

**Annex A**  
**TITLE 25. ENVIRONMENTAL PROTECTION**  
**PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION**  
**Subpart D. ENVIRONMENTAL HEALTH AND SAFETY**  
**ARTICLE VIII. MUNICIPAL WASTE**  
**CHAPTER 271. MUNICIPAL WASTE MANAGEMENT—GENERAL PROVISIONS**  
**Subchapter A. GENERAL**

**§ 271.1. Definitions.**

The following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

\* \* \* \* \*

*Autoclave*—A pressure vessel in which **[infectious] regulated medical** waste is disinfected using high temperature steam, directly or indirectly, to maintain specified temperatures for retention times consistent with the waste being processed.

\* \* \* \* \*

*Body fluids*—Liquids emanating or derived from humans and limited to the following: blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; semen and vaginal secretions; and amniotic fluid. The term also includes the following fluids if they contain visible blood: feces, sputum, **saliva**, urine and vomitus.

\* \* \* \* \*

*Commercial [infectious] regulated medical or chemotherapeutic waste facility*—A facility that processes **[infectious] regulated medical** or chemotherapeutic waste **[not generated primarily onsite. The term includes facilities where one of the following exist] under either of the following conditions:**

- (i) **[Of the waste processed, less than 50% on a monthly average was generated onsite.**
- (ii) **Greater than 50% of the waste processed on a monthly average is not generated from entities that are wholly-owned by the owner of the waste processing facility.]**

**The facility does not generate any of the regulated medical or chemotherapeutic waste that it processes.**

**(ii) If the facility generates the regulated medical or chemotherapeutic waste that it processes, the amount of waste on a monthly average that is generated onsite and offsite by wholly-owned generators of the facility is less than 50% of the waste that it processes.**

\* \* \* \* \*

*Disinfection*—The treatment or processing of **[infectious] regulated medical** waste so that it poses no risk of infection or other health risk to individuals handling or otherwise coming into contact with the waste. The term includes autoclaving; dry heat, gas or chemical disinfection; radiation and irradiation; and incineration.

\* \* \* \* \*

*Environmental protection acts*—The act, The Clean Streams Law (35 P.S. §§ 691.1—691.1001), the Municipal Waste Planning, Recycling and Waste Reduction Act (53 P.S. §§ 4001.101—4001.1904), the Hazardous Sites Cleanup Act (35 P.S. §§ 6020.101—6020.1305), the Low-Level Radioactive Waste Disposal Act [(35 P.S. §§ 7130.101—7130.906)] (35 P.S. §§ 7130.101—7130.905), the act of July 13, 1988 (35 P.S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Disposal Law, the Air Pollution Control Act (35 P.S. §§ 4001—4015), the Surface Mining Conservation and Reclamation Act [(52 P.S. §§ 1396.1—1396.31)] (52 P.S. §§ 1396.1—1396.19b), the Noncoal Surface Mining Conservation and Reclamation Act [(35 P.S. §§ 3301—3326)] (52 P.S. §§ 3301—3326), the Dam Safety and Encroachments Act (32 P.S. §§ 693.1—693.27), and other State or Federal statutes relating to environmental protection or the protection of public health, including statutes adopted or amended after April 9, 1988.

\* \* \* \* \*

*General composting facility*—A composting facility other than an individual backyard composting facility or yard waste composting facility operating under § 271.103(h) (relating to permit-by-rule for municipal waste processing facilities other than for [**infectious**] **regulated medical** or chemotherapeutic waste; qualifying facilities; general requirements).

\* \* \* \* \*

*Household hazardous waste*—

- (i) Waste generated by a household that could be chemically or physically classified as a hazardous waste under the standards of Article VII (relating to hazardous waste management).
- (ii) For the purpose of this definition, the term “household” includes those places described as “households” in 40 CFR 261.4(b)(1) (relating to exclusions).

**Incineration—The act of reducing to ashes by combustion.**

*Incinerator*—An enclosed device using controlled combustion for the primary purpose of thermally breaking down solid waste, and which is equipped with a flue as defined in § 121.1 (relating to definitions).

\* \* \* \* \*

*Infectious agent*—

- (i) An organism, such as a virus or bacteria, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

**(ii) THE TERM DOES NOT INCLUDE AGENTS CLASSIFIED AS BIOSAFETY LEVEL 1 BY A FACILITY ENGAGED IN THE PRODUCTION OR RESEARCH AND DEVELOPMENT OF VACCINES OR OTHER BIOLOGICS CLASSIFIED UNDER THE NORTH AMERICAN**

**INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) AS CODE 325414 – BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING OR CODE 541711 – RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY, AS DETERMINED BY THE PROTOCOLS ESTABLISHED IN THE MOST RECENT EDITION OF THE CENTERS FOR DISEASE CONTROL’S BIOSAFETY IN MICROBIAL AND BIOMEDICAL LABORATORIES (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED.**

*Infectious waste—*

(i) *General.* Municipal and residual waste which is generated in the diagnosis, treatment, immunization or autopsy of human beings or animals, in research pertaining thereto, in the preparation of human or animal remains for interment or cremation, or in the production or testing of biologicals, and which falls under one or more of the following categories:

(A) *Cultures and stocks.* Cultures and stocks of infectious agents and associated biologicals, including the following:

**(I)** ~~[cultures]~~ **CULTURES** from medical and pathological laboratories[;].

**(II)** ~~[cultures]~~ **CULTURES** and stocks of infectious agents, **AND CELL LINES THAT HAVE BEEN EXPOSED TO INFECTIOUS AGENTS** from research and industrial laboratories[;].

**(III)** ~~[wastes]~~ **WASTES** from the production of biologicals[;].

**(IV)** ~~[discarded]~~ **DISCARDED** live and attenuated vaccines except for residue in emptied containers, **AS DETERMINED BY APPLYING THE CRITERIA IN 40 CFR § 261.7(b)(1) OR (2) TO THE RESIDUE REMAINING IN THE CONTAINER[; and].**

**(V)** ~~[culture]~~ **CULTURE** dishes, assemblies and devices used to conduct diagnostic tests or to transfer, inoculate and mix cultures.

(B) *Pathological wastes.* Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth ~~[or tissues that have been preserved with formaldehyde or other approved preserving agents].~~

(C) *Human blood and body fluid waste.*

\* \* \* \* \*

(V) Intravenous bags that have been used for blood transfusions, **including soft plastic pipettes and plastic blood vials.**

\* \* \* \* \*

(D) *Animal wastes.* Contaminated animal carcasses, body parts, blood, blood products, secretions, excretions and bedding of animals that were known to have been exposed to zoonotic infectious agents or nonzoonotic human pathogens ~~[during research]~~ **[(including research in veterinary schools and hospitals)]**, production of biologicals, or testing of pharmaceuticals.

\* \* \* \* \*

(F) *Used sharps.* [~~Sharps~~]

(I) **BROKEN GLASS, HYPODERMIC NEEDLES, SYRINGES TO WHICH A NEEDLE IS OR CAN BE ATTACHED, RAZORS, PASTEUR PIPETTES, SCALPEL BLADES, BLOOD VIALS, NEEDLES WITH ATTACHED TUBING, CULTURE DISHES, SUTURE NEEDLES, SLIDES, COVER SLIPS, AND OTHER BROKEN OR UNBROKEN GLASS OR PLASTICWARE** that have been in contact with infectious agents or that have been used in animal or human patient care or treatment[, **at medical, research or industrial laboratories**].

(II) **THE TERM DOES NOT INCLUDE BROKEN OR UNBROKEN PLASTICWARE GENERATED AT FACILITIES ENGAGED IN THE PRODUCTION OR RESEARCH AND DEVELOPMENT OF VACCINES OR OTHER BIOLOGICS AND CLASSIFIED UNDER THE NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) AS CODE 32514 – BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING OR CODE 541711 - RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY, WHERE NO AGENT IN THE WASTE IS CLASSIFIED AS BIOSAFETY LEVEL 2-4 AS DETERMINED BY THE PROTOCOLS ESTABLISHED IN THE MOST RECENT EDITION OF THE CENTERS FOR DISEASE CONTROL’S BIOSAFETY IN MICROBIAL AND BIOMEDICAL LABORATORIES (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED.**

\* \* \* \* \*

(iii) *Exceptions.* The term does not include the following:

\* \* \* \* \*

(D) Samples of [**infectious**] **regulated medical** waste transported offsite by Commonwealth or United States government enforcement personnel during an enforcement proceeding.

(E) Body fluids, **tissues, specimens** or biologicals [**which**] **that** are being transported to or stored at a laboratory prior to laboratory testing.

(F) Ash residue from the incineration of materials identified in subparagraphs (i) and (ii) if the incineration was conducted in accordance with [**§ 283.402**] **§ 284.321** (relating to [**infectious**] **regulated medical** waste monitoring requirements). The ash residue shall be managed as special handling municipal waste.

\* \* \* \* \*

(H) Soiled diapers [**which**] **that** do not contain materials identified in subparagraph (i).

(I) Mixtures of hazardous waste subject to Article VII (relating to hazardous waste management) and materials identified in subparagraph (i) shall be managed as hazardous waste and not [**infectious**] **regulated medical** waste.

(J) Mixtures of materials identified in subparagraph (i) and regulated radioactive waste shall be managed as radioactive waste in accordance with applicable Commonwealth and Federal statutes and regulations, including[, **but not limited to,**] § 236.521 (relating to minimum requirements for classes of waste).

\* \* \* \* \*

**(L) WASTES, MIXTURES OF WASTES OR CELL LINES FROM FACILITIES ENGAGED IN THE PRODUCTION OR RESEARCH AND DEVELOPMENT OF VACCINES OR OTHER BIOLOGICS AND CLASSIFIED UNDER THE NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) AS CODE 325414 – BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING OR CODE 541711 – RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY, WHERE NO AGENT IN THE WASTE IS CLASSIFIED AS BIOSAFETY LEVEL 2-4 AS DETERMINED BY THE PROTOCOLS ESTABLISHED IN THE MOST RECENT EDITION OF THE CENTERS FOR DISEASE CONTROL’S BIOSAFETY IN MICROBIAL AND BIOMEDICAL LABORATORIES (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED.**

\* \* \* \* \*

*Mobile [infectious] regulated medical waste processing facility*—[An infectious] **A regulated medical waste processing unit [which] that** is moved from one waste generation site to another for the purpose of onsite processing of a generator’s [infectious] **regulated medical waste**. The term refers to any processing activity designed to disinfect [infectious] waste in accordance with § 284.321 (relating to [infectious] **regulated medical waste** monitoring requirements) to render the waste noninfectious. The term does not include any permanently placed waste processing units.

\* \* \* \* \*

*Regional groundwater table*—The fluctuating upper water level surface of an unconfined or confined aquifer, where the hydrostatic pressure is equal to the ambient atmospheric pressure. The term does not include the perched water table or the seasonal high water table.

**Regulated medical waste—Infectious waste.**

**Regulated medical OR CHEMOTHERAPEUTIC waste aggregation facility—A facility that accepts, aggregates or stores regulated medical OR CHEMOTHERAPEUTIC waste, OR BOTH.**

*Related party*—A person or municipality engaged in solid waste management that has a financial relationship to a permit applicant or operator. The term includes a partner, associate, officer, parent corporation, subsidiary corporation, contractor, subcontractor, agent or principal shareholder of another person or municipality, or a person or municipality that owns land on which another person or municipality operates a municipal waste processing or disposal facility.

\* \* \* \* \*

**[Sharps—Broken glass] [that has been in contact with pathogenic organisms][, hypodermic needles][,] [and][, syringes to which a needle is or can be attached,][with or without the attached needle, suture needles, disposable][razors, pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, culture dishes, suture needles, slides, cover slips and other broken or unbroken glass or plasticware.]**

\* \* \* \* \*

*Special handling waste*—Solid waste that requires the application of special storage, collection, transportation, processing or disposal techniques due to the quantity of material generated or its unique physical, chemical or biological characteristics. The term includes dredged material, sewage sludge, **[infectious waste] regulated medical waste**, chemotherapeutic waste, ash residue from a solid waste incineration facility, friable asbestos-containing waste, **[PCB containing waste and] PCB-containing waste**, waste oil that is not hazardous waste.

\* \* \* \* \*

*Thermal processing*—A method, technique or process, excluding incineration and autoclaving, designed to disinfect **[infectious] regulated medical** waste by means of exposure to high thermal temperatures through methods such as ionizing radiation or electric or plasma arc technologies.

\* \* \* \* \*

*Unrecognizable [infectious] regulated medical waste* —All components of the waste have been processed to produce indistinguishable and unusable pieces smaller than 3/4 of an inch, except that all **USED** sharps must be smaller than 1/2 inch. The term does not mean compaction or encapsulation except through:

\* \* \* \* \*

(iii) Processes that melt plastics and fully encapsulate metallic or other **USED** sharps and seals where completely in a container that will not be penetrated by untreated **USED** sharps.

**271.2. Scope.**

\* \* \* \* \*

(b) Management of the following types of residual waste is subject to this article instead of Article IX (relating to residual waste management), and shall be regulated as if the waste is municipal waste, regardless of whether the waste is a municipal waste or residual waste.

\* \* \* \* \*

(2) **[Infectious] Regulated medical** and chemotherapeutic waste.

**Subchapter B. GENERAL REQUIREMENTS FOR PERMITS AND PERMIT APPLICATIONS**

**EXISTING FACILITIES**

271.111. [Reserved].

271.112. [Reserved].

271.113. Closure plan.

271.114. ~~[Transition period]~~ **[RESERVED]**.

**REQUIREMENT**

**§ 271.101. Permit requirement.**

\* \* \* \* \*

(b) A person or municipality is not required to obtain a permit:

\* \* \* \* \*

**[(4) For temporary storage, which facilitates the transportation or transfer of infectious or chemotherapeutic waste, that does not exceed 24 hours. The stored waste shall remain in its original packaging, as received for storage.]**

(5) For the use of waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material if the waste is not hazardous. A person managing waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material, shall implement best management practices. The Department will prepare a manual for the management of waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material which identifies best management practices and may approve additional best management practices on a case-by-case basis. If a person fails to implement best management practices for managing waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material, the Department may require compliance with the disposal, composting, processing and storage operating requirements of this chapter and Chapters 281, 283 and 285 (relating to composting facilities; resource recovery and other processing ~~[facility]~~ **FACILITIES**; and storage, collection and transportation of municipal waste).

\* \* \* \* \*

§ 271.103. Permit-by-rule for municipal waste processing facilities other than for ~~[infectious]~~ **regulated medical** or chemotherapeutic waste; qualifying facilities; general requirements.

\* \* \* \* \*

**EXISTING FACILITIES**

§ 271.114. ~~[Transition period]~~ **(RESERVED)**.

~~[A person or municipality possessing a permit for a municipal waste disposal or processing facility which was issued by the Department prior to December 23, 2000, shall file with the Department an application for permit modification to bring the facility operation into compliance with the following requirements for radioactive material monitoring and detection that became effective on December 23, 2000, according to the following schedule, unless the Department imposes in writing an earlier date in a specific situation for reasons of public health, safety or environmental protection:~~

~~(1) *Municipal waste landfill.* An application for a permit modification addressing the requirements of § 273.133(a)(14) and 273.140(a) (relating to map and grid requirements; and radiation protection action plan) shall be filed by December 23, 2001.~~

~~(2) *Construction/demolition waste landfills.* An application for a permit modification addressing the requirements of § 277.133(a)(14) and 277.140 (relating to map and grid requirements and radiation protection action plan) shall be filed by December 23, 2001.~~

~~(3) *Municipal waste transfer facility.* An application for a permit modification addressing the requirements of §§ 279.103(a)(18) and 279.110 (relating to maps and related information; and radiation protection action plan) shall be filed by December 23, 2002.~~

~~(4) *Commercial municipal waste composting facility that will receive sewage sludge or unseparated municipal waste, or both.* An application for a permit modification addressing the requirements of §§ 281.112(a)(20) and 281.119 (relating to maps and related information; and radiation protection action plan) shall be filed by June 23, 2001.~~

~~(5) *Resource recovery and other processing facilities. Including* [infectious] regulated medical [and chemotherapeutic waste processing facilities, an application for a permit modification addressing the requirements of §§ 283.103(20) and 283.113 (relating to maps and related information; and radiation protection action plan) shall be filed by September 23, 2001.]~~

### Subchapter E. CIVIL PENALTIES AND ENFORCEMENT

#### ENFORCEMENT

##### § 271.421. Administrative inspections.

\* \* \* \* \*

(c) The Department, its ~~[employees]~~ employees and agents intend to conduct inspections under the act of:

\* \* \* \* \*

(2) Municipal waste processing facilities other than resource recovery facilities, which process or incinerate ~~[infectious]~~ regulated medical or chemotherapeutic waste, at least 2 times per year.

(3) Municipal waste processing facilities other than resource recovery facilities, which do not process or incinerate ~~[infectious]~~ regulated medical or chemotherapeutic waste, at least once per year.

(4) Hospitals where ~~[infectious]~~ regulated medical or chemotherapeutic waste is generated, at least 2 times per year.

(5) Locations other than hospitals where ~~[infectious]~~ regulated medical or chemotherapeutic waste is generated, at least once per year.

\* \* \* \* \*

(7) Facilities and beneficial use areas subject to permit-by-rule under § 271.103 (relating to permit-by-rule for municipal waste processing facilities other than for ~~[infectious]~~ regulated medical or chemotherapeutic waste; qualifying facilities; general requirements), a general permit for beneficial use or processing, or both, under Subchapter I (relating to beneficial use), or a permit for the land application of sewage sludge under Subchapter J (relating to beneficial use of sewage sludge by land application), at least once per year.

\* \* \* \* \*

### Subchapter G. RESIDUAL WASTE



**GENERAL PROVISIONS**

**§ 271.601. Scope.**

\* \* \* \* \*

(c) The Department may require analyses under this subchapter for special handling waste other than sewage sludge, **[infectious] regulated medical** waste, chemotherapeutic waste and ash residue from a resource recovery facility.

**ADDITIONAL APPLICATION REQUIREMENTS**

**§ 271.611. Chemical analysis of waste.**

\* \* \* \* \*

(f) *Waiver.* The Department may, in writing, waive the requirements of this section for special handling waste, waive or modify the requirements of this section for general permits issued under Subchapter I and waive or modify the chemical analysis requirements under § 271.103 (relating to permit-by-rule for municipal waste processing facilities other than for **[infectious] regulated medical** or chemotherapeutic waste; qualifying facilities; general requirements).

**Subchapter I. BENEFICIAL USE**

**SCOPE**

**§ 271.801. Scope.**

(a) This subchapter sets forth requirements for general permits for the processing and beneficial use of municipal waste, except as follows:

(1) This subchapter does not set forth requirements for general permits for the processing or beneficial use of **[infectious] regulated medical** or chemotherapeutic waste.

\* \* \* \* \*

**GENERAL PERMIT FOR PROCESSING OR BENEFICIAL USE, OR BOTH, OF MUNICIPAL WASTE; AUTHORIZATION AND LIMITATIONS**

**§ 271.811. Authorization for general permit.**

\* \* \* \* \*

(g) The Department will not issue a general permit under this subchapter for the following:

\* \* \* \* \*

(3) The processing or beneficial use of **[infectious] regulated medical** or chemotherapeutic waste.

\* \* \* \* \*

**CHAPTER 272. MUNICIPAL WASTE PLANNING, RECYCLING AND WASTE REDUCTION**

**Subchapter C. MUNICIPAL WASTE PLANNING**

**PLAN CONTENT**

**§ 272.223. Description of waste.**

\* \* \* \* \*

(b) In describing the content of waste, the plan shall specifically address sewage sludge (including septage), **[infectious] regulated medical** and chemotherapeutic waste, ash from resource recovery facilities, construction/demolition waste other than waste from demolition of an industrial site and other municipal waste.

(c) In describing the origin of waste, the plan shall provide:

\* \* \* \* \*

(3) An inventory of hospitals in the county, and a representative sampling of different medical specialists, such as clinics, doctors, dentists, funeral directors and veterinarians, for **[infectious] regulated medical** and chemotherapeutic waste.

\* \* \* \* \*

**Subchapter F. HOUSEHOLD HAZARDOUS WASTE COLLECTION, TRANSPORTATION AND MANAGEMENT**

**OPERATION OF PROGRAMS**

**§ 272.532. Limitations on acceptable waste.**

(a) The following wastes may not be accepted at a collection event:

\* \* \* \* \*

(2) **[Infectious waste] Regulated medical WASTE, [except sharps] AND HYPODERMIC NEEDLES OR SYRINGES.**

\* \* \* \* \*

**CHAPTER 273. MUNICIPAL WASTE LANDFILLS**

**Subchapter D. ADDITIONAL APPLICATION REQUIREMENTS FOR SPECIAL HANDLING AND RESIDUAL WASTES SPECIFIC WASTES**

273.411. Processed **[infectious] regulated medical** or chemotherapeutic waste disposal.

273.412. Sewage sludge plan.

- 273.413. Plan for ash residue from municipal waste incineration.
- 273.414. Plan for disposal of PCBs, friable asbestos containing waste and other special handling waste.
- 273.421. [Reserved].

**SPECIFIC WASTES**

**§ 273.411. Processed [infectious] regulated medical or chemotherapeutic waste disposal.**

(a) An application for the disposal of processed [infectious] regulated medical or chemotherapeutic waste shall contain necessary plans and specifications showing how the applicant will comply with § 273.511 or § 273.512 (relating to processed [infectious] regulated medical waste disposal; and chemotherapeutic waste) or both, whichever is applicable.

\* \* \* \* \*

**Subchapter E. ADDITIONAL OPERATING REQUIREMENTS FOR SPECIAL HANDLING AND RESIDUAL WASTES**

**SPECIFIC WASTES**

- 273.511. Processed [infectious] regulated medical waste disposal.
- 273.512. Chemotherapeutic waste.
- 273.513. Sewage sludge.
- 273.514. Ash residue from municipal waste incineration.
- 273.515. PCBs, friable asbestos containing waste and other special handling wastes.
- 273.521. [Reserved].

**SPECIFIC WASTES**

**§ 273.511. Processed [infectious] regulated medical waste disposal.**

- (a) [Infectious] Regulated medical waste may not be disposed OF at a municipal waste landfill unless:
- (1) The waste has been disinfected in accordance with § 284.321 (relating to [infectious] regulated medical waste monitoring requirements).
  - (2) Prior to initial disposal the landfill operator has obtained the necessary approval for disposal from the Department based on the application provided under § 273.411 (relating to processed [infectious] regulated medical and chemotherapeutic waste disposal).

\* \* \* \* \*

(d) USED [Sharps] SHARPS AND UNUSED HYPODERMIC NEEDLES OR SYRINGES shall be rendered [~~unusable~~] INCAPABLE OF BEING REUSED prior to disposal.

**CHAPTER 284. [INFECTIONOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE**

**Subch.**

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**Subchapter A. GENERAL PROVISIONS**

**GENERAL PROVISIONS**

284.1. Scope.

284.2. [~~Permit-by-rule for infectious~~] Permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.

**GENERAL PROVISIONS**

**§ 284.1. Scope.**

This chapter sets forth application and operating requirements for a person or municipality that operates [~~an infectious~~] a regulated medical or chemotherapeutic waste facility. The requirements in this chapter are in addition to the applicable requirements in [~~Chapter 271~~] Chapters 271, 283 and 285 (relating to municipal waste management—general provisions; resource recovery and other processing facilities; and storage, collection and transportation of municipal waste).

**§ 284.2. [~~Permit-by-rule for infectious~~] Permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.**

**[(a) If the requirements of this section are met, the following onsite processing facilities for infectious and chemotherapeutic waste shall be deemed to have a municipal waste processing permit under this article:**

**(1) An onsite autoclave facility, including one which renders waste unrecognizable, which processes at least 50% of its own infectious waste generated onsite and accepts offsite waste for disinfection only from small quantity generators that generate less than 220 pounds per month of infectious waste if the following conditions are met:**

**(i) Processing of pathological waste is prohibited.**

**(ii) The retention time for processing bulk fluids (greater than 500 ml) allows for the complete vaporization of fluids.**

**(2) An onsite incineration facility that burns at least 50% of its own infectious or chemotherapeutic waste generated onsite and accepts offsite infectious or chemotherapeutic waste for incineration only from small quantity generators that generate less than 220 pounds per month of infectious or**

chemotherapeutic waste. This onsite incineration facility may process municipal waste generated onsite as long as the resulting ash is managed as processed infectious and chemotherapeutic waste.

(3) An onsite steam and superheated water disinfection facility which processes infectious waste, including one which renders waste unrecognizable, which processes at least 50% of its own infectious waste generated onsite and accepts offsite waste for disinfection only from small quantity generators that generate less than 220 pounds per month of infectious waste. Processing of pathological waste is prohibited.]

(a) The following processing facilities for regulated medical and chemotherapeutic waste will be deemed to have a municipal waste processing permit under this article if the following requirements in this subsection and subsection (c) are met:

(1) A processing facility with an autoclave if the following requirements are met:

(i) The facility processes at least 50% of its own regulated medical waste. The facility may not accept more than 50% of regulated medical waste for disinfection from small quantity generators that generate less than 220 pounds per month.

(ii) The facility does not process pathological waste or chemotherapeutic waste.

(iii) The facility may additionally process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.

(iv) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.

(v) The operator of the facility provides notice to the Department that includes the following:

(A) An intention to operate under permit-by-rule.

(B) The name and address of the facility.

(C) A description of the processing activity.

(D) The names and telephone numbers of the individuals responsible for operation of the processing facility.

(2) A processing facility with an incinerator if the following requirements are met:

(i) The facility processes at least 50% of its own regulated medical or chemotherapeutic waste. The facility may not accept more than 50% of regulated medical or chemotherapeutic waste for disinfection from small quantity generators that generate less than 220 pound per month.

(ii) The facility may process other municipal waste generated onsite if the resulting ash is managed as processed regulated medical or chemotherapeutic waste.

(iii) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.

**(iv) The operator of the facility provides notice to the Department that includes the following:**

**(A) An intention to operate under permit-by-rule.**

**(B) The name and address of the facility.**

**(C) A description of the processing activity.**

**(D) The names and telephone numbers of the individuals responsible for operation of the processing facility.**

**(3) A processing facility with steam and superheated water disinfection if the following requirements are met:**

**(i) The facility processes at least 50% of its own regulated medical waste. The facility may not accept more than 50% of regulated medical waste for disinfection from small quantity generators that generate less than 220 pounds per month.**

**(ii) The facility does not process pathological waste or chemotherapeutic waste.**

**(iii) The facility may additionally process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.**

**(iv) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.**

**(v) The operator of the facility provides notice to the Department that includes the following:**

**(A) An intention to operate under permit-by-rule.**

**(B) The name and address of the facility.**

**(C) A description of the processing activity.**

**(D) The names and telephone numbers of the individuals responsible for operation of the processing facility.**

**(4) Onsite processing of liquid blood and body fluids using a glutaraldehyde-based or hypochlorite-based product that encapsulates or converts liquid blood or body fluids into solids or gels so that no free liquids remain. The Department may approve the use of other disinfectant-based products under these provisions if their efficacy can be demonstrated. The processed [~~infectious waste~~] LIQUID BLOOD AND BODY FLUIDS may be disposed OF at a municipal waste landfill provided:**

**(i) No free liquids remain in the processed waste.**

**(ii) The landfill has received written approval from the Department authorizing disposal of the processed [~~medical waste~~] LIQUID BLOOD AND BODY FLUIDS.**

**(iii) THE FACILITY DOES NOT PROCESS CHEMOTHERAPEUTIC WASTE.**

**(5) Transfer facilities that temporarily store regulated medical or chemotherapeutic waste for less than 72 hours provided the stored waste remains in its original packaging, [and it] is not putrescent, AND DOES NOT ATTRACT VECTORS.**

(b) Generators that process and disinfect less than 220 pounds per month of **[infectious] regulated medical** waste onsite and render the waste unrecognizable will be deemed to have **a** municipal waste processing **[permits] permit** under this article if the requirements under **[subsections (c)—(g)] subsection (c)** are met. Generators that process and disinfect less than 220 pounds per month of **[infectious] regulated medical** waste onsite without rendering the waste unrecognizable will be deemed to have **a** municipal waste processing **[permits] permit** under this article if the **[requirements under subsections (c)—(g)] following requirements under this subsection and subsection (c)** are met **[and if the following requirements are met]:**

(1) The generator **[may] shall** dispose of the processed waste in a landfill or have the waste incinerated in a facility that has **[obtained]** written approval from the Department to accept **[the] this type of** waste.

(2) The generator shall comply with the **[manifest] LOG AND SHIPPING PAPER** requirements in § 284.701(b)(5) (relating to scope).

(c) The following requirements shall be met by facilities identified in subsections **[(a)] (a)(1)-(4)** and (b) to operate under a permit-by-rule:

(1) The facility complies with **[Chapter 285 and Subchapters E and F (relating to storage, collection and transportation of municipal waste; storage, collection and transportation)] Subchapters E and F (relating to segregation and storage; and collection and transportation) and Chapter 285 (relating to storage, collection and transportation of municipal waste).**

\* \* \* \* \*

(3) The operator maintains at the facility in a readily accessible place the following information:

(i) For a processing facility identified in subsection (a), a written plan for managing **[infectious] regulated medical** waste generated at the facility, including waste handling, equipment operation and maintenance, processing method, disinfection monitoring procedures including quality assurance procedures, **frequency of calibration** and a description of how noninfectious waste is managed to prevent commingling.

\* \* \* \* \*

(5) The waste is disinfected in accordance with § 284.321 (relating to **[infectious] regulated medical** waste monitoring requirements).

\* \* \* \* \*

(8) Remaining waste is managed in accordance with the act and the regulations promulgated thereunder. For onsite autoclave facilities **[which] that** do not render the waste unrecognizable, the **[processing residue] treated or processed regulated medical waste** shall be **[manifested] TRANSPORTED** in

accordance with Subchapter H (relating to ~~manifesting for~~ **TRACKING OF [infectious] regulated medical** and chemotherapeutic waste).

(9) For incineration facilities, an air quality permit shall be obtained **as required** under the Air Pollution Control Act (35 P.S. §§ 4001—4015).

**[(10) For facilities identified in subsection (a), notice is provided to the Department by the operator of a facility which indicates an intention to operate under permit-by-rule and which includes the following information:**

**(i) The name and address of the facility.**

**(ii) A description of the processing activity.**

**(iii) The names and telephone numbers of the individuals responsible for operation of the processing facility.**

**(11) For facilities identified in subsection (a), the processed waste is disposed of in a landfill or processed in an incinerator that has obtained written approval from the Department to dispose or process the waste.]**

(d) Chapter 271, Subchapter E (relating to civil penalties and enforcement) is applicable to facilities subject to permit-by-rule.

\* \* \* \* \*

**(f) [Generators who qualify for a permit-by-rule may render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.**

**(g) [The requirements under Chapter 271, Subchapter D (relating to financial assurances requirements) which that relate to bonding and insurance are waived for facilities which that are deemed to have a permit under this section.**

**(Editor's Note: The following section is new and printed in regular type to enhance readability.)**

**§ 284.3. Regulated medical OR CHEMOTHERAPEUTIC waste aggregation facilities.**

**(a) *Applicability.*** This section applies to operators of regulated medical **OR CHEMOTHERAPEUTIC** waste aggregation facilities.

**(b) *Permit-by-rule for regulated medical OR CHEMOTHERAPEUTIC waste aggregation facilities.*** The operator of an aggregation facility may operate under a permit-by-rule. For the operation of a regulated medical **OR CHEMOTHERAPEUTIC** waste aggregation facility to be authorized by a permit-by-rule, the owner or operator shall:

**(1) Comply with the generator standards in Subchapter E (relating to segregation and storage).**

**(2) Only accept the following regulated medical OR CHEMOTHERAPEUTIC waste generated:**

**(i) Onsite or offsite by the operator of the aggregation facility.**



(ii) By physicians in their independent practices or other medical personnel within the same building or complex of buildings.

(c) *Noncompliance.* The Department may require the operator of an aggregation facility operated under permit-by-rule to apply for and obtain a permit, or take other appropriate action, when the ~~[generator]~~ **OPERATOR** is not in compliance with the requirements for the permit-by-rule or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment.

## **Subchapter B. GENERAL PERMITS**

### **ISSUANCE OF A GENERAL PERMIT**

- 284.111. Application for general permit.
- 284.112. Completeness review.
- 284.113. Public notice and review period.
- 284.114. Approval or denial of an application.
- 284.115. Department-initiated general permits.
- 284.116. General permit renewal.**

### **CONTENT OF GENERAL PERMITS AND ~~{WAIVERS}~~ OR MODIFICATIONS**

- 284.121. Contents of general permits.
- 284.122. ~~{Waiver or modification}~~ **Modification** of certain requirements.

### **REGISTRATION [AND DETERMINATION OF APPLICABILITY]**

- 284.131. Authorization for persons or municipalities to be included in a general permit.
- 284.132. **Determination of applicability** **[RESERVED]**.
- 284.133. Registration.

## **GENERAL**

### **§ 284.101. Authorization for general permits.**

(a) In accordance with this subchapter, the Department may issue general permits on a regional or Statewide basis for a category of mobile or stationary **[infectious] regulated medical** waste processing facilities or stationary chemotherapeutic waste processing facilities if the Department determines the following:

\* \* \* \* \*

(c) The Department may issue a general permit for the mixing of disinfection products with **[infectious] regulated medical** waste to perform processing.

(d) The Department may issue a general permit for the processing of mixtures of the same types of waste that are **[infectious] regulated medical** or residual wastes.

\* \* \* \* \*

(f) The Department will not issue a general permit for a commercial **[infectious] regulated medical** or chemotherapeutic waste processing facility, including commercial incinerators.

**§ 284.102. Nature of a general permit; substitution for individual applications and permits.**

(a) When the Department issues a general permit for **[an infectious] a regulated medical** or chemotherapeutic waste processing facility on either a regional or Statewide basis, persons or municipalities who intend to process **[infectious] regulated medical** or chemotherapeutic waste in accordance with the terms and conditions of the general permit may do so without filing an individual application for, and first obtaining, an individual permit.

(b) The use of an applicable general permit shall satisfy the requirement to obtain a permit in § 271.101 (relating to permit requirement) if the following are met:

\* \* \* \* \*

(2) The person or municipality conducting the processing activities is authorized to operate under the general permit at the time that the Department issued the general permit or under the applicable general permit in accordance with **[§ 284.132 or] § 284.133** (relating to **[determination of applicability; and] registration**).

(c) Notwithstanding subsections (a) and (b), the Department may require a person or municipality authorized by a general permit to apply for, and obtain, an individual permit **if a general permit is not available to conduct an activity**, when the person or municipality is not in compliance with the conditions of **[the] a** general permit or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

**ISSUANCE OF A GENERAL PERMIT**

**§ 284.111. Application for general permit.**

(a) A person or municipality may apply to the Department for the issuance of a general permit for a specific category of processing of **[infectious] regulated medical** or chemotherapeutic waste.

(b) An application for the issuance of a general permit for processing **[infectious] regulated medical** or chemotherapeutic waste shall be submitted on a form prepared by the Department and shall contain the following:

\* \* \* \* \*

(2) A characterization of the waste as either **[infectious] regulated medical** or chemotherapeutic.

(3) An operation plan which contains the following:

\* \* \* \* \*

(ii) A description of the method proposed to receive **[infectious] regulated medical** or chemotherapeutic waste which ensures the waste is handled separately from other solid waste until processing and disposal, and that prevents unauthorized persons from having access to or contact with the waste.

\* \* \* \* \*

(iv) A description of the method proposed to unload and process **[infectious] regulated medical** or chemotherapeutic waste, limiting the number of persons handling the waste and minimizing the possibility of exposure of that waste to **[employees] employees** and the public using or visiting the facility.

(v) A description of the method proposed for disinfecting emptied, reusable **[infectious] regulated medical** waste containers, transport vehicles and facility equipment which are known or suspected to be contaminated with **[infectious] regulated medical** waste.

(vi) A description of the method proposed for handling and disposal of **[infectious] regulated medical** or chemotherapeutic waste containers which cannot be reused.

\* \* \* \* \*

(viii) A description of the means by which provisions will be made to require the use of clean gloves and clean uniforms along with other protective clothing to provide protection of **[employees] employees** against exposure to **[infectious] REGULATED MEDICAL** or chemotherapeutic waste.

(ix) A description of the means by which provisions will be made to require decontamination of a person having had bodily contact with **[infectious] regulated medical** or chemotherapeutic waste while handling that waste at the facility.

(x) A description of the method proposed to quantify, on a weight basis, the maximum amount of **[infectious] regulated medical** or chemotherapeutic waste to be stored and processed each month.

\* \* \* \* \*

(xiii) A description of periodic testing using biological indicators which demonstrate effective disinfection of the waste, in accordance with § 284.321 (relating to **[infectious] regulated medical** waste monitoring requirements).

\* \* \* \* \*

(4) A contingency plan which provides procedures to be used for emergency situations including, at a minimum, spills of **[infectious] regulated medical** or chemotherapeutic waste and ruptures of containers containing the waste. The plan shall include procedures for cleanup and disinfection of spill area, protection of personnel, disposal of spill residue and repackaging of the waste. The plan shall also include a description of an alternative waste handling system during periods when the proposed facility is not in operation, including procedures to be followed in the case of equipment breakdown. Alternate waste handling procedures may include use of standby equipment, extension of operating hours and contractual agreements for diversion of **[infectious] regulated medical** or chemotherapeutic waste to other facilities.

(5) A personnel training plan which describes the hiring of equipment operators and the training of personnel involved in the handling and processing of **[infectious] regulated medical** or chemotherapeutic waste. The plan shall include a detailed explanation of the operation and contingency plans.

\* \* \* \* \*

(d) The application requirements in subsection (b) may be waived or modified for the mixing of disinfection products with **[infectious] regulated medical** waste to perform processing.

**§ 284.112. Completeness review.**

(a) After receipt of an application for the issuance of a general permit[, or an application for a **determination of applicability under § 284.132 (relating to determination of applicability)**], the Department will determine whether the application is administratively complete. For purposes of this subchapter, an application is administratively complete if it contains the necessary analyses, fees, documents and information, regardless of whether the analyses, fees, documents and information would be sufficient for the issuance of the permit **[or the determination of applicability]**.

\* \* \* \* \*

**§ 284.113. Public notice and review period.**

\* \* \* \* \*

(b) The notice shall include:

(1) A brief description of the waste and the category of processing of **[infectious] regulated medical** or chemotherapeutic waste which is identified in the application as a candidate for a general permit.

\* \* \* \* \*

**§ 284.114. Approval or denial of an application.**

The Department may not issue a general permit for a category of processing of **[infectious] regulated medical** or chemotherapeutic waste unless the applicant has affirmatively demonstrated the following:

\* \* \* \* \*

**§ 284.115. Department-initiated general permits.**

(a) The Department may issue or modify a general permit for a category of processing of **[infectious] regulated medical** or chemotherapeutic waste upon its own motion in accordance with this section.

\* \* \* \* \*

(c) The notice required by subsection (b) shall include the following:

(1) A clear and specific description of the category of processing of **[infectious] regulated medical** or chemotherapeutic waste eligible for coverage under the proposed general permit.

\* \* \* \* \*

(5) The **[Departmental] Department** address and telephone number at which interested persons or municipalities may obtain further information and review a copy of the proposed general permit.

\* \* \* \* \*

*(Editor's Note: The following section is new and printed in regular type to enhance readability.)*

**§ 284.116. General permit renewal.**

- (a) A person or municipality that plans to process regulated medical or chemotherapeutic waste after the expiration of the term in the general permit shall file notice to the Department of intent to continue operating under the permit at least 180 days before the expiration date of the permit. The notice must include updated registration information on forms provided by the Department, a check payable to the "Commonwealth of Pennsylvania" for \$250 and any suggested changes to the terms or conditions of the permit.
- (b) A permit renewal may include all persons or municipalities that have applied for renewal within the time period provided in subsection (a). A person or municipality that does not meet the time period provided in subsection (a) shall be required to register under a renewed general permit.
- (c) At least 120 days prior to the permit expiration, the Department will provide public notice of the permit renewal along with an update of the terms or conditions in accordance with the public notice requirements of §284.115 (relating to Department-initiated general permits.)
- (d) General permits will be renewed for a maximum term of 10 years.
- (e) If the Department is unable to reissue the general permit prior to its expiration date, the Department may extend the term of a general permit for a period not to exceed 1 year for any permittee that is operating in compliance with the terms and conditions of the general permit and the environmental statutes and regulations of the Commonwealth.

**CONTENT OF GENERAL PERMITS AND ~~{WAIVERS}~~ OR MODIFICATIONS**

**§ 284.121. Contents of general permits.**

Each general permit issued by the Department will include, at a minimum:

- (1) A clear and specific description of the category of processing of **[infectious] regulated medical** or chemotherapeutic waste eligible for coverage under the general permit.

\* \* \* \* \*

- (3) A specification of registration **[or determination of applicability]** requirements established in accordance with § 284.131 (relating to authorization for persons or municipalities to be included in a general permit) and the fee imposed on registrants **[or applicants]** for coverage under the general permit.

\* \* \* \* \*

- (8) A requirement that waste be accompanied by a properly completed **[manifest] LOG OR SHIPPING PAPER**, in accordance with Subchapter H (relating to **[manifesting for] TRACKING OF [infectious] regulated medical** and chemotherapeutic waste)[, **when appropriate**].

- (9) A requirement that waste be delivered by a licensed transporter in accordance with Subchapter G (relating to transporter licensing for **[infectious] regulated medical** and chemotherapeutic waste), when

appropriate.

\* \* \* \* \*

(11) A requirement that the processing residue be **[disposed of in a landfill that has obtained written approval by the Department to dispose of the waste] managed in accordance with the Solid Waste Management Act (35 P.S. §§ 6018.101—6018.1003) and the regulations promulgated thereunder.**

(12) A requirement that an up-to-date list of names, addresses and telephone numbers of **[employees] employees** that have been designated by the permittee to respond to emergencies at the processing facility be maintained at the facility.

(13) A requirement that individual **[employee] employee** training records be maintained at the processing facility.

\* \* \* \* \*

(18) **[A requirement that autoclaves meet the following:] A prohibition against processing pathological waste or chemotherapeutic waste in an autoclave.**

**[(i) Processing of pathological waste is prohibited.]**

**[(ii) The retention time for processing bulk fluids (greater than 500 ml) allows for the complete vaporization of fluids.]**

**§ 284.122. ~~[Waiver or modification]~~ [Modification] of certain requirements.**

\* \* \* \* \*

(b) For an operation that is approved under this subchapter, the Department may ~~[waive or]~~ modify any application and operating requirements in this article~~], except the Department may not waive § 271.123 and may not waive or modify Chapter 271, Subchapter A, §§ 271.124, 271.125, 271.129 and Chapter 271, Subchapter E].~~

#### **REGISTRATION [AND DETERMINATION OF APPLICABILITY]**

**§ 284.131. Authorization for persons or municipalities to be included in a general permit.**

(a) A person or municipality is authorized to operate under a general permit if **[one of the following occurs:**

**(1) If the applicable general permit requires persons or municipalities to register with the Department prior to operating under the general permit,]** the person or municipality has registered in accordance with the terms of the general permit and the requirements of this subchapter.

**[(2) If the applicable general permit requires persons or municipalities to apply for and obtain a determination of applicability from the Department prior to operating under the general permit, and the Department has made this determination.]**

(b) Registration **[or application]** requirements and time limits, if any, shall be set forth in the general

permit governing each category of processing **[infectious] regulated medical** or chemotherapeutic waste. The general permit shall also set forth the area or region within which each category of processing is allowed.

(c) At a minimum, the registration **[or application for determination of applicability shall] MUST** include:

\* \* \* \* \*

(2) A description of the waste, including a characterization of the waste as either **[infectious] regulated medical** or chemotherapeutic, that will be processed in accordance with the general permit.

\* \* \* \* \*

(6) A signed and notarized statement by the person or municipality conducting the activity authorized by the general permit, on a form prepared by the Department, which states that the person or municipality agrees to accept the conditions imposed by the general permit for processing of **[infectious] regulated medical** or chemotherapeutic waste under the general permit.

(d) A person or municipality that registers for coverage under a general permit **[or applies to the Department for a determination of applicability of a general permit]** shall submit a copy of the registration **[or application]** to each municipality in which the processing activity will be located. The submission shall occur at the same time that the person or municipality files the registration **[or application]** with the Department.

**§ 284.132. [Determination of applicability] (Reserved).**

**[If a general permit specifies that potential users of the permit shall obtain a determination of applicability from the Department prior to conducting the activity authorized by the general permit, the procedures in this section shall be followed in addition to those stated in § 284.131 (relating to authorization for persons or municipalities to be included in a general permit):**

**(1) An application for a determination of applicability shall be accompanied by a nonrefundable fee in the form of a check payable to the "Commonwealth of Pennsylvania" for \$ 500.**

**(2) The Department will provide notice in the *Pennsylvania Bulletin* of each application for a determination of applicability for a general permit which the Department has determined to be administratively complete. The Department may indicate in the notice that interested persons or municipalities may submit comments to the Department within a 60-day period. If a comment period is provided, counties may recommend to the Department conditions, revisions or disapproval of the application. The Department may hold a public meeting or public hearing on an application for determination of applicability for a general permit.**

**(3) The Department will make a determination that a general permit is or is not applicable to an activity for which an application for determination of applicability is filed within 60 days from the publication of the notice under paragraph (2) or, if a comment period is provided, within 120 days after publication of the notice. The time period does not include periods beginning with the date the Department has requested in writing that the applicant make substantive corrections or changes to the application and ending with the date that the applicant submits corrections or changes to the Department's satisfaction. Failure by the Department to comply with this timetable will not be**

construed or understood to constitute grounds for a determination that the general permit applies to the proposed activity.

(4) The Department will determine that the general permit does not apply to the proposed processing activity and deny coverage under the general permit if the applicant fails to demonstrate the following to the Department's satisfaction:

(i) That the proposed activity is consistent with the terms and conditions of the general permit.

(ii) That the activity does not have the potential to harm or present a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

(5) The Department will publish notice of its decision regarding each determination of applicability in the *Pennsylvania Bulletin*. If a county has made recommendations to the Department concerning conditions, revisions or disapproval of the permit during a 60-day comment period, and the Department has overridden the recommendations, the Department will publish its justification for overriding the recommendations in the *Pennsylvania Bulletin*. The applicant for a determination of applicability for coverage under a general permit shall provide written notice to each municipality in which the applicant intends to operate pursuant to the general permit.

(6) The Department may amend, suspend or revoke coverage under a general permit if the waste or the activity is not consistent with the terms and conditions of the general permit.]

### Subchapter C. TRANSFER FACILITIES

284.201. Scope.

284.210. Application requirements.

284.220. Operating requirements.

#### **284.230. STORAGE REQUIREMENTS.**

##### **§ 284.201. Scope.**

This subchapter sets forth application and operating requirements for a person or municipality that operates a transfer facility for [infectious] **regulated medical** or chemotherapeutic waste. The requirements in this subchapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general **provisions**).

##### **§ 284.210. Application requirements.**

An application to operate a transfer facility shall comply with §§ 279.101—279.111 [(relating to general requirements)].

##### **§ 284.220. Operating requirements.**

A person or municipality that operates a transfer facility shall comply with [§§ 279.201, 279.202, 279.211—279.223, 279.231—279.234, 279.241—279.243, 279.251, 279.252, 279.261 and 279.262] Chapter 279, Subchapters A and C (relating to general; and operating requirements for transfer facilities).

#### **§ 284.230. STORAGE REQUIREMENTS**



**A TRANSFER FACILITY MAY STORE REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE FOR UP TO 72 HOURS PROVIDED THAT THE STORED WASTE REMAINS IN ITS ORIGINAL PACKAGING, IS NOT PUTRESCENT, AND DOES NOT ATTRACT VECTORS.**

**Subchapter D. PROCESSING FACILITIES**

- 284.301. Scope.
- 284.310. Application requirements.
- 284.311. Plan for monitoring.
- 284.320. Operating requirements.
- 284.321. [**Infectious**] **Regulated medical** waste monitoring requirements.
- 284.322. Autoclave validation testing requirements.**

**§ 284.301. Scope.**

This subchapter sets forth application and operating requirements for a person or municipality that operates a processing facility, other than a transfer or composting facility, for [**infectious**] **regulated medical** or chemotherapeutic waste. The requirements in this subchapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions).

**§ 284.311. Plan for monitoring.**

An application for a processing facility for [**infectious**] **regulated medical** waste shall contain a plan, including necessary designs, procedures and test protocols on forms provided by the Department, for meeting the requirements of § 284.321 (relating to [**infectious**] **regulated medical** waste monitoring requirements), including the following:

\* \* \* \* \*

**§ 284.320. Operating requirements.**

A person or municipality that operates a processing facility shall comply with [§§ 283.201, 283.202, 283.211—283.223, 283.231—283.234, 283.241, 283.242, 283.251—283.253, 283.261, 283.262, 283.271 and 283.272] **Chapter 283, Subchapter C (relating to operating requirements).**

**§ 284.321. [**Infectious**] **Regulated medical** waste monitoring requirements.**

(a) A person or municipality that disinfects [**infectious**] **regulated medical** waste shall monitor the waste to ensure the following:

\* \* \* \* \*

(2) For other disinfection processes, both of the following are met:

(i) The process shall be capable of inactivating [**vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites and**] mycobacteria at a 6 log 10 reduction or greater.

(ii) The process shall be capable of inactivating [**B.**] **Geobacillus** stearothermophilus spores, [**B.**] **Bacillus**

pumilus or [**B. subtilis**] **Bacillus atrophaeus** spores at a 4 log 10 reduction or greater.

(b) The operator of a facility that incinerates or thermally processes [**infectious**] **regulated medical** waste shall submit to the Department a microbiological analysis of a composite sample of the processing or ash residue on forms provided by the Department at a minimum, [**quarterly**] **annually** during the life of the facility.

(c) The operator of a facility that incinerates [**infectious**] **regulated medical** waste shall submit to the Department, at least annually during the life of the facility, a chemical analysis of composite samples of the ash residue on forms provided by the Department.

(d) If the facility disinfects [**infectious**] **regulated medical** waste by means other than incineration or thermal processing, the operator shall perform a microbiological analysis of indicators removed from the processed waste. The analysis shall be conducted at a minimum, every 40 hours during the operational life of the facility, unless otherwise provided in a permit. The analyses shall be made available to the Department upon request.

(e) Unless the Department approves another indicator or test in writing, the following indicators shall be used to establish and verify the following processes:

(1) For autoclaving, spores of [**Bacillus**] **Geobacillus** stearothermophilus.

(2) For dry heat, gas or chemical disinfection, spores of Bacillus [**subtilis**] **atrophaeus** variety niger (globigii). Ethylene oxide may not be used for gas disinfection.

\* \* \* \* \*

(f) Indicators used for methods of disinfection other than incineration or thermal processing shall be located prior to disinfection at a point **within the load** where disinfection will be most difficult to achieve.

(g) [**Infectious**] **Regulated medical** waste will be considered to be infectious [~~after disinfection,~~] unless one of the following has occurred:

\* \* \* \* \*

(i) Ash or other processing residue shall be stored in accordance with § 284.418 or § 284.419 (relating to storage and containment of ash residue from [**infectious**] **regulated medical** or chemotherapeutic waste incineration; and storage and containment of processing residue from [**an infectious**] **a regulated medical** or chemotherapeutic waste processing facility).

(j) Ash or other processing residue shall be transported in accordance with § 284.511 or § 284.514 (relating to transportation of ash residue from [**infectious**] **regulated medical** or chemotherapeutic waste incineration; and transportation of processing residue from [**an infectious**] **a regulated medical** or chemotherapeutic waste facility).

(k) Compactors, grinders or similar devices may not be used to reduce the volume of [**infectious**] **regulated medical** waste before the waste has been rendered noninfectious. If the volume reduction device is within a continuous, enclosed disinfection process and part of one processing system, then the reduction device may be used.

(l) The operator of **[an infectious] a regulated medical** waste processing facility shall dispose of ash or other processing residue from the facility in a landfill that has been approved by the Department to accept the waste, if the waste is disposed in this Commonwealth.

(m) **[In addition to other applicable requirements, an autoclave facility shall comply with the following:] An autoclave facility shall comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.**

**[(1) The processing of pathological waste is prohibited.**

**(2) The facility shall maintain a retention time for processing bulk fluids (greater than 500 ml) which allows for the complete vaporization of fluids.]**

**(n) Unless otherwise approved in writing by the Department, an operator of an autoclave facility shall employ the procedures in § 284.322 (relating to autoclave validation testing requirements) to validate the operating parameters and protocols of the processing equipment. These procedures must be employed AT AN ON-GOING FREQUENCY SPECIFIED BY THE MANUFACTURER OF THE AUTOCLAVE AND in the following circumstances:**

**(1) When a new autoclave is installed.**

**(2) When an autoclave is modified, REPAIRED OR HAS EXPERIENCED A MALFUNCTION with respect to hardware, software, controls or ancillary equipment.**

**~~[(3) To validate existing systems by \_\_\_\_\_, (Editor's Note: The blank refers to 6 months after the effective date of adoption of this proposed rulemaking.) and at a frequency specified by the manufacturer, but not less than 1 year.~~**

**~~(4) When a significant change in the waste stream occurs or a problem is evident.]~~**

**(o) The facility shall maintain a record of the autoclave validation testing protocols and procedures.**

**(p) FOR FACILITIES ENGAGED IN THE PRODUCTION OR RESEARCH AND DEVELOPMENT OF VACCINES OR OTHER BIOLOGICS THAT ARE CLASSIFIED UNDER THE NAICS AS CODE 325414 – BIOLOGICAL PROTOCOL (EXCEPT DIAGNOSTIC) MANUFACTURING AND WHO MEET THE FOLLOWING CRITERIA MAY UTILIZE THE ALTERNATE DISINFECTION REQUIREMENTS SPECIFIED IN PARAGRAPH (5) BELOW IN LIEU OF THE REQUIREMENTS OF SUBSECTIONS (A)-(O) TO PROCESS WASTE CONTAINING AN INFECTIOUS AGENT CLASSIFIED AS BIOSAFETY LEVEL 2 OR BELOW, AS DETERMINED BY THE PROTOCOLS ESTABLISHED IN THE MOST RECENT EDITION OF THE CENTERS FOR DISEASE CONTROL'S BIOSAFETY IN MICROBIAL AND BIOMEDICAL LABORATORIES (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED:**

**(1) UTILIZE ON-SITE PROCESSING FACILITIES AT WHICH AT LEAST 50% OF THE WASTE PROCESSED IS GENERATED ON-SITE.**

**(2) OPERATE IN ACCORDANCE WITH FDA GOOD MANUFACTURING PRACTICES (GMP)**

**OR GOOD LABORATORY PRACTICES (GLP).**

**(3) EMPLOY A PRODUCTION PROCESS WHERE THE INFECTIOUS AGENTS OR BIOLOGICAL, OR BOTH, ARE KNOWN AND WELL CHARACTERIZED, INACTIVATION CRITERIA ARE DETERMINED AND BIOBURDEN IS MEASURED AND CONTROLLED INCLUDING SCREENING FOR OBJECTIONABLE ORGANISMS.**

**(4) SPECIFY AND APPROVE THE DECONTAMINATION PROCESS, METHOD AND MONITORING, AND VALIDATION PROCEDURES FOR EACH SPECIFIC INFECTIOUS AGENT IN ITS WASTE BY ONE OF THE FOLLOWING:**

**(i) ESTABLISHING AND UTILIZING AN INSTITUTIONAL BIOSAFETY COMMITTEE CONSTITUTED IN ACCORDANCE WITH THE CENTERS FOR DISEASE CONTROL AND THE NATIONAL INSTITUTE OF HEALTH GUIDELINES OR COMPOSED IN WHOLE OR IN PART OF A PANEL OF EXPERTS, A MEMBER OF WHICH IS A BIOSAFETY OFFICER CERTIFIED BY THE AMERICAN BIOLOGICAL SAFETY ASSOCIATION OR THE AMERICAN SOCIETY FOR MICROBIOLOGY OR EQUIVALENT.**

**(ii) RETAINING A CONTRACTOR CERTIFIED BY THE AMERICAN BIOLOGICAL SAFETY ASSOCIATION OR THE AMERICAN SOCIETY FOR MICROBIOLOGY WHO ACCEPTS RESPONSIBILITY FOR THE PROCESS, METHOD AND PROCEDURES THAT THE CONTRACTOR SPECIFIED AND APPROVES (“INDEPENDENT CERTIFIED BIOSAFETY PROFESSIONAL”).**

**(5) THE ALTERNATE DISINFECTION PROCESS MUST BE CONDUCTED AS FOLLOWS:**

**(i) DISINFECTION SHALL BE CONDUCTED BY INACTIVATING ALL WASTE MATERIAL IN ACCORDANCE WITH THE PRACTICES, METHODS AND MINIMUM PARAMETERS FOR BIOLOGICAL KILL ESTABLISHED BY THE FACILITY’S INSTITUTIONAL BIOSAFETY COMMITTEE OR INDEPENDENT CERTIFIED BIOSAFETY PROFESSIONAL, OR BOTH, CONSISTENT WITH THE CENTERS FOR DISEASE CONTROL AND THE NATIONAL INSTITUTE OF HEALTH GUIDELINES OR SCIENTIFICALLY ACCEPTED PROTOCOLS, OR BOTH.**

**(ii) EFFICACY OF THE INACTIVATION OPERATIONS SHALL BE DEMONSTRATED THROUGH REVIEW OF DECONTAMINATION CYCLE DATA BY TRAINED TECHNICIANS OR OTHER TESTING METHODS OR STUDIES SPECIFIED BY THE INSTITUTIONAL BIOSAFETY COMMITTEE OR INDEPENDENT CERTIFIED BIOSAFETY PROFESSIONAL, OR BOTH, AS APPROPRIATE, FOR THE SPECIFIC INFECTIOUS AGENT OR BIOLOGIC, OR BOTH, PRESENT IN THE WASTE. THE PROCEDURES FOR DEMONSTRATING THE EFFICACY OF THE INACTIVATION OPERATIONS SHALL BE SET FORTH IN STANDARD OPERATING PROCEDURES OR OTHER WRITTEN PROCEDURES MAINTAINED AT THE FACILITY, OR BOTH.**

**(iii) PREVENTATIVE MAINTENANCE AND CALIBRATION PROGRAMS FOR DECONTAMINATION EQUIPMENT CONSISTENT WITH GENERALLY ACCEPTED INDUSTRY STANDARDS AS SPECIFIED BY THE INSTITUTIONAL BIOSAFETY COMMITTEE OR INDEPENDENT CERTIFIED BIOSAFETY PROFESSIONAL, OR BOTH, SHALL BE ESTABLISHED AND ROUTINELY IMPLEMENTED.**

**(q) WITH THE EXCEPTION OF USED SHARPS, WHICH REMAIN SUBJECT TO THE ADDITIONAL REQUIREMENTS OF THIS CHAPTER, REGULATED MEDICAL WASTE THAT IS GENERATED BY MANUFACTURERS OF VACCINES AND OTHER BIOLOGICS WHO SATISFY THE CRITERIA OF SUBSECTION (p)(1)-(4) AND DECONTAMINATED IN ACCORDANCE WITH THE PROCEDURES SPECIFIED IN SUBSECTION (p)(5) OF THIS SECTION, MAY BE MANAGED, STORED, TRANSPORTED AND DISPOSED OF AS ORDINARY MUNICIPAL WASTE AND SHALL NOT BE SUBJECT TO ANY OF THE ADDITIONAL RESTRICTIONS OR REQUIREMENTS PERTAINING TO SPECIAL HANDLING WASTE OR REGULATED MEDICAL WASTE.**

*(Editor's Note: The following section is new and printed in regular type to enhance readability.)*

**§ 284.322. Autoclave validation testing requirements.**

Autoclave operating parameters must be established in accordance with the following:

- (1) For facilities with one autoclave or multiple autoclaves that are not identical, each autoclave must have an initial validation test that establishes its operating parameters.
- (2) For facilities with multiple autoclaves that are identical, one autoclave may have an initial validation test that establishes the operating parameters for all identical autoclaves at that facility.
- (3) Autoclaves shall be tested using the manufacturer's recommended vacuum pulse plan, operating temperature, operating pressure and residence time at the maximum weight and with the most difficult heat transfer challenge anticipated with the indicators located where disinfection would be most difficult to achieve.
- (4) If multiple vacuum pulse plans, residence times, temperatures and pressures are recommended, the autoclave shall be tested to validate its performance at each recommended vacuum pulse plan, residence time, temperature and pressure. If a test fails, more stringent operating parameters shall be used incrementally until a satisfactory test and set of operating parameters is determined.
- (5) Autoclave operating parameters must be validated to achieve a minimum of 250°F or 121°C measured at a point where disinfection would be most difficult to achieve.
- (6) The residence time required to achieve a 6 log 10 reduction of mycobacteria and a 4 log 10 reduction of *Geobacillus stearothermophilus* spores for the level of heat transfer challenge selected shall be the residence time set into that autoclave's controls.
- (7) The vacuum pulse plan, residence time, operating temperature and operating pressure established in the validation test will form the permitted operating parameters for the autoclave tested.

**(8) IN LIEU OF THE TEMPERATURE, RESIDENCE TIME AND OTHER REQUIREMENTS OF THIS SECTION, MANUFACTURERS OF VACCINES OR OTHER BIOLOGICS WHO SATISFY THE APPLICABILITY CRITERION OF § 284.321(p) (RELATING TO REGULATED MEDICAL WASTE MONITORING REQUIREMENTS) MAY ESTABLISH AND VALIDATE AUTOCLAVE OPERATING PARAMETERS AND RESIDENCE TIME BASED UPON THE REQUIREMENTS DETERMINED BY THE INSTITUTIONAL BIOSAFETY COMMITTEE OR INDEPENDENT CERTIFIED BIOSAFETY PROFESSIONAL, OR BOTH, AS NECESSARY, TO ACHIEVE THE REQUIRED DISINFECTION UNDER § 284.321(p)(5)(ii) FOR THE SPECIFIC**

**INFECTIOUS AGENT OR BIOLOGIC, OR BOTH, PRESENT IN THE WASTES.**

**Subchapter E. SEGREGATION AND STORAGE**

284.401. Scope.

284.411. [Basic storage requirements] Segregation.

284.412. [Sorting] Basic storage requirements.

284.413. [Duration of storage of infectious waste for generators] Storage containers.

284.414. [Duration of storage of infectious waste for processors] Marking of containers.

284.415. [Storage containers] Duration of storage of regulated medical AND CHEMOTHERAPEUTIC waste for generators.

284.416. [Marking of containers] Duration of storage of regulated medical AND CHEMOTHERAPEUTIC waste for processors.

284.417. Reuse of containers.

284.418. Storage and containment of ash residue from [infectious] regulated medical or chemotherapeutic waste incineration.

284.419. Storage and containment of processing residue from [an infectious] a regulated medical or chemotherapeutic waste processing facility.

**§ 284.401. Scope.**

This subchapter sets forth operating requirements for a person or municipality that stores [infectious] regulated medical or chemotherapeutic waste, ash residue from [infectious] regulated medical or chemotherapeutic waste incineration and processing residue from [an infectious] a regulated medical or chemotherapeutic waste processing facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions) and the requirements in §§ 285.111—285.115 and 285.121 [(relating to general; and types of storage)].

**§ 284.411. [Basic storage requirements] Segregation.**

**[(a) Infectious and chemotherapeutic waste shall be stored and contained in a manner that:**

**(1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers and provides protection from water, rain and wind.**

**(2) Prevents the spread of infectious or chemotherapeutic agents.**

**(3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.**

**(4) Maintains the waste in a nonputrescent state, using refrigeration (  $\leq 7^{\circ}\text{C}$  ) or freezing (  $\leq -18^{\circ}\text{C}$  ) when necessary.**

**(5) Prevents odors from emanating from the container.**

**(6) Prevents unauthorized access to the waste. As part of this requirement, the following shall be met:**

**(i) Enclosures and containers used for storage of infectious or chemotherapeutic waste shall be secured to deny access to unauthorized persons.**

(ii) Enclosures and containers shall also be marked with prominent warning signs indicating the storage of infectious or chemotherapeutic waste.

(b) Enclosures at a waste generating or processing facility that are used for the storage of infectious or chemotherapeutic waste shall be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Storage areas shall be ventilated to minimize human exposure to the exhaust air.

(c) Infectious and chemotherapeutic waste may not be commingled with other waste.

(d) The generator may store infectious and municipal waste that has been sorted and separately containerized on the same cart for movement to an onsite processing or disposal facility. Chemotherapeutic waste may also be stored on the cart with municipal and infectious waste if it is sorted and separately containerized and if it is moved to an onsite incinerator.]

(a) Regulated medical waste and chemotherapeutic waste shall be segregated at the point of origin at the generating facility into the following three categories:

(1) Regulated medical waste, excluding pathological waste.

(2) Pathological waste.

(3) Chemotherapeutic waste.

(b) Each category of waste segregated under subsection (a) shall be placed in a separate container, except USED sharps that qualify as regulated medical waste may be placed in a chemotherapeutic waste used sharps container.

(c) When bags are used as containers to segregate the waste, the bags must be fluorescent orange, orange-red or red in color for regulated medical waste [~~and yellow in color for chemotherapeutic waste~~] OR PATHOLOGICAL WASTE.

(d) WHEN BAGS ARE USED AS CONTAINERS TO SEGREGATE THE WASTE, THE BAGS MUST BE YELLOW IN COLOR FOR CHEMOTHERAPEUTIC WASTE, UNLESS THE CHEMOTHERAPEUTIC WASTE IS PROCESSED ONSITE IN AN INCINERATOR THAT OPERATES IN ACCORDANCE WITH § 284.2 (RELATING TO PERMIT-BY-RULE FOR REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE PROCESSING FACILITIES; QUALIFYING FACILITIES; GENERAL REQUIREMENTS) OR IN ACCORDANCE WITH A PERMIT AUTHORIZED BY THE DEPARTMENT.

(e) When bags are used to segregate and store the waste, the requirements of § 284.413 (relating to storage containers) must be satisfied.

§ 284.412. [Sorting] Basic storage requirements.

[(a) Infectious and chemotherapeutic waste shall be placed in separate containers from other waste at the point of origin in the generating facility.

(b) Infectious and chemotherapeutic waste may be stored together in the same container if

approved in writing by the Department.

(c) Used sharps, regardless of whether they are infectious or chemotherapeutic waste, may be stored in the same container if the requirements of §§ 284.413(a) and 284.415(a) and (b) (relating to duration of storage of infectious waste for generators; and storage containers) are met.

(d) Infectious waste shall be sorted at the point of origin in the generating facility into the following three classes, and each class shall be placed in a separate container:

(1) Used sharps.

(2) Fluids—quantities greater than 20 cubic centimeters.

(3) Other infectious waste.

(e) Chemotherapeutic waste shall be sorted at the point of origin in the generating facility into the following three classes, and each class shall be placed in a separate container:

(1) Used sharps.

(2) Fluids.

(3) Other chemotherapeutic waste.

(f) Sorted and separately containerized infectious waste may be placed together into another container for onsite handling or offsite transportation.]

**(a) After regulated medical and chemotherapeutic waste has been segregated and collected for transportation to an onsite or offsite processing facility, the waste shall be stored and contained in a manner that:**

**(1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers and provides protection from water, rain and wind.**

**(2) Prevents the spread of regulated medical waste or chemotherapeutic agents.**

**(3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.**

**(4) Maintains the waste in a nonputrescent state, using refrigeration ( $\leq 7^{\circ}\text{C}$  or  $\leq 45^{\circ}\text{F}$ ) or freezing ( $\leq -18^{\circ}\text{C}$  or  $\leq -0^{\circ}\text{F}$ ) when necessary.**

**(5) Prevents odors from emanating from the container.**

**(6) Prevents unauthorized access to the waste. As part of this requirement, the following shall be met:**

**(i) Enclosures and containers used for storage of regulated medical or chemotherapeutic waste shall be secured to deny access to unauthorized persons.**



**(ii) Enclosures and containers shall be marked with prominent warning signs indicating the storage of regulated medical or chemotherapeutic waste.**

**(b) Enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste must be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. CONTAINERS LOCATED IN ENCLOSURES USED FOR THE STORAGE OF REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE MUST BE MAINTAINED IN COMPLIANCE WITH § 284.413 (RELATING TO STORAGE CONTAINERS) AND IN A MANNER THAT MINIMIZES HUMAN EXPOSURE AND VECTORS. Exhaust air from storage areas must be ventilated to minimize human exposure.**

**(c) Regulated medical and chemotherapeutic waste may not be commingled with other waste IN THE SAME CONTAINER.**

**(d) The generator may store regulated medical WASTE, ~~[and]~~ chemotherapeutic waste ~~[and/]~~ or municipal waste that has been sorted and separately containerized IN THE SAME LOCATION, INCLUDING ON A CART ~~[on the same cart for movement to an onsite processing or disposal facility. Chemotherapeutic waste may also be stored on the cart with municipal and regulated medical waste if it is sorted and separately containerized and if it is moved to an onsite incinerator.]~~**

§ 284.413. [Duration of storage of infectious waste for generators] Storage containers.

[(a) Generators that store infectious or chemotherapeutic waste onsite shall meet the following requirements:

(1) Infectious waste, excluding used sharps, may be stored at room temperature until the storage container is full, but for no longer than 30 days from the date waste was first placed in the container.

(2) A storage container filled with infectious waste may be stored in a refrigeration unit for up to 30 days from the date waste was first placed in the container.

(3) A storage container of infectious waste that has been filled within 30 days from the date waste was first placed in the container may be frozen immediately for up to 90 days from the date waste was first placed in the container.

(b) If the infectious waste becomes putrescent during the storage period identified in subsection (a), the waste shall be moved offsite within 24 hours for processing or disposal.

(c) Used sharps containers may be used until full as long as the storage is in accordance with § 284.411 (relating to basic storage requirements).]

**(a) Regulated medical ~~[and]~~ OR chemotherapeutic waste shall be placed in containers that are:**

**(1) Leakproof ON THE SIDES AND BOTTOM AND MAINTAINED IN AN UPRIGHT POSITION.**

**(2) Impervious to moisture.**

**(3) Sufficient in strength to prevent puncturing, tearing or bursting during storage.**

**(b) In addition to the requirements of subsection (a), used sharps shall be placed in containers that are:**

**(1) Rigid.**

**(2) Tightly lidded.**

**(3) Puncture resistant.**

**(c) In addition to the requirements of subsection (a), regulated medical waste fluids in quantities greater than 20 cubic centimeters and chemotherapeutic waste fluids shall be placed in containers that are:**

**(1) Break resistant.**

**(2) Tightly lidded or tightly stoppered.**

**(d) When bags are used as the only container, double or multiple bagging shall be employed and the following requirements shall be met:**

**(1) Upon packaging, the bags shall be securely tied.**

**(2) The [bag] BAGS must be constructed of material of sufficient single thickness strength to meet the following:**

**(i) The ASTM Standard D1709, *Test Method for Impact Resistance of Polyethylene Film by the Free Falling Dart Method*, with an impact resistance of 165 grams or greater (Method A).**

**(ii) The ASTM Standard D1922, *Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method*, with a tearing resistance, parallel and perpendicular to the length of the bag of 480 grams.**

**(iii) If the standards in subparagraphs (i) and (ii) are modified by ASTM, the standard that is in effect on the date of manufacture of the bags shall be applied.**

**(3) Bags must include one of the following certifications indicating that the ASTM standards have been met:**

**(i) Each bag must contain a printed certification by the manufacturer.**

**(ii) The manufacturer may issue a certification letter to the regulated medical or chemotherapeutic waste generator and print a certification on each packaged lot of the bags.**

**(4) Bags must have sufficient seam strength that is at least equal in resistance to tearing and equally impermeable as the other portions of the bag.**

**(5) Bags must be fluorescent orange, orange-red or red in color for regulated medical waste and yellow in color for chemotherapeutic waste and contain colorants that are organic pigments with no heavy metal content.**

§ 284.414. [Duration of storage of infectious waste for processors] **Marking of containers.**

[If the waste processing facility is separate from the waste generating facility, infectious waste may not be stored at the waste processing facility for more than the following periods unless other periods are approved in a permit:

(1) Seventy-two hours at a temperature  $\leq 28^{\circ}\text{C}$ .

(2) Seven days in a refrigerator at  $\leq 7^{\circ}\text{C}$ .

(3) Thirty days in a freezer at  $\leq -18^{\circ}\text{C}$ .]

**(a) For onsite or offsite transportation of regulated medical or chemotherapeutic waste, [the following information must be provided on the outermost container:] THE OUTERMOST CONTAINERS OF REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE MUST BE LABELED WITH THE FOLLOWING:**

**(1) The words “chemotherapeutic waste” if chemotherapeutic waste is [containerized] PLACED IN THE CONTAINER.**

**(2) Until \_\_\_\_\_ (Editor’s Note: The blank refers to [1]2 [year] YEARS after the effective date of adoption of this proposed rulemaking.), the words “infectious waste” or “regulated medical waste” if regulated medical waste is [containerized] PLACED IN THE CONTAINER.**

**(3) After \_\_\_\_\_ (Editor’s Note: The blank refers to [1]2 [year] YEARS after the effective date of adoption of this proposed rulemaking.), the words “regulated medical waste” if regulated medical waste is [containerized] PLACED IN THE CONTAINER.**

**(4) The universal biohazard symbol that conforms to the design shown in 29 CFR 1910.1030(g)(1)(B) (relating to bloodborne pathogens) and the word “BIOHAZARD.”**

**(5) The date the container was full or the date that the generator sealed the container, whichever occurs earlier. [If the containers of regulated medical and chemotherapeutic waste are placed in a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility and available for inspection by the transporter or Department for 1 year.]**

**(6) THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE GENERATOR IF THE WASTE IS TRANSPORTED OFFSITE.**

**(b) [For offsite transportation of regulated medical or chemotherapeutic waste, the following information must be provided on the outermost container:] THE REQUIREMENTS OF SUBSECTION (a) DO NOT APPLY IF THE OUTERMOST CONTAINER IS A VEHICLE OR CONVEYANCE, INCLUDING A ROLL-OFF, AND ALL OF THE FOLLOWING ARE SATISFIED:**

**(1) [The name, address and telephone number of the generator.] THE WASTE IN THE VEHICLE**

**OR CONVEYANCE IS FROM A SINGLE GENERATOR;**

**(2) [~~The name of the transporter and, if applicable, Department-issued regulated medical and chemotherapeutic waste transporter license number.~~] THE VEHICLE OR CONVEYANCE IS TRANSPORTED OFF-SITE FOR PROCESSING OR DISPOSAL EVERY 30 DAYS;**

**(3) THE VEHICLE OR CONVEYANCE COMPLIES WITH THE REQUIREMENTS OF § 284.513 (RELATING TO TRANSPORTATION OF REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE; ADDITIONAL REQUIREMENTS);**

**(4) THE OUTSIDE OF THE VEHICLE OR CONVEYANCE DISPLAYS THE INFORMATION REQUIRED IN SUBSECTION (a)(5), EXCEPT WHEN A RECORD OF THE DATE THE VEHICLE OR CONVEYANCE IS FULL OR SEALED, WHICHEVER OCCURS EARLIER, IS MAINTAINED BY THE GENERATOR AND AVAILABLE FOR INSPECTION BY THE TRANSPORTER OR DEPARTMENT FOR 1 YEAR; AND**

**(5) THE OUTSIDE OF THE VEHICLE OR CONVEYANCE DISPLAYS THE INFORMATION REQUIRED IN SUBSECTION (a)(6).**

**(c) Nonwall-mounted used sharps containers storing regulated medical waste must have fluorescent orange, orange-red or red markings and chemotherapeutic waste must have yellow markings. The markings must sufficiently identify the waste as regulated medical or chemotherapeutic waste.**

**(d) The information required under this section must be clearly legible and produced with indelible ink in a color that contrasts with the color of the container, such as black. If a label is used to provide the information, the label must be securely attached to the container.**

**§ 284.415. [Storage containers] Duration of storage of regulated medical AND CHEMOTHERAPEUTIC waste for generators.**

**(a) Infectious and chemotherapeutic waste shall be placed in containers that are:**

**(1) Leakproof.**

**(2) Impervious to moisture.**

**(3) Sufficient in strength to prevent puncturing, tearing or bursting during storage.**

**(b) In addition to the requirements of subsection (a), used sharps shall be stored in containers that are:**

**(1) Rigid.**

**(2) Tightly lidded.**

**(3) Puncture resistant.**

**(c) In addition to the requirements of subsection (a), infectious waste fluids—quantities greater than 20 cubic centimeters—and chemotherapeutic waste fluids shall be stored in containers that are:**

**(1) Break resistant.**

**(2) Tightly lidded or tightly stoppered.**

**(d) When bags are used as the only storage container, double or multiple bagging shall be employed and the following requirements shall be met:**

**(1) Upon packaging, the bags shall be securely tied.**

**(2) The bag shall be constructed of material of sufficient single thickness strength to meet the following:**

**(i) The ASTM standard D1709-91, *Test Method for Impact Resistance of Polyethylene Film by the Free Falling Dart Method*, with an impact resistance of 165 grams or greater (Method A).**

**(ii) The ASTM standard D1922-89, *Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method*, with a tearing resistance, parallel and perpendicular to the length of the bag, of 480 grams.**

**(iii) If the standards in subparagraphs (i) and (ii) are modified by ASTM, the standard that is in effect on the date of manufacture of the bags shall be applied.**

**(3) Bags shall include one of the following certifications indicating that the ASTM standards have been met:**

**(i) Each bag shall contain a printed certification by the manufacturer.**

**(ii) The manufacturer may issue a certification letter to the infectious or chemotherapeutic waste generator and print a certification on each packaged lot of the bags.**

**(4) Bags used as containers shall have sufficient seam strength that is at least equal in resistance to tearing and equally impermeable as the other portions of the bag.**

**(5) Bags used as containers shall be yellow in color for each package of chemotherapeutic waste and fluorescent orange, orange-red or red in color for each package of infectious waste and shall be labeled in accordance with § 284.416(c) (relating to marking of containers).**

**(e) Fluorescent orange, orange-red or red or yellow containers shall contain colorants which are organic pigments with no heavy metal content.**

**(f) With the exception of persons who work at a small quantity generator's operation, where less than 220 pounds of infectious and chemotherapeutic waste is generated per month, persons packaging infectious or chemotherapeutic waste for offsite transportation shall wear:**

**(1) Protective overalls.**

**(2) Heavy gloves of neoprene or equivalent materials.]**

**(a) [Generators that store regulated medical waste onsite shall record on the container the date that**

~~the container was full or the date that the generator sealed the container, whichever occurs earlier. If the container is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility for 1 year.~~

~~(b) Regulated medical OR CHEMOTHERAPEUTIC waste may not be stored for longer than 30 days from the date that the storage container is full or sealed by the generator, whichever occurs earlier.~~

~~(e)(b) If the regulated medical OR CHEMOTHERAPEUTIC waste becomes putrescent during the storage period identified in subsection (b), the waste shall be moved offsite within 3 business days for processing or disposal.~~

**§ 284.416. [Marking of containers] Duration of storage of regulated medical AND CHEMOTHERAPEUTIC waste for processors.**

(a) The outermost container for each package of infectious or chemotherapeutic waste for offsite transportation shall be labeled immediately after packing. The label shall be securely attached and shall be clearly legible. Indelible ink shall be used to complete the information on the label. If handwritten, the label shall be at least 3 inches by 5 inches in dimension.

(b) The following information shall be included on the label:

(1) The name, address and telephone number of the generator.

(2) The date the waste was generated.

(3) The name of the transporter and, if applicable, Department-issued infectious and chemotherapeutic waste transporter license number.

(c) The following information shall be printed on the outermost container or bag for each package of infectious or chemotherapeutic waste for either onsite movement or offsite transportation:

(1) The words “infectious waste” or “chemotherapeutic waste,” whichever is applicable.

(2) The universal biohazard symbol that conforms to the design shown in regulations of the United States Occupational Safety and Health Administration at 29 CFR 1910.145(f)(8)(ii) (relating to specifications for accident prevention signs and tags).

(d) The color coding scheme for infectious and chemotherapeutic waste bags and nonwall-mounted used sharps containers shall be fluorescent orange, orange-red or red in color, or predominately so, for infectious waste and yellow in color, or predominately so, for chemotherapeutic waste, with lettering and symbols in a contrasting color (for example, black).

(e) Stationary waste storage containers shall be lined with the appropriate colored bag for infectious or chemotherapeutic waste.]

If the waste processing facility is separate from the waste generating facility, regulated medical OR CHEMOTHERAPEUTIC waste may not be stored at the waste processing facility for more than the following periods unless other periods are approved in [a] THE FACILITY’S permit:

**(1) Seventy-two hours at [a temperature  $\leq 25^{\circ}\text{C}$  or  $\leq 77^{\circ}\text{F}$ ] AMBIENT TEMPERATURE, UNLESS THE WASTE BECOMES PUTRESCENT OR ATTRACTS VECTORS.**

**(2) Seven days in a refrigerator at  $\leq 7^{\circ}\text{C}$  or  $\leq 45^{\circ}\text{F}$ , OR IF THE WASTE BECOMES PUTRESCENT OR ATTRACTS VECTORS.**

**(3) Thirty days in a freezer at  $\leq -18^{\circ}\text{C}$  or  $\leq 0^{\circ}\text{F}$ , OR IF THE WASTE BECOMES PUTRESCENT OR ATTRACTS VECTORS.**

**§ 284.417. Reuse of containers.**

(a) Nonrigid containers shall be managed as either **[infectious] regulated medical** or chemotherapeutic waste, based upon the contents of the container. These containers may not be reused.

(b) Corrugated fiberboard containers used for storage of **[infectious] regulated medical** or chemotherapeutic waste may be reused if the surface of the container has been protected from direct contact with the waste.

(c) A rigid, nonfiberboard container used for the storage of **[infectious] regulated medical** waste **or chemotherapeutic waste** may be reused if one of the following applies:

\* \* \* \* \*

(2) The surface of the container has been protected from direct contact with **[infectious] regulated medical and chemotherapeutic** waste, **as applicable**.

**[(d) A rigid container used for the storage of chemotherapeutic waste may be reused if the surface of the container has been protected from direct contact with chemotherapeutic waste.]**

**§ 284.418. Storage and containment of ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration.**

(a) Ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be stored in accordance with the following:

\* \* \* \* \*

(2) On a pad **for collecting a spill or release of ash** that is no more permeable than  $1 \times 10^{-7}$  cm./sec.

(3) **[To] In a manner to** prevent the release, dispersal or discharge of ash residue into the air, water or onto land.

\* \* \* \* \*

**§ 284.419. Storage and containment of processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste processing facility.**

(a) Processing residue from **[infectious] regulated medical** or chemotherapeutic waste processing facilities shall be stored in an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building, in order to:

\* \* \* \* \*

(b) Processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste processing facility may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

## **Subchapter F. COLLECTION AND TRANSPORTATION**

### **TYPES OF WASTE**

284.511. Transportation of ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration.

284.512. Transportation of **[infectious] regulated medical** and chemotherapeutic waste; general provisions.

284.513. Transportation of **[infectious] regulated medical** and chemotherapeutic waste; additional provisions.

284.514. Transportation of processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste facility.

### **GENERAL**

#### **§ 284.501. Scope.**

This subchapter sets forth the requirements for a person or municipality that collects and transports **[infectious] regulated medical** or chemotherapeutic waste, ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration and processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste processing facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions) and the requirements in §§ 285.211—285.219 (relating to general provisions).

### **TYPES OF WASTE**

#### **§ 284.511. Transportation of ash residue from [infectious] regulated medical or chemotherapeutic waste incineration.**

(a) Ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be wetted immediately prior to loading, and shall remain wetted during transportation and unloading at a municipal waste landfill, to prevent the dispersal of ash residue.

(b) Ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.

(c) **[A transporter shall transport separately each generator's ash residue from infectious or chemotherapeutic waste.] A generator's ash residue from regulated medical or chemotherapeutic waste incineration shall be transported separately from the ash residue of other generators.**

(d) **[A transporter may transport ash residue from an infectious or chemotherapeutic waste incinerator that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.] Municipal**



**waste from a generator may be commingled and transported with the generator's ash residue from regulated medical and chemotherapeutic waste incineration if the municipal waste and ash residue [is] ARE being transported separately from the waste of other generators.**

**§ 284.512. Transportation of [infectious] regulated medical and chemotherapeutic waste; general provisions.**

(a) *General.* This section sets forth general requirements for a person or municipality that transports [infectious] regulated medical or chemotherapeutic waste. Section 284.513 (relating to transportation of [infectious] regulated medical and chemotherapeutic waste; additional provisions) sets forth additional provisions relating to the transportation of the waste.

(b) *Manner of transportation.* [Infectious] Regulated medical and chemotherapeutic waste shall be transported in a manner that:

\* \* \* \* \*

(4) Maintains the waste in a nonputrescent state, using refrigeration ( $\leq 7^{\circ}\text{C}$  **or**  $\leq 45^{\circ}\text{F}$ ) or freezing ( $\leq -18^{\circ}\text{C}$  **or**  $\leq 0^{\circ}\text{F}$ ) when necessary.

\* \* \* \* \*

(c) *Containers.*

(1) [Infectious] Regulated medical and chemotherapeutic waste shall be transported in containers that are:

\* \* \* \* \*

(iv) Sufficient in strength to prevent puncturing, tearing or bursting during transportation. [A single-walled, corrugated fiberboard container shall be of a classified strength of at least 200 pounds per square inch, with a gross weight limit of at least 65 pounds at the time the container is manufactured. Compliance with these requirements shall be certified on the container by the manufacturer.]

**(v) Labeled in accordance with the requirements in § 284.414 (relating to marking of containers), EXCEPT AS PROVIDED IN § 284.414(b) (RELATING TO MARKING OF CONTAINERS).**

(2) In addition to the requirements of paragraph (1), used sharps shall be transported in containers that are tightly lidded.

(3) In addition to the [requirement] requirements of paragraph (1), [infectious] regulated medical waste fluids—quantities greater than 20 cubic centimeters—and chemotherapeutic waste fluids shall be transported in containers that are:

\* \* \* \* \*

(4) Bags meeting the requirements of [§ 284.415] § 284.413 (relating to storage containers) may be used to meet the requirements of this subsection that containers be leakproof and impervious to moisture.

(d) **[Infectious and chemotherapeutic waste may not be transported in the same containers, unless approved in writing by the Department. Infectious and chemotherapeutic waste shall be transported in separate vehicles from those used for other waste.**

(e) **Types of vehicles.** Vehicles for transporting **[infectious] regulated medical** or chemotherapeutic waste shall be noncompaction type vehicles.

(e) **Commingling of waste.** **SEPARATELY CONTAINERIZED regulated medical or chemotherapeutic waste may [not] be [commingled] TRANSPORTED IN THE SAME VEHICLE with CONTAINERIZED municipal waste [or transported in the same vehicle as residual waste].**

(f) **Cleaning of vehicles.** Load compartments of vehicles holding **[infectious] regulated medical** or chemotherapeutic waste for transportation shall be constructed of materials that are impermeable and easily cleaned. Surfaces of vehicles that have been in direct physical contact with **[infectious] regulated medical** or chemotherapeutic waste, because of a leak in the bag or container or because of another reason, shall be decontaminated as soon as possible after unloading.

(g) **Refrigeration.** **[Infectious] Regulated medical OR CHEMOTHERAPEUTIC** waste may **[not]** be kept in an unrefrigerated transport vehicle for **[more than 48] up to 72** hours **provided the waste is not putrescent AND DOES NOT ATTRACT VECTORS.** If the vehicle is refrigerated ( $\leq 7^{\circ}\text{C}$  or  $\leq 45^{\circ}\text{F}$ ) or maintained at freezing temperatures ( $\leq -18^{\circ}\text{C}$  or  $\leq 0^{\circ}\text{F}$ ), the in-transit storage period may not exceed 5 days.

(h) **Chutes.** Chutes may not be used by generators, processors or transporters to transfer **[infectious] regulated medical** or chemotherapeutic waste at onsite or offsite locations.

**§ 284.513. Transportation of **[infectious] regulated medical** and chemotherapeutic waste; additional provisions.**

(a) This section sets forth additional requirements for the transportation of **[infectious] regulated medical** and chemotherapeutic waste. This section does not apply to vehicles used by a generator of less than 220 pounds of **[infectious] regulated medical** and chemotherapeutic waste per month for transporting **[waste that he generated] the generator's own waste.**

(b) Vehicles **OR CONVEYANCES** for transporting **[infectious] regulated medical** or chemotherapeutic waste shall be identified on the two sides and back of the cargo compartment with the following:

(1) The transporter's Department-issued **[infectious] regulated medical** and chemotherapeutic waste license number, if applicable.

(2) A placard or decal containing the phrase "**[infectious] regulated medical** waste" or "chemotherapeutic waste," or both, **as applicable**, and the universal biohazard symbol that conforms to the design shown in the United States Occupational Safety and Health Administration's regulations at **[29 CFR 1910.145(f)(8)(ii) (relating to specifications for accident prevention signs and tags)] 29 CFR 1910.1030(g)(1)(B) (relating to bloodborne pathogens).** [The placard or decal shall be capable of being read at a distance of 25 feet.]

**(3) UNTIL \_\_\_\_\_ (EDITOR'S NOTE: THE BLANK REFERS TO 2 YEARS AFTER THE EFFECTIVE DATE OF ADOPTION OF THIS PROPOSED RULEMAKING.), THE WORDS**

**“INFECTIOUS WASTE” OR “REGULATED MEDICAL WASTE” IF REGULATED MEDICAL WASTE IS BEING TRANSPORTED.**

**(4) AFTER \_\_\_\_\_ (EDITOR’S NOTE: THE BLANK REFERS TO 2 YEARS AFTER THE EFFECTIVE DATE OF ADOPTION OF THIS PROPOSED RULEMAKING.), THE WORDS “REGULATED MEDICAL WASTE” IF REGULATED MEDICAL WASTE IS BEING TRANSPORTED.**

(c) A vehicle used for transporting **[infectious] regulated medical** or chemotherapeutic waste shall contain, in a readily accessible place, a portable decontamination and spill containment unit, including at a minimum the following:

\* \* \* \* \*

(2) One gallon of **[hospital grade] EPA-approved** disinfectant in an appropriate applicator.

(3) Fifty fluorescent orange, orange-red or red or yellow, or both, plastic bags that meet the requirements of § **[284.415] 284.413** (relating to storage containers). The bags shall be accompanied by seals and appropriate labels, and shall be large enough to overpack any container normally transported in the vehicle.

\* \* \* \* \*

(d) The **CARGO AREA [surface]** of vehicles **USED FOR TRANSPORTING REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE** that **[have] HAS** not been in direct physical contact with **[infectious] regulated medical** or chemotherapeutic waste shall be cleaned weekly. Drainage from the cleaning shall be discharged directly or through a holding tank to a sanitary sewer system or treatment facility.

**[(e) Individuals loading or unloading containers of infectious or chemotherapeutic waste onto or off transportation vehicles shall wear protective overalls and heavy gloves of neoprene or equivalent materials. Gloves and coveralls shall be decontaminated after each loading or unloading operation if the gloves and coveralls have been contaminated or are suspected of having been contaminated. If no contamination occurs or none is suspected, decontamination shall be completed at the end of the working day or work shift.]**

**§ 284.514. Transportation of processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste facility.**

(a) Processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste facility shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.

(b) A transporter shall transport **[separately each generator's]** processing residue from **[infectious] regulated medical** or chemotherapeutic waste **for each generator separately from other generators.**

(c) A transporter may transport processing residue from **[infectious] regulated medical** or chemotherapeutic waste that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.

**Subchapter G. TRANSPORTER LICENSING FOR [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE**

**OPERATIONAL REQUIREMENTS**

284.631. Basic limitations.

284.632. [Infectious] Regulated medical or chemotherapeutic waste discharges or spills.

284.633. Safety.

284.634. Annual report.

**GENERAL PROVISIONS**

**§ 284.601. Scope.**

This subchapter sets forth the Department's requirements for licensing of persons and municipalities that transport [infectious] regulated medical or chemotherapeutic waste.

**§ 284.602. License requirement.**

(a) Except as provided in subsection (b), a person or municipality may not transport [infectious] regulated medical or chemotherapeutic waste unless the person has first obtained a license from the Department in accordance with this subchapter.

(b) This subchapter does not apply to the following:

(1) Onsite movement of [infectious] regulated medical or chemotherapeutic waste by generators.

(2) [Onsite] Onsite movement of [infectious] regulated medical or chemotherapeutic waste by [owners or] operators of permitted [infectious] regulated medical or chemotherapeutic waste management facilities.

(3) Transportation by a generator of less than 220 pounds per month of [infectious] regulated medical or chemotherapeutic waste when transporting only [the infectious] the generator's own regulated medical or chemotherapeutic waste [he generated] if the [~~manifesting~~] LOG AND SHIPPING PAPER requirements under § 284.701(b)(3) (relating to scope) are met.

(4) The transportation of [infectious] regulated medical or chemotherapeutic waste generated outside this Commonwealth destined for processing or disposal outside this Commonwealth.

**§ 284.603. Identification number.**

A person or municipality subject to this chapter may not transport [infectious] regulated medical or chemotherapeutic waste without first receiving an identification number. The number shall be one of the following:

\* \* \* \* \*

**LICENSE APPLICATION REQUIREMENTS**

**§ 284.611. General application requirements.**

(a) An application for a license to transport **[infectious] regulated medical** or chemotherapeutic waste shall be submitted to the Department, in writing, on forms provided by the Department. An application for a license shall be accompanied by information, specifications and other data required by the Department to determine compliance with this subchapter.

(b) The application shall contain the following:

\* \* \* \* \*

(3) The average yearly total tonnage of **[infectious] regulated medical** and chemotherapeutic waste picked up or delivered in this Commonwealth.

\* \* \* \* \*

(5) Information concerning terminal locations that will store **[infectious] regulated medical** and chemotherapeutic waste in-transit.

\* \* \* \* \*

(9) A contingency plan consistent with § 284.632 (relating to **[infectious] regulated medical** or chemotherapeutic waste discharges or spills).

\* \* \* \* \*

**§ 284.612. Vehicular liability insurance.**

(a) The application shall include a certificate of insurance issued by an insurance company authorized to do business in this Commonwealth, certifying that the applicant has comprehensive vehicular liability insurance in force covering the operation of vehicles and associated **[infectious] regulated medical** and chemotherapeutic waste transportation activities.

(b) The certificate of insurance shall expressly document coverage for property damage and bodily injury to third parties. The insurance coverage shall include coverage for the cost of cleaning up **[an infectious] a regulated medical** or chemotherapeutic waste spill, and damages arising from the spill. Minimum insurance coverage shall be \$500,000 annual aggregate, exclusive of claims administration and legal defense costs.

\* \* \* \* \*

(e) An applicant for a transporter license to transport **[infectious] regulated medical** or chemotherapeutic waste which is a department or an agency of the United States or of the Commonwealth may fulfill the requirements under this section by means of one or more of the following:

\* \* \* \* \*

**LICENSE APPLICATION REVIEW**

**§ 284.623. Conditions of licenses.**

\* \* \* \* \*

(c) A license to transport **[infectious] regulated medical** and chemotherapeutic waste is nontransferable and nonassignable. A license applies to the licensee and its **[employees] employees**. Leased or subcontracted **[drivers]HAULERS**, and **[drivers]HAULERS** who provide equipment, have no authority to operate under the licensee's license without prior written approval from the Department.

**§ 284.624. License renewal.**

A licensee that plans to transport **[infectious] regulated medical** or chemotherapeutic waste after expiration of the current license term under § 284.622 (relating to term of license) shall file a complete application for license renewal on forms provided by the Department at least 90 days before the expiration date of the license. The application shall include a nonrefundable application fee in the form of a check payable to the "Commonwealth of Pennsylvania" for \$500. The license renewal application will be reviewed by the Department in the same manner as a new application for a license under this subchapter.

**OPERATIONAL REQUIREMENTS**

**§ 284.631. Basic limitations.**

(a) A person or municipality subject to this subchapter that transports **[infectious] regulated medical** or chemotherapeutic waste shall comply with the following:

\* \* \* \* \*

**§ 284.632. [Infectious] Regulated medical or chemotherapeutic waste discharges or spills.**

\* \* \* \* \*

(b) In the event of a discharge or spill of **[infectious] regulated medical** or chemotherapeutic waste during transportation, the transporter shall take appropriate immediate action to protect the health and safety of the public and the environment, in accordance with its approved TCP. The transporter shall also immediately telephone the Department and the affected municipality, and provide the following information:

\* \* \* \* \*

(2) The transporter's name, address, the Department-issued **[infectious] regulated medical** and chemotherapeutic waste transporter license number and identification number.

\* \* \* \* \*

(c) If a discharge or spill of **[infectious] regulated medical** or chemotherapeutic waste occurs during transportation, and if the immediate removal of the waste is necessary to protect public health and safety or the environment, the Department may authorize the removal of the waste to a selected receiving facility by transporters who do not have identification numbers, licenses, **LOGS** or **SHIPPING PAPERS** **[manifests]** under this subchapter.

(d) A transporter shall:

(1) Clean up **[an infectious] a regulated medical** or chemotherapeutic waste discharge or spill that occurs during transportation or take action that may be required or approved by the Department so that the discharge or spill no longer presents a hazard to public health, public safety or the environment.

\* \* \* \* \*

**§ 284.633. Safety.**

A transporter of **[infectious] regulated medical** or chemotherapeutic waste shall provide adequate personnel training to ensure transport activities are conducted safely, in compliance with applicable laws and regulations, and according to the contingency plan approved under § 284.632 (relating to **[infectious] regulated medical** or chemotherapeutic waste discharges or spills).

**§ 284.634. Annual report.**

\* \* \* \* \*

(b) The annual report shall be based on the shipments of **[infectious] regulated medical** or chemotherapeutic waste during the previous calendar year, and shall include the following:

(1) The name, location, telephone number and permit identification number of each processing or disposal facility to which the transporter delivered **[infectious] regulated medical** or chemotherapeutic waste.

(2) The weight or volume of each type of **[infectious] regulated medical** or chemotherapeutic waste transported.

(3) When more than one transporter is used to transport a single shipment of **[infectious] regulated medical** or chemotherapeutic waste from the generator to the processing or disposal facility, only the first transporter shall be required to submit information for that shipment on the annual report.

**BOND**

**§ 284.641. Bond requirement.**

(a) *General.* The applicant shall provide the Department a bond, secured by collateral as specified by this section and which bond is conditional upon compliance by the licensee with the requirements of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P.S. §§ 6019.1—6019.6), referred to as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license and Department orders issued to the licensee. The bond shall be consistent with, and subject to, the requirements of this section. The amount, duration, form, conditions and terms of the bond shall be specified by the Department. An additional bond amount will not be required of applicants that are also licensed hazardous waste transporters during the term of license or renewal thereof under this subchapter if the applicant or licensee submits a bond endorsement, including an increase in the amount of the bond of a minimum of \$10,000, to the Department that includes liability for **[infectious] regulated medical** and chemotherapeutic waste transportation on the hazardous waste transporter bond.

(b) *Approval by Department.* A license to transport **[infectious] regulated medical** or chemotherapeutic waste will not be issued by the Department before the applicant for the license has filed a collateral bond

payable to the Department on a form provided by the Department, and the bond has been approved by the Department.

\* \* \* \* \*

(f) **Review of bonds.** Bonds will be reviewed for legality and form according to established Department procedures.

**§ 284.642. Release of bond.**

\* \* \* \* \*

(b) The Department will not release a bond if the transporter is in violation of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P.S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license or Department orders issued to the licensee, whether or not the violation results from **[infectious] regulated medical** or chemotherapeutic waste transportation.

\* \* \* \* \*

**§ 284.643. Bond forfeiture.**

(a) The Department will declare a bond forfeit if the transporter is in violation of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P.S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the bond, the terms and conditions of the license or Department orders issued to the licensee, whether or not the violation results from **[infectious] regulated medical** or chemotherapeutic waste transportation.

\* \* \* \* \*

**Subchapter H. ~~[MANIFESTING FOR]~~ TRACKING OF [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE**

**GENERATOR RESPONSIBILITIES**

- 284.711. Use of **[manifest] LOGS OR SHIPPING PAPERS.**
- 284.712. Preparation of **[manifest] LOGS OR SHIPPING PAPERS.**
- 284.713. **[Generator's distribution of copies] [Reserved].**
- 284.714. Exception reporting.

**TRANSPORTER RESPONSIBILITIES**

- 284.721. **[Basic requirements] [Reserved].**
- 284.722. Preparation and use of **[manifest] LOGS OR SHIPPING PAPERS.**
- 284.723. **[Waste delivey] [Reserved].**
- 284.724. Transportation limitations.

**FACILITY RESPONSIBILITIES**

- 284.731. Scope.



284.732. Use of **[manifest] LOGS OR SHIPPING PAPERS.**

284.733. **[Distribution of copies] [Reserved].**

284.734. Significant discrepancies.

## GENERAL

### § 284.701. Scope.

(a) Except as provided in **[subsections (b) and (c)] subsection (b)**, this subchapter applies to a person or municipality that generates, transports, disposes or processes **[infectious] regulated medical** or chemotherapeutic waste or processed **[infectious] regulated medical** or chemotherapeutic waste that is recognizable.

(b) This subchapter does not apply to a person or municipality for the following activities:

(1) Onsite movement of **[infectious] regulated medical** or chemotherapeutic waste by generators.

(2) Onsite movement of **[infectious] regulated medical** or chemotherapeutic waste by **[owners or] operators of permitted [infectious] regulated medical** or chemotherapeutic waste management facilities.

(3) Transportation by a generator who generates less than 220 pounds per month of **[infectious] regulated medical** and chemotherapeutic waste if the following are met:

\* \* \* \* \*

(iii) The generator carries and delivers a copy of this **[record] log or shipping paper** with the waste shipment to the offsite processing or disposal facility.

(4) The transportation of **[used sharps from generators who generate less than 220 pounds per month of infectious and chemotherapeutic waste] regulated medical waste** if the following are met:

\* \* \* \* \*

(ii) **[The packaging meets the requirements of the United States Postal Service or other mail carriers.] The mailing standards of the United States Postal Service as set forth in 39 CFR 211.2 (relating to regulations of the Postal Service) and incorporated by reference into this chapter authorize the package to be mailed.**

(iii) **The package is mailed in compliance with United States Postal Service regulations.**

(iv) The generator maintains a log **or shipping paper** containing the following information:

\* \* \* \* \*

(5) The transportation by a generator **[of] who generates and processes onsite** less than 220 pounds per month of **[infectious] regulated medical** or chemotherapeutic waste **[that he generates and processes onsite, but]**, which is recognizable waste, if the following are met:

(i) **The generator only transports its own waste.**

**(ii)** The generator records on a log or shipping paper the following information for each shipment:

\* \* \* \* \*

**[(ii)] (iii)** A copy of the log or **[record shall be carried and delivered] shipping paper shall be provided** to the disposal facility by the transporter for each shipment of waste.

(6) The transportation through this Commonwealth of **[infectious] regulated medical** or chemotherapeutic waste generated outside this Commonwealth **[and which] that** is destined for processing or disposal outside this Commonwealth.

(7) The transportation of processed **[infectious] regulated medical** or chemotherapeutic waste to a disposal facility if the waste has been rendered unrecognizable.

**[(c) This subchapter does not apply to a person or municipality which receives infectious or chemotherapeutic waste generated in this Commonwealth and which processes or disposes of the waste outside this Commonwealth in a state that provides a manifest or tracking form if the following are met:**

**(1) The state requires a manifest or tracking form for infectious or chemotherapeutic waste, regardless of whether the state requires a manifest or tracking form for infectious or chemotherapeutic waste as defined in this article.**

**(2) The generator obtains a manifest or tracking form for infectious or chemotherapeutic waste from that state.**

**(3) The generator, transporter and owner or operator of a processing or disposal facility comply with the requirements on the manifest or tracking form and applicable state or Federal law, managing the infectious or chemotherapeutic waste as if it were regulated waste under applicable law. For purposes of this subsection, applicable law includes the provisions of this subchapter that are expressly applicable to waste that will be transported outside this Commonwealth for processing or disposal.]**

**§ 284.702. Transfer facilities.**

**[(a) Infectious or] Regulated medical waste, chemotherapeutic waste or processed **[infectious] regulated medical** or chemotherapeutic waste that is recognizable may be transported to or from a transfer **[facility under this subchapter. The use of a transfer facility shall require two manifests, one for the transportation of waste to the facility, and one for the transportation of waste from the facility.] facility in accordance with the following:****

**[(b) If infectious or chemotherapeutic waste or processed waste which is recognizable is]**

**(1) The transfer facility is permitted by the Department.**

**(2) If** transported to a transfer facility, the transfer facility shall be considered the designated facility for purposes of this subchapter.

**[When the waste is] (3) If** transported from the transfer facility to a processing or disposal facility, the transfer facility shall be considered the generator and the processing or disposal facility shall be considered the **[new]** designated facility for purposes of this subchapter.

**§ 284.703. Recordkeeping.**

**[(a)]** The records required under this subchapter shall be retained for at least **[5] 2** years from the date on which the **[report was required to be] record was** prepared. **Records shall be submitted to the Department upon request.** The retention period shall be extended automatically during the course of an enforcement action or as requested by the Department.

**[(b) Manifest copies shall be retained for at least 5 years from the date of shipment of the waste. Manifest copies retained under this subchapter shall be furnished to the Department upon request. The retention period shall be extended automatically during the course of an enforcement action or as requested by the Department.]**

**GENERATOR RESPONSIBILITIES**

**§ 284.711. Use of ~~[manifest]~~ LOGS OR SHIPPING PAPERS.**

**[(a)]** A generator who transports, or offers for transportation, **[infectious] regulated medical** or chemotherapeutic waste for offsite processing or disposal shall ensure proper segregation of **[infectious] regulated medical** and chemotherapeutic waste from other types of waste and prepare a **[manifest according to the instructions supplied with the manifest] log or shipping paper as required under this subchapter**. A processor who transports, or offers for transportation, processed **[infectious] regulated medical** or chemotherapeutic waste that is recognizable for offsite disposal shall be considered a generator for purposes of **[manifesting. The manifest shall be in at least four parts] this subchapter**.

**[(b) If the waste is to be processed or disposed in this Commonwealth, the generator shall use one of the manifest formats prescribed by the Department.**

**(c) The manifest copies shall be distributed as follows:**

**(1) A four-part manifest shall be used by a generator who designates only one transporter.**

**(i) Copy 4 of the manifest is retained by the generator.**

**(ii) Copy 3 of the manifest is retained by the transporter.**

**(iii) Copy 2 of the manifest is retained by the owner or operator of the processing or disposal facility.**

**(iv) Copy 1 of the manifest is mailed to the generator by the owner or operator of the processing or disposal facility.**

**(2) A five-part manifest shall be used by a generator who designates two transporters.**

**(i) Copy 4 of the manifest is retained by the generator.**

**(ii) Copy 3A of the manifest is retained by the first transporter.**

- (iii) Copy 3 of the manifest is retained by the second transporter.
- (iv) Copy 2 of the manifest is retained by the owner or operator of the processing or disposal facility.
- (v) Copy 1 of the manifest is mailed to the generator by the owner or operator of the processing or disposal facility.
- (3) A six-part manifest shall be used by a generator who designates three transporters.
  - (i) Copy 4 of the manifest is retained by the generator.
  - (ii) Copy 3B of the manifest is retained by the first transporter.
  - (iii) Copy 3A of the manifest is retained by the second transporter.
  - (iv) Copy 3 of the manifest is retained by the third transporter.
  - (v) Copy 2 of the manifest is retained by the owner or operator of the processing or disposal facility.
  - (vi) Copy 1 of the manifest is mailed to the generator by the owner or operator of the processing or disposal facility.
- (d) If the waste is to be processed or disposed outside this Commonwealth, the generator shall obtain the manifest from the destination state. If the destination state does not supply the manifest, the generator shall use the manifest format required by the Department.]

**§ 284.712. Preparation of [~~manifest~~] LOGS OR SHIPPING PAPERS.**

(a) The generator shall [~~provide the following information on each manifest~~] create a log or shipping paper of the following information and provide it to the transporter before the offsite transportation of the [~~manifested~~] waste occurs:

\* \* \* \* \*

- (2) [The total number of pages used to complete the manifest, counting the first page plus the number of continuation sheets, if any.
- (3)] Each transporter's company name, identification number, Pennsylvania [~~infectious~~] regulated medical and chemotherapeutic waste transporter license number and telephone number. [If three transporters are designated by the generator, enter the third transporter's name, identification number, Pennsylvania infectious and chemotherapeutic waste transporter license number, telephone number and the words "Transporter 3 sign here," in the Special Handling Instruction Section.
- (4)] (3) The number of containers, types of containers and the total quantity of the waste by weight or volume.

**[(5) The infectious or chemotherapeutic waste code number for each waste as indicated on the manifest instructions.]**

**(6) (4) ONE OF THE FOLLOWING REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE CODE NUMBERS FOR EACH WASTE TYPE, AS APPROPRIATE:**

**(i) A100 FOR REGULATED MEDICAL WASTE.**

**(ii) A200 FOR PROCESSED REGULATED MEDICAL WASTE THAT IS RECOGNIZABLE.**

**(iii) A300 FOR CHEMOTHERAPEUTIC WASTE.**

**(5)** The United States Department of Transportation proper shipping name, hazard class and identification number (UN or NA) for each waste identified by 49 CFR Subchapter C (relating to hazardous materials regulations), if applicable.

**[(7) [(5) [6] Special instructions and information necessary for proper handling of the waste during transportation, processing, storage or disposal, if any.**

**[(8) [(6) [7] The printed or typed name and handwritten signature of the generator's authorized representative, and the date of shipment.**

**[(9) [(7) [8] The printed or typed name and handwritten signature of the initial transporter's authorized representative, and the date of receipt.**

**[(10) The designated facility's name, site address, Pennsylvania State permit or identification number and phone number. One alternate facility's name, site address, Pennsylvania State permit or identification number and phone number may be designated on the manifest to receive the waste. A facility may only be designated if it has been approved by the Department to accept the generator's waste.]**

**(b) An authorized representative of the generator shall ensure that [the manifest has been completed and shall read the certification statement on the manifest prior to signing the manifest] a legible log or shipping paper has been completed.**

**(c) [The generator shall ensure before the waste is transported offsite that the required information on all parts of the manifest are capable of being read.] After the offsite transportation of the waste, the generator shall receive from the transporter and maintain as a record the log or shipping paper prepared by the transporter in accordance with §284.722(f) (relating to preparation and use of [manifest]LOGS AND SHIPPING PAPERS).**

**[(d) When the generator uses lab packs containing more than four different waste streams, the generator shall complete a continuation sheet (EPA Form 8700-22A).**

**(e) For a shipment containing more than four different waste streams, which is not a lab pack, the generator shall complete additional manifests as necessary for waste streams in excess of four, according to the instructions on the manifest.]**

**§ 284.713. [Generator's distribution of copies] (Reserved).**

**[(a) Except as provided in subsection (b), the generator shall detach and retain copy 4 of the manifest.]**

**(b) A generator located in this Commonwealth and designating a facility in a state that supplies the manifest shall provide information and distribute copies as required by the manifest in accordance with instructions supplied with the manifest and retain one copy of the manifest.**

**(c) The generator shall give the transporter the remaining copies of the manifest before the transporter leaves the generator's property.]**

**§ 284.714. Exception reporting.**

(a) A generator that does not receive a **[copy of the manifest with the handwritten signature of the owner or operator of the designated processing or disposal facility within 20] log or shipping paper indicating the designated facility that received its waste within 30** days of the date the generator's waste was accepted by the initial transporter shall:

(1) Contact the transporter or the **[owner or]** operator of the designated facility, or both, to determine the status of the **[infectious or chemotherapeutic waste or processed recognizable waste]** shipment.

\* \* \* \* \*

**(b) [A generator shall notify by telephone the Department's appropriate regional office and submit an exception report to the Department's central office if] If the generator has not received a [copy of the manifest with the handwritten signature of the owner or from the operator of the designated processing or disposal facility] log or shipping paper indicating the designated facility that received its waste from the transporter within 35 days of the date the generator's waste was accepted by the initial transporter, the generator shall notify the Department's appropriate regional office by telephone and submit an exception report to the Department's central office.**

(c) The exception report shall include the following:

(1) **[A legible copy of the manifest] A record of the waste** for which the generator does not have confirmation of delivery.

\* \* \* \* \*

**TRANSPORTER RESPONSIBILITIES**

**§ 284.721. [Basic requirements] (Reserved).**

**[Except as provided in § 284.701 (relating to scope), a transporter may not accept infectious or chemotherapeutic waste or processed infectious or chemotherapeutic waste that is recognizable unless it is accompanied by a manifest which has been completed and signed by the generator or the generator's authorized agent under § 284.712 (relating to preparation of manifest).]**

**§ 284.722. Preparation and use of [~~manifest~~] LOGS OR SHIPPING PAPERS.**

(a) Before transporting **[infectious] regulated medical** or chemotherapeutic waste or processed **[infectious] regulated medical** or chemotherapeutic waste that is recognizable, the transporter shall

[print or type his name, sign and date the manifest, and, by the signature, acknowledge acceptance of the waste from the generator] provide the generator with a dated[, handwritten] signature, INCLUDING, BUT NOT LIMITED TO, HANDWRITTEN, ELECTRONIC OR STAMPED SIGNATURES, [of] FROM an authorized representative of the transporter acknowledging that the transporter has accepted the waste from the generator on the date of acceptance.

(b) [Before leaving the generator's property, the transporter shall ensure that all copies of the manifest are properly completed and capable of being read, and shall return copy 4 of the manifest to the generator according to the instructions on the manifest.

(c) The transporter shall ensure that the [manifest] log or shipping paper required under subsections (c) and (d) accompanies the waste shipment.

[(d) The transporter may not add additional information to the generator's or designated facility's portions of the manifest or alter the generator's information on a manifest as it existed when the generator signed the manifest.

(e) (c) A transporter who delivers [infectious] regulated medical or chemotherapeutic waste or processed recognizable waste to the designated processing or disposal facility shall create a log or shipping paper containing the following information:

(1) [Obtain on the manifest the date of delivery, the printed or typed name and handwritten signature of the owner or operator of the designated facility.] The date that each container of waste was delivered to a designated facility.

(2) [Retain copy 3 of the manifest according to the instructions supplied with the manifest.] The name and address of the designated facility for each container of waste.

[(3) Give the remaining copies of the manifest to the owner or operator of the designated facility.

(f) (d) The transporter who delivers [infectious] regulated medical or chemotherapeutic waste to another transporter shall create a log or shipping paper containing the following information:

(1) [Obtain the following information on the original manifest and on an additional copy of the manifest provided by the generator:

(i) The date [of delivery] that each container of waste was delivered to the subsequent transporter.

[(ii) (2) The [printed or typed] name and address of the subsequent transporter [and his handwritten signature] that received each container of waste.

[(2) Retain the additional copy signed by the subsequent transporter.

(3) Give the remaining additional copies of the manifest to the subsequent transporter.]

(e) At the time the waste is delivered to the designated facility, the transporter shall provide the operator of the designated facility with a log or shipping paper containing the following information:

(1) The name, mailing address and telephone number of the generator for each container of waste.

**(2) The number of containers, types of containers and the total quantity of the waste by weight or volume for each generator.**

**(f) After the waste has been transported to the designated facility, the transporter shall provide the generator with a log or shipping paper containing the following information:**

**(1) The name, mailing address and telephone number of each designated facility that received each container of the generator's waste.**

**(2) The number of containers, types of containers and the total quantity of the waste by weight or volume received by each designated facility.**

**(3) The date that each designated facility received each container of the generator's waste.**

**(4) Acknowledgment from the designated facility that it accepted each container of the generator's waste.**

**§ 284.723. [Waste delivery] (Reserved).**

**(a) The transporter shall deliver the entire quantity of infectious or chemotherapeutic waste or processed infectious or chemotherapeutic waste that is recognizable which he has accepted from a generator, a processor or a transporter to one of the following:**

**(1) The designated facility listed on the manifest by the generator.**

**(2) The next designated transporter listed on the manifest by the generator.**

**(b) If the waste cannot be delivered in accordance with subsection (a), the transporter shall do one of the following:**

**(1) Return the waste to the generator.**

**(2) Deliver the waste to the alternate facility designated by the generator on the original manifest.**

**(3) Receive from the generator another properly completed manifest designating an alternate facility from the originally designated facility before transporting the waste to the alternate facility.]**

**§ 284.724. Transportation limitations.**

**(a) A transporter may not accept or transport a shipment of [**infectious**] **regulated medical** or chemotherapeutic waste or processed [**infectious**] **regulated medical** or chemotherapeutic waste that is recognizable if:**

**(1) The waste is in containers or packaging which appear to be leaking, damaged or otherwise in violation of § [**284.415**] **284.413** or § 284.512 (relating to storage containers; and transportation of [**infectious**] **regulated medical** and chemotherapeutic waste; general provisions).**



(2) The waste is not labeled or identified as required by § ~~[284.416]~~ **284.414** (relating to marking of containers).

(3) The number and type of containers and quantity of waste to be transported do not **appear to** correspond with the number and type of containers and quantity of waste stated **[on the manifest] in the generator's log or shipping paper at the time of acceptance by the transporter.**

**[(4) Any copy of the manifest is not completed according to the manifest instructions or if information on copies of the manifest is not capable of being read.]**

(b) A transporter shall ensure that the waste shipment complies with applicable United States Department of Transportation regulations and 67 Pa. Code Part I (relating to Department of Transportation).

### FACILITY RESPONSIBILITIES

#### § 284.731. Scope.

Sections 284.732[—] and 284.734 (relating to use of ~~[manifest]~~ **LOGS AND SHIPPING PAPERS; [distribution of copies;]** and significant discrepancies) apply to ~~[owners and]~~ operators of waste processing or disposal facilities that receive ~~[infectious]~~ **regulated medical** or chemotherapeutic waste or processed ~~[infectious]~~ **regulated medical** or chemotherapeutic waste that is recognizable from offsite sources.

#### § 284.732. Use of ~~[manifest]~~ **LOGS OR SHIPPING PAPERS.**

(a) Except for waste managed in accordance with § 284.701 (relating to scope), an ~~[owner or]~~ operator of a designated facility may not accept shipments of ~~[infectious]~~ **regulated medical** or chemotherapeutic waste or processed ~~[infectious]~~ **regulated medical** or chemotherapeutic waste that is recognizable from offsite sources unless the shipment is accompanied by **[a Pennsylvania manifest in accordance with] a log or shipping paper as required by** this subchapter.

(b) The ~~[owner or]~~ operator of the designated facility shall:

(1) **[Print or type his name, and sign and date each copy of the manifest to certify that the waste covered by the manifest was received.] Examine the records of the transporter.**

(2) Note significant discrepancies in the ~~[information on the manifest]~~ **log or shipping paper of the generator and transporter**, as defined in § 284.734 (relating to significant discrepancies).

(3) **[Note the rejection in the discrepancy indication space, and sign and date the manifest in accordance with paragraph (1) if either partially or totally rejecting the waste.] Provide the transporter with a dated~~[, handwritten]~~ signature, INCLUDING, BUT NOT LIMITED TO, HANDWRITTEN, ELECTRONIC OR STAMPED SIGNATURES, from an authorized representative of the facility, acknowledging that it has accepted the waste from the transporter on that date.**

(c) The owner or operator of the designated facility may not alter or add to the information in the generator or transporter sections of the manifest form.

(d) The owner or operator of the designated facility shall ensure that information entered on the manifest is capable of being read on all copies of the manifest.]

§ 284.733. [Distribution of copies] (Reserved).

[The owner or operator of a designated facility or an authorized representative shall:

(1) Immediately upon signing the manifest to either partially or totally accept or reject the waste shipment, give the transporter copy 3 of the signed manifest.

(2) Retain copy 2 of the manifest for his records.

(3) Send copy 1 of the manifest to the generator within 14 days of the date of receipt of the waste.]

§ 284.734. Significant discrepancies.

(a) This section applies if there is a significant discrepancy in [**a manifest**] the logs or shipping papers of the generator and transporter. A discrepancy is a difference between the quantity or type of waste designated [**on the manifest**] in the log or shipping paper, and the quantity or type of waste a facility actually receives. A significant discrepancy occurs if one or more of the following apply:

\* \* \* \* \*

(2) There is a variation in piece count, for batch waste, excluding 1% variation for generator-loaded trailers.

\* \* \* \* \*

(b) If there is a significant discrepancy in [**a manifest**] the logs or shipping papers, the [**owner or**] operator shall attempt to reconcile the discrepancy before the waste is processed or disposed of at the facility or before the waste is accepted at a transfer facility. If the discrepancy is not resolved within 3 business days of receipt of the waste, the [**owner or**] operator shall immediately notify the appropriate regional office of the Department by telephone. Within 7 business days of receipt of the waste, the [**owner or**] operator shall also send a letter to the regional office describing the discrepancy and attempts to reconcile it[ **and include a legible copy of the relevant manifest**].

## CHAPTER 285. STORAGE, COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE

### ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE

285.131. Storage and containment of ash residue from municipal waste incineration, including from [**infectious**] regulated medical or chemotherapeutic waste incineration.

285.132. [Reserved].

285.133. [Reserved].

285.134. Storage of sewage sludge in piles.

### ADDITIONAL REQUIREMENTS FOR [**INFECTIOUS**] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

285.141—285.145. [Reserved].  
285.146. [Reserved].  
285.147. [Reserved].  
285.148. [Reserved].

**Subchapter A. STORAGE OF MUNICIPAL WASTE**

**ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE**

**§ 285.131. Storage and containment of ash residue from municipal waste incineration, including from [infectious] regulated medical or chemotherapeutic waste incineration.**

(a) Ash residue from municipal waste incineration, including from [infectious] regulated medical or chemotherapeutic waste incineration, shall be stored in accordance with the following:

\* \* \* \* \*

(b) Ash residue from an [infectious] regulated medical or chemotherapeutic waste incinerator may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

**ADDITIONAL REQUIREMENTS FOR [INFECTIOUS] REGULATED MEDICAL AND  
CHEMOTHERAPEUTIC WASTE**

**§§ 285.141—285.145. (Reserved).**

**Subchapter B. COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE**

**GENERAL PROVISIONS**

**§ 285.218. Signs on vehicles.**

A vehicle or conveyance that is ordinarily or primarily used for the transportation of solid waste shall bear a sign that meets the following:

\* \* \* \* \*

(2) The sign shall include the specific type of solid waste transported by the vehicle or conveyance.

(i) [Infectious] Regulated medical or chemotherapeutic waste shall be designated: [Infectious] Regulated Medical/Chemotherapeutic Waste.

\* \* \* \* \*

**TYPES OF WASTE**

**§ 285.221. Transportation of ash residue from municipal waste incineration and from [infectious] regulated medical or chemotherapeutic waste incineration.**

(a) Ash residue from municipal waste incineration and from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be wetted immediately prior to loading, and shall remain wetted during transportation and unloading at a municipal waste landfill, to prevent the dispersal of ash residue.

(b) Ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.

(c) A transporter shall transport separately each generator’s ash residue from **[infectious] regulated medical** or chemotherapeutic waste.

(d) A transporter may transport ash residue from **[an infectious] a regulated medical** or chemotherapeutic waste incinerator that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator’s waste.

**ARTICLE IX. RESIDUAL WASTE MANAGEMENT**

**CHAPTER 287. RESIDUAL WASTE MANAGEMENT—GENERAL PROVISIONS**

**Subchapter A. GENERAL**

**§ 287.1. Definitions.**

The following words and terms, when used in this article, have the following meanings, unless the context clearly indicates otherwise:

\* \* \* \* \*

*Special handling waste*—Solid waste that requires the application of special storage, collection, transportation, processing or disposal techniques due to the quantity of material generated or its unique physical, chemical or biological characteristics. The term includes dredged material, sewage sludge, **[infectious] regulated medical** waste, chemotherapeutic waste, ash residue from a solid waste incineration facility, friable asbestos-containing waste, PCB-containing waste, waste oil that is not hazardous waste, fuel contaminated soil, waste tires and water supply treatment plant sludges.

\* \* \* \* \*

**§ 287.2. Scope.**

\* \* \* \* \*

(b) Management of the following types of residual waste is subject to Article VIII (relating to municipal waste) instead of this article, and shall be regulated as if the waste is municipal waste regardless of whether the waste is a municipal waste or residual waste:

\* \* \* \* \*

(2) **[Infectious] Regulated medical** and chemotherapeutic waste. The terms shall have the same meaning for residual waste as set forth in § 271.1.

\* \* \* \* \*

**CHAPTER 288. RESIDUAL WASTE LANDFILLS**

**Subchapter D. ADDITIONAL REQUIREMENTS FOR CLASS I RESIDUAL WASTE LANDFILLS**

**ADDITIONAL OPERATING REQUIREMENTS—GENERAL**

**§ 288.423. Minimum requirements for acceptable waste.**

\* \* \* \* \*

(b) A person or municipality may not dispose of municipal waste or special handling waste at a Class I residual waste landfill, except that the Department may, in the permit, approve the storage or disposal of the following types of waste generated by the operator:

\* \* \* \* \*

(2) Special handling waste, other than sewage sludge, **[infectious] regulated medical** or chemotherapeutic waste, waste oil or ash residue from the incineration of municipal waste.

\* \* \* \* \*

**CHAPTER 299. STORAGE AND TRANSPORTATION OF RESIDUAL WASTE**

**Subchapter B. STANDARDS FOR COLLECTING AND TRANSPORTING OF RESIDUAL WASTE**

**GENERAL PROVISIONS**

**§ 299.220. Signs on vehicles.**

A vehicle or conveyance that is ordinarily or primarily used for the transportation of solid waste shall bear a sign that meets the following:

\* \* \* \* \*

(2) The sign shall include the specific type of solid waste transported by the vehicle or conveyance.

(i) ~~[Infectious or chemotherapeutic waste shall be designated: Infectious/Chemotherapeutic waste.~~

~~(ii)~~ Other municipal waste shall be designated: Municipal Waste.

~~(iii)~~ ~~(ii)~~ Residual waste shall be designated: Residual Waste.

~~(iv)~~ ~~(iii)~~ Mixed municipal and residual waste shall be designated: Municipal/ Residual Waste.

\* \* \* \* \*