions for federal revisions adopted in the 2014 Electronic Manifest Rule. The commission proposes conforming revisions

to adopt the consolidated revisions associated with both federal e-manifest rulemakings.

Definition of Solid Waste Rule

In the May 30, 2018 issue of the *Federal Register* (83 FR 24664), the EPA revised existing hazardous secondary material recycling regulations associated with the definition of solid waste to comply with the United States Court of Appeals for the District of Columbia (D.C. Circuit) vacatur. The D.C. Circuit vacated portions of the 2015 Definition of Solid Waste Rule, promulgated in the *Federal Register* on January 13, 2015 (80 FR 1694), and reinstated portions of the 2008 Definition of Solid Waste Rule, promulgated in the *Federal Register* on October 30, 2008 (73 FR 64668). Specifically, the 2018 final rule: 1) vacated parts of the 2015 verified recycler exclusion and reinstated the 2008 transfer-based exclusion; 2) upheld the 2015 containment and emergency preparedness provisions for the reinstated transfer-based exclusion; and 3) vacated the fourth factor of the 2015 definition of legitimate recycling and reinstated the 2008 version of the fourth factor. The commission did not adopt the 2008 Definition of Solid Waste Rule. The commission adopted the 2015 Definition of Solid Waste Rule as published in the *Texas Register* on January 2, 2015 (40 TexReg 77).

Pharmaceutical Waste Rule

In the February 22, 2019 issue of the *Federal Register*, the EPA created a new 40 Code of Federal Regulations (CFR) Part 266, Subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the generator regulations in 40 CFR Part 262. New 40 CFR Part 266, Subpart P standards include: 1) prohibiting the disposal of hazardous waste pharmaceuticals into sewer systems; 2) eliminating the dual regulation of the RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration controlled substances by finalizing a conditional exemption; 3) maintaining the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events; 4) codifying the EPA's prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics; 5) finalizing an amendment to the P075 acute hazardous waste listing of nicotine and salts to exclude certain United States Food and Drug Administration approved over-the-counter nicotine replacement therapies; and 6) establishing in the preamble a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics.

Aerosol Can Waste Rule

As part of this rulemaking, the commission proposes to implement the EPA's final regulations promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202), which added hazardous waste aerosol cans to the universal waste program under the RCRA. The commission received a petition for rulemaking from Westlake Chemical Corporation on February 3, 2020, requesting that the commission amend its rules to incorporate the EPA's universal waste provisions for aerosol cans. On March 25, 2020, the commission considered the petition for rulemaking and ordered the executive director to initiate rulemaking (TCEQ Docket No. 2020-0220-PET). The commission now proposes this rulemaking to add hazardous waste aerosol cans to the list of universal wastes so they can be managed as universal waste. The commission anticipates that these rules would benefit a wide variety of establishments generating and managing aerosol cans, including the retail sector, by providing a practical system for handling discarded aerosol cans.

Foundry Sands Exclusion

In addition to federal rule changes proposed for adoption, the commission proposes to formalize the commission's regulation of spent foundry sands from the iron and steel casting industry. The proposed rulemaking would implement state-initiated revisions to clarify that spent foundry sands that are an intended output or result from the iron and steel casting process are not classified as an industrial solid waste when introduced into the stream of commerce and managed as an item of commercial value, including use constituting disposal. The executive director issued a regulatory determination letter dated June 22, 1995, which established that spent foundry sands reused as a substitute material would be considered a co-product and would not be regulated as industrial solid waste. Regulatory revisions implemented since the 1995 letter was issued have resulted in confusion regarding the status of the material.

All proposed new rules and rule changes are discussed further in the Section by Section Discussion portion of this preamble.

Section by Section Discussion

In addition to the proposed rules associated with this rulemaking, various stylistic, non-substantive changes are proposed to update rule language to current Texas Register style and format requirements. These changes are non-substantive and not specifically discussed in the Section by Section Discussion portion of this preamble.

Subchapter A: Industrial Solid Waste and Municipal Hazardous Waste in General

§335.1, Definitions

The commission proposes §335.1(6) to add the definition of "Acute hazardous waste" and adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment would add the definition of "Acute hazardous waste" consistent with the new definition of "Acute hazardous waste" in 40 CFR §260.10. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

The commission proposes §335.1(8) to add the definition of "Aerosol can" to adopt federal revisions associated with the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202). This amendment would add the definition of "Aerosol Can" consistent with the new definition of "Aerosol can" in 40 CFR §260.10. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

The commission proposes §335.1(29) to add the definition of "Central accumulation area" to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment would add the definition of "Central accumulation area" consistent with the new definition of "Central accumulation area" in 40 CFR §260.10. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

The commission proposes §335.1(38) to add a definition of "Conditionally exempt small quantity generator" (CESQG) and a person who generates no more than 100 kilograms of

hazardous waste in a calendar month to mean a "very small quantity generator" (VSQG) as defined in this section. The commission proposes this definition to clarify that the new term for the lowest tier hazardous waste generator category, VSQG, is applicable when the former term or the description of the lowest tier hazardous waste generator category, CESQG, is used in publications, authorizations or rules that are not included in this rulemaking. The EPA changed the name of the lowest tier hazardous waste generator category from "conditionally exempt small quantity generator" to "very small quantity generator" in the Hazardous Waste Generator Improvements Rule. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

The commission proposes to amend renumbered §335.1(49) for the definition of "Designated facility" to delete the reference to §335.12 and clarify that 40 CFR §264.72 is adopted by reference under §335.152, and 40 CFR §265.72 is adopted by reference under §335.112. These federal sections were previously adopted under §335.12 and are now proposed for adoption under §335.112 and §335.152 as described in the Section by Section Discussions for those sections.

The commission proposes to amend renumbered §335.1(70) for the definition of "Final closure" to replace the reference to §335.69 with a reference to Chapter 335, Subchapter C due to the adoption of regulations associated with the Hazardous Waste Generator Improvements Rule. Current §335.69 is proposed for repeal and would be replaced by the adoption of 40 CFR Part 262 provisions in Chapter 335, Subchapter C as described in the Section by Section Discussions for that subchapter.

The commission proposes §335.1(105) to add the definition of "Large quantity generator" to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment would add the definition of "Large quantity generator" consistent with the new definition of "Large quantity generator" in 40 CFR §260.10. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

The commission proposes to amend renumbered §335.1(111) to revise the definition of "Manifest" to remove the reference to "the instructions in §335.10", and to clarify that manifest users are subject to the applicable requirements of this chapter. The manifest requirements in 40 CFR Part 262, Subpart B that are currently adopted under §335.10 are proposed to be adopted by reference in §335.54 as described in the Section by Section Discussion for those sections.

The commission proposes to amend renumbered §335.1(119) to revise the definition of "No free liquids" by clarifying that the test methods in 40 CFR §261.4(a)(26) and (b)(18) are incorporated by reference under §335.31.

The commission proposes §335.1(120) to add the definition of "Non-acute hazardous waste" to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment would add the definition of "Non-acute hazardous waste" consistent with the new definition of "Non-acute hazardous waste" in 40 CFR §260.10. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

The commission proposes to amend renumbered §335.1(159) to revise the definition of "Small quantity generator" to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This amendment would revise the definition of "Small quantity generator" to be consistent with the revised definition of "Small quantity generator" in 40 CFR §260.10. The revisions would add the monthly quantities of acute hazardous waste generation that are allowed for small quantity generators.

The commission proposes to amend renumbered §335.1(160)(A)(iv) to revise the definition of "Solid waste" by removing references to numbered paragraphs of 40 CFR §261.4(a), removing references to the CFR dated citations for 40 CFR §§261.4 and 261.39 - 261.41, and adding language clarifying that these CFR sections are adopted by reference under §335.504 as described in the Section by Section Discussion for that section.

The commission proposes to amend Figure: 30 TAC §335.1(154)(D)(iv) to rename the figure "Figure: 30 TAC §335.1(160)(D)(iv) (Table 1)" consistent with the renumbering of the paragraphs in §335.1, and to revise the citations for Table 1 in renumbered §335.1(160)(D) and (D)(i) - (iv) accordingly. Table 1 is further proposed to be amended by revising the language in Footnote 2 of Table 1 to be consistent with the third column heading in 40 CFR §261.2(c)(4), Table 1.

The commission proposes §335.1(160)(N) to add a conditional exclusion from the definition of "Solid waste" for foundry sands that are an intended output or result from the iron and steel casting processes when such material is introduced into the stream of commerce, managed as an item of commercial value, including controlled use in a manner constituting disposal, and not managed as discarded material. This amendment would formalize existing state guidance.

The commission proposes to amend renumbered §335.1(178)(E) to revise the definition of "Treatability study" to remove the references to §335.69 and §335.78. The exemptions in 40 CFR §261.4(e) and (f) are adopted by reference under §335.504, and §335.69 and §335.78 contained statements clarifying these exemptions in writing. These sections are proposed to be repealed as described in the Section by Section Discussion for those sections. The exemption from permit requirements for treatability studies in §335.2(g) would not be impacted by this rulemaking and the reference to §335.2 would be retained.

The commission proposes to amend renumbered §335.1(186) to revise the definition of "Universal waste" to replace the cross-reference to §335.261(b)(16)(F) with §335.261(b)(19)(F) to reflect the renumbering of the paragraphs in §335.261(b). The revision to §335.261(b) is proposed to conform with the adoption of federal revisions associated with the Aerosol Can Waste Rule as described in the Section by Section Discussion for that section.

The commission proposes to amend renumbered §335.1(191) to revise the definition of "Used oil" by replacing the reference to "conditionally exempt small quantity generator" with "very small quantity generator" to conform with federal revisions associated with the adoption of the Hazardous Waste Generator Improvements Rule.

The commission proposes to amend renumbered §335.1(192)(C) to revise the definition of "User of the electronic manifest system" by replacing the reference to §335.10 with

references to 40 CFR §264.71(a)(2)(v) or §265.71(a)(2)(v). These federal sections are proposed to be adopted by reference under §335.112 and §335.152 as described in the Section by Section Discussion for those sections. This revision would make the definition for "User of the electronic manifest system" consistent with the federal definition for "User of the electronic manifest system" in 40 CFR §260.10.

The commission proposes §335.1(193) to add the definition of "Very small quantity generator" to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) which renamed the lowest tier hazardous waste generator category "conditionally exempt small quantity generator" as "very small quantity generator." This amendment would add the definition of "Very small quantity generator" consistent with the new definition of "Very small quantity generator" in 40 CFR §260.10. The commission proposes to renumber the subsequent paragraphs accordingly to account for the added definition.

§335.2, Permit Required

The commission proposes to amend §335.2(e) to replace "is a conditionally exempt small quantity generator as described in §335.78" with "meets the conditions for exemption for a very small quantity generator in 40 CFR §262.14" to conform with federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The conditions for exemption for a VSQG in 40 CFR §262.14 are proposed to be adopted in §335.53(c) as described in the Section by Section Discussion for that section.

The commission proposes to amend §335.2(f) and (g) to clarify that 40 CFR §261.4(c) - (f) are adopted under §335.504, and to remove the dated citation for 40 CFR §261.4(e) and (f) in §335.2(g). Revisions to implement 40 CFR §261.4 are described in the Section by Section Discussion for §335.504.

The commission proposes new §335.2(p) to adopt federal revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to implement these revisions by adding language consistent with 40 CFR §270.1(c)(2)(x).

§335.6, Notification and Registration Requirements

The commission proposes to repeal the existing §335.6. The section is proposed to be replaced under proposed §335.6.

The commission proposes new §335.6(a) to add catch line "Notification of unpermitted industrial solid waste activities"; clarify that the section applies to recycling activities; remove the current reference to §335.2(e); replace the prior phrase "in writing or using the electronic interface notification software provided by the executive director" with "using a method approved by the executive director"; and reorganize parts of the prior language into new paragraphs (1) and (2) to provide additional clarification of the notification requirements. The language is being reorganized to clarify the requirements once for the section and to reduce repetitive requirements. Proposed §335.6(a) would not include the remainder of current §335.6(a). The 90-day advance notice requirement for persons required to notify under §335.6(a) is proposed to be organized under new §335.6(a)(1). The notification requirements for large quantity generators are proposed to be revised and reorganized to §335.6(c) to reduce repetitive requirements as described in the Section by Section Discussion for that subsection.

The commission proposes new §335.6(b) to add catch line "Duty to notify of changed and new information"; add the statement "promptly notify the executive director using a method approved by the executive director of:"; and reorganize parts of the prior language into new paragraphs (1) - (4) to provide additional clarification of renotification requirements. The proposal does not include the remainder of §335.6(b). The notification requirements for large quantity generators are proposed to be revised and reorganized in proposed new §335.6(c) to reduce repetitive requirements as described in the Section by Section Discussion for that subsection.

The commission proposes new §335.6(c) to add catch line "Generator registration"; reorganize the language into paragraphs, subparagraphs, and clauses; and replace the quantity limits referenced in current §335.78 with the volumes of hazardous and Class 1 industrial waste generated by a very small quantity generator.

The commission proposes new §335.6(d) to add catch line "Transporter registration"; replace the reference to forms furnished by the executive director with a method approved by the executive director; list the maximum waste quantities allowed to be transported without registration; and not include prior paragraphs (1) and (2) because the prior language would be included within the proposed new subsection.

The commission proposes new §335.6(e) to add catch line "Transfer facility registration" and clarify that notification must be made using a method approved by the executive director.

The commission proposes new §335.6(f) to add catch line "Waste analysis" and add a statement that clarifies that the chemical analysis of a solid waste must be performed in accordance with Chapter 335, Subchapter R.

The commission proposes new §335.6(g) to add catch line "Notification prior to facility expansion."

The commission proposes new §335.6(h) to add catch line "Notification of recycling activities"; add recyclable materials and nonhazardous recyclable materials to the subject materials; clarify that notification must be made using a method approved by the executive director; and reorganize parts of the prior language into new paragraphs (1) and (2) to provide additional clarification of recycling notification requirements. The proposal does not include the remainder of prior §335.6(h), including an obsolete reference to persons engaged in recycling prior to the effective date of §335.6.

The commission proposes new §335.6(i) to add catch line "Notification of operating under the small quantity burner exemption."

The commission proposes new §335.6(j) to add catch line "Notification of used oil activities" and replace the prior reference to CESQG hazardous used oil with used oil generated by a VSQG to conform with the new definition of VSQG as described in the Section by Section Discussion for the definition of VSQG in §335.1.

The commission does not propose the prior §335.6(k) because the prior provision is repetitive of §335.24 and would be retained in that section.

The commission proposes new §335.6(k) to include catch line "Notification exemption for the disposal of animal carcasses" and include the provisions of the prior §335.6(l).

The commission proposes new §335.6(l) to establish the notification requirement for healthcare facilities operating under proposed Chapter 335, new Subchapter W.

The commission proposes new §335.6(m) to establish the registration requirements for reverse distributors operating under proposed Chapter 335, new Subchapter W.

§335.9, Recordkeeping and Annual Reporting Procedures Applicable to Generators

The commission proposes to amend §335.9(a) to add a statement that clarifies the applicability of additional recordkeeping and reporting requirements in this section.

The commission proposes to amend §335.9(a)(1)(A) - (G) by adding clarifying language including to reference the applicability of Chapter 335, Subchapter R; replacing the reference to the lowest hazardous waste generator category, "conditionally exempt small quantity generators", and describing the applicability of the requirement to report the amount of waste held in on-site storage at the end of the year with a description of the quantities of waste generated per month; and replacing the reference to hazardous waste accumulation areas at or near any point of generation under §335.69(d) with a reference to the satellite accumulation area regulations proposed for adoption under §335.53. Additional information is described in the Section by Section Discussion for §335.53 and §335.69.

The commission proposes to amend §335.9(a)(2) to clarify the procedures for submitting an Annual Waste Summary and to delete requirements proposed to be reorganized and adopted in subsequent paragraphs and subparagraphs.

The commission proposes to amend §335.9(a)(2)(A) and (B) to add clarifying language, including a statement regarding the applicability of an extension request. This requirement is proposed to be reorganized from §335.9(a)(2).

The commission proposes §335.9(a)(2)(C) to identify the information required to be included in an Annual Waste Summary. This requirement is proposed to be reorganized from §335.9(a)(2).

The commission proposes §335.9(a)(2)(D) to identify the requirement for large quantity generators to submit the Annual Waste Summary electronically. This requirement is proposed to be reorganized from §335.9(a)(2).

The commission proposes to amend §335.9(a)(3) and (4) to clarify applicability of the Annual Waste Summary by adding language; replacing hazardous waste volumes that identify the lowest hazardous waste generator category with the new term for this category, VSQG; requiring that a VSQG meet the conditions for exemption for a VSQG; and replacing the references to §335.78 which is proposed for repeal with a reference to proposed new §335.53. Additional information is described in the Section by Section Discussion for proposed §335.53 and §335.78.

The commission proposes to amend §335.9(b) to replace the reference to the biennial reporting requirements under §335.71 with proposed new §335.56. Additional information is described in the Section by Section Discussion for proposed §335.56 and §335.71.

§335.10, Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste

The commission proposes to amend §335.10 to clarify the applicability of the use of the uniform hazardous waste manifest for the transportation of hazardous waste and for the transportation of industrial Class 1 waste; to add references to sections of this chapter where manifesting requirements are proposed to be adopted; and to conform to proposed adoption of the re-named lowest tier hazardous waste generator classification.

The commission proposes to amend §335.10(a) to clarify the applicability of and reference the proposed adoption by reference of manifesting requirements in this chapter by deleting the adoption by references of 40 CFR §§262.20 - 262.25, 262.27, and 262.42, which are proposed to be adopted by reference under proposed new §335.54; deleting an adoption by reference of 40 CFR Part 262, Subpart H, which is proposed to be adopted by reference under proposed new §335.58; deleting an adoption by reference of the Appendix to 40 CFR Part 262 because it was removed from the federal regulations; and by requiring persons to comply with §§335.12, 335.13, 335.54, and 335.58.

The commission proposes to amend §335.10(a)(2) to remove the reference to §335.78, which is proposed for repeal; clarify that manifesting is not required when the conditions for an applicable exemption from manifesting have been met; and add §335.10(a)(2)(A) and (B) to further clarify manifesting exemptions applicable to transporters of hazardous waste.

The commission proposes to amend §335.10(b) to conform with the reorganization of the exception from manifesting requirements for the transportation of hazardous waste on a contiguous right of way and the reporting of discharges during such transportation by replacing the reference to the hazardous waste marking requirements under §335.67(b) with proposed new §335.55. Additional information is described in the Section by Section Discussion for §335.55 and §335.67.

The commission proposes to amend §335.10(c) to replace the reference to the adoption by reference of the manifest requirements in subsection (a), which are proposed to be deleted, with a reference to proposed new adoption by reference of manifesting requirements under §335.54. Additional information is described in the Section by Section Discussion for §335.54.

The commission proposes to amend §335.10(c)(1) and (2) to clarify the use of the TCEQ solid waste registration number or the United States Environmental Protection Agency identification number and to use the precise term of art, designated facility, in lieu of the term receiver.

The commission proposes §335.10(c)(3) - (7) to clarify the manifesting requirements for the transportation of Class 1 waste by adding language to the use of EPA ID number and Solid Waste Registration Number requirements; and by iterating changes to the federal manifesting rules applicable to the transportation of Class 1 waste.

The commission proposes to amend §335.10(d) to clarify the applicability of the exception from manifesting by replacing the reference to §335.78, which is proposed for repeal, with the quantity limit for Class 1 waste.

The commission proposes to amend §335.10(e) to clarify the applicability of specific exceptions from manifesting and reporting by organizing the language into proposed §335.10(e)(1) and (2), and by adding proposed paragraph (3) describing that the Annual Waste Summary is applicable to facilities that receive Class 1 industrial waste from off-site.

§335.11, Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste

The commission proposes to repeal §335.11. The section is proposed to be replaced under proposed new §335.11.

The commission proposes new §335.11(a) to incorporate by reference the manifest requirements of 40 CFR Part 263, Subpart B, including the revisions associated with the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420). The commission does not propose adoption of the Appendix to 40 CFR Part 262 because EPA has repealed the Appendix.

The commission proposes new §335.11(b)(1) - (6) to clarify and establish applicability of the manifesting requirements for hazardous waste by indicating that the manifesting requirements proposed to be adopted under §335.11(a), and the requirements in §§335.4, 335.6, 335.10, and 335.14 and Chapter 335, Subchapter D are applicable to persons who transport hazardous waste.

The commission proposes new §335.11(c) to clarify the manifesting requirements for Class 1 waste by indicating that the manifesting requirements proposed to be adopted under §335.11(a) and the requirements proposed to be listed under new §335.11(b)(1) - (6) are applicable to persons who transport Class 1 waste and by proposing §335.11(c)(1) - (8) to list the changes to the federal manifesting rules that are required for persons transporting Class 1 waste.

§335.12, Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities

The commission proposes to amend §335.12(a) to clarify that 40 CFR Part 264, Subpart E is adopted in §335.152 and 40 CFR Part 265, Subpart E is adopted in §335.112. The commission proposes to delete the remainder of §335.12(a) including the dated citations for 40 CFR §264.71 and §265.71, which are now proposed for adoption in §335.112 and §335.152, and the appendix to 40 CFR Part 262. This Appendix was removed from federal regulations in the Electronic Manifest Fee Rule.

The commission proposes to amend §335.12(b) to clarify that 40 CFR Part 264, Subpart E is adopted in §335.152, and by adding §335.12(b)(1) - (4) to clarify the use of federal manifesting requirements for Class 1 waste. The commission proposes to delete the remainder of §335.12(b) including the dated citations for 40 CFR §§264.71, 264.72, 264.76 and the Appendix to 40 CFR Part 262.

The commission proposes §335.12(c) to adopt by reference 40 CFR §260.4, a new federal requirement adopted in the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420) which implements manifest requirements applicable to designated facilities for interstate waste shipments.

The commission proposes §335.12(d) to adopt by reference 40 CFR §260.5, a new federal requirement adopted in the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420) which clarifies the applicability of the electronic manifest system and fees for state-only regulated wastes.

§335.13, Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste

The commission proposes to amend §335.13(a) to implement changes from the Hazardous Waste Generator Improvements Rule by replacing the reference to §335.78, which is proposed for repeal, with a description of the quantities of hazardous waste that determine applicability.

The commission proposes to amend §335.13(b) and (c) to implement plain language clarifications.

The commission proposes to amend §335.13(d) to clarify that the term registered generator means a generator with an active solid waste registration.

The commission proposes to amend §335.13(e) to organize the language into proposed §335.13(e)(1) - (3); replace the reference to §335.78, which is proposed for repeal, with the quantities of waste generated; and to clarify that the term unregistered generator also means an in-state generator that does not have an active solid waste registration.

The commission proposes to amend §335.13(f) to implement the Hazardous Waste Generator Improvements Rule and the Electronic Manifest Fee Rule by removing language adopting manifesting records retention requirements in writing, which is duplicative of requirements proposed for adoption in §335.56, and proposing language requiring generators to comply with the manifest and recordkeeping requirements under §335.10.

The commission additionally proposes to delete §335.13(g) - (i) adopting manifesting requirements in writing which are proposed for adoption under §335.15.

The commission additionally proposes to delete §335.13(j) which requires generators to comply with §335.12, which would still be applicable to generators without this reference and requires generators to comply with the hazardous waste import and export requirements under §335.76, which is proposed for repeal. The hazardous waste import and export requirements are proposed to be adopted under new §335.52(c).

§335.14, Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste

The commission proposes to repeal §335.14. The section is proposed to be replaced under proposed new §335.14.

The commission proposes new §335.14 to clarify the manifest and recordkeeping requirements applicable to transporters of hazardous and Class 1 wastes. The commission does not propose the prior §335.14(a) - (e) because the language in these subsections would be duplicative of requirements proposed for adoption in §335.11.

§335.15, Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities

The commission proposes to amend §335.15 to clarify the applicability of the section in implied subsection (a) and add catch lines to each of the paragraphs.

The commission proposes to amend §335.15(1) to clarify the manifest requirements applicable to owners and operators of treatment, storage, or disposal facilities and delete the reference to "primary exporter" since the term "primary exporter" was removed from 30 TAC Chapter 335, June 5, 2020 (45 TexReg 3773).

The commission proposes to amend §335.15(2) by reorganizing and replacing the language with proposed subparagraphs (A) - (D) for clarification.

The commission proposes to amend §335.15(3) by reorganizing and replacing the language with proposed subparagraphs (A) and (B) for clarification. Existing subparagraphs (A) - (G) would be replaced by clauses (i) - (vii) in proposed subparagraphs (A) and (B).

The commission proposes to amend §335.15(6) to replace "conditionally exempt small quantity generator" with the term "very small quantity generator", and to clarify the monthly waste receipt summary requirements applicable to VSQGs.

The commission proposes to amend §335.15(7) to clarify that 40 CFR §264.75 and §265.75 are adopted under §335.112 and §335.152, the location these federal sections are proposed to be adopted, and to update the method by which the biennial report is submitted.

The commission proposes §335.15(8) to clarify the reporting requirements applicable to facilities that receive Class 1 industrial waste from off-site.

§335.18, Non-Waste Determinations and Variances from Classification as a Solid Waste

The commission proposes to delete §335.18(a)(6) to conform to the removal of 40 CFR §260.30(f) associated with the Definition of Solid Waste Rule promulgated in the *Federal Register* on May 30, 2018 (83 FR 24664). This amendment would remove the reference to verified-reclamation facilities to comply with the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018 which voided the verified-reclamation exclusion.

§335.19, Standards and Criteria for Variances from Classification as a Solid Waste

The commission proposes to delete §335.19(d) to conform to the removal of 40 CFR §260.31(d) associated with the Definition of Solid Waste Rule promulgated in the *Federal Register* on May 30, 2018 (83 FR 24664). This amendment would remove the reference to verified-reclamation facilities to comply with the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018 which voided the verified-reclamation exclusion. The subsequent subsection would be relettered.

§335.24, Requirements for Recyclable Materials and Nonhazardous Recyclable Materials

The commission proposes to amend §335.24(b) to clarify the applicability of Subchapter A to recycling activities.

The commission proposes to amend §335.24(c)(1) to remove the dated citation for 40 CFR Part 262, Subpart H and to clarify that the subpart would be adopted by reference under §335.58.

The commission proposes to amend §335.24(c)(2) to clarify that 40 CFR §261.4(a)(13) is adopted by reference under §335.504.

The commission proposes to amend §335.24(c)(3) to remove the dated citation for 40 CFR §261.4(a)(12) and to clarify that the federal requirements is adopted by reference under §335.504.

The commission proposes to amend §335.24(d) to clarify the applicability of Chapter 335, Subchapters A and R to generators and transporters for recycling activities.

The commission proposes §335.24(f)(3) and (4) to require owners or operators of recycling facilities that do not store recyclable materials before recycling to comply with the monthly waste summary report requirements in §335.15 and clarify that such owners and operators are subject to the biennial reporting requirements of 40 CFR §264.75 or §265.75. These amendments would conform with 40 CFR §261.6(c)(2)(iv) added to federal regulations in the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). Owners or operators of recycling facilities that do not store recyclable materials before recycling are subject to the biennial reporting requirements of 40 CFR §264.75 or §265.75, and the monthly waste summary report requirements in §335.15 would fulfill the federal biennial reporting requirements.

The commission proposes to amend §335.24(o) to remove the dated citation for 40 CFR Part 262, Subpart H and to clarify that the subpart would be adopted by reference under §335.58.

The commission proposes to amend §335.24(p) to add references to §335.26, §335.27, and Chapter 335, Subchapter V to clarify that hazardous secondary materials requirements relate to solid waste recycling.

§335.26, Notification Requirements for Hazardous Secondary Materials

The commission proposes to amend §335.26 to adopt by reference revisions associated with the Definition of Solid Waste Rule published in the May 30, 2018 issue of the *Federal Register* (83 FR 24664) by updating the federal citation for to 40 CFR §260.42. This revision is a consequence of the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018 which voided the verified-reclamation exclusion.

§335.27, Legitimate Recycling of Hazardous Secondary Materials

The commission proposes to amend §335.27 to adopt by reference revisions associated with the Definition of Solid Waste Rule published in the May 30, 2018, issue of the *Federal Register* (83 FR 24664) by updating the federal citation for 40 CFR §260.43. This revision is a consequence of the vacaturs ordered by the United States Court of Appeals for the District of Columbia on July 7, 2017 as modified on March 6, 2018.

§335.31, Incorporation of References

The commission proposes to amend §335.31 to adopt by reference federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by updating the federal citation for 40 CFR §260.11. Specifically, the language in 40 CFR §260.11(d)(1) was modified in the Hazardous Waste Generator Improvements Rule.

Subchapter B: Hazardous Waste Management General Provisions

§335.41, Purpose, Scope and Applicability

The commission proposes to amend §335.41(d)(4) to replace the reference to §335.77 with 40 CFR §262.70 proposed under new §335.57 as described in the Section by Section Discussion for that section.

The commission proposes §335.41(d)(9) to establish that Chapter 335, Subchapters E and F are not applicable to the owner or operator of an authorized municipal or industrial waste facility when the only hazardous waste managed at the facility is generated by a VSQG and excluded from regulation. This amendment would adopt revisions in 40 CFR §264.1(g)(1) and §265.1(c)(5) associated with the Hazardous Waste Generator Improvements

Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

The commission proposes §335.41(d)(10) to establish that Chapter 335, Subchapters E and F are not applicable to a generator accumulating waste on-site in compliance with a condition for exemption proposed to be adopted under §335.53. This amendment would adopt certain revisions in 40 CFR §264.1(g)(3) and §265.1(c)(7) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

The commission proposes §335.41(d)(11) to establish that Chapter 335, Subchapters E and F are not applicable to reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals in compliance with proposed new Subchapter W. This amendment would adopt revisions in 40 CFR §264.1(g)(13) and §265.1(c)(16) associated with the Pharmaceutical Waste Rule and promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816).

The commission proposes to amend §335.41(e)(1) by replacing the reference to §335.78 with the new term for the lowest hazardous waste generator category, "very small quantity generator", and language making the exception from applicability of Chapter 335, Subchapter E dependent upon the VSQG meeting the conditions for exemption in 40 CFR §262.14 which is proposed to be adopted under §335.53. The definition of VSQG is proposed to be adopted under §335.1 as described in the Section by Section Discussion for that definition. This proposed amendment would implement the adoption of the Hazardous Waste Generator Improvements Rule as further described in the Section by Section Discussion for §335.53.

The commission proposes to amend §335.41(e)(2) to add an exception from applicability of Chapter 335, Subchapter E for generators accumulating hazardous waste on-site in compliance with conditions for exemption for eligible academic entities and episodic generation. This amendment would adopt revisions in 40 CFR §265.1(c)(7) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The existing provision in §335.41(e)(2) is proposed to be deleted because it is duplicative of language proposed in §335.41(d)(10).

The commission proposes §335.41(f)(2)(D) to establish applicability of the proposed adoption of requirements for residues of hazardous waste pharmaceuticals under the requirements for residues of hazardous waste in containers. This amendment would adopt revisions in 40 CFR §261.7(c) associated with the Pharmaceutical Waste Rule and promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816).

§335.46, Sharing of Information

The commission proposes §335.46(b) to adopt by reference 40 CFR §260.2(c) as amended in the federal Electronic Manifest Rule which was promulgated in the *Federal Register* on February 7, 2014 (79 FR 7518).

The commission proposes §335.46(c) to adopt by reference 40 CFR §260.2(d) as adopted in the federal Export and Import Confidentiality Rule which was promulgated in the *Federal Register* on December 26, 2017 (82 FR 60894).

Subchapter C: Standards Applicable to Generators of Hazardous Waste

§335.51, Definitions

The commission proposes new §335.51(1) to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by adopting the definition of "Condition for exemption" consistent with the new definition of "Condition for exemption" in 40 CFR §262.1. If the conditions for exemption are not met, then the generator would be subject to the permitting or interim facility regulations in Chapter 335, Subchapters E and F.

The commission proposes new §335.51(2) to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by adopting the definition of "Independent requirement" consistent with the new definition of "Independent requirement" in 40 CFR §262.1. All hazardous waste generators must comply with the independent requirements of 40 CFR Part 262, as adopted by reference under this subchapter.

§335.52, Purpose, Scope, and Applicability

The commission proposes new §335.52(a) to establish the purpose scope and applicability of Chapter 335, Subchapter C; conform with revisions to 40 CFR §262.10 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816); and to require persons who import hazardous waste into the state to comply with the generator regulations in Chapter 335, Subchapter A because this requirement under §335.61 is proposed for repeal.

The commission proposes new §335.52(a)(1) to identify the independent requirements applicable to hazardous waste generators based on generator category and correspond with 40 CFR §262.10(a)(1).

The commission proposes new §335.52(a)(2) to identify the conditions for exemption for VSQGs, small quantity generators, and large quantity generators and correspond with 40 CFR §262.10(a)(2).

The commission proposes new §335.52(b) to identify the requirement for hazardous waste generators to conduct a generator category determination and correspond with 40 CFR §262.10(b).

The commission proposes new §335.52(c) to identify the provisions applicable to hazardous waste exporters or importers and correspond with 40 CFR §262.10(d).

The commission proposes new §335.52(d) to establish the applicability of this chapter to hazardous waste importers and correspond with 40 CFR §262.10(e).

The commission proposes new §335.52(e) to identify the provisions applicable to farmers that generate hazardous waste pesticides and correspond with 40 CFR §262.10(f).

The commission proposes new §335.52(f) to identify the consequences applicable to hazardous waste generators that violate an independent requirement or fail to comply with a condition for exemption and correspond with 40 CFR §262.10(g).

The commission proposes new §335.52(g) to identify the applicability of this subchapter to owners or operators of treatment, storage, or disposal facilities shipping hazardous wastes and correspond with 40 CFR §262.10(h).

The commission proposes new §335.52(h) to identify the exemption from this subchapter for a person responding to an explosives or munitions emergency and correspond with 40 CFR §262.10(i).

The commission proposes new §335.52(i) to identify exclusions applicable to laboratories owned by eligible academic entities and correspond with 40 CFR §262.10(l).

The commission proposes new §335.52(j) to identify the exemption for reverse distributors from this subchapter and correspond with 40 CFR §262.10(m).

The commission proposes new §335.52(k) to identify the exemption from this subchapter for healthcare facilities that are not VSQGs, and to clarify the provisions of this subchapter applicable to healthcare facilities that are VSQGs and correspond with 40 CFR §262.10(n).

§335.53, General Standards Applicable to Generators of Hazardous Waste

The commission proposes new §335.53 to adopt by reference the federal regulations in 40 CFR §§262.11 - 262.18 as described further in this preamble.

The commission proposes new §335.53(a) to adopt by reference new 40 CFR §262.11(e) - (g) associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state requirement to conduct a hazardous waste determination in current §335.62 is proposed for repeal and would be replaced by this section. The remainder of revised 40 CFR §262.11 is proposed for adoption in §335.504, as described in the Section by Section Discussion for that section.

The commission proposes new §335.53(b) to adopt by reference new 40 CFR §262.13 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The exclusion for hazardous wastes from the generator category determination in current §335.78(c) and (d) is proposed for repeal and would be replaced by this section.

The commission proposes new §335.53(c) to adopt by reference new 40 CFR §262.14 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The state provisions for conditionally exempt small quantity generators (the term was replaced in the Hazardous Waste Generator Improvements Rule with "very small quantity generator") in current §335.78 are proposed for repeal and would be replaced by this section.

The commission proposes new §335.53(d) to adopt by reference new 40 CFR §262.15 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provisions for satellite accumulation in current §335.69(d) and (e) are proposed for repeal and would be replaced by this section.

The commission proposes new §335.53(e) to adopt by reference new 40 CFR §262.16 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provisions for small quantity generators in current §335.69(f) - (h) are proposed for repeal and would be replaced by this section.

The commission proposes new §335.53(f) to adopt by reference new 40 CFR §262.17 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provisions for large quantity generators in current §335.69(a) - (b) and (j) - (l) are proposed for repeal and would be replaced by this section.

The commission proposes new §335.53(g) to adopt by reference new 40 CFR §262.18 associated with the Hazardous Waste Generator Improvements Rule and promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The state provision for the EPA identification number requirement in current §335.63 is proposed for repeal and would be replaced by this section.

§335.54, Hazardous Waste Manifest

The commission proposes new §335.54 to adopt by reference federal regulations in 40 CFR Part 262, Subpart B and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Electronic Manifest Fee Rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420). This section would establish manifest requirements for generators. This section would replace the adoption of sections in 40 CFR Part 262, Subpart B currently in §335.10 so the federal provisions would be adopted only once in Chapter 335.

§335.55, Pre-transport Requirements Applicable to Small and Large Quantity Generators

The commission proposes new §335.55 to adopt by reference federal regulations in 40 CFR Part 262, Subpart C, and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section would establish the pre-transport requirements for small and large quantity generators of hazardous waste and would replace current §§335.65 - 335.68 which are proposed for repeal.

§335.56, Recordkeeping and Reporting Applicable to Small and Large Quantity Generators

The commission proposes new §335.56 to adopt by reference federal regulations in 40 CFR Part 262, Subpart D and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section would establish the recordkeeping and reporting requirements for small and large quantity generators of hazardous waste. This federal language was previously adopted in current §§335.13(g) - (i), 335.70, 335.71, 335.73, and 335.74 which are proposed for repeal.

§335.57, Farmers

The commission proposes new §335.57 to adopt by reference federal regulations in 40 CFR Part 262, Subpart G and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section would establish the requirements for farmers disposing of hazardous waste

pesticides and would replace current §335.77 which is proposed for repeal.

§335.58, Transboundary Movements of Hazardous Waste for Recovery or Disposal

The commission proposes new §335.58 to adopt by reference federal regulations in 40 CFR Part 262, Subpart H and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), and the Export and Import Confidentiality Rule promulgated in the *Federal Register* on December 26, 2017 (82 FR 60894), and amended in the *Federal Register* on August 6, 2018 (83 FR 38262). This section would establish the requirements for transboundary movements of hazardous waste and would reorganize the adoption by reference in current §335.76 which is proposed for repeal.

§335.59, Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

The commission proposes new §335.59 to adopt by reference federal regulations in 40 CFR Part 262, Subpart K and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section would establish the alternative requirements for laboratories owned by eligible academic entities and would replace current §335.79 which is proposed for repeal.

§335.60, Alternative Standards for Episodic Generation

The commission proposes new §335.60 to adopt by reference new federal regulations in 40 CFR Part 262, Subpart L and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This section would establish requirements for alternative standards for episodic generation of hazardous waste applicable to VSQGs and small quantity generators.

§335.61, Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators

The commission proposes new §335.61 to adopt by reference new federal regulations in 40 CFR Part 262, Subpart M and to adopt federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). This new federal subpart was established to repeat the requirements in 40 CFR Part 265, Subparts C and D applicable to large quantity generators of hazardous waste in 40 CFR Part 262. 40 CFR Part 265, Subparts C and D remain adopted by reference in §335.112.

Repealed Subchapter C: Standards Applicable to Generators of Hazardous Waste

§335.61, Purpose, Scope and Applicability

The commission proposes to repeal current §335.61. This section would be replaced by proposed new §335.52 as described in the Section by Section Discussion for that section.

§335.62, Hazardous Waste Determination and Waste Classification

The commission proposes to repeal §335.62. This section would be replaced by proposed new §335.53 as described in the Section by Section Discussion for that section.

§335.63, EPA Identification Numbers

The commission proposes to repeal §335.63. This section would be replaced by proposed new §335.53 as described in the Section by Section Discussion for that section.

§335.65, Packaging

The commission proposes to repeal §335.65. This section would be replaced by proposed new §335.55 as described in the Section by Section Discussion for that section.

§335.66, Labeling

The commission proposes to repeal §335.66. This section would be replaced by proposed new §335.55 as described in the Section by Section Discussion for that section.

§335.67, Marking

The commission proposes to repeal §335.67. This section would be replaced by proposed new §335.55 as described in the Section by Section Discussion for that section.

§335.68, Placarding

The commission proposes to repeal §335.68. This section would be replaced by proposed new §335.55 as described in the Section by Section Discussion for that section.

§335.69, Accumulation Time

The commission proposes to repeal §335.69. This section would be replaced by proposed new §335.53 as described in the Section by Section Discussion for that section.

§335.70, Recordkeeping

The commission proposes to repeal §335.70. This section would be replaced by proposed new §335.56 as described in the Section by Section Discussion for that section.

§335.71, Biennial Reporting

The commission proposes to repeal §335.71. This section would be replaced by proposed new §335.56 as described in the Section by Section Discussion for that section.

§335.73, Additional Reporting

The commission proposes to repeal §335.73. This section would be replaced by proposed new §335.56 as described in the Section by Section Discussion for that section.

§335.74, Special Requirements for Generators of Between 100 and 1,000 Kilograms per Month

The commission proposes to repeal §335.74. This section would be replaced by proposed new §335.56 as described in the Section by Section Discussion for that section.

§335.75, Notification Requirements for Interstate Shipments

The commission proposes to repeal §335.75. This section is duplicative of requirements in §335.13 as described in the Section by Section Discussion for that section.

§335.76, Additional Requirements Applicable to International Shipments

The commission proposes to repeal §335.76. This section would be replaced by proposed new §335.58 as described in the Section by Section Discussion for that section.

§335.77, Farmers

The commission proposes to repeal §335.77. This section would be replaced by proposed new §335.57 as described in the Section by Section Discussion for that section.

§335.78, Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators

The commission proposes to repeal §335.78. This section would be replaced by proposed new §335.52 and §335.53 as described in the Section by Section Discussions for those sections.

§335.79, Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

The commission proposes to repeal §335.79. This section would be replaced by proposed new §335.59 as described in the Section by Section Discussion for that section.

Subchapter D, Standards Applicable to Transporters of Hazardous Waste

§335.91, Scope

The commission proposes to amend §335.91(a) to implement plain language clarifications.

The commission proposes to amend §335.91(c) to clarify additional sections and subchapters applicable to hazardous waste transporters.

The commission proposes to amend §335.91(e) to remove the dated citation for 40 CFR Part 262, Subpart H and to clarify that 40 CFR Part 262, Subpart H, 40 CFR §262.83(d), and 40 CFR §262.84(d) would be adopted by reference under proposed new §335.58.

§335.94, Transfer Facility Requirements

The commission proposes to amend §335.94(a) to add the term "independent requirements", and replace the reference to §335.65, which is proposed for repeal, with 40 CFR §262.30 as adopted under §335.55.

The commission proposes §335.94(c) to adopt the language added to 40 CFR §263.12(b) in the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

Subchapter E: Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities

§335.112, Standards

The commission proposes to amend §335.112 to adopt by reference revisions associated with the adoption of the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission proposes to accomplish the adoption of these revisions by updating the federal citations for 40 CFR Part 265, Subparts B, E, I, J, AA, BB, and DD in §335.112(a)(1), (4), (8), (9), (19), (20), and (22) respectively.

The commission proposes to amend §335.112(a)(4) to adopt revisions associated with the Electronic Manifest Fee Rule by updating the federal citation for 40 CFR Part 265 Subpart E, and revising the list of CFR sections excepted from the adoption of 40 CFR Part 265, Subpart E.

The commission proposes to amend §335.112(a)(7) to correct a typographical error by replacing the incorrect citation 40 CFR §264.146 with 40 CFR §265.146.

The commission proposes to amend §335.112(a)(21) to adopt revisions associated with the Electronic Manifest Fee Rule by updating the federal citation for 40 CFR Part 265, Subpart CC.

The commission proposes §335.112(a)(24) to adopt revisions associated with the Electronic Manifest Fee Rule by adopting by reference 40 CFR Part 265, Subpart FF and renumbering the subsequent paragraphs.

The commission proposes to amend §335.112(b) to adopt revisions associated with the Electronic Manifest Fee Rule by adding exception language clarifying that the changes listed in subsection (b) do not apply to the use of the manifest system requirements under 40 CFR §265.71 or the fees for the electronic hazardous waste manifest program requirements under 40 CFR Part 265, Subpart FF.

The commission additionally proposes to amend §335.112(b)(7) to adopt revisions associated with the Electronic Manifest Fee Rule by removing 40 CFR §265.71 and §265.72 from the list of CFR sections that when referenced in regulations adopted by reference under this section must be substituted with references to sections in Chapter 335.

The commission proposes to delete §335.112(c) because the necessity and practice of maintaining and making available to the public on demand an up-to-date physical copy of the CFR has been superseded by the CFR being maintained accessible and available to the public on the internet.

Subchapter F: Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities

§335.152, Standards

The commission proposes to amend §335.152 to adopt by reference the changes associated with the adoption of the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission proposes to accomplish the adoption of these revisions by updating the federal citations for 40 CFR Part 264, Subparts B, E, I, J, AA, BB, and DD in §335.152(a)(1), (4), (7), (8), (17), (18), and (20) respectively.

The commission proposes to amend §335.152(a)(4) to adopt revisions associated with the Electronic Manifest Fee Rule by updating the federal citation for 40 CFR Part 264, Subpart E, and revising the list of CFR sections excepted from the adoption of 40 CFR Part 264, Subpart E.

The commission proposes to amend §335.152(a)(4) and (19) and add §335.152(a)(22) to adopt by reference revisions associated with the Electronic Manifest Fee rule promulgated in the *Federal Register* on January 3, 2018 (83 FR 420). The commission proposes to accomplish the adoption of these revisions by updating the federal citation for 40 CFR Part 264, Subpart CC; adding new 40 CFR Part 264, Subpart FF as §335.152(a)(22); and renumbering the subsequent paragraph.

The commission proposes to amend §335.152(c) to clarify that the changes listed in subsection (c) do not apply to the state adoption of 40 CFR §264.71 or 40 CFR Part 264, Subpart FF, and to amend §335.152(c)(7) to remove 40 CFR §264.71 and §264.72 from the list of CFR references that are changed to references in Chapter 335.

The commission proposes to delete the last sentence of §335.152(b), and the entirety of §335.152(d), because the necessity and practice of maintaining and making available to the public on demand an up-to-date physical copy of the CFR

has been superseded by the CFR being maintained accessible and available to the public on the internet.

Subchapter H: Standards for the Management of Specific Wastes and Specific Types of Facilities

Division 2: Hazardous Waste Burned for Energy Recovery

§335.221, Applicability and Standards

The commission proposes to amend §335.221(a)(19) to remove and replace the reference to §335.78 with the phrase "generated by a very small quantity generator" in order to conform with federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The definition for VSQG is proposed in §335.1 as described in the Section by Section Discussion for that definition.

The commission proposes to amend §335.221(b) to remove and replace references to §335.78 and the term "conditionally exempt small quantity generator." In §335.221(b)(1), "conditionally exempt small quantity generator" would be replaced with the phrase "a generator that meets the conditions for exemption for a very small quantity generator during the calendar month in which the hazardous waste was generated." The language in current §335.221(b)(2) would be separated into revised paragraph (2) and proposed paragraph (3), and the subsequent paragraphs would be renumbered. Proposed §335.221(b)(3) would replace the references to CESQGs and §335.78 with VSQGs.

Division 3: Recyclable Materials Utilized for Precious Metal Recovery

§335.241, Applicability and Requirements

The commission proposes to amend §335.241(b)(3) to correct the titles of §335.10 and §335.11 by deleting the terms "Industrial" and "Solid" and to add the sections applicable to recycling activities subject to this section, in accordance with the proposed relocation of adoption of several federal requirements to §335.54 and §335.112. These changes are described in the Section by Section Discussion for those sections.

The commission proposes to amend §335.241(b)(4) to incorporate federal revisions associated with the Imports and Exports of Hazardous Waste Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85696) by revising the language in §335.241(b)(4) to be consistent with the federal language in 40 CFR §266.70(b)(3). The Imports and Exports of Hazardous Waste Rule was adopted June 5, 2020 (45 TexReg 3773), however §335.241 was not opened and revised at that time. The commission proposes to further amend §335.241(b)(4) to remove the reference to §335.76, which is proposed for repeal, and clarify that proposed new §335.58 applies to exports and imports of precious metals for recovery.

Division 4: Spent Lead-Acid Batteries Being Reclaimed

§335.251, Applicability and Requirements

The commission proposes to amend §335.251(a) to adopt by reference the revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) by updating the *Federal Register* citation for 40 CFR Part 266, Subpart G.

The commission proposes to amend §335.251(c) and (e) - (g) to replace references to §335.63 with proposed new §335.53 as described in the Section by Section Discussion for those sections.

Division 5: Universal Waste Rule

§335.261, Universal Waste Rule

The commission proposes revisions to the universal waste regulations, as described in the Section by Section Discussion for this section, to add aerosol cans to the list of hazardous waste recognized as universal waste.

The commission proposes to amend §335.261(a) to update the *Federal Register* citation for 40 CFR Part 273 to adopt by reference revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816), and the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202).

The commission proposes to amend §335.261(b)(4) to replace the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission proposes to amend §335.261(b)(8) to replace the reference to §335.77 with proposed new §335.57 as described in the Section by Section Discussion for those sections.

The commission proposes to amend §335.261(b)(12) to replace the citation to §335.261(b)(16)(E) with §335.261(b)(19)(E) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission proposes §335.261(b)(14) - (16) to conform with revisions associated with the Aerosol Can Waste Rule by adding references to Chapter 335 instead of reference to 40 CFR Part 261, adding a reference to §335.41(f) instead of 40 CFR §261.7 and renumbering the subsequent paragraphs.

The commission proposes to amend renumbered §335.261(b)(17) to replace the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission proposes to further amend renumbered §335.261(b)(17) to add that 40 CFR §261.4(b)(1) is changed to both §335.1 and §335.402(5). The reference to §335.402(5) was mistakenly listed in renumbered §335.261(b)(18).

The commission proposes to amend renumbered §335.261(b)(18) to replace the reference to 40 CFR §261.5 with 40 CFR §262.14 to conform with revised 40 CFR §273.8 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). Additionally, the commission proposes to amend renumbered §335.261(b)(18) by replacing the reference to §335.78 with proposed new §335.53 as described in the Section by Section Discussion for those sections, and by replacing the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule and the renumbering of paragraphs in this subsection.

The commission proposes to further amend renumbered §335.261(b)(18) to remove the reference to §335.402(5).

The commission proposes §335.261(b)(19)(F)(vi) to implement revisions associated with the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202). This revision would add aerosol cans to the list of hazardous wastes recognized as a universal waste regulated under this division.

The commission proposes to amend renumbered §335.261(b)(20) to replace the citation to §335.261(b)(16)(D) with §335.261(b)(19)(D) to conform with revisions associated with the Aerosol Can Waste Rule and the renumbering of paragraphs in this subsection.

The commission proposes to amend renumbered §335.261(b)(23) to implement revisions associated with the Aerosol Can Waste Rule by replacing the reference to "40 CFR §262.34" with "40 CFR parts 260 through 272" to correspond with revised 40 CFR §273.13, and by replacing the reference to §335.69 with Chapter 335.

The commission proposes §335.261(b)(25) and (26) to conform with revisions associated with the Aerosol Can Waste Rule by adding references to §335.53 instead of the references to 40 CFR §§262.11 and 262.14 - 262.17, adding a reference to Chapter 335 instead of the reference to 40 CFR Parts 260 - 272, and renumbering the subsequent paragraphs.

The commission proposes to amend renumbered §335.261(b)(28) to replace the citation to §335.261(b)(16)(C) with §335.261(b)(19)(C) to conform with revisions associated with the Aerosol Can Waste Rule and renumbering the subsequent paragraphs.

The commission proposes to amend renumbered §335.261(b)(31) to implement revisions associated with the Aerosol Can Waste Rule by replacing the reference to "40 CFR §262.34" with "40 CFR parts 260 through 272" to correspond with revised 40 CFR §273.33, and by replacing the reference to §335.69 with Chapter 335.

The commission proposes §335.261(b)(35) and (36) to conform with revisions associated with the Aerosol Can Waste Rule by adding references to §335.53 instead of the reference to 40 CFR §§262.11 or 262.14 - 262.17 and reference to Chapter 335 instead of the reference to 40 CFR Parts 260 - 272 and renumbering the subsequent paragraphs.

The commission proposes to amend renumbered §335.261(b)(41) to replace the citation to §335.261(b)(16)(A) with §335.261(b)(19)(A) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission proposes to amend renumbered §335.261(b)(45) to replace the citation to §335.261(b)(16)(F) with §335.261(b)(19)(F) to conform with revisions associated with the Aerosol Can Waste Rule.

The commission proposes to amend §335.261(c) to implement revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes language consistent with 40 CFR §273.80(a).

The commission proposes §335.261(c)(4) to implement revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes language consistent with 40 CFR §273.80(d). Specifically, the EPA added 40 CFR §273.80(d) to exclude hazardous waste pharmaceuticals from being added as a universal waste category.

Division 6: Military Munitions

§335.272, Standards.

The commission proposes to amend §335.272(b)(6) to replace the reference to §335.61(h) with proposed new §335.52 as described in the Section by Section Discussion for those sections.

The commission proposes to amend §335.272(b)(7) to replace the section title for §335.91, which was incorrectly identified as "Standards Applicable to Transporters of Hazardous Waste", the title for Chapter 335, Subchapter D.

Subchapter O: Land Disposal Restrictions

§335.431, Purpose, Scope, and Applicability

The commission proposes to amend §335.431(c)(1) to adopt by reference revisions to 40 CFR Part 268 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). Specifically, the EPA amended 40 CFR §§268.1, 268.7, and 268.50 in the Hazardous Waste Generator Improvements Rule.

The commission proposes to further amend §335.431(c)(1) to adopt by reference revisions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these revisions by amending the *Federal Register* citation for 40 CFR Part 268. Specifically, the EPA amended the section heading in 40 CFR §268.7 and the subject heading in 40 CFR §268.7(a) to include reverse distributors. The EPA also added 40 CFR §268.50(a)(4) and (5) to clarify that healthcare facilities and reverse distributors that meet certain conditions are not subject to the prohibition of storage of hazardous wastes restricted from land disposal under the RCRA.

The commission proposes to amend §335.431(d)(5) to replace the federal citation for 40 CFR §262.34 with 40 CFR §262.16 and §262.17 consistent with the revised language in 40 CFR §268.50(a)(1), and replace the reference to §335.69 with proposed new §335.53 as described in the Section by Section Discussion for that section.

The commission proposes §335.431(d)(6) and (7) to conform with revisions associated with the Pharmaceutical Waste Rule by adding state replacements for the new federal language proposed for adoption.

Subchapter Q: Pollution Prevention: Source Reduction and Waste Minimization

§335.471, Definitions

The commission proposes to delete §335.471(1) and renumber the subsequent paragraphs. The definition for "Acute hazardous waste" is proposed in §335.1(6) as further described in the Section by Section Discussion for that section.

The commission proposes to delete §335.471(3) and renumber the subsequent paragraphs. The EPA renamed the generator classification "conditionally exempt small quantity generator" as "very small quantity generator" in the Hazardous Waste Generator Improvements Rule, and definitions for "conditionally exempt small quantity generator" and "very small quantity generator" are proposed in §335.1(38) and (193) respectively as further described in the Section by Section Discussions for that section.

The commission proposes to delete §335.471(5) and renumber the subsequent paragraphs. The definition for "Environmental management system" would no longer be needed due to the proposed deletion of §335.477(3) as described in the Section by Section Discussion for that section.

The commission proposes to delete §335.471(8) and renumber the subsequent paragraphs. The definition for "Large quantity generator" is proposed in §335.1(105) as further described in the Section by Section Discussion for that section.

The commission proposes to delete §335.471(12) and renumber the subsequent paragraphs. The definition for "Small quantity generator" would no longer be needed in this subchapter due to the proposed expansion for the definition in §335.1(159) as further described in the Section by Section Discussion for that section.

§335.474, Pollution Prevention Plans

The commission proposes to amend §335.474(1) to replace the citation for the definition of "Large quantity generators" in §335.471(8) with §335.1, and to remove the citation for the definition of "TRI Form R reporters" in §335.471(15).

The commission proposes to amend §335.474(2) to replace the citation for the definition of "Small quantity generators" in §335.471(12) with §335.1, and to remove the citation for the definition of "TRI Form R reporters" in §335.471(15).

§335.477, Exemptions

The commission proposes to delete §335.477(3). The referenced section, 30 TAC §90.36, was repealed as published in the July 13, 2012 issue of the *Texas Register* (37 TexReg 5310).

Subchapter R: Waste Classification

§335.503, Waste Classification and Waste Coding Required

The commission proposes to amend §335.503(a)(1) to clarify that hazardous waste and industrial solid waste are subject to this chapter.

The commission proposes to amend §335.503(b) to clarify how a waste code number is assigned and the use of characters and digits in the waste code number.

The commission proposes to amend §335.503(b)(1) to clarify that the four characters of a waste code number which constitute the four-character sequence number may consist of numeric and or alpha characters.

The commission proposes to amend §335.503(b)(2) to delete the last two sentences since the commission no longer assigns alphanumeric sequences codes for one-time shipments for registered generators. The commission would continue to assign alphanumeric sequences codes for one-time shipments for unregistered generators in accordance with §335.503(b)(3).

The commission proposes to amend §335.503(b)(6) and (7) to replace references to CESQGs with generators meeting the conditions for exemption for a VSQG in order to conform with federal revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The definition for VSQG is proposed in §335.1 as described in the Section by Section Discussion for that definition.

The commission proposes to further amend §335.503(b)(6) and (7) to replace the "CESQ" waste code with "VSQG." The commission intends to implement these proposed amendments by allowing generators who are not required to use a waste manifest to use the new four-character sequence number "VSQG" as the first four characters of the waste code or to continue using the four-character sequence number that is proposed for repeal "CESQ" through December 31, 2024. The commission intends to require the use of the sequence number "VSQG" beginning on January 1, 2025.

The commission proposes to amend §335.503(b)(8) by implementing plain language clarifications regarding the TSDF sequence code when shipping waste received from off-site, and by deleting manifesting instructions that have been reorganized and are proposed to be adopted under §335.54 and §335.12.

The commission proposes §335.503(b)(9) to conform to changes associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816) by adding the requirement for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility to use the sequence code "PHRM" for the first four characters of the waste code.

§335.504, Hazardous Waste Determination

The commission proposes to amend §335.504 to adopt revisions to 40 CFR §262.11 associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission proposes to accomplish the adoption of these revisions by labeling implied subsection (a) as subsection (a) and adding the catch line "Hazardous waste determination", and adding §335.504(a)(3)(A) and (B), (B)(i) and (ii), (b), and (c) to adopt certain requirements of 40 CFR §262.11 in writing.

The commission proposes to amend §335.504(a)(1) to adopt by reference revisions to 40 CFR Part 261, Subpart A associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), the Definition of Solid Waste Rule promulgated in the *Federal Register* on May 30, 2018 (83 FR 24664), the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816), and the Aerosol Can Waste Rule promulgated in the *Federal Register* on December 9, 2019 (84 FR 67202). The commission proposes to accomplish the adoption of these revisions by amending the *Federal Register* citation for 40 CFR Part 261, Subpart A.

The commission proposes to amend §335.504(a)(1) to adopt by reference revisions to 40 CFR Part 261, Subpart E associated with the Export and Import Confidentiality rule promulgated in the *Federal Register* on December 26, 2017 (82 FR 60894) and amended in the *Federal Register* on August 6, 2018 (83 FR 38262). The commission proposes to accomplish the adoption of these revisions by amending the *Federal Register* citation for 40 CFR Part 261, Subpart E.

The commission proposes to amend §335.504(a)(2) to adopt revisions in the hazardous waste determination requirements of 40 CFR §262.11 and to adopt by reference revisions to 40 CFR Part 261, Subpart D associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732) and the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816), The commission proposes to accomplish the adoption of these revisions by amending the *Federal Register* citation for 40 CFR Part 261, Subpart D.

§335.510, Sampling Documentation

The commission proposes to amend §335.510(a) to add the reference to 40 CFR §262.11(f) as adopted by reference at §335.53 to clarify the documentation required for generators to conform with revisions associated with the Hazardous Waste Genera-

tor Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

§335.511, Use of Process Knowledge

The commission proposes to amend §335.511(a) to require generators to follow §335.504 when using process knowledge to classify hazardous waste and to add language specifying what constitutes acceptable process knowledge generators may use to classify nonhazardous industrial waste. These amendments would conform with revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

§335.513, Documentation Required

The commission proposes to amend §335.513(a) to add the reference to 40 CFR §262.11(f) as adopted by reference at §335.53 to the documentation required for generators to conform with revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732).

§335.521, Appendices

The commission proposes to amend the Figure in 30 TAC §335.521(a)(2) to replace the word "non-hazardous" with "nonhazardous" for consistency with the rest of the chapter.

The commission proposes to amend §335.521(b) to revise the name of the agency and the agency website.

Subchapter T: Permitting Standards for Owners and Operators of Commercial Industrial Nonhazardous Waste Landfill Facilities

§335.590, Operational and Design Standards

The commission proposes to amend §335.590(25) to adopt revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission proposes to accomplish the adoption of these revisions by replacing references to a CESQG with VSQG. The reference to §335.78(a), which is proposed for repeal, would be deleted.

Subchapter U: Standards for Owners and Operators of Hazardous Waste Facilities Operating Under a Standard Permit

§335.602, Standards

The commission proposes to amend §335.602(a)(4) to adopt by reference revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission proposes to accomplish the adoption of these revisions by amending the *Federal Register* citation for 40 CFR Part 267, Subpart E.

The commission proposes to amend §335.602(b)(2)(I) to adopt by reference revisions associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732). The commission proposes to accomplish the adoption of these revisions by replacing the reference to 40 CFR §262.34 with 40 CFR §262.16 or §262.17 in accordance with revisions to 40 CFR §267.71, and replacing the reference to §335.69 with proposed new §335.53, the location these federal sections are proposed for adoption.

Subchapter V: Standards for Reclamation of Hazardous Secondary Materials

§335.702, Standards

The commission proposes to amend §335.702(a)(3) to adopt by reference revisions to 40 CFR §261.420(g) associated with the Hazardous Waste Generator Improvements Rule promulgated in the *Federal Register* on November 28, 2016 (81 FR 85732), by adding a federal citation for 40 CFR Part 261, Subpart M.

§335.703, Financial Assurance Requirements

The commission proposes to amend §335.703(c)(1) to adopt revisions associated with the Definition of Solid Waste Rule published in the May 30, 2018 issue of the *Federal Register* (83 FR 24664) by deleting the phrase "receiving a variance for."

Subchapter W: Management Standards for Hazardous Waste Pharmaceuticals

§335.751, Definitions

The commission proposes new §335.751 to adopt definitions associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding definitions for the terms "Evaluated hazardous waste pharmaceutical", "Hazardous waste pharmaceutical", "Healthcare facility", "Household waste pharmaceutical", "Long-term care facility", "Non-creditable hazardous waste pharmaceutical", "Nonhazardous waste pharmaceutical", "Non-pharmaceutical hazardous waste", "Pharmaceutical", "Potentially creditable hazardous waste pharmaceutical", and "Reverse distributor", consistent with the definitions in 40 CFR §266.500.

§335.753, Applicability

The commission proposes new §335.753 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.501 to establish the applicability of Chapter 335, Subchapter W to healthcare facilities and reverse distributors for the management of hazardous waste pharmaceuticals.

§335.755, Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The commission proposes new §335.755 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.502 to establish the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

§335.757, Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

The commission proposes new §335.757 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.503 to establish the standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

§335.759, Healthcare Facilities That are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste

The commission proposes new §335.759 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in

the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.504 to establish the standards applicable to healthcare facilities that are also VSQGs.

§335.761, Prohibition of Sewering Hazardous Waste Pharmaceuticals

The commission proposes new §335.761 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.505 to establish the sewering prohibition applicable to all hazardous waste pharmaceuticals.

§335.763, Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program

The commission proposes new §335.763 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.506 to establish the conditional exemption from regulation under this subchapter for hazardous waste pharmaceuticals that are also subject to regulation by the federal Drug Enforcement Administration.

§335.765, Residues of Hazardous Waste Pharmaceuticals in Empty Containers

The commission proposes new §335.765 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.507 to describe the requirements for containers with residues of hazardous waste pharmaceuticals to be considered empty.

§335.767, Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor

The commission proposes new §335.767 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.508 and adopting 40 CFR §266.508(a)(1)(iii)(b) by reference, to establish the shipping requirements for hazardous waste pharmaceuticals that are not eligible for a manufacturer's credit.

§335.769, Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor

The commission proposes new §335.769 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.509 to establish the shipping requirements for hazardous waste pharmaceuticals that are potentially eligible for a manufacturer's credit.

§335.771, Standards for the Management of Potentially Creditable and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors

The commission proposes new §335.771 to adopt regulations associated with the Pharmaceutical Waste Rule promulgated in the *Federal Register* on February 22, 2019 (84 FR 5816). The commission proposes to accomplish the adoption of these regulations by adding language consistent with language in 40 CFR §266.510 to establish the standards applicable to reverse distributors for the management of hazardous waste pharmaceuticals. This section would also establish registration and reporting requirements for reverse distributors.

Fiscal Note: Costs to State and Local Government

Jené Bearse, Analyst in the Budget and Planning Division, determined that for the first five-year period the proposed rules would be in effect, no fiscal implications are anticipated for the agency or for other units of state or local government as a result of administration or enforcement of the proposed rulemaking.

This rulemaking addresses necessary changes in order to comply with federal waste regulations and codify a regulatory letter regarding foundry sand.

Public Benefits and Costs

Ms. Bearse determined that for each year of the first five years the proposed rules would be in effect, the public benefit anticipated would be compliance with federal regulations and increased flexibility under the hazardous waste generator regulatory program for managing or recycling hazardous secondary materials, pharmaceuticals and aerosol cans. This increased flexibility could result in greater compliance with hazardous waste regulations.

Local Employment Impact Statement

The commission reviewed this proposed rulemaking and determined that a Local Employment Impact Statement is not required because the proposed rulemaking would not adversely affect a local economy in a material way for the first five years that the proposed rulemaking would be in effect.

Rural Communities Impact Assessment

The commission reviewed this proposed rulemaking and determined that the proposed rulemaking would not adversely affect rural communities in a material way for the first five years that the proposed rules would be in effect. The rules would apply statewide and have the same effect in rural communities as in urban communities.

Small Business and Micro-Business Assessment

No adverse fiscal implications are anticipated for small or micro-businesses due to the implementation or administration of the proposed rulemaking for the first five-year period the proposed rules would be in effect.

Small Business Regulatory Flexibility Analysis

The commission reviewed this proposed rulemaking and determined that a Small Business Regulatory Flexibility Analysis is not required because the proposed rule would not adversely affect a small or micro-business in a material way for the first five years the proposed rules would be in effect.

Government Growth Impact Statement

The commission prepared a Government Growth Impact Statement assessment for this proposed rulemaking. The proposed rulemaking would not create or eliminate a government program and would not require an increase or decrease in future legislative appropriations to the agency. The proposed rulemaking would not require the creation of new employee positions, eliminate current employee positions, nor require an increase or decrease in fees paid to the agency. The proposed rulemaking would not create, expand, repeal or limit an existing regulation, nor would the proposed rulemaking increase or decrease the number of individuals subject to its applicability. During the first five years, the proposed rule should not impact positively or negatively the state's economy.

Draft Regulatory Impact Analysis Determination

The commission reviewed the proposed rulemaking in light of the regulatory analysis requirements of the Texas Government Code, §2001.0225, and determined that the action is not subject to Texas Government Code, §2001.0225, because it does not meet the definition of a "Major environmental rule" as defined in that statute. A "Major environmental rule" is a rule the specific intent of which is to protect the environment or reduce risks to human health from environmental exposure, and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The proposed rulemaking is not a major environmental rule because it is not anticipated to adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state since the proposed rulemaking implements requirements already imposed on the regulated community under 42 United States Code (USC), §6926(g). Likewise, there would be no adverse effect in a material way on the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state from those revisions outside 42 USC, §6926(g), because either the changes are not substantive, or the regulated community would benefit from the greater flexibility and reduced compliance burden.

Texas Government Code, §2001.0225, applies to a major environmental rule, the result of which is to: exceed a standard set by federal law, unless the rule is specifically required by state law; exceed an express requirement of state law, unless the rule is specifically required by federal law; exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; or adopt a rule solely under the general authority of the commission. The proposed rulemaking does not meet any of the four applicability requirements listed in Texas Government Code, §2001.0225.

First, the rulemaking would not exceed a standard set by federal law because the commission is proposing this rulemaking to implement revisions to the federal hazardous waste program. The commission must meet the minimum standards and mandatory requirements of the federal program to maintain authorization of the state hazardous waste program.

Second, although the rulemaking proposes some requirements that are more stringent than existing state laws, federal law requires the commission to promulgate rules that are as stringent as federal law for the commission to maintain authorization of the state hazardous waste program.

Third, the rulemaking would not exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government, where the delegation agreement or contract is to implement a state and federal program. On the contrary, the commission is proposing rules that are required to maintain authorization of the state hazardous waste program.

And fourth, this rulemaking would not seek to adopt a rule solely under the general powers of the agency. Rather, this rulemaking is authorized by specific sections of the Texas Water Code and the Texas Health and Safety Code that are cited in the Statutory Authority section of this preamble.

Written comments on the Draft Regulatory Impact Analysis Determination may be submitted to the contact person at the address listed under the Submittal of Comments section of this preamble.

Takings Impact Assessment

The commission evaluated the proposed rulemaking and performed analysis of whether the proposed rules constitute a taking under Texas Government Code, Chapter 2007. The specific purpose of the proposed rules is to maintain state's authorization to implement RCRA hazardous waste program by adopting state hazardous waste rules that are equivalent to the federal regulations. The proposed rulemaking substantially advances these stated purposes by proposing rules that are equivalent to the federal regulations or incorporate the federal regulations.

The commission's analysis indicates that Texas Government Code, Chapter 2007 does not apply to the portions of the proposed rulemaking that propose to adopt rules that meet the minimum standards of the federal hazardous waste program because Texas Government Code, §2007.003(b)(4), exempts an action reasonably taken, by a state agency, to fulfill an obligation mandated by federal law from the requirements of Texas Government Code, Chapter 2007. Under 42 USC, §6926(g), the state must adopt rules that meet the minimum standards of the federal hazardous waste program administered by EPA in order to maintain authorization to administer the program. Therefore, the portions of the proposed rulemaking adopting rules that meet the minimum standards of the federal hazardous waste program are exempt from the requirements of Texas Government Code, Chapter 2007 because the rules are required by federal law.

Finally, to the extent that portions of the proposed rulemaking are not exempt under Texas of the proposed rules would be neither a statutory nor a constitutional taking of private real property. Specifically, the subject proposed regulations would not affect a landowner's rights in real property because the proposed rulemaking would not burden (constitutionally); nor restrict or limit the owner's right to property and reduce its value by 25% or more beyond that which would otherwise exist in the absence of the regulations.

Consistency with the Coastal Management Program

The commission reviewed the proposed rulemaking and found that the proposal is subject to the Texas Coastal Management Program (CMP) in accordance with the Coastal Coordination Act, Texas Natural Resources Code, §§33.201 et seq., and therefore must be consistent with all applicable CMP goals and policies. The commission conducted a consistency de-

termination for the proposed rules in accordance with Coastal Coordination Act implementation rules, 31 TAC §505.22 and found the proposed rulemaking is consistent with the applicable CMP goals and policies. The CMP goals applicable to the proposed rules include protect, preserve, restore, and enhance the diversity, quality, quantity, functions, and values of coastal natural resource areas (CNRAs); to ensure sound management of all coastal resources by allowing for compatible economic development and multiple human uses of the coastal zone; and to make agency and subdivision decision-making affecting CNRAs efficient by identifying and addressing duplication and conflicts among local, state, and federal regulatory and other programs for the management of CNRAs. CMP policies applicable to the proposed rules include to construction and operation of solid waste treatment, storage, and disposal facilities, such that new solid waste facilities and areal expansions of existing solid waste facilities shall be sited, designed, constructed, and operated to prevent releases of pollutants that may adversely affect CNRAs and, at a minimum, comply with standards established under the federal Solid Waste Disposal Act, 42 United States Code, §§6901 et seq. Promulgation and enforcement of these rules would not violate or exceed any standards identified in the applicable CMP goals and policies because the proposed rules are consistent with these CMP goals and policies, because these rules do not create or have a direct or significant adverse effect on any coastal natural resource areas, and because the proposed rules would update and enhance the commission's rules concerning hazardous waste facilities.

Written comments on the consistency of this rulemaking may be submitted to the contact person at the address listed under the Submittal of Comments section of this preamble.

Announcement of Virtual Hearing

The commission will hold a *virtual* public hearing on this proposal on August 23, 2021 at 10:00 A.M.. The hearing is structured for the receipt of oral or written comments by interested persons. Individuals may present oral statements when called upon in order of registration. Open discussion will not be permitted during the hearing; however, staff will be available to discuss the proposal 30 minutes prior to the hearing.

Registration

The hearing will be conducted remotely using an internet meeting service. Individuals who plan to attend the hearing and want to provide oral comments and/or want their attendance on record must register by Friday, August 20, 2021. To register for the hearing, please email *Rules@tceq.texas.gov* and provide the following information: your name, your affiliation, your email address, your phone number, and whether or not you plan to provide oral comments during the hearing. Instructions for participating in the hearing will be sent on August 20, 2021 to those who register for the hearing.

For the public who do not wish to provide oral comments but would like to view the hearing may do so at no cost at:

https://teams.microsoft.com/l/meetup-join/19%3ameeting_MTg1NzUyNmYtODFkZS00YjgyLTg1NmYtZjVkNjg0MTJlNGM0%40thread.v2/0?context=%7b%22Tid%22%3a%22871a83a4-a1ce-4b7a-8156-3bcd93a08fba%22%2c%22Oid%22%3a%22e74a40ea-69d4-469d-a8ef-06f2c9ac2a80%22%2c%22IsBroadcastMeeting%22%3atrue%7d.

Persons who have special communication or other accommodation needs who are planning to attend the hearing should contact Sandy Wong, Office of Legal Services at (512) 239-1802 or 1 (800) RELAY-TX (TDD). Requests should be made as far in advance as possible.

Submittal of Comments

Written comments may be submitted to Ms. Gwen Ricco, MC 205, Office of Legal Services, Texas Commission on Environmental Quality, P.O. Box 13087, Austin, Texas 78711-3087, or faxed to *fax4808@tceq.texas.gov.* Electronic comments may be submitted at: *https://www6.tceq.texas.gov/rules/ecomments/.* File size restrictions may apply to comments being submitted via the *eComments* system. All comments should reference Rule Project Number 2021-006-332-WS. The comment period closes August 30, 2021. Please choose one form of submittal when submitting *written* comments.

Copies of the proposed rulemaking can be obtained from the commission's website at *https://www.tceq.texas.gov/rules/propose_adopt.html.* For further information, please contact Jarita Sepulvado, Waste Permits Division, (512) 239-4413

SUBCHAPTER A. INDUSTRIAL SOLID WASTE AND MUNICIPAL HAZARDOUS WASTE IN GENERAL

30 TAC §§335.1, 335.2, 335.6, 335.9 - 335.15, 335.18, 335.19, 335.24, 335.26, 335.27, 335.31

Statutory Authority

The amendments and new sections are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments and new sections are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendments and new sections implement THSC, Chapter 361.

§335.1. Definitions.

In addition to the terms defined in Chapter 3 of this title (relating to Definitions), the following words and terms, when used in this chapter, have the following meanings.

(1) Aboveground tank--A device meeting the definition of "Tank" in this section and that is situated in such a way that the entire surface area of the tank is completely above the plane of the adjacent surrounding surface and the entire surface area of the tank (including the tank bottom) is able to be visually inspected.

(2) Act--Texas Health and Safety Code, Chapter 361.

(3) Active life--The period from the initial receipt of hazardous waste at the facility until the executive director receives certification of final closure.

(4) Active portion--That portion of a facility where processing, storage, or disposal operations are being or have been conducted after November 19, 1980, and which is not a closed portion. (See also "Closed portion" and "Inactive portion.")

(5) Activities associated with the exploration, development, and production of oil or gas or geothermal resources--Activities associated with:

(A) the drilling of exploratory wells, oil wells, gas wells, or geothermal resource wells;

(B) the production of oil or gas or geothermal resources, including:

(i) activities associated with the drilling of injection water source wells that penetrate the base of usable quality water;

(ii) activities associated with the drilling of cathodic protection holes associated with the cathodic protection of wells and pipelines subject to the jurisdiction of the commission to regulate the production of oil or gas or geothermal resources;

(iii) activities associated with gasoline plants, natural gas or natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants;

(iv) activities associated with any underground natural gas storage facility, provided the terms "Natural gas" and "Storage facility" shall have the meanings set out in the Texas Natural Resources Code, §91.173;

(v) activities associated with any underground hydrocarbon storage facility, provided the terms "Hydrocarbons" and "Underground hydrocarbon storage facility" shall have the meanings set out in the Texas Natural Resources Code, §91.201; and

(vi) activities associated with the storage, handling, reclamation, gathering, transportation, or distribution of oil or gas prior to the refining of such oil or prior to the use of such gas in any manufacturing process or as a residential or industrial fuel;

(C) the operation, abandonment, and proper plugging of wells subject to the jurisdiction of the commission to regulate the exploration, development, and production of oil or gas or geothermal resources; and

(D) the discharge, storage, handling, transportation, reclamation, or disposal of waste or any other substance or material associated with any activity listed in subparagraphs (A) - (C) of this paragraph, except for waste generated in connection with activities associated with gasoline plants, natural gas or natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants if that waste is a hazardous waste as defined by the administrator of the United States Environmental Protection Agency in accordance with the Federal Solid Waste Disposal Act, as amended (42 United States Code, §§6901 et seq.).

(6) Acute hazardous waste--Hazardous wastes that meet the listing criteria in 40 Code of Federal Regulations (CFR) §261.11(a)(2) and therefore are either listed in 40 CFR §261.31 with the assigned hazard code of (H) or are listed in 40 CFR §261.33(e).

(7) [~~(6)~~] Administrator--The administrator of the United States Environmental Protection Agency or his designee.

(8) Aerosol can--A non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

(9) [~~(7)~~] AES filing compliance date--The date that the United States Environmental Protection Agency (EPA) announces in the *Federal Register*, on or after which exporters of hazardous waste and exporters of cathode ray tubes for recycling are required to file EPA information in the Automated Export System or its successor system, under the International Trade Data System platform.

(10) [~~(8)~~] Airbag waste--Any hazardous waste airbag modules or hazardous waste airbag inflators.

(11) [~~(9)~~] Airbag waste collection facility--Any facility that receives airbag waste from airbag handlers subject to regulation under §335.281 of this title (relating to Airbag Waste) and accumulates the waste for more than ten days.

(12) [~~(10)~~] Airbag waste handler--Any person, by site, who generates airbag waste that is subject to regulation under this chapter.

(13) [~~(11)~~] Ancillary equipment--Any device that is used to distribute, meter, or control the flow of solid waste or hazardous waste from its point of generation to a storage or processing tank(s), between solid waste or hazardous waste storage and processing tanks to a point of disposal on site, or to a point of shipment for disposal off site. Such devices include, but are not limited to, piping, fittings, flanges, valves, and pumps.

(14) [~~(12)~~] Aquifer--A geologic formation, group of formations, or part of a formation capable of yielding a significant amount of groundwater to wells or springs.

(15) [~~(13)~~] Area of concern--Any area of a facility under the control or ownership of an owner or operator where a release to the environment of hazardous wastes or hazardous constituents has occurred, is suspected to have occurred, or may occur, regardless of the frequency or duration.

(16) [~~(14)~~] Authorized representative--The person responsible for the overall operation of a facility or an operation unit (i.e., part of a facility), e.g., the plant manager, superintendent, or person of equivalent responsibility.

(17) [~~(15)~~] Battery--As defined in §335.261 of this title (relating to Universal Waste Rule).

(18) [~~(16)~~] Boiler--An enclosed device using controlled flame combustion and having the following characteristics:

(A) the unit must have physical provisions for recovering and exporting thermal energy in the form of steam, heated fluids, or heated gases;

(B) the unit's combustion chamber and primary energy recovery section(s) must be of integral design. To be of integral design, the combustion chamber and the primary energy recovery section(s) (such as waterwalls and superheaters) must be physically formed into one manufactured or assembled unit. A unit in which the combustion chamber and the primary energy recovery section(s) are joined only by ducts or connections carrying flue gas is not integrally designed; however, secondary energy recovery equipment (such as economizers or air preheaters) need not be physically formed into the same unit as the combustion chamber and the primary energy recovery section. The following units are not precluded from being boilers solely because they are not of integral design:

(i) process heaters (units that transfer energy directly to a process stream); and

(ii) fluidized bed combustion units;

(C) while in operation, the unit must maintain a thermal energy recovery efficiency of at least 60%, calculated in terms of the recovered energy compared with the thermal value of the fuel; and

(D) the unit must export and utilize at least 75% of the recovered energy, calculated on an annual basis. In this calculation, no credit shall be given for recovered heat used internally in the same unit. (Examples of internal use are the preheating of fuel or combustion air, and the driving of induced or forced draft fans or feedwater pumps); or

(E) the unit is one which the executive director has determined, on a case-by-case basis, to be a boiler, after considering the standards in §335.20 of this title (relating to Variance To Be Classified as a Boiler).

(19) [~~(17)~~] Captive facility--A facility that accepts wastes from only related (within the same corporation) off-site generators.

(20) [~~(18)~~] Captured facility--A manufacturing or production facility that generates an industrial solid waste or hazardous waste that is routinely stored, processed, or disposed of on a shared basis in an integrated waste management unit owned, operated by, and located within a contiguous manufacturing complex.

(21) [~~(19)~~] Captured receiver--A receiver that is located within the property boundaries of the generators from which it receives waste.

(22) [~~(20)~~] Carbon dioxide stream--Carbon dioxide that has been captured from an emission source (e.g., power plant), plus incidental associated substances derived from the source materials and the capture process, and any substances added to the stream to enable or improve the injection process.

(23) [~~(21)~~] Carbon regeneration unit--Any enclosed thermal treatment device used to regenerate spent activated carbon.

(24) [~~(22)~~] Cathode ray tube (CRT)--A vacuum tube, composed primarily of glass, which is the visual or video display component of an electronic device. A used, intact CRT means a CRT whose vacuum has not been released. A used, broken CRT means its glass has been removed from its housing, or casing whose vacuum has been released.

(25) [~~(23)~~] Cathode ray tube (CRT) collector--A person who receives used, intact CRTs for recycling, repair, resale, or donation.

(26) [~~(24)~~] Cathode ray tube (CRT) exporter--Any person in the United States who initiates a transaction to send used CRTs outside the United States or its territories for recycling or reuse, or any intermediary in the United States arranging for such export.

(27) [~~(25)~~] Cathode ray tube (CRT) glass manufacturer--An operation or part of an operation that uses a furnace to manufacture CRT glass.

(28) [~~(26)~~] Cathode ray tube (CRT) processing--Conducting all of the following activities:

(A) receiving broken or intact CRTs;

(B) intentionally breaking intact CRTs or further breaking or separating broken CRTs; and

(C) sorting or otherwise managing glass removed from CRT monitors.

(29) Central accumulation area--Any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either 40 Code of Federal Regulations (CFR) §262.16 or §262.17, as these sections are adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste). In accordance with 40 CFR Part 262, Subpart K, as adopted by reference under §335.59 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities), a central accumulation area at an eligible academic entity that chooses to operate under 40 CFR Part 262, Subpart K, is also subject to 40 CFR §262.211 as adopted by reference under §335.59 of this title when accumulating unwanted material and/or hazardous waste.

(30) [~~(27)~~] Certification--A statement of professional opinion based upon knowledge and belief.

(31) [~~(28)~~] Class 1 wastes--Any industrial solid waste or mixture of industrial solid wastes which because of its concentration, or physical or chemical characteristics, is toxic, corrosive, flammable, a strong sensitizer or irritant, a generator of sudden pressure by decomposition, heat, or other means, or may pose a substantial present or potential danger to human health or the environment when improperly processed, stored, transported, or disposed of or otherwise managed, as further defined in §335.505 of this title (relating to Class 1 Waste Determination).

(32) [~~(29)~~] Class 2 wastes--Any individual solid waste or combination of industrial solid waste which cannot be described as hazardous, Class 1, or Class 3 as defined in §335.506 of this title (relating to Class 2 Waste Determination).

(33) [~~(30)~~] Class 3 wastes--Inert and essentially insoluble industrial solid waste, usually including, but not limited to, materials such as rock, brick, glass, dirt, and certain plastics and rubber, etc., that are not readily decomposable, as further defined in §335.507 of this title (relating to Class 3 Waste Determination).

(34) [~~(31)~~] Closed portion--That portion of a facility which an owner or operator has closed in accordance with the approved facility closure plan and all applicable closure requirements. *(See* also "Active portion" and "Inactive portion.")

(35) [~~(32)~~] Closure--The act of permanently taking a waste management unit or facility out of service.

(36) [~~(33)~~] Commercial hazardous waste management facility--Any hazardous waste management facility that accepts hazardous waste or polychlorinated biphenyl compounds for a charge, except a captured facility or a facility that accepts waste only from other facilities owned or effectively controlled by the same person.

(37) [~~(34)~~] Component--Either the tank or ancillary equipment of a tank system.

(38) Conditionally exempt small quantity generator--A conditionally exempt small quantity generator (CESQG) is a very small quantity generator as defined in this section that meets the independent requirements and the conditions for exemption for a very small quantity generator under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste). A reference to a conditionally exempt small quantity generator, "CESQG", or a person who generates no more than 100 kilograms of hazardous waste in a calendar month is a reference to a very small quantity generator.

(39) [~~(35)~~] Confined aquifer--An aquifer bounded above and below by impermeable beds or by beds of distinctly lower permeability than that of the aquifer itself; an aquifer containing confined groundwater.

(40) [~~(36)~~] Contained--Hazardous secondary materials held in a unit (including a "Land-based unit" as defined in this section) that meets the following criteria:

(A) the unit is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the hazardous secondary materials to the environment, and is designed, as appropriate for the hazardous secondary materials, to prevent releases of hazardous secondary materials to the environment. Unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures;

(B) the unit is properly labeled or otherwise has a system (such as a log) to immediately identify the hazardous secondary materials in the unit;

(C) the unit holds hazardous secondary materials that are compatible with other hazardous secondary materials placed in the unit and is compatible with the materials used to construct the unit and addresses any potential risks of fires or explosions; and

(D) hazardous secondary materials in units that meet the requirements of 40 Code of Federal Regulations Parts 264 and 265 are presumptively contained.

(41) [~~(37)~~] Container--Any portable device in which a material is stored, transported, processed, or disposed of, or otherwise handled.

(42) [~~(38)~~] Containment building--A hazardous waste management unit that is used to store or treat hazardous waste under the provisions of §335.112(a)(21) or §335.152(a)(19) of this title (relating to Standards).

(43) [~~(39)~~] Contaminant--Includes, but is not limited to, "Solid waste," "Hazardous waste," and "Hazardous waste constituent" as defined in this section; "Pollutant" as defined in Texas Water Code (TWC), §26.001, and Texas Health and Safety Code (THSC), §361.401; "Hazardous substance" as defined in THSC, §361.003; and other substances that are subject to the Texas Hazardous Substances Spill Prevention and Control Act, TWC, §§26.261 - 26.267.

(44) [~~(40)~~] Contaminated medium/media--A portion or portions of the physical environment to include soil, sediment, surface water, groundwater or air, that contain contaminants at levels that pose a substantial present or future threat to human health and the environment.

(45) [~~(41)~~] Contingency plan--A document setting out an organized, planned, and coordinated course of action to be followed in case of a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.

(46) [~~(42)~~] Control--To apply engineering measures such as capping or reversible treatment methods and/or institutional measures such as deed restrictions to facilities or areas with wastes or contaminated media which result in remedies that are protective of human health and the environment when combined with appropriate maintenance, monitoring, and any necessary further corrective action.

(47) [~~(43)~~] Corrosion expert--A person who, by reason of his knowledge of the physical sciences and the principles of engineering and mathematics, acquired by a professional education and related practical experience, is qualified to engage in the practice of corrosion control on buried or submerged metal piping systems and metal tanks. Such a person must be certified as being qualified by the National Association of Corrosion Engineers or be a registered professional engineer who has certification or licensing that includes education and experience in corrosion control on buried or submerged metal piping systems and metal tanks.

(48) [~~(44)~~] Decontaminate--To apply a treatment process(es) to wastes or contaminated media whereby the substantial present or future threat to human health and the environment is eliminated.

(49) [~~(45)~~] Designated facility--A hazardous waste treatment, storage, or disposal facility which: has received a permit (or interim status) in accordance with the requirements of 40 Code of Federal Regulations (CFR) Parts 124 and 270; has received a permit (or interim status) from a state authorized in accordance with 40 CFR Part 271; or is regulated under 40 CFR §261.6(c)(2) or 40 CFR Part 266, Subpart F and has been designated on the manifest by the generator pursuant to 40 CFR §262.20. For hazardous wastes, if a waste is destined to a facility in an authorized state which has not yet obtained authorization to regulate that particular waste as hazardous, then the designated facility must be a facility allowed by the receiving state to accept such waste. For Class 1 wastes, a designated facility is any treatment, storage, or disposal facility authorized to receive the Class 1 waste that has been designated on the manifest by the generator. Designated facility also means a generator site designated on the manifest to receive its waste as a return shipment from a facility that has rejected the waste in accordance with 40 CFR §264.72(f) as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.72(f) as adopted under §335.112 of this title (relating to Standards) [~~§335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities)~~].

(50) [~~(46)~~] Destination facility--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(51) [~~(47)~~] Dike--An embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids, or other materials.

(52) [~~(48)~~] Dioxins and furans (D/F)--Tetra, penta, hexa, hepta, and octa-chlorinated dibenzo dioxins and furans.

(53) [~~(49)~~] Discharge or hazardous waste discharge--The accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of waste into or on any land or water.

(54) [~~(50)~~] Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (whether containerized or uncontainerized) into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including groundwaters.

(55) [~~(51)~~] Disposal facility--A facility or part of a facility at which solid waste is intentionally placed into or on any land or water, and at which waste will remain after closure. The term "Disposal facility" does not include a corrective action management unit into which remediation wastes are placed.

(56) [~~(52)~~] Drip pad--An engineered structure consisting of a curbed, free-draining base, constructed of non-earthen materials and designed to convey preservative kick-back or drippage from treated wood, precipitation, and surface water run-on to an associated collection system at wood preserving plants.

(57) [~~(53)~~] Electronic import-export reporting compliance date--The date that the United States Environmental Protection Agency (EPA) announces in the *Federal Register,* on or after which exporters, importers, and receiving facilities are required to submit certain export

and import related documents to EPA using EPA's waste Import Export Tracking System, or its successor system.

(58) [~~(54)~~] Electronic manifest or e-Manifest--The electronic format of the hazardous waste manifest that is obtained from the United States Environmental Protection Agency's (EPA's) national e-Manifest system and transmitted electronically to the system, and that is the legal equivalent of EPA Forms 8700-22 (Manifest) and 8700-22A (Continuation Sheet).

(59) [~~(55)~~] Electronic manifest system or e-Manifest system--The United States Environmental Protection Agency's national information technology system through which the electronic manifest may be obtained, completed, transmitted, and distributed to users of the electronic manifest and to regulatory agencies.

(60) [~~(56)~~] Elementary neutralization unit--A device which:

(A) is used for neutralizing wastes which are hazardous only because they exhibit the corrosivity characteristic defined in 40 Code of Federal Regulations (CFR) §261.22, or are listed in 40 CFR Part 261, Subpart D, only for this reason; or is used for neutralizing the pH of nonhazardous industrial solid waste; and

(B) meets the definition of "Tank," "Tank system," "Container," or "Transport vehicle," as defined in this section; or "Vessel" as defined in 40 CFR §260.10.

(61) [~~(57)~~] Essentially insoluble--Any material, which if representatively sampled and placed in static or dynamic contact with deionized water at ambient temperature for seven days, will not leach any quantity of any constituent of the material into the water in excess of current United States Public Health Service or United States Environmental Protection Agency limits for drinking water as published in the *Federal Register*.

(62) [~~(58)~~] Equivalent method--Any testing or analytical method approved by the administrator under 40 Code of Federal Regulations §260.20 and §260.21.

(63) [~~(59)~~] Existing portion--That land surface area of an existing waste management unit, included in the original Part A permit application, on which wastes have been placed prior to the issuance of a permit.

(64) [~~(60)~~] Existing tank system or existing component--A tank system or component that is used for the storage or processing of hazardous waste and that is in operation, or for which installation has commenced on or prior to July 14, 1986. Installation will be considered to have commenced if the owner or operator has obtained all federal, state, and local approvals or permits necessary to begin physical construction of the site or installation of the tank system and if either:

(A) a continuous on-site physical construction or installation program has begun; or

(B) the owner or operator has entered into contractual obligations--which cannot be canceled or modified without substantial loss--for physical construction of the site or installation of the tank system to be completed within a reasonable time.

(65) [~~(61)~~] Explosives or munitions emergency--A situation involving the suspected or detected presence of unexploded ordnance, damaged or deteriorated explosives or munitions, an improvised explosive device, other potentially explosive material or device, or other potentially harmful military chemical munitions or device, that creates an actual or potential imminent threat to human health, including safety, or the environment, including property, as determined by an explosives or munitions emergency response specialist. These situations may require immediate and expeditious action by an explosives or munitions emergency response specialist to control, mitigate, or eliminate the threat.

(66) [~~(62)~~] Explosives or munitions emergency response--All immediate response activities by an explosives and munitions emergency response specialist to control, mitigate, or eliminate the actual or potential threat encountered during an explosives or munitions emergency, subject to the following:

(A) an explosives or munitions emergency response includes in-place render-safe procedures, treatment or destruction of the explosives or munitions and/or transporting those items to another location to be rendered safe, treated, or destroyed;

(B) any reasonable delay in the completion of an explosives or munitions emergency response caused by a necessary, unforeseen, or uncontrollable circumstance will not terminate the explosives or munitions emergency; and

(C) explosives and munitions emergency responses can occur on either public or private lands and are not limited to responses at hazardous waste facilities.

(67) [~~(63)~~] Explosives or munitions emergency response specialist--An individual trained in chemical or conventional munitions or explosives handling, transportation, render-safe procedures, or destruction techniques, including United States Department of Defense (DOD) emergency explosive ordnance disposal, technical escort unit, and DOD-certified civilian or contractor personnel; and, other federal, state, or local government, or civilian personnel similarly trained in explosives or munitions emergency responses.

(68) [~~(64)~~] Extrusion--A process using pressure to force ground poultry carcasses through a decreasing-diameter barrel or nozzle, causing the generation of heat sufficient to kill pathogens, and resulting in an extruded product acceptable as a feed ingredient.

(69) [~~(65)~~] Facility--Includes:

(A) all contiguous land, and structures, other appurtenances, and improvements on the land, used for storing, processing, or disposing of municipal hazardous waste or industrial solid waste, or for the management of hazardous secondary materials prior to reclamation. A facility may consist of several treatment, storage, or disposal operational units (e.g., one or more landfills, surface impoundments, or combinations of them);

(B) for the purpose of implementing corrective action under §335.167 of this title (relating to Corrective Action for Solid Waste Management Units) or §335.602(a)(5) of this title (relating to Standards), all contiguous property under the control of the owner or operator seeking a permit for the treatment, storage, and/or disposal of hazardous waste. This definition also applies to facilities implementing corrective action under Texas Water Code, §7.031 (Corrective Action Relating to Hazardous Waste);

(C) regardless of subparagraph (B) of this paragraph, a "Remediation waste management site," as defined in 40 Code of Federal Regulations §260.10, is not a facility that is subject to §335.167 of this title, but is subject to corrective action requirements if the site is located within such a facility.

(70) [~~(66)~~] Final closure--The closure of all hazardous waste management units at the facility in accordance with all applicable closure requirements so that hazardous waste management activities under Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) and Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste

Treatment, Storage, or Disposal Facilities) are no longer conducted at the facility unless subject to the provisions in Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste) [~~§335.69 of this title (relating to Accumulation Time)~~].

(71) [~~(67)~~] Food-chain crops--Tobacco, crops grown for human consumption, and crops grown for feed for animals whose products are consumed by humans.

(72) [~~(68)~~] Freeboard--The vertical distance between the top of a tank or surface impoundment dike, and the surface of the waste contained therein.

(73) [~~(69)~~] Free liquids--Liquids which readily separate from the solid portion of a waste under ambient temperature and pressure.

(74) [~~(70)~~] Gasification--A process through which recoverable feedstocks are heated and converted into a fuel-gas mixture in an oxygen-deficient atmosphere and the mixture is converted into a valuable raw, intermediate, or final product, including a plastic, monomer, chemical, wax, lubricant, or chemical feedstock or crude oil, diesel, gasoline, diesel and gasoline blendstock, home heating oil, ethanol, or another fuel.

(75) [~~(71)~~] Gasification facility--A facility that receives, separates, stores, and converts post-use polymers and recoverable feedstocks using gasification.

(76) [~~(72)~~] Generator--Any person, by site, who produces municipal hazardous waste or industrial solid waste; any person who possesses municipal hazardous waste or industrial solid waste to be shipped to any other person; or any person whose act first causes the solid waste to become subject to regulation under this chapter. For the purposes of this regulation, a person who generates or possesses Class 3 wastes only shall not be considered a generator.

(77) [~~(73)~~] Groundwater--Water below the land surface in a zone of saturation.

(78) [~~(74)~~] Hazardous industrial waste--Any industrial solid waste or combination of industrial solid wastes identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency in accordance with the Resource Conservation and Recovery Act of 1976, §3001 (42 United States Code, §6921). The administrator has identified the characteristics of hazardous wastes and listed certain wastes as hazardous in 40 Code of Federal Regulations Part 261. The executive director will maintain in the offices of the commission a current list of hazardous wastes, a current set of characteristics of hazardous waste, and applicable appendices, as promulgated by the administrator.

(79) [~~(75)~~] Hazardous secondary material--A secondary material (e.g., spent material, by-product, or sludge) that, when discarded, would be identified as "Hazardous waste" as defined in this section.

(80) [~~(76)~~] Hazardous secondary material generator--Any person whose act or process produces hazardous secondary materials at the generating facility. For purposes of this paragraph, "generating facility" means all contiguous property owned, leased, or otherwise controlled by the hazardous secondary material generator. For the purposes of 40 Code of Federal Regulations §261.4(a)(23), a facility that collects hazardous secondary materials from other persons is not the hazardous secondary material generator.

(81) [~~(77)~~] Hazardous substance--Any substance designated as a hazardous substance under 40 Code of Federal Regulations Part 302.

(82) [~~(78)~~] Hazardous waste--Any solid waste identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency in accordance with the federal Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, 42 United States Code, §§6901 *et seq.*

(83) [~~(79)~~] Hazardous waste constituent--A constituent that caused the administrator to list the hazardous waste in 40 Code of Federal Regulations (CFR) Part 261, Subpart D or a constituent listed in Table 1 of 40 CFR §261.24.

(84) [~~(80)~~] Hazardous waste management facility--All contiguous land, including structures, appurtenances, and other improvements on the land, used for processing, storing, or disposing of hazardous waste. The term includes a publicly- or privately-owned hazardous waste management facility consisting of processing, storage, or disposal operational hazardous waste management units such as one or more landfills, surface impoundments, waste piles, incinerators, boilers, and industrial furnaces, including cement kilns, injection wells, salt dome waste containment caverns, land treatment facilities, or a combination of units.

(85) [~~(81)~~] Hazardous waste management unit--A landfill, surface impoundment, waste pile, industrial furnace, incinerator, cement kiln, injection well, container, drum, salt dome waste containment cavern, or land treatment unit, or any other structure, vessel, appurtenance, or other improvement on land used to manage hazardous waste.

(86) [~~(82)~~] In operation--Refers to a facility which is processing, storing, or disposing of solid waste or hazardous waste.

(87) [~~(83)~~] Inactive portion--That portion of a facility which is not operated after November 19, 1980. (*See* also "Active portion" and "Closed portion.")

(88) [~~(84)~~] Incinerator--

(A) Any enclosed device that:

(i) uses controlled flame combustion and neither meets the criteria for classification as a boiler, sludge dryer, or carbon regeneration unit, nor is listed as an industrial furnace; or

(ii) meets the definition of "Infrared incinerator" or "Plasma arc incinerator."

(B) Does not include a "Gasification facility" or "Pyrolysis facility[~~,~~]" managing "Recoverable feedstock[~~,~~]" as defined in this section.

(89) [~~(85)~~] Incompatible waste--A hazardous waste which is unsuitable for:

(A) placement in a particular device or facility because it may cause corrosion or decay of containment materials (e.g., container inner liners or tank walls); or

(B) commingling with another waste or material under uncontrolled conditions because the commingling might produce heat or pressure, fire or explosion, violent reaction, toxic dusts, mists, fumes, or gases, or flammable fumes or gases.

(90) [~~(86)~~] Individual generation site--The contiguous site at or on which one or more solid waste or hazardous wastes are generated. An individual generation site, such as a large manufacturing plant, may have one or more sources of solid waste or hazardous waste, but is considered a single or individual generation site if the site or property is contiguous.

(91) [~~(87)~~] Industrial furnace--Includes any of the following enclosed devices that use thermal treatment to accomplish recovery of materials or energy:

(A) cement kilns;

(B) lime kilns;

(C) aggregate kilns;

(D) phosphate kilns;

(E) coke ovens;

(F) blast furnaces;

(G) smelting, melting, and refining furnaces (including pyrometallurgical devices such as cupolas, reverberator furnaces, sintering machines, roasters, and foundry furnaces);

(H) titanium dioxide chloride process oxidation reactors;

(I) methane reforming furnaces;

(J) pulping liquor recovery furnaces;

(K) combustion devices used in the recovery of sulfur values from spent sulfuric acid;

(L) halogen acid furnaces for the production of acid from halogenated hazardous waste generated by chemical production facilities where the furnace is located on the site of a chemical production facility, the acid product has a halogen acid content of at least 3.0%, the acid product is used in a manufacturing process, and, except for "Hazardous waste" burned as fuel, hazardous waste fed to the furnace has a minimum halogen content of 20% as generated; and

(M) other devices the commission may list, after the opportunity for notice and comment is afforded to the public.

(92) [~~(88)~~] Industrial solid waste--Solid waste resulting from or incidental to any process of industry or manufacturing, or mining or agricultural operation, which may include "Hazardous waste" as defined in this section.

(93) [~~(89)~~] Infrared incinerator--Any enclosed device that uses electric powered resistance heaters as a source of radiant heat followed by an afterburner using controlled flame combustion and which is not listed as an industrial furnace.

(94) [~~(90)~~] Inground tank--A device meeting the definition of "Tank" in this section whereby a portion of the tank wall is situated to any degree within the ground, thereby preventing visual inspection of that external surface area of the tank that is in the ground.

(95) [~~(91)~~] Injection well--A well into which fluids are injected. *(See* also "Underground injection.")

(96) [~~(92)~~] Inner liner--A continuous layer of material placed inside a tank or container which protects the construction materials of the tank or container from the contained waste or reagents used to treat the waste.

(97) [~~(93)~~] Installation inspector--A person who, by reason of his knowledge of the physical sciences and the principles of engineering, acquired by a professional education and related practical experience, is qualified to supervise the installation of tank systems.

(98) [~~(94)~~] Intermediate facility--Any facility that stores hazardous secondary materials for more than ten days, other than a hazardous secondary material generator or reclaimer of such material.

(99) [~~(95)~~] International shipment--The transportation of hazardous waste into or out of the jurisdiction of the United States.

(100) [~~(96)~~] Lamp--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(101) [~~(97)~~] Land-based unit--When used to describe recycling of hazardous secondary materials, an area where hazardous secondary materials are placed in or on the land before recycling. This definition does not include land-based production units.

(102) [~~(98)~~] Land treatment facility--A facility or part of a facility at which solid waste or hazardous waste is applied onto or incorporated into the soil surface and that is not a corrective action management unit; such facilities are disposal facilities if the waste will remain after closure.

(103) [~~(99)~~] Landfill--A disposal facility or part of a facility where solid waste or hazardous waste is placed in or on land and which is not a pile, a land treatment facility, a surface impoundment, an injection well, a salt dome formation, a salt bed formation, an underground mine, a cave, or a corrective action management unit.

(104) [~~(100)~~] Landfill cell--A discrete volume of a solid waste or hazardous waste landfill which uses a liner to provide isolation of wastes from adjacent cells or wastes. Examples of landfill cells are trenches and pits.

(105) Large quantity generator--A generator who generates any of the following amounts in a calendar month:

(A) greater than or equal to 1,000 kilograms (2,200 pounds) of non-acute hazardous waste; or

(B) greater than 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 Code of Federal Regulations (CFR) §261.31 or §261.33(e); or

(C) greater than 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR §261.31 or §261.33(e).

(106) [~~(101)~~] Leachate--Any liquid, including any suspended components in the liquid, that has percolated through or drained from solid waste or hazardous waste.

(107) [~~(102)~~] Leak-detection system--A system capable of detecting the failure of either the primary or secondary containment structure or the presence of a release of solid waste or hazardous waste or accumulated liquid in the secondary containment structure. Such a system must employ operational controls (e.g., daily visual inspections for releases into the secondary containment system of aboveground tanks) or consist of an interstitial monitoring device designed to detect continuously and automatically the failure of the primary or secondary containment structure or the presence of a release of solid waste or hazardous waste into the secondary containment structure.

(108) [~~(103)~~] Licensed professional geoscientist--A geoscientist who maintains a current license through the Texas Board of Professional Geoscientists in accordance with its requirements for professional practice.

(109) [~~(104)~~] Liner--A continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment, landfill, or landfill cell, which restricts the downward or lateral escape of solid waste or hazardous waste, hazardous waste constituents, or leachate.

(110) [~~(105)~~] Management or hazardous waste management--The systematic control of the collection, source separation, storage, transportation, processing, treatment, recovery, and disposal of solid waste or hazardous waste.

(111) [~~(106)~~] Manifest--The waste shipping document, United States Environmental Protection Agency (EPA) Form 8700-22 (including, if necessary, EPA Form 8700-22A), or the electronic man-

ifest, originated and signed by the generator or offeror in accordance with [~~the instructions in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste) and~~] the applicable requirements of this chapter and 40 Code of Federal Regulations Parts 262 - 265.

(112) [~~(107)~~] Manifest tracking number--The alphanumeric identification number (i.e., a unique three-letter suffix preceded by nine numerical digits), which is pre-printed in Item 4 of the manifest by a registered source.

(113) [~~(108)~~] Military munitions--All ammunition products and components produced or used by or for the Department of Defense (DOD) or the United States Armed Services for national defense and security, including military munitions under the control of the DOD, the United States Coast Guard, the United States Department of Energy (DOE), and National Guard personnel. The term "military munitions":

(A) includes confined gaseous, liquid, and solid propellants, explosives, pyrotechnics, chemical and riot control agents, smokes, and incendiaries used by DOD components, including bulk explosives and chemical warfare agents, chemical munitions, rockets, guided and ballistic missiles, bombs, warheads, mortar rounds, artillery ammunition, small arms ammunition, grenades, mines, torpedoes, depth charges, cluster munitions and dispensers, demolition charges, and devices and components thereof; and

(B) includes non-nuclear components of nuclear devices, managed under DOE's nuclear weapons program after all required sanitization operations under the Atomic Energy Act of 1954, as amended, have been completed; but

(C) does not include wholly inert items, improvised explosive devices, and nuclear weapons, nuclear devices, and nuclear components thereof.

(114) [~~(109)~~] Miscellaneous unit--A hazardous waste management unit where hazardous waste is stored, processed, or disposed of and that is not a container, tank, surface impoundment, pile, land treatment unit, landfill, incinerator, boiler, industrial furnace, underground injection well with appropriate technical standards under Chapter 331 of this title (relating to Underground Injection Control), corrective action management unit, containment building, staging pile, or unit eligible for a research, development, and demonstration permit or under Chapter 305, Subchapter K of this title (relating to Research, Development, and Demonstration Permits).

(115) [~~(110)~~] Movement--That solid waste or hazardous waste transported to a facility in an individual vehicle.

(116) [~~(111)~~] Municipal hazardous waste--A municipal solid waste or mixture of municipal solid wastes which has been identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency.

(117) [~~(112)~~] Municipal solid waste--Solid waste resulting from or incidental to municipal, community, commercial, institutional, and recreational activities; including garbage, rubbish, ashes, street cleanings, dead animals, abandoned automobiles, and all other solid waste other than industrial waste.

(118) [~~(113)~~] New tank system or new tank component--A tank system or component that will be used for the storage or processing of hazardous waste and for which installation has commenced after July 14, 1986; except, however, for purposes of 40 Code of Federal Regulations (CFR) §264.193(g)(2) (incorporated by reference at §335.152(a)(8) of this title (relating to Standards)) and 40 CFR §265.193(g)(2) (incorporated by reference at §335.112(a)(9) of this title (relating to Standards)), a new tank system is one for which construction commences after July 14, 1986. *(See* also "Existing tank system.")

(119) [~~(114)~~] No free liquids--As used in 40 Code of Federal Regulations §261.4(a)(26) and (b)(18), means that solvent-contaminated wipes may not contain free liquids as determined by Method 9095B (Paint Filter Liquids Test), included in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" (EPA Publication SW-846), which is incorporated by reference at §335.31 of this title (relating to Incorporation of References), and that there is no free liquid in the container holding the wipes.

(120) Non-acute hazardous waste--All hazardous wastes that are not acute hazardous waste, as defined in this section.

(121) [~~(115)~~] Off-site--Property which cannot be characterized as on-site.

(122) [~~(116)~~] Onground tank--A device meeting the definition of "Tank" in this section and that is situated in such a way that the bottom of the tank is on the same level as the adjacent surrounding surface so that the external tank bottom cannot be visually inspected.

(123) [~~(117)~~] On-Site--The same or geographically contiguous property which may be divided by public or private rights-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing, as opposed to going along, the right-of-way. Noncontiguous properties owned by the same person but connected by a right-of-way which he controls and to which the public does not have access, is also considered on-site property.

(124) [~~(118)~~] Open burning--The combustion of any material without the following characteristics:

(A) control of combustion air to maintain adequate temperature for efficient combustion;

(B) containment of the combustion-reaction in an enclosed device to provide sufficient residence time and mixing for complete combustion; and

(C) control of emission of the gaseous combustion products. *(See* also "Incinerator" and "Thermal processing.")

(125) [~~(119)~~] Operator--The person responsible for the overall operation of a facility.

(126) [~~(120)~~] Owner--The person who owns a facility or part of a facility.

(127) [~~(121)~~] Partial closure--The closure of a hazardous waste management unit in accordance with the applicable closure requirements of Subchapters E and F of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; and Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) at a facility that contains other active hazardous waste management units. For example, partial closure may include the closure of a tank (including its associated piping and underlying containment systems), landfill cell, surface impoundment, waste pile, or other hazardous waste management unit, while other units of the same facility continue to operate.

(128) [~~(122)~~] PCBs or polychlorinated biphenyl compounds--Compounds subject to 40 Code of Federal Regulations Part 761.

(129) [~~(123)~~] Permit--A written permit issued by the commission which, by its conditions, may authorize the permittee to con-

struct, install, modify, or operate a specified municipal hazardous waste or industrial solid waste treatment, storage, or disposal facility in accordance with specified limitations.

(130) [~~(124)~~] Personnel or facility personnel--All persons who work at, or oversee the operations of, a solid waste or hazardous waste facility, and whose actions or failure to act may result in noncompliance with the requirements of this chapter.

(131) [~~(125)~~] Pesticide--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(132) [~~(126)~~] Petroleum substance--A crude oil or any refined or unrefined fraction or derivative of crude oil which is a liquid at standard conditions of temperature and pressure.

(A) Except as provided in subparagraph (C) of this paragraph for the purposes of this chapter, a "Petroleum substance" shall be limited to a substance in or a combination or mixture of substances within the following list (except for any listed substance regulated as a hazardous waste under the federal Solid Waste Disposal Act, Subtitle C (42 United States Code (USC), §§6921, *et seq.))* and which is liquid at standard conditions of temperature (20 degrees Centigrade) and pressure (1 atmosphere):

(i) basic petroleum substances--i.e., crude oils, crude oil fractions, petroleum feedstocks, and petroleum fractions;

(ii) motor fuels--a petroleum substance which is typically used for the operation of internal combustion engines and/or motors (which includes, but is not limited to, stationary engines and engines used in transportation vehicles and marine vessels);

(iii) aviation gasolines--i.e., Grade 80, Grade 100, and Grade 100-LL;

(iv) aviation jet fuels--i.e., Jet A, Jet A-1, Jet B, JP-4, JP-5, and JP-8;

(v) distillate fuel oils--i.e., Number 1-D, Number 1, Number 2-D, and Number 2;

(vi) residual fuel oils--i.e., Number 4-D, Number 4-light, Number 4, Number 5-light, Number 5-heavy, and Number 6;

(vii) gas-turbine fuel oils--i.e., Grade O-GT, Grade 1-GT, Grade 2-GT, Grade 3-GT, and Grade 4-GT;

(viii) illuminating oils--i.e., kerosene, mineral seal oil, long-time burning oils, 300 oil, and mineral colza oil;

(ix) lubricants--i.e., automotive and industrial lubricants;

(x) building materials--i.e., liquid asphalt and dust-laying oils;

(xi) insulating and waterproofing materials--i.e., transformer oils and cable oils; and

(xii) used oils--See definition for "Used oil" in this section.

(B) For the purposes of this chapter, a "Petroleum substance" shall include solvents or a combination or mixture of solvents (except for any listed substance regulated as a hazardous waste under the federal Solid Waste Disposal Act, Subtitle C (42 USC, §§6921, *et seq.))* and which is liquid at standard conditions of temperature (20 degrees Centigrade) and pressure (1 atmosphere) i.e., Stoddard solvent, petroleum spirits, mineral spirits, petroleum ether, varnish makers' and painters' naphthas, petroleum extender oils, and commercial hexane.

(C) The following materials are not considered petroleum substances:

(i) polymerized materials, i.e., plastics, synthetic rubber, polystyrene, high and low density polyethylene;

(ii) animal, microbial, and vegetable fats;

(iii) food grade oils;

(iv) hardened asphalt and solid asphaltic materials--i.e., roofing shingles, roofing felt, hot mix (and cold mix); and

(v) cosmetics.

(133) [~~(127)~~] Pile--Any noncontainerized accumulation of solid, nonflowing solid waste or hazardous waste that is used for processing or storage, and that is not a corrective action management unit or a containment building.

(134) [~~(128)~~] Plasma arc incinerator--Any enclosed device using a high intensity electrical discharge or arc as a source of heat followed by an afterburner using controlled flame combustion and which is not listed as an industrial furnace.

(135) [~~(129)~~] Post-closure order--An order issued by the commission for post-closure care of interim status units, a corrective action management unit unless authorized by permit, or alternative corrective action requirements for contamination commingled from Resource Conservation and Recovery Act and solid waste management units.

(136) [~~(130)~~] Post-use polymers--Plastic polymers that derive from industrial sources or activities that would be classified as a nonhazardous industrial solid waste if not converted into a valuable raw, intermediate, or final product. Post-use polymers include used polymers that contain incidental contaminants or impurities such as paper labels or metal rings but do not include used polymers mixed with solid waste, medical waste, hazardous waste, electronic waste, tires, or construction or demolition debris.

(137) [~~(131)~~] Poultry--Chickens or ducks being raised or kept on any premises in the state for profit.

(138) [~~(132)~~] Poultry carcass--The carcass, or part of a carcass, of poultry that died as a result of a cause other than intentional slaughter for use for human consumption.

(139) [~~(133)~~] Poultry facility--A facility that:

(A) is used to raise, grow, feed, or otherwise produce poultry for commercial purposes; or

(B) is a commercial poultry hatchery that is used to produce chicks or ducklings.

(140) [~~(134)~~] Processing--The extraction of materials, transfer, volume reduction, conversion to energy, or other separation and preparation of solid waste for reuse or disposal, including the treatment or neutralization of solid waste or hazardous waste, designed to change the physical, chemical, or biological character or composition of any solid waste or hazardous waste so as to neutralize such waste, or so as to recover energy or material from the waste or so as to render such waste nonhazardous, or less hazardous; safer to transport, store or dispose of; or amenable for recovery, amenable for storage, or reduced in volume. The transfer of solid waste for reuse or disposal as used in this definition does not include the actions of a transporter in conveying or transporting solid waste by truck, ship, pipeline, or other means. Unless the executive director determines that regulation of such activity is necessary to protect human health or the environment, the definition of "Processing" does not include activities relating to those materials exempted by the administrator of the United States

Environmental Protection Agency in accordance with the federal Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, 42 United States Code, §§6901 *et seq.,* as amended.

(141) [~~(135)~~] Publicly-owned treatment works (POTW)--Any device or system used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature which is owned by a state or municipality (as defined by the federal Clean Water Act, §502(4)). The definition includes sewers, pipes, or other conveyances only if they convey wastewater to a POTW providing treatment.

(142) [~~(136)~~] Pyrolysis--A manufacturing process through which post-use polymers are heated in an oxygen-deficient atmosphere until melted and thermally decomposed and then cooled, condensed, and converted into a valuable raw, intermediate, or final product, including a plastic, monomer, chemical, wax, lubricant, or chemical feedstock or crude oil, diesel, gasoline, diesel and gasoline blendstock, home heating oil, ethanol, or another fuel.

(143) [~~(137)~~] Pyrolysis facility--A manufacturing facility that receives, separates, stores, and converts post-use polymers using pyrolysis.

(144) [~~(138)~~] Qualified groundwater scientist--A scientist or engineer who has received a baccalaureate or post-graduate degree in the natural sciences or engineering, and has sufficient training and experience in groundwater hydrology and related fields as may be demonstrated by state registration, professional certifications, or completion of accredited university courses that enable that individual to make sound professional judgments regarding groundwater monitoring and contaminant fate and transport.

(145) [~~(139)~~] Recognized trader--A person domiciled in the United States, by site of business, who acts to arrange and facilitate transboundary movements of wastes destined for recovery or disposal operations, either by purchasing from and subsequently selling to United States and foreign facilities, or by acting under arrangements with a United States waste facility to arrange for the export or import of the wastes.

(146) [~~(140)~~] Recoverable feedstock--One or more of the following materials, derived from nonhazardous industrial solid waste, other than coal refuse, that has been processed so that it may be used as feedstock in a "Gasification facility" or "Pyrolysis facility" as defined in this section:

(A) post-use polymers; and

(B) material, including municipal solid waste containing post-use polymers and other post-industrial waste containing post-use polymers, that has been processed into a fuel or feedstock for which the commission or the United States Environmental Protection Agency has made a non-waste determination under 40 Code of Federal Regulations §241.3(c), as amended through February 8, 2016 (81 FR 6742).

(147) [~~(141)~~] Regional administrator--The regional administrator for the United States Environmental Protection Agency region in which the facility is located, or his designee.

(148) [~~(142)~~] Remanufacturing--Processing a higher-value hazardous secondary material in order to manufacture a product that serves a similar functional purpose as the original commercial-grade material. For the purpose of this definition, a hazardous secondary material is considered higher-value if it was generated from the use of a commercial-grade material in a manufacturing process and can be remanufactured into a similar commercial-grade material.

(149) [~~(143)~~] Remediation--The act of eliminating or reducing the concentration of contaminants in contaminated media.

(150) [~~(144)~~] Remediation waste--All solid and hazardous wastes, and all media (including groundwater, surface water, soils, and sediments) and debris, which contain listed hazardous wastes or which themselves exhibit a hazardous waste characteristic, that are managed for the purpose of implementing corrective action requirements under §335.167 of this title (relating to Corrective Action for Solid Waste Management Units) and Texas Water Code, §7.031 (Corrective Action Relating to Hazardous Waste). For a given facility, remediation wastes may originate only from within the facility boundary, but may include waste managed in implementing corrective action for releases beyond the facility boundary under §335.166(5) of this title (relating to Corrective Action Program) or §335.167(c) of this title.

(151) [~~(145)~~] Remove--To take waste, contaminated design or operating system components, or contaminated media away from a waste management unit, facility, or area to another location for treatment, storage, or disposal.

(152) [~~(146)~~] Replacement unit--A landfill, surface impoundment, or waste pile unit:

(A) from which all or substantially all the waste is removed; and

(B) that is subsequently reused to treat, store, or dispose of hazardous waste. "Replacement unit" does not apply to a unit from which waste is removed during closure, if the subsequent reuse solely involves the disposal of waste from that unit and other closing units or corrective action areas at the facility, in accordance with an approved closure plan or United States Environmental Protection Agency or state approved corrective action.

(153) [~~(147)~~] Representative sample--A sample of a universe or whole (e.g., waste pile, lagoon, groundwater) which can be expected to exhibit the average properties of the universe or whole.

(154) [~~(148)~~] Run-off--Any rainwater, leachate, or other liquid that drains over land from any part of a facility.

(155) [~~(149)~~] Run-on--Any rainwater, leachate, or other liquid that drains over land onto any part of a facility.

(156) [~~(150)~~] Saturated zone or zone of saturation--That part of the earth's crust in which all voids are filled with water.

(157) [~~(151)~~] Shipment--Any action involving the conveyance of municipal hazardous waste or industrial solid waste by any means off-site.

(158) [~~(152)~~] Sludge dryer--Any enclosed thermal treatment device that is used to dehydrate sludge and that has a maximum total thermal input, excluding the heating valve of the sludge itself, of 2,500 British thermal units per pound of sludge treated on a wet-weight basis.

(159) [~~(153)~~] Small quantity generator--A generator who generates the following amounts in a calendar month: [~~less than 1,000 kilograms of hazardous waste in a calendar month.~~]

(A) greater than 100 kilograms (220 pounds) but less than 1,000 kilograms (2,200 pounds) of non-acute hazardous waste;

(B) less than or equal to 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 Code of Federal Regulations (CFR) §261.31 or §261.33(e); and

(C) less than or equal to 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR §261.31 or §261.33(e).

(160) [~~(154)~~] Solid waste--

(A) Any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant or air pollution control facility, and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, municipal, commercial, mining, and agricultural operations, and from community and institutional activities, but does not include:

(i) solid or dissolved material in domestic sewage, or solid or dissolved material in irrigation return flows, or industrial discharges subject to regulation by permit issued in accordance with Texas Water Code, Chapter 26 (an exclusion applicable only to the actual point source discharge that does not exclude industrial wastewaters while they are being collected, stored, or processed before discharge, nor does it exclude sludges that are generated by industrial wastewater treatment);

(ii) uncontaminated soil, dirt, rock, sand, and other natural or man-made inert solid materials used to fill land if the object of the fill is to make the land suitable for the construction of surface improvements. The material serving as fill may also serve as a surface improvement such as a structure foundation, a road, soil erosion control, and flood protection. Man-made materials exempted under this provision shall only be deposited at sites where the construction is in progress or imminent such that rights to the land are secured and engineering, architectural, or other necessary planning have been initiated. Waste disposal shall be considered to have occurred on any land which has been filled with man-made inert materials under this provision if the land is sold, leased, or otherwise conveyed prior to the completion of construction of the surface improvement. Under such conditions, deed recordation shall be required. The deed recordation shall include the information required under §335.5(a) of this title (relating to Deed Recordation of Waste Disposal), prior to sale or other conveyance of the property;

(iii) waste materials which result from "Activities associated with the exploration, development, or production of oil or gas or geothermal resources," as those activities are defined in this section, and any other substance or material regulated by the Railroad Commission of Texas in accordance with the Texas Natural Resources Code, §91.101, unless such waste, substance, or material results from activities associated with gasoline plants, natural gas, or natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants and is a hazardous waste as defined by the administrator of the United States Environmental Protection Agency (EPA) in accordance with the federal Solid Waste Disposal Act, 42 United States Code, §§6901 *et seq.,* as amended;

(iv) a material excluded by 40 Code of Federal Regulations (CFR) §§261.4(a), 261.39, or 261.40, as adopted under §335.504 of this title (relating to Hazardous Waste Determination), [~~§261.40, as amended through January 13, 2015 (80 FR 1694), §261.4(a)(1) - (15), (17) - (24), (26), and (27), as amended through April 8, 2015 (80 FR 18777), or §261.39, as amended through November 28, 2016 (81 FR 85696),~~] subject to the changes in this clause, by variance, or by non-waste determination granted under §335.18 of this title (relating to Non-Waste Determinations and Variances from Classification as a Solid Waste), §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste), §335.21 of this title (relating to Procedures for Variances from Classification as a Solid Waste or To Be Classified as a Boiler or for Non-Waste Determinations), and §335.32 of this title (relating to Standards and Criteria for Non-Waste Determinations). For the purposes of the exclusions under 40 CFR §261.39 and §261.40, 40 CFR §261.41 is adopted by reference under §335.504 of this title [~~as amended through July 28, 2006 (71 FR 42928)~~]; or

(v) recoverable feedstocks that are processed through pyrolysis or gasification at a pyrolysis facility or gasification facility, where the primary function of the facility is to convert recoverable feedstocks into materials that have a resale value greater than the cost of processing the recoverable feedstock for subsequent beneficial use and where solid waste generated from converting recoverable feedstock is disposed of at an authorized solid waste management facility.

(B) A discarded material is any material which is:

(i) abandoned, as explained in subparagraph (C) of this paragraph;

(ii) recycled, as explained in subparagraph (D) of this paragraph;

(iii) considered inherently waste-like, as explained in subparagraph (E) of this paragraph; or

(iv) a military munition identified as a solid waste in 40 CFR §266.202.

(C) Materials are solid wastes if they are abandoned by being:

(i) disposed of;

(ii) burned or incinerated;

(iii) accumulated, stored, or processed (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated; or

(iv) sham recycling as explained in subparagraph (J) of this paragraph.

(D) Except for materials described in subparagraph (H) of this paragraph, materials are solid wastes if they are "recycled" or accumulated, stored, or processed before recycling as specified in this subparagraph. The chart referred to as Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [~~§335.1(154)(D)(iv)~~] indicates only which materials are considered to be solid wastes when they are recycled and is not intended to supersede the definition of "Solid waste" provided in subparagraph (A) of this paragraph.

(i) Used in a manner constituting disposal. Materials noted with an asterisk in Column 1 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [~~§335.1(154)(D)(iv)~~] are solid wastes when they are:

(I) applied to or placed on the land in a manner that constitutes disposal; or

(II) used to produce products that are applied to or placed on the land or are otherwise contained in products that are applied to or placed on the land (in which cases the product itself remains a solid waste). However, commercial chemical products listed in 40 CFR §261.33 are not solid wastes if they are applied to the land and that is their ordinary manner of use.

(ii) Burning for energy recovery. Materials noted with an asterisk in Column 2 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [~~§335.1(154)(D)(iv)~~] are solid wastes when they are:

(I) burned to recover energy; or

(II) used to produce a fuel or are otherwise contained in fuels (in which cases the fuel itself remains a solid waste). However, commercial chemical products, which are listed in 40 CFR §261.33, not listed in §261.33, but that exhibit one or more of the hazardous waste characteristics, or will be considered nonhazardous waste

if disposed, are not solid wastes if they are fuels themselves and burned for energy recovery.

(iii) Reclaimed. Materials noted with an asterisk in Column 3 of Table 1 are solid wastes when reclaimed (unless they meet the requirements of 40 CFR §261.4(a)(17), (23), (24), or (27)). Materials without an asterisk in Column 3 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [~~§335.1(154)(D)(iv)~~] are not solid wastes when reclaimed.

(iv) Accumulated speculatively. Materials noted with an asterisk in Column 4 of Table 1 in Figure: 30 TAC §335.1(160)(D)(iv) [~~§335.1(154)(D)(iv)~~] are solid wastes when accumulated speculatively.

Figure: 30 TAC §335.1(160)(D)(iv)

[~~Figure: 30 TAC §335.1(154)(D)(iv)~~]

(E) Materials that are identified by the administrator of the EPA as inherently waste-like materials under 40 CFR §261.2(d) are solid wastes when they are recycled in any manner.

(F) Materials are not solid wastes when they can be shown to be recycled by being:

(i) used or reused as ingredients in an industrial process to make a product, provided the materials are not being reclaimed;

(ii) used or reused as effective substitutes for commercial products;

(iii) returned to the original process from which they were generated, without first being reclaimed or land disposed. The material must be returned as a substitute for feedstock materials. In cases where the original process to which the material is returned is a secondary process, the materials must be managed such that there is no placement on the land. In cases where the materials are generated and reclaimed within the primary mineral processing industry, the conditions of the exclusion found at 40 CFR §261.4(a)(17) apply rather than this provision; or

(iv) secondary materials that are reclaimed and returned to the original process or processes in which they were generated where they are reused in the production process provided:

(I) only tank storage is involved, and the entire process through completion of reclamation is closed by being entirely connected with pipes or other comparable enclosed means of conveyance;

(II) reclamation does not involve controlled flame combustion (such as occurs in boilers, industrial furnaces, or incinerators);

(III) the secondary materials are never accumulated in such tanks for over 12 months without being reclaimed; and

(IV) the reclaimed material is not used to produce a fuel, or used to produce products that are used in a manner constituting disposal.

(G) Except for materials described in subparagraph (H) of this paragraph, the following materials are solid wastes, even if the recycling involves use, reuse, or return to the original process, as described in subparagraph (F) of this paragraph:

(i) materials used in a manner constituting disposal, or used to produce products that are applied to the land;

(ii) materials burned for energy recovery, used to produce a fuel, or contained in fuels;

(iii) materials accumulated speculatively; or

(iv) materials deemed to be inherently waste-like by the administrator of the EPA, as described in 40 CFR §261.2(d)(1) and (2).

(H) With the exception of contaminated soils which are being relocated for use under §350.36 of this title (relating to Relocation of Soils Containing Chemicals of Concern for Reuse Purposes) and other contaminated media, materials that will otherwise be identified as nonhazardous solid wastes if disposed of are not considered solid wastes when recycled by being applied to the land or used as ingredients in products that are applied to the land, provided these materials can be shown to meet all of the following criteria:

(i) a legitimate market exists for the recycling material as well as its products;

(ii) the recycling material is managed and protected from loss as will be raw materials or ingredients or products;

(iii) the quality of the product is not degraded by substitution of raw material/product with the recycling material;

(iv) the use of the recycling material is an ordinary use and it meets or exceeds the specifications of the product it is replacing without treatment or reclamation, or if the recycling material is not replacing a product, the recycling material is a legitimate ingredient in a production process and meets or exceeds raw material specifications without treatment or reclamation;

(v) the recycling material is not burned for energy recovery, used to produce a fuel, or contained in a fuel;

(vi) the recycling material can be used as a product itself or to produce products as it is generated without treatment or reclamation;

(vii) the recycling material must not present an increased risk to human health, the environment, or waters in the state when applied to the land or used in products which are applied to the land and the material, as generated:

(I) is a Class 3 waste under Subchapter R of this chapter (relating to Waste Classification), except for arsenic, cadmium, chromium, lead, mercury, nickel, selenium, and total dissolved solids; and

(II) for the metals listed in subclause (I) of this clause:

(-a-) is a Class 2 or Class 3 waste under Subchapter R of this chapter; and

(-b-) does not exceed a concentration limit under §312.43(b)(3), Table 3 of this title (relating to Metal Limits); and

(viii) with the exception of the requirements under §335.17(a)(8) of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials):

(I) at least 75% (by weight or volume) of the annual production of the recycling material must be recycled or transferred to a different site and recycled on an annual basis; and

(II) if the recycling material is placed in protective storage, such as a silo or other protective enclosure, at least 75% (by weight or volume) of the annual production of the recycling material must be recycled or transferred to a different site and recycled on a biennial basis.

(I) Respondents in actions to enforce the industrial solid waste regulations and facility operators who raise a claim that a certain

material is not a solid waste, or is conditionally exempt from regulation, must demonstrate that there is a known market or disposition for the material, and that they meet the terms of the exclusion or exemption. In doing so, they must provide appropriate documentation (such as contracts showing that a second person uses the material as an ingredient in a production process) to demonstrate that the material is not a waste, or is exempt from regulation. In addition, owners or operators of facilities claiming that they actually are recycling materials must show that they have the necessary equipment to do so and that the recycling activity is legitimate and beneficial.

(J) A hazardous secondary material found to be sham recycled is considered discarded and a solid waste. Sham recycling is recycling that is not legitimate recycling as defined in §335.27 of this title (relating to Legitimate Recycling of Hazardous Secondary Materials).

(K) Materials that are reclaimed from solid wastes and that are used beneficially are not solid wastes and hence are not hazardous wastes under 40 CFR §261.3(c) unless the reclaimed material is burned for energy recovery or used in a manner constituting disposal.

(L) Other portions of this chapter that relate to solid wastes that are recycled include §335.6 of this title (relating to Notification Requirements), §§335.17 - 335.19 of this title, §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), and Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities).

(M) Steel slag may not be considered as solid waste if the steel slag is an intended output or result of the use of an electric arc furnace to make steel, introduced into the stream of commerce, and managed as an item of commercial value, including through a controlled use in a manner constituting disposal, and not as discarded material.

(N) Foundry sand from the iron and steel casting industry may not be considered as solid waste if the sand is an intended output or result of the use of an iron or steel casting process to make cast iron and steel products, introduced into the stream of commerce, and managed as an item of commercial value, including through a controlled use in a manner constituting disposal, and not as discarded material.

(161) [~~(155)~~] Solvent-contaminated wipe--A wipe that, after use or after cleaning up a spill, either:

(A) contains one or more of the F001 through F005 solvents listed in 40 Code of Federal Regulations (CFR) §261.31 or the corresponding P- or U-listed solvents found in 40 CFR §261.33;

(B) exhibits a hazardous characteristic found in 40 CFR Part 261, Subpart C, when that characteristic results from a solvent listed in 40 CFR Part 261; and/or

(C) exhibits only the hazardous waste characteristic of ignitability found in 40 CFR §261.21 due to the presence of one or more solvents that are not listed in 40 CFR Part 261. Solvent-contaminated wipes that contain listed hazardous waste other than solvents, or exhibit the characteristic of toxicity, corrosivity, or reactivity due to contaminants other than solvents, are not eligible for the exclusions at 40 CFR §261.4(a)(26) and (b)(18).

(162) [~~(156)~~] Sorbent--A material that is used to soak up free liquids by either adsorption or absorption, or both. Sorb means to either adsorb or absorb, or both.

(163) [~~(157)~~] Spill--The accidental spilling, leaking, pumping, emitting, emptying, or dumping of solid waste or hazardous wastes or materials which, when spilled, become solid waste or hazardous wastes into or on any land or water.

(164) [~~(158)~~] Staging pile--An accumulation of solid, nonflowing "Remediation waste," as defined in this section, that is not a containment building and that is used only during remedial operations for temporary storage at a facility. Staging piles must be designated by the executive director according to the requirements of 40 Code of Federal Regulations §264.554, as adopted by reference under §335.152(a) of this title (relating to Standards).

(165) [~~(159)~~] Standard permit--A Resource Conservation and Recovery Act permit authorizing management of hazardous waste issued under Chapter 305, Subchapter R of this title (relating to Resource Conservation and Recovery Act Standard Permits for Storage and Treatment Units) and Subchapter U of this chapter (relating to Standards for Owners and Operators of Hazardous Waste Facilities Operating Under a Standard Permit). The standard permit may have two parts, a uniform portion issued in all cases and a supplemental portion issued at the executive director's discretion.

(166) [~~(160)~~] Storage--The holding of solid waste for a temporary period, at the end of which the waste is processed, disposed of, recycled, or stored elsewhere.

(167) [~~(161)~~] Sump--Any pit or reservoir that meets the definition of "Tank" in this section and those troughs/trenches connected to it that serve to collect solid waste or hazardous waste for transport to solid waste or hazardous waste treatment, storage, or disposal facilities; except that as used in the landfill, surface impoundment, and waste pile rules, "sump" means any lined pit or reservoir that serves to collect liquids drained from a leachate collection and removal system or leak detection system for subsequent removal from the system.

(168) [~~(162)~~] Surface impoundment or impoundment--A facility or part of a facility which is a natural topographic depression, man-made excavation, or diked area formed primarily of earthen materials (although it may be lined with man-made materials), which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well or a corrective action management unit. Examples of surface impoundments are holding, storage, settling, and aeration pits, ponds, and lagoons.

(169) [~~(163)~~] Tank--A stationary device, designed to contain an accumulation of solid waste which is constructed primarily of non-earthen materials (e.g., wood, concrete, steel, plastic) which provide structural support.

(170) [~~(164)~~] Tank system--A solid waste or hazardous waste storage or processing tank and its associated ancillary equipment and containment system.

(171) [~~(165)~~] TEQ--Toxicity equivalence, the international method of relating the toxicity of various dioxin/furan congeners to the toxicity of 2,3,7,8-tetrachlorodibenzo-p-dioxin.

(172) [~~(166)~~] Thermal processing--The processing of solid waste or hazardous waste in a device which uses elevated temperatures as the primary means to change the chemical, physical, or biological character or composition of the solid waste or hazardous waste. Examples of thermal processing are incineration, molten salt, pyrolysis, calcination, wet air oxidation, and microwave discharge. *(See* also "Incinerator" and "Open burning.")

(173) [~~(167)~~] Thermostat--Has the definition adopted under §335.261 of this title (relating to Universal Waste Rule).

(174) [~~(168)~~] Totally enclosed treatment facility--A facility for the processing of hazardous waste which is directly connected to an industrial production process and which is constructed and op-

erated in a manner which prevents the release of any hazardous waste or any constituent thereof into the environment during processing. An example is a pipe in which acid waste is neutralized.

(175) [~~(169)~~] Transfer facility--Any transportation-related facility including loading docks, parking areas, storage areas, and other similar areas where shipments of hazardous or industrial solid waste or hazardous secondary materials are held during the normal course of transportation.

(176) [~~(170)~~] Transport vehicle--A motor vehicle or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (trailer, railroad freight car, etc.) is a separate transport vehicle. Vessel includes every description of watercraft, used or capable of being used as a means of transportation on the water.

(177) [~~(171)~~] Transporter--Any person who conveys or transports municipal hazardous waste or industrial solid waste by truck, ship, pipeline, or other means.

(178) [~~(172)~~] Treatability study--A study in which a hazardous or industrial solid waste is subjected to a treatment process to determine:

(A) whether the waste is amenable to the treatment process;

(B) what pretreatment (if any) is required;

(C) the optimal process conditions needed to achieve the desired treatment;

(D) the efficiency of a treatment process for a specific waste or wastes; or

(E) the characteristics and volumes of residuals from a particular treatment process. Also included in this definition for the purpose of the exemptions under 40 Code of Federal Regulations §261.4(e) and (f) and §335.2 of this title (relating to Permit Required) [~~(§§335.2, 335.69, and 335.78 of this title (relating to Permit Required; and Accumulation Time; and Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators))~~ exemptions] are liner compatibility, corrosion, and other material compatibility studies and toxicological and health effects studies. A treatability study is not a means to commercially treat or dispose of hazardous or industrial solid waste.

(179) [~~(173)~~] Treatment--To apply a physical, biological, or chemical process(es) to wastes and contaminated media which significantly reduces the toxicity, volume, or mobility of contaminants and which, depending on the process(es) used, achieves varying degrees of long-term effectiveness.

(180) [~~(174)~~] Treatment zone--A soil area of the unsaturated zone of a land treatment unit within which hazardous constituents are degraded, transferred, or immobilized.

(181) [~~(175)~~] Underground injection--The subsurface emplacement of fluids through a bored, drilled, or driven well; or through a dug well, where the depth of the dug well is greater than the largest surface dimension. *(See* also "Injection well.")

(182) [~~(176)~~] Underground tank--A device meeting the definition of "Tank" in this section whose entire surface area is totally below the surface of and covered by the ground.

(183) [~~(177)~~] Unfit-for-use tank system--A tank system that has been determined through an integrity assessment or other inspection to be no longer capable of storing or processing solid waste or hazardous waste without posing a threat of release of solid waste or hazardous waste to the environment.

(184) [~~(178)~~] United States Environmental Protection Agency (EPA) hazardous waste number--The number assigned by the EPA to each hazardous waste listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D and to each characteristic identified in 40 CFR Part 261, Subpart C.

(185) [~~(179)~~] United States Environmental Protection Agency (EPA) identification number--The number assigned by the EPA or the commission to each generator, transporter, and processing, storage, or disposal facility.

(186) [~~(180)~~] Universal waste--Any of the hazardous wastes defined as universal waste under §335.261(b)(19)(F) [~~§335.261(b)(16)(F)~~] of this title (relating to Universal Waste Rule) that are managed under the universal waste requirements of Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule).

(187) [~~(181)~~] Universal waste handler--Has the definition adopted as "Large quantity handler of universal waste" and "Small quantity handler of universal waste" under §335.261 of this title (relating to Universal Waste Rule).

(188) [~~(182)~~] Universal waste transporter--Has the definition adopted under 40 Code of Federal Regulations §273.9.

(189) [~~(183)~~] Unsaturated zone or zone of aeration--The zone between the land surface and the water table.

(190) [~~(184)~~] Uppermost aquifer--The geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected within the facility's property boundary.

(191) [~~(185)~~] Used oil--Any oil that has been refined from crude oil, or any synthetic oil, that has been used, and, as a result of such use, is contaminated by physical or chemical impurities. Used oil fuel includes any fuel produced from used oil by processing, blending, or other treatment. Rules applicable to nonhazardous used oil, oil characteristically hazardous from use versus mixing, very [~~conditionally exempt~~] small quantity generator hazardous used oil, and household used oil after collection that will be recycled are found in Chapter 324 of this title (relating to Used Oil Standards) and 40 Code of Federal Regulations Part 279 (Standards for Management of Used Oil).

(192) [~~(186)~~] User of the electronic manifest system--A hazardous waste generator, a hazardous waste transporter, an owner or operator of a hazardous waste treatment, storage, recycling, or disposal facility, or any other person that:

(A) is required to use a manifest to comply with:

(i) any federal or state requirement to track the shipment, transportation, and receipt of hazardous waste or other waste material that is shipped from the site of generation to an off-site designated facility for treatment, storage, recycling, or disposal; or

(ii) any federal or state requirement to track the shipment, transportation, and receipt of rejected wastes or regulated container residues that are shipped from a designated facility to an alternative facility, or returned to the generator; and

(B) elects to use the system to obtain, complete and transmit an electronic manifest format supplied by the United States Environmental Protection Agency electronic manifest system; or

(C) elects to use the paper manifest form and submits to the system for data processing purposes a paper copy of the manifest (or data from such a paper copy), in accordance with 40 Code of Federal Regulations (CFR) §264.71(a)(2)(v) as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.71(a)(2)(v) as adopted under §335.112 of this title (relating to Standards) [~~§335.10 of this ti-~~

tle (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste)]. These paper copies are submitted for data exchange purposes only and are not the official copies of record for legal purposes.

(193) Very small quantity generator--A generator who generates less than or equal to the following amounts in a calendar month:

(A) 100 kilograms (220 pounds) of non-acute hazardous waste; and

(B) 1 kilogram (2.2 pounds) of acute hazardous waste listed in 40 Code of Federal Regulations (CFR) §261.31 or §261.33(e); and

(C) 100 kilograms (220 pounds) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in 40 CFR §261.31 or §261.33(e).

(194) [(187)] Wastewater treatment unit--A device which:

(A) is part of a wastewater treatment facility subject to regulation under either the Federal Water Pollution Control Act (federal Clean Water Act), 33 United States Code, §§466 *et seq.,* §402 or §307(b), as amended;

(B) receives and processes or stores an influent wastewater which is a hazardous or industrial solid waste, or generates and accumulates a wastewater treatment sludge which is a hazardous or industrial solid waste, or processes or stores a wastewater treatment sludge which is a hazardous or industrial solid waste; and

(C) meets the definition of "Tank" or "Tank system" as defined in this section.

(195) [(188)] Water (bulk shipment)--The bulk transportation of municipal hazardous waste or Class 1 industrial solid waste which is loaded or carried on board a vessel without containers or labels.

(196) [(189)] Well--Any shaft or pit dug or bored into the earth, generally of a cylindrical form, and often walled with bricks or tubing to prevent the earth from caving in.

(197) [(190)] Wipe--A woven or non-woven shop towel, rag, pad, or swab made of wood pulp, fabric, cotton, polyester blends, or other material.

(198) [(191)] Zone of engineering control--An area under the control of the owner/operator that, upon detection of a solid waste or hazardous waste release, can be readily cleaned up prior to the release of solid waste or hazardous waste or hazardous constituents to groundwater or surface water.

§335.2. Permit Required.

(a) Except with regard to storage, processing, or disposal to which subsections (c) - (h) of this section apply, and as provided in §335.45(b) of this title (relating to Effect on Existing Facilities), and in accordance with the requirements of §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) and §335.25 of this title (relating to Handling, Storing, Processing, Transporting, and Disposing of Poultry Carcasses), and as provided in §332.4 of this title (relating to General Requirements), no person may cause, suffer, allow, or permit any activity of storage, processing, or disposal of any industrial solid waste or municipal hazardous waste unless such activity is authorized by a permit, amended permit, or other authorization from the Texas Commission on Environmental Quality (commission) or its predecessor agencies, the Texas Department of State Health Services (DSHS), or other valid authorization from a Texas state agency. No person may commence physical construction of a new hazardous waste management facility without first having submitted Part A and Part B of the permit application and received a finally effective permit.

(b) In accordance with the requirements of subsection (a) of this section, no generator, transporter, owner or operator of a facility, or any other person may cause, suffer, allow, or permit its wastes to be stored, processed, or disposed of at an unauthorized facility or in violation of a permit. In the event this requirement is violated, the executive director will seek recourse against not only the person who stored, processed, or disposed of the waste, but also against the generator, transporter, owner or operator, or other person who caused, suffered, allowed, or permitted its waste to be stored, processed, or disposed.

(c) Any owner or operator of a solid waste management facility that is in existence on the effective date of a statutory or regulatory change that subjects the owner or operator to a requirement to obtain a hazardous waste permit who has filed a hazardous waste permit application with the commission in accordance with the rules and regulations of the commission, may continue the storage, processing, or disposal of hazardous waste until such time as the commission approves or denies the application, or, if the owner or operator becomes subject to a requirement to obtain a hazardous waste permit after November 8, 1984, except as provided by the United States Environmental Protection Agency (EPA) or commission rules relative to termination of interim status. If a solid waste facility which has become a commercial hazardous waste management facility as a result of the federal toxicity characteristic rule effective September 25, 1990, and is required to obtain a hazardous waste permit, such facility that qualifies for interim status is limited to those activities that qualify it for interim status until the facility obtains the hazardous waste permit. Owners or operators of municipal hazardous waste facilities that satisfied this requirement by filing an application on or before November 19, 1980, with the EPA are not required to submit a separate application with the DSHS. Applications filed under this section shall meet the requirements of §335.44 of this title (relating to Application for Existing On-Site Facilities). Owners and operators of solid waste management facilities that are in existence on the effective date of statutory or regulatory amendments under the Texas Solid Waste Disposal Act (Vernon's Supplement 1991), Texas Civil Statutes, Article 4477-7, or the Resource Conservation and Recovery Act (RCRA), 42 United States Code, §§6901 *et seq.,* that render the facilities subject to the requirement to obtain a hazardous waste permit, may continue to operate if Part A of their permit application is submitted no later than six months after the date of publication of regulations by the EPA under RCRA, which first require them to comply with the standards in Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities), or Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities); or 30 days after the date they first become subject to the standards in these subchapters, whichever first occur; or for generators who generate greater than 100 kilograms but less than 1,000 kilograms of hazardous waste in a calendar month and who process, store, or dispose of these wastes on-site, a Part A permit application shall be submitted to the EPA by March 24, 1987, as required by 40 Code of Federal Regulations (CFR) §270.10(e)(1)(iii). This subsection shall not apply to a facility if it has been previously denied a hazardous waste permit or if authority to operate the facility has been previously terminated. Applications filed under this section shall meet the requirements of §335.44 of this title. For purposes of this subsection, a solid waste management facility is in existence if the owner or operator has obtained all necessary federal, state, and local preconstruction approvals or permits, as required by applicable federal, state, and local hazardous waste control statutes, regulations, or ordinances; and either:

(1) a continuous physical, on-site construction program has begun; or

(2) the owner or operator has entered into contractual obligations, which cannot be cancelled or modified without substantial loss, for construction of the facility to be completed within a reasonable time.

(d) No permit shall be required for:

(1) the processing or disposal of nonhazardous industrial solid waste, if the waste is processed or disposed on property owned or otherwise effectively controlled by the owner or operator of the industrial plant, manufacturing plant, mining operation, or agricultural operation from which the waste results or is produced; the property is within 50 miles of the plant or operation; and the waste is not commingled with waste from any other source or sources (An industrial plant, manufacturing plant, mining operation, or agricultural operation owned by one person shall not be considered an "other source" with respect to other plants and operations owned by the same person.);

(2) the storage of nonhazardous industrial solid waste, if the waste is stored on property owned or otherwise effectively controlled by the owner or operator of the industrial plant, manufacturing plant, mining operation, or agricultural operation from which the waste results or is produced, and the waste is not commingled with waste from any other source or sources (An industrial plant, manufacturing plant, mining operation, or agricultural operation owned by one person shall not be considered an "other source" with respect to other plants and operations owned by the same person.);

(3) the storage or processing of nonhazardous industrial solid waste, if the waste is processed in an elementary neutralization unit;

(4) the collection, storage, or processing of nonhazardous industrial solid waste, if the waste is collected, stored, or processed as part of a treatability study;

(5) the storage of nonhazardous industrial solid waste, if the waste is stored in a transfer facility in containers for a period of ten days or less, unless the executive director determines that a permit should be required in order to protect human health and the environment;

(6) the storage or processing of nonhazardous industrial solid waste, if the waste is processed in a publicly owned treatment works with discharges subject to regulation under the federal Clean Waste Act, §402, as amended through October 4, 1996, if the owner or operator has a National Pollutant Discharge Elimination System permit and complies with the conditions of the permit;

(7) the storage or processing of nonhazardous industrial solid waste, if the waste is stored or processed in a wastewater unit and is discharged in accordance with a Texas Pollutant Discharge Elimination System authorization issued under Texas Water Code, Chapter 26;

(8) the storage or processing of nonhazardous industrial solid waste, if the waste is stored or processed in a wastewater treatment unit that discharges to a publicly owned treatment works and the units are located at a noncommercial solid waste management facility; or

(9) the storage or processing of nonhazardous industrial solid waste, if the waste is processed in a wastewater treatment unit that discharges to a publicly owned treatment works liquid wastes that are incidental to the handling, processing, storage, or disposal of solid wastes at municipal solid waste facilities or commercial industrial solid waste landfill facilities.

(e) No permit shall be required for the on-site storage of hazardous waste by a person who meets the conditions for exemption for a very small quantity generator in 40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [~~is a conditionally exempt small quantity generator as described in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)~~].

(f) No permit under this chapter shall be required for the storage, processing, or disposal of hazardous waste by a person described in §335.41(b) - (d) of this title (relating to Purpose, Scope, and Applicability) or for the storage of hazardous waste under the provisions of 40 CFR §261.4(c) and (d) as adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(g) No permit under this chapter shall be required for the storage, processing, or disposal of hazardous industrial waste or municipal hazardous waste that is generated or collected for the purpose of conducting treatability studies. Such samples are subject to the requirements in 40 CFR §261.4(e) and (f) [~~, as amended through November 28, 2016 (81 FR 83696), which are adopted by reference~~] as adopted under §335.504 of this title.

(h) A person may obtain authorization from the executive director for the storage, processing, or disposal of nonhazardous industrial solid waste in an interim status landfill that has qualified for interim status in accordance with 40 CFR Part 270, Subpart G, and that has complied with the standards in Subchapter E of this chapter, by complying with the notification and information requirements in §335.6 of this title (relating to Notification Requirements). The executive director may approve or deny the request for authorization or grant the request for authorization subject to conditions, which may include, without limitation, public notice and technical requirements. A request for authorization for the disposal of nonhazardous industrial solid waste under this subsection shall not be approved unless the executive director determines that the subject facility is suitable for disposal of such waste at the facility as requested. At a minimum, a determination of suitability by the executive director must include approval by the executive director of construction of a hazardous waste landfill meeting the design requirements of 40 CFR §265.301(a). In accordance with §335.6 of this title, such person shall not engage in the requested activities if denied by the executive director or unless 90 days' notice has been provided and the executive director approves the request except where express executive director approval has been obtained prior to the expiration of the 90 days. Authorization may not be obtained under this subsection for:

(1) nonhazardous industrial solid waste, the storage, processing, or disposal of which is expressly prohibited under an existing permit or site development plan applicable to the facility or a portion of the facility;

(2) polychlorinated biphenyl compounds wastes subject to regulation by 40 CFR Part 761;

(3) explosives and shock-sensitive materials;

(4) pyrophorics;

(5) infectious materials;

(6) liquid organic peroxides;

(7) radioactive or nuclear waste materials, receipt of which will require a license from the DSHS or the commission or any other successor agency; and

(8) friable asbestos waste unless authorization is obtained in compliance with the procedures established under §330.171(c)(3)(B)

- (E) of this title (relating to Disposal of Special Wastes). Authorizations obtained under this subsection shall be effective during the pendency of the interim status and shall cease upon the termination of interim status, final administrative disposition of the subject permit application, failure of the facility to operate the facility in compliance with the standards set forth in Subchapter E of this chapter, or as otherwise provided by law.

(i) Owners or operators of hazardous waste management units must have permits during the active life (including the closure period) of the unit. Owners or operators of surface impoundments, landfills, land treatment units, and waste pile units that received wastes after July 26, 1982, or that certified closure (according to 40 CFR §265.115) after January 26, 1983, must have post-closure permits, unless they demonstrate closure by removal or decontamination as provided under 40 CFR §270.1(c)(5) and (6), or obtain an order in lieu of a post-closure permit, as provided in subsection (m) of this section. If a post-closure permit is required, the permit must address applicable provisions of 40 CFR Part 264, and Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) provisions concerning groundwater monitoring, unsaturated zone monitoring, corrective action, and post-closure care requirements. The denial of a permit for the active life of a hazardous waste management facility or unit does not affect the requirement to obtain a post-closure permit under this section.

(j) Upon receipt of the federal Hazardous and Solid Waste Act (HSWA) authorization for the commission's Hazardous Waste Program, the commission shall be authorized to enforce the provisions that the EPA imposed in hazardous waste permits that were issued before the HSWA authorization was granted.

(k) Any person who intends to conduct an activity under subsection (d) of this section shall comply with the notification requirements of §335.6 of this title.

(l) No permit shall be required for the management of universal wastes by universal waste handlers or universal waste transporters, in accordance with the definitions and requirements of Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule).

(m) At the discretion of the commission, an owner or operator may obtain a post-closure order in lieu of a post-closure permit for interim status units, a corrective action management unit unless authorized by a permit, or alternative corrective action requirements for contamination commingled from RCRA and solid waste management units. The post-closure order must address the facility-wide corrective action requirements of §335.167 of this title (relating to Corrective Action for Solid Waste Management Units) and groundwater monitoring requirements of §335.156 of this title (relating to Applicability of Groundwater Monitoring and Response).

(n) Except as provided in subsection (d)(9) of this section, owners or operators of commercial industrial solid waste facilities that receive industrial solid waste for discharge to a publicly owned treatment works are required to obtain a permit under this subchapter. By June 1, 2006, owners or operators of existing commercial industrial solid waste facilities that receive industrial solid waste for discharge to a publicly owned treatment works must have a permit issued under this subchapter or obtain a general permit issued under Chapter 205 of this title (relating to General Permits for Waste Discharges) to continue operating. A general permit issued under Chapter 205 of this title will authorize operations until a final decision is made on the application for an individual permit or 15 months, whichever is earlier. The general permit shall authorize operations for a maximum period of 15 months except that authorization may be extended on an individual basis in one-year increments at the discretion of the executive director. Should an application for a general permit issued under Chapter 205 of this title be submitted, the applicant shall also submit to the commission, by June 1, 2006, the appropriate information to demonstrate compliance with financial assurance requirements for closure of industrial solid waste facilities in accordance with Chapter 37, Subchapter P of this title (relating to Financial Assurance for Hazardous and Nonhazardous Industrial Solid Waste Facilities). Owners or operators of commercial industrial solid waste facilities that receive industrial solid waste for discharge to a publicly owned treatment works operating under a general permit issued under Chapter 205 of this title shall submit an application for a permit issued under this subchapter prior to September 1, 2006.

(o) Treatment, storage, and disposal facilities that are otherwise subject to permitting under RCRA and that meet the criteria in paragraphs (1) or paragraph (2) of this subsection, may be eligible for a standard permit under Subchapter U of this chapter (relating to Standards for Owners and Operators of Hazardous Waste Facilities Operating Under a Standard Permit) if they satisfy one of the two following criteria:

(1) facility generates hazardous waste and then non-thermally treats and/or stores hazardous waste on-site; or

(2) facility receives hazardous waste generated off-site by a generator under the same ownership as the receiving facility.

(p) No permit under this chapter shall be required for a reverse distributor accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in §335.751 of this title (relating to Definitions) in compliance with Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals). Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals in compliance with Subchapter W of this chapter shall notify the executive director in accordance with §335.6 of this title.

§335.6. Notification Requirements.

(a) Notification of unpermitted industrial solid waste activities. Any person who intends to store, process, recycle, or dispose of industrial solid waste without a permit, as authorized by §335.2(d), (f), or (h) of this title (relating to Permit Required) or §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), shall notify the executive director using a method approved by the executive director, that storage, processing, recycling, or disposal activities are planned.

(1) A person required to notify of activities under this subsection shall notify at least 90 days before conducting an activity under this subsection.

(2) A person required to notify under this section shall submit additional information, upon request, to the executive director to demonstrate that storage, processing, recycling, or disposal is compliant with the terms of this chapter, including but not limited to information listed under subsection (b)(3) of this section.

(b) Duty to notify of changed and new information. Any person who stores, processes, or disposes of municipal hazardous waste or industrial solid waste shall promptly notify the executive director using a method approved by the executive director of:

(1) any new information concerning storage, processing, and disposal described in paragraph (3) of this subsection; and

(2) any changes to information previously submitted or reported under subsection (a) of this section:

(A) authorized in any permit issued by the commission; or

(B) submitted or reported to the commission in any application filed with the commission.

(3) Information concerning storage, processing, and disposal required to be submitted under this subsection includes and is not limited to:

(A) waste composition;

(B) waste management methods;

(C) facility engineering plans and specifications; and

(D) the geology where the facility is located.

(4) A person who notifies the executive director under this section shall immediately document and notify the executive director within 90 days of changes in information previously provided and additional information that was not provided.

(c) Generator registration.

(1) Any person, by site, that generates in any calendar month more than 100 kilograms of non-acute hazardous waste, more than 1 kilogram of acute hazardous waste, or more than 100 kilograms of industrial Class 1 waste shall register in a method approved by the executive director.

(2) Large quantity generators must meet the requirements of this subsection using the electronic interface provided by the executive director unless:

(A) the executive director has granted a written request to use paper forms or an alternative notification method; or

(B) the software does not have features capable of meeting the requirements.

(3) Notifications submitted pursuant to this section shall be in addition to information provided in any permit applications required by §335.2 of this title, or any reports required by §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), and §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste).

(4) If waste is recycled on-site or managed pursuant to §335.2(d)(1) - (4) or (6) - (9) of this title, the generator must also comply with the notification requirements specified in subsection (h) of this section.

(5) The information submitted pursuant to the notification requirements of this subchapter and to the additional requirements of §335.503 of this title (relating to Waste Classification and Waste Coding Required) shall include, but is not limited to:

(A) a description of the waste including:

(i) a description of the process generating the waste; and

(ii) the composition of the waste;

(B) a hazardous waste determination in accordance with §335.504 of this title (relating to Hazardous Waste Determination), which includes the appropriate United States Environmental Protection Agency (EPA) hazardous waste number(s) described in 40 Code of Federal Regulations (CFR) Part 261;

(C) the disposition of each solid waste generated, if subject to the notification requirement of this subsection, including:

(i) whether the waste is managed on-site and/or off-site;

(ii) a description of the type and use of each on-site waste management facility unit;

(iii) a listing of the wastes managed in each unit; and

(iv) whether each unit is permitted, or qualifies for an exemption, under §335.2 of this title.

(d) Transporter registration. Any person who transports hazardous waste or industrial Class 1 waste shall notify the executive director of such activity by registering using a method approved by the executive director. A person, by site, that generates in any calendar month less than 100 kilograms of non-acute hazardous waste, less than 1 kilogram of acute hazardous waste, and less than 100 kilograms of industrial Class 1 waste and only transports their own waste is not required to comply with this subsection.

(e) Transfer facility registration. A person that intends to operate a transfer facility in accordance with §335.94 of this title (relating to Transfer Facility Requirements) shall notify the executive director of such activity by registering using a method approved by the executive director.

(f) Waste analysis. Any person who ships, stores, processes, or disposes of industrial solid waste or hazardous waste shall provide the chemical analysis of the solid waste performed in accordance with Subchapter R of this chapter (relating to Waste Classification) to the executive director upon written request.

(g) Notification prior to facility expansion. Any person who stores, processes, or disposes of industrial solid waste or municipal hazardous waste shall notify the executive director in writing of any activity or facility expansion not authorized by permit, at least 90 days prior to conducting such activity. Such person shall submit to the executive director upon request such information as may reasonably be required to enable the executive director to determine whether such activity is compliant with this chapter.

(h) Notification of recycling activities. Any person who intends to ship off-site or transfer to another person for recycling, or who conducts or intends to conduct the recycling of, industrial solid waste, municipal hazardous waste, recyclable materials, or nonhazardous recyclable materials as defined in §335.24 of this title or Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities) and who is required to notify under §335.24 of this title or Subchapter H of this chapter shall notify the executive director using a method approved by the executive director.

(1) A person that is required to notify under this subsection shall include, at a minimum, the following information:

(A) the type(s), classification(s), Texas waste code(s) and EPA hazardous waste number(s) described in 40 CFR Part 261, if any, of each industrial solid waste and municipal hazardous waste intended to be recycled;

(B) the method of storage prior to recycling; and

(C) the nature of the recycling activity.

(2) A person required to notify the executive director of the intent to recycle under this subsection may begin recycling activities 90 days after submitting notification of intent to recycle under this subsection if the executive director has not requested additional information

in response to the notification or upon receipt of an acknowledgment from the executive director.

(i) Notification of operating under the small quantity burner exemption. The owner or operator of a facility qualifying for the small quantity burner exemption under 40 CFR §266.108 must provide a one-time signed, written notification to the EPA and to the executive director indicating the following:

(1) the combustion unit is operating as a small quantity burner of hazardous waste;

(2) the owner and operator are in compliance with the requirements of 40 CFR §266.108, §335.221(a)(19) of this title (relating to Applicability and Standards) and this subsection; and

(3) the maximum quantity of hazardous waste that the facility may burn as provided by 40 CFR §266.108(a)(1).

(j) Notification of used oil activities. Notification and regulation requirements on nonhazardous used oil, oil made characteristically hazardous by use (instead of mixing), used oil generated by a very small quantity generator, and household used oil after collection that will be recycled shall notify in accordance with Chapter 324 of this title (relating to Used Oil).

(k) Notification exemption for the disposal of animal carcasses. A landowner who disposes of domestic or exotic animal carcasses and who complies with a certified water quality management plan developed for their site under Texas Agriculture Code, §201.026(f) as added by Acts 2001, 77th Legislature, Chapter 1189, §1 (relating to Nonpoint Source Pollution) is exempt from the notification requirements of subsections (a) and (b) of this section.

(l) Healthcare facilities notification. A person required to notify the executive director under §335.755 of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals) shall notify using a method approved by the executive director.

(m) Reverse distributor registration. A person required to notify the executive director under §335.771 of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors) shall register using a method approved by the executive director.

§335.9. Recordkeeping and Annual Reporting Procedures Applicable to Generators.

(a) A generator of hazardous or industrial solid waste shall comply with the recordkeeping and reporting requirements of this section. Nonhazardous recyclable materials regulated under §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), are not subject to the requirements of this section. [~~Except with regard to nonhazardous recyclable materials regulated pursuant to §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), each generator of hazardous or industrial solid waste shall comply with the following.~~]

(1) A [~~The~~] generator shall make and keep records of all hazardous and industrial solid waste activities regarding the quantities generated, received from off-site, stored, processed, and disposed of on-site or shipped off-site for storage, processing, recycling, or disposal. These records must [~~and which~~], at a minimum, include [~~includes~~] the information described in subparagraphs (A) - (G) of this paragraph. These records must [~~may~~] be maintained in a readily retrievable format [~~any format, provided they are retrievable and easy to copy~~]. The required records must be sufficiently detailed and complete to support any contentions or claims made by the generator with respect to:

(A) the description, character, and classification of each waste, in accordance with Subchapter R of this chapter (relating to Waste Classification) and any changes and additional information required under §335.6(c) and (d) of this title (relating to Notification Requirements);

(B) the quantity generated;

(C) except generators that generate less than 100 kilograms of non-acute hazardous waste, less than 1 kilogram of acute hazardous waste, and less than 100 kilograms of industrial Class 1 waste per calendar month [~~for conditionally exempt small quantity generators regulated under §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated By Conditionally Exempt Small Quantity Generators)~~], the quantity held in on-site storage as of December 31 of each calendar year;

(D) the quantity processed or disposed of at each on-site facility unit during the calendar year;

(E) the method of storage, processing, or disposal as described by codes listed on the form or instructions;

(F) the quantity shipped off-site for storage, processing, or disposal each calendar year, including the transporter and the name, address, and location of each off-site facility [~~and transporter~~] receiving shipments; and

(G) the location of each [~~all~~] hazardous waste satellite accumulation area [~~areas, situated at or near any point of generation,~~] where hazardous wastes are temporarily accumulated in accordance with §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [~~under the control of the operator of the process generating the wastes are placed in containers and initially accumulated without a permit or interim status in accordance with §335.69(d) of this title (relating to Accumulation Time)~~].

(2) The generator shall submit to the executive director a complete and correct Annual Waste Summary using the electronic interface, paper forms, or other method approved by the executive director by the deadlines provided in, and in accordance with, this paragraph. [~~detailing the management of each hazardous and Class 1 waste generated on-site during the reporting calendar year. The Annual Waste Summary shall also include the management of any hazardous or Class 1 waste generated in a year previous to the reporting year, but managed in the reporting calendar year. The Annual Waste Summary shall be submitted using electronic software or paper forms provided or approved by the executive director. Upon written request by the generator, the executive director may authorize an extension to the report due date. Any registered generator who generates 1,000 kilograms or more of hazardous waste in any calendar month, must submit the Annual Waste Summary using software provided by the executive director unless the executive director has granted a written request to use paper forms or an alternative reporting method. Generators shall report as follows.~~]

(A) Generators submitting their Annual Waste Summary on paper forms must do so on or before January 25 of the year following the reporting calendar year unless the executive director has approved a request for an extension.

(B) Generators submitting their Annual Waste Summary electronically must do so on or before March 1 of the year following the reporting calendar year unless the executive director has approved a request for an extension.

(C) The Annual Waste Summary shall include the information under paragraph (1) of this subsection and detailed information regarding:

(i) the management of each hazardous and industrial Class 1 waste generated on-site during the reporting calendar year;

(ii) the management of each hazardous and industrial Class 1 waste received from off-site during the reporting calendar year; and

(iii) the management of each hazardous and industrial Class 1 waste received from off-site or generated in a year prior to the reporting year and managed on-site during the reporting calendar year.

(D) A large quantity generator must submit the Annual Waste Summary using the electronic interface provided by the executive director unless the executive director has approved an alternative reporting method.

(3) A generator that certifies on the Annual Waste Summary that the generator met the conditions in this paragraph during the reporting calendar year is not required to submit the information in paragraph (2) of this subsection. [~~Generators are not required to submit the information required in paragraph (1) of this subsection if they certify on the annual summary that all of the following conditions have been met:~~]

(A) The volume of hazardous waste accumulated on-site did not exceed the volumes for a very small generator classification in 40 Code of Federal Regulations (CFR) §262.14(a)(3) and (4) as adopted under §335.53 of this title [~~during the year, total on-site accumulation of hazardous waste did not equal or exceed 1,000 kilograms~~];

(B) The generator generated less than: [~~no acute hazardous waste was generated or accumulated during the year exceeding the limits specified in §335.78(e)(1) and (2) of this title;~~]

(i) 1,200 kilograms of non-acute hazardous waste;

(ii) 1,200 kilograms of industrial Class 1 waste; and

(iii) 1 kilogram of acute hazardous waste.

[~~(C) a total of less than 1,200 kilograms of hazardous waste, and a total of less than 1,200 kilograms of Class 1 waste (2,400 kilograms or less of hazardous waste plus Class 1 waste combined) was generated during the year.~~]

(4) A generator is not required to submit an Annual Waste Summary if, during the entire calendar year, that generator: [~~Generators who are regulated under §335.78 of this title and also meet the requirements of paragraph (3) of this subsection are not required to submit an annual summary~~].

(A) meets the conditions for exemption for a very small quantity generator under §335.53 of this title;

(B) generates less than 100 kilograms of industrial class 1 waste per month; and

(C) meets the requirements of paragraph (3) of this subsection.

(b) A large quantity generator that ships hazardous waste offsite, treats, stores, or disposes of hazardous waste onsite, or receives hazardous waste from very small quantity generators must submit the biennial report information required by 40 CFR §262.41, adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators). Information submitted in accordance with Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste), and Subchapter R of this chapter (relating to Waste Classification) is not required to be resubmitted in a biennial report required by 40 CFR §262.41. [~~A generator who ships his hazardous waste off-site must also report the information specified in §335.71 of this title (relating to Biennial Reporting). Any waste related information that has already been submitted by generators under the requirements of this section or §335.71 of this title need not be included in the reports from permitted or interim status facilities under 40 CFR §264.75 or §265.75.~~]

§335.10. Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste.

(a) Except as provided in paragraph (2) of this subsection, no person who generates, transports, processes, stores, or disposes of hazardous waste shall cause, suffer, allow, or permit the shipment of hazardous waste unless the person complies with this subsection, §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste), §335.54 of this title (relating to Hazardous Waste Manifest), and §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal) [~~he complies with the requirements of paragraph (1) of this subsection, and the manifest requirements in 40 Code of Federal Regulations (CFR) §§262.20 - 262.25, 262.27, and 262.42, as these sections are amended through February 7, 2014 (79 FR 7518), and 40 CFR Part 262, Subpart H, and the Appendix to 40 CFR Part 262, as amended through November 28, 2016 (81 FR 85696)~~].

(1) In addition, generators and owners or operators of treatment, storage, or disposal facilities shall include a Texas waste code for each hazardous waste itemized on the manifest.

(2) The manifest required by this subsection is not required for the transportation of hazardous waste when all of the conditions of an applicable exemption from manifesting have been met, including and not limited to the exemptions in this paragraph and subsection (b) of this section [~~No manifest is required for a hazardous waste generated by a generator that generates less than the quantity limits of hazardous waste specified in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators) or a municipal generator that generates less than the quantity limit of hazardous waste specified in §335.78 of this title~~].

(A) The manifesting requirements of this section are not applicable to the transportation of hazardous waste generated by a very small quantity generator (VSQG) that meets the conditions for exemption in 40 Code of Federal Regulations (CFR) §262.14 as adopted in §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(B) The manifesting requirements of this section are not applicable to the transportation of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor in compliance with §335.769 of this title (relating to Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor).

(b) The manifesting and marking requirements of §335.55 of this title (relating to Pre-Transport Requirements Applicable to Small and Large Quantity Generators) are not applicable to the transportation of hazardous waste [~~No manifest and no marking in accordance with~~

§335.67(b) of this title (relating to Marking) is required for hazardous waste transported] on a public or private right-of-way within or along the border of contiguous property under the control of the same person, even if such contiguous property is divided by a public or private right-of-way. However, in the event of a hazardous waste discharge on a public or private right-of-way, the generator or transporter must comply with the requirements of §335.93 of this title (relating to Hazardous Waste Discharges).

(c) Except as provided in subsections (d) and (e) of this section, persons who generate, transport, process, store, or dispose of Class 1 waste shall not cause, suffer, allow, or permit the shipment of Class 1 waste unless the person complies with the manifest requirements adopted in §335.54 of this title with the following changes and additions: [listed in subsection (a) of this section, with the following changes:]

(1) when Class 1 waste is itemized on the manifest, either [use] the Texas Commission on Environmental Quality solid waste registration (SWR) number or the United States Environmental Protection Agency (EPA) identification number must [to] identify the generator, transporter, and designated facility [receiver]; and [use] the Texas waste code, instead [in place] of the EPA waste code, must identify the waste; [and]

(2) when both hazardous and Class 1 waste are itemized on the same manifest, the [use] EPA identification numbers, not SWR numbers, must [to] identify the generator, transporter, and designated facility [receiver]; and [use] the Texas waste codes must identify [for] each waste itemized on the manifest; [.]

(3) the term "Designated facility" has the meaning in §335.1 of this title (relating to Definitions);

(4) the term "Hazardous waste" is replaced by the term "Class 1 waste";

(5) the exceptions for hazardous waste being reclaimed under 40 CFR §262.20(e) are not applicable to transportation of Class 1 waste;

(6) in the event of a discharge on a public right of way, the generator or transporter must comply with Chapter 327 of this title (relating to Spill Prevention and Control) and §335.93 of this title instead of complying with 40 CFR §263.30 and §263.31 as required by 40 CFR §262.20(f); and

(7) waste minimization certification required by 40 CFR §262.27 is not applicable to Class 1 waste.

(d) No manifest is required for the shipment of Class 1 waste generated by a person that generated less than 100 kilograms of Class 1 waste during the calendar month in which the subject Class 1 waste was generated [where the generator is an industrial generator that generates less than the quantity limits of Class 1 waste specified in §335.78 of this title or is a municipal generator that generates less than the quantity limit of Class 1 waste specified in §335.78 of this title].

(e) No manifest is required for the shipment of Class 1 waste to property owned or otherwise effectively controlled by the owner or operator of an industrial plant, manufacturing plant, mining operation, or agricultural operation from which the waste results or is produced, provided that:

(1) the property is within 50 miles of the plant or operation; [and]

(2) the waste is not commingled with waste from any other source or sources. An industrial plant, manufacturing plant, mining operation, or agricultural operation owned by one person shall not be considered another source with respect to other plants or operations owned by the same person; and [.]

(3) the owner or operator of a facility that receives and stores, processes, or disposes Class 1 waste from off-site in compliance with an exception from permit required in §335.2(d)(1) or (2) of this title (relating to Permit Required) must report Class 1 industrial waste received from off-site in the Annual Waste Summary submitted for the receiving facility in accordance with §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators).

§335.11. Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste.

(a) Incorporation by reference. The commission adopts by reference 40 Code of Federal Regulations (CFR) Part 263, Subpart B (Compliance With the Manifest System and Recordkeeping), as amended through the January 3, 2018 issue of the *Federal Register* (83 FR 420).

(b) Hazardous waste transporters. Except as provided by §335.10(a)(2) of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), persons who transport hazardous waste must comply with:

(1) subsection (a) of this section;

(2) §335.4 of this title (relating to General Prohibitions);

(3) §335.6 of this title (relating to Notification Requirements);

(4) §335.10 of this title;

(5) §335.14 of this title (relating to Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste); and

(6) Subchapter D of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste).

(c) Class 1 industrial waste transporters. Except as provided by §335.10 of this title, a person who transports Class 1 waste shall comply with subsection (b)(1) - (5) of this section and the manifesting requirements adopted under subsection (a) of this section, with the changes and additions in this subsection.

(1) When only Class 1 waste is itemized on the manifest, a Texas Commission on Environmental Quality solid waste registration (SWR) number or a United States Environmental Protection Agency (EPA) identification number may be used for the generator, transporter, and designated facility.

(2) When both hazardous and Class 1 industrial waste are itemized on the same manifest, an EPA identification number must be used for the generator, transporter, and designated facility.

(3) A Texas waste code, instead of an EPA waste code, must identify each Class 1 waste itemized on the manifest.

(4) The term "Hazardous waste" is changed to the term "Class 1 waste."

(5) The import and export requirements of 40 CFR §263.20(a)(2), (c), and (g) are not applicable to the transportation of Class 1 waste.

(6) The exclusion from manifesting requirements for hazardous waste being transported pursuant to a reclamation agreement under 40 CFR §263.20(h) is not applicable to the transportation of Class 1 waste.

(7) In the event of a spill or discharge of Class 1 waste during transportation, the transporter shall notify the commission in accordance with Chapter 327 of this title (relating to Spill Prevention and Control), and Texas Water Code, §26.039, and take appropriate immediate action to protect human health and the environment (e.g., notify local authorities, dike the discharge).

(8) A transporter shall clean up any Class 1 waste spill or discharge that occurs during transportation or take such action as required in §327.5 of this title (relating to Actions Required) so that the Class 1 waste discharge no longer presents a hazard to human health or the environment.

§335.12. Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities.

(a) Except as provided by §335.10(a)(2) of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste), persons who generate, process, store, or dispose of hazardous waste must comply with this subsection as well as subsections (c) and (d) of this section and 40 Code of Federal Regulations (CFR) Part 264, Subpart E (Manifest System, Recordkeeping, and Reporting), as adopted in §335.152 of this title (relating to Standards) or 40 CFR Part 265, Subpart E (Manifest System, Recordkeeping, and Reporting), as adopted in §335.112 of this title (relating to Standards) [40 Code of Federal Regulations (CFR) §264.72 or §265.72, depending on the status of the person, as these sections are amended through February 7, 2014 (79 FR 7518); and 40 CFR §264.71 or §265.71, depending on the status of the person, as these sections are amended through November 28, 2016 (81 FR 85696), and with the Appendix to 40 CFR Part 262, as amended through November 28, 2016 (81 FR 85696). The references in §335.112(b)(1) and (10) and §335.152(c)(1) and (10) of this title (relating to Standards) do not apply to this provision].

(b) Except as provided by §335.10(d) and (e) of this title, persons who generate, transport, process, store, or dispose of Class 1 waste must comply with this subsection as well as subsections (c) and (d) of this section and 40 CFR Part 264, Subpart E as adopted in §335.152 of this title with the changes in this subsection [40 CFR §264.72 and §264.76, as amended through February 7, 2014 (79 FR 7518), and §264.71 and the Appendix to 40 CFR Part 262, as amended through November 28, 2016 (81 FR 85696), and a manifest or copy of e-Manifest must accompany the shipment which designates that facility to receive the waste].

(1) "Hazardous waste" is changed to "Class 1 waste."

(2) When only Class 1 waste is itemized on the manifest a Texas Commission on Environmental Quality solid waste registration number or a United States Environmental Protection Agency identification number may be used for the generator, transporter, and designated facility.

(3) "Regional Administrator" is changed to "Executive director."

(4) The requirements of 40 CFR Part 262, Subpart H (Transboundary Movements of Hazardous Waste for Recovery or Disposal) are not applicable to Class 1 waste imported from outside of the United States.

(c) The commission adopts by reference 40 CFR §260.4 (Manifest copy submission requirements for certain interstate waste shipments), as adopted in the *Federal Register* on January 3, 2018 (83 FR 420).

(d) The commission adopts by reference 40 CFR §260.5 (Applicability of electronic manifest system and user fee requirements to facilities receiving state-only regulated waste shipments) as adopted in the *Federal Register* on January 3, 2018 (83 FR 420).

§335.13. Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste.

(a) The requirements of this section do not apply to a generator that generates less than 100 kilograms of Class 1 waste, 100 kilograms of hazardous waste, and 1 kilogram of acute hazardous in a calendar month, by site. [The requirements of this section do not apply to generators who generate hazardous waste or Class 1 waste in quantities less than 100 kilograms in a calendar month, or acute hazardous waste in quantities specified in §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators).]

(b) An unregistered generator that ships [Unregistered generators who ship] hazardous waste or Class 1 waste shall prepare a complete and correct Waste Shipment Summary from the manifests.

(c) The Waste Shipment Summary shall be prepared in a form provided or approved by the executive director and submitted to the executive director on or before the 25th of each month for shipments originating during the previous month. An [The] unregistered generator must keep a copy of each summary for a period of at least three years from the due date of the summary. An unregistered generator must [These generators are required to] prepare and submit a Waste Shipment Summary only for those months in which shipments are actually made.

(d) A registered generator is defined as an in-state generator who has complied with §335.6 of this title (relating to Notification Requirements) and has an active [, and is assigned a] solid waste registration number.

(e) An unregistered generator is defined as an in-state generator that:

(1) does not have an active solid waste registration;

(2) in a calendar month generates more than 100 kilograms of non-acute hazardous waste, 1 kilogram of acute hazardous waste, or 100 kilograms of Class 1 waste; and [who is not a conditionally exempt small quantity generator, as defined in §335.78 of this title, that]

(3) ships hazardous waste and/or Class 1 industrial waste using a temporary solid waste registration number and a temporary Texas waste code number assigned by the executive director.

(f) Both registered and unregistered generators shall comply with the manifest and recordkeeping requirements under §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste). [The registered/unregistered generator shall retain a copy of each manifest required by §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste) for at least three years from the date of shipment by the registered/unregistered generator.]

[(g) A registered/unregistered generator who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the waste was accepted by the initial transporter must contact the transporter and/or the owner or operator of the designated facility to determine the status of the hazardous waste or Class 1 waste.]

[(h) A registered/unregistered generator must submit an exception report to the executive director if he has not received a copy of the manifest with the handwritten signatures of the owner or operator of the designated facility within 45 days of the date that the waste was accepted by the initial transporter. The exception report must be retained by the registered/unregistered generator for at least three years

from the date the waste was accepted by the initial transporter and must include:]

[(1) a legible copy of the manifest for which the generator does not have confirmation of delivery; and]

[(2) a copy of a letter signed by the generator or his authorized representative explaining the efforts taken to locate the hazardous waste or Class 1 waste and the results of those efforts.]

[(i) The periods of record retention required by this section are automatically extended during the course of any unresolved enforcement action regarding the regulated activity.]

[(j) Any person who exports or imports hazardous waste must comply with 40 CFR §262.12 and 40 CFR Part 262, Subpart H, as adopted by reference under §335.76(a) of this title (relating to Additional Requirements Applicable to International Shipments).]

§335.14. Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste.

A hazardous waste transporter and a Class 1 waste transporter shall comply with the manifesting and recordkeeping requirements of 40 Code of Federal Regulations (CFR) Part 263, Subpart B as adopted under §335.11 of this title (relating to Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste).

§335.15. Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities.

This section applies to owners and operators of facilities that receive hazardous waste or Class 1 waste from off-site sources and owners and operators of facilities that have notified the executive director of the intent to receive hazardous waste or Class 1 waste from off-site sources. [who receive hazardous or Class 1 waste from off-site sources or who have notified that they intend to receive hazardous or Class 1 waste from off-site sources.]

(1) Manifest requirements. The owner or operator of the treatment, storage, or disposal facility designated on the manifest shall comply with the manifesting and recordkeeping requirements of 40 Code of Federal Regulations (CFR) Part 264, Subpart E as adopted under §335.152 of this title (relating to Standards) or 40 CFR Part 265, Subpart E as adopted under §335.112 of this title (relating to Standards), the manifest copy submission requirements for certain interstate waste shipments in 40 CFR §260.4 as adopted under §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), the electronic manifest system and user fees for facilities that receive state-only regulated waste shipments requirements in 40 CFR §260.5 as adopted under §335.12 of this title, and 40 CFR Part 262, Subpart B as adopted under §335.54 of this title (relating to Hazardous Waste Manifest). [retain a copy of each manifest or, in the case of shipments by rail or water (bulk shipment), a copy of each manifest and shipping paper, for a minimum of three years from the date of initial shipment by the generator or primary exporter where appropriate.]

(2) Monthly Waste Receipt Summary. Except as provided in paragraph (6) of this section or as provided in §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), the owner or operator shall prepare a complete and correct Monthly Waste Receipt Summary in accordance with this paragraph. The owner or operator shall: [for all manifested and unmanifested hazardous or Class 1 waste shipments received. The Monthly Waste Receipt Summary shall be submitted electronically, using software provided by the executive director. Upon written request by the receiver, authorization may be given by the executive director to use paper forms or an alternative reporting method. The Monthly Waste Receipt Summary shall be submitted to the executive director on or before the 25th of each month for wastes or manifests received during the previous month. (The appropriate abbreviations for method of treatment, storage, and disposal of waste and for units of measure may be found on the form or accompanying instructions.) Any owner or operator of a treatment, storage, or disposal facility required to comply with this paragraph shall prepare and submit a Monthly Waste Receipt Summary each month even if no waste was received.]

(A) submit a Monthly Waste Receipt Summary on or before the 25th of every month;

(B) include all manifested and unmanifested hazardous and Class 1 waste shipments received during the previous month, if any;

(C) use the electronic interface provided by the executive director unless the executive director has approved an alternative reporting method; and

(D) identify the methods of treatment, storage, and disposal of waste and units of measure using abbreviations and codes provided by the executive director.

(3) Unmanifested waste report. An owner or operator shall comply with the unmanifested waste reporting requirements of this paragraph. [If a facility accepts for treatment, storage, or disposal any hazardous waste or Class 1 waste from an off-site source without an accompanying manifest, or without an accompanying shipping paper as described in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste), and if the waste is not excluded from the manifest requirement of this chapter, then the owner or operator must prepare and submit a letter to the executive director within 15 days after receiving the waste. The unmanifested waste report must contain the following information:]

(A) An owner or operator that accepts hazardous waste from an off-site source that is not excluded from the manifest requirements of this chapter and is not accompanied by a manifest shall complete and submit an unmanifested waste report within 15 days after receiving the waste to the executive director that includes:

(i) the United States Environmental Protection Agency (EPA) identification (ID) number, solid waste registration (SWR) number, name, and address of the facility;

(ii) the date the facility received the waste;

(iii) the EPA ID number, SWR number, name, and address of the generator and the transporter, if available;

(iv) a description and the quantity of each unmanifested hazardous waste the facility received which was not accompanied by a manifest;

(v) the method of treatment, storage, or disposal for each hazardous waste;

(vi) the certification signed by the owner or operator of the facility or his authorized representative; and

(vii) a brief explanation of why the waste was unmanifested, if known.

(B) An owner or operator that accepts Class 1 waste, that is not excluded from the manifest requirements of this chapter, from an off-site source without an accompanying manifest shall complete and submit an unmanifested waste report to the executive director within 15 days after receiving the waste that contains:

(i) [~~(A)~~] the EPA ID number, SWR number, [~~United States Environmental Protection Agency (EPA) identification number~~] name, and address of the receiving facility;

(ii) [~~(B)~~] the date the facility received the waste;

(iii) [~~(C)~~] the EPA identification number, SWR number, name, and address of the generator and the transporter, if available;

(iv) [~~(D)~~] a description and the quantity of each unmanifested Class 1 [~~hazardous~~] waste the facility received which was not accompanied by a manifest;

(v) [~~(E)~~] the method of treatment, storage, or disposal for each Class 1 hazardous waste;

(vi) [~~(F)~~] the certification signed by the owner or operator of the facility or his authorized representative; and

(vii) [~~(G)~~] a brief explanation of why the waste was unmanifested, if known.

(4) Records retention. The owner or operator shall retain a copy of each summary required by paragraphs (2) and (3) of this section for a minimum of three years from the date of each summary.

(5) Extended records retention. The period of record retention required by this section is automatically extended during the course of any unresolved enforcement action regarding the regulated activity.

(6) Monthly Waste Receipt Summary for reclamation of hazardous waste generated by very small quantity generators. An owner or operator reclaiming hazardous wastes received from a very small quantity generator shall complete and submit a Monthly Waste Receipt Summary unless the executive director has approved an exception from reporting. [~~An owner or operator reclaiming hazardous wastes received from a conditionally exempt small quantity generators is subject to the requirements of this section requiring completion of a Monthly Waste Receipt Summary, from his copy of all manifests received during the month, unless he has requested in writing a modification in the reporting requirements. A modification relieving the owner or operator of having to report each manifested shipment on the Monthly Waste Receipt Summary may be granted at the discretion of the executive director on a case-by-case basis.~~]

(7) Biennial report information provided in a Monthly Waste Receipt Summary. Information which has already been submitted by permitted or interim status facilities under the requirements of this section and of Subchapter A of this chapter need not be included in the reports required by 40 CFR §264.75 or §265.75 (relating to Biennial Reports), as adopted under §335.112 and §335.152 of this title; these biennial reports must be submitted to the executive director using a method approved by the executive director [~~in letter format~~] rather than by EPA form.

(8) Class 1 industrial waste received from off-site reported in Annual Waste Summary. The owner or operator of a facility that stores, processes or disposes Class 1 industrial waste received from off-site in accordance with an exception from permit required under §335.2(d)(1) or (2) of this title (relating to Permit Required), must report Class 1 industrial waste received from off-site on the Annual Waste Summary submitted for the receiving facility in accordance with §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators).

§335.18. Non-Waste Determinations and Variances from Classification as a Solid Waste.

(a) In accordance with the standards and criteria in §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste) and §335.32 of this title (relating to Standards and Criteria for Non-Waste Determinations), and in accordance with the procedures in §335.21 of this title (relating to Procedures for Variances from Classification as a Solid Waste or To Be Classified as a Boiler or for Non-Waste Determinations) the executive director may determine on a case-by-case basis that the following recyclable materials and nonhazardous recyclable materials are not solid wastes:

(1) materials that are accumulated speculatively without sufficient amounts being recycled (as defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials));

(2) materials that are reclaimed and then reused within the original production process in which they were generated;

(3) materials that have been reclaimed but must be reclaimed further before the materials are completely recovered;

(4) hazardous secondary materials that are reclaimed in a continuous industrial process; or

(5) hazardous secondary materials that are indistinguishable in all relevant aspects from a product or intermediate. [~~; or~~]

[~~(6) hazardous secondary materials that are transferred for reclamation under 40 Code of Federal Regulations §261.4(a)(24) and are managed at a verified reclamation facility or intermediate facility where the management of the hazardous secondary materials is not addressed under a Resource Conservation and Recovery Act Part B permit or interim status standards.~~]

(b) Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid waste," §335.6 of this title (relating to Notification Requirements), §335.17 of this title, §335.19 of this title, §335.20 of this title (relating to Variance To Be Classified as a Boiler), §335.21 of this title, §335.22 of this title (relating to Additional Regulation of Certain Hazardous Waste Recycling Activities on a Case-by-Case Basis), §335.23 of this title (relating to Procedures for Case-by-Case Regulation of Hazardous Waste Recycling Activities), §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities), and Subchapter V of this title (relating to Standards for Reclamation of Hazardous Secondary Materials).

§335.19. Standards and Criteria for Variances from Classification as a Solid Waste.

(a) The executive director may grant requests for a variance from classifying as a solid waste those materials that are accumulated speculatively without sufficient amounts being recycled if the applicant demonstrates that sufficient amounts of the material will be recycled or transferred for recycling in the following year. If a variance is granted, it is valid only for the following year, but can be renewed, on an annual basis, by filing a new application. The executive director's decision will be based on the following criteria:

(1) the manner in which the material is expected to be recycled, when the material is expected to be recycled, and whether this expected disposition is likely to occur (for example, because of past practice, market factors, the nature of the material, or contractual arrangements for recycling);

(2) the reason that the applicant has accumulated the material for one or more years without recycling 75% of the weight or volume accumulated at the beginning of the year;

(3) the quantity of material already accumulated and the quantity expected to be generated and accumulated before the material is recycled;

(4) the extent to which the material is handled to minimize loss; and

(5) other relevant factors.

(b) The executive director may grant requests for a variance from classifying as a solid waste those materials that are reclaimed and then reused as feedstock within the original production process in which the materials were generated if the reclamation operation is an essential part of the production process. This determination will be based on the following criteria:

(1) how economically viable the production process would be if it were to use virgin materials, rather than reclaimed materials;

(2) the extent to which the material is handled before reclamation to minimize loss;

(3) the time periods between generating the material and its reclamation, and between reclamation and return to the original primary production process;

(4) the location of the reclamation operation in relation to the production process;

(5) whether the reclaimed material is used for the purpose for which it was originally produced when it is returned to the original process, and whether it is returned to the process in substantially its original form;

(6) whether the person who generates the material also reclaims it; and

(7) other relevant factors.

(c) The executive director may grant requests for a variance from classifying as a solid waste those hazardous secondary materials that have been partially reclaimed, but must be reclaimed further before recovery is completed, if the partial reclamation has produced a commodity-like material. A determination that a partially-reclaimed material for which the variance is sought is commodity-like material will be based on whether the hazardous secondary material is legitimately recycled as specified in §335.27 of this title (relating to Legitimate Recycling of Hazardous Secondary Materials) and on whether all of the following decision criteria are satisfied:

(1) whether the degree of partial reclamation the material has undergone is substantial as demonstrated by using a partial reclamation process other than the process that generated the hazardous waste;

(2) whether the partially reclaimed material has sufficient economic value that it will be purchased for further reclamation;

(3) whether the partially reclaimed material is a viable substitute for a product or intermediate produced from virgin or raw materials which is used in subsequent production steps;

(4) whether there is a market for the partially reclaimed material as demonstrated by known customer(s) who are further reclaiming the material (e.g., records of sales and/or contracts and evidence of subsequent use, such as bills of lading);

(5) whether the partially reclaimed material is handled to minimize loss; and

(6) other relevant factors.

~~[(d) The executive director may grant requests for a variance from classifying as a solid waste those hazardous secondary materials that are transferred for reclamation in accordance with the requirements of 40 Code of Federal Regulations (CFR) §261.4(a)(24) and are managed at a verified reclamation facility or intermediate facility where the management of the hazardous secondary materials is not addressed under a Resource Conservation and Recovery Act (RCRA) Part B permit or interim status standards. The executive director's decision will be based on the following criteria:]~~

~~[(1) the reclamation facility or intermediate facility must demonstrate that the reclamation process for the hazardous secondary materials is legitimate pursuant to §335.27 of this title;]~~

~~[(2) the reclamation facility or intermediate facility must satisfy the financial assurance requirements of §335.703 of this title (relating to Financial Assurance Requirements);]~~

~~[(3) the reclamation facility or intermediate facility must not be subject to a formal enforcement action in the previous three years and not be classified as a significant non-complier under RCRA, Subtitle C, or must provide credible evidence that the facility will manage the hazardous secondary materials properly. Credible evidence may include a demonstration that the facility has taken remedial steps to address the violations and prevent future violations, or that the violations are not relevant to the proper management of the hazardous secondary materials;]~~

~~[(4) the intermediate or reclamation facility must have the equipment and trained personnel needed to safely manage the hazardous secondary material and must meet emergency preparedness and response requirements under 40 CFR Part 261, Subpart M;]~~

~~[(5) if residuals are generated from the reclamation of the excluded hazardous secondary materials, the reclamation facility must have the permits required (if any) to manage the residuals, have a contract with an appropriately permitted facility to dispose of the residuals or present credible evidence that the residuals will be managed in a manner that is protective of human health and the environment; and]~~

~~[(6) the intermediate or reclamation facility must address the potential for risk to proximate populations from unpermitted releases of the hazardous secondary material to the environment (i.e., releases that are not covered by a permit, such as a permit to discharge to water or air), which may include, but are not limited to, potential releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures), and must include consideration of potential cumulative risks from other nearby potential stressors.]~~

(d) ~~[(e)]~~ Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid waste," §335.6 of this title (relating to Notification Requirements), §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), §335.18 of this title (relating to Non-Waste Determinations and Variances from Classification as a Solid Waste), §335.20 of this title (relating to Variance To Be Classified as a Boiler), §335.21 of this title (relating to Procedures for Variances from Classification as a Solid Waste or To Be Classified as a Boiler or for Non-Waste Determinations), §335.22 of this title (relating to Additional Regulation of Certain Hazardous Waste Recycling Activities on a Case-by-Case Basis), §335.23 of this title (relating to Procedures for Case-by-Case Regulation of Hazardous Waste Recycling Activities), §335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and

Specific Types of Facilities), and Subchapter V of this chapter (relating to Standards for Reclamation of Hazardous Secondary Materials).

§335.24. Requirements for Recyclable Materials and Nonhazardous Recyclable Materials.

(a) Hazardous wastes that are recycled are subject to the requirements for generators, transporters, and storage facilities of subsections (d) - (f) of this section, except for the materials listed in subsections (b) and (c) of this section. Hazardous wastes that are recycled will be known as recyclable materials. Nonhazardous industrial wastes that are recycled will be known as nonhazardous recyclable materials. Nonhazardous recyclable materials are subject to the requirements of subsections (h) - (l) of this section.

(b) The following recyclable materials are not subject to the requirements of this section, except as provided in subsections (g) and (h) of this section, but are regulated under the applicable provisions of Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter H of this chapter (relating to Standards for the Management of Specific Wastes and Specific Types of Facilities) and all applicable provisions in Chapter 305 of this title (relating to Consolidated Permits); Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 17 of this title (relating to Tax Relief for Property Used for Environmental Protection); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution Procedure); Chapter 50 of this title (relating to Action on Applications and Other Authorizations); Chapter 55 of this title (relating to Requests for Reconsideration and Contested Case Hearings; Public Comment); Chapter 70 of this title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); and Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings).

(1) recyclable materials used in a manner constituting disposal;

(2) hazardous wastes burned for energy recovery in boilers and industrial furnaces that are not regulated under Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) or Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities);

(3) recyclable materials from which precious metals are reclaimed;

(4) spent lead-acid batteries that are being reclaimed.

(c) The following recyclable materials are not subject to regulation under Subchapters B - I or O of this chapter (relating to Hazardous Waste Management General Provisions; Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Location Standards for Hazardous Waste Storage, Processing, or Disposal; Standards for the Management of Specific Wastes and Specific Types of Facilities; Prohibition on Open Dumps; and Land Disposal Restrictions); Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 17 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; Chapter 86 of this title; or Chapter 305 of this title, except as provided in subsections (g) and (h) of this section:

(1) Industrial ethyl alcohol that is reclaimed except that exports and imports of such recyclable materials must comply with the requirements of 40 Code of Federal Regulations (CFR) Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal) [~~amended though November 28, 2016 (81 FR 85696)~~]. Transporters transporting a shipment for export may not accept a shipment if they know the shipment does not conform to the United States Environmental Protection Agency (EPA) acknowledgment of consent, must ensure that a copy of the EPA acknowledgment of consent accompanies the shipment, and must ensure that it is delivered to the facility designated by the person initiating the shipment;

(2) scrap metal that is not already excluded under 40 CFR §261.4(a)(13) as adopted under §335.504 of this title (relating to Hazardous Waste Determination);

(3) fuels produced from the refining of oil-bearing hazardous waste along with normal process streams at a petroleum refining facility if such wastes result from normal petroleum refining, production, and transportation practices (this exemption does not apply to fuels produced from oil recovered from oil-bearing hazardous waste, where such recovered oil is already excluded under 40 CFR §261.4(a)(12), as adopted under §335.504 of this title [~~amended through April 8, 2015 (80 FR 18777)~~)]; and

(4) the following hazardous waste fuels:

(A) Hazardous waste fuel produced from oil-bearing hazardous wastes from petroleum refining, production or transportation practices, or produced from oil reclaimed from such hazardous wastes where such hazardous wastes are reintroduced into a process that does not use distillation or does not produce products from crude oil so long as the resulting fuel meets the used oil specification under 40 CFR §279.11 and so long as no other hazardous wastes are used to produce the hazardous waste fuel;

(B) Hazardous waste fuel produced from oil-bearing hazardous waste from petroleum refining production, and transportation practices, where such hazardous wastes are reintroduced into a refining process after a point at which contaminants are removed, so long as the fuel meets the used oil fuel specification under 40 CFR §279.11;

(C) Oil reclaimed from oil-bearing hazardous wastes from petroleum refining, production, and transportation practices, which reclaimed oil is burned as fuel without reintroduction to a refining process, so long as the reclaimed oil meets the used oil fuel specification under 40 CFR §279.11.

(d) Generators and transporters of recyclable materials are subject to the applicable requirements of Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter C of this chapter, Subchapter D of this chapter, and Subchapter R of this chapter [~~Subchapter C of this chapter and Subchapter D of this chapter~~], and the notification requirements of §335.6 of this title (relating to Notification Requirements), except as provided in subsections (a) - (c) of this section.

(e) Owners or operators of facilities that store recyclable materials before they are recycled are regulated under all applicable provisions of this chapter, and Chapter 305 of this title; Chapter 1 of this title; Chapter 3 of this title; Chapter 10 of this title; Chapter 17 of this title; Chapter 20 of this title; Chapter 37 of this title; Chapter 39 of this title; Chapter 40 of this title; Chapter 50 of this title; Chapter 55 of this title; Chapter 70 of this title; Chapter 80 of this title; and the

notification requirements under §335.6 of this title, except as provided in subsections (a) - (c) of this section. The recycling process itself is exempt from regulation.

(f) Owners or operators of facilities that recycle recyclable materials without storing them before they are recycled are subject to the following requirements, except as provided in subsections (a) - (c) of this section:

(1) notification requirements under §335.6 of this title; [~~and~~]

(2) Section 335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities); [~~.~~]

(3) Section 335.15 of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities); and

(4) the biennial reporting requirements of 40 Code of Federal Regulations §264.75 or §265.75 as adopted under §335.112 or §335.152 of this title (relating to Standards; or Standards).

(g) Recyclable materials (excluding those listed in subsections (b)(4), and (c)(1) - (5) of this section) remain subject to the requirements of §§335.4, 335.6, and 335.9 - 335.15 of this title (relating to General Prohibitions; Notification Requirements; Recordkeeping and Annual Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste; Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste; Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities; Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste; Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste; and Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities, respectively), as applicable. Recyclable materials listed in subsections (b)(4) and (c)(2) of this section remain subject to the requirements of subsection (h) of this section.

(h) Industrial solid wastes that are nonhazardous recyclable materials and recyclable materials listed in subsections (b)(4) and (c)(2) of this section remain subject to the requirements of §335.4 of this title. In addition, industrial solid wastes that are nonhazardous recyclable materials and recyclable materials listed in subsection (c)(2) of this section remain subject to the requirements of §335.6 of this title. Industrial solid wastes that are nonhazardous recyclable materials and recyclable materials listed in subsections (b)(4) and (c)(2) of this section may also be subject to the requirements of §§335.10 - 335.15 of this title, as applicable, if the executive director determines that such requirements are necessary to protect human health and the environment. In making the determination, the executive director shall consider the following criteria:

(1) the waste's toxicity, corrosivity, flammability, ability to sensitize or irritate, or propensity for decomposition and creation of sudden pressure;

(2) the potential for the objectionable constituent to migrate from the waste into the environment if improperly managed;

(3) the persistence of any objectionable constituent or any objectionable degradation product in the waste;

(4) the potential for the objectionable constituent to degrade into nonharmful constituents;

(5) the degree to which the objectionable constituent bioaccumulates in ecosystems;

(6) the plausible types of improper management to which the waste could be subjected;

(7) the nature and severity of potential damage to the public health and environment;

(8) whether subjecting the waste to additional regulation will provide additional protection for human health and the environment; and

(9) other relevant factors.

(i) Except as provided in Texas Health and Safety Code, §361.090, facilities managing recyclable materials that are required to obtain a permit under this section may also be permitted to manage nonhazardous recyclable materials at the same facility if the executive director determines that such regulation is necessary to protect human health and the environment. In making this determination, the executive director shall consider the following criteria:

(1) whether managing nonhazardous recyclable materials will create an additional risk of release of the hazardous recyclable materials into the environment;

(2) whether hazardous and nonhazardous wastes that are incompatible are stored and/or processed in the same or connected units;

(3) whether the management of recyclable materials and nonhazardous recyclable materials is segregated within the facility;

(4) the waste's toxicity, corrosivity, flammability, ability to sensitize or irritate, or propensity for decomposition and creation of sudden pressure;

(5) the potential for the objectionable constituent to migrate from the waste into the environment if improperly managed;

(6) the persistence of any objectionable constituent or any objectionable degradation product in the waste;

(7) the potential for the objectionable constituent to degrade into harmful constituents;

(8) the degree to which the objectionable constituent bioaccumulates in ecosystems;

(9) the plausible types of improper management to which the waste could be subjected;

(10) the nature and severity of potential damage to the public health and environment;

(11) whether subjecting the waste to additional regulation will provide additional protection for human health and the environment; and

(12) other relevant factors.

(j) Closure cost estimates.

(1) Except as otherwise approved by the executive director, an owner or operator of a recycling facility that stores combustible nonhazardous materials outdoors, or that poses a significant risk to public health and safety as determined by the executive director, shall provide a written cost estimate, in current dollars, showing the cost of hiring a third party to close the facility by disposition of all processed and unprocessed materials in accordance with all applicable regulations. The closure cost estimate for financial assurance must be submitted with any new notification in accordance with §335.6 within 60 days of the

effective date of this rule for existing facilities or as otherwise requested by the executive director.

(2) The estimate must:

(A) equal the costs of closure of the facility, including disposition of the maximum inventories of all processed and unprocessed combustible materials stored outdoors on site during the life of the facility, in accordance with all applicable regulations;

(B) be based on the costs of hiring a third party that is not affiliated (as defined in §328.2 of this title (relating to Definitions)) with the owner or operator; and

(C) be based on a per cubic yard and/or short ton measure for collection and disposition costs.

(k) Financial assurance. An owner or operator of a recycling facility that stores nonhazardous combustible recyclable materials outdoors, or that poses a significant risk to public health and safety as determined by the executive director, shall establish and maintain financial assurance for closure of the facility in accordance with Chapter 37, Subchapter J of this title (relating to Financial Assurance for Recycling Facilities).

(l) Closure requirements.

(1) Closure must include collecting processed and unprocessed materials, and transporting the materials to an authorized facility for disposition unless otherwise approved or directed in writing by the executive director.

(2) Closure of the facility must be completed within 180 days following the most recent acceptance of processed or unprocessed materials unless otherwise approved or directed in writing by the executive director.

(m) Used oil that is recycled and is also a hazardous waste solely because it exhibits a hazardous characteristic is not subject to the requirements of Subchapters A - I or O of this chapter, but is regulated under Chapter 324 of this title (relating to Used Oil Standards). Used oil that is recycled includes any used oil which is reused, following its original use, for any purpose (including the purpose for which the oil was originally used). Such term includes, but is not limited to, oil which is re-refined, reclaimed, burned for energy recovery, or reprocessed.

(n) Owners or operators of facilities subject to hazardous waste permitting requirements with hazardous waste management units that recycle hazardous wastes are subject to the requirements of 40 CFR Part 264 or Part 265, Subparts AA and BB, as adopted by reference under §335.152(a)(17) and (18) and §335.112(a)(19) and (20) of this title (relating to Standards).

(o) Hazardous waste that is exported or imported for purpose of recovery is subject to the requirements of 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title [~~amended through November 28, 2016 (81 FR 85696)~~].

(p) Other portions of this chapter that relate to solid wastes that are recycled include §335.1 of this title (relating to Definitions), under the definition of "Solid waste," §335.6 of this title, §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), §335.18 of this title (relating to Variances from Classification as a Solid Waste), §335.19 of this title (relating to Standards and Criteria for Variances from Classification as a Solid Waste), §335.26 of this title (relating to Notification Requirement for Hazardous Secondary Materials, §335.27 of this title (relating to Legitimate Recycling of Hazardous Secondary Materials), [~~and~~] Subchapter H of this chapter, and Subchapter V of this chapter (relating to Standards for Reclamation of Hazardous Secondary Materials).

§335.26. Notification Requirement for Hazardous Secondary Materials.

Persons who generate, process, store or recycle hazardous secondary materials must comply with the requirements of 40 Code of Federal Regulations (CFR) §260.42 (Notification requirements for hazardous secondary materials) as adopted and amended through May 30, 2018 (83 FR 24664) [~~January 13, 2015 (80 FR 1694)~~]. For the purposes of this section and 40 CFR §260.42, the term "Regional Administrator" is changed to the term "executive director" of the Texas Commission on Environmental Quality.

§335.27. Legitimate Recycling of Hazardous Secondary Materials.

Persons who generate, process, store or recycle hazardous secondary materials must comply with the requirements of 40 Code of Federal Regulations (CFR) §260.43 (Legitimate recycling of hazardous secondary materials) as adopted and amended through May 30, 2018 (83 FR 24664) [~~January 13, 2015 (80 FR 1694)~~]. For the purposes of this section and 40 CFR §260.43, the term, "Regional Administrator" is changed to the term "executive director" of the Texas Commission on Environmental Quality.

§335.31. Incorporation of References.

When used in this chapter, the references contained in 40 Code of Federal Regulations (CFR) §260.11 are incorporated by reference as amended and adopted in the CFR through November 28, 2016 (81 FR 85732) [~~November 28, 2016 (81 FR 85696)~~].

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on July 16, 2021.

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Robert Martinez
Deputy Director, Environmental Law Division
Texas Commission on Environmental Quality
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For further information, please call: (512) 239-2678

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30 TAC §§335.6, 335.11, 335.14

Statutory Authority

The repealed rules are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The repealed rules are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal

law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed repealed rules implement THSC, Chapter 361.

§335.6. Notification Requirements.

§335.11. Shipping Requirements for Transporters of Hazardous Waste or Class 1 Waste.

§335.14. Recordkeeping Requirements Applicable to Transporters of Hazardous Waste or Class 1 Waste.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER B. HAZARDOUS WASTE MANAGEMENT GENERAL PROVISIONS

30 TAC §335.41, §335.46

Statutory Authority

The amendments are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendments implement THSC, Chapter 361.

§335.41. Purpose, Scope and Applicability.

(a) The purpose of this chapter is to implement a state hazardous waste program which controls from point of generation to ultimate disposal those wastes which have been identified by the administrator of the United States Environmental Protection Agency (EPA) in 40 Code of Federal Regulations (CFR) Part 261.

(b) Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities); Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste, Treatment, Storage, or Disposal Facilities); §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities); and §335.15 of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities) do not apply to an owner or operator of a totally enclosed treatment facility, as defined in §335.1 of this title (relating to Definitions).

(c) Except as provided in §335.47 of this title (relating to Special Requirements for Persons Eligible for a Federal Permit by Rule), Subchapters E and F of this chapter do not apply to the owner or operator of a publicly owned treatment works (POTW) that processes, stores, or disposes of hazardous waste.

(d) Subchapters E and F of this chapter do not apply to:

(1) the owner or operator of an elementary neutralization unit provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40, Table Treatment Standards for Hazardous Wastes), or reactive (D003) waste, to remove the characteristic before land disposal, the owner/operator must comply with the requirements in 40 CFR §264.17(b);

(2) persons engaged in processing or containment activities during immediate response to a discharge of a hazardous waste; an imminent and substantial threat of discharge of hazardous waste; a discharge of a material which, when discharged, becomes a hazardous waste; or an immediate threat to human health, public safety, property, or the environment, from the known or suspected presence of military munitions, other explosive material, or an explosive device, as determined by an explosive or munitions emergency response specialist as defined in §335.1 of this title, except that:

(A) an owner or operator of a facility otherwise regulated under Subchapter E of this chapter must comply with all applicable requirements of §335.112(a)(2) and (3) of this title (relating to Standards) and §335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator);

(B) an owner or operator of a facility otherwise regulated under Subchapter F of this chapter must comply with all applicable requirements of §335.152(a)(2) and (3) of this title (relating to Standards) and §335.153 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator);

(C) any person who continues or initiates hazardous waste processing or containment activities after the immediate response is over is subject to all applicable requirements of Subchapters E and F of this chapter and Chapter 305 of this title (relating to Consolidated Permits); and

(D) in the case of an explosives or munitions emergency response, if a federal, state, tribal, or local official acting within the scope of his or her official responsibilities, or an explosives or emergency response specialist, determines that immediate removal of the material is necessary to protect human health or the environment, that official or specialist may authorize the removal of the material or waste by transporters who do not have EPA identification numbers and without the preparation of a manifest. In the case of emergencies involving military munitions, the responding military emergency response specialist's organizational unit must retain records for three years identifying the dates of the response, the responsible persons responding, the type and description of material addressed, and its disposition;

(3) persons adding absorbent material to waste in a container, as defined in §335.1 of this title and persons adding waste to absorbent material in a container, provided that these actions occur at the time that waste is first placed in the container, and that in the case of permitted facilities, 40 CFR §§264.17(b), 264.171, and 264.172 are complied with, and for all other facilities, 40 CFR §§265.17(b), 265.171, and 265.172 are complied with;

(4) a farmer disposing of waste pesticides from the farmer's own use in compliance with 40 CFR §262.70 as adopted under §335.57 [~~§335.77~~] of this title (relating to Farmers);

(5) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, provided that the wastewater is discharged in accordance with a Texas Pollutant Discharge Elimination System authorization issued under Texas Water Code, Chapter 26, and if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b);

(6) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, located at a noncommercial solid waste management facility that discharges to a publicly owned treatment works, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b);

(7) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, located at a municipal solid waste facility or commercial industrial solid waste landfill disposal facility that discharges to a publicly owned treatment works liquid wastes that are incidental to the handling, processing, storage, or disposal of solid wastes, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b); [~~or~~]

(8) the owner or operator of a wastewater treatment unit, as defined in §335.1 of this title, located at a commercial industrial solid waste facility that receives waste for discharge to a publicly owned treatment works, provided that if the owner or operator is diluting hazardous ignitable (D001) wastes (other than the D001 High TOC Subcategory as defined in 40 CFR §268.40) or reactive (D003) waste to remove the characteristic before land disposal, must comply with the requirements in 40 CFR §264.17(b), but is subject to the permitting requirements of §335.2(n) of this title (relating to Permit Required); [~~.~~]

(9) the owner or operator of a facility permitted, licensed, or registered by a state to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under this chapter by 40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste);

(10) a generator accumulating waste on-site in compliance with applicable conditions for exemption in 40 CFR §§262.14, 262.15, 262.16, or 262.17 as adopted under §335.53 of this title except to the extent the requirements of Subchapter E or F of this chapter are included in 40 CFR §§262.14 - 262.17; or

(11) a reverse distributor accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, in compliance with Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals).

(e) Subchapter E of this chapter does not apply to:

(1) a very small quantity generator that meets the conditions for exemption for a very small quantity generator in 40 CFR §262.14 as adopted under §335.53 of this title that [~~person who~~] stores, processes, or disposes of hazardous waste on-site [~~and meets the requirements of §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)~~]; or

(2) A generator accumulating waste on-site in compliance with applicable conditions for exemption in and 40 CFR Part 262, Subparts K and L as adopted under §335.59 and §335.60 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities; and Alternative Standards for Episodic Generation), except to the extent the requirements of Subchapter E of this chapter are included in 40 CFR Part 262, Subparts K and L [~~the owner or operator of a solid waste facility who stores, processes, or disposes of hazardous waste received from a conditionally exempt small quantity generator~~].

(f) The following requirements apply to residues of hazardous waste in containers.

(1) Subchapters B - F and O of this chapter (relating to Hazardous Waste Management General Provisions; Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for Owners and Operators of Hazardous Waste, Treatment, Storage, or Disposal Facilities; and Land Disposal Restrictions) do not apply to any hazardous waste remaining in either an empty container or an inner liner removed from an empty container, as defined in paragraph (2) of this subsection. This exemption does not apply to any hazardous waste in either a container that is not empty or an inner liner removed from a container that is not empty.

(2) For purposes of determining whether a container is empty under this subsection, the following provisions apply:

(A) a container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in 40 CFR §§261.31, 261.32, or 261.33(e) is empty if:

(i) all wastes have been removed that can be using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, and aspirating; and

(ii) no more than 2.5 centimeters (one inch) of residue remains on the bottom of the container or inner liner; or

(iii) no more than 3.0% by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size, or no more than 0.3% by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size;

(B) a container that has held a hazardous waste that is a compressed gas is empty when the pressure in the container approaches atmosphere; [~~or~~]

(C) a container or an inner liner removed from a container that has held an acute hazardous waste listed in 40 CFR §§261.31, 261.32, or 261.33(e) is empty if:

(i) the container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) the container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) in the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container has been removed.

(D) A container of hazardous waste pharmaceuticals is subject to §335.765 of this title (relating to Residues of Hazardous Waste Pharmaceuticals in Empty Containers) instead of this section for determining when it is considered empty, except as provided by §335.765(c) and (d) of this title.

(g) Subchapters B - F and O of this chapter do not apply to hazardous waste that is managed as a recyclable material described in §335.24(b) and (c) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), except to the extent that requirements of these subchapters are referred to in Subchapter H of this chapter and Chapter 324 of this title (relating to Used Oil Standards).

(h) Subchapters E and F of this chapter apply to owners or operators of all facilities that treat, store, or dispose of hazardous waste referred to in Subchapter O of this chapter.

(i) Except as provided in §335.47 of this title, Subchapter F of this chapter does not apply to persons disposing of hazardous waste by means of underground injection. However, Subchapter F of this chapter does apply to the aboveground storage or processing of hazardous waste before it is injected underground.

(j) Except as specified in Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule), Subchapters B - F and O of this chapter and Chapter 305 of this title do not apply to universal wastes, universal waste handlers, or universal waste transporters as defined in §335.261 of this title (relating to Universal Waste Rule). Universal wastes are not fully regulated hazardous wastes, but are subject to regulation under Subchapter H, Division 5 of this chapter.

§335.46. Sharing of Information.

(a) Any information obtained or used by the commission in the administration of a hazardous waste program authorized under the Resource Conservation and Recovery Act of 1976, §3006 and 40 Code of Federal Regulations (CFR) Part 271 shall be available to the Environmental Protection Agency upon request without restriction. If the information has been submitted to the commission under a claim of confidentiality, the commission shall submit that claim to the Environmental Protection Agency when providing information under this section. Any information obtained from the commission and subject to a claim of confidentiality will be treated by the Environmental Protection Agency in accordance with 40 CFR Part 2. If the Environmental Protection Agency obtains information that is not claimed to be confidential, the Environmental Protection Agency may make that information available to the public without further notice.

(b) The commission adopts by reference 40 CFR §260.2(c) as amended through February 7, 2014 in the *Federal Register* (79 FR 7518).

(c) The commission adopts by reference 40 CFR §260.2(d) as amended through December 26, 2017 in the *Federal Register* (82 FR 60894).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Robert Martinez
Deputy Director, Environmental Law Division
Texas Commission on Environmental Quality
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SUBCHAPTER C. STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

30 TAC §§335.51 - 335.61

Statutory Authority

The new rules are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The new rules are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed new rules implement THSC, Chapter 361.

§335.51. Definitions.

The following terms have the following meanings when used in this subchapter.

(1) Condition for exemption--Any requirement in 40 Code of Federal Regulations (CFR) §262.14 (Conditions for exemption for a very small quantity generator), §262.15 (Satellite accumulation area regulations for small and large quantity generators), §262.16 (Conditions for exemption for a small quantity generator that accumulates hazardous waste), §262.17 (Conditions for exemption for a large quantity generator that accumulates hazardous waste), §262.70 (Farmers), or 40 CFR Part 262, Subpart K (Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities), or 40 CFR Part 262, Subpart L (Alternative Standards for Episodic Generation), as adopted under this subchapter, that states an event, action, or standard that must occur or be met in order to obtain an exemption from any applicable requirement in Chapter 37 of this title (relating to Financial Assurance), Chapter 39 of this title (relating to Public Notice), and Chapter 305 of this title (relating to Consolidated Permits), Chapter 335 of this title (relating to Industrial Solid Waste and Municipal

Hazardous Waste), or from any requirement for notification under Resource Conservation and Recovery Act, §3010.

(2) Independent requirement--A requirement of 40 Code of Federal Regulations (CFR) Part 262 (Standards Applicable to Generators of Hazardous Waste), as adopted under this chapter, that states an event, action, or standard that must occur or be met; and that applies without relation to, or irrespective of, the purpose of obtaining a conditional exemption from storage facility permit, interim status, and operating requirements under 40 CFR §§262.14 - 262.17, or 40 CFR Part 262, Subpart K (Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities), or 40 CFR Part 262, Subpart L (Alternative Standards for Episodic Generation), as adopted in this subchapter.

§335.52. Purpose, Scope, and Applicability.

(a) The regulations in this subchapter establish standards for generators of hazardous waste. These standards are in addition to any applicable provisions contained in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General).

(1) A person who generates a hazardous waste as defined by 40 Code of Federal Regulations (CFR) §261.3, as adopted under §335.504 of this title (relating to Hazardous Waste Determination), is subject to all applicable independent requirements listed in this section.

(A) Independent requirements of a very small quantity generator:

(i) §335.504 of this title; and

(ii) 40 CFR §262.13 (Generator category determination) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(B) Independent requirements of a small quantity generator:

(i) §335.504 of this title;

(ii) 40 CFR §262.11(e) and (f) (Hazardous waste determination and recordkeeping), as adopted under §335.53 of this title;

(iii) 40 CFR §262.13, as adopted under §335.53 of this title;

(iv) 40 CFR §262.18 (EPA identification numbers and re-notification for small quantity generators and large quantity generators), as adopted under §335.53 of this title;

(v) 40 CFR Part 262, Subpart B (Manifest Requirements Applicable to Small and Large Quantity Generators), as adopted under §335.54 of this title (relating to Hazardous Waste Manifest);

(vi) 40 CFR Part 262, Subpart C (Pre-Transport Requirements Applicable to Small and Large Quantity Generators) as adopted under §335.55 of this title (relating to Pre-Transport Requirements Applicable to Large and Small Quantity Generators);

(vii) 40 CFR §262.40 (Recordkeeping) as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Large and Small Quantity Generators);

(viii) 40 CFR §262.44 (Recordkeeping for small quantity generators) as adopted under §335.56 of this title;

(ix) §§335.6(b), (c) and (f), 335.9, 335.10(a) and 335.13 of this title (relating to Notification Requirements; Recordkeeping and Annual Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste; and Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste); and

(x) 40 CFR Part 262, Subpart H (Transboundary Movements of Hazardous Waste for Recovery or Disposal), as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal).

(C) Independent requirements of a large quantity generator:

(i) §335.504 of this title;

(ii) 40 CFR §262.11(e) and (f) as adopted under §335.53 of this title;

(iii) 40 CFR §262.13 as adopted under §335.53 of this title;

(iv) 40 CFR §262.18 as adopted under §335.53 of this title;

(v) 40 CFR Part 262, Subpart B as adopted under §335.54 of this title;

(vi) 40 CFR Part 262, Subpart C as adopted under §335.55 of this title;

(vii) 40 CFR Part 262, Subpart D (Recordkeeping and Reporting Applicable to Small and Large Quantity Generators), as adopted under §335.56 of this title except 40 CFR §262.44;

(viii) §§335.6(b), (c) and (f), 335.9, 335.10(a) and 335.13 of this title; and

(ix) 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title.

(2) A generator that accumulates hazardous waste on-site is a person that stores hazardous waste and is subject to the applicable requirements of Chapter 37 of this title (relating to Financial Assurance), Chapter 39 of this title (relating to Public Notice), Chapter 305 of this title (relating to General Provisions), Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste), and Section 3010 of Resource Conservation and Recovery Act (RCRA) unless it is one of the following:

(A) a very small quantity generator that meets the conditions for exemption in 40 CFR §262.14 (Conditions for exemption for a very small quantity generator), as adopted under §335.53 of this title;

(B) a small quantity generator that meets the conditions for exemption in 40 CFR §262.16 (Conditions for exemption for a small quantity generator that accumulates hazardous waste) and meets the requirements of 40 CFR §262.15 (Satellite accumulation area regulations for small and large quantity generators), as 40 CFR §262.15 and §262.16 are adopted under §335.53 of this title; and

(C) a large quantity generator that meets the conditions for exemption in 40 CFR §262.17 (Conditions for exemption for a large quantity generator that accumulates hazardous waste) and meets the requirements of 40 CFR §262.15, as 40 CFR §262.15 and §262.17 are adopted under §335.53 of this title.

(3) A generator shall not transport, offer its hazardous waste for transport, or otherwise cause its hazardous waste to be sent to a facility that is not a designated facility, as defined in §335.1 of this title (relating to Definitions), or not otherwise authorized to receive the generator's hazardous waste.

(b) A generator must use 40 CFR §262.13 as adopted under §335.53 of this title to determine their generator category and which provisions of this subchapter are applicable to the generator based on the quantity of hazardous waste generated per calendar month.

(c) Any person who exports or imports hazardous wastes must comply with 40 CFR §262.18 as adopted under §335.53 of this title and 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title.

(d) Any person who imports hazardous waste into the United States must comply with the standards applicable to generators established in 40 CFR Part 262.

(e) A farmer who generates waste pesticides which are hazardous waste and who complies with all of the requirements of 40 CFR §262.70 (Farmers), as adopted under §335.57 of this title (relating to Farmers), is not required to comply with other standards in this subchapter or this chapter with respect to such pesticides.

(f) This subsection describes the consequences of violating of an independent requirement and not complying with a condition for exemption.

(1) A generator's violation of an independent requirement is subject to penalty and injunctive relief under Texas Health and Safety Code, Chapter 361, Texas Water Code, Chapter 7, and Section 3008 of RCRA.

(2) A generator's noncompliance with a condition for exemption in this part is not subject to penalty or injunctive relief under Texas Health and Safety Code, Chapter 361, Texas Water Code, Chapter 7, or Section 3008 of RCRA as a violation of a Texas Administrative Code section adopting a 40 CFR Part 262 condition for exemption. Noncompliance by any generator with an applicable condition for exemption from storage permit and operations requirements means that the facility is a storage facility operating without an exemption from the permit, interim status, operations, and notification requirements in this chapter, and in Chapters 37, 39, and 305 of this title. Without an exemption, any violations of such storage requirements are subject to penalty and injunctive relief under Texas Health and Safety Code, Chapter 361, Texas Water Code, Chapter 7, and Section 3008 of RCRA.

(g) An owner or operator who initiates a shipment of hazardous waste from a treatment, storage, or disposal facility must comply with the generator standards established in this subchapter.

(h) Persons responding to an explosives or munitions emergency in accordance with §335.41(d)(2) of this title (relating to Purpose, Scope and Applicability) are not required to comply with the standards of this subchapter.

(i) The laboratories owned by an eligible academic entity (for purposes of this paragraph, the terms "laboratory" and "eligible academic entity" shall have the meaning defined in 40 CFR §262.200, as adopted under §335.59 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities) that elect to be subject to the requirements of 40 CFR Part 262, Subpart K, as adopted by reference under §335.59 of this title are not subject to:

(1) the independent requirements of §335.504 of this title or 40 CFR §262.11 as adopted under §335.53 of this title;

(2) the regulations in 40 CFR §262.15 as adopted under §335.53 of this title for large quantity generators and small quantity generators, except as provided in 40 CFR Part 262, Subpart K, as adopted under §335.59 of this title; or

(3) the conditions of 40 CFR §262.14 as adopted under §335.53 of this title, except as provided in 40 CFR Part 262, Subpart K, as adopted by reference under §335.59 of this title.

(j) A reverse distributor as defined in §335.751 of this title (relating to Definitions) is subject to Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals) for the management of hazardous waste pharmaceuticals instead of this subchapter.

(k) A healthcare facility, as defined in §335.751 of this title, must determine whether it is subject to Subchapter W of this chapter for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kilograms (kg) (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in 40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title (relating to Hazardous Waste Determination), is subject to Subchapter W of this chapter for the management of hazardous waste pharmaceuticals in lieu of this subchapter. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 40 CFR §262.14 as adopted in §335.53 of this title, and is not subject to Subchapter W of this chapter, except for §335.761 and §335.765 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; and Residues of Hazardous Waste Pharmaceuticals in Empty Containers), and the optional provisions of §335.759 of this title (relating to Healthcare Facilities That are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste).

§335.53. General Standards Applicable to Generators of Hazardous Waste.

(a) The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) §262.11(e) - (g) (Hazardous waste determination and record keeping) as adopted and amended in the Federal Register through November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In 40 CFR §262.11(e), "parts 261, 264, 265, 266, 267, 268, and 273 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(2) In 40 CFR §262.11(f), "40 CFR 261.3" means as this section is adopted under §335.504 of this title (relating to Hazardous Waste Determination); "paragraphs (c) and (d) of this section" are changed to "§335.504(a)(2) and (3) of this title"; "paragraph (d)(1)" is changed to "§335.504(a)(3)(A) of this title"; and the term "Administrator" is changed to the term "executive director."

(3) In 40 CFR §262.11(g), "subparts C and D of part 261 of this chapter" is changed to "40 CFR Part 261, Subparts C and D, as adopted by reference under §335.504 of this title"; and "§262.32" is changed to "40 CFR §262.32 as adopted by reference under §335.55 of this title (relating to Pre-Transport Requirements Applicable to Small and Large Quantity Generators)."

(b) The commission adopts by reference the regulations contained in 40 CFR §262.13 (Generator category determination), including Table 1, as adopted in the Federal Register on November 28, 2016 (81 FR 85732), and amended in the Federal Register through February 22, 2019 (84 FR 5816) subject to the changes in this subsection.

(1) In the introductory text to 40 CFR §262.13, "§260.10 of this chapter" is changed to "§335.1 of this title (relating to Definitions)."

(2) In 40 CFR §262.13(c), "this part" is changed to "this chapter."

(3) In 40 CFR §262.13(c)(1), "40 CFR 261.4(c) through (f), 261.6(a)(3), or 261.7(a)(1)" is changed to "§335.2(f) and (g) of this title (relating to Permit Required), §335.24(c)(1) - (4) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials), and §335.41(f) of this title (relating to Purpose, Scope and Applicability)."

(4) In 40 CFR §262.13(c)(2), "40 CFR 260.10" is changed to "§335.1 of this title."

(5) In 40 CFR §262.13(c)(3), "40 CFR 261.6(c)(2)" is changed to "§335.24(g) of this title."

(6) In 40 CFR §262.13(c)(4), "40 CFR 261.6(a)(4) and 40 CFR part 279" is changed to "§335.24(m) of this title and Chapter 324 of this title (relating to Used Oil Standards)."

(7) In 40 CFR §262.13(c)(5), "40 CFR part 266 subpart G" is changed to "Subchapter H, Division 4 of this chapter (relating to Spent Lead-Acid Batteries Being Reclaimed)."

(8) In 40 CFR §262.13(c)(6), "40 CFR 261.9 and 40 CFR part 273" is changed to "40 CFR §261.9 as adopted under §335.504(a)(1) of this title and Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule)."

(9) In 40 CFR §262.13(c)(7), "listed in 40 CFR part 261 subpart D or exhibiting one or more characteristics in 40 CFR part 261 subpart C" is changed to "listed in 40 CFR Part 261, Subpart D or exhibiting one or more characteristics in 40 CFR Part 261, Subpart C as adopted under §335.504 of this title"; "§262.213" is changed to "§335.59 of this title (relating to Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities)"; and "§262.200" is changed to "40 CFR §262.200 as adopted under §335.59 of this title."

(10) In 40 CFR §262.13(c)(8), "subpart L of this part" is changed to "§335.60 of this title (relating to Alternative Standards for Episodic Generation)."

(11) In 40 CFR §262.13(c)(9), "§266.500" is changed to "§335.751 of this title (relating to Definitions); "40 CFR part 266 subpart P" is changed to "Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals)"; and "§266.506" is changed to "§335.763 of this title (relating to Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program)."

(12) In 40 CFR §262.13(e), "§262.10" is changed to "§335.52 of this title (relating to Purpose, Scope, and Applicability)"; and "§§262.14, 262.15, 262.16 or 262.17" is changed to "40 CFR §§262.14, 262.15, 262.16 or 262.17 as adopted under subsections (c) - (f) of this section."

(13) In 40 CFR §262.13(f)(1)(i):

(A) "§262.14" is changed to "40 CFR §262.14 as adopted in subsection (c) of this section";

(B) "§260.10 of this chapter" is changed to "§335.1 of this title"; and

(C) "part 261 subpart C of this chapter" is changed to "40 CFR Part 261, Subpart C as adopted under §335.504 of this title."

(14) In 40 CFR §262.13(f)(1)(ii), "40 CFR 260.10 of this chapter" is changed to "§335.1 of this title."

(15) In 40 CFR §262.13(f)(1)(iii), "40 CFR part 279" is changed to "Chapter 324 of this title."

(16) In 40 CFR §262.13(f)(2)(i):

(A) "§§261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i)" are changed to "40 CFR §§261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i) as adopted under §335.504 of this title";

(B) "§268.3(a)" is changed to "40 CFR §268.3(a), as adopted under §335.431(c) of this title (relating to Purpose, Scope, and Applicability)";

(C) "§268.40" is changed to "40 CFR §268.40 as adopted under §335.431(c) of this title"; and

(D) "§262.11" is changed to "§335.504 of this title and 40 CFR §262.11(e) - (g) as adopted under subsection (a) of this section."

(17) In 40 CFR §262.13(f)(2)(ii), "§260.10 of this chapter" is changed to "§335.1 of this title."

(c) The commission adopts by reference the regulations contained in 40 CFR §262.14, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), and amended in the *Federal Register* through February 22, 2019 (84 FR 5816) subject to the changes in this subsection.

(1) In 40 CFR §262.14(a), "parts 124, 262 (except §§262.10 - 262.14) through 268 and 270 of this chapter" is changed to "40 CFR Part 262, except §§262.10 - 262.14, as adopted in this subchapter; §335.2 of this title (relating to Permit Required); Subchapters D - H and O of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; Location Standards for Hazardous Waste Storage, Processing, or Disposal; Standards for the Management of Specific Wastes and Specific Types of Facilities; and Land Disposal Restrictions); and Chapters 37, 39, and 305 of this title (relating to Financial Assurance; Public Notice; and Consolidated Permits)."

(2) In 40 CFR §262.14(a)(1), "§260.10 of this chapter" is changed to "§335.1 of this title (relating to Definitions)."

(3) In 40 CFR §262.14(a)(2), "§262.11(a) through (d)" is changed to "§335.504 of this title."

(4) In 40 CFR §262.14(a)(3), "§§261.31 or 261.33(e) of this chapter" is changed to "40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title."

(5) In 40 CFR §262.14(a)(3)(ii), "§262.17(a) through (g)" is changed to "40 CFR §262.17(a) - (g) as adopted under subsection (f) of this section."

(6) In 40 CFR §262.14(a)(4)(iii), "§262.16(b)(2) through (f)" is changed to "40 CFR §262.16(b)(2) - (f) as adopted under subsection (e) of this section."

(7) In 40 CFR §262.14(a)(5)(i), "part 270 of this chapter" is changed to "40 CFR Part 270 or Chapter 335 of this title";

(8) In 40 CFR §262.14(a)(5)(ii), "parts 265 and 270 of this chapter" is changed to "40 CFR Parts 265 and 270 or Chapter 335 of this title;"

(9) In 40 CFR §262.14 (a)(5)(vii), after "part 273 of this chapter" is changed to "40 CFR Part 273 or Chapter 335, Subchapter H, Division 5 of this title (relating to Universal Waste Rule)."

(10) In 40 CFR §262.14(a)(5)(viii)(A), "§260.10 of this chapter" is changed to "§3.2 of this title (relating to Definitions)."

(11) In 40 CFR §262.14(a)(5)(ix), "§266.500" is changed to "§335.751 of this title (relating to Definitions)."

(12) In 40 CFR §262.14(a)(5)(x), "§266.500" is changed to "§335.751 of this title"; and "§§266.502(l) and 266.503(b)" is changed to "§335.755(l) and §335.757(b) of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals; and Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals)."

(13) In 40 CFR §262.14(a)(5)(xi), "§261.4(j) of this chapter" is changed to "§335.281 of this title (relating to Airbag Waste)."

(14) In 40 CFR §262.14(c), "subpart L of this part" is changed to "§335.60 of this title (relating to Alternative Standards for Episodic Generation))"; and "§§262.15, 262.16, and 262.17" is changed to "40 CFR §§262.15, 262.16 and 262.17 as adopted under subsections (d) - (f) of this section."

(d) The commission adopts by reference the regulations contained in 40 CFR §262.15, as adopted in the Federal Register on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In 40 CFR §262.15(a):

(A) "§261.31 or §261.33(e) of this chapter" is changed to "40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title";

(B) "parts 124, 264 through 267, and 270 of this chapter" is changed to "§335.2 of this title; Subchapters E - H of this chapter; Chapters 37, 39, and 305 of this title; and Chapter 281 of this title (relating to Consolidated Permits); and

(C) "§262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8)" is changed to "40 CFR §262.16(b) or §262.17(a), except as required in §262.15(a)(7) and (8) as adopted under subsections (d) - (f) of this section."

(2) In 40 CFR §262.15(a)(1), "§262.16(b) or §262.17(a)" is changed to "40 CFR §262.16(b) or §262.17(a)" as adopted under subsections (e) and (f) of this section.

(3) In 40 CFR §262.15(a)(3)(i), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(a)(25)(D) of this title (relating to Standards)"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(4) In 40 CFR §262.15(a)(3)(ii), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(a)(24)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(5) In 40 CFR §262.15(a)(6), "§261.31 or §261.33(e) of this chapter" is changed to "40 CFR §261.31 or §261.33(e) as adopted under §335.504 of this title."

(6) In 40 CFR §262.15(a)(6)(i), "§262.16(b) or §262.17(a)" is changed to "40 CFR §262.16(b) or §262.17(a) as adopted under subsections (e) and (f) of this section."

(7) In 40 CFR §262.15(a)(6)(ii)(A), "§262.16(b) or §262.17(a)" is changed to "40 CFR §262.16(b) or §262.17(a) as adopted under subsections (e) and (f) of this section."

(8) In 40 CFR §262.15(a)(7), "§262.16(b)(8)" is changed to "40 CFR §262.16(b)(8) as adopted under subsection (e) of this section"; and "§262.16(b)(9)" is changed to "40 CFR §262.16(b)(9) as adopted under subsection (e) of this section."

(9) In 40 CFR §262.15(a)(8), "subpart M of this part" is changed to "40 CFR Part 262, Subpart M as adopted under §335.61 of this title (relating to Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators)."

(e) The commission adopts by reference the regulations contained in 40 CFR §262.16, as adopted in the Federal Register on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In the introductory text to 40 CFR §262.16, "parts 124, 264 through 267, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H of this chapter."

(2) In 40 CFR §262.16(a), "§260.10 of this chapter" is changed to "§335.1 of this title."

(3) In 40 CFR §262.16(b), "paragraphs (d) and (e)" is changed to "paragraphs (c) and (d)";

(4) In 40 CFR §262.16(b)(2)(v)(A), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(25)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(5) In 40 CFR §262.16(b)(2)(v)(B), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(25)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(6) In 40 CFR §262.16(b)(3)(ii)(A), "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(7) In 40 CFR §262.16(b)(3)(vi), "§261.3(c) or (d) of this chapter" is changed to "40 CFR §261.3(c) or (d) as adopted under 335.504"; and "parts 262, 263, 265 and 268 of this chapter" is changed to "Chapter 335 of this title and all applicable chapters of this title."

(8) In 40 CFR §262.16(b)(3)(vii)(A)(1), "§261.21 or §261.23 of this chapter" is changed to "40 CFR §261.21 or §261.23 as adopted under §335.504 of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(9) In 40 CFR §262.16(b)(3)(vii)(B), "§260.11" is changed to "40 CFR §260.11, which is incorporated by reference under §335.31 of this title (relating to Incorporation of References)."

(10) In 40 CFR §262.16(b)(3)(vii)(C)(1), "part 265 appendix V " is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(24)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(11) In 40 CFR §262.16(b)(3)(vii)(C)(2), "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(12) In 40 CFR §262.16(b)(4)(i), "Subpart W of 40 CFR part 265 (except §265.445 (c))" is changed to "40 CFR Part 265, Subpart W (except §265.445(c)) as adopted under §335.112(a)(18) of this title."

(13) In 40 CFR §262.16(b)(4)(ii), "§262.15" is changed to "40 CFR §262.15 as adopted under subsection (d) of this section."

(14) In 40 CFR §262.16(b)(5), "40 CFR part 265 subpart DD" is changed to "40 CFR Part 265, Subpart DD as adopted under §335.112(a)(22) of this title."

(15) In 40 CFR §262.16(b)(5)(i), "40 CFR 265.1101" is changed to "40 CFR §265.1101 as adopted under §335.112(a)(22) of this title."

(16) In 40 CFR §262.16(b)(7), "40 CFR part 268" is changed to "40 CFR Part 268 as adopted under Subchapter O of this title."

(17) In 40 CFR §262.16(b)(8)(iv)(A) and (B), "(a)(8)(ii)" is changed to "(b)(8)(ii)."

(18) In 40 CFR §262.16(d), "40 CFR parts 264, 265, 267, 268, and 270 of this chapter" is changed to "Chapter 335 of this title and the applicable chapters of this title" and the terms "EPA" and "Regional Administrator" are changed to the term "executive director."

(19) In 40 CFR §262.16(e), "§264.72 or §265.72 of this chapter" is changed to "40 CFR §264.72 or §265.72 as adopted under §§335.112 or 335.152 of this title (relating to Standards and Standards)."

(20) In 40 CFR §262.16(f), "subpart L of this part" is changed to "§335.60 of this title (relating to Alternative Standards for Episodic Generation)"; and "§262.17" is changed to "40 CFR §262.17 as adopted under subsection (f) of this section."

(f) The commission adopts by reference the regulations contained in 40 CFR §262.17, as adopted in the Federal Register on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) In the introductory text to 40 CFR §262.17, "parts 124, 264 through 267, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title, and Subchapters E - H of this chapter."

(2) In 40 CFR §262.17(a)(1)(i), "subparts AA, BB, and CC of 40 CFR part 265" is changed to "40 CFR Part 265, Subparts AA, BB, and CC as adopted under §335.112(a)(19) - (21) of this title (relating to Standards)."

(3) In 40 CFR §262.17(a)(1)(vii)(A), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(25)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(4) In 40 CFR §262.17(a)(1)(vii)(B), "appendix V of part 265" is changed to "Appendix V of 40 CFR Part 265 as adopted under §335.112(A)(24)(D) of this title"; and "§265.17(b) of this chapter" is changed to "40 CFR §265.17(b) as adopted under §335.112(a)(1) of this title."

(5) In 40 CFR §262.17(a)(2), "subparts J, except §265.197(c) of Closure and post-closure care and §265.200" is changed to "40 CFR Part 265, Subpart J, except §265.197(c) of Closure and post-closure care and §265.200 as adopted under §335.112(a)(9) of this title"; and "AA, BB, and CC of 40 CFR part 265" is changed to "40 CFR Part 265, Subparts AA, BB, and CC as adopted under §335.112(a)(19) - (21) of this title."

(6) In 40 CFR §262.17(a)(3)(i), "Subpart W of 40 CFR part 265 " is changed to "40 CFR Part 265, Subpart W as adopted under §335.112(a)(18) of this title."

(7) In 40 CFR §262.17(a)(3)(ii), "§262.15" is changed to "40 CFR §262.15 as adopted under subsection (d) of this section."

(8) In 40 CFR §262.17(a)(4), "40 CFR part 265 subpart DD" is changed to "40 CFR Part 265, Subpart DD as adopted under §335.112(a)(22) of this title."

(9) In 40 CFR §262.17(a)(4)(i), "40 CFR 265.1101" is changed to "40 CFR §265.1101 as adopted under §335.112(a)(22) of this title."

(10) In 40 CFR §262.17(a)(6), "subpart M of this part" is changed to "40 CFR Part 262, Subpart M as adopted under §335.61."

(11) In 40 CFR §262.17(a)(7)(i)(A), "(a)(7)(iv)" is changed to "(a)(7)(iv)(C)."

(12) In 40 CFR §262.17(a)(8)(ii)(B), "§265.310 of this chapter" is changed to "40 CFR §265.310 as adopted under §335.112(a)(13) of this title"; and "§265.445(b)" is changed to "40 CFR §265.445(b) as adopted under §335.112(a)(18) of this title."

(13) In 40 CFR §262.17(a)(8)(iii)(A)(2), "§261.3(d) of this chapter" is changed to "40 CFR §261.3(d) as adopted under §335.504 of this title."

(14) In 40 CFR §262.17(a)(8)(iii)(A)(3), "parts 262, 263, 265 and 268 of this chapter" is changed to "Chapter 335 of this title, and all applicable chapters of this title."

(15) In 40 CFR §262.17(a)(8)(iii)(A)(4), "(a)(8)(ii)(A)(2)" is changed to "(a)(8)(iii)(A)(2)"; "§265.310 of this chapter" is changed to "40 CFR §265.310 as adopted under §335.112(a)(13) of this title"; and "subparts G and H of part 265 of this chapter" is changed to "40 CFR Part 265, Subparts G and H as adopted under §335.112(a)(6) and (7) of this title."

(16) In 40 CFR §262.17(a)(8)(iv), "§265.445(a) and (b) of this chapter" is changed to "40 CFR §265.445(a) and (b) as adopted under §335.112(a)(18) of this title."

(17) In 40 CFR §262.17(a)(9), "40 CFR part 268" is changed to "40 CFR Part 268 as adopted under Subchapter O of this title."

(18) In 40 CFR §262.17(b), "40 CFR parts 124, 264 through 268, and part 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter" and the terms "EPA" and "Regional Administrator" are changed to the term "executive director."

(19) In 40 CFR §262.17(c), "parts 124, 264 through 267 and part 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter."

(20) In 40 CFR §262.17(c)(4)(i)(C), "subpart DD of 40 CFR part 265" is changed to "40 CFR Part 265, Subpart DD as adopted under §335.112(a)(22) of this title"; and "40 CFR 265.1101" is changed to "40 CFR §265.1101 as adopted under §335.112(a)(22) of this title."

(21) In 40 CFR §262.17(c)(4)(ii), "subparts G and H of part 265" is changed to "40 CFR Part 265, Subparts G and H as adopted under §335.112(a)(6) and (7) of this title."

(22) In 40 CFR §262.17(d), "parts 124, 264 through 267, 270" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H of this chapter."

(23) In 40 CFR §262.17(e), "40 CFR parts 124, 264 through 268, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter"; and the terms "EPA" and "Regional Administrator" are changed to the term "executive director."

(24) In 40 CFR §262.17(f), "§260.10 of this chapter" is changed to "§3.2 of this title (relating to Definitions)" and "parts 124, 264 through 268, and 270 of this chapter" is changed to "Chapters 37, 39, 281 and 305 of this title, §335.2 of this title and Subchapters E - H and O of this chapter."

(25) In 40 CFR §262.17(f)(1), "EPA" is changed to "TCEQ"; and "EPA Form 8700-12" is changed to "a method approved by the executive director."

(26) In 40 CFR §262.17(f)(1)(ii), "Site ID form (EPA Form 8700-12)" is changed to "notification using a method approved by the executive director."

(27) In 40 CFR §262.17(f)(3), "§262.10(a)(1)(iii)" is changed to "§335.52(a)(1)(C) of this title (relating to Purpose, Scope, and Applicability)."

(28) In 40 CFR §262.17(g), "§264.72 or §265.72 of this chapter" is changed to "40 CFR §264.72 or §265.72 as adopted under §§335.112 or 335.152 of this title."

(g) The commission adopts by reference the regulations contained in 40 CFR §262.18 (EPA identification numbers and re-notification for small quantity generators and large quantity generators), as adopted in the Federal Register on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) The term "Administrator" is changed to the term "executive director."

(2) The generator shall provide the information required by the RCRA Site Identification Form (EPA Form 8700-12) using a method approved by the executive director.

(3) In 40 CFR §262.18(d)(1), the re-notification required of a small and large quantity generator must be made to the executive director instead of the EPA.

(4) In 40 CFR §262.18(d)(2), "Biennial Report required under §262.41" is changed to "Biennial Report required under 40 CFR §262.41 as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators).

§335.54. Hazardous Waste Manifest.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart B, §§262.20 (General requirements), 262.21(a) - (f)(4) - (8) and (g) - (m) (Manifest tracking numbers, manifest printing, and obtaining manifests), 262.22 (Number of copies), 262.23 (Use of the manifest), 262.24 (Use of the electronic manifest), 262.25 (Electronic manifest signatures), and 262.27 (Waste minimization certification), as amended in the Federal Register through January 3, 2018 (83 FR 420), subject to the changes in this subsection.

(1) In the event of a discharge of hazardous waste on a public or private right-of-way during the transportation of hazardous wastes the generator or transporter must also comply with the requirements of §335.93 of this title (relating to Hazardous Waste Discharges) and Chapter 327 of this title (relating to Spill Prevention and Control).

(2) The reference to §262.40(a)(Recordkeeping) means 40 CFR §262.40(a) as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators).

(3) References to 40 CFR §§264.71, 264.72, or 265.72 mean as the section is adopted under §335.112 or §335.152 of this title (relating to Standards).

(4) Generators shall comply with §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste).

(5) Users of the manifest are subject to 40 CFR §260.2(c) as adopted under §335.46(b) of this title (relating to Sharing of Information).

§335.55. Pre-Transport Requirements Applicable to Small and Large Quantity Generators.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart C, §§262.30 - 262.35 as amended in the *Federal Register* through November 28, 2016 (81 FR 85732), with the reference to §268.42(c) changed to "40 CFR §268.42(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability)."

§335.56. Recordkeeping and Reporting Applicable to Small and Large Quantity Generators.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart D, §§262.40 - 262.44 as amended in the Federal Register through November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) The term "Administrator" is changed to the term "executive director."

(2) The terms "Regional Administrator" and "EPA Regional Administrator for the Region" are changed to the term "executive director."

(3) Under 40 CFR §262.41:

(A) a large quantity generator shall submit the information in United States Environmental Protection Agency (EPA) Form 8700-13 A/B required by 40 CFR §262.41 (Biennial report for large quantity generators), using the method approved by the executive director; and

(B) "in accordance with the provisions of 40 CFR parts 264, 265, 266, 267 and 270" means in accordance with Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste) and the applicable chapters of this title.

(4) References to "§261.31" or "§261.33(e)" mean as these sections are adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(5) References to "§262.11(f)" or "§262.17(f)" mean as these sections are adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(6) Reference to "§262.23(a)" means 40 CFR §262.23(a) as that section is adopted under §335.54 of this title (relating to Hazardous Waste Manifest).

(7) Reference to §262.83(g) means 40 CFR §262.83(g) as that section is adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal)."

(8) References to "40 CFR §264.72(e)(1) through (6)" or "40 CFR §265.72(e)(1) through (6)" mean as these sections are adopted under §335.112 and §335.152 of this title (relating to Standards).

§335.57. Farmers.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart G, §262.70 as amended in the Federal Register through July 14, 2006 (71 FR 40254), subject to the clarifications in this subsection.

(1) Reference to "§261.7(b)(3)" is changed to "40 CFR §261.7(b)(3) as adopted under §335.504 of this title (relating to Hazardous Waste Determination)."

(2) Reference to "40 CFR parts 264, 265, 268, or 270" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Solid Waste), or the applicable chapters of this title."

§335.58. Transboundary Movements of Hazardous Waste for Recovery or Disposal.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations Part 262, Subpart H, §§262.80 - 262.84 as amended in the Federal Register through August 6, 2018 (83 FR 38262). Availability and confidentiality of hazardous waste export, import, and transit information is subject to 40 CFR §260.2(d) as adopted under §335.46(c) of this title (relating to Sharing of Information).

§335.59. Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart K, §§262.200 - 262.216 as amended in the *Federal Register* through November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) "Operating under this subpart" is changed to "operating under 40 CFR Part 262, Subpart K as adopted under this section."

(2) "Provisions of this subpart" is changed to "provisions of 40 CFR Part 262, Subpart K as adopted under this section."

(3) "Requirements of this subpart" is changed to "requirements of 40 CFR Part 262, Subpart K as adopted under this section."

(4) An eligible academic entity notifying in accordance with 40 CFR §262.201 and §262.203 shall notify using a method approved by the executive director.

(5) References to "§260.10" are changed to "§335.1 of this title (relating to Definitions)."

(6) References to 40 CFR §§261.2, 261.3 and 261.5 mean as these sections are adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(7) References to "40 CFR part 261, subpart D", "40 CFR part 261, subpart C", and "§261.33(e)" mean as these parts and this section are adopted under §335.504 of this title.

(8) Reference to "40 CFR part 262" means "40 CFR Part 262 as adopted under this subchapter."

(9) References to 40 CFR §§262.11, 262.13, 262.14, 262.15, 262.16, and 262.17 mean as these sections are adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(10) References to 40 CFR §§262.203 and 262.206 - 262.214 mean as these sections are adopted under this section.

(11) Reference to "§265.16(e)" is changed to "40 CFR §265.16(e) as adopted under §335.112 of this title (relating to Standards)."

(12) In 40 CFR §262.213(a)(1), "1 kg or solid reactive acutely hazardous unwanted material" is changed to "1 kg of solid reactive acutely hazardous unwanted material."

(13) Eligible academic entities who are also registered generators as defined in §335.13(d) of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste) must report any laboratory waste in accordance with §335.9(a)(2) of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators). Such generators must report the management of the laboratory waste but are not required to report the quantities generated.

§335.60. Alternative Standards for Episodic Generation.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart L, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) Reference to "subpart B of this part" is changed to "40 CFR Part 262, Subpart B as adopted under §335.54 of this title (relating to Hazardous Waste Manifest)."

(2) Reference to "§260.10 of this chapter" is changed to "§335.1 of this title (relating to Definitions)."

(3) The term "EPA" is changed to the term "executive director."

(4) The term "Regional Administrator" is changed to the term "executive director."

(5) References to 40 CFR "§262.16(b)(2) of this chapter", "§262.16(b)(3)", and "§262.16(b)(9)(i)" mean as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(6) Under 40 CFR §262.232(a)(1), the reference to "§262.233" means as 40 CFR §262.233 is adopted under this section.

(7) Under 40 CFR §262.232(a)(2) the very small quantity generator shall:

(A) notify the executive director 30 days prior to initiating a planned episodic event by submitting the information required in United States Environmental Protection Agency (EPA) Form 8700-12 using a method approved by the executive director;

(B) notify the executive director within 72 hours of an unplanned event in a manner approved by the executive director;

(C) notify the executive director of an unplanned episodic event by submitting the information required in EPA Form 8700-12 using a method approved by the executive director.

(D) When complying with the emergency procedures for a very small quantity generator under 40 CFR §262.16(b)(9)(i) referenced in 40 CFR §262.232(a)(2) or for a small quantity generator referred to in 40 CFR §262.232(b)(2), very small and small quantity generators shall also notify in accordance with and comply with §335.93 of this title (relating to Hazardous Waste Discharges), and Chapter 327 of this title (relating to Spill Prevention and Control).

(8) Under 40 CFR §262.232(a)(3), the very small quantity generator that has not been issued an EPA identification (ID) number must obtain an EPA ID number by submitting the information required in EPA Form 8700-12 to the executive director using a method approved by the executive director.

(9) In 40 CFR §262.232(b)(4), "from an episodic event waste on drip pads" is changed to "from an episodic event on drip pads."

(10) In 40 CFR §262.232(b)(4)(ii)(C), "the date upon which each period of accumulation begins and ends" is changed to "the date upon which each episodic event begins."

§335.61. Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators.

The commission adopts by reference the regulations contained in 40 Code of Federal Regulations (CFR) Part 262, Subpart M, §§262.250 - 262.256 and §§262.260 - 262.265, as adopted in the *Federal Register* on November 28, 2016 (81 FR 85732), subject to the changes in this subsection.

(1) "Regulations of this subpart" means regulations of 40 CFR Part 262, Subpart M as adopted under this section.

(2) "Standards of this part" means standards of 40 CFR Part 262 as adopted under this subchapter.

(3) Reference to "§261.3(c) or (d) of this chapter" is changed to "40 CFR §261.3(c) or (d) as adopted under §335.504 of this title (relating to Hazardous Waste Determination)."

(4) References to 40 CFR §§262.250, 262.252, 262.256, 262.260, 262.264, and 262.265 mean as these sections are adopted by reference under this section.

(5) Reference to "part 262 of this chapter" mean "40 CFR Part 262 as adopted under this subchapter."

(6) Reference to "part 263 of this chapter" is changed to "§335.11 and §335.14 of this title and Subchapter D of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste)."

(7) Reference to "the applicable requirements and conditions for exemption in Parts 262, 263, and 265 of this chapter" is changed to "the applicable requirements and conditions for exemption in this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on July 16, 2021.

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Robert Martinez
Deputy Director, Environmental Law Division
Texas Commission on Environmental Quality
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For further information, please call: (512) 239-2678

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30 TAC §§335.61 - 335.63, 335.65 - 335.71, 335.73 - 335.79

Statutory Authority

The repealed rules are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The repealed rules are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed repealed rules implement THSC, Chapter 361.

§335.61. Purpose, Scope and Applicability.

§335.62. Hazardous Waste Determination and Waste Classification.

§335.63. EPA Identification Numbers.

§335.65. Packaging.

§335.66. Labeling.

§335.67. Marking.

§335.68. Placarding.

§335.69. Accumulation Time.

§335.70. Recordkeeping.

§335.71. Biennial Reporting.

§335.73. Additional Reporting.

§335.74. Special Requirements for Generators of Between 100 and 1,000 Kilograms per Month.

§335.75. Notification Requirements for Interstate Shipments.

§335.76. Additional Requirements Applicable to international Shipments.

§335.77. Farmers.

§335.78. Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators.

§335.79. Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER D. STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

30 TAC §335.91, §335.94

Statutory Authority

The amendments are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also proposed under Texas

Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendments implement THSC, Chapter 361.

§335.91. Scope.

(a) This subchapter establishes standards for persons [~~transporters~~] transporting hazardous waste to off-site storage, processing, or disposal facilities. These standards are in addition to any applicable provisions contained in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste Management in General).

(b) This subchapter does not apply to on-site transportation of hazardous waste by generators or by owners or operators of storage, processing or disposal facilities.

(c) A hazardous waste transporter must also comply with the standards applicable to generators of hazardous waste found in §§335.6, 335.9, 335.10, and 335.13 of this title (relating to Notification Requirements; Recordkeeping and Annual Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste; and Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste), Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste) including §335.52(d) of this title (relating to Purpose, Scope, and Applicability), and Subchapter R of this chapter (relating to Waste Classification) if the transporter [~~A transporter of hazardous waste must also comply with any standards applicable to generators of hazardous waste if he~~]:

(1) transports hazardous waste into the state from a foreign country; or

(2) mixes hazardous waste of different Department of Transportation shipping descriptions by placing them into a single container.

(d) Transporters who store hazardous waste are owners or operators of storage facilities and, as such, are also subject to the permit requirements and storage standards contained in this chapter.

(e) A transporter of hazardous waste that is being imported from or exported to any other country for purposes of recovery or disposal is subject to all relevant requirements of 40 Code of Federal Regulations (CFR), Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal), including, but not limited to, 40 CFR §262.83(d) and §262.84(d) for movement documents [~~, as amended through November 28, 2016 (81 FR 85696)~~].

(f) The regulations in this chapter do not apply to transportation during an explosives or munitions emergency response conducted in accordance with §335.41(d)(2) of this title (relating to Purpose, Scope and Applicability).

(g) 40 CFR §266.203, as adopted by reference under Subchapter H, Division 6 of this chapter (relating to Military Munitions), identifies how the requirements of this subchapter apply to military munitions classified as solid waste under 40 CFR §266.202.

§335.94. Transfer Facility Requirements.

(a) Unless the executive director determines that a permit should be required in order to protect human health and the environment, a transporter who stores manifested shipments of hazardous waste in containers meeting the independent requirements of 40 Code of Federal Regulations (CFR) §262.30 (Packaging) as adopted under §335.55 of this title (relating to Pre-Transport Requirements Applicable to Small and Large Quantity Generators) [~~§335.65 of this title (relating to Packaging)~~] at a transfer facility owned or operated by a registered transporter for a period of ten days or less is not subject to the requirement for a permit under §335.2 of this title (relating to Permit Required), with respect to the storage of those wastes provided that the transporter complies with the following sections:

(1) 40 CFR [~~Code of Federal Regulations (CFR)~~] §265.14 ([~~relating to~~] Security);

(2) 40 CFR §265.15 ([~~relating to~~] General Inspection Requirements);

(3) 40 CFR §265.16 ([~~relating to~~] Personnel Training);

(4) 40 CFR Part 265, Subpart C;

(5) 40 CFR Part 265, Subpart D (except §265.56(j)) and §335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator); and

(6) 40 CFR Part 265, Subpart I.

(b) The executive director may require a permit for that portion of a facility otherwise exempted from that requirement under subsection (a) of this section, with respect to the storage of hazardous waste in containers, if the facility's operation also includes other storage and processing of hazardous waste which is not exempt under subsection (a) of this section.

(c) When consolidating the contents of two or more containers with the same hazardous waste into a new container, or when combining and consolidating two different hazardous wastes that are compatible with each other, the transporter must mark its containers of 119 gallons or less with the following information:

(1) The words "Hazardous Waste"; and

(2) The applicable United States Environmental Protection Agency hazardous waste number(s) in 40 CFR Part 261, Subparts C and D, as adopted under §335.504 of this title (relating to Hazardous Waste Determination) or in compliance with 40 CFR §262.32(c), as adopted under §335.55 of this title.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER E. INTERIM STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, OR DISPOSAL FACILITIES

30 TAC §335.112

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.112. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 265 (including all appendices to 40 CFR Part 265) (except as otherwise specified in this section) are adopted by reference as amended in the *Federal Register* through June 1, 1990 (55 FR 22685) and as further amended as indicated in each paragraph of this subsection:

(1) Subpart B - General Facility Standards (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [(~~81 FR 85696~~)]);

(2) Subpart C - Preparedness and Prevention;

(3) Subpart D - Contingency Plan and Emergency Procedures (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §265.56(d);

(4) Subpart E - Manifest System, Recordkeeping, and Reporting (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [~~November 28, 2016 (81 FR 85696)~~]), except 40 CFR §265.76 and §265.77 [~~§§265.71, 265.72, and 265.75 - 265.77~~];

(5) Subpart F - Groundwater Monitoring (as amended in the *Federal Register* through April 4, 2006 (71 FR 16862)), except 40 CFR §265.90 and §265.94;

(6) Subpart G - Closure and Post-Closure (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)); except 40 CFR §265.112(d)(3) and (4) and §265.118(e) and (f);

(7) Subpart H - Financial Requirements (as amended in the *Federal Register* through September 16, 1992 (57 FR 42832)); except 40 CFR §§265.140, 265.141, 265.142(a)(2), (b) and (c), 265.143(a) - (g), 265.144(b) and (c), 265.145(a) - (g), 265.146 [~~264.146~~], 265.147(a) - (d), and (f) - (k), and 265.148 - 265.150;

(8) Subpart I - Use and Management of Containers (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(9) Subpart J - Tank Systems (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(10) Subpart K - Surface Impoundments (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(11) Subpart L - Waste Piles (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §265.253;

(12) Subpart M - Land Treatment (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)) except, 40 CFR §§265.272, 265.279, and 265.280;

(13) Subpart N - Landfills (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §§265.301(f) - (i), 265.314, and 265.315;

(14) Subpart O - Incinerators (as amended in the *Federal Register* through October 12, 2005 (70 FR 59402));

(15) Subpart P - Thermal Treatment (as amended in the *Federal Register* through July 17, 1991 (56 FR 32692));

(16) Subpart Q - Chemical, Physical, and Biological Treatment (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(17) Subpart R - Underground Injection;

(18) Subpart W - Drip Pads (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(19) Subpart AA - Air Emission Standards for Process Vents (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(20) Subpart BB - Air Emission Standards for Equipment Leaks (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~April 4, 2006 (71 FR 16862)~~]);

(21) Subpart CC - Air Emission Standards for Tanks, Surface Impoundments, and Containers (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [~~July 14, 2006 (71 FR 40254)~~]);

(22) Subpart DD - Containment Buildings (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(23) Subpart EE - Hazardous Waste Munitions and Explosives Storage (as amended in the *Federal Register* through February 12, 1997 (62 FR 6622)); [~~and~~]

(24) Subpart FF - Fees for the Electronic Hazardous Waste Manifest Program (as amended in the *Federal Register* through January 3, 2018 (83 FR 420); and

(25) [~~(24)~~] the following appendices contained in 40 CFR Part 265:

(A) Appendix I - Recordkeeping Instructions (as amended in the *Federal Register* through March 24, 1994 (59 FR 13891));

(B) Appendix III - EPA Interim Primary Drinking Water Standards;

(C) Appendix IV - Tests for Significance;

(D) Appendix V - Examples of Potentially Incompatible Waste; and

(E) Appendix VI - Compounds With Henry's Law Constant Less Than 0.1 Y/X.

(b) Except in 40 CFR §265.71 adopted under subsection (a)(4) of this section and 40 CFR Part 265, Subpart FF adopted under subsection (a)(24) of this section, the [~~The~~] regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality or to the commission, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B.

(2) The term "treatment" is changed to "processing."

(3) Reference to Resource Conservation and Recovery Act, §3008(h) is changed to Texas Water Code, §7.031(c) - (e) (Corrective Action Relating to Hazardous Waste).

(4) Reference to:

(A) 40 CFR §260.10 is changed to §335.1 of this title (relating to Definitions);

(B) 40 CFR §264.90 is changed to §335.156 of this title (relating to Applicability of Groundwater Monitoring and Response);

(C) 40 CFR §264.101 is changed to §335.167 of this title (relating to Corrective Action for Solid Waste Management Units);

(D) 40 CFR §264.310 is changed to §335.174 of this title (relating to Closure and Post-Closure Care (Landfills));

(E) 40 CFR §265.1 is changed to §335.111 of this title (relating to Purpose, Scope, and Applicability);

(F) 40 CFR §265.90 is changed to §335.116 of this title (relating to Applicability of Groundwater Monitoring Requirements);

(G) 40 CFR §265.94 is changed to §335.117 of this title (relating to Recordkeeping and Reporting);

(H) 40 CFR §265.314 is changed to §335.125 of this title (relating to Special Requirements for Bulk and Containerized Waste);

(I) 40 CFR §270.1 is changed to §335.2 of this title (relating to Permit Required);

(J) 40 CFR §270.28 is changed to §305.50 of this title (relating to Additional Requirements for an Application for a Hazardous or Industrial Solid Waste Permit and for a Post-Closure Order);

(K) 40 CFR §270.41 is changed to §305.62 of this title (relating to Amendments);

(L) 40 CFR §270.42 is changed to §305.69 of this title (relating to Solid Waste Permit Modification at the Request of the Permittee); and

(M) Qualified professional engineer is changed to Texas licensed professional engineer.

(5) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapters 50, 305, and 335 of this title (relating to Action on Applications and Other Authorizations; Consolidated Permits; and Industrial Solid Waste and Municipal Hazardous Waste), as applicable.

(6) Reference to 40 CFR Part 265, Subpart D (Contingency Plan and Emergency Procedures) is changed to §335.112(a)(3) of this title (relating to Standards) and §335.113 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator).

(7) References to 40 CFR §265.76 and §265.77 are changed to [~~Reference to 40 CFR §§265.71, 265.72, 265.76, and 265.77 is changed to §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), §335.12(a) of this title,~~] §335.15(3) of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), and §335.115 of this title (relating to Additional Reports), respectively.

(8) Reference to 40 CFR Part 264, Subpart F is changed to §335.156 of this title, §335.157 of this title (relating to Required Programs), §335.158 of this title (relating to Groundwater Protection Standard), §335.159 of this title (relating to Hazardous Constituents), §335.160 of this title (relating to Concentration Limits), §335.161 of this title (relating to Point of Compliance), §335.162 of this title (relating to Compliance Period), §335.163 of this title (relating to General Groundwater Monitoring Requirements), §335.164 of this title (relating to Detection Monitoring Program), §335.165 of this title (relating to Compliance Monitoring Program), §335.166 of this title (relating to Corrective Action Program), and §335.167 of this title.

(9) Reference to 40 CFR Part 265, Subpart F is changed to include §335.116 and §335.117 of this title, in addition to the reference to 40 CFR Part 265, Subpart F, except §265.90 and §265.94.

(10) Reference to the EPA is changed to the Texas Commission on Environmental Quality.

[~~(c) A copy of 40 CFR Part 265 is available for inspection at the library of the Texas Commission on Environmental Quality, located on the first floor of Building A at 12100 Park 35 Circle, Austin, Texas.~~]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER F. PERMITTING STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, OR DISPOSAL FACILITIES

30 TAC §335.152

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commis-

sion authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.152. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 264 (including all appendices to Part 264) are adopted by reference as amended in the *Federal Register* through June 1, 1990 (55 FR 22685) and as further amended and adopted as indicated in each paragraph of this subsection:

(1) Subpart B--General Facility Standards (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~(81 FR 85696)~~]); in addition, the facilities which are subject to 40 CFR Part 264, Subpart X, are subject to regulation under 40 CFR §264.15(b)(4) and §264.18(b)(1)(ii);

(2) Subpart C--Preparedness and Prevention;

(3) Subpart D--Contingency Plan and Emergency Procedures (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §264.56(d);

(4) Subpart E--Manifest System, Recordkeeping and Reporting (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [~~November 28, 2016 (81 FR 85696)~~]), except 40 CFR §264.76 and §264.77 [~~40 CFR §§264.71, 264.72, 264.76, and 264.77~~]; facilities which are subject to 40 CFR Part 264, Subpart X, are subject to 40 CFR §264.73(b)(6);

(5) Subpart G--Closure and Post-Closure (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)); facilities which are subject to 40 CFR Part 264, Subpart X, are subject to 40 CFR §§264.90(d), 264.111(c), 264.112(a)(2), 264.114, 264.117(a)(1)(i) and (ii), and 264.118(b)(1) and (2)(i) and (ii);

(6) Subpart H--Financial Requirements (as amended in the *Federal Register* through April 4, 2006 (71 FR 16862)); except 40 CFR §§264.140, 264.141, 264.142(a)(2), (b) and (c), 264.143(a) - (h), 264.144(b) and (c), 264.145(a) - (h), 264.146, 264.147(a) - (d), and (f) - (k), and 264.148 - 264.151; and subject to the following limitations: facilities which are subject to 40 CFR Part 264, Subpart X, are subject to 40 CFR§264.142(a) and §264.144(a), and §37.6031(c) of this title (relating to Financial Assurance Requirements for Liability);

(7) Subpart I--Use and Management of Containers (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(8) Subpart J--Tank Systems (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(9) Subpart K--Surface Impoundments (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §264.221 and §264.228:

(A) reference to 40 CFR §264.221 is changed to §335.168 of this title (relating to Design and Operating Requirements (Surface Impoundments));

(B) reference to 40 CFR §264.228 is changed to §335.169 of this title (relating to Closure and Post-Closure Care (Surface Impoundments));

(10) Subpart L--Waste Piles (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §264.251;

(11) Subpart M--Land Treatment (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254)), except 40 CFR §264.273 and §264.280;

(12) Subpart N--Landfills (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989)), except 40 CFR §§264.301, 264.310, 264.314, and 264.315;

(13) Subpart O--Incinerators (as amended in the *Federal Register* through April 8, 2008 (73 FR 18970));

(14) Subpart S--Special Provisions for Cleanup (as amended in the *Federal Register* through March 18, 2010 (75 FR 12989));

(15) Subpart W--Drip Pads (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(16) Subpart X--Miscellaneous Units (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(17) Subpart AA--Air Emission Standards for Process Vents (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) with the reference to "40 CFR 262.34(a)" replaced with "40 CFR §262.17 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" [~~July 14, 2006 (71 FR 40254)~~]);

(18) Subpart BB--Air Emission Standards for Equipment Leaks (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) with the reference to "40 CFR 262.34(a)" replaced with "40 CFR §262.17 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" [~~July 14, 2006 (71 FR 40254)~~]);

(19) Subpart CC--Air Emission Standards for Tanks, Surface Impoundments, and Containers (as amended in the *Federal Register* through January 3, 2018 (83 FR 420) [~~July 14, 2006 (71 FR 40254)~~]);

(20) Subpart DD--Containment Buildings (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732) [~~July 14, 2006 (71 FR 40254)~~]);

(21) Subpart EE--Hazardous Waste Munitions and Explosives Storage (as amended in the *Federal Register* through August 1, 2005 (70 FR 44150)); [~~and~~]

(22) Subpart FF--Fees for the Electronic Hazardous Waste Manifest Program (as amended in the *Federal Register* through January 3, 2018 (83 FR 420); and

(23) [~~(22)~~] the following appendices contained in 40 CFR Part 264:

(A) Appendix I--Recordkeeping Instructions (as amended in the *Federal Register* through March 24, 1994 (59 FR 13891));

(B) Appendix IV--Cochron's Approximation to the Behrens-Fisher Students' T-Test;

(C) Appendix V--Examples of Potentially Incompatible Waste;

(D) Appendix VI--Political Jurisdictions in Which Compliance With §264.18(a) Must Be Demonstrated; and

(E) Appendix IX--Ground-Water Monitoring List (as amended in the *Federal Register* through June 13, 1997 (62 FR 32451)).

(b) The provisions of 40 CFR §264.18(b) are applicable to owners and operators of hazardous waste management facilities, for which a permit is being sought, which are not subject to the requirements of §§335.201 - 335.206 of this title (relating to Purpose, Scope, and Applicability; Definitions; Site Selection to Protect Groundwater or Surface Water; Unsuitable Site Characteristics; Prohibition of Permit Issuance; and Petitions for Rulemaking). [~~A copy of 40 CFR §264.18(b) is available for inspection at the library of the Texas Commission on Environmental Quality, located on the first floor of Building A at 12100 Park 35 Circle, Austin, Texas.~~]

(c) Except in 40 CFR §264.71 adopted under subsection (a)(4) of this section and 40 CFR Part 264, Subpart FF adopted under subsection (a)(22) of this section, the [~~The~~] regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality or to the commission, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B.

(2) The term "treatment" is changed to "processing."

(3) Reference to Resource Conservation and Recovery Act, §3008(h) is changed to Texas Water Code, §7.031(c) - (e) (Corrective Action Relating to Hazardous Waste).

(4) Reference to:

(A) 40 CFR §260.10 is changed to §335.1 of this title (relating to Definitions);

(B) 40 CFR §264.1 is changed to §335.151 of this title (relating to Purpose, Scope, and Applicability);

(C) 40 CFR §264.280 is changed to §335.172 of this title (relating to Closure and Post-Closure Care (Land Treatment Units));

(D) 40 CFR §264.90 is changed to §335.156 of this title (relating to Applicability of Groundwater Monitoring and Response);

(E) 40 CFR §264.101 is changed to §335.167 of this title (relating to Corrective Action for Solid Waste Management Units);

(F) 40 CFR §264.310 is changed to §335.174 of this title (relating to Closure and Post-Closure Care (Landfills));

(G) 40 CFR §270.41 is changed to §305.62 of this title (relating to Amendments); and

(H) 40 CFR §270.42 is changed to §305.69 of this title (relating to Solid Waste Permit Modification at the Request of the Permittee).

(5) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapters 50, 305, and 335 of this title (relating to Action on Applications and Other Authorizations; Consolidated Permits; and Industrial Solid Waste and Municipal Hazardous Waste), as applicable.

(6) Reference to 40 CFR Part 264, Subpart D is changed to §335.152(a)(3) of this title (relating to Standards) and §335.153 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator).

(7) References [~~Reference~~] to 40 CFR §264.76 and §264.77 are changed to [~~§§264.71, 264.72, 264.76, and 264.77 is changed to §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), §335.12(a) of this title,~~] §335.15(3) of this title (relating to Recordkeeping and Reporting Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities), and §335.155 of this title (relating to Additional Reports), respectively.

(8) Reference to 40 CFR Part 264, Subpart F is changed to §335.156 of this title, §335.157 of this title (relating to Required Programs), §335.158 of this title (relating to Groundwater Protection Standard), §335.159 of this title (relating to Hazardous Constituents), §335.160 of this title (relating to Concentration Limits), §335.161 of this title (relating to Point of Compliance), §335.162 of this title (relating to Compliance Period), §335.163 of this title (relating to General Groundwater Monitoring Requirements), §335.164 of this title (relating to Detection Monitoring Program), §335.165 of this title (relating to Compliance Monitoring Program), §335.166 of this title (relating to Corrective Action Program), and §335.167 of this title.

(9) Reference to 40 CFR Part 265, Subpart F is changed to include §335.116 of this title (relating to Applicability of Groundwater Monitoring Requirements) and §335.117 of this title (relating to Recordkeeping and Reporting), in addition to the reference to 40 CFR Part 265, Subpart F, except §265.90 and §265.94.

(10) Reference to the EPA is changed to the Texas Commission on Environmental Quality.

(11) Reference to qualified professional engineer is changed to Texas licensed professional engineer.

[~~(d) A copy of 40 CFR Part 264 is available for inspection at the library of the Texas Commission on Environmental Quality, located on the first floor of Building A at 12100 Park 35 Circle, Austin, Texas.~~]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Texas Commission on Environmental Quality
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SUBCHAPTER H. STANDARDS FOR THE MANAGEMENT OF SPECIFIC WASTES AND SPECIFIC TYPES OF FACILITIES
DIVISION 2. HAZARDOUS WASTE BURNED FOR ENERGY RECOVERY

30 TAC §335.221

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103,

which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.221. Applicability and Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 266 (including all appendices to 40 CFR Part 266) are adopted by reference, as amended and adopted in the CFR through April 8, 2008 (73 FR 18970), except as noted in this section:

(1) 40 CFR §266.100--Applicability (as amended through July 14, 2006 (71 FR 40254)), except 40 CFR §266.100(c); and reference to "the applicable requirements of subparts A through H, BB, and CC of parts 264 and 265 of this chapter" is changed to "the applicable requirements of §§335.111 of this title (relating to Purpose, Scope, and Applicability), 335.112(a)(1) - (7), (20), and (21) of this title (relating to Standards), 335.151 of this title (relating to Purpose, Scope, and Applicability), and 335.152(a)(1) - (6), (18), and (19) of this title (relating to Standards)";

(2) 40 CFR §266.102(a)--Permit Standards for Burners - Applicability, excepting those portions of 40 CFR §266.102(a) containing references to 40 CFR §§264.56(d), 264.71 - 264.72, 264.75 - 264.77, 264.90, 264.101, and 264.142(a)(2);

(3) 40 CFR §266.102(b)--Permit Standards for Burners - Hazardous Waste Analysis;

(4) 40 CFR §266.102(c)--Permit Standards for Burners - Emission Standards;

(5) 40 CFR §266.102(d)--Permit Standards for Burners - Permits;

(6) 40 CFR §266.102(e)--Permit Standards for Burners - Operating Requirements (as amended in the *Federal Register* through July 14, 2006 (71 FR 40254));

(7) 40 CFR §266.103 (a)(1) - (3)--Interim Status Standards for Burners - Purpose, Scope, and Applicability--General; Exemptions; and Prohibition on Burning Dioxin-Listed Wastes, respectively, except 40 CFR §266.103(a)(1)(iii) and §266.103(a)(2);

(8) 40 CFR §266.103(a)(4)--Interim Status Standards for Burners--Purpose, Scope, and Applicability--Applicability of Part 265 Standards (as amended in the *Federal Register* through (July 14, 2006 (71 FR 40254))), excepting those portions of 40 CFR §266.103(a)(4) containing references to 40 CFR §§265.56(d), 265.71 - 265.72, 265.75 - 265.77, 265.142(a)(2); facilities qualifying for a corporate guarantee for liability are subject to 40 CFR §265.147(g)(2) and §264.151(h)(2), as amended;

(9) 40 CFR §266.103(a)(5) - (6)--Interim Status Standards for Burners - Purpose, Scope, and Applicability: Special Requirements for Furnaces; and Restrictions on Burning Hazardous Waste That Is Not a Fuel;

(10) 40 CFR §266.103(b)--Interim Status Standards for Burners - Certification of Precompliance (as amended through (July 14, 2006 (71 FR 40254))), except 40 CFR §266.103(b)(1) and (6);

(11) 40 CFR §266.103(c)--Interim Status Standards for Burners - Certification of Compliance (as amended through (July 14, 2006 (71 FR 40254))), except 40 CFR §266.103(c)(3)(i);

(12) 40 CFR §266.103(f)--Interim Status Standards for Burners - Start-Up and Shut-Down;

(13) 40 CFR §266.103(g)(1) - (2)--Interim Status Standards for Burners - Automatic Waste Feed Cutoff (as amended in the *Federal Register* through [{]July 14, 2006 (71 FR 40254))[}];

(14) 40 CFR §266.103(h) - (l)--Interim Status Standards for Burners: Fugitive Emissions; Changes; Monitoring and Inspections; Recordkeeping; and Closure, respectively, as amended in the *Federal Register* through April 4, 2006 (71 FR 16862);

(15) 40 CFR §266.104--Standards to Control Organic Emissions, except 40 CFR §266.104(h);

(16) 40 CFR §266.105--Standards to Control Particulate Matter, except 40 CFR §266.105(d);

(17) 40 CFR §266.106--Standards to Control Metals Emissions (as amended in the *Federal Register* through (July 14, 2006 (71 FR 40254))), except 40 CFR §266.106(i);

(18) §266.107--Standards to Control Hydrogen Chloride (HCl) and Chlorine Gas ($C1_2$) Emissions, except 40 CFR §266.107(h);

(19) 40 CFR §266.108--Small Quantity On-Site Burner Exemption, except §266.108(d), and except that hazardous wastes generated by a very small quantity generator [~~subject to §335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)~~] may not be burned in an off-site device under the exemption provided by 40 CFR §266.108;

(20) 40 CFR §266.109--Low-Risk Waste Exemption (as amended in the *Federal Register* through (July 14, 2006 (71 FR 40254)));

(21) 40 CFR §266.110--Waiver of DRE Trial Burn for Boilers;

(22) 40 CFR §266.111--Standards for Direct Transfer; and

(23) 40 CFR §266.112--Regulation of Residues.

(b) The following hazardous wastes and facilities are not regulated under this division:

(1) used oil burned for energy recovery that is also a hazardous waste solely because it exhibits a characteristic of hazardous waste identified in 40 CFR Part 261, Subpart C, from use versus mixing. Such used oil is subject to regulation by the United States Environmental Protection Agency (EPA) under 40 CFR Part 279 and Chapter 324 of this title (relating to Used Oil Standards). This exception does not apply if the used oil has been made hazardous by mixing with characteristic or listed hazardous waste other than by a generator that meets the conditions for exemption for a very [~~conditionally exempt~~] small quantity generator or household generator;

(2) hazardous wastes that are exempt from regulation under [~~the provisions of~~] 40 CFR §261.4 [~~,~~] and §335.24(c)(3) - (4) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials)[~~, and hazardous wastes that are subject to the special requirements for conditionally exempt small quantity generators under the provisions of §335.78 of this title~~];

(3) hazardous wastes generated by a very small quantity generator that meets the conditions for exemption of a very small quantity generator;

(4) [~~(3)~~] gas recovered from hazardous or solid waste landfills when such gas is burned for energy recovery; and

(5) [~~(4)~~] coke ovens, if the only hazardous waste burned is EPA Hazardous Waste No. K087, decanter tank tar sludge from coking operations.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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DIVISION 3. RECYCLABLE MATERIALS UTILIZED FOR PRECIOUS METAL RECOVERY

30 TAC §335.241

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.241. Applicability and Requirements.

(a) The regulations of this section apply to recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, platinum, palladium, iridium, osmium, rhodium, ruthenium, or any combination of these.

(b) Persons who generate, transport, or store recyclable materials that are regulated under this section are subject to the following requirements:

(1) §335.4 of this title (relating to General Prohibitions);

(2) §335.6 of this title (relating to Notification Requirements);

(3) §§335.9 - 335.12 of this title (relating to Shipping and Reporting Procedures Applicable to Generators; Shipping and Reporting Procedures Applicable to Generators of Municipal Hazardous Waste or Class 1 [~~Industrial Solid~~] Waste; Shipping Requirements for Transporters of Municipal Hazardous Waste or Class 1 [~~Industrial Solid~~] Waste; Shipping Requirements Applicable to Owners or Operators of Storage, Processing, or Disposal Facilities), §335.54 of this title (relating to Hazardous Waste Manifest), 40 Code of Federal Regulations (CFR) §265.71 and §265.72 as adopted by reference under §335.112(a)(4) of this title (relating to Standards), and 40 CFR §264.71 and §264.72 as adopted by reference under §335.152(a)(4) of this title (relating to Standards), for generators, transporters, or persons who store, as applicable; and

(4) For precious metals exported to or imported from other countries for recovery [~~designated OECD member countries for recovery~~], 40 Code of Federal Regulations (CFR) Part 262, Subpart H[~~,~~] and §265.12 adopted by reference under §335.112 of this title (relating to Standards). [~~§265.12(a). For precious metals exported to or imported from non-OECD countries for recovery, §335.13 of this title (relating to Recordkeeping and Reporting Procedures Applicable to Generators Shipping Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste and §335.76 of this title (relating to Additional Requirements Applicable to International Shipments).~~]

(c) Persons who store recyclable materials that are regulated under this section shall keep the following records to document that they are not accumulating these materials speculatively, as defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials):

(1) records showing the volume of these materials stored at the beginning of the calendar year;

(2) the amount of these materials generated or received during the calendar year; and

(3) the amount of materials remaining at the end of the calendar year.

(d) Recyclable materials that are regulated under this section that are accumulated speculatively, as defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials), are subject to all applicable provisions of this chapter (excluding this subchapter), Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution); Chapter 50 of this title (relating to Actions on Applications); Chapter 55 of this title (relating to Request for Contested Case Hearings); Chapter 70 of this title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings; Chapter 261 of this title (relating to Introductory Provisions); Chapter 277 of this title (relating to Use Determinations for Tax Exemption for Pollution Control Property); and Chapter 305 of this title (relating to Consolidated Permits).

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DIVISION 4. SPENT LEAD-ACID BATTERIES BEING RECLAIMED

30 TAC §335.251

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.251. Applicability and Requirements.

(a) The regulations of this section adopt by reference 40 Code of Federal Regulations (CFR) Part 266, Subpart G as amended in the *Federal Register* through November 28, 2016 (81 FR 85732 [~~85696~~]). This section applies to persons who reclaim (including regeneration) spent lead-acid batteries that are recyclable materials (spent batteries). Persons who generate, transport, or collect spent batteries, who regenerate spent batteries, who store spent batteries that are to be regenerated, or who store spent batteries but do not reclaim them (other than spent batteries that are to be regenerated), are not subject to regulation under this chapter, except that §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) applies; and are not subject to regulation under Chapter 1 of this title (relating to Purpose of Rules, General Provisions); Chapter 3 of this title (relating to Definitions); Chapter 10 of this title (relating to Commission Meetings); Chapter 20 of this title (relating to Rulemaking); Chapter 37 of this title (relating to Financial Assurance); Chapter 39 of this title (relating to Public Notice); Chapter 40 of this title (relating to Alternative Dispute Resolution Procedure); Chapter 50 of this title (relating to Action on Applications and Other Authorizations); Chapter 55 of this title (relating to Requests for Contested Case Hearings; Public Comment); Chapter 70 of this title (relating to Enforcement); Chapter 80 of this title (relating to Contested Case Hearings); Chapter 86 of this title (relating to Special Provisions for Contested Case Hearings); or Chapter 305 of this title (relating to Consolidated Permits). Such persons, however, remain subject to the requirements of the Texas Water Code, Chapter 26.

(b) Owners or operators of facilities that store spent lead-acid batteries before reclaiming them (other than spent batteries that are to be regenerated) are subject to the following requirements:

(1) all applicable provisions in Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter B of this chapter (relating to Hazardous Waste Management General Provisions), Subchapter E of this chapter (relating to Interim Standards of Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities), Subchapter F of this chapter (relating to Permitting Standards of Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities), and Subchapter U of this chapter (relating to Standards for Owners and Operators of Hazardous Waste Facilities Operating under a Standard Permit), except for the requirements in §335.12 of this title (relating to Shipping Requirements Applicable to Owners or Operators of Treatment, Storage, or Disposal Facilities) and 40 CFR §265.13; and

(2) all applicable provisions in Chapters 1, 3, 10, 20, 37, 39, 40, 50, 55, 70, 80, and 305 of this title.

(c) Persons who export spent batteries for reclamation in a foreign country where they will be reclaimed through regeneration or any other means are not subject to the requirements of Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste), except for §335.53(a) and (g) of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [~~§335.63 of this title (relating to EPA Identification Numbers)~~]; Subchapter D of this chapter (relating to Standards Applicable to Transporters of Hazardous Waste), except for §335.91(e) of this title (relating to Scope); Subchapter E of this chapter (relating to Interim Standards of Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities); Subchapter F of this chapter (relating to Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities); or Subchapter O of this chapter (relating to Land Disposal Restrictions), or Chapter 1, 3, 10, 20, 37, 39, 40, 50, 55, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [~~, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504~~] of this title (relating to Hazardous Waste Determination).

(d) Persons who transport spent batteries in the United States to export them for reclamation in a foreign country where they will be reclaimed through regeneration or any other means are not subject to the requirements of Subchapter C of this chapter; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter; or Subchapter O of this chapter, or Chapter 1, 3, 10, 20, 37, 39, 40, 50, 55, 70, 80, 86, or 305 of this title. Such persons, however, remain subject to the requirements of §335.91(e) of this title.

(e) Persons who import spent batteries from a foreign country and store these spent batteries, but are not the reclaimer, and where the spent battery will be reclaimed other than through regeneration, are not subject to the requirements of Subchapter C of this chapter, except for §335.53(a) and (g) [~~§335.63~~] of this title; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter, or Chapter 1, 3, 10, 37, 39, 40, 50, 55, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [~~, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504~~] of this title, and applicable provisions of Subchapter O of this chapter.

(f) Persons who import spent batteries from a foreign country and store these spent batteries before reclaiming them, and where the spent battery will be reclaimed other than through regeneration, are not subject to the requirements of Subchapter C of this chapter, except for §335.53(a) and (g) [~~§335.63~~] of this title; Subchapter D of this chapter,

except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter, or Chapter 1, 3, 10, 37, 39, 40, 50, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [~~, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504~~] of this title, and applicable provisions of Subchapter O of this chapter.

(g) Persons who import spent batteries from a foreign country and do not store these spent before reclaiming them, and where they will be reclaimed other than through regeneration, are not subject to the requirements of Subchapter C of this chapter, except for §335.53(a) and (g) of this title [~~§335.63 of this title~~]; Subchapter D of this chapter, except for §335.91(e) of this title; Subchapter E of this chapter; Subchapter F of this chapter, or Chapter 1, 3, 10, 37, 39, 40, 50, 70, 80, 86, or 305 of this title. Such persons must comply with §335.504 [~~, however, remain subject to the requirements of §§335.63, 335.91(e), and 335.504~~] of this title, and applicable provisions of Subchapter O of this chapter.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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DIVISION 5. UNIVERSAL WASTE RULE

30 TAC §335.261

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.261. Universal Waste Rule.

(a) This section establishes requirements for managing universal wastes as defined in this section, and provides an alternative set of management standards in lieu of regulation, except as provided in this section, under all otherwise applicable chapters under 30 Texas Administrative Code. Except as provided in subsection (b) of this section, 40 Code of Federal Regulations (CFR) Part 273 is adopted by reference as amended in the *Federal Register* through December 9, 2019 (84 FR 67202) [~~November 28, 2016 (81 FR 85696)~~].

(b) 40 CFR Part 273, except 40 CFR §§273.1, 273.20, 273.39(a) and (b), 273.40, 273.56, 273.62(a), and 273.70, is adopted subject to the following changes:

(1) The term "regional administrator" is changed to "executive director" or "commission" consistent with the organization of the commission as set out in the Texas Water Code, Chapter 5.

(2) The terms "U.S. Environmental Protection Agency" and "EPA" are changed to "the Texas Commission on Environmental Quality," "the agency," or "the commission" consistent with the organization of the commission as set out in Texas Water Code, Chapter 5. This paragraph does not apply to 40 CFR §273.32(a)(3) or §273.52 or to references to the following: "EPA Acknowledgment of Consent" or "EPA Identification Number."

(3) The term "treatment" is changed to "processing."

(4) The term "universal waste" is changed to "universal waste as defined under §335.261(b)(19)(F) [~~§335.261(b)(16)(F)~~] of this title (relating to Universal Waste Rule)."

(5) The term "this part" is changed to "Chapter 335, Subchapter H, Division 5 of this title (relating to Universal Waste Rule)."

(6) In 40 CFR §273.2(a) and (b), references to "40 CFR Part 266, Subpart G," are changed to "§335.251 of this title (relating to Applicability and Requirements)."

(7) In 40 CFR §273.2(b)(2), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(8) In 40 CFR §273.3(b)(1), the reference to "40 CFR §262.70" is changed to "§335.57 [~~§335.77~~] of this title (relating to Farmers)." Also, the phrase "(40 CFR §262.70 addresses pesticides disposed of on the farmer's own farm in a manner consistent with the disposal instructions on the pesticide label, providing the container is triple rinsed in accordance with 40 CFR §261.7(b)(3))" is deleted.

(9) In 40 CFR §273.3(b)(2), the reference to "40 CFR parts 260 through 272" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(10) In 40 CFR §273.3(b)(3), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(11) In 40 CFR §273.3(d)(1)(i) and (ii), references to "40 CFR §261.2" are changed to "§335.1 of this title (relating to Definitions)."

(12) In 40 CFR §273.4(a), the reference to "§273.9" as it relates to the definition of "mercury-containing equipment" is amended to include the commission definition of "thermostats" as contained in §335.261(b)(19)(E) [~~§335.261(b)(16)(E)~~] of this title (relating to Universal Waste Rule) and in 40 CFR §273.4(b)(1), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(13) In 40 CFR §273.5(b)(1), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(14) In 40 CFR §273.6(b)(1), the reference to "part 261 of this chapter" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(15) In 40 CFR §273.6(b)(2), the references to "part 261, subpart C, of this chapter" and "part 261, subpart D, of this chapter" are changed to "Chapter 335, Subchapter R of this title (relating to Waste Classification)."

(16) In 40 CFR §273.6(b)(3), the reference to "§261.7 of this chapter" is changed to "§335.41(f) of this title (relating to Purpose, Scope and Applicability)."

(17) [~~(14)~~] In 40 CFR §273.8(a)(1), the reference to "40 CFR §261.4(b)(1)" is changed to "§335.1 and §335.402(5) of this title (relating to Definitions; and Definitions)" and the reference to "§273.9" is changed to "§335.261(b)(19)(F) [~~§335.261(b)(16)(F)~~] of this title (relating to Universal Waste Rule)."

(18) [~~(15)~~] In 40 CFR §273.8(a)(2), the reference to "40 CFR §262.14 [~~§261.5~~]" is changed to "40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) [~~§335.78 of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators)~~]" [~~and to "§335.402(5) of this title (relating to Definitions)"~~] and the reference to "§273.9" is changed to "§335.261(b)(19)(F) [~~§335.261(b)(16)(F)~~] of this title (relating to Universal Waste Rule)."

(19) [~~(16)~~] In 40 CFR §273.9, the following definitions are changed to the meanings described in this paragraph.

(A) Destination facility--A facility that treats, disposes, or recycles a particular category of universal waste, except those management activities described in 40 CFR §273.13(a) and (c) and 40 CFR §273.33(a) and (c), as adopted by reference in this section. A facility at which a particular category of universal waste is only accumulated is not a destination facility for purposes of managing that category of universal waste.

(B) Generator--Any person, by site, whose act or process produces hazardous waste identified or listed in 40 CFR Part 261 or whose act first causes a hazardous waste to become subject to regulation.

(C) Large quantity handler of universal waste--A universal waste handler (as defined in this section) who accumulates at any time 5,000 kilograms or more total of universal waste (as defined in this section), calculated collectively. This designation as a large quantity handler of universal waste is retained through the end of the calendar year in which 5,000 kilograms or more total universal waste is accumulated.

(D) Small quantity handler of universal waste--A universal waste handler (as defined in this section) who does not accumulate at any time 5,000 kilograms or more total of universal waste (as defined in this section), calculated collectively.

(E) Thermostat--A temperature control device that contains metallic mercury in an ampule attached to a bimetal sensing element, and mercury-containing ampules that have been removed from these temperature control devices in compliance with the requirements of 40 CFR §273.13(c)(2) or §273.33(c)(2) as adopted by reference in this section.

(F) Universal waste--Any of the following hazardous wastes that are subject to the universal waste requirements of this section:

(i) batteries, as described in 40 CFR §273.2;

(ii) pesticides, as described in 40 CFR §273.3;

(iii) mercury-containing equipment, including thermostats, as described in 40 CFR §273.4;

(iv) paint and paint-related waste, as described in §335.262(b) of this title (relating to Standards for Management of Paint and Paint-Related Waste); [~~and~~]

(v) lamps, as described in 40 CFR §273.5; and [~~,~~]

(vi) aerosol cans, as described in 40 CFR §273.6.

(20) [~~(17)~~] In 40 CFR §273.10, the reference to "40 CFR §273.9" is changed to "§335.261(b)(19)(D) [~~§335.261(b)(16)(D)~~] of this title (relating to Universal Waste Rule)."

(21) [~~(18)~~] 40 CFR §273.11(b) is changed to read as follows: "Prohibited from diluting or treating universal waste, except when responding to releases as provided in 40 CFR §273.17; managing specific wastes as provided in 40 CFR §273.13; or crushing lamps under the control conditions of §335.261(e) of this title (relating to Universal Waste Rule)."

(22) [~~(19)~~] In 40 CFR §273.13(a)(3)(i), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(23) [~~(20)~~] In 40 CFR §273.13(c)(2)(iii) and (iv), references to "40 CFR parts 260 through 272 [~~§262.34~~]" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste) [~~§335.69 of this title (relating to Accumulation Time)~~]."

(24) [~~(21)~~] In 40 CFR §273.13(d)(1), the phrase "adequate to prevent breakage" is changed to "adequate to prevent breakage, except as specified in §335.261(e) of this title (relating to Universal Waste Rule)."

(25) In 40 CFR §273.13(e)(4)(iv), the reference to "40 CFR 262.14, 262.15, 262.16, or 262.17" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)."

(26) In 40 CFR §273.13(e)(4)(v), the reference to "40 CFR 262.11" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" and the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(27) [~~(22)~~] In 40 CFR §273.17(b), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(28) [~~(23)~~] In 40 CFR §273.30, the reference to "§273.9" is changed to "§335.261(b)(19)(C) [~~§335.261(b)(16)(C)~~] of this title (relating to Universal Waste Rule)."

(29) [~~(24)~~] 40 CFR §273.31(b) is changed to read as follows: "Prohibited from diluting or treating universal waste, except when responding to releases as provided in 40 CFR §273.37; managing specific wastes as provided in 40 CFR §273.33; or crushing lamps under the control conditions of §335.261(e) of this title (relating to Universal Waste Rule)."

(30) [~~(25)~~] In 40 CFR §273.33(a)(3)(i), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(31) [~~(26)~~] In 40 CFR §273.33(c)(2)(iii) and (iv), the references to "40 CFR parts 260 through 272 [~~§262.34~~]" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Munic-

ipal Hazardous Waste) [§335.69 of this title (relating to Accumulation Time)]."

(32) [(27)] In 40 CFR §273.33(c)(4)(i), the reference, "40 CFR part 261, subpart C," is changed to "Chapter 335, Subchapter R of this title (relating to Waste Classification)."

(33) [(28)] In 40 CFR §273.33(c)(3)(ii), the reference, "40 CFR parts 260 through 272," is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(34) [(29)] In 40 CFR §273.33(d)(1), the phrase "adequate to prevent breakage" is changed to "adequate to prevent breakage, except as specified in §335.261(e) of this title (relating to Universal Waste Rule)."

(35) In 40 CFR §273.33(e)(4)(iv), the reference to "40 CFR 262.14, 262.15, 262.16, or §262.17" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)."

(36) In 40 CFR §273.33(e)(4)(v), the reference to "40 CFR 262.11" is changed to "§335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)" and the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(37) [(30)] In 40 CFR §273.37(b), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(38) [(31)] In 40 CFR §273.52(a), the reference to "40 CFR part 262" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(39) [(32)] In 40 CFR §273.52(b), the reference to "40 CFR part 262" is changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(40) [(33)] In 40 CFR §273.54(b), the reference to "40 CFR parts 260 through 272" and the reference to "40 CFR part 262" are changed to "Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste)."

(41) [(34)] In 40 CFR §273.60(a), the reference to "§273.9" is changed to "§335.261(b)(19)(A) [§335.261(b)(16)(A)] of this title (relating to Universal Waste Rule)" and the reference to "parts 264, 265, 266, 268, 270, and 124 of this chapter" is changed to " 30 Texas Administrative Code (relating to Environmental Quality)."

(42) [(35)] In 40 CFR §273.60(b), the reference to "40 CFR §261.6(c)(2)" is changed to "§335.24 of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials)."

(43) [(36)] In 40 CFR §273.80(a), the reference to "40 CFR §260.20 and §260.23" is changed to "§20.15 of this title (relating to Petition for Adoption of Rules) and §335.261(c) of this title (relating to Universal Waste Rule)."

(44) [(37)] In 40 CFR §273.80(b), the reference to "40 CFR §260.20(b)" is changed to "§20.15 of this title (relating to Petition for Adoption of Rules)."

(45) [(38)] In 40 CFR §273.81(a), the reference to "40 CFR §260.10" is changed to "§335.1 of this title (relating to Definitions) and the reference to "§273.9" is changed to "§335.261(b)(19)(F) [§335.261(b)(16)(F)] of this title (relating to Universal Waste Rule)."

(c) Except as provided in paragraph (4) of this subsection, any [Any] person seeking to add a hazardous waste or a category of hazardous waste to the universal waste rule may file a petition for rulemaking under this section, §20.15 of this title, and 40 CFR Part 273, Subpart G as adopted by reference in this section.

(1) To be successful, the petitioner must demonstrate to the satisfaction of the commission that regulation under the universal waste rule: is appropriate for the waste or category of waste; will improve management practices for the waste or category of waste; and will improve implementation of the hazardous waste program. The petition must include the information required by §20.15 of this title. The petition should also address as many of the factors listed in 40 CFR §273.81 as are appropriate for the waste or category of waste addressed in the petition.

(2) The commission will grant or deny a petition using the factors listed in 40 CFR §273.81. The decision will be based on the commission's determinations that regulation under the universal waste rule is appropriate for the waste or category of waste, will improve management practices for the waste or category of waste, and will improve implementation of the hazardous waste program.

(3) The commission may request additional information needed to evaluate the merits of the petition.

(4) Hazardous waste pharmaceuticals are regulated under Subchapter W of this chapter (relating to Management Standards for Hazardous Waste Pharmaceuticals) and may not be added as a category of hazardous waste for management under this section.

(d) Any waste not qualifying for management under this section must be managed in accordance with applicable state regulations.

(e) Crushing lamps is permissible only in a crushing system for which the following control conditions are met:

(1) an exposure limit of no more than 0.05 milligrams of mercury per cubic meter is demonstrated through sampling and analysis using Occupational Safety and Health Administration (OSHA) Method ID-140 or National Institute for Occupational Safety and Health Method Number 6009, based on an eight-hour time-weighted average of samples taken at the breathing zone height near the crushing system operating at the maximum expected level of activity;

(2) compliance with the notification requirements of §106.262 of this title (relating to Facilities (Emission and Distance Limitations) (Previously SE 118)) is demonstrated;

(3) documentation of the demonstrations under paragraphs (1) and (2) of this subsection is provided in a written report to the executive director; and

(4) the executive director approves the crushing system in writing.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Robert Martinez
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Texas Commission on Environmental Quality
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DIVISION 6. MILITARY MUNITIONS

30 TAC §335.272

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.272. Standards.

(a) The regulations contained in 40 Code of Federal Regulations (CFR) Part 266 Subpart M, as amended in the *Federal Register* through February 12, 1997[,] (at 62 FR [~~FedReg~~] 6622) are adopted by reference, subject to the changes indicated in subsection (b) of this section.

(b) Reference to:

(1) August 12, 1997 is changed to the effective date of this rule;

(2) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapter 50 of this title (relating to Action on Applications and Other Authorizations), Chapter 305 of this title (relating to Consolidated Permits), and Chapter 335 of this title (relating to Industrial Solid Waste and Municipal Hazardous Waste), as applicable;

(3) 40 CFR Parts 260 - 279 means the commission's rules including, but not limited, to Chapter 50 of this title, Chapter 305 of this title, Chapter 328 of this title (relating to Waste Minimization and Recycling), and Chapter 335 of this title, as applicable;

(4) 40 CFR §260.10 is changed to §335.1 of this title (relating to Definitions);

(5) 40 CFR §261.2 is changed to the definition of "solid waste" in §335.1 of this title);

(6) 40 CFR §262.10(i) means as this section is adopted by reference under §335.52 of this title (relating to Purpose, Scope, and Applicability) [~~is changed to §335.61(h) of this title (relating to Standards Applicable to Generators of Hazardous Waste)~~];

(7) 40 CFR §263.10(e) means as this section is adopted under [~~is changed to~~] §335.91(f) of this title (relating to Scope [~~Standards Applicable to Transporters of Hazardous Waste~~]);

(8) 40 CFR §§264.1(g)(8), 265.1(c)(11), and 270.1(c)(3) are changed to §335.41(d)(2) of this title (relating to Hazardous Waste Management General Provisions);

(9) 40 CFR §270.61 is changed to §335.402 of this title (related to Emergency Actions Concerning Hazardous Waste);

(10) Resource Conservation and Recovery Act (RCRA) §1004(27) is changed to Texas Health and Safety Code (THSC), §361.003(34) (related to the definition of Solid Waste);

(11) RCRA §3004(u) is changed to Texas Water Code (TWC), §7.031(a) and (b) (relating to Corrective Action Relating to Hazardous Waste);

(12) RCRA §3008(h) is changed to TWC, §7.031(c) - (e) (relating to Corrective Action Relating to Hazardous Waste);

(13) RCRA §7003 is changed to THSC, §361.272 (relating to Administrative Orders Concerning Imminent and Substantial Endangerment), THSC, §361.273 (relating to Injunction as Alternative to Administrative Order), THSC, §361.301 (relating to Emergency Order), TWC, §26.121, (relating to Unauthorized Discharges Prohibited.)

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SUBCHAPTER O. LAND DISPOSAL RESTRICTIONS

30 TAC §335.431

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.431. Purpose, Scope, and Applicability.

(a) Purpose. The purpose of this subchapter is to identify hazardous wastes that are restricted from land disposal and define those

limited circumstances under which an otherwise prohibited waste may continue to be land disposed.

(b) Scope and Applicability.

(1) Except as provided in paragraph (2) of this subsection, the requirements of this subchapter apply to persons who generate or transport hazardous waste and owners and operators of hazardous waste treatment, storage, and disposal facilities.

(2) The requirements of this subchapter do not apply to any entity that is either specifically excluded from coverage by this subchapter or would be excluded from the coverage of 40 Code of Federal Regulations (CFR) Part 268 by 40 CFR Part 261, if those parts applied.

(3) Universal waste handlers and universal waste transporters, as defined in and subject to regulation under Subchapter H, Division 5 of this chapter (relating to Universal Waste Rule) are exempt from 40 CFR §268.7 and §268.50.

(c) Adoption by Reference.

(1) Except as provided in paragraph (2) of this subsection, and subject to the changes indicated in subsection (d) of this section, the regulations contained in 40 CFR Part 268, as amended in the *Federal Register* through February 22, 2019 (84 FR 5816) [~~June 13, 2011 (76 FR 34147)~~] are adopted by reference.

(2) The following sections of 40 CFR Part 268 are excluded from the sections adopted in paragraph (1) of this subsection: 40 CFR §§268.1(f), 268.5, 268.6, 268.7(a)(10), 268.13, 268.42(b), and 268.44.

(3) Appendices IV, VI - IX, and XI of 40 CFR Part 268 are adopted by reference as amended through July 14, 2006 (71 FR 40254).

(d) Changes to Adopted Parts. The parts of the CFR that are adopted by reference in subsection (c) of this section are changed as follows:

(1) The words "Administrator" or "Regional Administrator" are changed to "Executive Director;"

(2) The word "treatment" is changed to "processing;"

(3) The words *"Federal Register,"* when they appear in the text of the regulation, are changed to *"Texas Register;"*

(4) In 40 CFR §268.7(a)(6) and (7) [~~(a)(7)~~], the applicable definition of hazardous waste and solid waste is the one that is set out in this chapter rather than the definition of hazardous waste and solid waste that is set out in 40 CFR Part 261.

(5) In 40 CFR §268.50(a)(1), the reference to "§§262.16 and 262.17" [~~the citation to "§262.34"~~] is changed to "40 CFR §262.16 and §262.17 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste)." ["~~§335.69.~~"]

(6) In 40 CFR §268.50(a)(4), the reference to "§§266.502 and 266.503 of this chapter" is changed to "§335.755 of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals) and §335.757 of this title (relating to Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals)."

(7) In 40 CFR §268.50(a)(5), the reference to "§266.510 of this chapter" is changed to "§335.771 of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors)."

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SUBCHAPTER Q. POLLUTION PREVENTION: SOURCE REDUCTION AND WASTE MINIMIZATION

30 TAC §§335.471, 335.474, 371.477

Statutory Authority

The amendments are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendments implement THSC, Chapter 361.

§335.471. Definitions.

The words and terms used in this subchapter have the meanings given in the Waste Reduction Policy Act of 1991, or the regulations promulgated thereunder. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Further, the following words and terms, as defined herein, shall only have application to this subchapter.

[~~(1) Acute hazardous waste--Hazardous waste listed by the administrator of the EPA under the federal Solid Waste Disposal Act, as amended by RCRA, because the waste meets the criteria for listing hazardous waste identified in 40 Code of Federal Regulations §261.11(a)(2).~~]

(1) [~~(2)~~] Base year--The year preceding the first year of the plan.

[~~(3) Conditionally exempt small quantity generator--A generator that does not accumulate more than 1,000 kilograms of hazardous waste at any one time at his facility and who generates less than 100 kilograms of hazardous waste in any given month.~~]

(2) [~~(4)~~] Environment--Water, air, and land and the interrelationship that exists among and between water, air, land, and all living things.

[~~(5) Environmental management system--As defined in §90.30(3) of this title (relating to Definitions). A documented management system to address applicable environmental regulatory requirements that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing, and maintaining an environmental policy directed toward continuous improvement.~~]

(3) [~~(6)~~] Facility--All buildings, equipment, structures, and other stationary items located on a single site or on contiguous or adjacent sites that are owned or operated by a person who is subject to this subchapter or by a person who controls, is controlled by, or is under common control with a person subject to this subchapter.

(4) [~~(7)~~] Generator and generator of hazardous waste--Has the meaning assigned by Texas Health and Safety Code, §361.131. A person whose act or process produces industrial solid waste or hazardous waste or whose act first causes an industrial solid waste or a hazardous waste to be regulated by the commission.

[~~(8) Large quantity generator--A generator that generates, through ongoing processes and operations at a facility:~~]

[~~(A) more than 1,000 kilograms of hazardous waste in a month; or~~]

[~~(B) more than one kilogram of acute hazardous waste in a month.~~]

(5) [~~(9)~~] Media and medium--Air, water, and land into which waste is emitted, released, discharged, or disposed.

(6) [~~(10)~~] Pollutant or contaminant--Includes any element, substance, compound, disease-causing agent, or mixture that after release into the environment and on exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions, including malfunctions in reproduction, or physical deformations in the organism or its offspring. The term does not include petroleum, crude oil, or any fraction of crude oil that is not otherwise specifically listed or designated as a hazardous substance under §101(14)(A) - (F) of the environmental response law, nor does it include natural gas, natural gas liquids, liquefied natural gas, synthetic gas of pipeline quality, or mixtures of natural gas and synthetic gas.

(7) [~~(11)~~] Release--Any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment. The term does not include:

(A) a release that results in an exposure to a person solely within a workplace, concerning a claim that the person may assert against the person's employer;

(B) an emission from the engine exhaust of a motor vehicle, rolling stock, aircraft, vessel, or pipeline pumping station engine;

(C) a release of source, by-product, or special nuclear material from a nuclear incident, as those terms are defined by the Atomic Energy Act of 1954, as amended ((42 United States Code, §§2011 *et seq.),* if the release is subject to requirements concerning financial protection established by the United States Nuclear Regulatory Commission under that Act, §170;

(D) for the purposes of the federal Comprehensive Environmental Responsibility, Compensation and Liability Act [~~CERCLA~~] (Superfund), §104, or other response action, a release of source, by-product, or special nuclear material from a processing site designated under the Uranium Mill Tailings Radiation Control Act of 1978 (42 United States Code, §7912 and §7942), §102(a)(1), or §302(a)); and

(E) the normal application of fertilizer.

[~~(12) Small quantity generator--A generator that generates through ongoing processes and operation at a facility:~~]

[~~(A) equal to or less than 1,000 kilograms but more than or equal to 100 kilograms of hazardous waste in a month; or~~]

[~~(B) equal to or less than one kilogram of acute hazardous waste in a month.~~]

(8) [~~(13)~~] Source reduction--Has the meaning assigned by the federal Pollution Prevention Act of 1990, Publication Law 101-508, §6603, 104 Stat. 1388. The term "source reduction" means any practice which:

(A) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and

(B) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants. The term includes equipment or technology modifications, process or procedure modifications, reformulation or redesign of products, substitution of raw materials, and improvements in housekeeping, maintenance, training, or inventory control.

(9) [~~(14)~~] Tons--2,000 pounds, also referred to as short tons.

(10) [~~(15)~~] Toxic release inventory--A program which includes those chemicals on the list in Committee Print Number 99-169 of the United States Senate Committee on Environment and Public Works, titled "Toxic Chemicals Subject to the Emergency Planning and Community Right-To-Know Act of 1986 (EPCRA, 42 United States Code, §11023), 313" including any revised version of the list as may be made by the administrator of the EPA.

(11) [~~(16)~~] Waste minimization--A practice that reduces the environmental or health hazards associated with hazardous wastes, pollutants, or contaminants. Examples may include reuse, recycling, neutralization, and detoxification.

§335.474. Pollution Prevention Plans.

All persons identified under §335.473 of this title (relating to Applicability) shall prepare a five-year pollution prevention plan that shall be updated as necessary. Plans shall be maintained on-site and available to commission personnel for inspection. Prior to expiration of the initial plan and each succeeding five-year plan, a new five-year plan shall be prepared. Plans prepared under paragraphs (1) - (3) of this section shall contain a separate component addressing source reduction activities and a separate component addressing waste minimization activities.

(1) Large quantity generators or toxic release inventory (TRI) Form R reporters. For facilities that are large quantity generators as defined in §335.1 [~~§335.471(8)~~] of this title (relating to Definitions) or TRI Form R reporters [~~defined in §335.471(15) of this title~~], the plan shall include, at a minimum:

(A) an initial survey that identifies:

(i) for facilities described in §335.473(1) of this title, all activities that generate hazardous waste; and

(ii) for facilities described in §335.473(3), all activities that result in a release of TRI reportable chemicals;

(B) based on the initial survey, a prioritized list of economically and technologically feasible source reduction and waste minimization projects;

(C) an explanation of source reduction or waste minimization projects to be undertaken, with a discussion of technical and economic considerations, and environmental and human health risks considered in selecting each project to be undertaken;

(D) an estimate of the type and amount of reduction anticipated;

(E) a schedule for the implementation of each source reduction and waste minimization project;

(F) measurable source reduction and waste minimization goals for the entire facility, including incremental goals to aid in evaluating progress;

(G) an explanation of employee awareness and training programs to aid in accomplishing source reduction and waste minimization goals;

(H) identification of cases where the implementation of a source reduction or waste minimization activity designed to reduce risk to human health or the environment may result in the release of a different pollutant or contaminant or may shift the release to another medium;

(I) certification that the plan is complete and correct by the owner of the facility, or, if the facility is owned by a corporation, by an officer of the corporation that owns the facility who has the authority to commit the corporation's resources to implement the plan. A copy of the certification is to be submitted to the commission; and

(J) an executive summary of the plan submitted to the commission that shall include at a minimum:

(i) a description of the facility that shall include:

(I) name of facility;

(II) mailing and physical address;

(III) point-of-contact, including phone number and electronic mail (e-mail) address, if available;

(IV) a general description of the facility;

(V) applicable identification numbers, including: Texas Commission on Environmental Quality (TCEQ) solid waste registration number, EPA identification number, and TRI identification number;

(VI) primary standard industrial classification (SIC) code and, if applicable, North American Industry Classification System (NAICS); and

(VII) the specific time period the five-year plan is in effect;

(ii) a list of all hazardous wastes generated and the volume of each;

(iii) a list of all reportable TRI releases and transfers and the volume of each;

(iv) a prioritized list of pollutants and contaminants to be reduced;

(v) a statement of measurable reduction goals;

(vi) an explanation of environmental and human health risks considered in determining reduction goals;

(vii) a list of source reduction and waste minimization projects with an associated schedule toward implementation;

(viii) an implementation schedule for future reduction goals; and

(ix) identification and description of cases where the implementation of source reduction or waste minimization activity designed to reduce risk to human health or the environment may result in the release of a different pollutant or contaminant or may shift the release to another medium. Included in this description shall be a discussion of the change in characteristic of the normal waste stream or release and how it will be managed in the affected medium.

(K) The executive summary of the plan may include:

(i) a discussion of the person's previous efforts at the facility to reduce risk to human health and the environment or to reduce the generation of hazardous waste or the release of pollutants or contaminants;

(ii) a discussion of the effect changes in environmental regulations have had on the achievement of the source reduction and waste minimization goals;

(iii) the effect that events the person could not control have had on the achievement of the source reduction and waste minimization goals;

(iv) a description of projects that have reduced the generation of hazardous waste or the release of pollutants or contaminants; and

(v) a discussion of the operational decisions made at the facility that have affected the achievement of the source reduction or waste minimization goals or other risk reduction efforts.

(2) Small quantity generators/non-TRI Form R reporters. For facilities that are small quantity generators as defined in §335.1 [~~§335.471(12)~~] of this title and are not TRI Form R reporters [~~as defined in §335.471(15) of this title~~], the plan shall include, at a minimum:

(A) a description of the facility which shall include:

(i) name of the facility;

(ii) mailing and physical address;

(iii) point-of-contact, including phone numbers and electronic mail (e-mail) address, if available;

(iv) general description of the facility; and

(v) applicable identification numbers, including: TCEQ solid waste registration number and EPA identification number;

(B) a list of all hazardous wastes generated and the volume of each;

(C) a prioritized list of pollutants and contaminants to be reduced;

(D) a statement of measurable reduction goals;

(E) information on environmental and human health risks, such as material safety data sheets or other available documentation, considered in determining reduction goals;

(F) A list of source reduction and waste minimization projects with an associated schedule of implementation;

(G) an implementation schedule for future reduction goals;

(H) certification that the plan is complete and correct by the owner of the facility or if the facility is owned by a corporation, by an officer of the corporation that owns the facility who has the authority to commit the corporation's resources to implement the plan. A copy of the certification must be submitted to the commission; and

(I) an executive summary of the plan submitted to the commission that shall include at a minimum:

(i) a description of the facility that shall include:

(I) name of facility;

(II) mailing and physical address;

(III) point-of-contact, including a phone number and email, if available;

(IV) EPA identification number and TCEQ solid waste registration number;

(V) primary SIC code; and if applicable, NAICS;

(VI) the specific time period the five-year plan is in effect;

(ii) a projection of the amount of hazardous waste that the facility will generate (based on what is reported as hazardous waste under §335.9 of this title (relating to Record Keeping and Annual Reporting Procedures Applicable to Generators)) at the end of the five-year period that the plan is in place;

(iii) prioritized list of pollutants and contaminants to be reduced;

(iv) a list of source reduction activities associated with reductions of pollutants and contaminants identified under subparagraph (C) of this paragraph.

(J) The executive summary of the plan may include:

(i) a discussion of the person's previous effort at the facility to reduce hazardous waste or the release of pollutants or contaminants through the pollution prevention plan;

(ii) a discussion of the effect that changes in environmental regulations have had on the achievement of the source reduction and waste minimization goals;

(iii) the effects that events the person could not control have had on the achievement of the source reduction and waste minimization goals;

(iv) a discussion of the operational decisions the person has made that have affected the achievement of the source reduction and waste minimization goals; and

(v) identification and description of cases where the implementation of source reduction and waste minimization activities designed to reduce risk to human health or the environment may result in the release of a different pollutant or contaminant or may shift the release to another medium. Included in this description shall be a discussion of the change in characteristic of the normal waste stream or release and how it will be managed in the affected medium.

§335.477. Exemptions.

This subchapter does not apply to:

(1) facilities regulated by the Railroad Commission of Texas under the Natural Resources Code, §91.101 or §141.012;

(2) owners and operators of facilities listed in §335.473 of this title (relating to Applicability) who may apply on a case-by-case basis to the executive director for an exemption from this subchapter. The executive director may grant an exemption if the applicant demonstrates that sufficient reductions have been achieved. If an exemption is granted, it is valid only for the following year, but can be renewed, on an annual basis, by filing a new application. The executive director's decision will be based upon the following standards and criteria for determining practical economic and technical completion of the plan:

(A) the facility has reduced the amount of pollutants and contaminants being generated or released by 90% since the base year;

(B) potential impact on human health and the environment of any remaining hazardous waste generated, or pollutant or contaminant released; and

(C) a demonstration that additional reductions are not economically and technically feasible.

~~[(3) facilities that have an environmental management system (EMS) that meets the requirements and is approved by the executive director, as described in §90.36 of this title (relating to Evaluation of an Environmental Management System by the Executive Director) and report annually under the EMS program.]~~

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER R. WASTE CLASSIFICATION

30 TAC §§335.503, 335.504, 335.510, 335.511, 335.513, 335.521

Statutory Authority

The amendments are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendments implement THSC, Chapter 361.

§335.503. Waste Classification and Waste Coding Required.

(a) All industrial solid and municipal hazardous waste generated, stored, processed, transported, or disposed of in the state shall be classified according to the provisions of this subchapter.

(1) All solid waste shall be classified at the point of generation of the waste. A generator may not dilute a waste to avoid a Class 1 classification; however, combining nonhazardous waste streams for subsequent legitimate processing, storage, or disposal does not constitute dilution and is acceptable. Wastes shall be classified prior to, and following any type of processing or mixing of the waste. Hazardous waste and industrial solid waste are subject to the waste management requirements of this chapter.

(2) All industrial solid and municipal hazardous waste shall be classified as either:

(A) hazardous;

(B) Class 1;

(C) Class 2; or

(D) Class 3.

(3) A person who generates a solid waste shall first determine if that waste is hazardous pursuant to §335.504 of this title (relating to Hazardous Waste Determination).

(4) After making the hazardous waste determination as required in paragraph (3) of this subsection, if the waste is determined to be nonhazardous, the generator shall then classify the waste as Class 1, Class 2, or Class 3, pursuant to §§335.505 - 335.507 of this title (relating to Class 1 Waste Determination, Class 2 Waste Determination, and Class 3 Waste Determination) using one or more of the following methods:

(A) use the criteria for waste classification as provided in §§335.505 - 335.507 of this title;

(B) use process knowledge as provided in §335.511 of this title (relating to Use of Process Knowledge);

(C) classify the waste as directed under §335.508 of this title (relating to Classification of Specific Industrial Wastes); or

(D) choose to classify a nonhazardous waste as Class 1 without any analysis to support that classification. However, documentation (analytical data and/or process knowledge) is necessary to classify a waste as Class 2 or Class 3, pursuant to §335.513 of this title (relating to Documentation Required).

(b) All industrial solid waste and municipal hazardous waste generated, stored, processed, transported or disposed of in the state shall be coded with an eight-digit waste code number that consists of a four-character sequence number followed by a three-digit form code provided in §335.521(c) of this title (relating to Appendix 3) followed by one-character, H, 1, 2, or 3, depicting the waste classification identified in subsection (a)(2) of this section. Procedures for assigning sequence numbers are outlined as follows [~~which shall include a four-digit waste sequence number, a three-digit form code, and a one-character classification (either H, 1, 2, or 3). Form codes are provided in §335.521(c) of this title (relating to Appendix 3). Procedures for assigning waste code numbers and sequence numbers are outlined as follows and available from the agency at the address listed in §335.521(b) of this title (relating to Appendix 2)~~].

(1) The four-character sequence number consists of alpha and/or numeric characters [~~A waste code is represented by the following 8-digit character string: sequence number + form code + classification code (H, 1, 2, or 3)~~].

(2) Registered generators must assign a unique numeric sequence number between 0001 to 9999 to each individual waste. Sequence numbers need not be assigned in sequential order [~~In-state generators will assign a unique four-digit sequence number to each individual waste. These sequence numbers will range from 0001 to 9999. They need not be assigned in sequential order. An in-state registered generator may choose to request the executive director assign a sequence number to a specific waste which is not regularly generated by a facility and is being shipped as a one-time shipment or choose to add that waste to the regular sequence numbers on a notice of registration. Sequence numbers provided by the executive director may be a combination of alpha and numeric characters~~].

(3) The executive director will provide [~~in-state~~] unregistered generators a [~~four-digit~~] sequence number for each regulated waste it generates, which may be a combination of alpha and numeric characters.

(4) Generators of wastes resulting from a spill may obtain a sequence number for the spill related wastes from the agency's Emergency Response Section.

(5) Out-of-state generators must use the sequence number "OUTS" as the first four characters of the waste code [~~will use the sequence code "OUTS" in the first four digits of the waste code~~].

(6) A generator that meets the conditions of an applicable exemption from manifesting requirements that manifests their hazardous and/or Class 1 nonhazardous waste must use the sequence number "VSQG" as the first four characters of the waste code [~~CESQGs or industrial Class 1 non-hazardous waste generators that are exempt from manifesting as specified in §335.10 of this title (relating to Shipping and Reporting Procedures Applicable to Generators of Hazardous Waste or Class 1 Waste and Primary Exporters of Hazardous Waste) who voluntarily manifest their hazardous and or Class 1 nonhazardous waste may use "CESQ" as the first four digits of the waste code~~].

(7) A facility which receives and consolidates like waste from a person who meets the conditions for exemption for a very small quantity generator and generated less than 100 kilograms of non-acute hazardous waste, 1 kilogram of acute hazardous waste, and 100 kilograms of Class 1 industrial waste in the calendar month during which the waste was generated must use the sequence number "VSQG" as the first four characters of the waste code for any manifesting and/or reporting associated with that waste [~~Municipal Conditionally Exempt Small Quantity Generators should use "CESQ" in the first four positions of the waste code for any manifesting and/or reporting associated with that waste~~].

(8) A facility which receives a waste from off-site and consolidates that waste with other like waste received from off-site, other than its own (thus not changing the form code of the waste stream or its composition, hazardous waste classification, or Texas waste class), or stores a waste without treating, processing (as defined in §335.1 of this title (relating to Definitions), and without changing the form or composition of that waste may use the sequence number "TSDF" as the first four characters of the waste code. The sequence number TSDF may not be used to identify wastes which are treated or altered or combined with unlike wastes. The sequence number TSDF is only to be used by facilities that store and/or accumulate a quantity of wastes from more than one site for subsequent shipment to a treatment or disposal facility. [~~A facility which receives a waste and consolidates that waste with other like waste, other than its own, (thus not changing the form code of the waste stream or its composition, hazardous, or Texas waste class), or stores a waste without treating, processing (as defined in §335.1 of~~

this title (relating to Definitions)), or changing the form or composition of that waste may ship that waste to a storage, treatment, or disposal facility using the sequence code "TSDF" in the first four positions of the waste code. This does not pertain to wastes which are treated or altered or combined with unlike wastes. This "TSDF" designation is only to be used by facilities that store and/or accumulate a quantity of wastes from more than one site for subsequent shipment to a treatment or disposal facility. Manifest documents must note a final destination designated to receive a consolidated waste. The designated "final destination" receiving facility noted on the manifest must be a permitted facility in order to terminate the manifest, unless the waste is nonhazardous and does not require manifesting in accordance with §335.10(e) of this title and is going to a facility described in §335.10(e) of this title. A consolidated waste shipped to a non-permitted facility prior to being shipped to the final destination must proceed with the original manifests (noted with any appropriate changes) to the facility designated on the manifest for final handling.]

(9) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a designated facility must use the sequence number "PHRM" as the first four characters of the waste code.

§335.504. Hazardous Waste Determination

(a) Hazardous waste determination. A person who generates a solid waste, as defined in §335.1 of this title (relating to Definitions), must make an accurate determination as to whether that waste is a hazardous waste in order to ensure wastes are properly managed according to applicable Resource Conservation and Recovery Act (RCRA) and Texas Administrative Code regulations. The hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste such that the RCRA classification of the waste may change. A hazardous waste determination is made using the following steps [must determine if that waste is hazardous using the following method]:

(1) A person must determine whether the material is excluded or exempted from regulation as a solid waste or as hazardous waste under the definition of solid waste in §335.1 of this title or identified in 40 Code of Federal Regulations (CFR) Part 261, Subpart A as amended in the *Federal Register* through February 22, 2019 (84 FR 5816), or Subpart E as amended in the Federal Register through August 6, 2018 (83 FR 38262) [Determine if the material is excluded or exempted from being a solid waste or hazardous waste per §335.1 of this title (relating to Definitions)] or identified in 40 Code of Federal Regulations (CFR) Part 261, Subpart A or E, as amended through November 28, 2016 (81 FR 85696)].

(2) If the waste is not excluded from regulation as a solid waste, the person must then use knowledge of the waste to determine whether the waste is a hazardous waste because it meets any of the listing descriptions, or is mixed with or derived from a waste that meets any of the listing descriptions identified in 40 CFR Part 261, Subpart D, as amended in the *Federal Register* through February 22, 2019 (84 FR 5816). Acceptable knowledge that may be used in making an accurate determination as to whether the waste is listed may include waste origin, composition, the process producing the waste, feedstock, and other reliable and relevant information [If the material is a solid waste, determine if the waste is listed as, or mixed with, or derived from a listed hazardous waste identified in 40 CFR Part 261, Subpart D, as amended through April 13, 2012 (77 FR 22229)].

(3) The person must also determine whether the waste exhibits one or more hazardous characteristics as identified in 40 CFR Part 261, Subpart C, as amended in the *Federal Register* through March 18, 2010 (75 FR 12989) by following the procedures in subparagraph (A) or (B) of this paragraph or a combination of both [If the material is a solid waste, determine whether the waste exhibits any characteristics of a hazardous waste as identified in 40 CFR Part 261, Subpart C, as amended through March 18, 2010 (75 FR 12989)].

(A) The person must apply knowledge of the hazard characteristic of the waste in light of the materials or the processes used to generate the waste. Acceptable knowledge may include process knowledge (e.g., information about chemical feedstocks and other inputs to the production process); knowledge of products, by-products, and intermediates produced by the manufacturing process; chemical or physical characterization of wastes; information on the chemical and physical properties of the chemicals used or produced by the process or otherwise contained in the waste; testing that illustrates the properties of the waste; or other reliable and relevant information about the properties of the waste or its constituents. A test other than a test method set forth in 40 CFR Part 261, Subpart C or an equivalent test method approved by the United States Environmental Protection Agency (EPA) Administrator under 40 CFR §260.21, or by the executive director under §335.509 of this title (relating to Waste Analysis), may be used as part of a person's knowledge to determine whether a solid waste exhibits a characteristic of hazardous waste. However, such tests do not, by themselves, provide definitive results. Persons testing their waste must obtain a representative sample, as defined in §335.1 of this title, of the waste for the testing,

(B) When available knowledge is inadequate to make an accurate determination, the person must test the waste according to the applicable methods set forth in 40 CFR Part 261, Subpart C or according to an equivalent method approved by the EPA Administrator under 40 CFR §260.21, or approved by the executive director under §335.509 of this title, and in accordance with the following:

(i) Persons testing their waste must obtain a representative sample, as defined in §335.1 of this title, of the waste for the testing.

(ii) Where a test method is specified in 40 CFR Part 261, Subpart C, the results of the regulatory test, when properly performed, are definitive for determining the regulatory status of the waste.

(b) Recordkeeping for small or large quantity generators. A large quantity generator and a small quantity generator shall maintain records supporting its hazardous waste determinations in accordance with 40 CFR §262.11(f) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(c) Recordkeeping for hazardous waste and Class 1 waste generators. Generators shall make and maintain records of a hazardous waste determination in accordance with §335.513 of this title (relating to Documentation Required), and 40 CFR §262.11(f) as adopted under §335.53 of this title.

§335.510. Sampling Documentation.

(a) Generators who use analytical data to classify their waste pursuant to §335.509 of this title (relating to Waste Analysis) must maintain documentation of their sampling procedures in accordance with this section and 40 Code of Federal Regulations §262.11(f) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(b) The sampling documentation must, at a minimum, include the following:

(1) dates samples were collected;

(2) a description of the site or unit from which the sample is taken and sampling location(s) at the site unit;

(3) sample methods and sample equipment utilized; and

(4) description of sample handling techniques, including containerization, preservation, and chain of custody.

(c) Generators shall document all the information listed in subsection (b) of this section, and shall retain copies on-site in accordance with §335.513 of this title (relating to Documentation Required).

(d) Generators who have existing sampling documentation, which includes the information listed in subsection (b) of this section, do not need to prepare any new documentation specifically for this section.

§335.511. Use of Process Knowledge.

(a) Generators using knowledge of the waste and the process producing the waste to classify or assist in classifying a waste as hazardous shall comply with §335.504 of this title (relating to Hazardous Waste Determination). Generators using knowledge of the waste to classify or assist in classifying a waste as Class 1, Class 2, or Class 3 shall comply with this section and consider the waste origin, composition, the process producing the waste, feedstock, and other reliable and relevant information [~~Generators may use their existing knowledge about the process to classify or assist in classifying a waste as hazardous, Class 1, Class 2, or Class 3~~]. Process knowledge must be documented and maintained on-site pursuant to §335.513 of this title (relating to Documentation Required), and 40 CFR §262.11(f) as adopted by reference under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste). Material safety data sheets, manufacturers' literature, and other documentation generated in conjunction with a particular process may be used to classify a waste provided that the literature provides reliable and relevant [~~sufficient~~] information about the waste and addresses the criteria set forth in §§335.504 - 335.508 of this title (relating to Hazardous Waste Determination, Class 1 Waste Determination, Class 2 Waste Determination, Class 3 Waste Determination, and Classification of Specific Industrial Solid Wastes). For classes other than hazardous or Class 1, a generator must be able to demonstrate requisite knowledge of his or her process by satisfying all of the following.

(1) The generator must have a full description of the process, including a list of chemical constituents that enter the process. Constituents listed in Appendix 1 in §335.521 of this title (relating to Appendices) [~~of this subchapter~~] must be addressed in this description.

(2) The generator must have a full description of the waste, including a list of chemical constituents likely to be in the waste. This list should be based on paragraph (1) of this subsection.

(3) The generator may develop a subset of Appendix 1 of §335.521 of this title constituents by which to evaluate the waste utilizing the information from paragraphs (1) and (2) of this subsection.

(4) Documentation of the waste classification must be maintained and, if requested or required, provided to the executive director pursuant to §335.513 of this title.

(b) If the total concentration of the constituents demonstrates that individual analytes are not present in the waste, or that they are present but at such low concentrations that the appropriate maximum leachable concentrations could not possibly be exceeded, the Toxicity Characteristic Leaching Procedure (TCLP) [~~TCLP~~] extraction procedure discussed in §335.505(1) of this title need not be run. If an analysis of any one of the liquid fractions of the TCLP extract indicates that a regulated constituent is present at such high concentrations that, even after accounting for dilution from the other fractions of the extract, the concentration would be equal to or greater than the maximum leachable concentration for that constituent, then the waste is Class 1, and it is not necessary to analyze the remaining fractions of the extract.

§335.513. Documentation Required.

(a) Documentation on each waste stream is required to be maintained by the generator in accordance with the requirements of this subchapter, [~~and in accordance with~~] §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), and 40 Code of Federal Regulations §262.11(f) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(b) The following documentation shall be submitted by the generator to the executive director prior to waste shipment or disposal and not later than 90 days of initial waste generation:

(1) description of waste;

(2) date of initial waste generation;

(3) description of process that generated the waste;

(4) hazardous waste determination;

(5) all analytical data and/or process knowledge allowed under §335.511 of this title (relating to Use of Process Knowledge) used to characterize Class 3 wastes, including quality control data; and

(6) waste classification determination.

(c) The following documentation shall be maintained by the generator on site immediately upon waste generation and for a minimum of three years after the waste is no longer generated or stored or until site closure:

(1) all information required under subsection (b) of this section;

(2) all analytical data and/or process knowledge allowed under §335.511 of this title used to characterize hazardous, Class 1, Class 2, and Class 3 wastes, including quality control data.

(d) The executive director may request that a generator submit all documentation listed in subsections (b) and (c) of this section for auditing the classification assigned. Documentation requested under this section shall be submitted within ten working days of receipt of the request.

(e) Any changes to the information required in sections (b) and (c) of this subsection shall be maintained or submitted according to the timing requirements of this section.

(f) A generator may request information provided to the agency remain confidential in accordance with the Texas Open Records Act, the Texas Government Code, Chapter 552.

§335.521. Appendices.

(a) Appendix 1.

(1) Table 1.
Figure: 30 TAC §335.521(a)(1) (No change.)

(2) Table 2.
Figure: 30 TAC §335.521(a)(2)
[~~Figure: 30 TAC §335.521(a)(2)~~]

(3) Table 3.
Figure: 30 TAC §335.521(a)(3) (No change.)

(b) Appendix 2.
Figure: 30 TAC §335.521(b)
[~~Figure: 30 TAC §335.521(b)~~]

(c) Appendix 3.
Figure: 30 TAC §335.521(c)
[~~Figure: 30 TAC §335.521(c)~~]

(d) Appendix 4.

Figure: 30 TAC §335.521(d) (No change.)

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER T. PERMITTING STANDARDS FOR OWNERS AND OPERATORS OF COMMERCIAL INDUSTRIAL NONHAZARDOUS WASTE LANDFILL FACILITIES

30 TAC §335.590

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.590. Operational and Design Standards.

The following requirements, including those applicable to municipal solid waste facilities, apply to owners and operators of facilities subject to this subchapter:

(1) §330.121 of this title (relating to General);

(2) §330.123 of this title (relating to Pre-operation Notice);

(3) §330.125 of this title (relating to Recordkeeping Requirements), except that the requirements under §330.125(b)(3) of this title concerning recordkeeping for gas monitoring and remediation plans relating to explosive and other gases do not apply, except as determined necessary by the executive director;

(4) §330.127 of this title (relating to Site Operating Plan);

(5) §330.129 of this title (relating to Fire Protection);

(6) §330.131 of this title (relating to Access Control);

(7) §330.133(a) - (c) of this title (relating to Unloading of Waste);

(8) §330.137 of this title (relating to Site Sign);

(9) §330.139 of this title (relating to Control of Windblown Waste and Litter);

(10) §330.141 of this title (relating to Easements and Buffer Zones);

(11) §330.143(a) of this title (relating to Landfill Markers and Benchmark);

(12) §330.149 of this title (relating to Odor Management Plan);

(13) §330.153 of this title (relating to Site Access Roads);

(14) §330.155 of this title (relating to Salvaging and Scavenging);

(15) §330.157 of this title (relating to Endangered Species Protection);

(16) §330.159 of this title (relating to Landfill Gas Control) as determined necessary by the executive director;

(17) §330.161 of this title (relating to Oil, Gas, and Water Wells);

(18) §330.163 of this title (relating to Compaction);

(19) §330.165 of this title (relating to Landfill Cover);

(20) §330.167 of this title (relating to Ponded Water);

(21) §330.175 of this title (relating to Visual Screening of Deposited Waste);

(22) §330.207 of this title (relating to Contaminated Water Management);

(23) the owner or operator shall have and follow procedures for the suppression and control of dust; and

(24) the owner or operator shall ensure that each commercial industrial nonhazardous waste landfill unit meets the requirements of subparagraphs (A) - (F) of this paragraph.

(A) Design criteria.

(i) Landfill cells shall be designed and constructed in accordance with subclause (I) or (II) of this clause, and shall also be constructed in accordance with subclause (III) of this clause.

(I) a design that ensures that the concentration values for constituents listed in §330.419(a) of this title (relating to Constituents for Detection Monitoring) will not be exceeded in the uppermost aquifer at the point of compliance, as specified by the executive director under clause (iv) of this subparagraph; or

(II) a composite liner, as defined in clause (ii) of this subparagraph, and a leachate collection system that is designed and constructed in accordance with subparagraph (B) of this paragraph; and

(III) unless the executive director approves an engineered design that the applicant has demonstrated will provide equal or greater protection to human health and the environment, a landfill cell must be constructed where the base of the containment structure, which includes the sides and bottom of the containment structure, is at least five feet above the uppermost saturated soil unit

having a Unified Soil Classification of GW (well-graded gravel), GP (poorly-graded gravel), GM (silty gravel), GC (clayey gravel), SW (well-graded sand), SP (poorly-graded sand), or SM (silty sand), or a hydraulic conductivity greater than 1 x 10^{-5} cm/sec, unless such saturated soil unit is not sufficiently thick and laterally continuous to provide a significant pathway for waste migration.

(ii) For purposes of this section, "composite liner" means a system consisting of two components. The upper component shall consist of a minimum 30-mil (0.75 mm) geomembrane liner and the lower component shall consist of at least a three-foot layer of compacted soil with a hydraulic conductivity of no more than 1 x 10-7 cm/sec. Geomembrane liner components consisting of high density polyethylene shall be at least 60-mil thick. The geomembrane liner component must be installed in direct and uniform contact with the compacted soil component.

(iii) When approving a design that complies with clause (i)(I) of this subparagraph, the executive director may consider at least the following factors:

(I) the hydrogeologic characteristics of the facility and surrounding land;

(II) the climatic factors of the area; and

(III) the volume and physical and chemical characteristics of the leachate.

(iv) For purposes of this paragraph, the point of compliance is defined in §330.3 of this title (relating to Definitions). In determining the point of compliance, the executive director may consider at least the following factors:

(I) the hydrogeologic characteristics of the facility and surrounding land;

(II) the volume and physical and chemical characteristics of the leachate;

(III) the quantity, quality, and direction of flow of groundwater;

(IV) the proximity and withdrawal rate of the groundwater users;

(V) the availability of alternative drinking water supplies;

(VI) the existing quality of the groundwater, including other sources of contamination and their cumulative impacts on the groundwater and whether groundwater is currently used or reasonably expected to be used for drinking water;

(VII) public health, safety, and welfare effects; and

(VIII) practicable capability of the owner or operator.

(B) Landfill cells shall have a leachate-collection system designed and constructed to maintain less than a 30-cm depth of leachate over the liner. The leachate-collection and leachate-removal system shall be:

(i) constructed of materials that are chemically resistant to the leachate expected to be generated;

(ii) of sufficient strength and thickness to prevent collapse under the pressures exerted by overlying wastes, waste cover materials, and by any equipment used at the landfill; and

(iii) designed and operated to function through the scheduled closure and post-closure period of the landfill.

(C) Storm water run-on/run-off facilities such as berms and ditches shall be provided in accordance with §330.63 of this title (relating to Contents of Part III of the Application).

(D) The site shall have a groundwater monitoring system installed that is capable of detecting the migration of pollutants from the landfill and is sampled semiannually for the parameters specified in Chapter 330, Subchapter J of this title (relating to Groundwater Monitoring and Corrective Action).

(E) The final cover placed over the commercial industrial nonhazardous waste landfill unit shall consist of a minimum of 18 inches of uncontaminated topsoil overlying four feet of compacted clay-rich soil material meeting the requirements of §330.457 of this title (relating to Closure Requirements for Municipal Solid Waste Landfill Units That Receive Waste on or after October 9, 1993). The final cover over the aerial fill shall meet the requirements of §330.457 of this title and shall include a flexible membrane component.

(F) Nonhazardous waste may be placed above natural grade in commercial industrial nonhazardous waste landfill units provided the conditions in clauses (i) - (vi) of this subparagraph are met, except as provided in clause (vii) of this subparagraph:

(i) waste placed above grade shall be laterally contained by dikes that are constructed to:

(I) prevent washout, release, or exposure of waste;

(II) be physically stable against slope failure, with a minimum safety factor of 1.5;

(III) prevent washout from hydrostatic and hydrodynamic forces from storms and floods;

(IV) prevent storm water from reaching the waste;

(V) minimize release of leachate; and

(VI) minimize long-term maintenance;

(ii) the liner required in paragraph (22) of this section shall extend to the crest of the dike;

(iii) waste placed against the dike is placed no higher that three feet below the crest of the dike;

(iv) the slope of the wastes placed in the commercial industrial nonhazardous waste landfill units does not exceed 3% to the center of the unit;

(v) no waste is placed higher than the lowest elevation of the dike crest; and

(vi) a dike certification report is submitted with Attachment 10 of Part III of the permit application. The certification shall be in the following form:
Figure: 30 TAC §335.590(24)(F)(vi) (No change.)

(vii) a commercial industrial nonhazardous waste landfill is not subject to the requirements of clauses (ii) - (v) of this subparagraph provided that the owner or operator submits a demonstration that the standards of clause (i) of this subparagraph can be met without meeting the requirements of clauses (ii) - (v) of this subparagraph, the demonstration is approved in writing by the executive director, and the owner or operator enters the approval into the facility operating record.

(25) Hazardous waste generated by a very small quantity generator that meets the conditions for exemption for a very small quantity generator [from a conditionally exempt small quantity generator as defined in §335.78(a) of this title (relating to Special Requirements for Hazardous Waste Generated by Conditionally Exempt Small Quantity Generators),] may be accepted for disposal in a [any] commercial industrial nonhazardous waste landfill facility provided the amount of hazardous waste accepted from each very [conditionally exempt] small quantity generator does not exceed 220 pounds (100 kilograms) a calendar month, and provided the landfill owner or operator is willing to accept the hazardous waste.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER U. STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE FACILITIES OPERATING UNDER A STANDARD PERMIT

30 TAC §335.602

Statutory Authority

The amendment is proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendment is also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendment implements THSC, Chapter 361.

§335.602. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 267 (including all appendices to 40 CFR Part 267) are adopted by reference as amended in the *Federal Register* through September 8, 2005 (70 FR 53420) and as further amended and adopted as indicated in each paragraph of this subsection:

(1) 40 CFR Part 267, Subpart B--General Facility Standards;

(2) 40 CFR Part 267, Subpart C--Preparedness and Prevention:

(3) 40 CFR Part 267, Subpart D--Contingency Plan and Emergency Procedures;

(4) 40 CFR Part 267, Subpart E--Recordkeeping, Reporting, and Notifying (as amended in the *Federal Register* through November 28, 2016 (81 FR 85732 [85696]);

(5) 40 CFR Part 267, Subpart F--Releases from Solid Waste Management Units;

(6) 40 CFR Part 267, Subpart G--Closure;

(7) 40 CFR Part 267, Subpart I--Use and Management of Containers;

(8) 40 CFR Part 267, Subpart J--Tank Systems;

(9) 40 CFR Part 267, Subpart DD--Containment buildings; and

(10) 40 CFR §267.142, concerning Cost estimate for closure.

(b) The regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality or to the commission, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B.

(2) Reference to:

(A) 40 CFR Part 261 is changed to §335.504 of this title (relating to Hazardous Waste Determination);

(B) 40 CFR Part 262 is changed to Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste):

(C) 40 CFR §264.1 is changed to §335.151 of this title (relating to Purpose, Scope, and Applicability);

(D) Reference to 40 CFR Part 264, Subpart D is changed to §335.152(a)(3) of this title (relating to Standards) and §335.153 of this title (relating to Reporting of Emergency Situations by Emergency Coordinator);

(E) 40 CFR Part 264, Subpart S is changed to §335.152(a)(14) of this title;

(F) 40 CFR Part 265 is changed to Subchapter E of this chapter (relating to Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities);

(G) 40 CFR Part 268 is changed to Subchapter O of this chapter (relating to Land Disposal Restrictions);

(H) 40 CFR Part 270, Subpart J is changed to Chapter 305, Subchapter R of this title (relating to Resource Conservation and Recovery Act Standard Permits for Storage and Treatment Units);

(I) 40 CFR §262.16 or §262.17 are [§262.34 is] changed to §335.53 [§335.69] of this title (relating to General Standards Applicable to Generators of Hazardous Waste [Accumulation Time]);

(J) 40 CFR §264.101 is changed to §335.167 of this title (relating to Corrective Action for Solid Waste Management Units); and

(K) Reference to "standardized permit" is changed to "standard permit".

(3) 40 CFR Parts 260 - 270 means the commission's rules including, but not limited to, Chapters 50, 305, and 335 of this title (relating to Action on Applications and Other Authorizations; Consolidated Permits; and Industrial Solid Waste and Municipal Hazardous Waste, respectively), as applicable.

(c) An owner or operator of a unit that treats, stores, or disposes of hazardous waste in tanks, containers, and containment buildings authorized by a standard permit as specified in this section shall establish and maintain financial assurance in accordance with Chapter 37, Subchapter P of this title (relating to Financial Assurance for Hazardous and Nonhazardous Industrial Solid Waste Facilities).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER V. STANDARDS FOR RECLAMATION OF HAZARDOUS SECONDARY MATERIALS

30 TAC §335.702, §335.703

Statutory Authority

The amendments are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The amendments are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed amendments implement THSC, Chapter 361.

§335.702. Standards.

(a) The following regulations contained in 40 Code of Federal Regulations (CFR) Part 261 (including all appendices to 40 CFR Part 261) are adopted by reference as amended and adopted in the CFR through January 13, 2015 (80 FR 1694) and as further amended and adopted as indicated in each paragraph of this subsection:

(1) 40 CFR Part 261, Subpart I--Use and Management of Containers;

(2) 40 CFR Part 261, Subpart J--Tank Systems:

(3) 40 CFR Part 261, Subpart M--Emergency Preparedness and Response for Management of Excluded Hazardous Secondary Materials as amended through November 28, 2016 (81 FR 85732), except all references to "operating under a verified recycler variance under 40 CFR §260.31(d)";

(4) 40 CFR Part 261, Subpart AA--Air Emission Standards for Process Vents;

(5) 40 CFR Part 261, Subpart BB--Air Emission Standards for Equipment Leaks; and

(6) 40 CFR Part 261, Subpart CC--Air Emission Standards for Tanks and Containers.

(b) The regulations of the United States Environmental Protection Agency (EPA) that are adopted by reference in this section are adopted subject to the following changes.

(1) The term "regional administrator" is changed to the "executive director" of the Texas Commission on Environmental Quality, consistent with the organization of the commission as set out in Texas Water Code, Chapter 5, Subchapter B;

(2) 40 CFR §260.10 is changed to §335.1 of this title [~~chapter~~] (relating to Definitions);

(3) The terms "EPA" and "Environmental Protection Agency" are changed to "Texas Commission on Environmental Quality."

§335.703. Financial Assurance Requirements.

(a) Applicability.

(1) The requirements of this section apply to owners or operators of reclamation facilities and intermediate facilities managing hazardous secondary materials excluded under 40 Code of Federal Regulations (CFR) §261.4(a)(24), except:

(2) States and the Federal government are exempt from the financial assurance requirements of this section.

(b) When used in this section, the following words and terms shall have the same meanings as the definitions in §37.11 and §335.1 of this title (relating to Definitions) except:

(1) Closure--Includes the activities under §335.8 of this title (relating to Closure and Remediation) and applicable closure requirements of 40 CFR Parts 264 and 265.

(2) Closure plan--Includes the removal and decontamination plan for release as set out in §335.705 of this title (relating to Removal and Decontamination Plan for Release).

(c) Owners and operators of a reclamation facility or an intermediate facility required by 40 CFR §261.4(a)(24) to provide financial assurance, shall establish and maintain financial assurance for removal and decontamination and corrective action as a condition of the exclusion under 40 CFR §261.4(a)(24) and comply with Chapter 37, Subchapters A and B of this title (relating to General Financial Assurance Requirements; and Financial Assurance Requirements for Closure, Post Closure, and Corrective Action) except:

(1) an owner or operator must submit an acceptable originally signed mechanism to the executive director prior to [~~receiving a variance for~~] the management of hazardous secondary materials under the exclusion in 40 CFR §261.4(a)(24);

(2) in addition to the reasons to draw specified in §37.101 of this title (relating to Drawing on the Financial Assurance Mechanisms), the executive director may draw on the financial assurance mechanism(s) following a determination by the executive director that the hazardous secondary materials do not meet the conditions of the exclusion under 40 CFR §261.4(a)(24).

(d) Owners or operators of a reclamation facility or intermediate facility required by 40 CFR §261.4(a)(24) to provide financial assurance must comply with Chapter 37, Subchapter C of this title (relating to Financial Assurance Mechanisms for Closure, Post Closure, and Corrective Action), by establishing financial assurance for removal and decontamination and corrective action using any of the following mechanisms as specified in Chapter 37, Subchapter C of this title:

(1) Trust fund (fully funded), except reimbursements to the owner or operator as specified under §37.201(j) of this title (relating to Trust Fund) may only be made if the owner or operator begins final closure under the applicable requirements of 40 CFR Part 264 or 265;

(2) Surety bond guaranteeing payment, except:

(A) the bond must guarantee that the owner or operator will fund the standby trust fund in an amount equal to the penal sum of the bond before the loss of the exclusion under 40 CFR §261.4(a)(24) rather than the criteria set out in §37.211(d) of this title (relating to Surety Bond Guaranteeing Payment); and

(B) the alternate financial assurance to be provided by the Principal must meet the requirements specified in this section;

(3) Irrevocable standby letter of credit, except:

(A) the executive director may draw pursuant to subsection (c)(2) of this section in addition to §37.231 of this title (relating to Irrevocable Standby Letter of Credit); and

(B) alternate financial assurance must meet the requirements specified in this section;

(4) Financial test, except:

(A) the financial assurance amounts required by this section, for hazardous secondary materials must be included as an additional environmental obligation when determining eligibility for the financial test in accordance with §37.251 of this title (relating to Financial Test); and

(B) alternate financial assurance must meet the requirements of this section;

(5) Corporate guarantee except:

(A) the terms of the guarantee specified in §37.261(e)(1) of this title (relating to Corporate Guarantee), shall provide that following a determination by the executive director that the hazardous secondary materials at the owner or operator's facility covered by this guarantee do not meet the requirements of the exclusion under 40 CFR §261.4(a)(24) the guarantor will dispose of any hazardous secondary material as hazardous waste and close the facility in accordance with the applicable closure requirements of 40 CFR Part 264 or 265, or establish a trust fund as specified in this section, in the name of the owner or operator in the amount of the current cost estimate; and

(B) the terms of the guarantee requiring alternate financial assurance in §37.261(e)(3) of this title must meet the requirements of this section.

(e) Owners or operators of a reclamation facility or intermediate facility required by 40 CFR §261.4(a)(24) to provide financial assurance for removal and decontamination and corrective action shall comply with the wording requirements of Chapter 37, Subchapter D of this title (relating to Wording of the Mechanisms for Closure, Post Closure and Corrective Action) for the mechanisms indicated in subsection (d) of this section except:

(1) the phrases in the Payment Bond under §37.311 of this title (relating to Payment Bond) shall be revised by:

(A) replacing the following language identified here by quotation marks "Now, therefore, the conditions of the obligation are such that if the Principal shall faithfully, before the beginning of final closure of, or corrective action at, each facility identified above, fund into the standby trust fund the amount(s) identified above for the facility," with the following language identified here by quotation marks "Now, therefore, the conditions of the obligation are such that if the Principal shall faithfully, before the beginning of final closure of, or corrective action at, each facility identified above, fund into the standby trust fund the amount(s) identified above for the facility; or, if the Principal shall satisfy all the requirements for exclusion of hazardous secondary materials from classification as solid waste under 40 CFR §261.4(a)(24) and be released from the financial assurance requirements by the executive director"; and

(B) replacing the following language identified here by quotation marks "Or, if the Principal shall provide alternate financial assurance, as specified in 30 Texas Administrative Code, Chapter 37 (relating to Financial Assurance)" with the following language set off here by quotation marks "Or, if the Principal shall provide alternate financial assurance, as specified in 30 Texas Administrative Code, §335.703 (relating to Financial Assurance Requirements)"; and

(C) replacing the certification statement at the end of the Payment Bond with the following statement identified by quotation marks "The persons whose signatures appear below hereby certify that they are authorized to execute this surety bond on behalf of the Principal and Surety(ies) and that the wording of this surety bond is identical to the wording specified in 30 Texas Administrative Code §37.311 (relating to Payment Bond), as modified by 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements), as such regulations were constituted on the date the bond was executed.";

(2) The Chief Financial Officer's letter associated with the financial test specified in §37.351 of this title (relating to Financial Test), shall include the environmental obligations associated with the exclusion in paragraph 5(f) of the Chief Financial Officer's Letter in Figure: 30 TAC §37.351;

(3) The wording of the Corporate Guarantee required by §37.361 of this title (relating to Corporate Guarantee) shall be revised by:

(A) replacing Recital number 4 with "For value received from (owner or operator) (describe consideration and dollar amount), guarantor guarantees to the TCEQ that in the event of a determination by the executive director that the hazardous secondary materials at the owner or operator's facility covered by this guarantee do not meet the conditions of the exclusion under 40 CFR §261.4(a)(24), the guarantor will dispose of any hazardous secondary material as hazardous waste, and close the facility in accordance with the applicable closure requirements of 40 CFR Part 264 or 265, or establish a trust fund as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements) in the name of the (owner or operator) in the amount of the current cost estimate";

(B) replacing Recital number 5 with "Guarantor agrees that if, at the end of any fiscal year before termination of this guarantee, the guarantor fails to meet the financial test criteria, guarantor shall send within 90 days, by certified mail, notice to the TCEQ executive di-

rector and to (owner or operator) that the guarantor intends to provide alternate financial assurance as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements), as applicable, in the name of (owner or operator). Within 120 days after the end of such fiscal year, the guarantor shall establish such financial assurance unless (owner or operator) has done so";

(C) replacing Recital number 7 with "Guarantor agrees that within 30 days after being notified by the TCEQ executive director of a determination that guarantor no longer meets the financial test criteria or is disallowed from continuing as a guarantor of (closure, post closure, or corrective action), guarantor shall establish alternate financial assurance as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements) in the name of (owner or operator) unless (owner or operator) has done so";

(D) replacing Recital number 11 with "Guarantor agrees that if (owner or operator) fails to provide alternate financial assurance as specified in 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements), and obtain written approval of alternate financial assurance from the TCEQ executive director within 90 days after a notice of termination by the guarantor is received by the TCEQ executive director from guarantor, guarantor shall provide such alternate financial assurance in the name of the (owner or operator)"; and

(E) The wording of the certification statement at the end of the Corporate Guarantee shall be replaced with the following language identified by quotation marks "I hereby certify that the wording of this guarantee is identical to the wording specified in 30 Texas Administrative Code §37.361 (relating to Corporate Guarantee) as modified by 30 Texas Administrative Code §335.703 (relating to Financial Assurance Requirements) as such regulations were constituted on the date first above written."

(f) An owner or operator of a reclamation or intermediate facility, or a group of facilities, subject to financial assurance requirements under 40 CFR §261.4(a)(24) shall establish and maintain financial assurance for bodily injury and property damage to third parties caused by sudden accidental occurrences arising from operations of the facility or group of facilities. The owner or operator must have and maintain liability coverage for sudden accidental occurrences in the amount of at least $1 million per occurrence with an annual aggregate of at least $2 million, exclusive of legal defense costs.

(g) An owner or operator of a reclamation or intermediate facility, or group of facilities, with a land-based unit as defined in §335.1 of this title shall establish and maintain financial assurance for bodily injury and property damage to third parties caused by nonsudden accidental occurrences arising from operations of the facility or group of facilities. The owner or operator must have and maintain liability coverage for nonsudden accidental occurrences in the amount of at least $3 million per occurrence with an annual aggregate of at least $6 million, exclusive of legal defense costs.

(h) An owner or operator who must meet the requirements of subsections (f) and (g) of this section may combine the required per-occurrence coverage levels for sudden and nonsudden [~~non-sudden~~] accidental occurrences into a single per-occurrence level, and combine the required annual aggregate level. Owners or operators who combine coverage levels for sudden and nonsudden [~~non-sudden~~] accidental occurrences must maintain liability coverage in the amount of $4 million per occurrence and $8 million annual aggregate.

(i) Owners or operators of a reclamation facility or intermediate facility, or a group of facilities, subject to financial assurance requirements under 40 CFR §261.4(a)(24) must also comply with Chapter 37, Subchapters A and E of this title (relating to General Financial Assurance Requirements; and Financial Assurance Requirements for Liability Coverage) and shall use any of the mechanisms specified in Chapter 37, Subchapter F of this title (relating to Financial Assurance Mechanisms for Liability) to meet the liability requirements of this section except:

(1) liability insurance may only be demonstrated by providing an Endorsement for Liability as specified in §37.641 of this title (relating to Endorsement for Liability); and

(2) when using the financial test in accordance with §37.541 of this title (relating to Financial Test for Liability) the financial assurance amounts required by of this section, for hazardous secondary materials excluded under 40 CFR §261.4(a)(24) must be included as an additional environmental obligation.

(j) An owner or operator of a reclamation facility, an intermediate facility, or a group of facilities required by 40 CFR §261.4(a)(24) to provide financial assurance demonstrating liability coverage shall comply with the requirements of Chapter 37, Subchapter G of this title (relating to Wording of the Mechanisms for Liability) for the mechanisms required by subsection (i) of this section except The Chief Financial Officer's letter associated with the financial test for liability specified in §37.651 of this title (relating to Financial Test for Liability), must include the financial assurance amounts required by this section, for hazardous secondary materials excluded under 40 CFR §261.4(a)(24) as an additional environmental obligation in paragraph 5(f) of the Chief Financial Officer's Letter in Figure: 30 TAC §37.351.

(k) If the state of Texas either assumes legal responsibility for an owner's or operator's compliance with the closure, post closure, corrective action, or liability requirements of this chapter, or assures that funds will be available from state sources to cover those requirements, the owner or operator will be in compliance with the requirements of this chapter if the executive director determines that the state's assumption of responsibility is at least equivalent to the financial mechanisms specified in this chapter. The executive director will evaluate the equivalency of state guarantees principally in terms of certainty of the availability of funds for the required closure, post closure, or corrective action activities, or liability coverage; and the amount of funds that will be made available. The executive director may also consider other factors as the executive director deems appropriate. The owner or operator must submit to the executive director a letter from the State of Texas describing the nature of the state's assumption of responsibility together with a letter from the owner or operator requesting that the state's assumption of responsibility be considered acceptable for meeting the requirements of this chapter. The letter from the state must include the following information: the facility's permit number and/or solid waste registration number, name, physical and mailing addresses, and the amount of funds for closure, post closure, or corrective action or liability coverage that are guaranteed by the state. The executive director will notify the owner or operator of the determination regarding the acceptability of the state's guarantee in lieu of financial mechanisms specified in this chapter. The executive director may require the owner or operator to submit additional information as is deemed necessary to make this determination. Upon approval by the executive director, the owner or operator will be deemed to be in compliance with the requirements of this chapter. If the State of Texas' assumption of responsibility is found acceptable as specified in this section except for the amount of funds available, the owner or operator may satisfy the requirements of this chapter by use of both the state's assurance and additional financial mechanisms as specified in this chapter. The amount of funds available through the state and the owner or operator's mechanisms shall equal at least the required amount.

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SUBCHAPTER W. MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

30 TAC §§335.751, 335.753, 335.755, 335.757, 335.759, 335.761, 335.763, 335.765, 335.767, 335.769, 335.771

Statutory Authority

The new rules are proposed under Texas Water Code (TWC), §5.013, which establishes the general jurisdiction of the commission; TWC, §5.102, which provides the commission with the authority to carry out its duties and general powers under its jurisdictional authority as provided by the TWC; and TWC, §5.103, which requires the commission to adopt any rule necessary to carry out its powers and duties under the TWC and other laws of the state. The new rules are also proposed under Texas Health and Safety Code (THSC), §361.017, which provides the commission authority to manage industrial solid waste and hazardous municipal waste; THSC, §361.024, which authorizes the commission to adopt rules regarding the management and control of solid waste; THSC, §361.036, which provides the commission authority to adopt rules regarding records and manifests for Class 1 industrial solid waste or hazardous waste; THSC, §361.078, which relates to the maintenance of state program authorization under federal law; and THSC, §361.119, which authorizes the commission to regulate industrial solid waste and hazardous waste and to adopt rules consistent with THSC, Chapter 361.

The proposed new rules implement THSC, Chapter 361.

§335.751. Definitions.

The following definitions apply to this subchapter:

(1) Evaluated hazardous waste pharmaceutical--A prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with §335.771(a)(3) of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

(2) Hazardous waste pharmaceutical--A pharmaceutical that is a solid waste, as defined in §335.1 of this title (relating to Definitions), and exhibits one or more characteristics identified in 40 Code of Federal Regulations (CFR) Part 261, Subpart C, or is listed in 40 CFR Part 261, Subpart D as these subparts are adopted by reference under §335.504 of this title (relating to Hazardous Waste Determination). A pharmaceutical is not a solid waste, as defined in §335.1 of this title, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in §335.1 of this title, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

(3) Healthcare facility--Any person that is lawfully authorized to:

(A) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure for the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(B) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

(4) Household waste pharmaceutical--A pharmaceutical that is a solid waste, as defined in §335.1 of this title (relating to Definitions), but is excluded from being a hazardous waste under 40 Code of Federal Regulations §261.4(b)(1) as adopted under §335.504 of this title (relating to Hazardous Waste Determination).

(5) Long-term care facility--A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

(6) Non-creditable hazardous waste pharmaceutical--A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

(7) Nonhazardous waste pharmaceutical--A pharmaceutical that is a solid waste, as defined in §335.1 of this title (relating to Definitions), and is not listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D, and does not exhibit a characteristic identified in 40 CFR Part 261, Subpart C.

(8) Non-pharmaceutical hazardous waste--A solid waste, as defined in §335.1 of this title (relating to Definitions), that is listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D or exhibits one or more characteristics identified in 40 CFR Part 261, Subpart C, but is not a pharmaceutical, as defined in this section.

(9) Pharmaceutical--Any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 Code of Federal Regulations §203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

(10) Potentially creditable hazardous waste pharmaceutical--A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and:

(A) is in original manufacturer packaging (except pharmaceuticals that were subject to a recall);

(B) is undispensed;

(C) is unexpired or less than one year past expiration date; and

(D) is not an evaluated hazardous waste pharmaceutical.

(11) Reverse distributor--Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

§335.753. Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to 40 Code of Federal Regulations (CFR) §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) and is not subject to this subchapter, except for §335.761 and §335.765 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; and Residues of Hazardous Waste Pharmaceuticals in Empty Containers) and the optional provisions of §335.759 of this title (relating to Healthcare Facilities That Are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste).

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with subsection (d) of this section for the management of its hazardous waste pharmaceuticals as an alternative to complying with 40 CFR §262.14 as adopted in §335.53 of this title and the optional provisions of §335.759 of this title.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations for the management of its non-pharmaceutical hazardous waste.

(d) Unless a healthcare facility is managing waste in compliance with subsection (a) of this section, a healthcare facility is subject to this subsection instead of Subchapters C, D, E, and F of this chapter (relating to Standards Applicable to Generators of Hazardous Waste; Standards Applicable to Transporters of Hazardous Waste; Interim Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities; and Permitting Standards for Owners and Operators of Hazardous Waste Treatment, Storage, or Disposal Facilities) except as provided in this subchapter.

(1) A healthcare facility managing potentially creditable hazardous waste pharmaceuticals that are not destined for a reverse distributor or non-creditable hazardous waste pharmaceuticals must comply with §335.755 of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals) and §§335.761, 335.763, 335.765, and 335.767 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program; Residues of Hazardous Waste Pharmaceuticals in Empty Containers; and Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor).

(2) A healthcare facility managing potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor must comply with §335.755(a) and §335.757 (relating to Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals), §§335.761, 335.763, 335.765, and 335.769 of this title (relating to Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor).

(e) A reverse distributor is subject to §§335.761, 335.763, 335.765, 335.767, 335.769, and 335.771 of this title (relating to Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors) of this title in lieu of Subchapters C, D, E or F of this chapter for the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this subchapter. Other generators are subject to Subchapter C of this chapter for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) Except as specified in this subsection and §335.4 of this title (relating to General Prohibitions), and unless the Commission finds or the executive director determines that industrial solid waste or recycling requirements are necessary to protect human health, the environment, or property, the following are not subject to this chapter:

(1) pharmaceuticals that are not solid waste, as defined by §335.1 of this title (relating to Definitions), because they are legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed;

(2) over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined in §335.1 of this title, because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed;

(3) pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration (FDA) in accordance with 21 CFR Part 7, Subpart C, until the FDA approves the destruction of the pharmaceuticals or the pharmaceuticals are discarded;

(4) pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR Part 1115, until

the Consumer Product Safety Commission approves the destruction of the recalled pharmaceuticals;

(5) pharmaceuticals stored according to a preservation order, or stored in accordance with a litigation hold pursuant to an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded or the pharmaceuticals are discarded;

(6) investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR Part 312, until the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste; and

(7) household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §335.763(a)(2) and §335.763(b) of this title.

(h) Healthcare facilities and reverse distributors regulated under this subchapter remain subject to Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter B of this chapter (relating to Hazardous Waste Management General Provisions), Subchapter O of this chapter (relating to Land Disposal Restrictions), and Subchapter R of this chapter (relating to Waste Classification), except as provided under this subchapter.

§335.755. Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals.

(a) Notification and withdrawal from this subchapter for healthcare facilities managing hazardous waste pharmaceuticals. A healthcare facility must notify the executive director that it is either subject to this subchapter, or is withdrawing from regulation under this subchapter, using the following procedures.

(1) Notification. A healthcare facility must notify the executive director that it is a healthcare facility operating under this subchapter using a method approved by the executive director within 60 days of becoming subject to this chapter. The method approved by the executive director collects the information required by the United States Environmental Protection Agency (EPA) Site Identification Form.

(A) A healthcare facility must submit a separate notification for each site or EPA identification number.

(B) A healthcare facility is not required to submit EPA hazardous waste numbers with this notification.

(C) A healthcare facility must retain a copy of a notification as long as the healthcare facility is subject to this subchapter.

(2) Withdrawal. A healthcare facility that elects to withdraw from this subchapter because it is a very small quantity generator that meets the conditions for exemption for a very small quantity generator under 40 Code of Federal Regulations (CFR) §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) must notify the executive director that it elects to withdraw from this subchapter using a method approved by the executive director. A healthcare facility is not required to submit any EPA hazardous waste numbers with this notification. A healthcare facility must submit a separate notification for each site or EPA identification number.

(A) A healthcare facility must submit the notification that it is withdrawing from this subchapter in accordance with this paragraph before it begins operating under the conditions for exemption of a very small quantity generator in 40 CFR §262.14 as adopted under §335.53 of this title.

(B) A healthcare facility must retain a copy of a notification of withdrawal for three years from the date of the signature on the notification of withdrawal.

(b) Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) Hazardous waste determination for non-creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical by determining if it exhibits a characteristic identified in 40 CFR Part 261, Subpart C or is listed in 40 CFR Part 261, Subpart D as adopted under §335.504 of this title (relating to Hazardous Waste Determination) in order to determine whether the waste is subject to this subchapter. A healthcare facility may elect to manage its nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subchapter.

(d) Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must store containers containing non-creditable hazardous waste pharmaceuticals in accordance with the following container management standards.

(1) Container requirements. A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) Ignitable, reactive, or incompatible wastes. A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(E) through other like means threaten human health or the environment.

(3) Container security. A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) Accumulating non-creditable waste pharmaceuticals in the same container. A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and nonhazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of 40 CFR §268.3(c) as adopted under §335.431 of this title (relating to Purpose,

Scope, and Applicability) must be accumulated in separate containers and labeled with all applicable EPA hazardous waste numbers.

(e) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must observe the following standards for on-site accumulation time of non-creditable hazardous waste pharmaceuticals.

(1) Maximum accumulation time. A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for one year or less without a permit or having interim status.

(2) Accumulation start date. A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(A) marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(B) maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(C) placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) Land disposal restrictions for non-creditable hazardous waste pharmaceuticals. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR Part 268 as adopted under Subchapter O of this chapter (relating to Land Disposal Restrictions). A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with 40 CFR §268.7(a) requirements as adopted under §335.431 of this title, except that it is not required to include the EPA hazardous waste numbers on the land disposal restrictions notification.

(h) Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 40 CFR §264.72 as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.72 as adopted under §335.112 of this title (relating to Standards) may accumulate the returned non-creditable hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with subsections (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must complete the following.

(1) Healthcare facility manifest signature. The healthcare facility must sign either:

(A) item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) item 20 of the new manifest, if a new manifest was used for the returned shipment.

(2) Transporter manifest copy. The healthcare facility must provide the transporter a copy of the manifest used for the returned shipment.

(3) Designated facility manifest copy. Within 30 days of receipt of the rejected shipment, the healthcare facility must send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Maximum time to re-ship a rejected shipment. Within 90 days of receipt of the rejected shipment, the healthcare facility must transport or offer for transport the returned shipment in accordance with the shipping standards of §335.767(a) of this title (relating to Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor).

(i) Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals. A healthcare facility must comply with the following reporting requirements.

(1) Biennial and annual waste reporting by healthcare facilities. A healthcare facility is not subject to the Annual Waste Summary reporting requirements under §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators) or the biennial reporting requirements under 40 CFR §262.41 as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators) for non-creditable hazardous waste pharmaceuticals managed under this subchapter.

(2) Exception reporting by healthcare facilities for a missing copy of the manifest. A healthcare facility must submit an exception report to the executive director in the following situations.

(A) For shipments from a healthcare facility to a designated facility, if a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(i) a legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the executive director; and

(ii) a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility, if a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(i) a legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the executive director; and

(ii) a handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(3) Additional reports. The executive director may require a healthcare facility to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals. A healthcare facility is subject to the following recordkeeping requirements.

(1) Signed manifest retention. A healthcare facility must keep a copy of each manifest signed in accordance with 40 CFR §262.23(a) as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) Exception report retention. A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) Waste determination documentation retention. A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with 40 CFR §262.11(f) as adopted under §335.53 of this title, for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all its non-creditable nonhazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) Documentation retention extension. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(5) Record inspections. All records must be readily available upon request by an inspector.

(k) Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subchapter.

(l) Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under 40 CFR §262.14 as adopted under §335.53 of this title, without a permit or without having interim status, if the receiving healthcare facility complies with the following.

(1) Consolidating waste pharmaceuticals at another healthcare facility under the control of the same person. The healthcare facility must be under the control of the same person as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility. "Control," for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person shall not be deemed to "control" such healthcare facilities.

(2) Operating under this subchapter. The healthcare facility must be operating under this subchapter for the management of its non-creditable hazardous waste pharmaceuticals.

(3) Compliance with this subchapter. The healthcare facility must manage the non-creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subchapter.

(4) Recordkeeping requirements. The healthcare facility must keep records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off-site for three years from the date that the shipment is received.

§335.757. Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals.

(a) Hazardous waste determination for potentially creditable pharmaceuticals. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical by determining if it is listed in 40 Code of Federal Regulations (CFR) Part 261, Subpart D or exhibits a characteristic identified in 40 CFR Part 261, Subpart C as adopted under §335.504 of this title (relating to Hazardous Waste Determination). A healthcare facility may choose to manage its potentially creditable nonhazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subchapter.

(b) Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under 40 CFR §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) without a permit or without having interim status, provided the receiving healthcare facility:

(1) is under the control of the same person as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off-site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) is operating under this subchapter for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) manages the potentially creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subchapter; and

(4) keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off-site for three years from the date that the shipment is received.

(c) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) Biennial and Annual Waste Summary reporting by healthcare facilities. A healthcare facility is not subject to the Annual Waste Summary reporting requirements under §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators) or the biennial reporting requirements in 40 CFR §262.41 as adopted under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators) for poten-

tially creditable hazardous waste pharmaceuticals managed under this subchapter.

(e) Recordkeeping by healthcare facilities. Healthcare facilities are subject to the following recordkeeping requirements for managing potentially creditable hazardous waste pharmaceuticals.

(1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(A) the confirmation of delivery; and

(B) the shipping papers prepared in accordance with 49 CFR Part 172, Subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(3) All records must be readily available upon request by an inspector.

(f) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subchapter.

§335.759. Healthcare Facilities That are Very Small Quantity Generators for Both Hazardous Waste Pharmaceuticals and Non-pharmaceutical Hazardous Waste.

(a) Potentially creditable hazardous waste pharmaceuticals. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator. A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) the receiving healthcare facility meets the conditions in §335.755(l) and §335.757(b) of this title (relating to Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals; Standards for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals), as applicable; or

(2) the very small quantity generator healthcare facility meets the conditions in 40 Code of Federal Regulations (CFR) §262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in 40 CFR §262.17(f), both as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(c) Long-term care facilities that are very small quantity generators. A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) Long-term care facilities with 20 beds or fewer. A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to 40 CFR §262.14 as adopted under §335.53 of this title for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this subchapter, except for §335.761 and §335.765 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals; and Residues of Hazardous Waste Pharmaceuticals in Empty Containers) and the other optional provisions of this section. A long-term care facility with 20 beds or fewer is subject to this subchapter if the executive director determines that the facility generates quantities of hazardous waste in excess of the very small quantity generator limits as defined in §335.1 of this title (relating to Definitions). A long-term care facility with more than 20 beds that operates as a very small quantity generator under 40 CFR §262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by §335.1 of this title.

§335.761. Prohibition of Sewering Hazardous Waste Pharmaceuticals.

All healthcare facilities--including very small quantity generators operating under 40 Code of Federal Regulations (CFR) §262.14 as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste) in lieu of this subchapter--and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR §403.5(b)(1).

§335.763. Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Controlled Substances and Household Waste Pharmaceuticals Collected in a Take-back Event or Program.

(a) Conditional exemptions. Provided the conditions of subsection (b) of this section are met, the following are exempted from the requirements of this chapter:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 Code of Federal Regulations (CFR) Part 1308; and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) Conditions for exemption. The hazardous waste pharmaceuticals must be:

(1) managed in compliance with the sewer prohibition of §335.761 of this title (relating to Prohibition of Sewering Hazardous Waste Pharmaceuticals);

(2) collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(A) a permitted large municipal waste combustor, subject to 40 CFR Part 62, Subpart FFF or applicable state plan for existing

large municipal waste combustors, or 40 CFR Part 60, Subpart Eb for new large municipal waste combustors;

(B) a permitted small municipal waste combustor, subject to 40 CFR Part 62, Subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR Part 60, Subpart AAAA for new small municipal waste combustors;

(C) a permitted hospital, medical and infectious waste incinerator, subject to 40 CFR Part 62, Subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR Part 60, Subpart Ec for new hospital, medical and infectious waste incinerators;

(D) a permitted commercial and industrial solid waste incinerator, subject to 40 CFR Part 62, Subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR Part 60, Subpart CCCC for new commercial and industrial solid waste incinerators; or

(E) a permitted hazardous waste combustor subject to 40 CFR Part 63, Subpart EEE.

§335.765. Residues of Hazardous Waste Pharmaceuticals in Empty Containers.

(a) Stock, dispensing and unit-dose containers. A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) Syringes. A syringe is considered empty and the residues are not regulated as hazardous waste under this subchapter provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subchapter and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) Intravenous (IV) bags. An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subchapter, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as described in §335.41(f) of this title (relating to Purpose, Scope, and Applicability).

(d) Other containers, including delivery devices. Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subchapter, unless the container held non-acute hazardous waste pharmaceuticals and is empty as described in §335.41(f) of this title. This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§335.767. Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor.

(a) Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with this subsection.

(1) The healthcare facility and reverse distributor must comply with the pre-transport requirements in this paragraph before transporting or offering non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals for transport off-site.

(A) Packaging. Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 Code of Federal Regulations (CFR) Parts 173, 178, and 180.

(B) Labeling. Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR Part 172, Subpart E.

(C) Marking. Mark hazardous waste pharmaceuticals in accordance with this subparagraph.

(i) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable federal Department of Transportation (DOT) regulations on hazardous materials under 49 CFR Part 172, Subpart D.

(ii) Mark each container of 119 gallons or less used in such transportation in accordance with 40 CFR §266.508(a)(1)(iii)(B) which is adopted by reference as adopted in the *Federal Register* on February 22, 2019 (84 FR 5940).

(iii) Lab packs that will be incinerated in compliance with 40 CFR §268.42(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste number(s).

(D) Placarding. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR Part 172, Subpart F.

(2) The healthcare facility and reverse distributor must comply with the manifest requirements of 40 CFR Part 262, Subpart B as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) and list a complete Texas waste code in Item 13 of the manifest), except:

(A) a healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable EPA hazardous waste numbers in Item 13 of the manifest; and

(B) a healthcare facility shipping non-creditable hazardous waste pharmaceuticals must use the four-letter sequence code "PHRM" in addition to the applicable Texas form code and classification code in Item 13 of the manifest.

(b) Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal).

(c) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. Any person that

imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR Part 262, Subpart H, as adopted by reference under §335.58 of this title, Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter B of this chapter (relating to Hazardous Waste Management General Provisions), Subchapter O of this chapter (relating to Land Disposal Restrictions), and Subchapter R of this chapter (relating to Waste Classification), except as provided under this subchapter. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that authorizes the owner or operator of the facility to accept hazardous waste from off-site.

§335.769. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor.

(a) Shipping potentially creditable hazardous waste pharmaceuticals. A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable United States Department of Transportation regulations in 49 Code of Federal Regulations (CFR) Parts 171 - 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR §171.8. For purposes of the federal Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the United States Environmental Protection Agency specified in 40 CFR Part 262 as adopted under Subchapter C of this title (relating to Standards Applicable to Generators of Hazardous Waste). Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) Delivery confirmation. Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) Procedures for when delivery confirmation is not received within 35 days. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) Exporting potentially creditable hazardous waste pharmaceuticals. A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR Part 262, Subpart H, as adopted under §335.58 of this title (relating to Transboundary Movements of Hazardous Waste for Recovery or Disposal), except the manifesting requirement of 40 CFR §262.83(c), in addition to subsections (a) - (c) of this section.

(e) Importing potentially creditable hazardous waste pharmaceuticals. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to subsections (a) - (c) of this section instead of 40 CFR Part 262, Subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subchapter.

§335.771. Standards for the Management of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals by Reverse Distributors.

(a) A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a hazardous waste permit or without having interim status, provided that it complies with the conditions in this section. The following standards apply to reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(1) Registration. A reverse distributor must register with the executive director in accordance with §335.6 of this title (relating to Notification Requirements) using a method approved by the executive director within 60 days of becoming subject to this chapter.

(2) Inventory by the reverse distributor. A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(A) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(B) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(C) A reverse distributor that meets the inventory requirements of this paragraph by complying with other regulatory requirements, such as the Texas State Board of Pharmacy regulations, is not required to provide a separate inventory pursuant to this section.

(3) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(A) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with subsection (b) of this section.

(B) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with subsection (c) of this section.

(4) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility. Following the evaluation, the reverse distributor must manage the evaluated hazardous waste pharmaceuticals in accordance with subsection (c) of this section.

(5) Maximum accumulation time. The maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor is outlined in subparagraphs (A) and (B) of this paragraph.

(A) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(B) Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with subsection (a) of this section and the container labeling and management standards in §335.771(c)(4)(A) - (F).

(6) Security at the reverse distributor facility. A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(A) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(i) a 24-hour continuous monitoring surveillance system;

(ii) an artificial barrier such as a fence; or

(iii) a means to control entry, such as keycard access.

(B) If the reverse distributor already meets the security requirements of this subsection because of other regulatory requirements, such as Drug Enforcement Administration or Texas State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 Code of Federal Regulations (CFR) Part 262, Subpart M as adopted under §335.61 of this title (relating to Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators).

(8) Closure of a reverse distributor. When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with §335.8 of this title (relating to Closure and Remediation) and 40 CFR §262.17(a)(8)(ii) and (iii) as adopted under §335.53 of this title (relating to General Standards Applicable to Generators of Hazardous Waste).

(9) Reporting. Reverse distributors are subject to the following reporting requirements.

(A) A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off-site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the executive director within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(i) the United States Environmental Protection Agency (EPA) identification number, name and address of the reverse distributor;

(ii) the date the reverse distributor received the unauthorized waste;

(iii) the EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(iv) a description and the quantity of each unauthorized waste the reverse distributor received;

(v) the method of treatment, storage, or disposal for each unauthorized waste; and

(vi) a brief explanation of why the waste was unauthorized, if known.

(B) The executive director may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(A) A copy of its notification on file for as long as the facility is subject to this subchapter;

(B) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(C) A copy of its current inventory for as long as the facility is subject to this subchapter.

(b) Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in subsection (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow subsection (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow subsection (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with §335.769 of this title (relating to Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor).

(4) Recordkeeping by reverse distributors. A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(A) The confirmation of delivery; and

(B) The DOT shipping papers prepared in accordance with 49 CFR Part 172, Subpart C, if applicable.

(c) Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals. A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of subsection (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) Accumulation area at the reverse distributor. A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) Inspections of on-site accumulation area. A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) Personnel training at a reverse distributor. Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of 40 CFR §262.17(a)(7) as adopted under §335.53 of this title.

(4) Labeling and management of containers at on-site accumulation areas. A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(A) label the containers with the words, "hazardous waste pharmaceuticals";

(B) ensure the containers are in good condition and managed to prevent leaks;

(C) use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(D) keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(E) manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(i) generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(v) through other like means threaten human health or the environment; and

(F) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of 40 CFR §268.3(c) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) United States Environmental Protection Agency (EPA) hazardous waste numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off-site, all containers must be marked with the applicable EPA hazardous waste numbers. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste number(s).

(6) Shipments. A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in §335.767(a) or (b) of this title (relating to Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor).

(7) Procedures for a reverse distributor for managing rejected shipments. A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 40 CFR §264.72 as adopted under §335.152 of this title (relating to Standards) or 40 CFR §265.72 as adopted under §335.112 of this title (relating to Standards) may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with subsection (a) or (c) of this section. Upon receipt of the returned shipment, the reverse distributor must:

(A) Sign either:

(i) item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) item 20 of the new manifest, if a new manifest was used for the returned shipment;

(B) Provide the transporter a copy of the manifest;

(C) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(D) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of §335.767(a) or (b) of this title.

(8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR Part 268 as adopted under Subchapter O of this chapter (relating to

Land Disposal Restrictions). A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with 40 CFR §268.7(a) as adopted under §335.431 of this title (relating to Purpose, Scope, and Applicability).

(9) Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals. Reverse distributors are subject to the following reporting requirements.

(A) A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must:

(i) comply with the reporting requirements of §335.9 of this title (relating to Recordkeeping and Annual Reporting Procedures Applicable to Generators), and

(ii) in every even-numbered year, submit supplemental biennial reporting information for the previous odd-numbered report year required by 40 CFR §262.41 as adopted by reference under §335.56 of this title (relating to Recordkeeping and Reporting Applicable to Small and Large Quantity Generators), upon request, in a method approved by the executive director within the specified timeframe. Information submitted to the executive director in accordance with Subchapter A of this chapter (relating to Industrial Solid Waste and Municipal Hazardous Waste in General), Subchapter C of this chapter (relating to Standards Applicable to Generators of Hazardous Waste), and Subchapter R of this chapter (relating to Waste Classification) is not required to be resubmitted in a biennial report.

(B) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(C) A reverse distributor must submit an exception report to the executive director if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(i) a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(ii) a cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(D) For shipments rejected by the designated facility and shipped to an alternate facility, a reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(E) For shipments rejected by the designated facility and shipped to an alternate facility, a reverse distributor must submit an exception report to the executive director if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The exception report must include:

(i) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(ii) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals. Reverse distributors are subject to the following recordkeeping requirements.

(A) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by subsection (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(B) A reverse distributor must keep a copy of each manifest signed in accordance with 40 CFR §262.23(a) as adopted under §335.54 of this title (relating to Hazardous Waste Manifest) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(C) A reverse distributor must keep a copy of each report required by subparagraph (9)(A) of this subsection for at least three years from the due date of the report.

(D) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(E) A reverse distributor must keep records to document personnel training, in accordance with 40 CFR §262.17(a)(7)(iv) as adopted under §335.53 of this title.

(F) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the executive director.

(d) When a reverse distributor must have a permit. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the permitting and other requirements of this chapter if the reverse distributor:

(1) does not meet the conditions of this section;

(2) accepts manifested hazardous waste from off-site; or

(3) treats or disposes of hazardous waste pharmaceuticals on-site.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on July 16, 2021.

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Robert Martinez
Deputy Director, Environmental Law Division
Texas Commission on Environmental Quality
Earliest possible date of adoption: August 29, 2021
For further information, please call: (512) 239-2678

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TITLE 37. PUBLIC SAFETY AND CORRECTIONS

PART 1. TEXAS DEPARTMENT OF PUBLIC SAFETY

CHAPTER 4. COMMERCIAL VEHICLE REGULATIONS AND ENFORCEMENT PROCEDURES

SUBCHAPTER F. COOPERATION WITH THE TEXAS ANIMAL HEALTH COMMISSION

37 TAC §4.81

The Texas Department of Public Safety (the department) proposes new §4.81, concerning Cooperation with the Texas Animal Health Commission Regarding Enforcement of Entry Requirements. The new rule satisfies the requirements of Texas Agricultural Code, §161.051 which directs the department and the Texas Animal Health Commission to adopt a memorandum of understanding that includes provisions under which officers of the department check for health papers and permits when a livestock vehicle is stopped for other reasons in the regular course of the officers' duties.

Suzy Whittenton, Chief Financial Officer, has determined that for each year of the first five-year period this rule is in effect there will be no fiscal implications for state or local government or local economies.

Ms. Whittenton has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities required to comply with the section as proposed. There is no anticipated economic cost to individuals who are required to comply with the rule as proposed. There is no anticipated negative impact on local employment.

In addition, Ms. Whittenton has also determined that for each year of the first five-year period the rule is in effect, the public benefit anticipated as a result of this rule will be a clearer understanding of the memorandum of understanding between the department and the Texas Animal Health Commission regarding the enforcement of entry requirements for livestock vehicles and the maximum efficiency of the Motor Carrier Safety Assistance Program.

The department has determined this proposal is not a "major environmental rule" as defined by Texas Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule that the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

The department has determined that Chapter 2007 of the Texas Government Code does not apply to this proposal. Accordingly, the department is not required to complete a takings impact assessment regarding this proposal.

The department prepared a Government Growth Impact Statement assessment for this proposed rulemaking. The proposed rulemaking does not create or eliminate a government program; will not require an increase or decrease in future legislative appropriations to the agency; will not require the creation of new employee positions nor eliminate current employee positions; nor will it require an increase or decrease in fees paid to the agency. The proposed rulemaking does not create, expand, or limit an existing regulation. The proposed rulemaking does not increase or decrease the number of individuals subject to its applicability. During the first five years the proposed rule is in effect, the proposed rule should not impact positively or negatively the state's economy.

The Texas Department of Public Safety, in accordance with the Administrative Procedures Act, Texas Government Code, §2001, *et seq.*, and Texas Transportation Code, Chapter 644, will hold a public hearing on Wednesday, August 11, 2021, at 9:00 a.m., at the Texas Department of Public Safety, Texas Highway Patrol Division, Building G Annex, 5805 North Lamar, Austin, Texas. The purpose of this hearing is to receive comments from all interested persons regarding adoption of the proposed amendments to Administrative Rule §4.81 regarding Cooperation with the Texas Animal Health Commission Regarding Enforcement of Entry Requirements, proposed for adoption under the authority of Texas Transportation Code, Chapter 644, which provides that the director shall, after notice and a public hearing, adopt rules regulating the safe operation of commercial motor vehicles.

Persons interested in attending this hearing are encouraged to submit advance written notice of their intent to attend the hearing and to submit a written copy of their comments. Correspondence should be addressed to Major Chris Nordloh, Texas Highway Patrol Division, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0500.

Persons with special needs or disabilities who plan to attend this hearing and who may need auxiliary aids or services are requested to contact Major Chris Nordloh at (512) 424-2775 at least three working days prior to the hearing so that appropriate arrangements can be made.

Other comments on this proposal may be submitted to Major Chris Nordloh, Texas Highway Patrol Division, Texas Department of Public Safety, P.O. Box 4087, Austin, Texas 78773-0500, (512) 424-2775. Comments must be received no later than thirty (30) days from the date of publication of this proposal.

These amendments are proposed pursuant to Texas Transportation Code, §644.051, which authorizes the director to adopt rules regulating the safe transportation of hazardous materials and the safe operation of commercial motor vehicles; and authorizes the director to adopt all or part of the federal safety regulations, by reference and Texas Agriculture Code, §161.051 which authorizes the department adopt a joint memorandum of understanding with the agricultural commission that includes provisions to check for health papers and permits when a livestock vehicle is stopped for other reasons in the regular course of an officer's duties.

Texas Transportation Code, §644.051 and Texas Agriculture Code, §161.051 are affected by this proposal.

Figure: 30 TAC §335.1(160)(D)(iv)
[Figure: 30 TAC §335.1(154)(D)(iv)]

TABLE 1

	Use Constituting Disposal S.W. Def. (D)(i)	Energy Recovery/Fuel S.W. Def. (D)(ii)	Reclamation S.W. Def. (D)(iii)[2]	Speculative Accumulation S.W. Def. (D)(iv)
Spent materials (listed hazardous and not listed characteristically hazardous)	*	*	*	*
Spent materials (nonhazardous)[1]	*	*	*	*
Sludges (listed hazardous in 40 CFR §261.31 or §261.32)	*	*	*	*
Sludges (not listed characteristically hazardous)	*	*		*
Sludges (nonhazardous)[1]	*	*		*
By-products (listed hazardous in 40 CFR §261.31 or §261.32)	*	*	*	*
By-products (not listed characteristically hazardous)	*	*		*
By-products (nonhazardous)[1]	*	*		*
Commercial chemical products (listed, not listed characteristically hazardous, and nonhazardous)	*	*		
Scrap metal that is not excluded under subparagraph (A)	*	*	*	*

of this paragraph (hazardous)				
Scrap metal other than excluded scrap metal (see §335.17(a)(9) of this title) (nonhazardous)[1]	*	*	*	*

NOTE: The terms "spent materials," "sludges," "by-products," "scrap metal," and "excluded scrap metal" are defined in §335.17 of this title (relating to Special Definitions for Recyclable Materials and Nonhazardous Recyclable Materials).

[1] These materials are governed by the provisions of §335.24(h) of this title (relating to Requirements for Recyclable Materials and Nonhazardous Recyclable Materials) only.

[2] Reclamation (40 CFR §261.2(c)(3)), except as provided in [Except as provided in 40 CFR §261.2(c)(3) and] §261.4(a)(17) for mineral processing secondary materials or as provided in 40 CFR §261.4(a)(23), (24), or (27) for hazardous secondary materials.

Figure: 30 TAC §335.521(a)(2)
[Figure: 30 TAC §335.521(a)(2)]

Appendix 1, Table 2.

Examples of Ignitable Solids.
Constituents listed from Department of Transportation Regulations, 49 CFR Part 173 Subpart E, October 1, 1993. (Note: The presence of a constituent on this table in a nonhazardous [non-hazardous] waste does not automatically identify that waste as a Class 1 ignitable waste. The constituents on this table are examples of materials which could be considered Class 1 ignitable waste. The physical characteristics of the waste will be the determining factor as to whether or not a waste is ignitable. Refer to §335.505(2) of this title (relating to Class 1 Waste Determination) for the Class 1 ignitable criteria.)
Compound or Material
Aluminum, metallic, powder
Alkali metal amalgams
Alkali metal amides
Aluminum alkyl halides
Aluminum alkyl hydrides
Aluminum alkyls
Aluminum borohydrides
Aluminum carbide
Aluminum ferrosilicon powder
Aluminum hydride
Aluminum phosphide
Aluminum resinate
Aluminum silicon powder
Ammonium picrate
2, 2'-Azodi-(2,4-dimethyl-4-methoxyvaleronitrile)
2, 2'-Azodi-(2,4-dimethylvaleronitrile)
1, 1' Azodi-(hexahydrobenzonitrile)
2,2'-Azodi (2-methyl-butryronitrile)
Azodiisobutryonitrile
Barium, metallic
Barium alloys, pyrophoric
Barium azide
Benzene-1,3-disulfohydrazide
Benzene sulfohydrazide
4-(Benzyl(ethyl)amino)-3-ethoxybenzenediazonium zinc chloride
4-(Benzyl(methyl)amino)-3-ethoxybenzenediazonium zinc chloride
Borneol
Boron trifluoride dimethyl etherate
5-tert-Butyl-2,4,6-trinitro-m-xylene
Calcium, metallic
Calcium carbide

Calcium chlorite
Calcium cyanamide
Calcium dithionite
Calcium hypochlorite
Calcium manganese silicon
Calcium silicon powder
Calcium phosphide
Calcium pyrophoric
Calcium resinate
Calcium silicide
Camphor, synthetic
Carbon, activated
Celluloid
Cerium
Cesium metal
Chromic acid or chromic acid mixture, dry
Cobalt naphthenates, powder
Cobalt resinate
Decaborane
2-Diazo-1-naphthol-4-sulpho-chloride
2-Diazo-1-naphthol-5-sulpho-chloride
2,5-Diethoxy-4-morpholinobenzenediazonium zinc chloride
Diethylzinc
4-Dimethylamino-6-(2-dimethyaminoethoxy) toluene-2-diazonium zinc chloride
Dimethylzinc
Dinitrophenolates
Dinitroresorcinol
N,N'-Dinitroso-N,N'-dimethyl terephthalamide
N,N'-Dinitrosopentamethylenetetramine
Diphenyloxide-4,4'disulfohydrazide
Dipicryl sulfide
4-Dipropylaminobenzenediazonium zinc chloride
Ferrocerium
Ferrosilicon
Ferrous metal
Hafnium powder
Hexamine
Hydrides, metal
3-(2-Hydroxyethoxy)-4-pyrrolidin-1-ylbenzenediazonium zinc chloride
Iron oxide, spent
Isosorbide dinitrate mixture
Lead phosphite, dibasic
Lithium acetylide-ethylene diamine complex
Lithium alkyls
Lithium aluminum hydride
Lithium amide, powdered
Lithium borohydride
Lithium ferro silicon

Lithium hydride
Lithium metal
Lithium nitride
Lithium silicon
Magnesium granules
Magnesium aluminum phosphide
Magnesium diamide
Magnesium phosphide
Magnesium silicide
Maneb
Manganese resinate
Methyl magnesium bromide
Methyldichlorosilane
Mono-(trichloro) tetra-(monopotassium dichloro)-penta-s-triazinetrione
N-methyl-N'-nitro-Nitrosoguanidine
Naphthalene
Nitrocellulose mixtures
Nitroguanidine
p-Nitrosodimethylaniline
Paraformaldehyde
Pentaborane
Peratic acid
Phosphorous, amorphous, red
Phosphorous, white or yellow
Phosphoric anhydride
Phosphorous pentachloride
Phosphorus pentasulfide
Phosphorus sesquisulfide
Phosphorus trisulfide
Picric acid
Potassium, metallic
Potassium dichloro-s-triazine-trione
Potassium borohydride
Potassium dithionite
Potassium phosphide
Potassium sulfide, anhydrous
Rubidium metal
Silicon powder, amorphous
Silver picrate
Sodium, metallic
Sodium aluminum hydride
Sodium amide
Sodium borohydride
Sodium chlorite
Sodium 2-diazo-1-naphthol-4-sulphonate
Sodium 2-diazo-1-naphthol-5-sulphonate
Sodium dichloro-s-triazine-trione
Sodium dinitro-ortho-cresolate

Sodium hydride
Sodium hydrosulfite
Sodium methylate
Sodium nitrite and mixtures
Sodium picramate, wet
Sodium potassium alloys
Sodium sulfide, anhydrous
Stannic phosphide
Strontium phosphide
Sulfur
Titanium metal powder
Titanium hydride
Trichloroisocyanuric acid
Trichlorosilane
Trichloro-s-triazinetrione
Trinitrobenzoic acid
Trinitrophenol
Trinitrotoluene
Urea nitrate
Zinc ammonium nitrite
Zinc phosphide
Zinc powder
Zinc resinate
Zirconium hydride, powdered
Zirconium picramate
Zirconium powder
Zirconium scrap

Figure: 30 TAC §335.521(b)
[Figure: 30 TAC §335.521(b)]

Appendix 2
Texas Commission on Environmental Quality [Texas Natural Resource Conservation Commission]
Waste Permits Division
Industrial and Hazardous Waste Permits Section
MC 130
P.O.Box 13087
Austin, Texas 78711-3087

https://www.tceq.texas.gov/ [http://home.tnrcc.state.tx.us/]

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Figure: 30 TAC §335.521(c)
[Figure: 30 TAC §335.521(c)]

Appendix 3.

FORM CODES
_____
Code Waste description
_____
LAB PACKS
LAB PACKS - Lab packs of mixed wastes, chemicals, lab wastes
001 Lab packs of old chemicals only
002 Lab packs of debris only
003 Mixed lab packs
004 Lab packs containing acute hazardous wastes
005 Waste pharmaceuticals managed as hazardous waste
006 Airbag waste (airbag modules or airbag inflators managed as hazardous waste
009 Other lab packs (Specify in Comments)
LIQUIDS
INORGANIC LIQUIDS - Waste that is primarily inorganic and highly fluid (e.g., aqueous), with low suspended inorganic solids and low organic content
101 Aqueous waste with low solvents
102 Aqueous waste with low other toxic organics
103 Spent acid with metals
104 Spent acid without metals
105 Acidic aqueous waste
106 Caustic solution with metals but no cyanides
107 Caustic solution with metals and cyanides
108 Caustic solution with cyanides but no metals
109 Spent caustic
110 Caustic aqueous waste
111 Aqueous waste with reactive sulfides
112 Aqueous waste with other reactives (e.g., explosives)
113 Other aqueous waste with high dissolved solids
114 Other aqueous waste with low dissolved solids
115 Scrubber water
116 Leachate
117 Waste liquid mercury
119 Other inorganic liquids (Specify in Comments)
198 Nonhazardous photographic chemical wastes (inorganic)
199 Brine solution that could also bear the form code 113
ORGANIC LIQUIDS - Waste that is primarily organic and is highly fluid, with low inorganic solids content and low-to-moderate water content
201 Concentrated solvent-water solution
202 Halogenated (e.g., chlorinated) solvent
203 Non-halogenated solvent
204 Halogenated/non-halogenated solvent mixture
205 Oil-water emulsion or mixture

206 Waste oil
207 Concentrated aqueous solution of other organics
208 Concentrated phenolics
209 Organic paint, ink, lacquer, or varnish
210 Adhesives or epoxies
211 Paint thinner or petroleum distillates
212 Reactive or polymerizable organic liquids
219 Other organic liquids (Specify in Comments)
296 Ethylene glycol based antifreeze
297 Nonhazardous liquids containing greater than or equal to ( ) 50 and less than ( ) 500 ppm PCBs
298 Nonhazardous liquids containing greater than or equal to ( ) 500 ppm PCBs
299 Nonhazardous photographic chemical waste (organic)
SOLIDS
INORGANIC SOLIDS - Waste that is primarily inorganic and solid, with low organic content and low-to-moderate water content; not pumpable
301 Soil Contaminated with organics
302 Soil contaminated with inorganics only
303 Ash, slag, or other residue from incineration of wastes
304 Other "dry" ash, slag, or thermal residue
305 "Dry" lime or metal hydroxide solids chemically "fixed"
306 "Dry" lime or metal hydroxide solids not "fixed"
307 Metal scale, filings, or scrap
308 Empty or crushed metal drums or containers
309 Batteries or battery parts, casings, cores
310 Spent solid filters or adsorbents
311 Asbestos solids and debris
312 Metal-cyanide salts/chemicals
313 Reactive cyanide salts/chemicals
314 Reactive sulfide salts/chemicals
315 Other reactive salts/chemicals
316 Other metal salts/chemicals
319 Other waste inorganic solids (Specify in Comments)
388 Empty or crushed glass containers
389 Nonhazardous sandblasting waste
390 Nonhazardous concrete/cement/construction debris
391 Nonhazardous dewatered wastewater treatment sludge
392 Nonhazardous dewatered air pollution control device sludge
393 Catalyst waste
394 Nonhazardous solids containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
395 Nonhazardous solids containing greater than or equal to ( ) 500 ppm PCBs
396 Nonhazardous electrical equipment/devices containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs.
397 Nonhazardous electrical equipment/devices containing greater than or equal to ( ) 500 ppm PCBs
398 Nonhazardous soils containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
399 Nonhazardous soils containing greater than or equal to ( ) 500 ppm PCBs

ORGANIC SOLIDS - Waste that is primarily organic and solid, with low-to-moderate inorganic content and water content; not pumpable
401 Halogenated pesticide solid
402 Non-halogenated pesticide solid
403 Solids resins or polymerized organics
404 Spent carbon
405 Reactive organic solid
406 Empty fiber or plastic containers
407 Other halogenated organic solids (Specify in Comments)
409 Other non-halogenated organic solids (Specify in Comments)
488 Wood debris
489 Petroleum contaminated solids
490 Sand blasting waste
491 Dewatered biological treatment sludge
492 Dewatered sewage or other untreated biological sludge
493 Catalyst waste
494 Solids containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
495 Solids containing greater than or equal to ( ) 500 ppm PCBs
496 Electrical equipment/devices containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs.
497 Electrical equipment/devices containing greater than or equal to ( ) 500 ppm PCBs
498 Soils containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
499 Soils containing greater than or equal to ( ) 500 ppm PCBs
SLUDGES
INORGANIC SLUDGES - Waste that is primarily inorganic, with moderate-to-high water content and low organic content, and pumpable
501 Lime sludge without metals
502 Lime sludge with metals/metal hydroxide sludge
503 Wastewater treatment sludge with toxic organics
504 Other wastewater treatment sludge
505 Untreated plating sludge without cyanides
506 Untreated plating sludge with cyanides
507 Other sludge with cyanides
508 Sludge with reactive sulfides
509 Sludge with other reactives
510 Degreasing sludge with metal scale or filings
511 Air pollution control device sludge (e.g., fly ash, wet scrubber sludge)
512 Sediment or lagoon dragout contaminated with organics
513 Sediment or lagoon dragout contaminated with inorganics only
514 Drilling mud
515 Asbestos slurry or sludge
516 Chloride or other brine sludge
519 Other inorganic sludges (Specify in Comments)
597 Catalyst waste
598 Nonhazardous sludges containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
599 Nonhazardous sludges containing greater than or equal to ( ) 500 ppm PCBs
ORGANIC SLUDGES - Waste that is primarily organic with low-to-
moderate inorganic solids content and water content, and pumpable

601 Still bottoms of halogenated (e.g., chlorinated) solvents or other organic liquids
602 Still bottoms of non-halogenated solvents or other organic liquids
603 Oily sludge
604 Organic paint or ink sludge
605 Reactive or polymerizable organics
606 Resins, tars, or tarry sludge
607 Biological treatment sludge
608 Sewage or other untreated biological sludge
609 Other organic sludges (Specify in Comments)
695 Petroleum contaminated sludges other than still bottoms and oily sludges
696 Grease
697 Catalyst waste
698 Nonhazardous sludges containing greater than or equal to ( ) 50 ppm and less than (<) 500 ppm PCBs
699 Nonhazardous sludges containing greater than or equal to ( ) 500 ppm PCBs
GASES
INORGANIC GASES - Waste that is primarily inorganic with a low organic content and is a gas at atmospheric pressure
701 Inorganic gases
ORGANIC GASES - Waste that is primarily organic with low-to-moderate inorganic content and is a gas at atmospheric pressure
801 Organic gases
PLANT TRASH
902 Supplemental plant production refuse - Class 2 waste from production, manufacturing, or laboratory operations. The total amount of the supplemental plant production refuse shall not exceed 20% of the annual average of the total plant refuse (form code 999) volume or weight, whichever is less.
999 Plant Trash - Class 2 waste originating in the facility offices or plant production area that is composed of paper, cardboard, linings, wrappings, paper and/or wooden packaging materials, food wastes, cafeteria waste, glass, aluminum foil, aluminum cans, aluminum scrap, stainless steel, steel, iron scrap, plastics, styrofoam, rope, twine, uncontaminated rubber, uncontaminated wooden materials, equipment belts, wirings, uncontaminated cloth, metal bindings, empty containers with a holding capacity of five gallons or less, uncontaminated floor sweepings, and/or food packaging, that are produced as a result of plant production, manufacturing, laboratory, general office, cafeteria, or food services operations. Personal cosmetics generated by facility personnel, excluding those cosmetics generated as a result of manufacturing or plant production operations.

Texas Commission on Environmental Quality

ORDER REPEALING RULES AND ADOPTING NEW AND AMENDED RULES

Docket No. 2019-1058-RUL

Rule Project No. 2019-086-335-WS

On January 12, 2022, the Texas Commission on Environmental Quality (Commission) repealed rules and adopted new and amended rules in 30 Texas Administrative Code Chapter 335, concerning Industrial Solid Waste and Municipal Hazardous Waste. The proposal was published for comment in the July 30, 2021 issue of the *Texas Register* (46 TexReg 4586).

IT IS THEREFORE ORDERED BY THE COMMISSION that the repealed, new, and amended rules are hereby adopted. The Commission further authorizes staff to make any non-substantive revisions to the rules necessary to comply with *Texas Register* requirements. The adopted new and amended rules and repealed rules and the preamble to the adopted and repealed rules are incorporated by reference in this Order as if set forth at length verbatim in this Order.

This Order constitutes the Order of the Commission required by the Administrative Procedure Act, Tex. Gov't Code Ann., Chapter 2001 (West 2016).

If any portion of this Order is for any reason held to be invalid by a court of competent jurisdiction, the invalidity of any portion shall not affect the validity of the remaining portions.

TEXAS COMMISSION ON
ENVIRONMENTAL QUALITY

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Jon Niermann, Chairman

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Date Signed