

SUBCHAPTER D: OPERATIONS REQUIRING A NOTIFICATION
§§326.37, 326.39, 326.41, 326.43
Effective May 26, 2016

§326.37. General Requirements.

(a) Generators that are not exempt and that intend to store or process medical waste authorized under this subchapter shall provide written notification to the executive director, and any local pollution agency with jurisdiction that has requested in writing to the commission to be notified that storage or processing activities are planned. The required notifications must be submitted at least 90 days prior to a generator engaging in these activities, except for recycling and other activities as may be specifically exempted. Additional information may be requested to enable the executive director to determine whether such storage or processing is in compliance with the terms of this chapter. This information may include, but is not limited to, type of waste, waste management methods, and facility design. Any information provided under this subsection shall be submitted to the executive director in duplicate with one copy sent directly to the appropriate regional office. A person shall include a statement justifying the facility's eligibility for a notification as established under this section. The executive director is authorized to approve requests to submit this information electronically if the commission develops electronic systems to manage the data.

(b) Any person that stores or processes medical waste authorized under this subchapter shall have the continuing obligation to provide prompt written notice to the executive director of any changes or additional information concerning type of waste, waste management methods, facility design plans additional to that reported in subsection (a) of this section authorized in any 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 provide written notification to the executive director, and any local pollution agency with jurisdiction that has requested in writing to the commission to be notified of any closure activity or activity of facility expansion not authorized by any notification. The required notifications must be submitted at least 90 days prior to a person 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 provide written notification to the executive director of the operation of an approved treatment process unit used only for the treatment of medical waste generated on-site in accordance with the provisions of 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition). Alternative treatment technologies may be approved in accordance with requirements found in 25 TAC §1.135 (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities). This one-time notification shall include:

(1) contact information for the generator;

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

(3) the method/conditions of treatment.

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

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

(2) the dates of treatment; and

(3) 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.

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§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 provide written notification to the executive director of the operation of an approved treatment process unit used only for the treatment of medical waste generated on-site in accordance with the provisions of 25 TAC §1.136 (relating to Approved Methods of Treatment and Disposition). Alternative treatment technologies may be approved in accordance with requirements found in

25 TAC §1.135 (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities). This one-time notification shall include:

(1) the contact information for the generator;

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

(3) the method/conditions of treatment.

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

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

(2) the dates of treatment;

(3) the amounts of waste treated; and

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

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

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

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

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

(B) For those processes that the manufacturer has documented compliance with the performance standard prescribed in 25 TAC §1.135, based on

specified parameters (for example, pH, temperature, pressure), and for previously approved treatment processes that a continuous readout and record of operating parameters is available, the operator may substitute routine parameter monitoring for biological monitoring. The operator shall confirm that any chemicals or reagents used as part of the treatment process are at the effective treatment strength. The operator will maintain records of operating parameters and reagent strength, if applicable, for three years.

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

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

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

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

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

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

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

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

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§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 provide written notification to the executive director of the operation as a medical waste collection station. The hospital's notice shall acknowledge the following:

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

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

(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.

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