

Legend: (Final Amendments - With additional changes not proposed)

Double underline = New language not proposed

~~[Strikethrough, underline, and brackets]~~ = Proposed new language now being deleted

~~[Strikethrough and Brackets]~~ = Final language now being deleted

Regular print = Current language incorporating proposed changes for final adoption

(No change) = No changes are being considered for the designated subdivision

#### §1.132. Definitions.

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

(1) - (2) (No change.)

(3) Approved alternate treatment process--A process for waste treatment which has been approved by the department in accordance with §1.135 of this title (relating to Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities).

(4) - (17) (No change.)

(18) Cremation--The irreversible process of reducing tissue or remains to ashes or bone fragments through extreme heat and evaporation. Under this subchapter, this term includes the process of incineration.

(19) - (20) (No change.)

(21) Department--Texas Department of State Health Services.

(22) - (26) (No change.)

(27) Executive Commissioner--In this title, Executive Commissioner means the Executive Commissioner of the Health and Human Services Commission.

(28) Fetal Tissue--A fetus, body parts, organs or other tissue from a pregnancy. This term does not include the umbilical cord, placenta, gestational sac, blood or body fluids.

(29) Grave--A space of ground in a burial park that is used, or intended to be used for the permanent interment in the ground of pathological waste.

(30) Grinding--That physical process which pulverizes materials, thereby rendering them as unrecognizable, and for sharps, reduces the potential for the material to cause injuries such as puncture wounds.

(31) Immersed--A process in which waste is submerged fully into a liquid chemical agent in a container, or that a sufficient volume of liquid chemical agent is poured over a containerized waste, such that the liquid completely surrounds and covers the waste item(s) in the container.

(32) Incineration--That process of burning SWFHCRF in an incinerator as defined in 30 TAC Chapter 101 under conditions in conformance with standards prescribed in 30 TAC Chapter 111 by the Texas Commission on Environmental Quality.

(33) Interment--The disposition of pathological waste using the process of [by] cremation, entombment, burial, or placement in a niche or by using the process of cremation followed by placement of the ashes in a niche, grave, or scattering of ashes as authorized by law, unless prohibited by this subchapter.

(34) Log<sub>10</sub>--Logarithm to the base ten.

(35) Log<sub>10</sub> reduction--A mathematically defined unit used in reference to level or degree of microbial inactivation. A 4 log<sub>10</sub> reduction represents a 99.99% reduction in the numbers of active microorganisms, while a 6 log<sub>10</sub> reduction represents a 99.9999% reduction in the numbers of active microorganisms.

(36) Mausoleum--A structure or building of most durable and lasting fireproof construction used, or intended to be used, for the entombment pathological waste.

(37) Microbial inactivation--Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 log<sub>10</sub> reduction or greater; and inactivation of *Bacillus subtilis* endospores or *Bacillus stearothermophilus* endospores at a 4 log<sub>10</sub> reduction or greater.

(38) Microbiological waste--Microbiological waste includes:

(A) discarded cultures and stocks of infectious agents and associated biologicals;

(B) discarded cultures of specimens from medical, pathological, pharmaceutical, research, clinical, commercial, and industrial laboratories;

(C) discarded live and attenuated vaccines, but excluding the empty containers thereof;

(D) discarded, used disposable culture dishes; and

(E) discarded, used disposable devices used to transfer, inoculate or mix cultures.

(39) Moist heat disinfection--The subjection of:

(A) internally shredded waste to moist heat, assisted by microwave radiation under those conditions which effect disinfection; or

(B) unshredded waste in sealed containers to moist heat, assisted by low-frequency radiowaves under those conditions which effect disinfection, followed by shredding of the waste to the extent that the identity of the waste is unrecognizable.

(40) Niche--A recess or space in a columbarium used, or intended to be used, for the permanent interment of the cremated remains of pathological waste.

(41) Parametric controls--Measurable standards of equipment operation appropriate to the treatment equipment including, but not limited to pressure, cycle time, temperature, irradiation dosage, pH, chemical concentrations, or feed rates.

(42) Pathological waste--Pathological waste includes but is not limited to:

(A) human materials removed during surgery, labor and delivery, autopsy, embalming, or biopsy, including:

- (i) body parts;
- (ii) tissues or fetuses;
- (iii) organs; and
- (iv) bulk blood and body fluids;

(B) products of spontaneous or induced human abortions, regardless of the period of gestation[,], except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services) including:

- (i) body parts;
- (ii) tissues or fetuses;
- (iii) organs; and
- (iv) bulk blood and body fluids;

(C) laboratory specimens of blood and tissue after completion of laboratory examination; and

(D) anatomical remains.

(43) Saturated--Thoroughly wet such that liquid or fluid flows freely from an item or surface without compression.

(44) Sharps--Sharps include, but are not limited to the following materials:

(A) when contaminated:

(i) hypodermic needles;

(ii) hypodermic syringes with attached needles;

(iii) scalpel blades;

(iv) razor blades, disposable razors, and disposable scissors used in surgery, labor and delivery, or other medical procedures;

(v) intravenous stylets and rigid introducers (e.g., J wires);

(vi) glass pasteur pipettes, glass pipettes, specimen tubes, blood culture bottles, and microscope slides;

(vii) broken glass from laboratories; and

(viii) tattoo needles, acupuncture needles, and electrolysis needles;

(B) regardless of contamination:

(i) hypodermic needles; and

(ii) hypodermic syringes with attached needles.

(45) Shredding--That physical process which cuts, slices, or tears materials into small pieces.

(46) Special waste from health care-related facilities--A solid waste which if improperly treated or handled may serve to transmit an infectious disease(s) and which is comprised of the following:

(A) animal waste;

(B) bulk blood, bulk human blood products, and bulk human body fluids;

(C) microbiological waste;

(D) pathological waste; and

(E) sharps.

(47) Steam disinfection--The act of subjecting waste to steam under pressure under those conditions which effect disinfection. This was previously called steam sterilization.

(48) Thermal inactivation--The act of subjecting waste to dry heat under those conditions which effect disinfection.

(49) Unrecognizable--The original appearance of the waste item has been altered such that neither the waste nor its source can be identified.

§1.133. Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services.

(a) Exemptions.

(1) Unless an item is specifically exempted, all special waste from health care-related facilities must be treated as provided in these sections.

(2) These sections do not apply to:

(A) teeth;

(B) human tissue, including fetal tissue, donated for research or teaching purposes, with the consent of the person authorized to consent as otherwise provided by law, to an institution of higher learning, medical school, a teaching hospital affiliated with a medical school, or to a research institution or individual investigator subject to the jurisdiction of an institutional review board required by 42 United States Code 289;

(C) placentas designated for sale and obtained from a licensed hospital or a licensed birthing center;

(D) in vitro tissue cultures that have not been intentionally exposed to pathogens;

(E) any material included in the definition of special waste from health care-related facilities which has been sold, donated, or in any way transferred from one health care-related facility to a subsequent facility(s) and other entities specified in subparagraph (B) of this paragraph for research or teaching purposes until it is discarded; ~~and~~

(F) disposition of fetal remains of a single pregnancy, body parts, or tissue (including bulk blood), transferred for disposition to a licensed funeral director in accordance with the Health and Safety Code, Chapter 711, and Chapter 181 of this title (relating to Vital Statistics) with the consent of the person or persons authorized to consent to the disposition of the fetal remains, body parts, or tissue (including bulk blood). All subcategories of pathological waste, unless otherwise exempted, must be treated and disposed of in accordance with §1.136 of this title (relating to Approved Methods of Treatment and Disposition);

(G) human tissue, including fetal tissue, that is expelled or removed from the human body once the person is outside of a healthcare facility;

(H) fetal remains required to be released to the parent of an unborn child pursuant to Texas Health and Safety Code, §241.010; and

(I) a placenta removed from a hospital or birthing center pursuant to Texas Health and Safety Code, Chapter 172.

(b) Minimum parametric standards for waste treatment technologies previously approved by the department.

(1) - (5) (No change.)

§1.134. Application.

(a) This subchapter may not be used to require or authorize disclosure of confidential information, including personally identifiable or personally sensitive information, not permitted to be disclosed by state or federal privacy or confidentiality laws. This subchapter does not require the issuance of a birth or death certificate for the proper disposition of special waste from health care-related facilities. This subchapter does not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716 or Texas Occupations Code, Chapter 651 to disposition of fetal tissue.

(b) These sections apply to special waste from health care-related facilities generated by the operation of the following publicly or privately owned or operated health care-related facilities, including but not limited to:

(1) - (11) (No change.)

(12) freestanding emergency medical care facilities;

(13) funeral establishments;

(14) home and community support services agencies;

(15) hospitals;

(16) long term care facilities;

(17) facilities providing mental health and intellectual disability services, including but not limited to hospitals, schools, and community centers;

(18) minor emergency centers;

(19) occupational health clinics and clinical laboratories;

(20) pharmacies;

(21) pharmaceutical manufacturing plants and research laboratories;

(22) professional offices, including but not limited to the offices of physicians, dentists, and acupuncturists;

(23) special residential care facilities;

(24) tattoo studios; and

(25) veterinary clinical and research laboratories.

§1.135. Performance Standards for Commercially-Available Alternate Treatment Technologies for Special Waste from Health Care-Related Facilities.

All manufacturers of commercially-available alternate technologies, equipment, or processes designed or intended for the treatment of special waste from health care-related facilities, except those meeting the standards of §1.133(b) of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services), shall apply to the department on forms prescribed by the department for approval of said technologies, equipment, or processes to ensure that established performance standards are met.

(1) Levels of microbial inactivation.

(A) (No change.)

(B) All manufacturers of commercially-available alternate technologies, equipment, or processes designed and intended for the treatment of special waste from health care-related facilities shall provide specific laboratory evidence that demonstrates:

(i) inactivation of representative samples of vegetative bacteria, mycobacteria, lipophilic/hydrophilic viruses, fungi, and parasites at a level of 6 log<sub>10</sub> reduction or greater, as determined by the department; and

(ii) inactivation of *Bacillus stearothermophilus* endospores or *Bacillus subtilis* endospores at a level of 4 log<sub>10</sub> reduction or greater, as determined by the department.

(C) - (E) (No change.)

(2) Documentation requirements.

(A) (No change.)

(B) Documentation must be submitted to the department on forms provided by the department.

(3) - (4) (No change.)

§1.136. Approved Methods of Treatment and Disposition.

(a) Introduction. The following treatment and disposition methods for special waste from health care-related facilities are approved by the department for the waste specified. Where a special waste from a health care-related facility is also subject to the sections in Chapter 289 of this title (relating to Radiation Control), the sections in Chapter 289 shall prevail over the sections in this subchapter. Disposal of special waste from health care-related facilities in sanitary landfills or otherwise is under the jurisdiction of the Texas Commission on Environmental Quality and is governed by its rules found in 30 TAC Chapter 326 (relating to Medical Waste Management) and Chapter 330 (relating to Municipal Solid Waste).

(1) - (2) (No change.)

(3) Microbiological waste. Microbiological waste shall be subjected to one of the following methods of treatment and disposal.

(A) - (C) (No change.)

(D) Discarded disposable culture dishes shall be subjected to one of the following methods of treatment and disposal.

(i) All discarded, unused disposable culture dishes shall be disposed of in accordance with 30 TAC Chapters 326 and 330.

(ii) (No change.)

(E) (No change.)

(4) Pathological waste. Pathological waste shall be subjected to one of the following methods of treatment and disposal.

(A) Human materials removed during surgery, labor and delivery, autopsy, embalming, or biopsy shall be subjected to one of the following methods of treatment and disposal:

(i) body parts, other than fetal tissue:

(I) interment;

(II) incineration followed by deposition of the residue in a sanitary landfill;

(III) steam disinfection followed by interment;

(IV) moist heat disinfection, provided that the grinding/shredding renders the item as unrecognizable, followed by deposition in a sanitary landfill;



(V) chlorine disinfection/maceration, provided that the grinding/shredding renders the item as unrecognizable, followed by deposition in a sanitary landfill; or

(VI) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(ii) tissues, other than fetal tissue:

(I) incineration followed by deposition of the residue in a sanitary landfill;

(II) grinding and discharging to a sanitary sewer system;

(III) interment;

(IV) steam disinfection followed by interment;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iii) organs, other than fetal tissue:

(I) incineration followed by deposition of the residue in a sanitary landfill;

(II) grinding and discharging to a sanitary sewer system;

(III) interment;

(IV) steam disinfection followed by interment;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iv) bulk human blood and bulk human body fluids removed during surgery, labor and delivery, autopsy, embalming, or biopsy:

(I) discharging into a sanitary sewer system;

(II) steam disinfection followed by deposition in a sanitary landfill;

- (III) incineration followed by deposition of the residue in a sanitary landfill;
- (IV) thermal inactivation followed by deposition in a sanitary landfill;
- (V) thermal inactivation followed by grinding and discharging into a sanitary sewer system;
- (VI) chemical disinfection followed by deposition in a sanitary landfill;
- (VII) chemical disinfection followed by grinding and discharging into a sanitary sewer system;
- (VIII) moist heat disinfection followed by deposition in a sanitary landfill;
- (IX) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (X) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(v) fetal tissue, regardless of the period of gestation, except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services):

(I) interment;

~~(II) cremation;~~

~~(II)~~ ~~(III)~~ incineration followed by interment; or

~~(III)~~ ~~(IV)~~ steam disinfection followed by interment.

(B) The products of spontaneous or induced human abortion shall be subjected to one of the following methods of treatment and disposal:

(i) fetal tissue, regardless of the period of gestation, except as provided by §1.133 of this title (relating to Scope, Covering Exemptions and Minimum Parametric Standards for Waste Treatment Technologies Previously Approved by the Texas Department of State Health Services):

(I) incineration followed by interment;

(II) steam disinfection followed by interment; or

(III) interment; ~~or~~

~~[(IV) cremation;]~~

(ii) blood and body fluids:

(I) discharging into a sanitary sewer system;

(II) steam disinfection followed by deposition in a sanitary landfill;

(III) incineration followed by deposition of the residue in a sanitary landfill;

(IV) thermal inactivation followed by deposition in a sanitary landfill;

(V) thermal inactivation followed by grinding and discharging into a sanitary sewer system;

(VI) chemical disinfection followed by deposition in a sanitary landfill;

(VII) chemical disinfection followed by grinding and discharging into a sanitary sewer system;

(VIII) moist heat disinfection followed by deposition in a sanitary landfill;

(IX) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(X) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill;

(iii) any other tissues, including placenta, umbilical cord and gestational sac:

(I) grinding and discharging to a sanitary sewer system;

(II) incineration followed by deposition of the residue in a sanitary landfill;

(III) steam disinfection followed by interment;

(IV) interment;

(V) moist heat disinfection followed by deposition in a sanitary landfill;

(VI) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or

(VII) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

(C) Discarded laboratory specimens of blood and/or tissues shall be subjected to one of the following methods of treatment and disposal:

- (i) grinding and discharging into a sanitary sewer system;
- (ii) steam disinfection followed by deposition in a sanitary landfill;
- (iii) steam disinfection followed by grinding and discharging into a sanitary sewer system;
- (iv) incineration followed by deposition of the residue in a sanitary landfill;
- (v) moist heat disinfection followed by deposition in a sanitary landfill;
- (vi) chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- (vii) an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

(D) Anatomical remains shall be disposed of in a manner specified by §479.4 of this title (relating to Final Disposition of the Body and Disposition of Remains).

(5) Sharps.

(A) All discarded unused sharps shall be disposed of in accordance with 30 TAC Chapters 326 and 330.

(B) (No change.)

(b) Records. The facility treating the wastes shall maintain records to document the treatment of the special waste from health care-related facilities processed at the facility as to method and conditions of treatment in accordance with 30 TAC Chapter 326.

(c) (No change.)

§1.137. Enforcement.

The appropriate regulatory programs of the department shall incorporate the definition and methodology contained in these provisions into their respective general program rules and shall formulate and present for the Executive Commissioner's consideration such additional rules as are necessary for the internal collection, storage, handling, movement, and treatment of special waste from health care-related facilities generated within or by the following facilities or activities:

- (1) abortion clinics;
- (2) ambulatory surgical centers;
- (3) birthing centers;

- (4) emergency medical service providers;
- (5) end stage renal disease facilities;
- (6) freestanding emergency medical care facilities;
- (7) hospitals;
- (8) special residential care facilities; and
- (9) tattoo studios.