

The Texas Commission on Environmental Quality (TCEQ, agency, or commission) proposes 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.

Background and Summary of the Factual Basis for the Proposed Rules

House Bill (HB) 2244, passed by the 84th Texas Legislature, 2015, amends the 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 proposed rulemaking would primarily involve extracting the rules related to medical waste from 30 Texas Administrative Code (TAC) Chapter 330 (Municipal Solid Waste), and moving them to proposed new 30 TAC Chapter 326 (Medical Waste Management). 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

The requirements of proposed new Chapter 326 address the handling, storage, disposal, and transportation of medical waste. Proposed new §326.1, Purpose and Applicability, establishes that the proposed 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, and other authorizations issued by the commission and its predecessors, that existed before Chapter 326 becomes effective remain valid for two years from the effective date of that chapter, until a final decision is made on a timely application for an existing authorization to comply with Chapter 326. The existing Chapter 330 rules governing medical waste, which are being repealed in a corresponding rulemaking, remain in effect and applicable to existing and pending authorizations obtained under those rules. Applications received within two years of the effective date of Chapter 326 for an existing authorization 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.

Applications pending before the effective date of Chapter 326 are subject to review under the existing Chapter 330 rules. Authorizations 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 authorizations terminate if a timely

application to update is not filed. Existing authorizations remain in effect until a final determination is made on a timely filed application.

§326.3, Definitions

Proposed 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 rules in 25 TAC §1.132 and §133.2 (Definitions). When the definitions found in 25 TAC §1.132 are changed, such changes would prevail over the definitions found in §326.3. This section clearly identifies that 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 would be considered to be managed on-site. 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 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 proposed Chapter 326 to allow medical waste facility owners and operators to manage these wastes.

§326.5, General Prohibitions

Proposed 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, or to extract materials from medical wastes under 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 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.

§326.7, Other Authorizations

Proposed 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

Proposed 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 would be considered to be medical waste.

§326.19, Packaging

Proposed 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, which addresses infectious substances. 49 CFR Subtitle B, Chapter 1, Subchapter C specifically regulates infectious substances to abate future outbreaks of infectious disease.

§326.21, Labeling

Proposed 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.

§326.23, Shipping

Proposed 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

Proposed 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), large quantity generators (LQGs), and SQG transporters. 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. SQG Transporters generate and transport less than 50 pounds per month to an authorized medical waste storage or processing facility.

Persons who transport medical waste within Texas when the transportation neither originates nor terminates in Texas would 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, is incorporated by reference in 39 CFR Part 111 and would be considered exempt from medical waste authorizations under Chapter 326.

Subchapter D: Operations Requiring a Notification

§326.37, General Requirements

Proposed new §326.37 establishes the process for medical waste operations to notify the

Agency of certain operations. Proposed 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 proposed in this section.

§326.39, On-Site Treatment by Small Quantity Generators

Proposed 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 proposed §326.3(23).

§326.41, On-Site Treatment by Large Quantity Generators

Proposed new §326.41(a) establishes that an LQG may treat their medical waste on-site.

However, the notification requirements for LQGs are proposed to be more stringent than for SQGs; LQGs would 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.

Proposed 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 proposed frequency of testing is based on the number of pounds generated per month for a facility.

Proposed 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).

Proposed 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.

Proposed 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.

Proposed 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 would follow disposal requirements applicable to incinerator ash and label the waste as treated medical waste.

Proposed 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.

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

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

§326.43, Medical Waste Collection and Transfer by Licensed Hospitals

Proposed 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 SQG 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.

Proposed new §326.43(b)(1) - (5) establish the items that the notification must address; such as the packaging, storage, transporting, and treatment requirements.

Subchapter E: Operations Requiring a Registration by Rule

§326.53, Transporters

Proposed new §326.53(a) establishes that a registration by rule is available to transporters and that they would provide information to the commission 60 days prior to beginning transportation operations. A form would be provided by the commission and proposed 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).

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

Proposed 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.

Proposed new §326.53(b)(7) establishes that transportation units used to transport untreated medical waste would not be used to transport any other material until the transportation unit has been cleaned and the cargo compartment disinfected.

Recordkeeping would be required to document the date and the process used to clean and disinfect the transportation unit and records would be maintained for three years. The record would identify the transportation unit by motor vehicle identification number or

license tag number. The owner of the transportation unit, if not the operator, would 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.

Proposed new §326.53(b)(8) establishes that a transporter would 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.

Proposed 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 would also provide the generator with a written or electronic statement of the total weight or volume of the containers within 45 days.

Proposed new §326.53(b)(10) establishes that the transporter would 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 would accompany each shipment of untreated medical waste to its final destination and the transporter would be responsible for the proper collection and deposition of untreated medical waste accepted for transport.

Proposed new §326.53(b)(11) - (13) establish that shipments of untreated medical waste would 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 would be deposited at a facility that is authorized by the appropriate agency having jurisdiction over such waste.

Proposed new §326.53(b)(14) establishes that the storage of medical waste would 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 would be managed so as not to provide a breeding place or food for insects or rodents, and not generate noxious odors.

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

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

Proposed new §326.53(b)(17) establishes that packages of untreated medical waste would 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.

Proposed 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 would 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 would comply with §326.53(b)(6) and (7).

Proposed 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 would 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, would be notified of the incident no later than the end of the next working day after the accident.

Proposed 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.

Proposed 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

Proposed 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 would complete a registration by rule form provided by the commission and provide the required information at least 60 days before commencing operations.

Proposed 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.

Proposed 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).

Proposed 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 would be submitted to the commission and the corresponding financial assurance must be established in accordance with Chapter 37, Subchapter R (Financial Assurance for Municipal Solid Waste Facilities).

Proposed new §326.55(a)(10) requires the owner or operator to provide a description of each mobile on-site treatment unit. Proposed new §326.5(11) explains how a registrant by rule submits the annual fee.

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

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

Proposed 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 would 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 would not transport medical waste unless they are a registered medical waste transporter.

Proposed 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

Proposed new §326.61(a) and (b) establish that registrations would 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.

Proposed new §326.61(c) - (h) establish that a registration application is not subject to the opportunity for a contested case hearing. All aspects of the application and design requirements would be addressed even if only to show why requirements are not

applicable to a particular site. The owner or operator would 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. Municipal solid waste, which would be classified as medical waste if it were generated by health care-related facilities, would 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 would 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

Proposed 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.

§326.65, Relationships with Other Governmental Entities

Proposed 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, Relationships with County Licensing System

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

Proposed new §326.67(c) and (d) provide for the contents of a license and the licensee's responsibilities. The license contents would 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 would need to operate in compliance with regulations of the commission and the county.

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

Proposed new §326.69(a) - (d) require that owner or operator submit three copies of the application. The application would 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 proposed formatting and drawing requirements.

Proposed new §326.69(e) - (g) require 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 would post on its website the Web address link to the application and identify all owners and operators filing the application. The owner or operator would also provide documentation that the person signing the application meet the requirements of 30 TAC §305.44(a) and (b) (Signatories to Applications).

§326.71, Registration Application Contents

Proposed new §326.71(a) and (b) require 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 would 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 would be included. Land ownership information would be provided for property owner(s) within 1/4 mile of the facility. Mineral interest ownership would not be required.

Proposed new §326.71(c) and (d) require the owner or operator to acknowledge that they

would 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).

Proposed new §326.71(e) requires transportation data on the availability and adequacy of roads that the owner or operator would 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 project 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 would also submit documentation of coordination of all designs of proposed public roadway improvements and documentation of coordination with the Texas Department of Transportation for traffic and location restrictions.

Proposed new §326.71(f) establishes that the owner or operator include a certification statement to verify that the facility be constructed, maintained, and operated to manage run-on and run-off during the peak discharge of a 25-year rainfall event and 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 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 would 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.

Proposed 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.

Proposed new §326.71(h) requires a general description of the facility location and design. The owner or operator would 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 would not be subject to this requirement.

Proposed new §326.71(i) requires generalized construction information or manufacturer specifications of all medical waste storage and processing units. Additionally, the owner or operator would 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 would 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 would need to be maintained at a temperature of 45 degrees Fahrenheit or less. The 72-hour delay would not be allowed for putrescible or biohazardous untreated medical waste that has been refrigerated during pre-collection storage. In that case, the putrescible or biohazardous untreated medical waste would remain refrigerated during post-collection storage.

Proposed 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 would 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 would 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 would 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 would comply with the requirements prescribed in §111.123 in lieu of biological or parametric monitoring.

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

Proposed 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 would 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 would 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 would 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.

Proposed 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

Proposed 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 would be provided as specified in 30 TAC §39.501(e) (Application for Municipal Solid Waste Permit). Response to comments by the commission would not be required and there would be no opportunity for a contested case hearing. The owner, operator, or their authorized representative would attend the public meeting. The owner or operator would post a sign or signs at the site of the proposed facility declaring that an application has been filed with the commission and owner or operator may be contacted for further information under requirements listed in §326.73(a)(5)(A) - (I).

Proposed 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 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, would be required along any property line paralleling a public

highway, street, or road. The owner or operator would 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.

Proposed 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 [Water Quality Management Plan] Update), if the executive director acts on an application, the chief clerk would 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 would 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 would be explained in public notices given under 30 TAC Chapter 39 (Public Notice) and §50.133.

§326.75, Site Operating Plan

Proposed new §326.75 defines the contents of a site operating plan required under proposed new §326.71(o). Proposed new §326.75(a)(1) - (4) require owners or operators to provide the functions and minimum qualifications for key personnel; 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; general instructions that operating personnel would follow; and procedures for detection and prevention of the receipt of prohibited waste.

Proposed new §326.75(b) requires the owner or operator to identify the sources and characteristics of medical waste that they would receive for storage, processing or disposal. The information would 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.

Proposed new §326.75(c) establishes how all wastes generated and resulting from the facility operations be processed or disposed.

Proposed new §326.75(d) establishes how medical waste and recyclable materials be stored and kept separate. All areas used for storage would not constitute a fire, safety, or health

hazard or provide food or harborage for animals and vectors, and be contained or bundled so as not to result in litter. Containers would be maintained in a clean condition so that they do not constitute a nuisance and to prevent the harborage, feeding, and propagation of vectors.

Proposed new §326.75(e) establishes recordkeeping requirements. Owner or operator would 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 would 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).

Proposed 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.

Proposed new §326.75(g) establishes how access to the facility would 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 would be enclosed by walls or fencing. The facility access road from a publicly owned roadway would be designed for the expected traffic flow and safe on-site access for commercial collection vehicles and for residents. The access road design would include adequate turning radii according to the vehicles that would utilize the facility and avoid disruption of normal traffic patterns.

Proposed 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 would be provided to indicate where vehicles are to unload their waste. Signs and other means, such as forced lanes would also be used to direct traffic to unloading areas and to prevent unloading in unauthorized areas. The owner or operator would 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. The owner or operator would train their personnel on the contents of the fire protection plan. Access from publicly owned roadways would be at least a two-lane gravel or paved road.

Proposed new §326.75(i)(1) addresses the hours a facility would be open to conduct business. A site operating plan would 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.

Proposed new §326.75(i)(2) 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.

Proposed new §326.75(i)(3) 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.

Proposed new §326.75(j) establishes the required information and design for the facility sign. The sign would 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 would have this sign conspicuously displayed and the posting of erroneous or misleading information would constitute a violation of this section.

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

Proposed 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 would be minimized. A water source and necessary equipment or other means of dust control would be provided, all on-site and other access roadways would be maintained on a regular basis, and regraded as necessary to minimize depressions, ruts, and potholes.

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

Proposed 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 would not be allowed to accumulate medical waste in quantities that cannot be processed within such time that it would 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 would be required to restrict waste acceptance and divert all waste to an approved processing or disposal facility. The owner or operator would need to have alternative processing or disposal procedures for waste in the event the facility is inoperable longer than 24 hours.

Proposed 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 would

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.

Proposed 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 proposed rule would 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.

Proposed 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.

Proposed 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.

Proposed 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 would be required to follow disposal requirements applicable to incinerator ash. Any markings that identify the waste as a medical waste would 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.

Proposed 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 would also conform to the applicable local ordinance or rule, if such ordinance or rule is more stringent than §326.75(r).

Proposed 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).

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

§326.77, Duration, Limits and Additional Registration Conditions

Proposed new §326.77(a) - (g) establish how the executive director would 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 would 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 would automatically terminate and would be no longer be effective.

Proposed 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 would 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 would

contact the executive director and region office in writing and request a pre-opening inspection. A pre-opening inspection would 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 would provide a written or verbal response within 14 days of completion of the pre-opening inspection. The facility would 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

Proposed 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 would be required to enable equitable assessment and collection of fees.

Proposed 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 would 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 would be assessed penalties and interest in accordance with 30 TAC Chapter 12 (Payment of Fees).

§326.87, Fees

Proposed 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, would 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.

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

§326.89, Reports

Proposed 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.

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

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

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

Fiscal Note: Costs to State and Local Government

Jeffrey Horvath, Analyst in the Chief Financial Officer Division, has determined that for the first five-year period the proposed rules are in effect, no significant fiscal implications

are anticipated for the agency or for other units of state or local government.

The proposed rulemaking implements HB 2244. HB 2244 directs TCEQ to adopt a new chapter to consolidate all relevant medical waste rules currently in the Texas Administrative Code and to clearly separate these rules from those applicable to landfills. The proposed rulemaking would move the current rules related to medical waste from Chapter 330, to the proposed new Chapter 326. HB 2244 also requires the agency to adopt some new regulations under the proposed new Chapter 326. The new regulations will make minor operational changes such as revision of buffer zones and the revision of regulations related to the storage of medical waste in transport vehicles. These changes are minor and not expected to significantly increase reporting or compliance requirements for regulated entities.

There will be costs to the agency to implement the proposed rules; however, the costs can be reasonably absorbed using current resources. Because fees and essentially all other reporting requirements will remain unchanged, the proposed rules will not have significant fiscal implications for any state or local governments that handle, store, dispose, or transport medical waste. The proposed rules will affect medical waste transporters, treatment and transfer facilities, health care-related facilities (hospitals, clinics, nursing homes) and mobile treatment units.

Public Benefits and Costs

Mr. Horvath has also determined that for each year of the first five years the proposed rules are in effect, the public benefit anticipated from the administration and enforcement of the proposed rules will be enhanced compliance due to more clear and concise rules for the management of medical waste.

No significant fiscal implications are anticipated for businesses or individuals as a result of the administration of the proposed rules. The proposed rules would move the current rules related to medical waste from Chapter 330, to the proposed new Chapter 326. As required under HB 2244, the proposed rules will also make minor operational changes such as reducing buffer zones and changing regulations related to the storage of medical waste in transport vehicles. These changes are minor and not expected to significantly increase reporting or compliance requirements for regulated entities. The proposed rules will affect medical waste transporters, treatment and transfer facilities, health care-related facilities (hospitals, clinics, nursing homes) and mobile treatment units.

Small Business and Micro-Business Assessment

No adverse fiscal implications are anticipated for small or micro-businesses as a result of the proposed rules. A small business is expected to experience the same fiscal impact as that experienced by individuals or large business under the proposed rules. It is not known how many small or micro-businesses may be affected by the proposed rules. But for those that are, they can expect that the proposed rules will not change fees or most all other

reporting requirements. The proposed rules will make minor operational changes such as the reduction of buffer zones and regulations related to the storage of medical waste in transport vehicles. These changes are not expected to result in significant fiscal implications.

Small Business Regulatory Flexibility Analysis

The commission has reviewed this proposed rulemaking and determined that a small business regulatory flexibility analysis is not required because the proposed rules are necessary in order to comply with state law and does not adversely affect small or micro-businesses in a material way for the first five years that the proposed rules are in effect.

Local Employment Impact Statement

The commission has reviewed this proposed rulemaking and determined that a local employment impact statement is not required because the proposed rules do not adversely affect a local economy in a material way for the first five years that the proposed rules are in effect.

Draft Regulatory Impact Analysis Determination [if full RIA not required]

The commission reviewed the proposed 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 the specific intent of which is to

protect the environment or reduce risks to human health from environmental exposure, and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. The proposed rulemaking is 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 the industry or the public.

Furthermore, the proposal 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 proposed 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 proposed rules included revisions to reconcile any conflict with federal laws governing the transportation of medical waste. Second, the proposed 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 propose 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 propose the adoption of the rule solely under the commission's general powers.

Written comments on the Draft Regulatory Impact Analysis Determination may be submitted to the contact person at the address listed under the Submittal of Comments section of this preamble.

Takings Impact Assessment

The commission evaluated the proposed rulemaking and performed an assessment of whether the proposed rulemaking constitutes a taking under Texas Government Code, Chapter 2007. The specific intent of the proposed 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 proposed rulemaking does not impose a burden on a recognized real property interest and therefore does not constitute a taking. The promulgation of the proposed rulemaking is neither a statutory nor a constitutional taking of private real property by the commission. Specifically, the proposed 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 would otherwise exist in the absence of this rulemaking; nor would it reduce its value by 25% or more beyond that value which would exist in the absence of the proposed rules. Therefore, the proposed rulemaking will not constitute a taking under Texas Government Code, Chapter 2007.

Consistency with the Coastal Management Program

The commission reviewed the proposed 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 proposed rulemaking is not subject to the Texas Coastal Management Program.

Written comments on the consistency of this rulemaking may be submitted to the contact

person at the address listed under the Submittal of Comments section of this preamble.

Announcement of Hearing

The commission will hold a public hearing on this proposal in Austin on January 25, 2016 at 10:00 a.m. in Building E, Room 201S, at the commission's central office located at 12100 Park 35 Circle. The hearing is structured for the receipt of oral or written comments by interested persons. Individuals may present oral statements when called upon in order of registration. Open discussion will not be permitted during the hearing; however, commission staff members will be available to discuss the proposal 30 minutes prior to the hearing.

Persons who have special communication or other accommodation needs who are planning to attend the hearing should contact Sandy Wong, Office of Legal Services at (512) 239-1802 or 1-800-RELAY-TX (TDD). Requests should be made as far in advance as possible.

Submittal of Comments

Written comments may be submitted to Derek Baxter, MC 205, Office of Legal Services, Texas Commission on Environmental Quality, P.O. Box 13087, Austin, Texas 78711-3087, or faxed to (512) 239-4808. Electronic comments may be submitted at:

<http://www1.tceq.texas.gov/rules/ecomments/>. File size restrictions may apply to comments being submitted via the eComments system. All comments should reference

Rule Project Number 2015-019-326-WS. The comment period closes on February 8, 2016.

Copies of the proposed rulemaking can be obtained from the commission's website at

http://www.tceq.texas.gov/rules/propose_adopt.html. For further information, please

contact Mario Perez, Municipal Solid Waste Permits Section, (512) 239-6681.

SUBCHAPTER A: GENERAL INFORMATION

§§326.1, 326.3, 326.5, 326.7

Statutory Authority

The rules are proposed 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 proposed 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 two years from the effective date of this chapter, 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. 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 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.

(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. 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. Modification requests pending on the effective date of this chapter may be prepared and submitted in accordance with the provisions §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, nonhazardous 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. Nonhazardous pharmaceutical waste shall be incinerated or disposed at a facility authorized to accept this waste stream.

(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 waste--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 24 hours is considered a temporary storage period. Exceeding 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.

(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 proposed 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 proposed 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 which includes 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.

(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. 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 which includes 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 proposed 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 proposed 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 proposed 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 proposed 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.

(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 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). The notification shall include:

(1) 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 dates of treatment; and

(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). The notification shall include:

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

(1) dates of treatment;

(2) amounts of waste treated;

(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 as municipal solid waste. 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, 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 proposed 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 proposed 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 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 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) waste, and nonhazardous pharmaceutical waste may be commingled during transport or storage. Authorizations for the acceptance of APHIS waste shall be obtained from United States Department of Agriculture, Animal and Plant Health Inspection Service.

(13) Shipments of untreated medical waste, properly containerized APHIS waste, and nonhazardous 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, 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 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)(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 leakproof 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 proposed 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 proposed 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 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.

(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

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.

(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 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;

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

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

(A) random inspections of 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 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 as

municipal solid waste. 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 proposed 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 proposed 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.