

SUBCHAPTER A: GENERAL INFORMATION
§§326.1, 326.3, 326.5, 326.7
Effective May 26, 2016

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

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

(3) Modification requests submitted after the effective date of this chapter shall be prepared and submitted in accordance with the provisions of

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

(4) The requirement in §326.23(e) of this title (relating to Shipping) to provide notice to landfills that waste shipments include treated medical waste applies to existing authorizations regardless of any conflicting language in those authorizations or rules in Chapter 330 of this title.

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

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§326.3. Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(20) License--

(A) A document issued by an approved county authorizing and governing the operation and maintenance of a medical waste facility used to process or store medical waste, other than hazardous waste, in an area not in the territorial limits or extraterritorial jurisdiction of a municipality.

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

(21) Liquid waste--Any waste material that is determined to contain "free liquids" as defined by United States Environmental Protection Agency (EPA)

Method 9095 (Paint Filter Test), as described in "Test Methods for Evaluating Solid Wastes, Physical/Chemical Methods" (EPA Publication Number SW-846).

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

(23) Medical waste--Treated and untreated special waste from health care-related facilities that is comprised of animal waste, bulk blood, bulk human blood, bulk human body fluids, microbiological waste, pathological waste, and sharps as those terms are defined in 25 TAC §1.132 (relating to Definitions) from the sources specified in 25 TAC §1.134 (relating to Application), as well as regulated medical waste as defined in 49 Code of Federal Regulations §173.134(a)(5), except that the term does not include medical waste produced on a farm or ranch as defined in 34 TAC §3.296(f) (relating to Agriculture, Animal Life, Feed, Seed, Plants, and Fertilizer), nor does the term include artificial, nonhuman materials removed from a patient and requested by the patient, including, but not limited to, orthopedic devices and breast implants. Health care-related facilities do not include:

(A) single or multi-family dwellings; and

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

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

(25) Municipal solid waste--Solid waste resulting from or incidental to municipal, community, commercial, institutional, and recreational activities, including garbage, rubbish, ashes, street cleanings, dead animals, abandoned automobiles, and all other solid waste other than industrial solid waste.

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

(27) 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.

(28) 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.

(29) 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.

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

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

(32) 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.

(33) 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.

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

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

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

(37) 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.

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

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

(40) 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.

(41) 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.

(42) Putrescible medical waste--Medical waste that contains organic matter capable of being decomposed by microorganisms and of such a character and proportion as to cause odors or gases or are capable of providing food for or attracting birds, animals, and disease vectors.

(43) 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.

(44) 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.

(45) 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.

(46) 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).

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

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

(49) Site--Same as facility.

(50) 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.

(51) 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.).

(52) 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.

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

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

(B) Post-collection transporter--that storage by a transporter while the medical waste is in transit. Any vehicle inactivity such as not continuing a collection route for a period less than 72 hours is considered a temporary storage period. Exceeding 72 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.

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

(55) 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.

(56) 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.

(57) 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.

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

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

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

(61) 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.

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

(63) 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.

(64) 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.

(65) 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.

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

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§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 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.

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§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.

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