The Texas Commission on Environmental Quality (TCEQ, agency, or commission) adopts new §§326.1, 326.3, 326.5, 326.7, 326.17, 326.19, 326.21, 326.23, 326.31, 326.37, 326.39, 326.41, 326.43, 326.53, 326.55, 326.61, 326.63, 326.65, 326.67, 326.69, 326.71, 326.73, 326.75, 326.77, 326.85, 326.87, and 326.89.

Sections 326.1, 326.3, 326.5, 326.19, 326.21, 326.37, 326.39, 326.41, 326.43, 326.53, 326.55, 326.61, 326.63, 326.69, 326.71, 326.73 and 326.75 are adopted *with changes* to the proposed text as published in the December 25, 2015, issue of the *Texas Register* (40 TexReg 9507), and therefore will be republished. Sections 326.7, 326.17, 326.23, 326.31, 326.65, 326.67, 326.77, 326.85, 326.87, and 326.89 are adopted *without changes* to the proposed text and, therefore, will not be republished.

Background and Summary of the Factual Basis for the Adopted Rules

House Bill (HB) 2244, passed by the 84th Texas Legislature, 2015, amended Texas Health and Safety Code (THSC), Chapter 361 by adding THSC, §361.0905 (Regulation of Medical Waste) requiring the commission to adopt regulations under a new chapter specific for the handling, transportation, storage, and disposal of medical waste. The adopted rulemaking primarily involves extracting or replicating the rules related to medical waste from 30 TAC Chapter 330 (Municipal Solid Waste), and moving them to adopted new Chapter 326. HB 2244 was effective immediately on June 10, 2015. The legislation also states that the commission must adopt any rules required to implement HB 2244 by June 1, 2016.

Corresponding rulemaking is published in this issue of the *Texas Register* concerning Chapter 330 and 30 TAC Chapter 335 (Industrial Solid Waste and Municipal Hazardous Waste).

Section by Section Discussion

Subchapter A: General Information

§326.1, Purpose and Applicability

Adopted new Chapter 326 addresses the handling, storage, disposal, and transportation of medical waste. Adopted new §326.1 establishes that the adopted regulations in Chapter 326 are based primarily on the stated purpose of THSC, Chapter 361 and are under the authority of the commission. Permits and registrations issued by the commission and its predecessors, that existed before Chapter 326 becomes effective remain valid for the later of two years from the effective date of this chapter, or until a final decision is made on a timely application for an existing authorization to comply with Chapter 326. The adopted rule is revised to clarify that permits and registrations would remain effective until the later of two years or until a timely decision is made on a timely application. The adopted rule is revised to clarify that registrations by rule would remain effective until they are renewed under this chapter. The existing Chapter 330 rules governing medical waste, which are repealed in a corresponding rulemaking, remain in effect and applicable to existing and pending permits, registrations, and registrations by rule, obtained under those rules. Applications received within two years of the effective date of Chapter 326 for an existing permit or registration to comply with or transition to Chapter 326 will not be

subject to the standard procedures for processing applications, including any requirements for notice and public participation. Authorizations, other than permits, registrations, and registrations by rule, that existed before Chapter 326 became effective, remain valid and are subject to these rules when they become effective. These authorizations include exemptions and notifications.

Applications pending before the effective date of Chapter 326 are subject to review under the existing Chapter 330 rules. Permits and registrations issued under the existing Chapter 330 rules must be updated by filing a new application, which is not subject to public notice, within two years of the effective date of Chapter 326 to comply with the provisions of Chapter 326. The executive director is authorized to extend this deadline based on an authorized entity making a request supported by good cause. Existing permits or registrations terminate if a timely application to update is not filed. Existing permits or registrations remain in effect until a final determination is made on a timely filed application.

Adopted §326.1(a)(3) is revised to clarify that requests to modify buffer zones or operating hours under this chapter will be processed as modifications that do not require notice. The sealed and signed pages of the existing application can be incorporated into the new submittal as long as the owner and/or operator provides a statement that the application is revised to only replace references to Chapter 330 with Chapter 326 along with minor corrections. However, the commission continues to require new engineering seals and

signatures for submittals for substantive changes to a facility design or operation.

§326.3, Definitions

Adopted new §326.3 defines terms in Chapter 326. Additionally, this section provides that in addition to defined terms, the undefined words, terms, and abbreviations, when used in this chapter, are defined in Texas Department of State Health Services (DSHS) rules in 25 TAC §1.132 and §133.2 (Definitions). When the definitions found in 25 TAC §1.132 are changed, such changes will prevail over the definitions found in §326.3. On-site is defined to include medical waste managed on property that is owned or effectively controlled by one entity and that is within 75 miles of the point of generation or generated at an affiliated facility. Definitions for non-hazardous pharmaceutical and trace chemotherapy waste are included for the purposes of managing these waste streams as medical waste. At this time, there are no federal regulatory definitions for these waste streams and several states have adopted similar definitions. These waste streams are not included as regulated medical waste under 49 Code of Federal Regulations (CFR) §173.134, and therefore have been addressed in adopted Chapter 326 to allow medical waste facility owners and operators to manage these wastes.

In response to comments, §326.3(27), "Non-hazardous pharmaceuticals waste" and §326.3(57), "Trace chemotherapy waste", were modified at adoption to allow for future treatment methods that may be developed and approved prior to a medical waste facility requesting use of those methods to treat non-hazardous pharmaceutical wastes.

In response to comments, §326.3(43), "Putrescible waste" definition was modified to be specific to regulated medical waste.

In response to comments, §326.3(54)(B), "Storage" definition for post-collection transporter was modified to extend the storage time to 72 hours to accommodate long distance routes and multiple pickup locations prior to treatment or disposal.

§326.5, General Prohibitions

Adopted new §326.5 establishes that a person may not cause, suffer, allow, or permit the collection, storage, transportation, processing, or disposal of medical waste, or the use or operation of a solid waste facility to store, process, or dispose of solid waste in violation of the THSC, or any regulations, rules, permit, license, order of the commission, or in such a manner that causes the discharge or imminent threat of discharge, the creation and maintenance of a nuisance, or the endangerment of the human health and welfare or the environment. The proposed clause referencing THSC, §361.092 has been deleted because it is addressed under the provisions Chapter 330 for landfills.

§326.7, Other Authorizations

Adopted new §326.7 specifies that owners or operators of medical waste facilities should obtain appropriate authorizations for the prevention or abatement of air or water pollution, and all other permits or approvals that may be required by local, state, and federal agencies.

Subchapter B: Packaging, Labeling and Shipping Requirements

§326.17, Identification

Adopted new §326.17 establishes that prior to packaging, labeling and shipping, health care-related facilities must identify and segregate medical waste from ordinary rubbish and garbage produced within or by the facilities. Should other municipal solid waste be combined with medical waste, the combined waste will be considered to be medical waste.

§326.19, Packaging

Adopted new §326.19 specifies that the generator is responsible for ensuring that medical waste is packaged in accordance with applicable requirements under the United States Department of Transportation, 49 CFR §173.134 and 49 CFR §173.196 which address infectious substances. 49 CFR Subtitle B, Chapter 1, Subchapter C specifically regulates infectious substances to abate future outbreaks of infectious disease. The reference 49 CFR §173.196 was added to further clarify infectious substances packaging.

§326.21, Labeling Containers Excluding Sharps

Adopted new §326.21 requires that medical waste packages must be labeled appropriately and in accordance with applicable requirements under 49 CFR §173.134. This section also establishes that the generator is primarily responsible for labeling, but may receive transporter assistance.

Due to response to comments, the title for this section was modified from "Labeling" to "Labeling Containers Excluding Sharps." Sharps containers requirements for marking (labeling) sharps is addressed under §326.19(b).

§326.23, Shipping

Adopted new §326.23 provides general requirements and provisions for both generators and transporters to follow, such as recordkeeping and explains that shipments of untreated medical waste must be delivered only to facilities authorized to accept untreated medical waste. This section establishes maintenance of electronic waste shipping (manifest) documentation by generators and transporters in addition to hard copies. This section explains that treated medical waste shipments including sharps or residuals of sharps must include a statement to the landfill that the shipment has been treated by an approved method in accordance with 25 TAC §1.136 (Approved Methods of Treatment and Disposition). This section also establishes that persons who transport untreated medical waste from Texas to other states or countries or from other states or countries to Texas, or persons that collect or transport waste in Texas but have their place of business in another state, must comply with all of the requirements for transporters.

Subchapter C: Exempt Medical Waste Operations

§326.31, Exempt Medical Waste Operations

Adopted new §326.31 establishes that facilities that generate and store on-site medical waste are exempt from medical waste authorizations under this chapter. These facilities

are identified as small quantity generators (SQGs) and large quantity generators (LQGs). SQGs are facilities that generate up to 50 pounds of medical waste per month and LQG are facilities that generate more than 50 pounds per month. Exempt SQG Transporters generate and transport less than 50 pounds per month to an authorized medical waste storage or processing facility. In response to comments "of regulated medical waste" was added to distinguish small quantity and large quantity generators as it relates to medical waste management since similar terminology is used for hazardous waste generators as well.

Persons who transport medical waste within Texas when the transportation neither originates nor terminates in Texas will be exempt. Medical waste transported by the United States Postal Service in accordance with the Mailing Standards of the United States Postal Service, Domestic Mail Manual, as incorporated by reference in 39 CFR Part 111, will be considered exempt from medical waste authorizations under Chapter 326.

Subchapter D: Operations Requiring a Notification

§326.37, General Requirements

Adopted new §326.37 establishes the process for medical waste operations to notify the agency of certain operations. Adopted new §326.37(a) - (c) explains the requirements that are applicable to all notifiers and how to submit the written notification. There are three types of notifications that are adopted in this section.

In response to comments, §326.37(a) is revised to provide an electronic submittal option.

§326.39, On-Site Treatment by Small Quantity Generators

Adopted new §326.39 requires that an SQG notify the executive director of the operation of an approved processing unit used only for the treatment of on-site generated medical waste, as defined in adopted §326.3(23). The adopted rule is revised to clarify that this is a one-time notification and that the notice is not required to include the name and initials of the person performing treatment.

In response to comments, the name and initials of the person(s) performing the treatment in §326.39(a)(1) was replaced with contact information for the facility. The name and initials of the person(s) performing the treatment is needed for on-site recordkeeping. The commission has made the suggested change and also revised §326.39(b) and §326.41(b) to add the name and initials of the persons performing the treatment to those sections.

§326.41, On-Site Treatment by Large Quantity Generators

Adopted new §326.41(a) establishes that an LQG may treat their medical waste on-site. The adopted rule is revised to clarify that this is a one-time notification and that the notice is not required to include the name and initials of the person performing treatment. However, the notification requirements for LQGs are adopted to be more stringent than for SQGs; LQGs will need to maintain a written procedure for the operation and testing of any equipment used and for the preparation of any chemicals used in treatment. Adopted new

§326.41(b)(3)(A) requires the owner or operator to demonstrate a minimum reduction of microorganisms by a four log ten reduction as defined by reference in 25 TAC §1.132. The adopted frequency of testing is based on the number of pounds generated per month for a facility.

In response to comments, the individual's name and initials performing the treatment is needed for on-site recordkeeping. Section 326.41(b) is also revised to add the individual's name and initials performing the treatment. Adopted new §326.41(b)(3)(B) allows an owner or operator to substitute the biological monitoring under §326.41(b)(3)(A) based on manufacturer compliance with the performance standards prescribed under 25 TAC §1.135 (Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

Adopted new §326.41(b)(3)(C) establishes that the owner or operator is responsible for following the manufacturer's instructions and maintaining quality control for single-use, disposable treatment units.

Adopted new §326.41(b)(3)(D) requires an owner or operator of a medical waste incinerator to comply with the requirements prescribed in 30 TAC §111.123 (Medical Waste Incinerators) in lieu of biological or parametric monitoring.

Adopted new §326.41(c)(1) and (2) establish that treated medical waste such as

microbiological waste, blood, blood products, body fluids, laboratory specimens of blood and tissue, and animal bedding may be managed as routine municipal solid waste for the purposes of disposal in accordance with Chapter 330. The owner or operator will follow disposal requirements applicable to incinerator ash and label the waste as treated medical waste.

Adopted new §326.41(c)(3) establishes that treated carcasses and animal body parts designated as medical waste may be managed as routine municipal solid waste and be disposed of in a permitted landfill in accordance with Chapter 330.

Adopted new §326.41(c)(4) establishes that treated recognizable human body parts, tissues, fetuses, organs, and the product of human abortions, spontaneous or induced, will not be disposed of in a municipal solid waste landfill and must be managed in accordance with 25 TAC §1.136(a)(4).

Adopted new §326.41(c)(5) establishes how treated and unused sharps will be disposed of in a permitted landfill in accordance with Chapter 330.

§326.43, Medical Waste Collection and Transfer by Licensed Hospitals

Adopted new §326.43(a) establishes that a licensed hospital may provide a notification to the commission if the facility intends to function as a medical waste collection and transfer facility. Under this notification, the hospital may accept untreated medical waste from

SQGs that transport medical waste they generated. The hospital must be located in an incorporated area with a population of less than 25,000 and in a county with a population of less than one million; or in an unincorporated area that is not within the extraterritorial jurisdiction of a city with a population of more than 25,000 or within a county with a population of more than one million.

Adopted new §326.43(b)(1) - (5) establish the items that the notification must address; such as the packaging, storage, transporting, and treatment requirements. Adopted §326.43(b)(2) is revised to remove the requirement to maintain refrigeration of waste that was refrigerated before collection.

Subchapter E: Operations Requiring a Registration by Rule

§326.53, Transporters

Adopted new §326.53(a) establishes that a registration by rule is available to transporters and that they will provide information to the commission 60 days prior to beginning transportation operations. A form will be provided by the commission and adopted new §326.53(a)(1) - (5) details the contents of the form, such as the identification information for the applicant, and annual fees required for the commission as referenced under Chapter 326, Subchapter G (Fees and Reporting).

Adopted new §326.53(b)(1) - (5) establish that registrations by rule will expire after one year and specify that an operator should apply for a renewal in a timely fashion to ensure

continuous authorization.

Adopted new §326.53(b)(6)(A) - (B) provide for the design requirements of the transportation unit and the cargo compartment of the transportation vehicle, including temperature and post-collection storage time. The identification markings for the cargo compartment(s) applies to the use of compartment while it contains medical waste. Adopted §326.53(b)(6)(B)(vi) is revised to remove the requirement to maintain refrigeration of waste that was refrigerated before collection. In response to the comments, whether sealed wood floors are impervious and nonporous, the commission considers that wood floors are not impervious and nonporous. In cases where wood floors have been modified, the applicant must demonstrate that the modification of the wood floor renders it impervious and nonporous.

Adopted new §326.53(b)(7) establishes that transportation units used to transport untreated medical waste will not be used to transport any other material until the transportation unit has been cleaned and the cargo compartment disinfected. Recordkeeping will be required to document the date and the process used to clean and disinfect the transportation unit and records will be maintained for three years. The record will identify the transportation unit by motor vehicle identification number or license tag number. The owner of the transportation unit, if not the operator, will be notified in writing by the transporter that the transportation unit has been used to transport medical waste and when and how the transportation unit was disinfected.

Adopted new §326.53(b)(8) establishes that a transporter will be responsible for initiating and maintaining shipment records for each type of waste collected and deposited. This paragraph also details the information that must be documented on the shipping document. In response to comments, §326.53(b)(8)(G) is revised to add language to provide for future electronic documents.

Adopted new §326.53(b)(9) requires the transporter to provide the generator a signed manifest for each shipment at the time of collection of the waste and include information such as the name, address, telephone number, and registration number of the transporter, identify the generator, and list the total volume or weight of waste collected and date of collection. The transporter will also provide the generator with a written or electronic statement of the total weight or volume of the containers within 45 days.

Adopted new §326.53(b)(10) establishes that the transporter will provide documentation of each medical waste shipment from the point of collection through and including the unloading of the waste at a facility authorized to accept the waste. The original shipping document will accompany each shipment of untreated medical waste to its final destination and the transporter will be responsible for the proper collection and deposition of untreated medical waste accepted for transport. In response to comments, §326.53(b)(10) is revised to add language to provide for future electronic documents.

Adopted new §326.53(b)(11) - (13) establish that shipments of untreated medical waste will be deposited only at a facility that has been authorized by the commission to accept untreated medical waste. Untreated medical waste that is transported out of the state will be deposited at a facility that is authorized by the appropriate agency having jurisdiction over such waste. In response to comments, §326.53(b)(12) and (13) were revised to add "regulated garbage" since the "Animal and Plant Health Inspection Service (APHIS) regulated garbage" is the term used by APHIS to identify APHIS waste.

Adopted new §326.53(b)(14) establishes that the storage of medical waste will be in a secure manner and in a location that affords protection from theft, vandalism, inadvertent human or animal exposure, rain, water, and wind. The waste will be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

Adopted new §326.53(b)(15) establishes the items that the notification will address; such as the packaging, storage, and transporting requirements.

Adopted new §326.53(b)(16) allows for an exemption from some transportation requirements to persons who will transport medical waste within Texas when the transportation neither originates nor terminates in Texas.

Adopted new §326.53(b)(17) establishes that packages of untreated medical waste will not be transferred between transportation units unless the transfer occurs at and on the

premises of a facility authorized as a transfer station, or as a treatment/processing facility that has been approved to function as a transfer station except as provided in §326.43.

Adopted new §326.53(b)(18) establishes that a medical waste shipment may be transferred to an operational transportation unit in the event of a transportation unit malfunction, and that the transporter will notify the executive director in writing, along with any local pollution control agency with jurisdiction that has requested to be notified, within five working days of the incident. When transferring to a unit not registered, the transporter will comply with §326.53(b)(6) and (7).

Adopted new §326.53(b)(19) establishes that a waste shipment may be transferred to an operating transportation unit in case of a traffic accident. Containers of waste that are damaged in the accident will be repackaged as soon as possible and the nearest regional office, along with any local pollution control agency with jurisdiction that have requested to be notified, will be notified of the incident no later than the end of the next working day after the accident.

Adopted new §326.53(b)(20) establishes that a copy of the registration by rule be maintained, as annotated by the executive director with an assigned registration by rule number, at their designated place of business and with each transportation unit used to transport untreated medical waste.

Adopted new §326.53(c) establishes that changes to the transporter registration be provided by letter to the executive director, and with any local pollution control agency with jurisdiction that have requested to be notified within 30 days of any change.

§326.55, Mobile Treatment Unit

Adopted new §326.55(a) establishes that a registration by rule is available for persons that treat medical waste in mobile treatment units on the site of generation, but that are not the generator of the waste. The mobile on-site treatment unit owner or operator will complete a registration by rule form provided by the commission and provide the required information at least 60 days before commencing operations.

Adopted new §326.55(a)(1) - (3) require the operator to provide identification information such as the applicant's name, address, and telephone number, and pay an annual registration fee based on the total weight of medical waste treated on-site under each registration by rule.

Adopted new §326.55(a)(4) and (5) require the owner or operator to describe the approved treatment method to be used, chemical preparations, the procedure to be utilized for routine performance testing/parameter monitoring, and routine performance testing conducted in accordance with §326.41(b)(3).

Adopted new §326.55(a)(6) - (9) establish that the owner or operator provide evidence of

competency in the form of training certificates or description of work experience, a description of the management and disposal of process waters generated during treatment events, and a contingency plan to manage waste in the event of treatment failure or equipment breakdown. A cost estimate to remove, dispose, and disinfect equipment will be submitted to the commission and the corresponding financial assurance must be established in accordance with 30 TAC Chapter 37, Subchapter R (Financial Assurance for Municipal Solid Waste Facilities).

Adopted new §326.55(a)(10) requires the owner or operator to provide a description of each mobile on-site treatment unit. Adopted new §326.55(a)(11) explains how a registrant by rule submits the annual fee.

Adopted new §326.55(b)(1) - (5) establish other requirements, such as renewal, annual reporting and annual fee requirements.

Adopted new §326.55(b)(6) - (8) establish the requirements for the mobile on-site treatment units and associated cargo compartments and will prohibit the use of mobile treatment units to transport non-medical waste until the unit has been cleaned and disinfected. Records will be kept to document cleaning and disinfection dates, identification for each unit by motor vehicle identification number or license tag, and waste treatment information.

Adopted new §326.55(b)(9) - (14) require persons that apply for a registration by rule to maintain copies at their place of business and in each mobile on-site treatment unit. An owner or operator will provide the generator the documentation required in §326.55(b)(6)(A) and (B) and a statement that the medical waste was treated in accordance with 25 TAC §1.136 for the generator's record. Owners or operators of mobile treatment units will not transport medical waste unless they are a registered medical waste transporter.

Adopted new §326.55(c) requires the owner or operator to notify the executive director, by letter, of any changes to their registration within 30 days.

Subchapter F: Operations Requiring a Registration

§326.61, Applicability and General Information

Adopted new §326.61(a) and (b) establish that registrations will be required for facilities that store or process untreated medical waste, non-hazardous pharmaceutical waste and trace chemotherapy waste that are received from off-site sources, and that no person may begin physical construction of a new medical waste management facility subject to this registration requirement without first having received a registration from the commission.

Adopted new §326.61(c) establishes that a registration application is not subject to the opportunity for a contested case hearing.

Adopted new §326.61(d) - (g) establish that all aspects of the application and design requirements will be addressed even if only to show why requirements are not applicable to a particular site. The owner or operator will provide the executive director the information requested to address the application with sufficient completeness, accuracy, and clarity; and the executive director may return the application if the owner or operator fails to provide complete information as required by this chapter and the executive director.

Adopted new §326.61(h) establishes that municipal solid waste, which would be classified as medical waste if it were generated by health care-related facilities, will be managed as medical waste after it is accepted at a processing facility, excluding facilities operating as a transfer station only. This municipal solid waste will be subject to the same requirements as medical waste when it is accepted by a facility that is only a registered medical waste facility.

§326.63, Property Rights

Adopted new §326.63(a) and (b) require the owner or operator to acquire sufficient property interest to use the surface estate of the property including access routes and retain right of entry to the facility until the facility is properly closed. In response to comments, §326.63(b) is revised to replace the term "closure care period" with "closure activities" to clarify that reference to the closure was to address the period that would require closure activities not the post closure care period.

§326.65, Relationships with Other Governmental Entities

Adopted new §326.65(a) - (c) establish that municipalities and county governments may enforce and exercise the authority to require and issue licenses authorizing and governing the operation and maintenance of medical waste facilities under the conditions afforded by THSC, Chapters 361, 363, and 364.

§326.67, Relationship with County Licensing System

Adopted new §326.67(a) - (b) establish the licensing procedures for counties that may choose to exercise their licensing authority. Counties with regulations may promulgate regulations that are consistent with those established and approved by the commission. A county may not make regulations or issue licenses for medical waste management within the extraterritorial or territorial jurisdiction of incorporated areas. The commission will not require a registration for medical waste facilities that have obtained a license issued by a county. A county will offer an opportunity to request a public meeting and issue appropriate notifications in accordance with the procedures established in adopted §326.73.

Adopted new §326.67(c) and (d) provide for the contents of a license and the licensee's responsibilities. The license contents will include owner identification information, legal description of the land on which the facility is located, the terms of the license, and volume of waste to be managed. The licensee will need to operate in compliance with regulations of

the commission and the county.

§326.69, Registration Application Formatting, Posting, Appointment and Fees

Adopted new §326.69(a) - (d) require that the owner or operator submit three copies of the application. In response to comments, §326.69(a) is revised to provide for electronic submittal option. The application will be prepared in accordance with the Texas Occupations Code, Chapter 1001, Texas Engineering Practice Act or returned if the application documents are not sealed properly. The subsections also describe the adopted formatting and drawing requirements.

Adopted new §326.69(e) requires that the owner or operator post an application that requires public notice, subsequent revisions, and supplements to the application on a publicly accessible internet website, and provide the commission with the Web address link for the application materials. The commission will post on its website the Web address link to the application and identify all owners and operators filing the application.

Adopted new §326.69(f) requires the owner or operator provide documentation that the person signing the application meets the requirements of 30 TAC §305.44(a) and (b) (Signatories to Applications).

Adopted new §326.69(g) requires a fee of $150 for a registration, modification, or temporary authorization application.

§326.71, Registration Application Contents

Adopted new §326.71(a) requires the owner or operator to submit maps and drawings of the facility and surrounding areas with the required information for each map and drawing. The maps and drawings will include: a general location map, facility access and facility layout map or drawing, land-use map, published zoning map if available, land ownership map, and a metes and bounds drawing and description of the facility (registration) boundary. Information regarding likely impacts of the facility on cities, communities, property owners, or individuals by analyzing land use, zoning, and community-growth patterns will be included. Land ownership information will be provided for property owner(s) within 1/4 mile of the facility. Mineral interest ownership will not be required.

Adopted new §326.71(b) requires the applicant to provide a property owner affidavit that is signed by the owner. Property owner affidavit must include acknowledgment that the State of Texas may hold the property owner of record either jointly or severally responsible for the operation, maintenance, and closure of the facility and that the facility owner or operator and the State of Texas must have access to the property during the active life and after closure for the purpose of inspection and maintenance.

Adopted new §326.71(c) and (d) require the owner or operator to acknowledge that they will employ a licensed solid waste facility supervisor and to verify the owner's or operator's

legal status as required by 30 TAC §281.5 (Application for Wastewater Discharge, Underground Injection, Municipal Solid Waste, Radioactive Material, Hazardous Waste, and Industrial Solid Waste Management Permits).

Adopted new §326.71(e) requires transportation data on the availability and adequacy of roads that the owner or operator will use to access the site; the volume of vehicular traffic on access roads within one mile of the proposed facility during the expected life of the proposed facility; and the volume of traffic expected to be generated by the facility on the access roads within one mile of the proposed facility. The owner or operator will also submit documentation of coordination of all designs of adopted public roadway improvements and documentation of coordination with the Texas Department of Transportation for traffic and location restrictions.

Adopted new §326.71(f) establishes that the owner or operator include a certification statement to verify that the facility will be constructed, maintained, and operated to manage run-on and run-off during the peak discharge of a 25-year rainfall event and will obtain the appropriate Texas Pollutant Discharge Elimination System storm water permit or an individual wastewater permit if applicable. This subsection also establishes that the facility will be located outside of the 100-year floodplain unless the owner or operator demonstrates that the facility is designed and operated to prevent washout during a 100-year storm event. The facility also will not be allowed to locate in wetlands unless the owner or operator provides documentation to the extent required under federal Clean

Water Act, §404 or applicable state wetlands laws.

Adopted new §326.71(g) requires the owner or operator submit documentation that the application was submitted for review to the applicable council of governments for compliance with regional solid waste plans and documentation that a review letter was requested from any local governments as appropriate for compliance with local solid waste plans.

Adopted new §326.71(h) requires a general description of the facility location and design. The owner or operator will provide a description for access control including the use of fences or other means to protect the public from exposure to health and safety hazards, and to discourage unauthorized entry. This subsection establishes that the unloading, storage, or processing of solid waste may not occur within any easement or buffer zone and a minimum separating distance of 25 feet between the facility boundary and processing equipment, loading, unloading and storage areas. Transport vehicles that store medical waste in refrigerated units with temperatures below 45 degrees Fahrenheit will not be subject to this requirement.

Adopted new §326.71(i) requires generalized construction information or manufacturer specifications of all medical waste storage and processing units. Adopted §326.71(i) is revised to clarify that the number of waste management units be provided. Additionally, the owner or operator will provide design information for secondary containment

structures for storage and processing areas that are designed to control and contain spills and contaminated water from leaving the facility. The owner or operator will acknowledge that the storage of medical waste be secure and in a location that affords protection from theft, vandalism, inadvertent human or animal exposure, rain, water, and wind and managed so as not to provide a breeding place or food for insects or rodents, and not to generate noxious odors. Putrescible or biohazardous untreated medical waste stored for longer than 72 hours during post-collection storage period will need to be maintained at a temperature of 45 degrees Fahrenheit or less. Adopted §326.71(i)(5) is revised to remove the requirement to maintain refrigeration of waste that was refrigerated before collection.

Adopted new §326.71(j) requires that medical waste be treated in accordance with the provisions of 25 TAC §1.136. Alternative treatment technologies may be approved in accordance with requirements found in 25 TAC §1.135. The owner or operator will provide a written procedure for the operation and testing of any equipment used and a written procedure for the preparation of any chemicals used in treatment. The owner or operator will conduct weekly testing and demonstrate a minimum reduction of microorganisms to a four log ten reduction as defined by reference in 25 TAC §1.132. Owner or operator may substitute the biological monitoring based on manufacturer compliance with the performance standards prescribed under 25 TAC §1.135. The owner or operator will be responsible for following the manufacturer's instructions and maintaining quality control for single-use, disposable treatment units. Owner or operator of medical waste incinerators will comply with the requirements prescribed in §111.123 in lieu of biological or parametric

monitoring. In response to comments, adopted §326.71(j)(7) is added to clearly indicate that alternative treatment technologies must be approved by DSHS by moving the second sentence of §326.71(j) to adopted §326.71(j)(7).

Adopted new §326.71(k) and (l) establish the preparation of the closure plan and the certification for a final closure. The owner or operator will remove all waste to an authorized facility. All units will be dismantled and removed off site or decontaminated and closure will be completed within 180 days following the most recent acceptance of materials unless otherwise approved in writing by the executive director.

Adopted new §326.71(m) and (n) establish the criteria for owners or operators to prepare closure cost estimates to address the disposition of the maximum inventories of all processed and unprocessed waste. The estimate will be based on the costs of hiring a third party that is not affiliated with the owner or operator; and be based on a per cubic yard and/or short-ton measure for collection and disposition costs. Revisions to the closure cost estimate may be made once the changes are approved by the commission. Documentation will be required to demonstrate financial assurance as specified in Chapter 37, Subchapter R and be submitted 60 days prior to the initial receipt of waste. Continuous financial assurance coverage for closure will be provided until all requirements of the final closure plan have been completed and the site is determined to be closed in writing by the executive director.

Adopted new §326.71(o) and (p) establish that a site operating plan be prepared to address and implement all the provisions in §326.75. The site operating plan and all other pertinent documents and plans are considered to be a part of the operating record and are operational requirements of the facility.

§326.73, Registration Application Processing

Adopted new §326.73(a)(1) - (5) discuss registration application processing and require that the owner or operator and the commission provide the opportunity for a public meeting in accordance with the criteria under 30 TAC §55.154(c) (Public Meetings). Notice of a public meeting will be provided as specified in 30 TAC §39.501(e) (Application for Municipal Solid Waste Permit). Response to comments by the commission will not be required and there will be no opportunity for a contested case hearing. The owner, operator, or their authorized representative will attend the public meeting. The owner or operator will post a sign or signs at the site of the adopted facility declaring that an application has been filed with the commission and that the owner or operator may be contacted for further information under requirements listed in §326.73(a)(5)(A) - (I).

Adopted new §326.73(a)(6) - (8) establish that posted signs at the facility indicating that a proposed medical waste facility application has been filed and the signs must be located within ten feet of every property line bordering a public highway, street, or road and visible from the street and spaced at not more than 1,500-foot intervals. A minimum of one sign, but no more than three signs, will be required along any property line paralleling a public

highway, street, or road. The owner or operator will also post signs at the facility in an alternative language when the alternative language requirements in 30 TAC §39.405(h)(2) (General Notice Provisions) are met. Variances from sign posting requirements may be approved by the executive director.

Adopted new §326.73(b) and (c) establish that the executive director determine if the application be approved or denied and in accordance with 30 TAC §50.133(b) (Executive Director Action on Application or WQMP Update), if the executive director acts on an application, the chief clerk will mail or otherwise transmit notice of the action and an explanation of the opportunity to file a motion under 30 TAC §50.139 (Motion to Overturn Executive Director's Decision). The chief clerk will mail this notice to the owner and operator, the public interest counsel, and to other persons who timely filed public comment in response to public notice. The owner or operator, or a person affected may file with the chief clerk a motion to overturn the executive director's action on a registration application, under §50.139. The criteria regarding motions to overturn will be explained in public notices given under 30 TAC Chapter 39 (Public Notice) and §50.133.

§326.75, Site Operating Plan

Adopted new §326.75 defines the contents of a site operating plan required under adopted new §326.71(o). Adopted new §326.75(a)(1) - (3) require owners or operators to provide the functions and minimum qualifications for key personnel; general instructions that operating personnel will follow; and procedures for detection and prevention of the receipt

of prohibited waste. In response to comments, proposed §326.75(a)(3) requiring information about equipment has been deleted. In response to comments that employees would be required to open containers for random inspections, the commission did not intend to require the opening of containers for random inspections. Section 326.75(a)(3)(A) is revised to clarify this requirement.

Adopted new §326.75(b) requires the owner or operator to identify the sources and characteristics of medical waste that they will receive for storage, processing or disposal. The information will include the maximum amount of medical waste to be received daily, the maximum amount of medical waste to be stored, the maximum allowable period of time that all medical waste (unprocessed and processed) are to remain on-site, and the intended destination of the medical waste received at the facility. The rule makes clear that medical waste facilities may not receive regulated hazardous waste as defined in 40 CFR §261.3 unless the waste is excluded from regulation as a hazardous waste under 40 CFR §261.4(b), or was generated by a conditionally exempt SQG. In regards to the appropriate method of disposition (e.g., incineration, landfilling or transfer) required by the phrase ". . . the application must include the intended destination of the medical waste received" is not intended to require that a particular facility name and location be identified. Facility may have dual authorizations to accept hazardous and medical waste. However hazardous waste authorization is separate from medical waste registration authorization and cannot be accepted under medical waste registrations. This includes accepting, storing and/or processing of hazardous waste. All of these activities can only be authorized by an

industrial hazardous waste authorization separately. The commission has processed dual authorization facilities in the past and they are required to have physically separated waste management areas and units and the authorization boundaries for each should be depicted on a site layout drawing. There may be other requirements that must be addressed on a case-by-case basis.

The commission currently allows the recycling of source separated materials. The commission also understands there may be situations on a case-by-case basis. In such cases, the recycling of the material may be appropriate however it should be addressed in the application clearly.

Adopted new §326.75(c) establishes how all wastes generated and resulting from the facility operations be processed or disposed. In response to comments, §326.75(c)(5) is revised from requiring a copy of the authorization to discharge wastewater to a treatment facility permitted under Texas Water Code (TWC), Chapter 26 along with the application submittal to requiring making it available prior to beginning of facility's operations and for all inspections.

Adopted new §326.75(d) establishes how recyclable materials be stored and kept separate from solid waste processing areas. All areas used for storage will not constitute a fire, safety, or health hazard or provide food or harborage for animals and vectors, and recyclable materials will be contained or bundled so as not to result in litter. Containers

will be maintained in a clean condition so that they do not constitute a nuisance and to prevent the harborage, feeding, and propagation of vectors.

Adopted new §326.75(e) establishes recordkeeping requirements. The owner or operator will be required to maintain on site, hard copies of their registration, registration application, correspondence, and all other documents related to the management of medical waste at the facility. For treatment facilities, the owner or operator may send written or electronic copies of the shipping document to the generator that includes a statement that the medical waste was treated in accordance with 25 TAC §1.136. All documents submitted by the owner or operator to the executive director will be signed and certified by the owner or operator or by a duly authorized representative of the owner or operator in accordance with §305.44(a) and (b).

Adopted new §326.75(f) requires the owner or operator to have an adequate supply of water under pressure for firefighting purposes, firefighting equipment, and a fire protection plan that describes the procedures for employee training, safety procedures, and compliance with local fire codes.

Adopted new §326.75(g) establishes how access to the facility will be controlled at the perimeter of the facility boundary and at all entrances to the facility. The means may be artificial and/or natural barriers, and entrances have lockable gates with an attendant on-site during operating hours. The operating area and transport unit storage area will be

enclosed by walls or fencing. The facility access road from a publicly owned roadway must be designed for the expected traffic flow and safe on-site access for commercial collection vehicles and for residents. The access road design must include adequate turning radii according to the vehicles that will utilize the facility and avoid disruption of normal traffic patterns.

Adopted new §326.75(h) establishes that unloading areas be confined to as small an area as practical, and that an attendant monitor all incoming loads of waste. Signage must be provided to indicate where vehicles are to unload their waste. Signs and other means, such as forced lanes must also be used to direct traffic to unloading areas and to prevent unloading in unauthorized areas. The owner or operator will ensure that the unloading of prohibited waste does not occur and all prohibited waste is returned to the transporter or generator if it is unloaded. Access from publicly owned roadways will be at least a two-lane gravel or paved road.

Adopted new §326.75(i) addresses the hours a facility will be open to conduct business. A site operating plan will specify operating hours. The operating hours may be any time between the hours of 7:00 a.m. and 7:00 p.m., Monday through Friday, unless otherwise approved by the executive director or commission.

Adopted new §326.75(i)(1) establishes that the owner or operator has the option to request alternative operating hours of up to five additional days in a calendar year to accommodate

special occasions, special purpose events, holidays, or other special occurrences.

Adopted new §326.75(i)(2) establishes that the agency regional offices may allow additional temporary operating hours to address disaster or other emergency situations, or other unforeseen circumstances that could result in the disruption of waste management services in the area.

Adopted new §326.75(j) establishes the required information and design for the facility sign. The sign will measure at least four feet by four feet with letters at least three inches in height stating the facility name; type of facility; the hours and days of operation; the registration number or facility number, if applicable; and facility rules. All entrances to the facility will have this sign conspicuously displayed and the posting of erroneous or misleading information will constitute a violation of this section.

Adopted new §326.75(k) establishes the requirements to address windblown litter. The owner or operator will be required to collect litter within the registered boundary to minimize unhealthy, unsafe, or unsightly conditions as necessary.

Adopted new §326.75(l) requires that facility access roads be all-weather and provide for wet-weather operation. The tracking of mud and debris onto public roadways from the facility will be minimized. A water source and necessary equipment or other means of dust control will be provided, all on-site and other access roadways will be maintained on a

regular basis, and regraded as necessary to minimize depressions, ruts, and potholes.

Adopted new §326.75(m) requires the owner or operator to provide screening or other measures to minimize noise pollution and adverse visual impacts.

Adopted new §326.75(n) addresses overloading and breakdown and requires that the design capacity of the facility not be exceeded during operations. The owner or operator will not be allowed to accumulate medical waste in quantities that cannot be processed within such time that it will cause the creation of odors, insect breeding, or harborage of other vectors. Additionally, if a mechanical breakdown or other event causes a significant work stoppage, the owner or operator will be required to restrict waste acceptance and divert all waste to an approved processing or disposal facility. The owner or operator will need to have alternative processing or disposal procedures for waste in the event the facility is inoperable longer than 24 hours.

Adopted new §326.75(o) requires the owner or operator to have sanitary facilities for all employees and visitors, and to wash down all working surfaces that come into contact with wastes, wash waters used to wash down surfaces that come into contact with waste will be collected and disposed in an authorized manner and may not be accumulated onsite without proper treatment to prevent odors or an attraction to vectors.

Adopted new §326.75(p) requires that all facilities and air pollution abatement devices

obtain authorization, under THSC, Chapter 382 (Texas Clean Air Act) and 30 TAC Chapter 106 or 116 (Permits by Rule; and Control of Air Pollution by Permits for New Construction or Modification), from the Air Permits Division prior to the commencement of construction, except as authorized in THSC, §382.004. Additionally, the adopted rule will have all facilities and air pollution abatement devices operate in compliance with all applicable air-related rules including 30 TAC Chapter 101 (General Air Quality Rules) related to prevention of nuisance odors, minimizing maintenance, startup and shutdown emissions, and emission event reporting and recordkeeping.

Adopted new §326.75(q) establishes that the facility have a health and safety plan and that facility personnel are trained in the appropriate sections of the plan.

Adopted new §326.75(r) establishes that medical waste addressed in this section be treated in accordance with 25 TAC §1.136 and disposed and labeled appropriately.

Adopted new §326.75(r)(1) and (2) establish that treated medical waste such as microbiological waste, blood, blood products, body fluids, laboratory specimens of blood and tissue, and animal bedding may be managed as routine municipal solid waste for the purposes of disposal in accordance with Chapter 330. The owner or operator will be required to follow disposal requirements applicable to incinerator ash. Any markings that identify the waste as a medical waste will be covered with a label that identifies the waste as treated medical waste. The identification of the waste as treated may be accomplished by

the use of color-coded, disposable containers for the treated waste or by a label that states that the contents of the disposable container have been treated in accordance with 25 TAC §1.136.

Adopted new §326.75(r)(3) establishes that treated carcasses and animal body parts designated as medical waste may be managed as routine municipal solid waste and be disposed of in a permitted landfill in accordance with Chapter 330. Transport and disposal will also conform to the applicable local ordinance or rule, if such ordinance or rule is more stringent than §326.75(r).

Adopted new §326.75(r)(4) establishes that treated recognizable human body parts, tissues, fetuses, organs, and the product of human abortions, spontaneous or induced, be managed in accordance with 25 TAC §1.136(a)(4).

Adopted new §326.75(r)(5) establishes how treated and unused sharps will be disposed of in a permitted landfill in accordance with Chapter 330.

§326.77, Duration, Limits and Additional Registration Conditions

Adopted new §326.77(a) - (g) establish how the executive director will approve or deny a registration application based on whether the application meets the requirements of Chapter 326. A registration is issued for the life of the facility but may be revoked or modified at any time if the operating conditions do not meet the minimum standards in

Chapter 326. A registration may be transferred from one person to another. Except for transporters and mobile treatment units, a registration is attached to realty and may not be transferred from one facility location to another. For revocations and denials, the registration will be considered to be a permit for the purposes of revocation and denial in accordance with 30 TAC Chapter 305 (Consolidated Permits). The owner or operator may file a motion to overturn the executive director's denial of a registration under §50.139. Once a registration is issued, if the owner or operator does not commence physical construction within two years of issuance of a registration or within two years of the conclusion of the appeals process, whichever is longer, the registration will automatically terminate and will be no longer be effective.

Adopted new §326.77(h) - (k) establish that changes to the issued registration may be processed as a permit modification in accordance with §305.70 (Municipal Solid Waste Permit and Registration Modifications) and need to be approved prior to their implementation. The owner or operator will obtain and submit certification by a Texas-licensed professional engineer that the facility has been constructed as designed in accordance with the issued registration and in general compliance with the regulations prior to initial operation. Prior to accepting medical waste, the owner or operator will contact the executive director and region office in writing and request a pre-opening inspection. A pre-opening inspection will be conducted by the executive director within 14 days of notification by the owner or operator. Once the pre-opening inspection is complete, the executive director will provide a written or verbal response within 14 days of

completion of the pre-opening inspection. The facility will be considered approved for the acceptance of medical waste if the executive director has not provided a response within the 14 days.

Subchapter G: Fees and Reporting

§326.85, Purpose and Applicability

Adopted new §326.85(a) establishes that fees are mandated by THSC, §361.013, to collect a fee for solid waste disposed of within the state, and from transporters of solid waste who are required to register with the state. Reports will be required to enable equitable assessment and collection of fees.

Adopted new §326.85(b) establishes that the owner or operator of a medical waste processing facility, with the exception of facilities authorized as transfer stations only, to pay a fee to the agency based upon the amount of waste received as described in this rule. All registered facility operators are required to submit reports to the executive director covering the types and amounts of waste processed at the facility or process location and the amount of processing capacity of facilities in Texas. The information requested on forms provided is not considered to be confidential or classified unless specifically authorized by law, and refusal to submit the form complete with accurate information by the applicable deadline will be considered a violation of this section and subject to appropriate enforcement action and penalty. An owner or operator failing to make payment of the fees imposed under this subchapter when due will be assessed penalties

and interest in accordance with 30 TAC Chapter 12 (Payment of Fees).

§326.87, Fees

Adopted new §326.87(a) establishes that the owner or operator of a medical waste processing facility, with the exception of facilities authorized as transfer station only, will need to comply with the measurement options described in this rule to calculate the correct fees due and to provide accurate reports. Exemptions from a fee are provided for solid waste processing resulting from a public entity's effort to protect the public health and safety of the community from the effects of a natural or man-made disaster, or from structures that have been contributing to drug trafficking or other crimes if the disposal facility at which that solid waste is offered for disposal has donated to a municipality, county, or other political subdivision the cost of disposing of that waste.

Adopted new §326.87(b) establishes that all transporters, with the exception of self-transporters, and mobile on-site treatment unit operators will be required to comply with fees determined by the criteria described in this section.

§326.89, Reports

Adopted new §326.89(a) establishes that all medical waste facilities with the exception of transfer stations to provide quarterly reports on forms provided by the executive director with the information in this rule such as the reporting units, and weight/volume conversion factors. This section also establishes that failure to submit reports by the due

date shall be sufficient cause for the commission to revoke the authorization to process waste. The commission may assess interest penalties for late payment of fees and may also assess penalties (fines) in accordance with Texas Water Code, §7.051 or take any other action authorized by law to secure compliance.

Adopted new §326.89(b) requires medical waste process facilities to report. Each operator of a medical waste process facility will be required to comply with §326.89(b)(1) - (7) such as annual reporting, report form required, reporting units, and weight/volume conversion factors.

Adopted new §326.89(c) establishes the reporting requirements for mobile on-site treatment unit operators.

Adopted new §326.89(d) establishes the reporting requirements for transporters.

Final Regulatory Impact Analysis Determination

The commission reviewed the adopted rulemaking in light of the regulatory analysis requirements of Texas Government Code, §2001.0225, and determined the rules do not meet the definition of a "major environmental rule". Under Texas Government Code, §2001.0225, "major environmental rule" means a rule with the specific intent 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 adopted rulemaking is intended to implement HB 2244 by consolidating and revising the rules governing medical waste into one new chapter. In addition to implementing HB 2244, the new Chapter 326 includes other updates and revisions which are not expected to have a significant impact on industry or the public.

Furthermore, the adoption does not meet any of the four applicability requirements listed in Texas Government Code, §2001.0225(a). Texas Government Code, §2001.0225 only applies to a major environmental rule which: 1) exceeds a standard set by federal law, unless the rule is specifically required by state law; 2) exceeds an express requirement of state law, unless the rule is specifically required by federal law; 3) exceeds 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 4) adopts a rule solely under the general powers of the agency instead of under a specific state law.

In this case, the adopted rules do not meet any of these applicability requirements. First, there are no standards set for authorizing these types of facilities by federal law. The adopted rules included revisions to reconcile any conflict with federal laws governing the transportation of medical waste. Second, the adopted rules do not exceed an express requirement of state law. There are no specific statutory requirements for authorizing these types of facilities. Third, the rules do not exceed an express 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. Fourth, the commission does not adopt the rule solely under the general powers of the agency, but rather under the authority of: THSC, §361.011, which establishes the commission's jurisdiction over all aspects of the management of municipal solid waste; THSC, §361.024, which provides the commission with rulemaking authority; THSC, §361.061, which authorizes the commission to require and issue permits governing the construction, operation, and maintenance of solid waste facilities used to store, process, or dispose of solid waste; and, THSC, §361.0905 (HB 2244), which governs the regulation of medical waste. Therefore, the commission does not adopt the rules solely under the commission's general powers.

The commission invited public comment regarding the Draft Regulatory Impact Analysis Determination during the public comment period. No comments were received on the regulatory impact analysis determination.

Takings Impact Assessment

The commission evaluated the adopted rulemaking and performed an assessment of whether the adopted rulemaking constitutes a taking under Texas Government Code, Chapter 2007. The specific intent of the adopted rulemaking is to implement HB 2244 by consolidating and revising the rules governing medical waste into one new chapter. In addition to implementing HB 2244, the new Chapter 326 includes other updates and revisions which are not expected to have a significant impact on the industry or the public.

The adopted rulemaking does not impose a burden on a recognized real property interest and therefore does not constitute a taking. The promulgation of the adopted rulemaking is neither a statutory nor a constitutional taking of private real property by the commission. Specifically, the adopted rulemaking does not affect a landowner's rights in a recognized private real property interest because this rulemaking neither: burdens (constitutionally) or restricts or limits the owner's right to the property that will otherwise exist in the absence of this rulemaking; nor will it reduce its value by 25% or more beyond that value which will exist in the absence of the adopted rules. Therefore, the adopted rulemaking will not constitute a taking under Texas Government Code, Chapter 2007.

Consistency with the Coastal Management Program

The commission reviewed the adopted rulemaking and found that it is neither identified in Coastal Coordination Act Implementation Rules, 31 TAC §505.11(b)(2) or (4), nor would it affect any action/authorization identified in Coastal Coordination Act Implementation Rules, 31 TAC §505.11(a)(6). Therefore, the adopted rulemaking is not subject to the Texas Coastal Management Program (CMP).

The commission invited public comment regarding the consistency with the CMP during the public comment period. No comments were received.

Public Comment

The commission held a public hearing on January 25, 2016. The comment period closed on

February 8, 2016. The commission received comments from the Honorable John Zerwas, M.D., District 28, Texas House of Representatives, Biomedical Waste Solutions LLC. (BWS), Cook-Joyce, Inc. (CJI), Gulfwest Solutions (GS), Sharps Compliance, Inc. (SCI), Stericycle, Inc. (SI), Titanium Environmental Services (TES), and The University of Texas System Environmental Health & Safety Advisory Committee (UT System). The commission received written comment from seven entities, and one person provided verbal comment at the public hearing. All seven commenters suggested changes. The commissioner received several comments in support of the added definitions for "Non-hazardous pharmaceutical waste" and "Trace chemotherapy waste" with the exception that several commenters suggested to add additional treatment methods for each waste. CJI supported the change from a 50-foot buffer to a 25-foot buffer for medical waste facilities as well as the allowance of storage units being allowed in the buffer zone.

Chapter 326, Medical Waste Management

Comment

Representative Zerwas provided guidance stating that one of the goals of HB 2244 is to consolidate rules relating to medical waste into a separate, standalone chapter of the TCEQ administrative code in order to reduce confusion regarding the applicability of many of the rules that relate to municipal solid waste facilities. The other objective was to give the agency, industry and stakeholders the opportunity to review these regulations, which were inherited by TCEQ from the former Texas Department of Health, so that regulations deemed unnecessary or without reasoned justification can be eliminated or revised.

Response

The TCEQ appreciates Representative Zerwas' comments and has made changes throughout this rulemaking to address his concerns.

Comment

TES commented that it is unclear and requested clarification whether proposed Chapter 326 and amended Chapter 335 require a Class 2 Texas Waste Code for the Solid Waste Registration of an exempt medical waste operator for on-site medical waste generation and storage.

Response

Exempt medical waste facilities for on-site medical waste generation and storage are not industrial facilities, and therefore, are not required to obtain a Class 2 Texas Waste Code for the Solid Waste Registration. The commission has made no changes.

§326.1(a)(1) and (2), Purpose and Applicability

Comment

SI stated that reapplying for permits, registrations and other authorizations would be overly burdensome, if there is no substantive change to the documents. SI requested that there should not be a requirement to do a full refiling of all documents with engineering

approvals if there are not changes made to the submittals other than to change the regulatory citation in the application. SI indicated that a full application including an engineering design review would be a requirement if the applicant proposes additional amendments. BWS stated that the proposed rule to file for a new registration application would result in unnecessary costs for the medical waste industry and for the agency with no added environmental benefit. SCI requested a revision to the rule to allow entities operating under a valid existing TCEQ authorization to continue to operate for the remaining term of any existing authorizations instead of a two-year deadline. According to SCI, under this approach, transition to authorization under the new Chapter 326 requirements would occur at the renewal of the entity's permit.

Response

The commission agrees with the comments to the extent that it may not be necessary to submit a new registration application with new engineering seals and signatures. Therefore, the commission will accept a one-time submittal of a new permit or registration application without updated engineering seals and signatures for the purposes of complying with Chapter 326. The sealed and signed pages of the existing application can be incorporated into the new submittal as long as the owner and/or operator provides a statement that the application is revised to only replace references to Chapter 330 with Chapter 326 along with minor corrections. However, the commission continues to require new engineering seals and signatures for submittals for substantive

changes to a facility design or operation.

The commission has provided a two-year deadline to comply with updating existing permits and registrations with the option of allowing an extension to the two-year deadline for requests supported by good cause. Existing permits and registrations include many references to the existing Chapter 330 rules. It is necessary for these permits and registrations to be revised to correct these references to new Chapter 326 in order to avoid any future confusion about the applicable requirements for these facilities. The commission amended §326.1(a)(1) to explain that the existing processing facility registrations and permits which have no expiration date are the only authorization tiers that would be subject to this two-year time frame; existing notification tier authorizations are not required to renew their notification; and registration by rule tier authorizations are subject to an annual renewal schedule. Therefore, no changes have been made to the two-year deadline for a permit or registration.

§326.1(a)(3), Purpose and Applicability and §326.77(h), Duration, Limits and Additional Registration Conditions

Comment

SI commented that it is not clear what sections of the provisions under §305.70 would be required in addition to Chapter 326. SI indicated that Chapter 326 was intended to be

substantively inclusive of all that would be necessary for regulated medical waste operations. SI recommended that the agency either be more specific as to the provisions it intends to be applicable here or add them to Chapter 326 directly. SI also requested that certain operating activities that are administrative should not require a full modification or re-registration as well as certification by a Texas licensed professional engineer. Examples of this are stated as change in operating hours, replacement of type of operating equipment, landscaping and pavement changes and non-production area changes (offices/breakrooms).

Response

The provisions of Chapter 305 set the standards and requirements for applications, permits, and actions by the commission to carry out the responsibilities for management of waste disposal activities under TWC, Chapters 26 - 28 and 32, and THSC, Chapters 361 and 401. Specifically, §305.70 includes provisions that establish the types of changes that may be made to permits and registrations by either a modification with or without notice, new registration, or amendment to a permit. Even though, the commission references §305.70 for medical waste registration application modification requests, the commission has revised §326.1(a)(3) to provide that changes to operating hours and buffer zones (increases or decreases) will be processed as non-notice modifications under §305.70(l) to implement THSC, §361.0905(e)(2) (HB 2244). For all other changes, the commission

establishes the criteria (e.g., modification, amendment, etc.) for changing an authorization under §305.70. HB 2244 requires rulemaking for primarily extracting the rules related to medical waste from Chapter 330 and moving them to adopted new Chapter 326.

§326.3, Definitions, §326.71(a)(2)(i), Maps and Drawings and §326.71(i), Waste Management Unit Design

Comment

SI suggested to add a definition for "Waste Unit" since SI stated that medical waste facilities do not have waste management units as typically identified in landfill operations. In relation to the same comment, SI agreed with the sections under §326.71(i) regarding "Waste Management Unit Design" but suggested retitling the section as "Waste Management Operations Design."

Response

Waste management unit design is described with examples specifically for medical waste facilities under §326.71(i)(1) as all storage and processing units (autoclaves, incinerators, etc.) and ancillary equipment (i.e., tanks, foundations, sumps, etc.) with regard to approximate dimensions and capacities, construction materials, vents, covers, enclosures, protective coatings of surfaces, etc. Therefore, it is unnecessary to provide a separate definition for waste unit. The commission has made no changes.

§326.3(23), "Medical Waste" Definition

Comment

SI commented that it is unclear why treated waste is still medical waste. SI suggested to add a separate definition for "Treated medical waste" under §326.3.

Response

The definition for medical waste under §326.3 includes "treated medical waste" and is based on THSC, §361.003(18-a) as amended by HB 2244. It is unnecessary to add a definition for "treated medical waste" because it is understood to be medical waste that is treated by an approved method in accordance with 25 TAC §1.136. Therefore, the commission has made no changes in response to this comment.

§326.3(27), "Non-hazardous pharmaceutical waste" and §326.3(57), "Trace chemotherapy waste" Definitions

Comment

SI expressed agreement with added new definitions for non-hazardous pharmaceutical and trace chemotherapy wastes.

Response

The commission appreciates the comment.

§326.3(27), "Non-hazardous pharmaceutical waste" Definition

Comment

BWS commented that the definition of non-hazardous pharmaceutical waste seems to be specific to incineration, although other treatment technologies, such as autoclaves are allowed. CJI commented that medical waste facility owners and operators will be able to manage non-hazardous pharmaceutical wastes but not be allowed to treat the waste. However, the definition seems to be specific to incineration for the treatment technology followed by disposal only. CJI indicated that no evidence has been presented to show that current treatment technologies are not effective and that incineration facilities are limited in Texas and as such this regulatory requirement places an economic hardship on generators to have this waste stream segregated from other medical wastes and incinerated. Additionally, CJI indicated that by requiring only incineration of this waste is in essence providing exclusivity to incinerators when prior to the proposed Chapter 326 rules other treatment technologies were allowed to receive and treat the material and no deficiencies in those treatment technologies have been demonstrated as it relates to the effective management of these wastes. Both CJI and BWS requested review of this definition to enable facilities to use other treatment technologies to treat this waste stream and provided the following language: "...Non-hazardous pharmaceutical waste shall be treated by autoclave technology, approved alternate treatment technology as identified in 25 TAC §1.133 and §1.135) or incineration prior to or disposal at a facility authorized to accept this waste."

GWS commented that the United States Environmental Protection Agency (EPA) is currently working on proposed rules for the management of hazardous pharmaceuticals. EPA's proposed rules can be found in the September 25, 2015, issue of the *Federal Register* (80 FR 58029). This proposal has been developed to assist the healthcare industry in the proper management of pharmaceuticals. While the proposed rules pertain to hazardous pharmaceuticals there is a discussion on the management of non-hazardous pharmaceuticals. In the September 25, 2015, issue of the *Federal Register* (80 FR 58029) it states that non-hazardous wastes or non-pharmaceutical hazardous waste were not included in the scope of the rulemaking, however, EPA recognizes that these non-hazardous pharmaceuticals may pose some risks to public health and the environment. EPA also recognizes that a large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of Resource Conservation Recovery Act (RCRA) hazardous waste under RCRA, Subtitle C. Nonetheless, EPA provides guidance or Best Management Practices (BMP) for the disposal of these wastes because they understand that while these wastes will not be regulated under federal regulations they will be considered a solid waste, and must be managed in accordance with applicable federal, state and/or local regulatory requirements. The EPA also makes the statement that they endorse the recommendation made by Practice Greenhealth in their 2008 Blueprint for Healthcare Facilities in the United States which recommends incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste like quantities. This method of treatment/destruction ensures that the pharmaceuticals will be

completely destroyed for the protection of human health and the environment. Additionally, GWS commented that, in 2014, the United States Drug Enforcement Administration (DEA) finalized rules for the disposal of controlled substances (21 CFR Parts 1300, 1301, 1304, 1305, 1307 and 1317). The DEA does not specify a specific standard on how controlled substances must be destroyed as long as the destruction provides the desired result of being non-retrievable.

Recent federal rulemaking regarding the proper treatment/disposal of non-hazardous pharmaceutical and/or controlled substances identify that full destruction needs to be achieved and the waste needs to be rendered non-retrievable. The best option to achieve these end results is to require the incineration of these items. GWS suggested the following revision: "Nonhazardous pharmaceutical waste and controlled substances shall be incinerated prior to disposal."

Response

The commission disagrees that prior to the proposed new Chapter 326 rules other treatment technologies were allowed to receive and treat the non-hazardous pharmaceutical wastes and that no deficiencies in those treatment technologies have been demonstrated. Prior to proposed Chapter 326, the agency may have allowed facilities to accept non-hazardous pharmaceutical waste for transfer to an incineration facility. If the agency allowed the acceptance of non-hazardous pharmaceutical waste for autoclave treatment,

it may have been authorized as a waste stream under the medical waste definition. However, the commission finds that in the latest 2015 rulemaking for hazardous pharmaceuticals, (September 25, 2015, issue of the *Federal Register* (80 FR 58029)), it is stated that if a healthcare facility decides to segregate its hazardous and non-hazardous pharmaceuticals, EPA recommends that healthcare facilities follow the BMPs outlined in the "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States" (Practice Greenhealth, Revised August 2008) for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. This guidance document recommends incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste like quantities. This method of treatment/destruction ensures that the pharmaceuticals will be completely destroyed for the protection of human health and the environment as was also supported by GWS. The commission acknowledges the EPA recommendation. The commission also recognizes that there may be other treatment methods approved by DSHS to specifically treat non-hazardous pharmaceutical wastes in the future. The commission is unaware of any currently approved method that is proven to be effective to treat non-hazardous pharmaceutical waste other than incineration. Therefore, the commission revised the rule language to allow for future treatment methods that may be developed and approved prior to a medical waste facility requesting use of those methods to treat non-

hazardous pharmaceutical wastes. Additionally, the commission does not accept the revision in regards to the controlled substances which are under the jurisdiction of the DEA since Chapter 326 requires facilities to obtain authorization from DEA to manage those drugs under the jurisdiction of the DEA.

§326.3(43), "Putrescible Waste" Definition

Comment

SI requested amending the definition of "Putrescible waste" to be specific to regulated medical waste. SI proposed the definition to read "Regulated medical waste that contains organic matter capable of being decomposed by microorganisms and of such a character and proportion as to cause obnoxious odors and to be capable of attracting or providing food for birds or animals."

Response

The commission agrees that "Putrescible waste" definition should be more specific to medical waste related content. Therefore, the definition is amended as suggested with the exception of the word "Regulated."

§326.3(54), "Storage" Definition

Comment

BWS and CJI commented that the inclusion of a 24-hour storage time frame creates a

problem for those transporters that are providing collection services to communities that may be located several hundred miles away where routes may be conducted on Friday and Monday, with collection vehicles being parked for over 24 hours during the weekend, prior to transporting the waste to an authorized transfer or treatment facility. BWS recommends extending the storage time to 72 hours to accommodate long distance routes and multiple pickup locations prior to treatment and disposal. CJI commented that the inclusion of a 24-hour storage time frame is more restrictive than current regulations and no evidence has been provided to require an added regulatory burden to industry for no apparent benefit to the public or for environmental protection. CJI recommends a storage time of 96 hours with refrigeration required after 72 hours. CJI also provided suggested language to facilitate their recommendation as follows: "Any vehicle inactivity such as not continuing a collection route for a period less than 96 hours is considered a temporary storage period. Exceeding 96 hours of temporary storage will require the operator to obtain a medical waste registration per Subchapter F of this title (relating to Operations Requiring a Registration). If storage exceeds 72 hours, a storage temperature of 45 degrees Fahrenheit or less for putrescible waste will be maintained. Exceeding 96 hours of temporary storage will require the operator to obtain a medical waste registration per Subchapter F of this title (relating to Operations Requiring a Registration)."

Response

The commission acknowledges and agrees with the concern for those transporters that are providing collection services to communities that may

be located several hundred miles away where routes may be conducted on Friday and continue on Monday prior to transporting the waste to an authorized transfer or treatment facility. The commission considers providing additional storage time for up to 72 hours is sufficient in order to cover the need for weekend temporary storage without a storage registration. In addition, 72 hours coincides with the maximum storage time allowed without refrigeration. Therefore, the commission revised this section to extend the temporary storage time to 72 hours to accommodate long distance routes and multiple pickup locations prior to treatment or disposal.

§326.3(54), "Storage" Definition

Comment

SI suggested a grammatical correction to the definition of storage to remove "that" from the beginning of each sub-definition.

Response

The commission agrees. The definition is amended as suggested.

§326.3(57), "Trace chemotherapy waste" Definition

Comment

CJI commented that trace chemotherapy waste stream has historically been treated using various treatment technologies other than incineration and no evidence has been

presented that current management standards are ineffective or in any way not protective of human health and the environment. CJI indicated that incineration facilities are limited in Texas and as such this regulatory requirement places a financial burden on generators to segregate and separately manage these waste streams to be incinerated. CJI agreed that even though this new term is appropriate with the creation of the new medical waste rules as this is a waste stream that can be managed in the same manner as medical waste, CJI believes that those treatment technologies currently approved in the state of Texas are appropriate treatment. CJI recommended that if the commission proceeds with this proposed requirement for incineration of this newly defined waste stream, State of Texas Environmental Electronic Reporting System (STEERS) should be updated to allow medical waste generators to identify which of the special categories of medical waste are generated at their facilities so the agency, transporters, and processors can be aware of wastes that may be present at the site that will require special handling and/or be prohibited from being processed in their specific treatment units. CJI suggested replacing "incinerated" with "...and treated by approved DSHS treatment technologies...."

GWS agreed with the proposed rule and supported the definition that trace chemotherapy waste shall be managed as medical waste and incinerated.

Response

The commission disagrees that trace chemotherapy waste stream has historically been treated using various treatment technologies other than

incineration and that no evidence has been presented that current management standards are ineffective or in any way not protective of human health and the environment. Prior to proposed new Chapter 326, the agency may have allowed facilities to accept trace chemotherapy waste for transfer to an incineration facility. If the agency allowed the acceptance of trace chemotherapy waste for a treatment other than incineration, it may have been authorized as a waste stream under the medical waste definition. EPA recommends that healthcare facilities follow the BMPs outlined in the "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States" (Practice Greenhealth, Revised August 2008) for the management, treatment, storage and disposal of trace chemotherapy wastes. This guidance document recommends incineration rather than autoclaving any material. The commission also recognizes that there may be other treatment methods approved by DSHS to specifically treat trace chemotherapy waste in the future. The commission is unaware of any currently approved method that is proven to be effective to treat trace chemotherapy waste other than incineration. Therefore, the commission revised the rule language to allow for future treatment methods that may be developed and approved prior to a medical waste facility requesting approval from the executive director to use those methods to treat trace chemotherapy wastes.

§326.19(b), Packaging and §326.21(b), Labeling

Comment

SI commented that they would like to have a clarification for the applicability of §326.19(b) to sharps containers. SI also requested clarification if the lettering on sharps containers would be required to be 0.24 inches as referenced under 49 CFR §173.197. SI suggested the following clarification: "For shipments of sharps containers on racks meeting Federal Department of Transportation (DOT) requirements, each rack must be appropriately marked to identify the name and address of the generator and the date of shipment."

Response

The commission acknowledges that sharps containers must be packaged to comply with applicable requirements referenced or cross-referenced under 49 CFR §173.134. The commission acknowledges that §326.21(b) does not apply to sharps containers since the requirements for marking (labeling) sharps is addressed under §326.19(b). The commission recognizes that the title and the contents of §326.21(b) does not specifically exclude sharps from those requirements. Therefore, the title for §326.21 is amended from "Labeling" to "Labeling Containers Excluding Sharps" to clarify any ambiguity. Since marking/labeling for sharps containers are specifically referenced to appropriate federal requirements, additional language suggested by SI has not been added to the rule.

§326.31, Exempt Medical Waste Operations

Comment

CJI and GS commented that current and proposed rules have regulations pertaining to generators (generator status, packaging medical waste, storing medical waste) but the agency has not enforced these rules with generators by performing inspections to determine compliance of generators with these requirements. Since the commission is including new language to identify generator status, the commission should update the STEERS to provide a means for medical waste generators that use STEERS to provide this information electronically. The self-certification can also be done through STEERS reporting (for those facilities that have a STEERS account) and would assist generators in understanding their waste management obligations regarding the proper identification, packaging and labeling of medical waste. This reporting would add negligible regulatory burden and would not cause an economic hardship for those generator's that are already reporting through STEERS to the agency. By requiring those facilities that are already reporting to the commission to identify their generator status, the commission will have a greater opportunity to enforce packaging and specific management requirements for medical wastes and ensure proper management by waste transporters and management facilities. CJI and GS understand that while there are generators that are not currently reporting activities to the agency through STEERS, most generators that are large quantity generators of medical waste are doing so now. CJI and GS stated that it would also be easy for the generators to identify if they generate any medical wastes that require special management or treatment technologies (as required in this rulemaking) to enable

transporters and treatment facilities to assist generators in ensuring proper management of the medical wastes they generate. CJI and GS encouraged and requested that the commission provide a means for generators to easily document their status and the special classes of medical waste they generate in the adopted rules.

Response

The commission disagrees. Requiring generators to submit self-certification information to comply with identification, packaging and labeling medical waste through STEERS or any other mechanism is beyond the scope of the proposed rules and HB 2244. Additionally, the new terminology (SQG and LQG) is intended to classify the generators using existing rule language which distinguishes between those generators with less than 50 pounds per month of medical waste generation versus more than 50 pounds per month. The commission has made no change.

§326.31(a), Small Quantity Generator (SQG) and Large Quantity Generator (LQG) On-site Storage Facility

Comment

SI recommended a clarification edit to distinguish small quantity and large quantity generators as it relates to medical waste management since similar terminology is used for hazardous waste generators as well. SI suggested using "of regulated medical waste" for those terms.

Response

The commission understands that there is a reference to SQGs and LQGs in hazardous waste rules, however the commission intends that the terms listed under §326.3(14) define that these terms are for medical waste generators for the purposes of proposed Chapter 326. Therefore, the commission has made the change as suggested.

§326.37(a), General Requirements, §326.69(a), Registration Application Formatting, Posting, Appointment and Fees

Comment

SI commented that notifications should be made available to the agency in one hard copy stamped and otherwise submitted electronically. SI states that this makes it easier for both the agency and the regulated entity in providing appropriate documentation. SI also commented that registration applications should also have the option to be submitted in one hard copy and electronically.

Response

The commission agrees that providing a notification and a registration application electronically is a possible option. Currently, the agency has e-permitting and e-reporting systems established for municipal solid waste notifications for recycling facilities and for quarterly and annual reporting for

municipal solid waste facilities. At this time, the agency does not have the resources to accept electronic submittals for notifications and registration applications for medical waste management facilities. However, the commission recognizes that there should be an option for future use of these systems for medical waste facilities. Therefore, the commission is adding language to authorize the executive director to allow for future electronic submittals as its filing systems develop.

§326.39(a), On-Site Treatment by Small Quantity Generators and §326.41(a), On-Site Treatment by Large Quantity Generators

Comment

UT Systems commented that non-exempt generators who intend to store and process waste must notify the TCEQ and the intent is a one-time notification, but the proposed language is not specific and has been interpreted as requiring ongoing notification to the agency when personnel changes. UT Systems suggested a change in rule language to reflect one-time notification clarification.

Response

The commission agrees with the comment and has revised rule to include "one-time" notification.

§326.39(a)(1), On-Site Treatment by Small Quantity Generators and §326.41(a)(1), On-Site Treatment by Large Quantity Generators

Comment

UT Systems commented that the name (printed) and initials of the person(s) performing the treatment are not relevant to facility notifications and advised the following language: "Names and contact information for the responsible party or institutional department overseeing the treatment of waste."

Response

The commission acknowledges that contact information for the facility must be provided instead of name and initials of the person(s) performing the treatment. The name and initials of the person(s) are needed for on-site recordkeeping. The commission has made the suggested change and also revised §326.39(b) and §326.41(b) to add the name and initials of the person(s) performing the treatment to those sections.

§326.43(b)(2), Medical Waste Collection and Transfer by Licensed Hospitals, §326.53(b)(6)(B)(vi), Transporters-Other Requirements, and §326.71(i)(5), Waste Management Unit Design

Comment

SI, CJI, and GS commented that these rule provisions are burdensome and potentially unenforceable due to the inability of the agency or transporters to know if a medical waste

box has been previously refrigerated and if the boxes contained putrescible wastes. Commenters also stated that most route trucks are not refrigerated and routes are not currently established based on this type of waste. This regulatory requirement favors those companies that can easily absorb the cost of maintaining a fleet of refrigerated trucks. This inability to allow for the 72-hour delay will also cause increase cost for transporters and healthcare. Finally, CJI and GS commented that a review of the regulations leading up to the currently approved medical waste regulations (Chapter 330, Subchapter Y) could only identify that the primary concern for refrigeration is to prevent those organisms of concern from creating a public nuisance in the form of putrescence (Adopted Rules, December 6, 1994 (19 TexReg 9617)). The preamble for the 1991 rule adoption (May 7, 1991 (16 TexReg 2529)), provides a discussion as to why the health department chose to only require refrigeration of waste for transporters and storage facilities that hold waste longer than 72 hours. In this proposed rule making process, the agency has not presented any technically justifiable basis for requiring this increased regulatory burden. All commenters indicated that there is nothing in the federal regulations that require refrigeration today. This leaves this option to the generator based on the potential waste they generate and commenters are not aware of any instances where this has caused any public harm or environmental threat where once refrigerated material is unrefrigerated and then refrigerated again. Therefore, all commenters strongly recommended that the agency remove this requirement and not place a restriction that would require refrigeration from the time of pick up.

The suggested change by CJI and GS is also to add "or if objectionable odors are detected when transported and/or held for longer than 72 hours during the post-collection transporter storage period." to the end of §326.53(b)(6)(B)(vi) and to remove "The 72-hour delay is not allowed for putrescible or biohazardous untreated medical waste that has been elected to be refrigerated during pre-collection storage. In that case, the putrescible or biohazardous untreated medical waste must remain refrigerated during post-collection storage as well."

Additionally, CJI and GS stated that the rule requires refrigeration for "biohazardous waste" yet the proposed rules do not provide a definition for biohazardous waste. They indicated that they could not find a definition for “biohazardous waste" under U.S. DOT, Occupational Safety and Health Administration (OSHA), and EPA. The only reference to this term is in OSHA's Bloodborne Pathogen Standard as it relates to a "biohazardous symbol."

All commenters requested the agency review this proposed rule and consider adopting the current storage time frames for medical waste that have proven to be effective as identified in 30 TAC §330.1209(b) and §330.1211(c)(2)(F). CJI and GS also requested the agency to remove the undefined term "biohazardous" waste.

Response

The commission recognizes the concerns for the 72-hour refrigeration

requirement initiated at the time of pickup if the waste has already been refrigerated. The commission agrees to allow transporters to begin the 72-hour time limit for refrigeration at the time of collection whether or not the waste has been refrigerated during pre-collection storage. Therefore, the commission has made the suggested change to the rules citations included in the comment's heading.

In regards to the "biohazardous" definition, the commission acknowledges that the term biohazard has been brought over from Chapter 330, Subchapter Y as it existed. The commission agrees that the term "biohazardous" waste has not been defined under federal regulations. However, the commission finds that the "biohazardous" term and the label is universally accepted in the health care and medical waste management industry because of biohazard labeling references to OSHA standards in various federal and state regulations. Therefore, the commission will provide clarification for the "biohazard" terminology by referencing the OSHA standards for labeling. The commission considers that the healthcare industry and OSHA are better suited to classify biohazardous material. Therefore, the commission has made a change to §326.21(a) to add a reference to OSHA labeling standards for "biohazardous" materials.

§326.53(b)(6), Other Requirements

Comment

SI suggested a punctuation correction to the end of the sentence for this rule.

Response

The commission agrees and has made the correction to replace the period "." with a colon ":" at the end of the sentence.

§326.53(b)(6)(A), Other Requirements

Comment

SI questioned whether the identification requirement for the cargo-carrying compartments should be continued to be displayed regardless of waste being in the unit or not.

Response

The intention of the rule for identification requirement for the cargo-compartment applies to the use of the compartment while it contains medical waste. The commission considers that a clarification should be added to the preamble since the rule has been brought over from Chapter 330, Subchapter Y as it existed. The commission has not made any changes in response to this comment.

§326.53(b)(6)(B), Other Requirements

Comment

SI requested clarification as to whether sealed wood floors would be acceptable as an impervious, non-porous material since it has been causing inconsistencies for enforcement.

CJI commented that during stakeholder meetings the agency indicated that "The impervious flooring is needed for the protection of human health and the environment" without providing any evidence as to the basis for this statement. CJI stated that while this requirement is not a new requirement being proposed during this rulemaking, the basis for requiring impervious flooring, which is not defined in the rule, for the transportation of wastes which do not contain free liquids and/or are packed with sorbent materials is excessive. According to CJI, this requirement exceeds even the requirement for the transportation of hazardous wastes which can be shipped in drums and bulk containers of free liquids. CJI does not believe that the cargo compartment, with respect to the flooring, should be regulated more stringently for medical wastes than the cargo compartments used to transport hazardous wastes. CJI believes the need for impervious flooring was originally identified as a requirement at a time when the management of medical waste was just beginning to be regulated and federal and state agencies did not have enough information regarding the environmental impact of medical waste. Any impact to human health and the environment is minimized by the packaging requirements for medical wastes. Additionally, proposed §326.53(b)(6)(A)(iii) requires transporters to carry a spill kit to address any spills that may occur.

CJI also indicated that this requirement will be burdensome to smaller transport companies especially in the event of a transportation unit malfunction. In the event of a malfunction transporters will typically need to rent an additional vehicle. Obtaining rental vehicles with impervious flooring is difficult and is not always available. Therefore, CJI requested the requirement be revised to read that the cargo compartment must be constructed and maintained to prevent loss of waste material and minimize health and safety hazards to solid waste management personnel, the public, and the environment.

Response

The commission considers that human health and safety would be lessened by removing the criteria for an impervious and nonporous surface since waste may leak during transportation even if the packaging requirements are met; specifically if the transporter is involved in an accident. Sealed floors and sides would serve as an additional layer of protection from environmental contamination and exposure to contaminants. In addition, this rule has been brought over from Chapter 330, Subchapter Y as it existed and revising the requirement to reduce this criteria from "impervious and nonporous floor and sides" to generic requirement to "prevent loss of waste material" is excessively broad. The commission has made no changes. In regards to SI's request to clarify whether sealed wood floors are impervious and nonporous, the commission considers that wood floors are not impervious and nonporous. In cases where wood floors have been modified, the applicant

must demonstrate that the modification of the wood floor renders it impervious and nonporous.

§326.53(b)(8)(B), Other Requirements

Comment

SI commented that the requirement for listing the names of the persons collecting, transporting and unloading the waste on a manifest is an unreasonable burden and enforcement issue. SI indicated that the main concern for the agency should be the company. The names of the persons collecting, transporting and unloading the waste could all be different and ultimately the owner /operator of the facility is responsible for compliance therefore the employee names should be irrelevant. SI also requested clarification that whether the facility would be the ultimate responsible party and not the individual.

Response

The commission disagrees with the comment because the person collecting, transporting and unloading medical waste is responsible to ensure that medical waste has been packaged by the generator in accordance with the provisions of §§326.17, 326.19, and 326.21. Transporters must not accept containers of waste that are leaking or damaged unless or until the shipment has been repackaged. In addition the rule has been brought over from Chapter 330, Subchapter Y as it existed. SI also commented that providing the

individual names is burdensome and causes unreasonable enforcement issues for the facility/transporter. The commission has made no changes.

§326.53(b)(8)(G) and (b)(10), Other Requirements

Comment

SI requested that "or electronic record" option for name and signature of facility representative acknowledging receipt of the untreated medical waste and the weight or volume of containers of waste received be added to the rule. SI also requested to add "or electronic copies" as an option to the original manifest.

Response

At this time, the agency does not have the resources to accept electronic records of names and signatures on manifests or as an option for original manifests. However, the commission recognizes that there should be an option for future use of these systems for medical waste facilities. Therefore, the commission is adding language to authorize the executive director to allow for future electronic submittals if the commission implements such a system.

§326.53(b)(12) and (13), Other Requirements

Comment

SI requested addition of the term "or Regulated Garbage" after the term "Animal and Plant

Health Inspection Service (APHIS)" waste to ensure that it is clear for inspections by the agency since according to SI, they are required to include the term "Regulated Garbage" on shipping documents and containers.

Response

The commission agrees with the comment and has revised the language to reference "APHIS Regulated Garbage" instead of "APHIS waste."

§326.53(b)(17), Other Requirements

Comment

SI suggested a punctuation correction to replace the word "as" with "at" before "a treatment/processing facility."

Response

The commission agrees and has made the correction.

§326.61(a), Applicability and General Information

Comment

UT Systems commented that the proposed language in this section is intended to require registration by commercial medical waste treatment facilities. This subchapter could easily be misconstrued to include institutions, such as teaching hospitals, that store or process untreated medical waste. UT Systems recommended the addition of "This excludes small

and large quantity generators that may store or process untreated medical waste." to §326.21(a) to prevent misunderstanding and inclusion of hospitals.

Response

The commission agrees that licensed hospitals are not required to obtain a registration under Chapter 326, Subchapter F. The levels of authorizations clearly identify the types of entities that must apply for notification, registration by rule and registrations. Registration applications are not inclusive of licensed hospitals since they are referenced under the notification requirements of this chapter. The commission has made no changes in response to this comment.

§326.61(d) and (e), Applicability and General Information

Comment

SI commented that these rule provisions are vague, subjective and difficult to enforce and it could create public perception concern. SI also stated that if there are other requirements, they should be included or at least specifically referenced so that the applicant is clear on the expectation.

Response

The rule provides flexibility for the agency to request any additional information specific to a facility to assure compliance with applicable

statutory and regulatory requirements. Specific information would be listed in the facility's authorization under standard or special provisions which would address public and compliance concerns, and any requirements associated with those concerns. No changes have been made in response to this comment.

§326.61(h), Applicability and General Information

Comment

SI requested clarification whether this rule addresses home generated regulated medical wastes and pharmaceutical wastes or if it means that waste generated from a household will be processed as medical waste if it ends up at a medical waste facility.

Response

The commission's intention is to allow medical waste facilities to accept municipal solid waste from homes and workplaces where the municipal solid waste would be classified as medical waste if it were generated by health care-related facilities. Examples might be sharps used by individuals who self-medicate at home or at workplaces and would like to deliver them to an authorized treatment facility. This provision provides the processing facility with an option to accept this type of waste from the public. Therefore, no changes have been made.

§326.63(b), Property Rights

Comment

SI and CJI commented that medical waste facilities do not have post closure care. These facilities do not "dispose" of waste on site. SI indicated that it is not clear how or why the owner or operator would retain rights of entry to the facility especially if it were a leased property. SI stated that this may have been a carry-over from the solid waste regulations that should be removed. CJI also commented that only an unforeseen circumstance at the time of closure that caused waste constituents to be left in place would require post closure care and this circumstance would require an amendment to the approved closure which could require post closure care. CJI suggested the insertion of "if required" after "the end of closure care period."

Response

The commission acknowledges that the terminology requires clarification. The rule referencing the closure care period was to address closure activities not a post closure care period. Medical waste facilities similar to other municipal solid waste facilities do not require post closure care unless unforeseen circumstances occur that would require extended care. The commission does not agree with the insertion of "if required" since the rule is not intended for post closure care period but rather for closure activities. Therefore, the commission has only replaced the term "closure care period" with "closure activities."

§326.71(a)(2)(D), Facility access and facility layout and §326.75(m), Noise Pollution and Visual Screening

Comment

SI commented that the provisions for visual screening are more specific to municipal solid waste landfill operations. SI also indicated that medical waste operations are typically operated within enclosed facilities, would not have these same risks and, most often, regulated medical waste operations are within industrial areas.

Response

The commission disagrees, noise pollution and visual screening is specifically required by THSC, §361.0905(e)(18), HB 2244 as it applies to medical waste facilities. This information must be described in the site operating plan. In addition, reduced buffer zone distance may lead to close proximity to residents and/or landowners of adjacent properties. Even though the majority of activities are conducted in an enclosed building, most medical waste facilities would have trucks parked outdoors and there would be truck traffic which may require visual screening from surrounding neighbors. Therefore, the commission has made no changes in response to this comment.

§326.71(a)(2)(G), Facility access and facility layout

Comment

SI commented that a facility should identify the main roadways, but these facilities will not be the same type of operations as a landfill requiring heavy equipment. Therefore, SI requested to leave this section to address only the general location of roadways.

Response

The commission understands that medical waste facilities are not the same types of operations as the landfills, however, medical waste facilities utilize public roadways for incoming and outgoing waste that is transported in varying truck sizes designed for medical waste. The impact of a facility's expected volume of traffic in the area warrants the information including surface types of those roads to be depicted on a map for affected landowners, interested persons and the general public. Therefore, the commission has made no change in response to this comment.

§326.71(a)(2)(J and K), Facility Access and Facility Layout

Comment

SI commented that the requirements listed under §326.71(a)(2)(J) and (K) are typically needed for landfill operations and that there would not be any need to have construction phases that would mandate the extensive representations as would be needed for a landfill that would continue to grow or develop in phases. SI also commented that initial utilities should be identified as part of general construction process.

Response

The commission considers phased construction to provide flexibility to business owners to grow their operations in phases instead of establishing all at once and providing financial assurance as needed for each phase. Additionally drainage, pipeline and utility easements may need to be addressed for each phase of development. Therefore, the commission has made no change in response to this comment.

§326.71(a)(3), Land-use map and §326.71(a)(5), Impact on Surrounding Area

Comment

SI commented that surrounding property should be identified but that one mile is not necessary because of the way most medical waste facilities would be built. SI recommended the identification of owners in the immediate property line.

SI also commented that §326.71(a)(5) is too vague and subjective. SI believes that if a facility has met the criteria laid out in the regulations then it should be sufficient to be protective of the environment and that it would be difficult to enforce this section of the rule and could create a public perception concern. SI recommended this section be removed or revised to be more specific to regulated medical waste.

Response

The commission considers this information important to evaluate the impact of the facility and to assess the compatibility with the surrounding area.

Additionally, this information allows the commission to ensure that the use of land for a medical waste facility would not adversely impact human health or the environment. Therefore, the commission has made no change in response to this comment.

§326.71(e)(1) - (4), Transportation

Comment

SI commented that this section would be more appropriate for a solid waste transfer station that would have larger impact on the environment, such as larger equipment, frequent truck traffic, different types of truck traffic, etc. SI requested a modification to the section to make it more specific to regulated medical waste and minimize the amount of information requested such as the estimated number of trucks for the operation. SI also indicated that medical waste operations are even less impactful than a general common carrier operation and that evaluation of traffic within a one-mile radius is excessive.

Response

The commission disagrees. Transportation information is a component for development and design of a facility that would have incoming and outgoing trucks loaded with waste. It is necessary to evaluate the current and future impact of truck traffic expected to be generated by the facility within one mile of its intended location and coordination with the entity exercising maintenance responsibility of any and all public roadway improvements that

may be needed. Additionally, site development information is a requirement listed in THSC, §361.0905(e)(1)(B), HB 2244. Therefore, the commission has made no change in response to this comment.

§326.71(j), Treatment Criteria

Comment

SI requested clarification if these additional requirements for procedures are related to those alternative technology options as identified under 25 TAC §1.135.

Response

The written procedure for the operation and testing of any approved equipment used and for the preparation of any chemicals used in medical waste treatment must be maintained on site. Alternative treatment technologies are not related to the procedures listed in this rule. The listed procedures are required for approved treatment methods at authorized medical waste facilities. Alternative treatment technologies must be approved by DSHS prior to the commission allowing its use at a medical waste facility. The commission has made a change to the rule to clearly indicate that alternative treatment technologies must be approved by DSHS by moving the second sentence in §326.71(j) to adopted §326.71(j)(7).

§326.75(a), Personnel and Equipment

Comment

SI commented that all the information required under §326.75(a) is new and is already covered by regulations identified by other regulations (OSHA). SI indicated that the need to have this information in the site operating plan (size and type of equipment) can be very restrictive to a facility. With the advancement in personal protective equipment and changing regulations, facilities should have the freedom to provide the correct equipment to their employees with the need for a site operating plan modification. SI requested this section to be removed and replaced with something that states that the facility is required to provide adequate and appropriate equipment for employees for their operations and under all other applicable regulatory requirements. SI indicated concern that by putting something in the application it would require modifications any time there is a change to this equipment. If there was a concern based on the recent events (Ebola and other potential emerging diseases) then the regulation should point the operations to Center for Disease Prevention and Control requirements. Specifically, SI requested removal of §326.75(a)(3) since it will be specific to the functions of the operations and if there are minor modifications then each time something changes then it will require some type of modification.

SI also requested a revision to §326.75(a)(4) to the procedures for the detection and prevention of the receipt of prohibited wastes since SI believes that employees required to open containers for random inspections. The suggested language is as follows: "Employees should be trained on identification of improper waste; If waste is identified the generator

will be notified to ensure proper management of that waste; Records of unacceptable loads shall be maintained on site (sic) as part of operating record. "

Response

The commission's intent is not to require operators to provide information on personal protective equipment. Equipment is referenced in other parts of the rules such as processing, storage equipment or ancillary equipment. Therefore, the commission has removed the "and Equipment" from the title of this section and replaced it with "Functions." In addition, the commission has also removed §326.75(a)(2) which required duplicate information for equipment used at the facility. To require the number of processing and storage equipment that will be utilized at the facility, the commission has added "number of units" to §326.71(i). The key personnel functions and their titles are needed for the site operating plan to identify responsibilities for waste management activities such as but not limited to waste receipt, loading/unloading, processing of waste properly, inspections and recordkeeping. The commission is concerned with information regarding key personnel functions and not with individual's names occupying each position.

The commission does not intend to require the opening of containers for random inspections. Even though the commission does not accept the suggested language, the commission has provided clarification to this

requirement by adding "packaging for" after "random inspections of" to §326.75(a)(4)(A).

§326.75(b), Waste Acceptance

Comment

SI agreed that the medical waste operations should have waste acceptance protocols to reduce the potential of unacceptable waste being managed. SI stated that asking for "the sources and characteristics of medical wastes proposed to be received for storage and processing . . ." could be unrealistic depending on what the agency is asking. SI believes that the general definition of regulated medical waste identifies the types of things that a facility expects to be brought to the facility for treatment.

SI requested clarification if the commission is referring to identification of the landfill that the medical waste will go after treatment of if the waste is going to be transferred to another site with the phrase ". . . and the intended destination of the medical waste received."

SI also requested clarification if medical waste facilities could receive hazardous waste but not for treatment. SI considers a scenario at the same site where medical and hazardous waste may be stored together since many healthcare facilities are generating more hazardous waste. SI asked if the commission would consider a situation where a facility would be requested to permit a dual waste location.

Additionally, SI asked whether recyclable materials that are comingled with medical waste such as used medical devices can be segregated and sent back to generator or the manufacturer.

Response

Facilities may process different types of medical waste that would be subject to different types of handling, processing and final disposition. The commission requires the operator to identify sources and characteristics of the waste so the commission can determine if the waste management operations would be in compliance with the waste streams that are identified. Additionally, waste acceptance and analysis is specifically required by THSC, §361.0905(e)(4), HB 2244 as it applies to medical waste facilities.
The agency is referring to the appropriate method of disposition (e.g., incineration, landfilling or transfer) with the phrase ". . . and the intended destination of the medical waste received" not a particular facility name and location.

The commission agrees that a facility may have dual authorizations to accept hazardous and medical waste. However, hazardous waste authorization is separate from medical waste registration authorization and cannot be authorized or accepted under medical waste registrations. This includes

accepting, storing and/or processing of hazardous waste. All of these activities can only be authorized by an industrial hazardous waste authorization separately. The commission has processed dual authorization facilities in the past and they are required to have physically separated waste management areas and units and the authorization boundaries for each should be depicted on a site layout drawing. There may be other requirements that must be addressed on a case-by-case basis.

The commission currently allows the recycling of source separated materials. The commission also understands there may be situations on a case-by-case basis where it may be acceptable to allow the separation of recyclable material from medical waste. In such cases, the commission may consider the recycling of the material to be appropriate however it should be addressed in the application clearly and be evaluated by the commission on an application specific basis. The commission has made no changes in response to these comments.

§326.75(c)(4) and (5), Facility Generated Waste

Comment

SI commented that this section seems to be unnecessary as non-waste management rule is already covered under the Texas Pollution Discharge Elimination System Authority. SI recommended that it simply states that the facility must maintain compliance with these

provisions without further specification.

Response

The commission did not accept the suggested language, however, it agrees with the comment to the extent that a copy of the permit to discharge wastewater to a treatment facility permitted under TWC, Chapter 26 would be available for all inspections and it must be obtained prior to beginning of facility's operations. The commission therefore revised the language under §326.75(c)(5) from "The owner or operator shall provide a copy of the authorization to discharge wastewater to a treatment facility permitted under TWC, Chapter 26." to "The owner or operator shall make available the authorization to discharge wastewater to a treatment facility permitted under TWC, Chapter 26 prior to beginning of facility's operations and for all inspections."

§326.75(g)(2), Access Control, §326.75(l), Facility Access Roads

Comment

SI commented that the access control is a requirement more suitable for a municipal solid waste facility especially for those which would be accepting waste from the public. Most if not all regulated medical waste facilities are not generally open to the public. SI agrees that there should be safe access but it would be authorized access only for those employees that are fully aware and trained for the proper management of equipment on site. SI requested

removal of §326.75(g)(2).

SI also commented that requirements listed under §326.75(l) are more associated with heavy equipment, large and high volume of trucks and more occasions for there to be dust present. SI recommended §326.75(l)(1) to be modified further to be more specific to medical waste facilities. More specifically, SI requested removal of §326.75(l)(2) and (3).

Response

The commission provided an option for medical waste facilities to accept waste from the public as explained in a previous comment regarding §326.61(h). Therefore, the commission does not agree that the safe access would be required in all cases only for employees that are fully aware and trained for the proper management of equipment on site. The commission has neither removed nor made changes to §326.75(g)(2).

In regards to §326.75(l), the commission agrees that dust may be present more often with heavy equipment and higher truck volumes but the possibility of dust becoming a nuisance still exists with any volume of truck traffic or lack of dust controls. Access roads owned by the facility must be maintained so as not to create safety issues such as depressions, ruts and potholes and that is the responsibility of the facility owner as part of the site operating plan. In addition, the commission considers that it is the responsibility of the facility

owner to coordinate with the maintenance authority for other access roads to ensure public safety and safe transportation of waste to and from the facility. Therefore, the commission has made no changes.

§326.75(i) and (i)(1), Operating Hours

Comment

SI requested that the facility provide site operating hours instead of the specific hours and days provided by the commission and alternative operating hours of up to five days in a calendar year to accommodate special occasions, special purposed events, holidays, or other special occurrences. SI requested deleting those hours and days specified by the commission.

Response

The commission considers that it has a reasonable basis to restrict operating hours to limit impacts on the public as appropriate. Therefore, no change has been made.

§326.75(k), Control of Windblown Material and Litter

Comment

SI commented that this rule is more of a municipal waste facility requirement and recommended removal of it.

Response

The commission disagrees, control of litter including windblown material applies to medical waste facilities and is specifically required by THSC, §361.0905(e)(17), HB 2244.

SUBCHAPTER A: GENERAL INFORMATION

§§326.1, 326.3, 326.5, 326.7

Statutory Authority

The rules are adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017, and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rules implement THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.1. Purpose and Applicability.

(a) The regulations promulgated in this chapter cover aspects of medical waste management from medical waste facilities under the authority of the commission and are based primarily on the stated purpose of Texas Health and Safety Code (THSC), Chapter 361. The provisions of this chapter apply to any person as defined in §3.2 of this title (relating to Definitions) involved in any aspect of the management and control of medical

waste as defined in THSC, §361.003(18-a) and medical waste facilities and activities including storage, collection, handling, transportation, and processing. Furthermore, these regulations apply to any person that by contract, agreement, or otherwise arranges to process, store, or dispose of, or arranges with a transporter for transport to process, store, or dispose of, medical waste owned or possessed by the person, or by any other person or entity.

(1) Permits and registrations~~, and other authorizations~~ issued by the commission and its predecessors, that existed before this chapter became effective remain valid for the later of two years from the effective date of this chapter~~,~~ or until a final decision is made on a timely filed application for an existing authorization to comply with this chapter~~, until suspended or revoked, or as expressly provided otherwise in this chapter~~. Authorizations under the existing Chapter 330 rules must be updated by filing a new application within two years of the effective date of this chapter to comply with the provisions of this chapter. Registrations by rule, subject to annual renewal, remain in effect and must renew under this chapter. The executive director is authorized to extend this deadline based on an authorized entity making a request supported by good cause. Applications for an existing permit or registration ~~authorization~~ to comply with this chapter will not be subject to the standard procedures for processing applications, including any requirements for notice and public participation. Authorizations, other than permits, registrations, or registrations by rule, that existed before the adoption of this

chapter became effective, remain valid and are subject to these rules when they become effective.

(2) A person that has a pending application for the management of medical waste as of the effective date of this chapter shall be considered under the former rules of Chapter 330 of this title (relating to Municipal Solid Waste) unless the applicant elects otherwise. Permits or Registrations ~~Authorizations~~ issued under the former rules remain in effect for the later of two years from the effective date of this chapter or until the commission makes a final decision on an application to comply with this chapter.

(3) Modification requests submitted after the effective date of this chapter shall be prepared and submitted in accordance with the provisions of §305.70 of this title (relating to Municipal Solid Waste Permit and Registration Modifications) and in accordance with this chapter. Requests to modify buffer zones or operating hours under this chapter will be processed as modifications that do not require notice. Modification requests pending on the effective date of this chapter may be prepared and submitted in accordance with the provisions of §305.70 of this title and in accordance with the former rules in Chapter 330 of this title unless the applicant elects otherwise.

(4) The requirement in §326.23(e) of this title (relating to Shipping) to provide notice to landfills that waste shipments include treated medical waste applies to

existing authorizations regardless of any conflicting language in those authorizations or rules in Chapter 330 of this title.

(b) This chapter does not apply to waste that is subject to 25 TAC Chapter 289 (relating to Radiation Control).

§326.3. Definitions.

Unless otherwise defined in this chapter, those definitions of words, terms, and abbreviations used in this chapter which are defined in 25 TAC §1.132 and §133.2 (relating to Definitions) apply. Should the definitions found in 25 TAC §1.132 change, such changes shall prevail over the definitions found in this section. Unless otherwise noted, all terms contained in this section shall be defined by their plain meaning. This section contains definitions for terms that appear throughout this chapter. Additional definitions may appear in the specific section to which they apply. The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

(1) Active life--The period of operation beginning with the initial receipt of medical waste and ending at certification/completion of closure activities in accordance with §326.71 of this title (relating to Registration Application Contents).

(2) Affiliated facility--A health care-related facility that generates a medical waste that is routinely stored, processed, or disposed of on a shared basis in an integrated medical waste management unit owned, operated by a hospital, and located within a contiguous health care complex.

(3) Affiliated with--A person, "A," is affiliated with another person, "B," if either of the following two conditions applies:

(A) "A" owns or controls more than 20% of the voting interest, fair market value, profits, proceeds, or capital gains of "B;" or

(B) "B" owns or controls more than 20% of the voting interest, fair market value, profits, proceeds, or capital gains of "A."

(4) Buffer zone--A zone free of medical waste processing and storage activities within and adjacent to a facility boundary (registration boundary) on property owned or controlled by the owner or operator of the facility.

(5) Collection--The act of removing waste (or materials that have been separated for the purpose of recycling) for transport elsewhere.

(6) Commence physical construction--The initiation of physical on-site construction on a site for which an application to authorize a medical waste management facility is pending, the construction of which requires approval of the commission. Construction of actual facility and necessary appurtenances requires approval of the commission, but other features not specific to medical waste management are allowed without commission approval.

(7) Compacted waste--Waste that has been reduced in volume by a collection vehicle or other means with the exception of waste that has been reduced in volume by a small, in-house compactor device owned and/or operated by the generator of the waste.

(8) Conditionally exempt small quantity generator--A person that generates no more than 220 pounds of hazardous waste in a calendar month.

(9) Container--Any portable device in which a material is stored, transported, or processed.

(10) Contaminated water--Water that has come into contact with waste.

(11) Discharge--Includes deposit, conduct, drain, emit, throw, run, allow to seep, or otherwise release, or to allow, permit, or suffer any of these acts or omissions.

(12) Facility--All contiguous land and structures, other appurtenances, and improvements on the land used for the storage or processing of medical waste.

(13) Garbage--Solid waste consisting of putrescible animal and vegetable waste materials resulting from the handling, preparation, cooking, and consumption of food, including waste materials from markets, storage facilities, handling, and sale of produce and other food products.

(14) Generator--Any person, by site or location, that produces medical waste to be shipped to any other person, or whose act or process produces a medical waste or first causes it to become regulated.

(A) Small quantity generator (SQG)--A medical waste generator that produces 50 pounds or less per month of medical waste.

(B) Large quantity generator (LQG)--A medical waste generator that produces more than 50 pounds per month of medical waste.

(15) Hazardous waste--Any solid waste identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency under the federal Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, 42 United States Code, §§6901 *et seq*., as amended.

(16) Incinerator of Hospital/medical/infectious waste--Any device that combusts any amount of hospital waste and/or medical/infectious waste as defined under §113.2070(15) of this title (relating to Definitions).

(17) Incineration--The process of burning special waste from health care-related facilities in an incinerator as defined in Chapter 101 of this title (relating to General Air Quality Rules) under conditions in conformance with standards prescribed in Chapter 111 of this title (relating to Control of Air Pollution from Visible Emissions and Particulate Matter).

(18) Industrial solid waste--Solid waste resulting from or incidental to any process of industry or manufacturing, or mining or agricultural operations.

(19) Inert material--A natural or man-made non-putrescible, non-hazardous material that is essentially insoluble, usually including, but not limited to, soil, dirt, clay, sand, gravel, brick, glass, concrete with reinforcing steel, and rock.

(20) License--

(A) A document issued by an approved county authorizing and governing the operation and maintenance of a medical waste facility used to process or

store medical waste, other than hazardous waste, in an area not in the territorial limits or extraterritorial jurisdiction of a municipality.

(B) An occupational license as defined in Chapter 30 of this title (relating to Occupational Licenses and Registrations).

(21) Liquid waste--Any waste material that is determined to contain "free liquids" as defined by United States Environmental Protection Agency (EPA) Method 9095 (Paint Filter Test), as described in "Test Methods for Evaluating Solid Wastes, Physical/Chemical Methods" (EPA Publication Number SW-846).

(22) Manifest--The waste shipping document originated and signed by the generator or offeror in accordance with §326.53(b)(8) and (9) of this title (relating to Transporters) and any other applicable requirements under 49 Code of Federal Regulations §172.202.

(23) Medical waste--Treated and untreated special waste from health care-related facilities that is comprised of animal waste, bulk blood, bulk human blood, bulk human body fluids, microbiological waste, pathological waste, and sharps as those terms are defined in 25 TAC §1.132 (relating to Definitions) from the sources specified in 25 TAC §1.134 (relating to Application), as well as regulated medical waste as defined in 49 Code of Federal Regulations §173.134(a)(5), except that the term does not include medical waste

produced on a farm or ranch as defined in 34 TAC §3.296(f) (relating to Agriculture, Animal Life, Feed, Seed, Plants, and Fertilizer), nor does the term include artificial, nonhuman materials removed from a patient and requested by the patient, including, but not limited to, orthopedic devices and breast implants. Health care-related facilities do not include:

(A) single or multi-family dwellings; and

(B) hotels, motels, or other establishments that provide lodging and related services for the public.

(24) Municipal hazardous waste--Any municipal solid waste or mixture of municipal solid wastes that has been identified or listed as a hazardous waste by the administrator of the United States Environmental Protection Agency.

(25) 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 solid waste.

(26) New medical waste management facility--A medical waste facility that has not begun construction.

(27) Non-hazardous pharmaceutical waste--A prescription or over-the-counter human or veterinary drug that is not or does not contain federally or state-listed hazardous waste and that is not or does not contain any constituent that meets a federal or state hazardous waste characteristic under the Resource Conservation and Recovery Act, Subtitle C. In addition, the term does not contain any substance that is regulated under Chapter 336 of this title (relating to Radioactive Substance Rules). For the purposes of this chapter, owners or operators must seek an authorization from the United States Drug Enforcement Administration (USDEA) for drugs regulated by USDEA. Non-hazardous pharmaceutical waste shall be incinerated prior to disposal ~~or disposed~~ at a facility authorized to accept this waste stream. At the discretion of the executive director, other approved or alternative treatment methods may be considered, if proven to be as effective as incineration.

(28) Notification--The act of filing information with the commission for specific solid waste management activities that do not require a permit or a registration, as determined by this chapter.

(29) Nuisance--Waste that is stored, processed, or disposed of in a manner that causes the pollution of the surrounding land, the contamination of groundwater or surface water, the breeding of insects or rodents, or the creation of odors adverse to human health, safety, or welfare. A nuisance is further set forth in Texas Health and Safety Code,

Chapters 341 and 382; Texas Water Code, Chapter 26; and any other applicable regulation or statute.

(30) On-site--Medical waste managed on property that is owned or effectively controlled by one entity and that is within 75 miles of the point of generation or generated at an affiliated facility shall be considered to be managed on-site.

(31) Operate--To conduct, work, run, manage, or control.

(32) Operating hours--Those hours which the facility is open to receive waste, process, and transport waste or material.

(33) Operating record--All plans, submittals, and correspondence for a medical waste facility required under this chapter; required to be maintained at the facility or at a nearby site acceptable to the executive director.

(34) Operation--A medical waste site or facility is considered to be in operation from the date that waste is first received or deposited at the medical waste site or facility until the date that the site or facility is properly closed in accordance with this chapter.

(35) Operator--The person(s) responsible for operating the facility or part of a facility.

(36) Owner--The person that owns a facility or part of a facility.

(37) Permit--See the definition of permit contained in §3.2 of this title (relating to Definitions).

(38) Physical construction--The first placement of permanent construction on a site, such as the pouring of slab or footings, the installation of piles, the construction of columns, the laying of underground pipework, or any work beyond the stage of excavation. Physical construction does not include land preparation, such as clearing, grading, excavating, and filling; nor does it include the installation of roads and/or walkways. Physical construction includes issuance of a building or other construction permit, provided that permanent construction commences within 180 days of the date that the building permit was issued.

(39) Pollutant--Contaminated dredged spoil, solid waste, contaminated incinerator residue, sewage, sewage sludge, munitions, chemical wastes, or biological materials discharged into water.

(40) Pollution--The man-made or man-induced alteration of the chemical, physical, biological, or radiological integrity of an aquatic ecosystem.

(41) Processing--Activities including, but not limited to, 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 waste, designed to change the physical, chemical, or biological character or composition of any waste to neutralize such waste, or to recover energy or material from the waste, or render the waste safer to transport, store, dispose of, or make it amenable for recovery, amenable for storage, or reduced in volume.

(42) Public highway--The entire width between property lines of any road, street, way, thoroughfare, bridge, public beach, or park in this state, not privately owned or controlled, if any part of the road, street, way, thoroughfare, bridge, public beach, or park is opened to the public for vehicular traffic, is used as a public recreational area, or is under the state's legislative jurisdiction through its police power.

(43) Putrescible medical waste--Medical waste that contains organic matter capable of being decomposed by microorganisms and of such a character and proportion ~~Organic wastes, such as garbage, wastewater treatment plant sludge, and grease trap waste, that are capable of being decomposed by microorganisms with sufficient rapidity~~ as

to cause odors or gases or are capable of providing food for or attracting birds, animals, and disease vectors.

(44) Recycling--A process by which materials that have served their intended use or are scrapped, discarded, used, surplus, or obsolete are collected, separated, or processed and returned to use in the form of raw materials in the production of new products.

(45) Registration--The act of filing information with the commission for review and approval for specific solid waste management activities that do not require a permit, as determined by this chapter.

(46) Regulated hazardous waste--A solid waste that is a hazardous waste as defined in 40 Code of Federal Regulations (CFR) §261.3 and that is not excluded from regulation as a hazardous waste under 40 CFR §261.4(b), or that was not generated by a conditionally exempt small quantity generator.

(47) Rubbish--Non-putrescible solid waste (excluding ashes), consisting of both combustible and noncombustible waste materials. Combustible rubbish includes paper, rags, cartons, wood, excelsior, furniture, rubber, plastics, brush, or similar materials; noncombustible rubbish includes glass, crockery, tin cans, aluminum cans, and

similar materials that will not burn at ordinary incinerator temperatures (1,600 degrees Fahrenheit to 1,800 degrees Fahrenheit).

(48) Run-off--Any rainwater or other liquid that drains over land from any part of a facility.

(49) Run-on--Any rainwater or other liquid that drains over land onto any part of a facility.

(50) Site--Same as facility.

(51) Site operating plan--A document that provides general instruction for facility management and operating personnel throughout the operating life of the facility in a manner consistent with the engineer's design and the commission's regulations to protect human health and the environment and prevent nuisances.

(52) Solid waste--Garbage, rubbish, refuse, sludge from a wastewater treatment plant, water supply treatment plant, or air pollution control facility, and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, municipal, commercial, mining, and agricultural operations and from community and institutional activities. The term does not include:

(A) 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 under Texas Water Code, Chapter 26;

(B) 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; or

(C) waste materials that result from activities associated with the exploration, development, or production of oil or gas or geothermal resources and other substance or material regulated by the Railroad Commission of Texas under Texas Natural Resources Code, §91.101, unless the waste, substance, or material results from activities associated with gasoline plants, natural gas liquids processing plants, pressure maintenance plants, or repressurizing plants and is hazardous waste as defined by the administrator of the United States Environmental Protection Agency under the federal Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended (42 United States Code, §§6901 *et seq*.).

(53) Source-separated recyclable material--Recyclable material from those health care-related facilities as listed in 25 TAC §1.134 (relating to Application), that at the point of generation has been separated, collected, and transported separately from medical

waste, or transported in the same vehicle as medical waste, but in separate containers or compartments.

(54) Storage--The keeping, holding, accumulating, or aggregating of medical waste at the end of which the medical waste is processed, disposed, or stored elsewhere.

(A) Pre-collection--that storage by the generator, normally on the generator's premises, prior to initial collection;

(B) Post-collection transporter--that storage by a transporter while the medical waste is in transit. Any vehicle inactivity such as not continuing a collection route for a period less than 72 ~~24~~ hours is considered a temporary storage period. Exceeding 72 ~~24~~ hours of temporary storage will require the operator to obtain a medical waste registration per Subchapter F of this chapter (relating to Operations Requiring a Registration);

(C) Post-collection processor--that storage by a processor at a processing facility while the waste is awaiting processing or transfer to another storage, disposal, or recovery facility.

(55) Surface water--Surface water as included in water in the state.

(56) Tank--A stationary device, designed to contain an accumulation of waste, which is constructed primarily of non-earthen materials (e.g., wood, concrete, steel, and plastic) that provide structural support.

(57) Trace chemotherapy waste--Includes but is not limited to, the following items when they have come into contact with, or had the potential to come into contact with, chemotherapy agents: syringes, drug dispensing devices and broken or empty chemotherapy drug vials, gloves, disposable gowns, towels, empty intravenous solution bags and empty tubing. For hazardous chemotherapy agents (40 Code of Federal Regulations (CFR), Part 261, Subpart C), the containers must be empty as defined under 40 CFR §261.7. For the purposes of this chapter, trace chemotherapy waste shall be managed as medical waste and incinerated prior to disposal at a facility authorized to accept this waste stream. At the discretion of the executive director, other approved or alternative treatment methods may be considered if proven to be, as effective as incineration.

(58) Transfer station--A facility used for transferring medical waste from collection vehicles to long-haul vehicles (one transportation unit to another transportation unit). It is not a storage facility such as one where individual residents can dispose of their wastes in bulk storage containers that are serviced by collection vehicles.

(59) Transportation unit--A truck, trailer, open-top box, enclosed container, rail car, piggy-back trailer, ship, barge, or other transportation vehicle used to contain medical waste being transported from one geographical area to another.

(60) Transporter--A person that collects, conveys, or transports medical waste; does not include a person transporting his or her household waste.

(61) Trash--Same as "Rubbish."

(62) Treatment--Same as "Processing."

(63) Uncompacted waste--Any waste that is not a liquid or a sludge, has not been mechanically compacted by a collection vehicle, has not been driven over by heavy equipment prior to collection, or has not been compacted prior to collection by any type of mechanical device other than small, in-house compactor devices owned and/or operated by the generator of the waste.

(64) Unloading areas--Areas designated for unloading, including all storage areas, and other processing areas.

(65) Vector--An agent, such as an insect, snake, rodent, bird, or animal capable of mechanically or biologically transferring a pathogen from one organism to another.

(66) Water in the state--Groundwater, percolating or otherwise, lakes, bays, ponds, impounding reservoirs, springs, rivers, streams, creeks, estuaries, marshes, inlets, canals, the Gulf of Mexico inside the territorial limits of the state, and all other bodies of surface water, natural or artificial, inland or coastal, fresh or salt, navigable or non-navigable, and including the beds and banks of all watercourses and bodies of surface water, that are wholly or partially inside or bordering the state or inside the jurisdiction of the state.

(67) Waters of the United States--All waters that are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters that are subject to the ebb and flow of the tide, with their tributaries and adjacent wetlands, interstate waters and their tributaries, including interstate wetlands; all other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sandflats, and wetlands, the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters that are or could be used by interstate or foreign travelers for recreational or other purposes; from which fish or shellfish are or could be taken and sold in interstate or foreign commerce; that are used or could be used for industrial purposes by industries in interstate commerce;

and all impoundments of waters otherwise considered as navigable waters; including tributaries of and wetlands adjacent to waters identified in this paragraph.

(68) Wetlands--As defined in Chapter 307 of this title (relating to Texas Surface Water Quality Standards).

§326.5. General Prohibitions.

No person may cause, suffer, allow, or permit the collection, storage, transportation, processing, or disposal, or the use or operation of a solid waste facility to store, process, or dispose of solid waste~~, or to extract materials under Texas Health and Safety Code (THSC), §361.092,~~ in violation of the THSC, or any regulations, rules, permit, license, order of the commission, or in such a manner that causes:

(1) the discharge or imminent threat of discharge of medical waste into or adjacent to the waters in the state without obtaining specific authorization for the discharge from the commission;

(2) the creation and maintenance of a nuisance; or

(3) the endangerment of the human health and welfare or the environment.

§326.7. Other Authorizations.

(a) Air pollution control. All emission sources resulting from the operation of medical waste facilities shall be abated in a manner that will not cause a condition of air pollution. Owner or operator shall obtain authorization that may be required by local, state and federal agencies.

(b) Water pollution control. All liquids resulting from the operation of medical waste facilities shall be disposed of in a manner that will not cause surface water or groundwater pollution. Owner or operator shall provide for the treatment of wastewaters resulting from medical waste management activities and from cleaning and washing. Owners or operators shall ensure that storm water and wastewater management is in compliance with the regulations of the commission.

(c) It is also the responsibility of an owner or operator of a facility to obtain any other permits or approvals that may be required by local, state and federal agencies.

SUBCHAPTER B: PACKAGING, LABELING AND SHIPPING REQUIREMENTS §§326.17, 326.19, 326.21, 326.23

Statutory Authority

The rules are adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017 and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rules implement THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.17. Identification.

Prior to packaging, labeling and shipping, health care-related facilities shall identify and segregate medical waste, as defined in §326.3(23) of this title (relating to Definitions), from ordinary rubbish and garbage produced within or by the facilities. Other municipal solid waste may be combined with medical waste or may be identified and segregated as a separate waste stream. Where medical waste and other municipal solid wastes are

combined, the combined waste shall be considered to be medical waste.

§326.19. Packaging.

(a) The generator shall place the container which contains medical waste in an outer container that is rigid, leak resistant, impervious to moisture, of sufficient strength to prevent tearing and bursting under normal conditions of use and handling, and sealed to prevent leakage or as otherwise required by the United States Department of Transportation under regulations set forth in 49 Code of Federal Regulations (CFR) §173.134 and 49 CFR §173.196 which include~~s~~ infectious substances.

(b) The generator shall place sharps in a rigid, marked, and puncture-resistant container designed for sharps as described in 49 CFR §173.134.

§326.21. Labeling Containers Excluding Sharps.

(a) The generator shall conspicuously mark the outer container with a warning legend in English and in Spanish, along with the international symbol for biohazardous material as referenced under 29 Code of Federal Regulations (CFR) §1910.1030(g)(1)(i)(A). The warning must appear on the sides of the container, twice in English and twice in Spanish. The wording of the warning legend shall be: "CAUTION, contains medical waste which may be biohazardous" and "PRECAUCIÓN, contiene desechos medicos que pueden

ser peligro biológico" or as otherwise required by the United States Department of Transportation under regulations set forth in ~~49 Code of Federal Regulations (~~CFR~~)~~ §173.134 and 49 CFR §173.196 which include~~s~~ infectious substances.

(b) The generator shall affix to each container a label that contains at the minimum the name and address of the generator, and the date of shipment.

(c) If the transporter assists with weighing containers and label preparation, the generator shall ensure that the container labels meet the requirements of this section before releasing them to the transporter.

(d) The generator shall record the weight or volume on the manifest for reporting and fee purposes. If the generator chooses to use weight, the generator may have the transporter weigh each container for the generator and note the weight on the container label prior to offsite transport. Applicable fees are provided in Subchapter G of this chapter (relating to Fees and Reporting) for each recording method.

(e) The generator shall ensure that the transporter affixes to each container a label that contains the name, address, telephone number, and state registration number of the transporter. This information may be printed on the container.

(f) The generator shall ensure that the printing on required labels is done in

indelible ink with letters at least 0.25 inch in height.

(g) If a single label is used to identify the generator and the transporter, the transporter shall ensure the label is affixed to or printed on the container.

(h) The requirements of subsections (b) and (e) of this section shall not apply to shipments where the United States Postal Service or an equivalent delivery service is the transporter in accordance with the Mailing Standards of the United States Postal Service, Domestic Mail Manual, incorporated by reference in 39 CFR Part 111.

(i) The executive director may waive any or all of the requirements of this section if required to protect the public health and safety from the effects of a natural or man-made disaster.

§326.23. Shipping.

(a) Generators may transport their own untreated waste or shall release medical waste only to transporters who are registered with the executive director to transport untreated medical waste, as required in §326.53 of this title (relating to Transporters) and in compliance with 49 Code of Federal Regulations §173.6(a)(4).

(b) Except for medical waste shipped via First Class or Priority Mail using the

United States Postal Service, the generator shall obtain from the transporter a signed manifest for each shipment of medical waste.

(c) The generator shall maintain manifests regarding all shipments of untreated medical waste for a period of three years following the date of each shipment. This time period may be extended by the executive director for investigative purposes or in case of enforcement action.

(d) Generators and transporters shall maintain accurate and complete electronic or hard copy manifests for shipments of untreated medical waste and make them available for inspection by the executive director. Such manifest records shall be legible, complete and accurate originals or reproduced copies of the same, provided that any copy is authenticated by authorized personnel. The manifests may be available in electronic media with the capability for producing legible, accurate, and complete records for inspections. All documents must be available for viewing and/or copying at time of an inspection. The generator and transporter shall maintain adequate safeguards against tampering with and loss of records.

(e) Treated medical waste shipments including sharps or residuals of sharps originating from health care-related facilities shall be accompanied by a written statement to the solid waste landfill that the shipment has been treated by an approved method in accordance with 25 TAC §1.136 (relating to Approved Methods of Treatment and

Disposition).

(f) Shipments of untreated medical waste shall be stored, processed or deposited only at a facility that has been authorized by the commission to accept untreated medical waste. Untreated medical waste that is transported out of the state must be deposited at a facility that is authorized by the appropriate agency having jurisdiction over such waste.

(g) Persons that transport untreated medical waste from Texas to other states or countries or from other states or countries to Texas, or persons that collect or transport waste in Texas but have their principal place of business in another state, shall comply with all applicable requirements of this chapter for such transportation activities. If such persons engage in any activity of managing medical waste in Texas by storage, processing, or disposal, they shall follow the applicable requirements for facility operators of such activities.

SUBCHAPTER C: EXEMPT MEDICAL WASTE OPERATIONS

§326.31

Statutory Authority

The rule is adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017 and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rule implements THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.31. Exempt Medical Waste Operations.

(a) Small quantity generator (SQG) and large quantity generator (LQG) on-site storage facility. A permit, registration, notification, or other authorization is not required for on-site storage of medical waste for a generator that uses a medical waste storage facility only for medical waste generated on-site, so long as:

(1) medical waste is stored in a secure manner and location that affords protection from theft, vandalism, inadvertent human or animal exposure, rain, water, and wind; and

(2) medical waste is managed so as not to create a nuisance.

(b) SQG transporter. A permit, registration, notification, or other authorization is not required for a generator of less than 50 pounds per month of untreated medical waste that transport their own waste to an authorized medical waste storage or processing facility.

(c) All generators described in subsections (a) and (b) of this section shall follow the requirements prescribed in Subchapter B of this chapter (relating to Packaging, Labeling and Shipping Requirements) and must obtain any additional transportation authorizations necessary to comply with local, state and federal rules.

(d) A permit, registration, notification, or other authorization is not required for medical waste transported by the United States Postal Service or an equivalent delivery service in accordance with the Domestic Mail Manual, incorporated by reference in 39 Code of Federal Regulations Part 111.

(e) A person who engages in the transportation of waste within Texas when the

transportation neither originates nor terminates in Texas is exempt from the regulations of this chapter, except as to §326.53(b)(6)(A)(i) - (iii) and (B) of this title (relating to Transporters).

SUBCHAPTER D: OPERATIONS REQUIRING A NOTIFICATION
§§326.37, 326.39, 326.41, 326.43

Statutory Authority

The rules are adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017 and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rules implement THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.37. General Requirements.

(a) Generators that are not exempt and that intend to store or process medical waste authorized under this subchapter shall notify the executive director, and any local pollution agency with jurisdiction that has requested to be notified, in writing, that storage or processing activities are planned, at least 90 days prior to engaging in these activities, except for recycling and other activities as may be specifically exempted. Additional

information may be requested to enable the executive director to determine whether such storage or processing is in compliance with the terms of this chapter. This information may include, but is not limited to, type of waste, waste management methods, and facility design. Any information provided under this subsection shall be submitted to the executive director in duplicate with one copy sent directly to the appropriate regional office. A person shall include a statement justifying the facility's eligibility for a notification as established under this section. The executive director is authorized to approve requests to submit this information electronically if the commission develops electronic systems to manage the data.

(b) Any person that stores or processes medical waste authorized under this subchapter shall have the continuing obligation to provide prompt written notice to the executive director of any changes or additional information concerning type of waste, waste management methods, facility design plans additional to that reported in subsection (a) of this section authorized in ~~any permit or registration, or stated in~~ any notification filed with the executive director. Any information provided under this subsection shall be submitted to the executive director in duplicate form with copies sent directly to the appropriate regional office and any local pollution agency with jurisdiction that has requested to be notified.

(c) Any person that stores or processes medical waste authorized under this subchapter shall notify the executive director, and any local pollution agency with

jurisdiction that has requested to be notified, in writing of any closure activity or activity of facility expansion not authorized by any notification ~~permit or registration~~, at least 90 days prior to conducting this activity. The executive director may request additional information to determine whether such activity is in compliance with this chapter. Any information provided under this subsection shall be submitted to the executive director in duplicate form.

§326.39. On-Site Treatment by Small Quantity Generators.

(a) A small quantity generator (SQG) is required to notify the executive director of the operation of an approved treatment process unit used only for the treatment of medical waste generated on-site in accordance with the provisions of 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition). Alternative treatment technologies may be approved in accordance with requirements found in 25 TAC §1.135 (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities). This one-time ~~The~~ notification shall include:

(1) contact information for the generator ~~the name (printed) and initials of the person(s) performing treatment~~;

(2) if applicable, name, address, telephone number, and the Texas Commission on Environmental Quality authorization number of the mobile treatment operator providing treatment; and

(3) the method/conditions of treatment.

(b) An SQG shall maintain on-site a written record that contains the information listed in subsection (a) of this section and the following:

(1) the name (printed) and initials of the person(s) performing treatment;

(2) ~~(1)~~ the dates of treatment; and

(3) ~~(2)~~ the amounts of waste treated.

(c) A SQG shall follow the requirements listed in §326.41(c) of this title (relating to On-site Treatment by Large Quantity Generators) for disposal of medical wastes that have been treated in accordance with the provisions of 25 TAC §1.136.

§326.41. On-Site Treatment by Large Quantity Generators.

(a) A large quantity generator (LQG) that treats all or part of the medical waste

generated on-site shall notify the executive director of the operation of an approved treatment process unit used only for the treatment of medical waste generated on-site in accordance with the provisions of 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition). Alternative treatment technologies may be approved in accordance with requirements found in 25 TAC §1.135 (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities). This one-time ~~The~~ notification shall include:

(1) ~~the name (printed) and initials of the person(s) performing treatment~~ the contact information for the generator;

(2) if applicable, the name, address, telephone number, and the Texas Commission on Environmental Quality authorization number of the mobile treatment operator providing treatment; and

(3) the method/conditions of treatment.

(b) A LQG shall maintain on-site a written record that contains the information listed in subsection (a) of this section and the following:

(1) the name (printed) and initials of the person(s) performing treatment;

(2) ~~(1)~~ the dates of treatment;

(3) ~~(2)~~ the amounts of waste treated; and

(4) ~~(3)~~ written procedure for the operation and testing of any equipment used and written procedure for the preparation of any chemicals used in the treatment.

(A) The operator shall demonstrate a minimum four log ten reduction (as defined in 25 TAC §1.132 (relating to Definitions)) on routine performance testing using appropriate Bacillus species biological indicators (as defined in 25 TAC §1.132). The operator shall conduct testing at the following intervals:

(i) for generators of more than 50 pounds but less than or equal to 100 pounds per month, testing shall be conducted at least once per month;

(ii) for generators of more than 100 pounds but less than or equal to 200 pounds per month, testing shall be conducted at least every two weeks; and

(iii) for generators of more than 200 pounds per month testing shall be conducted at least weekly.

(B) For those processes that the manufacturer has documented compliance with the performance standard prescribed in 25 TAC §1.135, based on specified parameters (for example, pH, temperature, pressure), and for previously approved treatment processes that a continuous readout and record of operating parameters is available, the operator may substitute routine parameter monitoring for biological monitoring. The operator shall confirm that any chemicals or reagents used as part of the treatment process are at the effective treatment strength. The operator will maintain records of operating parameters and reagent strength, if applicable, for three years.

(C) The manufacturer of single-use, disposable treatment units shall be responsible for maintaining adequate quality control for each lot of single-use products. The treating facility or entity shall be responsible for following the manufacturer's instructions.

(D) Owners or operators of medical waste incinerators shall comply with the requirements in §111.123 of this title (relating to Medical Waste Incinerators) in lieu of biological or parametric monitoring.

(c) Disposal of treated medical waste. Medical wastes that have been treated in accordance with the provisions of 25 TAC §1.136 may be managed as routine municipal solid waste unless otherwise specified in paragraphs (1) - (5) of this subsection.

(1) Incinerator ash shall be disposed of in a permitted landfill in accordance with Chapter 330 of this title (relating to Municipal Solid Waste).

(2) Treated microbiological waste, blood, blood products, body fluids, laboratory specimens of blood and tissue, and animal bedding may be disposed of in a permitted landfill. Any markings that identify the waste as a medical waste shall be covered with a label that identifies the waste as treated medical waste. The identification of the waste as treated may be accomplished by the use of color-coded, disposable containers for the treated waste or by a label that states the contents of the disposable container have been treated in accordance with the provisions of 25 TAC §1.136.

(3) Treated carcasses and body parts of animals designated as a medical waste may, after treatment, be disposed of in a permitted landfill in accordance with Chapter 330 of this title. The collection and transportation of these wastes shall conform to the applicable local ordinance or rule, if such ordinance or rule is more stringent than this subsection.

(4) Treated recognizable human body parts, tissues, fetuses, organs, and the products of human abortions, spontaneous or induced, shall not be disposed of in a ~~as~~ municipal solid waste landfill. These items shall be disposed of in accordance with the provisions of 25 TAC §1.136(a)(4).

(5) Sharps treated and containerized with one of the approved methods as described under 25 TAC §1.136(a)(5) shall be disposed of in a permitted landfill in accordance with Chapter 330 of this title. Unused sharps shall be disposed of as treated sharps.

§326.43. Medical Waste Collection and Transfer by Licensed Hospitals.

(a) A licensed hospital may function as a medical waste collection and transfer facility and may accept untreated medical waste from generators that generate less than 50 pounds of untreated medical waste per month and that transport their own waste if:

(1) the hospital is located in an incorporated area with a population of less than 25,000 and in a county with a population of less than one million; or

(2) the hospital is located in an unincorporated area that is not within the extraterritorial jurisdiction of a city with a population of more than 25,000 or within a county with a population of more than one million.

(b) The hospital shall notify the executive director of the operation as a medical waste collection station. The hospital shall submit a written request to acknowledge the following:

(1) Waste delivered to a medical waste collection station must be packaged in accordance with the provisions of §§326.17, 326.19, and 326.21 of this title (relating to Identification; Packaging; and Labeling Containers Excluding Sharps, respectively) by the generator.

(2) For putrescible or biohazardous untreated medical waste, maintaining a temperature of 45 degrees Fahrenheit or less during pre-collection storage is optional. Such medical waste stored for longer than 72 hours during post-collection storage period shall be maintained at a temperature of 45 degrees Fahrenheit or less. ~~The 72-hour delay is not allowed for putrescible or biohazardous untreated medical waste that has been elected to be refrigerated during pre-collection storage. In that case, the putrescible or biohazardous untreated medical waste must remain refrigerated during post-collection storage as well.~~

(3) The storage of medical waste shall be in a secure manner and location that affords protection from theft, vandalism, inadvertent human or animal exposure, rain, water, and wind. The waste shall be managed so as not to create a nuisance.

(4) Medical waste must be released only to a registered medical waste transporter. A list of the waste collected at the medical waste collection station including the identity of the generator of medical waste must be provided to the transporter.

(5) Waste collected at a medical waste collection station may not be treated at the facility unless it is authorized as a treatment facility.

SUBCHAPTER E: OPERATIONS REQUIRING A REGISTRATION BY RULE §326.53, §326.55

Statutory Authority

The rules are adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017 and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rules implement THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.53. Transporters.

(a) A registration by rule is granted for persons that plan to transport medical waste. The transporter shall complete registration forms provided by the commission and submit the following information to the executive director at least 60 days prior to commencing operations:

(1) Applicant information. Name, address, and telephone number of registrant.

(2) Partner, corporate officer and director information. Name, address, and telephone number of partners, corporate officers, and directors, if applicable.

(3) Fee information. Transporters shall pay an annual registration fee to the commission based upon the total weight or volume of untreated medical waste transported. Transporter fees are located in Subchapter G of this chapter (relating to Fees and Reporting).

(4) Transportation unit information. Description of each transportation unit, including:

(A) make, model, and year;

(B) motor vehicle identification number, if applicable;

(C) license plate (tag) number, including state and year; and

(D) name of transportation unit owner or operator.

(5) Instructions for mailing fees. Fees assessed in §326.87(b) of this title (relating to Fees) by the executive director shall be paid by the registrant within 30 days of the date of the invoice and shall be submitted in the form of a check, money order, or a copy of an electronic payment confirmation made payable to the agency cashier.

(b) Other requirements.

(1) Registrations by rule expire annually on September 30th of each year for all transporters. Registrations by rule shall not be renewed unless the owner or operator has submitted to the executive director:

(A) an annual report in accordance with §326.89(d) of this title (relating to Reports);

(B) an annual fee in accordance with §326.87(b) of this title; and

(C) a renewal form to the executive director prior to the expiration of the registration by rule, but no later than August 1st.

(2) When an owner or operator has made timely application for the renewal of a registration by rule, the existing registration by rule will not be renewed until the application has been determined administratively complete by the executive director.

(3) The executive director shall, after review of any application for registration by rule, approve or deny the application. This action shall be based on whether the application meets the requirements of this chapter.

(4) Failure to timely pay the annual fee eliminates the option to manage wastes.

(5) The executive director will send a copy of the registration by rule issued with an assigned registration number, to the owner or operator.

(6) Requirements for a transportation unit and associated cargo compartment used to collect or transport untreated medical waste that is packaged and labeled as described in Subchapter B of this chapter (relating to Packaging, Labeling and Shipping Requirements) are as follows:.

(A) The transportation unit used to collect and or transport medical waste shall:

(i) have a fully enclosed, leak-proof, cargo-carrying body, such as a cargo compartment, box trailer, or roll-off box;

(ii) protect the waste from mechanical stress or compaction;

(iii) carry spill cleanup equipment including, but not limited to, disinfectants, absorbent materials, personal protective equipment such as gloves, coveralls, and eye protection, and leak-proof containers or packaging materials; and

(iv) have the following identification on the two sides and back of the cargo-carrying compartment in letters at least three inches high: (the name of the transporter); TCEQ; (registration by rule number); and Caution: Medical Waste.

(B) The cargo compartment of the vehicle or trailer shall:

(i) be maintained in a sanitary condition;

(ii) be locked when the vehicle or trailer is in motion;

(iii) be locked or secured when waste is present in the compartment except during loading or unloading of waste;

(iv) have a floor and sides made of an impervious, nonporous material;

(v) have all discharge openings securely closed during operation of the vehicle or trailer; and

(vi) maintain a temperature of 45 degrees Fahrenheit or less for putrescible or biohazardous untreated medical waste transported for longer than 72 hours during post-collection storage period. ~~The 72-hour delay is not allowed for putrescible or biohazardous untreated medical waste that has been elected to be refrigerated during pre-collection storage. In that case, the putrescible or biohazardous untreated medical waste must remain refrigerated during post-collection storage as well.~~

(7) Transportation units used to transport untreated medical waste shall not be used to transport any other material until the transportation unit has been cleaned and the cargo compartment disinfected. A written record of the date and the process used to clean and disinfect the transportation unit shall be maintained for three years unless the commission directs a longer holding period. The record must identify the transportation unit by motor vehicle identification number or license tag number. The owner or operator of the transportation unit, if not the registered transporter, shall be notified in writing by the transporter that the transportation unit has been used to transport medical waste and when and how the transportation unit was disinfected.

(8) The transporter shall maintain a record of each waste shipment collection and deposition. The record shall be in the form of a manifest or other similar

documentation and copies may be maintained in electronic media as described in §326.23(d) of this title (relating to Shipping). The transporter shall retain a copy of all manifests showing the collection and disposition of the medical waste. Copies of manifests shall be retained by the transporters for a minimum of three years in the transporter's main office and made available to the commission upon request. The manifest or other similar documentation shall include:

(A) transporter's name, address, telephone number, and assigned transporter registration number;

(B) name and address of the person that generated the untreated medical waste and the date collected;

(C) total volume or the total weight of the containers from each generator of untreated medical waste collected for transportation;

(D) name of persons collecting, transporting, and unloading the waste;

(E) date and place where the untreated medical waste was deposited or unloaded;

(F) identification (authorization number, location, and operator) of the facility where the untreated medical waste was deposited; and

(G) name and signature in writing or through an electronic record as allowed by the executive director of facility representative acknowledging receipt of the untreated medical waste and the weight or volume of containers of waste received.

(9) The transporter shall furnish the generator a signed manifest for each shipment at the time of collection of the waste. The manifest shall include the name, address, telephone number, and registration number of the transporter. The document shall also identify the generator by name and address, and shall list the weight of waste or volume of containers collected and date of collection. The transporter must provide the generator with a written or electronic statement of the total weight or volume of the containers collected within 45 days.

(10) The transporter must be able to provide a manifest for each shipment from the point of collection through and including the unloading of the waste at a facility authorized to accept the waste. The original manifest or an electronic record as allowed by the executive director must accompany each shipment of untreated waste to its final destination. The transporter shall ensure the proper collection and deposition of untreated medical waste accepted for transport.

(11) Shipments of untreated medical waste shall be stored or deposited only at a facility that has been authorized by the commission to accept untreated medical waste. Untreated medical waste that is transported out of the state shall be deposited at a facility that is authorized by the appropriate agency having jurisdiction over such waste.

(12) Shipments of untreated medical waste, properly containerized Animal and Plant Health Inspection Service (APHIS) regulated garbage ~~waste~~, and non-hazardous pharmaceutical waste may be commingled during transport or storage. Authorizations for the acceptance of APHIS regulated garbage ~~waste~~ shall be obtained from United Stated Department of Agriculture, Animal and Plant Health Inspection Service.

(13) Shipments of untreated medical waste, properly containerized APHIS regulated garbage ~~waste~~, and non-hazardous pharmaceutical waste that are commingled with any other waste (such as rubbish, garbage, hazardous waste, asbestos, or radioactive waste regulated under 25 TAC Chapter 289 (relating to Radiation Control)), shall be delivered to the same treatment facility.

(14) The post-collection storage of medical waste by a transporter shall be in a secure manner and location that affords protection from theft, vandalism, inadvertent human or animal exposure, rain, water, and wind. The waste shall be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

(15) Transporters shall not accept untreated medical waste unless the generator has packaged the waste in accordance with the provisions of §§326.17, 326.19, and 326.21 of this title (relating to Identification; Packaging; and Labeling Containers Excluding Sharps, respectively). Transporters shall not accept containers of waste that are leaking or damaged unless or until the shipment has been repackaged. All transporters described in this subsection must obtain any additional transportation authorizations to comply with local, state and federal rules.

(16) Persons who engage in the transportation of waste within Texas when the transportation neither originates nor terminates in Texas are exempt from these regulations, except for paragraph (6)(A)(i) - (iii) and (B) of this subsection.

(17) Packages of untreated medical waste shall not be transferred between transportation units unless the transfer occurs at and on the premises of a facility authorized as a transfer station, or at ~~as~~ a treatment/processing facility that has been approved to function as a transfer station except as provided in §326.43 of this title (relating to Medical Waste Collection and Transfer by Licensed Hospitals).

(18) In case of transportation unit malfunction, the waste shipment may be transferred to an operational transportation unit and the executive director, and any local pollution agency with jurisdiction that has requested to be notified, shall be notified of the incident in writing within five working days. The incident report shall list all transportation

units involved in transporting the waste and the cause, if known, of the transportation unit malfunction. Update to the transporter's registration by rule is required when the new unit or units are placed in medical waste transport service for a period of time exceeding five days. When using a unit not registered, the transporter shall comply with paragraphs (6) and (7) of this subsection.

(19) In case of a traffic accident, the waste shipment may be transferred to an operating transportation unit if necessary. Any containers of waste that were damaged in the accident shall be repackaged as soon as possible. The nearest regional office, and any local pollution agency with jurisdiction that has requested to be notified, shall be notified of the incident no later than the end of the next working day. The incident report shall list all vehicles involved in transporting the waste.

(20) Persons that apply for the registration by rule must maintain a copy of the registration by rule issued by the executive director with an assigned registration by rule number, at their designated place of business and with each transportation unit used to transport untreated medical waste.

(c) Changes to the registration by rule. Transporters shall notify the executive director, and any local pollution agency with jurisdiction that has requested to be notified, by letter, within 30 days of any changes to their registration if:

(1) the office or place of business is moved;

(2) the name of owner or operator of the operation is changed;

(3) the name of the partners, corporate directors, or corporate officers change; or

(4) the unit information has changed.

§326.55. Mobile Treatment Unit.

(a) A registration by rule is granted for an owner or operator of mobile treatment units conducting on-site treatment of medical waste but is not the generator of the waste. The mobile on-site treatment unit owner or operator completes registration by rule forms provided by the commission and submits the following information at least 60 days prior to commencing operations:

(1) Applicant information. Name, address, and telephone number of registrant.

(2) Partner, corporate officer and director information. Name, address, and telephone number of partners, corporate officers, and directors, if applicable.

(3) Fee information. The owner or operator of a mobile treatment unit shall pay an annual registration fee to the commission based upon the total weight of medical waste treated on-site under each registration by rule. Fees to be assessed of owners or operators of an on-site treatment unit are located in Subchapter G of this chapter (relating to Fees and Reporting).

(4) Approved treatment method. Description of approved treatment method to be employed and chemical preparations, as well as the procedure to be utilized for routine performance testing/parameter monitoring.

(5) Performance testing. A written procedure for the operation and testing of any equipment used and a written procedure for the preparation of any chemicals used in treatment. Routine performance testing using biological indicators and/or monitoring of parametric controls shall be conducted in accordance with §326.41(b)(4)~~(3)~~ of this title (relating to On-Site Treatment by Large Quantity Generators); and identification of performance test failures including date of occurrence, corrective action procedures, and retest dates.

(6) Evidence of competency. Documentation in the form of a relevant training certificate and/or description of work experience.

(7) Wastewater disposal. A description of the management and disposal of process waters generated during treatment events.

(8) Contingency plan. A written contingency plan that describes the handling and disposal of waste in the event of treatment failure or equipment breakdown. If there is any question as to the adequacy of treatment of any load, that load shall be run again utilizing biological indicators to test for microbial reduction before the material is released for landfill disposal. If the waste must be removed from the facility before treatment is accomplished, a registered transporter shall remove the waste and all other applicable sections of this chapter shall be in effect.

(9) Cost estimate and financial assurance. An estimate of the cost to remove and dispose of waste and disinfect the waste treatment equipment and evidence of financial assurance using procedures specified in §326.71(k) - (n) of this title (relating to Registration Application Contents) and Chapter 37, Subchapter R of this title (relating to Financial Assurance for Municipal Solid Waste Facilities).

(10) Mobile on-site treatment unit information. Description of each mobile treatment unit, including:

(A) make, model, and year;

(B) motor vehicle identification number, if applicable;

(C) license plate (tag) number, including state and year; and

(D) name of mobile treatment unit owner or operator.

(11) Instructions for mailing fees. Fees assessed in §326.87(b) of this title (relating to Fees) by the executive director shall be paid by the registrant within 30 days of the date of the invoice and shall be submitted in the form of a check or money order or copy of the confirmation of an electronic payment made payable to the agency cashier.

(b) Other requirements.

(1) Registrations by rule expire annually on September 30th of each year. Registrations by rule shall not be renewed unless the owner or operator has submitted to the executive director:

(A) an annual report in accordance with §326.89(d) of this title (relating to Reports);

(B) an annual fee in accordance with §326.87(b) of this title;

(C) evidence of financial assurance as of September 30th of the current year; and

(D) a registration by rule renewal form to the executive director by August 1st.

(2) When an owner or operator has made timely application for the renewal of a registration by rule, the existing registration by rule will not be renewed until the application has been determined administratively complete by the executive director.

(3) The executive director shall, after review of any application for registration by rule, approve or deny the application. This action shall be based on whether the application meets the requirements of this chapter.

(4) Failure to timely pay the annual fee eliminates the option to manage wastes.

(5) The executive director will send a copy of the registration by rule issued with an assigned registration number, to the owner or operator.

(6) Requirements for mobile treatment unit and associated cargo compartment used in the treatment of medical waste are as follows.

(A) The mobile treatment unit used to treat medical waste shall:

(i) have a fully enclosed, leak-proof, cargo-carrying body, such as a cargo compartment, box trailer, or roll-off box; and

(ii) carry spill cleanup equipment including, but not limited to, disinfectants, absorbent materials, personal protective equipment, such as gloves, coveralls, and eye protection, and leak-proof ~~leak proof~~ containers or packaging materials.

(B) The cargo compartment of the vehicle and any self-contained treatment unit(s) shall:

(i) be maintained in a sanitary condition;

(ii) be secured when the vehicle is in motion;

(iii) be made of such impervious, non-porous materials as to allow adequate disinfection/cleaning of the compartment or unit(s); and

(iv) have all discharge openings securely closed during operation of the vehicle.

(7) Mobile treatment units used in the treatment of medical waste shall not be used to transport any other material until the unit has been cleaned and disinfected. A written record of the date and the process used to clean and disinfect the unit shall be maintained for three years unless the executive director requires a longer holding period. The record must identify the unit by motor vehicle identification number or license tag number. The owner of the unit, if not the operator, shall be notified in writing that the unit has been used in the treatment of medical waste and when and how the unit was disinfected.

(8) Owners or operators of mobile on-site treatment units shall maintain records of all waste treatment, which includes the following information:

(A) the name, address, and phone number of each generator;

(B) the date of treatment;

(C) the amount of waste treated;

(D) the method/conditions of treatment; and

(E) the name (printed) and initials of the person(s) performing the treatment.

(9) Persons receiving a registration by rule shall maintain a copy of the registration by rule issued by the executive director with an assigned registration by rule number, at their designated place of business and in each mobile treatment unit used in treating medical waste.

(10) Owners or operators of mobile on-site treatment unit shall furnish the generator the documentation required in paragraph (6)(A) and (B) of this subsection and a statement that the medical waste was treated in accordance with 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition) for the generator's records.

(11) Untreated medical waste shall not be commingled or mixed with hazardous waste, asbestos, or radioactive waste regulated under 25 TAC Chapter 289 (relating to Radiation Control) either before or after treatment.

(12) Owners or operators of mobile on-site treatment unit shall not transport untreated waste unless they are registered as a transporter of medical waste.

(13) Owners or operators of mobile on-site treatment unit shall ensure adequate training of all operators in the use of any equipment used in treatment.

(14) Owners or operators shall maintain the treatment equipment so as to not result in the creation of nuisance conditions.

(c) Changes to the Registration by Rule. Owners or operators of mobile on-site treatment unit shall notify the executive director, by letter, within 30 days of any changes to their registration if:

(1) the method employed to treat medical waste changes;

(2) the office or place of business is moved;

(3) the name of owner or operator of the operation is changed;

(4) the name of the partners, corporate directors, or corporate officers change; or

(5) the unit information changes.

SUBCHAPTER F: OPERATIONS REQUIRING A REGISTRATION

§§326.61, 326.63, 326.65, 326.67, 326.69, 326.71, 326.73, 326.75, 326.77

Statutory Authority

The rules are adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017 and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rules implement THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.61. Applicability and General Information.

(a) A registration is required for facilities that store or process untreated medical waste, non-hazardous pharmaceutical waste and trace chemotherapy waste as defined in this chapter ~~and~~ that is received from off-site sources. For the purposes of this subsection, off-site shall be any location that does not meet the definition of on-site found in §326.3 of this title (relating to Definitions). No person may cause, suffer, allow, or permit any activity

of storage, processing, removal, or disposal of any medical waste unless that activity is authorized by a registration or other authorization from the commission. In the event this prohibition is violated, the executive director may seek recourse against not only the person that 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 waste to be stored, processed, or disposed.

(b) No person may commence physical construction of a new medical waste management facility subject to this registration requirement without having received a registration from the commission.

(c) Registration application. A registration application for a medical waste facility is not subject to an opportunity for a contested case hearing.

(d) The information required by this subchapter defines the basic elements for an application. All aspects of the application and design requirements must be addressed by the owner or operator, even if only to show why they are not applicable for that particular site.

(e) The applicant for a medical waste facility registration shall provide the executive director data of sufficient completeness, accuracy, and clarity to provide assurance that operation of the site will pose no endangerment of the human health and welfare or the

environment.

(f) Failure of the owner or operator to provide complete information as required by this chapter may provide cause for the executive director to return the application without further action.

(g) Submission of false information shall constitute grounds for denial of the registration application.

(h) Processing facilities registered under subsection (a) of this section, excluding facilities operating as transfer station only, may store or process municipal solid waste that would be classified as medical waste if it were generated by health care-related facilities. This municipal solid waste shall be subject to the same requirements as medical waste when it is accepted by a facility that is only a registered medical waste facility.

§326.63. Property Rights.

(a) It is the responsibility of an owner or operator to possess or acquire a sufficient interest in or right to the use of the surface estate of the property for which an authorization is issued, including the access route if access is not provided by public right of way. The granting of an authorization neither conveys any property rights or interest in either real or personal property nor authorizes any injury to private property, invasion of

personal rights, impairment of previous contract rights, or any infringement of federal, state, or local laws or regulations outside the scope of the authority under which an authorization is issued.

(b) The owner or operator shall retain the right of entry to the facility until the end of the closure activities ~~care period~~ for inspection and maintenance of the facility.

§326.65. Relationships with Other Governmental Entities.

(a) Special districts. The Texas Health and Safety Code (THSC) applies to political subdivisions of the state to which the legislature has given waste handling authority for two or more counties. The relationship between the agency and any such waste handling authority will be similar to that between the agency and a county.

(b) Municipal governments. Municipalities may enforce the provisions of this chapter as provided for in the THSC and the Texas Water Code (TWC). The commission is committed to assisting municipal governments in an educational and advisory capacity. The commission is a necessary and indispensable party to any suit filed by a local government under the THSC and the TWC.

(c) County governments. County governments may exercise the authority provided in THSC, Chapters 361, 363, and 364, regarding the management of solid waste including

the enforcement of the requirements of the THSC and of this chapter. The provisions of THSC, Chapters 361, 363, and 364, allow county governments to require and issue licenses authorizing and governing the operation and maintenance of facilities used for the storage, processing, or disposal of solid waste not in the territorial or extraterritorial jurisdiction of a municipality. THSC, Chapters 361, 363, and 364, provide that no license for disposal of solid waste may be issued, renewed, or extended without the prior approval of the commission. Under TWC, Chapter 7, the commission is a necessary and indispensable party to any suit filed by a local government for the violation of any provision of the Solid Waste Disposal Act. If an authorization is issued, renewed, or extended by the commission, the owner or operator of the facility does not need to obtain a separate license for the same facility from a county or from a political subdivision as defined in THSC, Chapters 361, 363, and 364.

§326.67. Relationship with County Licensing System.

(a) General procedures. Under Texas Health and Safety Code, Chapters 361, 363, and 364, counties are empowered to require and issue licenses authorizing and governing the operation and maintenance of medical waste storage, processing, or disposal facilities not within the territorial limits or extraterritorial jurisdiction of incorporated cities and towns. The county shall mail a copy of the approved license to the appropriate agency regional office. The territorial limits and the extraterritorial jurisdiction of incorporated cities and towns are excluded from county authority to make regulations for the governing

and controlling of medical waste collection, processing, and storage.

(b) Licensing procedures. The following pertain only to those counties that may choose to exercise licensing authority in accordance with this section.

(1) Licensing authority.

(A) Before exercising licensing authority for a medical waste facility required to obtain a registration, a county government shall promulgate regulations that are consistent with those established by the commission and that have been approved by the commission.

(B) Before exercising licensing authority for a medical waste facility that is not required to obtain a registration, a county government shall promulgate regulations that are compatible with those established by the commission. County regulations must be submitted to the commission for approval. At a minimum, county regulations shall be protective of human health and the environment.

(C) A county may not make regulations for medical waste management within the extraterritorial or territorial jurisdiction of incorporated cities or towns.

(D) Only the commission may issue registrations for medical waste facilities located within the extraterritorial or territorial jurisdiction of incorporated cities or towns within the county.

(E) A county license for a medical waste facility may not be issued, extended, or renewed without prior approval of the commission.

(F) Once a license is issued by a county and remains valid, a registration from the commission is not required.

(2) Public meeting. A county shall offer an opportunity to request for a public meeting, and issue appropriate notifications, in accordance with the procedures established in §326.73 of this title (relating to Registration Application Processing).

(c) Contents of a license. A license for a medical waste facility issued by a county must include:

(1) the name and address of each person that owns the land on which the medical waste facility is located and the person that is or will be the operator of the facility;

(2) a legal description of the land on which the facility is located;

(3) the terms and conditions on which the license is issued, including the duration of the license; and

(4) the volume of waste to be managed.

(d) Licensee's responsibilities. Medical waste facilities licensed by a county shall be operated in compliance with regulations of the commission and the county.

§326.69. Registration Application Formatting, Posting, Appointment and Fees.

(a) Registration applications for medical waste must be initially submitted in three copies. The owner or operator shall furnish additional copies of the application for use by required reviewing agencies, upon request of the executive director. The executive director is authorized to approve requests to submit this information electronically if the commission develops electronic systems to manage the data.

(b) Preparation. Preparation of the application must conform with the Texas Occupations Code, Chapter 1001, Texas Engineering Practice Act.

(1) The responsible engineer shall provide the firm number and seal, sign, and date the title page of each bound engineering report or individual engineering plan,

table of contents and each engineering drawing in the application as required by Texas Engineering Practice Act, §1001.401, and in accordance with 22 TAC §137.33 (relating to Sealing Procedures).

(2) Applications that have not been sealed shall be considered incomplete for the intended purpose and shall be returned to the owner or operator.

(c) Application format.

(1) Applications shall be submitted in three-ring binders.

(2) The title page shall include:

(A) name of the facility;

(B) medical waste registration application number, if assigned;

(C) name of owner and operator;

(D) location by city and county;

(E) date the application was prepared;

(F) the seal and signature of the engineer preparing the application; and the firm number; and

(G) when applicable, the number and date of the revision.

(3) The table of contents shall contain the main sections and the corresponding page numbers of the application.

(4) The narrative of the application shall be printed on 8-1/2 by 11 inches white paper. Drawings or other sheets shall be no larger than 11 by 17 inches so that they can be reproduced by standard office copy machines.

(5) All pages shall contain a page number and date.

(6) Revisions to text shall be tracked to document insertions, deletions and formatting changes. Revised pages shall have the revision date and indicate "Revised" in the footer of each revised page. A minimum of three clean copies of all revised pages shall also be provided.

(7) Dividers and tabs are recommended.

(d) Application drawings.

(1) All information contained on a drawing shall be legible, even if it has been reduced. The drawings shall be 8-1/2 by 11 inches or 11 by 17 inches. Standard-sized drawings (24 by 36 inches) folded to 8-1/2 by 11 inches may be submitted or required if reduction would render them illegible or difficult to interpret.

(2) If color coding is used, it should be distinct when reproduced on black and white photocopy machines.

(3) Drawings shall be submitted at a standard engineering scale.

(4) Each drawing, plan drawing or map shall have a:

(A) dated title block;

(B) bar scale at least one-inch long;

(C) revision block;

(D) responsible engineer's or geoscientist's seal, if required; and

(E) drawing number and a page number.

(5) Each plan drawing or map shall also have:

(A) a north arrow. Preferred orientation is to have the north arrow pointing toward the top of the page;

(B) a reference to the base map source and date, if the map is based upon another map. The latest published edition of the base map should be used; and

(C) a legible legend.

(6) Match lines and section lines shall reference the drawing where the match or section is shown. Section drawings should note from where the section was taken.

(e) Posting application information.

(1) Upon submittal of an application that requires public notice, the owner or operator shall provide a complete copy of the application, including all revisions and supplements to the application, on a publicly accessible internet website, and provide the commission with the Web address link for the application materials. This internet posting is for informational purposes only.

(2) The commission shall post on its website the identity of all owners and operators filing an application and the Web address link required by this subsection.

(f) Appointments. The owner or operator shall provide documentation that the person signing the application meets the requirements of §305.44(a) and (b) of this title (relating to Signatories to Applications). If the authority has been delegated, provide a copy of the document issued by the governing body of the owner or operator authorizing the person that signed the application to act as agent for the owner or operator.

(g) Application fees. In accordance with §305.53 of this title (relating to Application Fee), the application fee for a registration, modification, or temporary authorization is $150.

§326.71. Registration Application Contents.

(a) Maps and Drawings.

(1) General location map. The owner or operator shall submit a general location map of the facility at a scale of one inch equals 2,000 feet by using a United States Geological Survey 7 1/2-minute quadrangle sheet or equivalent as the base map.

(2) Facility access and facility layout. A set of maps or drawings showing:

(A) public access roads serving the facility;

(B) longitudinal and latitudinal geographic coordinates for the point of beginning of the facility boundary's metes and bounds description;

(C) facility boundary;

(D) provisions for the maintenance of any natural windbreaks, such as greenbelts, where they will improve the appearance and operation of the facility and, where appropriate, plans for screening the facility from public view;

(E) all site entrance roads from public access roads;

(F) fencing;

(G) general locations of main interior facility roadways; the location and surface type of all roads within one mile of the facility that will normally be used by the owner or operator for entering or leaving the facility;

(H) locations of buildings and a descriptive title of their purpose;

(I) outline of the waste management units and ancillary equipment for loading/unloading, storage and processing areas;

(J) drainage, pipeline, and utility easements within the facility; and

(K) any other graphic representations or marginal explanatory notes necessary to communicate the proposed construction phases of the facility, if applicable.

(3) Land-use map. This is a constructed map of the facility showing the facility boundary (registration boundary) of the facility and any existing zoning on or surrounding the property and actual uses (e.g., agricultural, industrial, residential) both within the facility and within one mile of the facility. The owner or operator shall make every effort to show the location of residences, commercial establishments, schools, licensed day-care facilities, churches, cemeteries, ponds or lakes, and recreational areas within one mile of the facility boundary.

(4) Published zoning map. If available, a published zoning map for the facility and within one mile of the facility for the county or counties in which the facility is or will be located. If the facility requires approval as a nonconforming use or a special permit from the local government having jurisdiction, a copy of such approval shall be submitted.

(5) Impact on surrounding area. The use of any land for a medical waste facility shall not adversely impact human health or the environment. The owner or operator shall provide information regarding the likely impacts of the facility on cities, communities, groups of property owners, or individuals by analyzing the compatibility of land use, zoning in the vicinity, community growth patterns, and any other factors associated with the public interest. To assist the commission in evaluating the impact of the facility on the surrounding area, the owner or operator shall provide the following:

(A) information about the character of surrounding land uses within one mile of the proposed facility;

(B) information about growth trends within five miles of the facility with directions of major development; and

(C) the proximity to residences and other uses (e.g., schools, churches, cemeteries, historic structures and sites, archaeologically significant sites, sites having exceptional aesthetic quality, etc.) within one mile of the facility. The owner or operator shall provide the approximate number of residences and commercial establishments within one mile of the proposed facility including the distances and directions to the nearest residences and commercial establishments. Population density and proximity to residences and other uses described in this paragraph may be considered for assessment of compatibility.

(6) Land ownership map with accompanying landowners list. The applicant shall include a list of landowners within 1/4 mile of the facility and their addresses along with an appropriately scaled map locating the property owned by these persons. The landowners' list shall be keyed to the land ownership map and shall give each property owner's name and mailing address. Notice of an application is not defective if property owners did not receive notice because they were not listed in the real property appraisal records. The list shall also be provided in electronic form.

(7) Metes and bounds. The applicant shall include a drawing and a description of the facility boundary signed and sealed by a registered professional land surveyor.

(b) Property owner affidavit. The applicant shall provide a property owner affidavit that is signed by the owner and includes:

(1) acknowledgment that the State of Texas may hold the property owner of record either jointly or severally responsible for the operation, maintenance, and closure of the facility; and

(2) acknowledgment that the facility owner or operator and the State of Texas shall have access to the property during the active life and after closure for the purpose of inspection and maintenance.

(c) Licensed operator. The owner or operator shall acknowledge that a licensed solid waste facility supervisor, as defined in Chapter 30 of this title (relating to Occupational Licenses and Registrations), be employed before commencing facility operation.

(d) Legal authority. The owner and operator shall provide verification of their legal status as required by §281.5 of this title (relating to Application for Wastewater Discharge, Underground Injection, Municipal Solid Waste, Radioactive Material, Hazardous Waste, and Industrial Solid Waste Management Permits). This shall be a one-page certificate of incorporation issued by the secretary of state.

(e) Transportation. The owner or operator shall:

(1) provide data on the availability and adequacy of roads that the owner or operator will use to access the site;

(2) provide data on the volume of vehicular traffic on access roads within one mile of the proposed facility, both existing and expected, during the expected life of the proposed facility;

(3) project the volume of traffic expected to be generated by the facility on the access roads within one mile of the proposed facility; and

(4) submit documentation of coordination of all designs of proposed public roadway improvements such as turning lanes, storage lanes, etc., associated with site entrances with the entity exercising maintenance responsibility of the public roadway involved. In addition, the owner or operator shall submit documentation of coordination with the Texas Department of Transportation for traffic and location restrictions.

(f) Facility surface water drainage report. The owner or operator of a medical waste facility shall include a certification statement that:

(1) The facility will be constructed, maintained, and operated to manage run-on and run-off during the peak discharge of a 25-year rainfall event and must prevent the off-site discharge of waste and feedstock material, including, but not limited to, in-process and/or processed materials.

(2) Surface water drainage in and around a facility will be controlled to minimize surface water running onto, into, and off the treatment area.

(3) The owner or operator will obtain the appropriate Texas Pollutant Discharge Elimination System storm water permit coverage when required; or shall provide the permit number for coverage under an individual wastewater permit.

(4) The facility will be located outside of the 100-year floodplain unless the owner or operator can demonstrate that the facility is designed and will be operated in a manner to prevent washout of waste during a 100-year storm event, or the facility obtains a conditional letter of map amendment from the Federal Emergency Management Administration administrator.

(5) The facility will not be located in wetlands unless the owner or operator provides documentation to the extent required under Clean Water Act, §404 or applicable state wetlands laws, that steps have been taken to attempt to achieve no net loss of wetlands.

(g) Council of governments and local government review request. The owner or operator shall submit documentation that the application was submitted for review to the applicable council of governments for compliance with regional solid waste plans. The owner or operator shall also submit documentation that a review letter was requested from any local governments as appropriate for compliance with local solid waste plans. Review letters from the aforementioned entities are not a prerequisite to a final determination on a registration application.

(h) General description of the facility location and design.

(1) Facility location. The owner or operator shall provide:

(A) a description of the location of the facility with respect to known or easily identifiable landmarks;

(B) the access routes from the nearest United States or state highway to the facility; and

(C) longitudinal and latitudinal geographic coordinates for the point of beginning of the facility boundary's metes and bounds description.

(2) Facility access. The owner or operator shall describe how access will be controlled for the facility such as the type and location of fences or other suitable means of access control to protect the public from exposure to potential health and safety hazards, and to discourage unauthorized entry.

(3) Buffer zones and easement protection. No solid waste unloading, storage, or processing operations shall occur within any easement, buffer zone, or right-of-way that crosses the facility. Processing equipment and storage areas shall maintain a minimum

separating distance of 25 feet between the facility boundary and processing equipment, loading, unloading and storage areas. Storage units in transport vehicles are not subject to this subsection provided that the waste is stored in refrigerated units with temperatures below 45 degrees Fahrenheit. The executive director may consider alternatives to the buffer zone requirements of this subsection where the owner or operator demonstrates that the buffer zone is not feasible and affords ready access for emergency response and maintenance. The buffer zone shall not be narrower than that necessary to provide for safe passage for firefighting and other emergency vehicles. The executive director may consider alternatives to buffer zone requirements for authorized medical waste storage and processing facilities.

(4) Flow diagrams and narrative. The owner or operator shall provide flow diagrams showing the various phases of collection, separation, processing, and disposal as applicable for the types of wastes received at the facility along with a narrative describing each phase;

(i) Waste management unit design.

(1) The owner or operator shall provide generalized construction information or manufacturer specifications of all storage and processing units (autoclaves, incinerators, etc.) and ancillary equipment (i.e., tanks, foundations, sumps, etc.) with regard to number

of units, approximate dimensions and capacities, construction materials, vents, covers, enclosures, protective coatings of surfaces, etc.

(2) The owner or operator shall provide generalized description of construction materials for slab and subsurface supports of all storage and processing components.

(3) The owner or operator shall provide storage and processing areas designed to control and contain spills and contaminated water from leaving the facility. The design shall be sufficient to control and contain a worst case spill or release. Unenclosed containment areas shall also account for precipitation from a 25-year, 24-hour storm.

(4) The owner or operator shall acknowledge that the storage of medical waste must be in a secure manner and in a location that affords protection from theft, vandalism, inadvertent human or animal exposure, rain, water, and wind. The waste must be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

(5) For putrescible or biohazardous untreated medical waste, maintaining a temperature of 45 degrees Fahrenheit or less during pre-collection storage is optional. Such medical waste stored for longer than 72 hours during post-collection storage period

shall be maintained at a temperature of 45 degrees Fahrenheit or less. ~~The 72-hour delay is not allowed for putrescible or biohazardous untreated medical waste that has been elected to be refrigerated during pre-collection storage. In that case, the putrescible or biohazardous untreated medical waste must remain refrigerated during post-collection storage as well.~~

(j) Treatment requirements. Medical waste shall be treated in accordance with the provisions of 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition). ~~Alternative treatment technologies may be approved in accordance with requirements found in 25 TAC §1.135 (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).~~ The owner or operator shall provide a written procedure for the operation and testing of any equipment used and for the preparation of any chemicals used in treatment and comply with the following:

(1) The operator shall demonstrate a minimum four log ten reduction as defined in 25 TAC §1.132 (relating to Definitions) on routine performance testing using appropriate Bacillus species biological indicators (as defined in 25 TAC §1.132).

(2) The operator shall conduct testing weekly.

(3) For those processes that the manufacturer has documented compliance with the performance standard prescribed in 25 TAC §1.135 based on specified parameters (for example, pH, temperature, pressure, etc.), and for previously approved treatment processes that a continuous readout and record of operating parameters is available, the operator may substitute routine parameter monitoring for biological monitoring. The operator shall confirm that any chemicals or reagents used as part of the treatment process are at the effective treatment strength. The operator will maintain records of operating parameters and reagent strength for three years.

(4) The manufacturer of single-use, disposable treatment units shall be responsible for maintaining adequate quality control for each lot of single-use products. The treating facility or entity shall be responsible for following the manufacturer's instructions.

(5) Operators of medical waste treatment equipment shall use backflow preventers on any potable water connections to prevent contamination of potable water supplies.

(6) Owners or operators of medical waste incinerators shall comply with the requirements in §111.123 of this title (relating to Medical Waste Incinerators) in lieu of biological or parametric monitoring.

(7) Alternative treatment technologies may be approved in accordance with requirements found in 25 TAC §1.135 (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

(k) Closure plan. The facility closure plan shall be prepared in accordance with the following criteria.

(1) Facility units shall be dismantled and removed off-site or decontaminated.

(2) The owner or operator shall remove all waste and material on-site (unprocessed, in process, and processed), transport them to an authorized facility and disinfect all contaminated water handling units and all processing areas.

(3) Closure of the facility must be completed within 180 days following the last acceptance of processed or unprocessed materials unless otherwise directed or approved in writing by the executive director.

(l) Certification of final closure.

(1) No later than 90 days prior to the initiation of a final facility closure, the owner or operator shall, through a published notice in the newspaper(s) of largest circulation in the vicinity of the facility, provide public notice for final facility closure. This notice shall provide the name, address, and physical location of the facility; the registration number, as appropriate; and the last date of intended receipt of waste. The owner or operator shall also make available an adequate number of copies of the approved final closure plan for public access and review. The owner or operator shall also provide written notification to the executive director of the intent to close the facility and place this notice of intent in the operating record.

(2) Upon notification to the executive director as specified in paragraph (1) of this subsection, the owner or operator of a medical waste management facility shall post a minimum of one sign at the main entrance and all other frequently used points of access for the facility notifying all persons who may utilize the facility of the date of closing for the entire facility and the prohibition against further receipt of waste materials after the stated date. Further, suitable barriers shall be installed at all gates or access points to adequately prevent the unauthorized dumping of solid waste at the closed facility.

(3) Within ten days after completion of final closure activities of a facility, the owner and operator shall submit to the executive director by registered mail:

(A) a certification, signed by an independent licensed professional engineer, verifying that final facility closure has been completed in accordance with the approved closure plan. The submittal to the executive director shall include all applicable documentation necessary for certification of final facility closure; and

(B) a request for voluntary revocation of the facility registration.

(m) Cost estimate for closure.

(1) The cost estimate must:

(A) equal the costs for closure of the facility, including disposition of the maximum inventories of all processed and unprocessed waste;

(B) be based on the costs of hiring a third party that is not affiliated with the owner or operator; and

(C) be based on a volume (cubic yard) and/or weight (pound, ton) measure for collection and disposition costs.

(2) An increase in the closure cost estimate and the amount of financial assurance provided under subsection (n) of this section must be made if changes to the

facility conditions increase the maximum cost of closure at any time during the active life of the facility.

(3) A reduction in the closure cost estimate and the amount of financial assurance provided under subsection (n) of this section may be approved if the cost estimate exceeds the maximum cost of closure at any time during the operation of the facility. A reduction in the cost estimate and the financial assurance must be considered a modification and the owner or operator shall provide a detailed justification for the reduction of the closure cost estimate and the amount of financial assurance.

(n) Financial assurance. A copy of the documentation required to demonstrate financial assurance as specified in Chapter 37, Subchapter R of this title (relating to Financial Assurance for Municipal Solid Waste Facilities) shall be submitted 60 days prior to the initial receipt of waste. Continuous financial assurance coverage for closure must be provided until all requirements of the final closure plan have been completed and the facility is determined to be closed in writing by the executive director.

(o) Site operating plan. This plan will provide general operating procedures for facility management for day-to-day operations at the facility. At a minimum, the site operating plan must include a description for how the items in §326.75 of this title (relating to Site Operating Plan) will be implemented. A facility that has an environmental management system that meets the minimum standards described in §90.30 of this title

(relating to Minimum Standards for Environmental Management Systems) and is approved to operate under an environmental management system in accordance with §90.31 of this title (relating to Review of Incentive Applications for Environmental Management System), is not subject to site operating plan requirements while the authorization to operate under the environmental management system remains in place. In the event the executive director terminates authorization to operate under an environmental management system, the facility must comply with the site operating plan requirements within 90 days.

(p) The approved site operating plan, the final closure plan, and all other documents and plans required by this chapter shall become operational requirements and shall be considered a part of the operating record of the facility. Any deviation from the registration, the incorporated plans, or any other documents associated with the registration is a violation of this chapter.

§326.73. Registration Application Processing.

(a) Opportunity for public meeting and posting notice signs.

(1) The owner or operator shall provide notice of the opportunity to request a public meeting and post notice signs for all registration applications not later than 45 days after the executive director's receipt of the application in accordance with the procedures

contained in §39.501(c) of this title (relating to Application for Municipal Solid Waste Permit) and by posting signs at the proposed site.

(2) The owner or operator and the commission shall hold a public meeting in the local area, prior to facility authorization, if a public meeting is required based on the criteria contained in §55.154(c) of this title (relating to Public Meetings).

(3) Notice of a public meeting shall be provided as specified in §39.501(e)(3) and (4) of this title. This section does not require the commission to respond to comments, and it does not create an opportunity for a contested case hearing.

(4) The owner, operator, or a representative authorized to make decisions and act on behalf of the owner or operator shall attend the public meeting. A public meeting conducted under this section is not a contested case hearing under the Texas Government Code, Chapter 2001 (Texas Administrative Procedure Act).

(5) At the owner's or operator's expense, a sign or signs must be posted at the site of the proposed facility declaring that the application has been filed and stating the manner in which the commission and owner or operator may be contacted for further information. Such signs must be provided by the owner or operator and must substantially meet the following requirements. Signs must:

(A) consist of dark lettering on a white background and must be no smaller than four feet by four feet with letters at least three inches in height and block printed capital lettering;

(B) be headed by the words "PROPOSED MEDICAL WASTE FACILITY;"

(C) include the words "REGISTRATION NO.~~,~~" and the number of the registration;

(D) include the words "for further information contact;"

(E) include the words "Texas Commission on Environmental Quality" and the address and telephone number of the appropriate permitting office;

(F) include the name of the owner or operator, and the address of the appropriate responsible official;

(G) include the telephone number of the owner or operator;

(H) remain in place and legible until the period for filing a motion to overturn has expired; and

(I) describe how persons affected may request that the executive director and applicant conduct a public meeting.

(6) Signs must be located within ten feet of every property line bordering a public highway, street, or road. Signs must be visible from the street and spaced at not more than 1,500-foot intervals. A minimum of one sign, but no more than three signs, shall be required along any property line paralleling a public highway, street, or road. This paragraph's sign requirements do not apply to properties under the same ownership that are noncontiguous or separated by intervening public highway, street, or road, unless the property is part of the registered facility.

(7) The owner or operator shall also post signs at the facility in an alternative language when the alternative language requirements in §39.405(h)(2) of this title (relating to General Notice Provisions) are met. These signs must meet the location and frequency requirements of paragraph (6) of this subsection.

(8) The owner or operator shall provide a certification to the executive director that the sign posting was conducted according to the requirements of this section.

(9) The executive director may approve variances from the requirements of paragraphs (5) and (6) of this subsection if the owner or operator has demonstrated that it

is not practical to comply with the specific requirements of those paragraphs and alternative sign posting plans proposed by the owner or operator are at least as effective in providing notice to the public. Approval from the executive director under this paragraph must be received before posting alternative signs for purposes of satisfying the requirements of this paragraph.

(b) Notice of final determination. The executive director shall, after review of an application for registration, determine if the application will be approved or denied in whole or in part. In accordance with §50.133(b) of this title (relating to Executive Director Action on Application or WQMP Update), if the executive director acts on an application, the chief clerk shall mail or otherwise transmit notice of the action and an explanation of the opportunity to file a motion under §50.139 of this title (relating to Motion to Overturn Executive Director's Decision). The chief clerk shall mail this notice to the owner and operator, the public interest counsel and to other persons who timely filed public comment in response to public notice.

(c) Motion to overturn. The owner or operator, or a person affected may file with the chief clerk a motion to overturn the executive director's action on a registration application, under §50.139 of this title. The criteria regarding motions to overturn shall be explained in the public notices provided in accordance with Chapter 39 of this title (relating to Public Notice) and §50.133 of this title.

§326.75. Site Operating Plan.

(a) Personnel functions ~~and equipment.~~

(1) A description of functions and minimum qualifications for each category of key personnel to be employed at the facility and for the supervisory personnel in the chain of command;

~~(2) A description, including the minimum number, size, type, and function, of the equipment to be utilized at the facility based on the estimated waste acceptance rate and other operational requirements, and a description of the provisions for back-up equipment during periods of breakdown or maintenance of this listed equipment;~~

(2) ~~(3)~~ A description of the general instructions that the operating personnel shall follow concerning the operational requirements of this subchapter; and

(3) ~~(4)~~ Procedures for the detection and prevention of the receipt of prohibited wastes; which must include:

(A) random inspections of packaging for incoming loads;

(B) records of all inspections; and

(C) training for appropriate facility personnel responsible for inspecting or observing loads to recognize prohibited waste.

(b) Waste acceptance. The applicant shall identify the sources and characteristics of medical wastes proposed to be received for storage and processing or disposal, the maximum amount of medical waste to be received daily, the maximum amount of medical waste to be stored, the maximum lengths of time that medical waste is to remain at the facility (specify the maximum allowable period of time that unprocessed and processed wastes are to remain on-site), and the intended destination of the medical waste received at this facility. Medical waste facilities may not receive regulated hazardous waste as defined in §326.3(46) of this title (relating to Definitions). Materials accepted for recycling may only be accepted from health care-related facilities as long as the recyclable materials have not been mixed or come into contact with medical waste. Materials mixed or contacting medical waste shall be managed as medical waste.

(c) Facility-generated waste.

(1) All liquids resulting from the facility operations shall be disposed of in a manner that will not cause surface water or groundwater pollution. The owner or operator may send wastewater off-site to an authorized facility or shall provide for the treatment of wastewaters resulting from managing the waste or from cleaning and washing. Except as

provided in subsection (b) of this section, the owner or operator shall provide a connection into a public sewer system, a septic system, or a small wastewater treatment plant. On-site wastewater treatment systems shall comply with Chapter 285 of this title (relating to On-site Sewage Facilities). The owner or operator shall obtain any permit or other approval required by state or local code for the system installed.

(2) Contaminated water shall be collected and contained until properly managed.

(3) Wastes generated by a facility must be processed or disposed at an authorized solid waste management facility.

(4) Off-site discharge of contaminated waters shall be made only after approval under the Texas Pollutant Discharge Elimination System authority.

(5) The owner or operator shall provide a copy of the authorization to discharge wastewater to a treatment facility permitted under Texas Water Code, Chapter 26.

(d) Storage requirements.

(1) All solid waste shall be stored in such a manner that it does not create a nuisance.

(2) Storage area(s) for source-separated or recyclable materials from medical waste facilities must be provided that are separate from solid waste processing areas. Control of odors, vectors, and windblown waste from the storage area shall be maintained.

(3) Containers must be maintained in a clean condition so that they do not constitute a nuisance. Containers to be mechanically handled must be designed to prevent spillage or leakage during storage, handling, or transport.

(4) If a stationary compactor is utilized, it shall be operated and maintained in such a way as not to create a public nuisance through material loss or spillage, odor, vector breeding or harborage, or other condition.

(e) Recordkeeping and reporting requirements.

(1) A copy of the registration, the approved registration application, and any other required plan or other related document shall be maintained at the medical waste facility at all times. These plans shall be made available for inspection by agency representatives or other interested parties. These documents shall be considered a part of the operating record for the facility.

(2) The owner or operator shall promptly record and retain in an operating record:

(A) all location-restriction demonstrations;

(B) inspection records and training procedures;

(C) closure plans, cost estimates, and financial assurance documentation relating to financial assurance for closure;

(D) copies of all correspondence and responses relating to the operation of the facility, modifications to the registration, approvals, and other matters pertaining to technical assistance; and

(E) all documents, manifests and any other document(s) as specified by the approved authorization or by the executive director.

(3) For signatories to reports, the following conditions apply.

(A) The owner or operator shall sign all reports and other information requested by the executive director as described in §305.128 of this title (relating to

Signatories to Reports) and §305.44(a) of this title (relating to Signatories to Applications) or by a duly authorized representative of the owner or operator. A person is a duly authorized representative only if:

(i) the authorization is made in writing by the owner or operator as described in §305.44(a) of this title;

(ii) the authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity or for environmental matters for the owner or operator, such as the position of plant manager, environmental manager, or a position of equivalent responsibility. A duly authorized representative may thus be either a named individual or any individual occupying a named position; and

(iii) the authorization is submitted to the executive director.

(B) If an authorization under this section is no longer accurate because of a change in individuals or position, a new authorization satisfying the requirements of this section must be submitted to the executive director prior to, or together with, any reports, information, or applications to be signed by an authorized representative.

(C) Any person signing a report shall make the certification in §305.44(b) of this title.

(4) All information contained in the operating record shall be furnished upon request to the executive director and shall be made available for inspection by the executive director.

(5) The owner or operator shall retain all information contained within the operating record and the different plans required for the facility for the life of the facility.

(6) The executive director may set alternative schedules for recordkeeping and notification requirements as specified in paragraphs (1) - (5) of this subsection.

(7) Owners or operators of a medical waste processing facility accepting delivery of untreated medical waste for which a shipping document is required for processing shall ensure each of the following requirements are met:

(A) a shipping document accompanies the shipment, which designates the facility to receive the waste;

(B) the owner or operator signs the shipping document and immediately gives at least one copy of the signed shipping document to the transporter;

(C) the owner or operator retains one copy of the shipping document;

(D) within 45 days after the delivery, the treatment facility owner or operator sends a written or electronic copy of the shipping document to the generator that includes the total weight of waste received and a statement that the medical waste was treated in accordance with 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition).

(f) Fire protection.

(1) An adequate supply of water under pressure must be available for firefighting purposes.

(2) Firefighting equipment must be readily available.

(3) A fire protection plan shall be established, and all employees shall be trained in its contents and use. This fire protection plan shall describe the source of fire protection (a local fire department, fire hydrants, fire extinguishers, water tanks, water well, etc.), procedures for using the fire protection source, and employee training and safety procedures. The fire protection plan shall comply with local fire codes.

(g) Access control.

(1) Public access to all medical waste facilities shall be controlled by means of artificial barriers, natural barriers, or a combination of both, appropriate to protect human health and safety and the environment. Uncontrolled access to other operations located at a medical waste facility shall be prevented.

(2) The facility access road from a publicly owned roadway must be at least a two-lane gravel or paved road, designed for the expected traffic flow. Safe on-site access for all vehicles must be provided. The access road design must include adequate turning radii according to the vehicles that will utilize the facility and avoid disruption of normal traffic patterns. Vehicle parking must be provided for equipment, employees, and visitors. Safety bumpers at hoppers must be provided for vehicles. A positive means to control dust and mud must be provided.

(3) Access to the facility shall be controlled by a perimeter fence, consisting of a four-foot barbed wire fence or a six-foot chain-link fence or equivalent, and have lockable gates. An attendant shall be on-site during operating hours. The operating area and transport unit storage area shall be enclosed by walls or fencing.

(h) Unloading of waste.

(1) The unloading of solid waste shall be confined to as small an area as practical. An attendant shall be provided at all facilities to monitor all incoming loads of waste. Appropriate signs shall also be used to indicate where vehicles are to unload. The owner or operator is not required to accept any solid waste that he/she determines will cause or may cause problems in maintaining full and continuous compliance with these sections.

(2) The unloading of waste in unauthorized areas is prohibited. The owner or operator shall ensure that any waste deposited in an unauthorized area will be removed immediately and managed properly.

(3) The unloading of prohibited wastes at the medical waste facility shall not be allowed. The owner or operator shall ensure that any prohibited waste will be returned immediately to the transporter or generator of the waste.

(i) Operating hours. A site operating plan must specify operating hours. The operating hours may be any time between the hours of 7:00 a.m. and 7:00 p.m., Monday through Friday, unless otherwise approved by the executive director or commission for a registration.

(1) In addition to the requirements of this subsection ~~(a) of this section~~, the authorization may include alternative operating hours of up to five days in a calendar-year

period to accommodate special occasions, special purpose events, holidays, or other special occurrences.

(2) The agency regional office may allow additional temporary operating hours to address disaster or other emergency situations, or other unforeseen circumstances that could result in the disruption of waste management services in the area.

(3) The facility must record, in the site operating record, the dates, times, and duration when any alternative operating hours are utilized.

(j) Facility sign. Each facility shall conspicuously display at all entrances to the facility through which wastes are received, a sign measuring at least four feet by four feet with letters at least three inches in height stating the facility name; type of facility; the hours and days of operation; the authorization number of the facility; and facility rules. The posting of erroneous or misleading information shall constitute a violation of this section.

(k) Control of windblown material and litter. Windblown material and litter within the registration boundary shall be collected as necessary to minimize unhealthy, unsafe, or unsightly conditions.

(l) Facility access roads.

(1) All-weather roads shall be provided within the facility to the unloading area(s) designated for wet-weather operation. The tracking of mud and debris onto public roadways from the facility shall be minimized.

(2) Dust from on-site and other access roadways shall not become a nuisance to surrounding areas. A water source and necessary equipment or other means of dust control shall be provided.

(3) All on-site access roads owned or controlled by the owner or operator shall be maintained to minimize depressions, ruts, and potholes on a regular basis. For the maintenance of other access roadways not owned or controlled by the owner or operator, the owner or operator shall coordinate with the Texas Department of Transportation, county, and/or local governments with maintenance authority over the roads.

(m) Noise pollution and visual screening. The owner or operator of a transfer station shall provide screening or other measures to minimize noise pollution and adverse visual impacts.

(n) Overloading and breakdown.

(1) The design capacity of the facility shall not be exceeded during operation. The facility shall not accumulate solid waste in quantities that cannot be processed within such time as will preclude the creation of odors, insect breeding, or harborage of other vectors. If such accumulations occur, additional solid waste shall not be received until the adverse conditions are abated.

(2) If a significant work stoppage should occur at a solid waste processing facility due to a mechanical breakdown or other causes, the facility shall accordingly restrict the receiving of solid waste. Under such circumstances, incoming solid waste shall be diverted to an approved backup processing or disposal facility. If the work stoppage is anticipated to last long enough to create objectionable odors, insect breeding, or harborage of vectors, steps shall be taken to remove the accumulated solid waste from the facility to an approved backup processing or disposal facility.

(3) The owner or operator shall have alternative processing or disposal procedures for the solid waste in the event that the facility becomes inoperable for periods longer than 24 hours.

(o) Sanitation.

(1) The owner or operator shall provide potable water and sanitary facilities for all employees and visitors.

(2) At processing facilities, all working surfaces that come in contact with wastes shall be washed down on a weekly basis at the completion of processing. Processing facilities that operate on a continuous basis shall be swept daily and washed down at least twice per week.

(3) Wash waters shall not be accumulated on site without proper treatment to prevent the creation of odors or an attraction to vectors.

(4) All wash waters shall be collected and disposed of in an authorized manner.

(p) Ventilation and air pollution control. All facilities and air pollution abatement devices must obtain authorization, under Texas Health and Safety Code (THSC), Chapter 382 (Texas Clean Air Act) and Chapter 106 or 116 of this title (relating to Permits by Rule; and Control of Air Pollution by Permits for New Construction or Modification), from the Air Permits Division prior to the commencement of construction, except as authorized in THSC, §382.004. Additionally, all facilities and air pollution abatement devices must operate in compliance with all applicable air related rules including Chapter 101 of this title (relating to General Air Quality Rules) related to prevention of nuisance odors, minimizing maintenance, startup and shutdown emissions, and emission event reporting and recordkeeping.

(q) Health and safety. Facility personnel shall be trained in the appropriate sections of the facility's health and safety plan.

(r) Disposal of treated medical waste. Medical wastes that have been treated in accordance with the provisions of 25 TAC §1.136 may be managed as routine municipal solid waste unless otherwise specified in paragraphs (1) - (5) of this subsection.

(1) Incinerator ash shall be disposed of in a permitted landfill in accordance with Chapter 330 of this title (relating to Municipal Solid Waste).

(2) Treated microbiological waste, blood, blood products, body fluids, laboratory specimens of blood and tissue, and animal bedding may be disposed of in a permitted landfill. Any markings that identify the waste as a medical waste shall be covered with a label that identifies the waste as treated medical waste. The identification of the waste as treated may be accomplished by the use of color-coded, disposable containers for the treated waste or by a label that states that the contents of the disposable container have been treated in accordance with the provisions of 25 TAC §1.136.

(3) Treated carcasses and body parts of animals designated as a medical waste may, after treatment, be disposed of in a permitted landfill in accordance with Chapter 330 of this title. The collection and transportation of these wastes shall conform to

the applicable local ordinance or rule, if such ordinance or rule is more stringent than this subsection.

(4) Treated recognizable human body parts, tissues, fetuses, organs, and the products of human abortions, spontaneous or induced, shall not be disposed of in a ~~as~~ municipal solid waste landfill. These items shall be disposed of in accordance with the provisions of 25 TAC §1.136(a)(4).

(5) Sharps treated and containerized with one of the approved methods as described under 25 TAC §1.136(a)(5) shall be disposed of in a permitted landfill in accordance with Chapter 330 of this title. Unused sharps shall be disposed of as treated sharps.

§326.77. Duration, Limits and Additional Registration Conditions.

(a) The executive director shall, after review of any application for registration, approve or deny an application. This action shall be based on whether the application meets the requirements of this chapter.

(b) A registration is normally issued for the life of the facility but may be revoked or modified at any time if the operating conditions do not meet the minimum standards set forth in this chapter or for any other good cause.

(c) A registration is issued to a specific person (see definition of "Person" contained in §3.2 of this title (relating to Definitions)) and may not be transferred from one person to another without complying with §305.62 and §305.70 of this title (relating to Amendments; and Municipal Solid Waste Permit and Registration Modifications).

(d) Except for transporters and mobile treatment units, a registration is attached to the realty to which it pertains and may not be transferred from one facility to another.

(e) If a registered facility does not commence physical construction within two years of issuance of a registration or within two years of the conclusion of the appeals process, whichever is longer, the registration shall automatically terminate and will no longer be effective.

(f) A registration shall be considered to be a permit for purposes of revocation and denial under Chapter 305 of this title (relating to Consolidated Permits).

(g) The owner or operator may file with the chief clerk a motion to overturn the executive director's denial of a registration under §50.139 of this title (relating to Motion to Overturn Executive Director's Decision).

(h) If at any time during the life of the facility the owner or operator becomes aware

of any condition in the registration that necessitates a change to accommodate new technology or improved methods or that makes it impractical to keep the facility in compliance, the owner or operator shall submit to the executive director requested changes to the registration in accordance with §305.70 of this title and must be approved prior to their implementation.

(i) The owner or operator shall obtain and submit certification by a Texas-licensed professional engineer that the facility has been constructed as designed in accordance with the issued registration and in general compliance with the regulations prior to initial operation. The owner or operator shall maintain that certification on-site for inspection.

(j) After all initial construction activity has been completed and prior to accepting any solid waste, the owner or operator shall contact the executive director and region office in writing and request a pre-opening inspection. A pre-opening inspection shall be conducted by the executive director within 14 days of notification by the owner or operator that all construction activities have been completed, accompanied by representatives of the owner or operator and the engineer.

(k) The facility shall not accept solid waste until the executive director has confirmed in writing that all applicable submissions required by the registration and this chapter have been received and found to be acceptable, and that construction is in compliance with the registration. If the executive director has not provided a written or

verbal response within 14 days of completion of the pre-opening inspection the facility shall be considered approved for acceptance of waste.

SUBCHAPTER G: FEES AND REPORTING

§§326.85, 326.87, 326.89

Statutory Authority

The rules are adopted under Texas Water Code (TWC), §5.103, which authorizes the commission to adopt any rules necessary to carry out its powers and duties; TWC, §26.011, which provides the commission with the authority to adopt any rules necessary to carry out its powers, duties, and policies and to protect water quality in the state; and Texas Health and Safety Code (THSC), §§361.011, 361.017 and 361.024, which provide the commission the authority to adopt rules necessary to carry out its powers and duties under the Texas Solid Waste Disposal Act.

The adopted rules implement THSC, §361.0905, which requires the commission to adopt rules in a new chapter to regulate medical waste.

§326.85. Purpose and Applicability.

(a) Purpose.

(1) Fees. The commission is mandated by Texas Health and Safety Code, §361.013, to collect a fee for solid waste disposed of within the state, and from transporters of solid waste who are required to register with the state. The fee amount may be raised or lowered in accordance with spending levels authorized by the legislature.

(2) Reports. The commission requires reports to track the amount of waste being stored and processed to track the amount of processing capacity and reserve (future) disposal capacity in Texas, and to enable equitable assessment and collection of fees.

(b) Applicability.

(1) Fees. The owner or operator of a medical waste processing facility, with the exception of facilities authorized as transfer station only, is required to pay a fee to the agency based upon the amount of waste received. For the purpose of this subchapter, "waste received" means the total amount of the waste (measured in tons or cubic yards) received by a facility at the gate, excluding only those wastes that are recycled or exempted from payment of fees under this subchapter or by law.

(2) Reports. All registered facility owners or operators must submit reports to the executive director covering the types and amounts of waste processed at the facility or processing location; other pertinent information necessary to track the amount of waste generated, recovered, or recycled; and the amount of processing capacity of facilities. The information requested on forms provided by the executive director shall not be considered confidential or classified information unless specifically authorized by law, and refusal to submit the form with complete and accurate information by the applicable deadline shall

be considered as a violation of this section and subject to appropriate enforcement action and penalty.

(3) Interest penalty. Owners or operators of a facility failing to make payment of the fees imposed under this subchapter when due shall be assessed penalties and interest in accordance with Chapter 12 of this title (relating to Payment of Fees).

§326.87. Fees.

(a) Each owner or operator of a medical waste processing facility, with the exception of a facility authorized as a transfer station only is required to comply with the following:

(1) Fee rates and measurement options. For purposes of this subsection, uncompacted waste means any waste that is not a liquid or a sludge, has not been mechanically compacted by a collection vehicle, has not been driven over by heavy equipment prior to collection, or has not been compacted subsequent or prior to collection by any type of mechanical device other than small, in-house, compactor devices owned and/or operated by the generator of the waste. Compacted waste is a liquid, sludge, or similar waste or any waste that has been reduced in volume by a collection vehicle or by any other means including, but not limited to, dewatering, composting, incineration, and similar processes. The volume or weight reported on the quarterly solid waste summary report must be consistent with the volume or weight of the waste received, as defined in

§326.85(b)(1) of this title (relating to Purpose and Applicability). The volume or weight of the waste received shall be determined prior to processing of the waste.

(A) Tons. The recommended method for measuring and reporting waste received at the gate is in tons. The operator must accurately measure and report the number of cubic yards or tons of waste received. For waste reported in tons, the fee rate is $0.47 per ton received and will be calculated by the executive director by using this rate.

(B) Cubic yards (compacted). For waste reported in compacted cubic yards, the fee rate is $0.15 per cubic yard received and will be calculated by the executive director using this rate.

(C) Cubic yards (uncompacted). For waste reported in uncompacted cubic yards, the fee rate is $0.095 per cubic yard received and will be calculated by the executive director using this rate.

(2) Fee calculation. The fee shall be calculated by the executive director using information obtained from the quarterly solid waste summary report. The total cubic yards or tonnage reported to the executive director in the quarterly solid waste summary report shall be derived from gate tickets (weight or volume) or invoices and records of recycled materials or any other information deemed relevant by the executive director. A billing

statement will be generated quarterly by the executive director and forwarded to the applicable owner or operator or a designated representative.

(3) Fee payment due date. All solid waste fees shall be due within 30 days of the date the payment is requested.

(4) Method of payment. The required fee shall be submitted in the form of a check or money order made payable to the commission and delivered or mailed to the return address designated by the executive director in the billing statement.

(5) Penalties. Failure of the facility owner or operator to submit the required fee payment by the due date shall be sufficient cause for the commission to revoke the registration and authorization to process waste. The commission may assess interest penalties for late payment of fees and may also assess penalties (fines) in accordance with Texas Water Code, §7.051, or take any other action authorized by law to secure compliance.

(6) Exemptions. A fee will not be charged on solid waste resulting from a public entity's effort to protect the public health and safety of the community from the effects of a natural or man-made disaster or from structures that have been contributing to drug trafficking or other crimes if the disposal facility at which that solid waste is offered for disposal has donated to a municipality, county, or other political subdivision the cost of disposing of that waste.

(b) All transporters and mobile on-site treatment unit operators are required to comply with the following;

(1) Transporters are required to pay an annual registration fee to the commission based upon the total weight or volume of untreated medical waste transported. Mobile treatment unit owners or operators are required to pay an annual fee to the commission based upon the total weight of medical waste treated on-site under each registration by rule.

(2) The amount of the annual fee shall be based upon the total weight or volume of untreated medical waste transported under each registration by rule for transporters or total weight of medical waste treated on-site under each mobile treatment unit registration by rule.

(3) The annual fees shall be determined as follows.

(A) For a total annual weight transported of 1,000 pounds of medical waste or less, the fee is $100.

(B) For a total annual weight transported greater than 1,000 pounds of medical waste but equal to or less than 10,000 pounds of medical waste, the fee is $250.

(C) For a total annual weight transported greater than 10,000 pounds of medical waste but equal to or less than 50,000 pounds of medical waste, the fee is $400.

(D) For a total annual weight transported greater than 50,000 pounds of medical waste, the fee is $500.

(E) For all medical waste reported on a volume basis, the fee is $500.

(4) Fees assessed in subsection (a) of this section by the executive director shall be paid by the registrant within 30 days of the date of the billing statement and shall be submitted in the form of a check or money order made payable to the agency cashier.

§326.89. Reports.

(a) Medical waste processing facilities with the exception of transfer stations are required to comply with the following for report submittal.

(1) Report frequency. Quarterly, each owner or operator of a medical waste processing facility, with the exception of facilities authorized as transfer station only shall report to the executive director the information requested on the report form for the appropriate reporting period. Annually, the owner or operator shall submit a summary of

the information to show the yearly totals and year-end status of the facility or process, as requested on the report form, for the appropriate reporting period. The owner or operator shall file a separate report for each facility that has a unique authorization number.

(2) Report form. The report shall be on a form furnished by the executive director or reproduced from a form furnished by the executive director or by an electronic or hard copy form provided by the executive director. The owner or operator must assure that the data entered on the form are applicable for the particular facility and period for which the data are reported.

(3) Report information. In addition to a statement of the amount of waste received for processing, the report shall contain other information requested on the form, including the facility owner's or operator's name, address, and phone number; the authorization number; the facility type, size, and capacity; and other information the executive director may request.

(4) Reporting units. The amount of waste received for processing shall be reported in tons (2,000 pounds) or in cubic yards as received (compacted or uncompacted) at the gate.

(5) General weight/volume conversion factors for various types of waste shall be as follows:

(A) one ton = 2,000 pounds; and

(B) one drum = 55 gallons.

(6) Report due date. The required quarterly solid waste summary report shall be submitted to the executive director not later than 20 days following the end of the fiscal quarter for which the report is applicable. The fiscal year begins on September 1st, and concludes on August 31st.

(7) Method of submission. The required report shall be submitted electronically, hand delivered or mailed to the agency to the return address designated by the executive director in the billing statement distributed quarterly.

(8) Penalties. Failure of the facility owner or operator to submit the required report by the due date shall be sufficient cause for the commission to revoke the facility authorization and authorization to process waste. The commission may assess interest penalties for late payment of fees and may also assess penalties (fines) in accordance with Texas Water Code, §7.051 or take any other action authorized by law to secure compliance.

(b) Medical waste processing facilities. Each owner or operator of a medical waste

processing facility is required to comply with the following:

(1) Report frequency. Annually, each owner or operator shall report to the executive director the information requested on the report form for the appropriate reporting period. An owner or operator shall file a separate report for each facility that has a unique authorization number. The operator shall ensure that the annual summary report quantities concur with the quantities from the quarterly reports for the appropriate reporting period.

(2) Report form. The form of the report shall be in accordance with subsection (a)(2) of this section.

(3) Report information. The information in the report shall be in accordance with subsection (a)(3) of this section.

(4) Reporting units. The units used in reporting shall be in accordance with subsection (a)(4) of this section.

(5) Report due date. The required annual report shall be submitted when requested by the executive director for the fiscal year which the report is applicable.

(6) Method of submission. The required report shall be submitted electronically, hand delivered, or mailed to the agency to the return address designated by the executive director in the billing statement distributed quarterly.

(7) Penalties. Failure of the owner or operator to submit the required report by the due date shall be sufficient cause for the commission to revoke the permit or registration and authorization to process waste. The commission may assess interest penalties for late payment of fees and may also assess penalties (fines) in accordance with Texas Water Code, §7.051 or take any other action authorized by law to secure compliance.

(c) Owners or operators of medical waste on-site mobile treatment units shall submit to the executive director an annual summary report of their activities for the calendar year from January 1st through December 31st of each year. The report shall be submitted no later than March 1st of the year following the end of the report period and shall contain all the information required in §326.55(b)(8) of this title (relating to Mobile Treatment Unit).

(1) A registrant failing to submit the annual summary report by the date due is subject to payment of the maximum fees specified in §326.87(b) of this title (relating to Fees).

(2) An owner or operator owing delinquent fees or failing to submit required reports will not be eligible to renew a registration to provide treatment of untreated medical waste until all fees and reports are submitted and accepted by the executive director.

(d) Transporters shall submit to the executive director an annual summary report of their activities for the preceding calendar year from January 1st through December 31st of each year. The report shall be submitted no later than March 1st of the following year. The report shall indicate the amount of waste shipped out of state, the amount of waste shipped into the state, and the amount of waste generated and unloaded in the state.

(1) The report shall include:

(A) the name(s) and address(es) of the facilities where the waste was deposited/unloaded;

(B) the authorization number of the facilities; and

(C) the amount of waste deposited/unloaded at each facility.

(2) A transporter failing to submit the annual summary report by the due date is subject to payment of the maximum fees specified in §326.87(b) of this title.

(3) A transporter owing delinquent fees or an applicant who has failed to submit required reports will not be eligible to renew their registration to transport untreated medical waste until all fees and reports are submitted and accepted by the executive director.