

**CHAPTER 284. INFECTIOUS AND CHEMOTHERAPEUTIC WASTE**

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**Authority**

The provisions of this Chapter 284 issued under section 105(a) of the Solid Waste Management Act (35 P. S. § 6018.105(a)); sections 5(b) and 402 of The Clean Streams Law (35 P. S. §§ 691.5(b) and 691.402); section 302 of the Municipal Waste Planning, Recycling and Waste Reduction Act (53 P. S. § 4000.302); section 104(a) of the Land Recycling and Environmental Remediation Standards Act (35 P. S. § 6026.104(a)); sections 2(b) and 4(b) of the Infectious and Chemotherapeutic Waste Law (35 P. S. §§ 6019.2(b) and 6019.4(b)); sections 1905-A, 1917-A, 1920-A and 1937-A of The Administrative Code of 1929 (71 P. S. §§ 510-5, 510-17, 510-20 and 510-37); section 207 of the Small Business and Household Pollution Prevention Program Act (35 P. S. § 6029.207); section 15(a) of the act of November 26, 1997 (P. L. 530, No. 57); Environmental Stewardship and Watershed Protection Act, 27 Pa.C.S. § 6105(g); and sections 301 and 302 of the Radiation Protection Act (35 P. S. §§ 7110.301 and 7110.302), unless otherwise noted.

**Source**

The provisions of this Chapter 284 adopted and renumbered December 22, 2000, effective December 23, 2000, 30 Pa.B. 6685, unless otherwise noted.

**Cross References**

This chapter cited in 25 Pa. Code § 252.3 (relating to scope); 25 Pa. Code § 266b.11 (relating to waste management for universal waste mercury-containing devices); and 25 Pa. Code § 271.2 (relating to scope).

**Subchapter A. GENERAL PROVISIONS**

**GENERAL PROVISIONS**

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**GENERAL PROVISIONS**

**§ 284.1. Scope.**

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

**§ 284.2. Permit-by-rule for infectious 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.

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

(1) The generator may 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 waste.

(2) The generator shall comply with the manifest requirements in § 284.701(b)(5) (relating to scope).

(c) The following requirements shall be met by facilities identified in subsections (a) 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).

- (2) The facility has necessary permits under the environmental protection acts, and is operating in accordance with the environmental protection acts and the regulations promulgated thereunder, the terms and conditions of permits and orders of the Department.
- (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 waste generated at the facility, including waste handling, equipment operation and maintenance, processing method, disinfection monitoring procedures including quality assurance procedures, and a description of how noninfectious waste is managed to prevent commingling.
  - (ii) For processing facilities subject to a permit-by-rule, daily records of the weight or volume of the waste that is processed, the method and location of disposal facilities for wastes from the processing facility, and waste handling problems and emergencies.
- (4) Processing does not have an adverse effect on public health, safety, welfare or the environment.
- (5) The waste is disinfected in accordance with § 284.321 (relating to infectious waste monitoring requirements).
- (6) Disinfection occurs before or during processing of the waste.
- (7) A log is maintained for each disinfection unit and is made available to the Department upon request. The log shall record the following:
  - (i) The date, time and operator for each use.
  - (ii) The dates and results of calibration.
  - (iii) The postdisinfection color reading of temperature sensitive tape and the results of biological indicator spore testing, in accordance with § 284.321 for steam disinfection facilities.
  - (iv) Results of ash testing which utilizes a methodology approved by the Department, for incineration facilities.
- (8) Remaining waste is managed in accordance with the act and the regulations promulgated thereunder. For onsite autoclave facilities which do not render the waste unrecognizable, the processing residue shall be manifested in accordance with Subchapter H (relating to manifesting for infectious and chemotherapeutic waste).
- (9) For incineration facilities, an air quality permit shall be obtained 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.

(e) Notwithstanding a provision in this section to the contrary, a facility will not be deemed to have a permit-by-rule if it causes or allows violations of the environmental protection acts, the regulations promulgated thereunder, the terms or conditions of a permit issued by the Department, or an order issued by the Department, or causes a public nuisance. A facility that is subject to permit-by-rule is not required to apply for a permit under this article, if that facility operates in accordance with this section.

(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 relate to bonding and insurance are waived for facilities which are deemed to have a permit under this section.

## **Subchapter B. GENERAL PERMITS**

### **GENERAL**

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**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 waste processing facilities or stationary chemotherapeutic waste processing facilities if the Department determines the following:

(1) The processing facilities and the waste to be processed in the category are substantially similar.

(2) The processing facilities in the category can be adequately regulated utilizing standard conditions without harming or presenting a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.

(3) The processing facilities in the category will comply with the requirements established in the permit and with the standards and requirements for design, construction, operation, maintenance and monitoring in Chapter 283 (relating to resource recovery and other processing facilities) and Subchapter D (relating to processing facilities).

(b) The Department may issue a general permit upon its own motion under § 284.115 (relating to Department-initiated general permits) or upon an application from a person or municipality under §§ 284.111—284.114.

(c) The Department may issue a general permit for the mixing of disinfection products with infectious 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 or residual wastes.

(e) The Department may modify, suspend, revoke or reissue general permits under this subchapter as it deems necessary to prevent harm or the threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.

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

**Cross References**

This section cited in 25 Pa. Code § 284.114 (relating to approval or denial of an application); 25 Pa. Code § 284.115 (relating to Department-initiated general permits); and 25 Pa. Code § 284.121 (relating to contents of general permits).

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

(a) When the Department issues a general permit for an infectious or chemotherapeutic waste processing facility on either a regional or Statewide basis, persons or municipalities who intend to process infectious 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:

(1) The processing activities are conducted in accordance with the terms and conditions of the applicable general permit.

(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 when the person or municipality is not in compliance with the conditions of the 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.

**Cross References**

This section cited in 25 Pa. Code § 284.114 (relating to approval or denial of an application).

**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 or chemotherapeutic waste.

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

(1) A description of the waste.

(2) A characterization of the waste as either infectious or chemotherapeutic.

(3) An operation plan which contains the following:

(i) A description of the proposed processing activity and equipment.

- (ii) A description of the method proposed to receive infectious 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.
  - (iii) A description of the procedure for managing containers which arrive in a leaking condition, which includes whether the waste is processed immediately, repacked or rejected.
  - (iv) A description of the method proposed to unload and process infectious or chemotherapeutic waste, limiting the number of persons handling the waste and minimizing the possibility of exposure of that waste to employees and the public using or visiting the facility.
  - (v) A description of the method proposed for disinfecting emptied, reusable infectious waste containers, transport vehicles and facility equipment which are known or suspected to be contaminated with infectious waste.
  - (vi) A description of the method proposed for handling and disposal of infectious or chemotherapeutic waste containers which cannot be reused.
  - (vii) A description of reuse of containers if the surfaces of the containers have been protected from direct contact with chemotherapeutic waste.
  - (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 against exposure to infectious 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 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 or chemotherapeutic waste to be stored and processed each month.
  - (xi) A schedule of the operating hours of the facility.
  - (xii) A description of the method proposed to assure that infectious or chemotherapeutic waste received at the facility is consistent with § 283.201 (relating to basic limitations).
  - (xiii) A description of periodic testing using biological indicators which demonstrate effective disinfection of the waste, in accordance with § 284.321 (relating to infectious waste monitoring requirements).
  - (xiv) A description of closure activities which are proposed to be carried out upon cessation of operations, in accordance with § 283.272 (relating to cessation of operations).
  - (xv) A description of how the processing residue will be managed.
  - (xvi) A description of how aerosols will be minimized and controlled during processing activities.
- (4) A contingency plan which provides procedures to be used for emergency situations including, at a minimum, spills of infectious or chemotherapeutic waste.

peutic 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 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 or chemotherapeutic waste. The plan shall include a detailed explanation of the operation and contingency plans.

(c) A nonrefundable fee in the form of a check payable to the "Commonwealth of Pennsylvania" for \$1,000 shall accompany the application.

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

#### **Cross References**

This section cited in 25 Pa. Code § 284.101 (relating to authorization for general permits); and 25 Pa. Code § 284.114 (relating to approval or denial of an application).

#### **§ 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.

(b) If the application is not administratively complete, the Department will return it to the applicant, within 60 days of receipt of the application. A written statement of the specific analyses, fees, documents or information that are required to make the application administratively complete will accompany an application which is returned.

(c) The Department will deny the application if the applicant fails to provide the analyses, fees, documents and information within 90 days of receipt of the notice in subsection (b).

#### **Cross References**

This section cited in 25 Pa. Code § 284.101 (relating to authorization for general permits); and 25 Pa. Code § 284.114 (relating to approval or denial of an application).

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

(a) The Department will publish notice of receipt of an application for a general permit in the *Pennsylvania Bulletin* when the Department determines that the application is administratively complete.

(b) The notice shall include:

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

(2) The Department's address and telephone number at which interested persons or municipalities may obtain further information and review a copy of the application for the general permit.

(3) A brief description of the procedures for public comment on the general permit application.

(4) A statement that interested persons or municipalities may submit comments to the Department within 60 days of the publication of the notice, and may recommend conditions upon, revisions to, approval or disapproval of the general permit application.

(c) The Department may hold a public meeting or public hearing on the application for a general permit.

(d) Upon issuance of a general permit, the Department will place a notice in the *Pennsylvania Bulletin* of the availability of the general permit. If a county has made recommendations to the Department concerning conditions, revisions or disapproval of the permit during the 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*.

(e) Each applicant for coverage under the general permit shall provide written notice to each municipality in which the applicant intends to operate under a general permit.

**Cross References**

This section cited in 25 Pa. Code § 284.101 (relating to authorization for general permits); and 25 Pa. Code § 284.114 (relating to approval or denial of an application).

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

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

(1) The application for the general permit is accurate and complete.

(2) The applicant has complied with the requirements of §§ 284.101, 284.102 and 284.111—284.113.

(3) The proposed processing activities will be conducted in a manner that will not harm or present a threat of harm to the health, safety or welfare of the

people or environment of this Commonwealth through exposure to constituents of the waste during the processing activities and afterwards.

#### Cross References

This section cited in 25 Pa. Code § 284.101 (relating to authorization for general permits).

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

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

(b) At least 60 days prior to the issuance or modification of a general permit under this section, the Department will publish a notice in the *Pennsylvania Bulletin* of intent to issue or modify a general permit under 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 or chemotherapeutic waste eligible for coverage under the proposed general permit.

(2) The standards in § 284.101(a) (relating to authorization for general permits), and a brief description of the reasons for the Department's determination that the category of processing is eligible for coverage under a general permit in accordance with these standards.

(3) A brief description of the terms and conditions of the proposed general permit.

(4) A brief description of the procedures for public comment on the general permit in accordance with this subchapter.

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

(6) A statement that interested persons or municipalities may submit comments to the Department within 60 days of the publication of the notice and may recommend conditions upon, revisions to, and approval or disapproval of the proposed general permit.

(d) The Department may hold a public meeting or public hearing on the proposed general permit or proposed modification to the general permit.

(e) Upon issuance or modification of a general permit, the Department will place a notice in the *Pennsylvania Bulletin* of the availability of the new or modified general permit.

#### Cross References

This section cited in 25 Pa. Code § 284.101 (relating to authorization for general permits).

**CONTENT OF GENERAL PERMITS AND WAIVERS****§ 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 or chemotherapeutic waste eligible for coverage under the general permit.

(2) The standards in § 284.101(a) (relating to authorization for general permits) and a brief explanation of the reasons for the Department's determination that the category of processing is eligible for coverage under the general permit in accordance with the standards in § 284.101(a).

(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.

(4) An effective date, and a fixed permit term, which may not exceed 10 years from the effective date. If the Department renews a general permit, the term may not exceed the term of the original permit.

(5) A set of terms and conditions governing the construction, operation, maintenance, inspection and monitoring of the processing activities covered by the general permit as are necessary to assure compliance with this act, this article and the environmental protection acts.

(6) A requirement that persons or municipalities who conduct activities authorized by the general permit shall allow authorized representatives of the Commonwealth, without advance notice or a search warrant, upon the presentation of appropriate credentials, and without delay, to have access to areas in which the activities covered by the general permit will be, are being or have been conducted to ensure compliance with the act and 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 promulgated thereunder and a permit, license or order issued by the Department under the act.

(7) A requirement that the activities authorized by the general permit will not harm or present a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.

(8) A requirement that waste be accompanied by a properly completed manifest, in accordance with Subchapter H (relating to manifesting for infectious 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 and chemotherapeutic waste), when appropriate.

(10) A requirement that the processing facility operate in accordance with local, State and Federal requirements.

(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.

(12) A requirement that an up-to-date list of names, addresses and telephone numbers of employes 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 employe training records be maintained at the processing facility.

(14) A requirement for use of additional indicators selected by the Department to monitor the disinfection process.

(15) A requirement that daily records of the weight or volume of the waste processed, the method and location of disposal facilities for wastes from the processing facility and waste handling problems and emergencies be maintained for 3 years.

(16) A requirement that a log be maintained for each disinfection unit for 3 years that records the following:

- (i) The date, time and operator for each use.
- (ii) The dates and results of calibration.
- (iii) The results of biological indicator spore testing.
- (iv) Other information that the Department may require relating to the disinfection process.

(17) Requirements for closure.

(18) A requirement that autoclaves meet the following:

- (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 of certain requirements.**

(a) An operation that is approved under this subchapter does not require an individual processing or disposal permit under this article.

(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 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 include:
- (1) The name, address and location of the person or municipality conducting the activity covered under the general permit.
  - (2) A description of the waste, including a characterization of the waste as either infectious or chemotherapeutic, that will be processed in accordance with the general permit.
  - (3) A description of the proposed method of processing of the waste.
  - (4) The name or number of the general permit being utilized for the activity.
  - (5) A demonstration that the activities which the person or municipality intends to conduct are authorized by 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 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.

#### Cross References

This section cited in 25 Pa. Code § 284.121 (relating to contents of general permits); 25 Pa. Code § 284.132 (relating to determination of applicability); and 25 Pa. Code § 284.133 (relating to registration).

#### § 284.132. Determination of applicability.

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.

**Cross References**

This section cited in 25 Pa. Code § 284.102 (relating to nature of a general permit; substitution for individual applications and permits); and 25 Pa. Code § 284.112 (relating to completeness review).

**§ 284.133. Registration.**

(a) When a general permit specifies that potential users are required to register with the Department prior to operating under the general permit, the procedures in this section shall be followed in addition to those in § 284.131 (relating to authorization for persons or municipalities to be included in a general permit).

(1) A registration to operate under a general permit shall be accompanied by a nonrefundable fee in the form of a check payable to the “Commonwealth of Pennsylvania” for \$250.

(2) The Department will publish notice of each registration to operate under a general permit in the *Pennsylvania Bulletin*. The registrant under a general permit shall provide written notice to each municipality in which the registrant intends to operate under the general permit.

(b) Persons or municipalities may conditionally operate under a general permit in accordance with the terms of the general permit immediately upon registering with the Department.

(c) Upon the request of the Department, a person or municipality shall provide sufficient information to demonstrate to the satisfaction of the Department that the person or municipality is authorized to operate under the general permit. The Department may refuse to issue or approve a registration if the person or municipality has failed to demonstrate that the person or municipality is in conformance with the general permit.

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

**Cross References**

This section cited in 25 Pa. Code § 284.102 (relating to nature of a general permit; substitution for individual applications and permits).

**Subchapter C. TRANSFER FACILITIES**

Sec.  
284.201. Scope.  
284.210. Application requirements.  
284.220. Operating requirements.

**§ 284.201. Scope.**

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

**§ 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.

**Subchapter D. PROCESSING FACILITIES**

Sec.

284.301. Scope.

284.310. Application requirements.

284.311. Plan for monitoring.

284.320. Operating requirements.

284.321. Infectious waste monitoring requirements.

**Cross References**

This subchapter cited in 25 Pa. Code § 284.101 (relating to authorization for general permits).

**§ 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 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).

**§ 284.310. Application requirements.**

An application to operate a processing facility shall comply with §§ 283.101—283.114 (relating to general provisions).

**§ 284.311. Plan for monitoring.**

An application for a processing facility for infectious 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 waste monitoring requirements), including the following:

- (1) The method by which disinfection will be accomplished.
- (2) A description of the monitoring and quality assurance program to ensure disinfection.

**§ 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.

**Source**

The provisions of this § 284.320 corrected July 20, 2001, effective March 3, 2001, 31 Pa.B. 3942. Immediately preceding text appears at serial page (273305).

**§ 284.321. Infectious waste monitoring requirements.**

- (a) A person or municipality that disinfects infectious waste shall monitor the waste to ensure the following:
  - (1) For thermal processing or incineration, the absence of anaerobic or aerobic bacterial growth in a composite sample of processing residue or ash.
  - (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. stearothermophilus* spores, *B. pumilus* or *B. subtilis* spores at a 4 log 10 reduction or greater.
- (b) The operator of a facility that incinerates or thermally processes infectious 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 during the life of the facility.
- (c) The operator of a facility that incinerates infectious 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 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 stearothermophilus*.
  - (2) For dry heat, gas or chemical disinfection, spores of *Bacillus subtilis* variety *niger* (*globigii*). Ethylene oxide may not be used for gas disinfection.
  - (3) For ionizing radiation, spores of *Bacillus pumilus*.

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

(g) Infectious waste will be considered to be infectious after disinfection, unless one of the following has occurred:

(1) For disinfection processes other than incineration or thermal processing, the indicator spores are determined by microbiological analysis to have been destroyed in accordance with subsection (a).

(2) For incineration or thermal processing using a test other than an indicator spore, a microbiological analysis determines that disinfection has occurred in accordance with subsection (a).

(h) The operator of the disinfection facility shall so certify that the requirements of subsection (a) have been met on a form provided by the Department.

(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 or chemotherapeutic waste incineration; and storage and containment of processing residue from an infectious or chemotherapeutic waste 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 or chemotherapeutic waste incineration; and transportation of processing residue from an infectious or chemotherapeutic waste facility).

(k) Compactors, grinders or similar devices may not be used to reduce the volume of infectious 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 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:

(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.

#### **Cross References**

This section cited in 25 Pa. Code § 271.1 (relating to definitions); 25 Pa. Code § 273.511 (relating to processed infectious waste disposal); 25 Pa. Code § 284.2 (relating to permit-by-rule for infectious or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); 25 Pa. Code § 284.111 (relating to application for general permit); and 25 Pa. Code § 284.311 (relating to plan for monitoring).

**Subchapter E. STORAGE**

Sec.

- 284.401. Scope.
- 284.411. Basic storage requirements.
- 284.412. Sorting.
- 284.413. Duration of storage of infectious waste for generators.
- 284.414. Duration of storage of infectious waste for processors.
- 284.415. Storage containers.
- 284.416. Marking of containers.
- 284.417. Reuse of containers.
- 284.418. Storage and containment of ash residue from infectious or chemotherapeutic waste incineration.
- 284.419. Storage and containment of processing residue from an infectious or chemotherapeutic waste processing facility.

**Cross References**

This subchapter cited in 25 Pa. Code § 284.2 (relating to permit-by-rule for infectious or chemotherapeutic waste processing facilities; qualifying facilities; general requirements).

**§ 284.401. Scope.**

This subchapter sets forth operating requirements for a person or municipality that stores infectious or chemotherapeutic waste, ash residue from infectious or chemotherapeutic waste incineration and processing residue from an infectious 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.**

- (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.

#### Cross References

This section cited in 25 Pa. Code § 284.413 (relating to duration of storage of infectious waste for generators).

#### § 284.412. Sorting.

- (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.

**§ 284.413. Duration of storage of infectious waste for generators.**

(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).

**Cross References**

This section cited in 25 Pa. Code § 284.412 (relating to sorting).

**§ 284.414. Duration of storage of infectious waste for processors.**

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  $\leq -18^{\circ}\text{C}$ .

**§ 284.415. Storage containers.**

(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.

**Cross References**

This section cited in 25 Pa. Code § 284.412 (relating to sorting); 25 Pa. Code § 284.512 (relating to transportation of infectious and chemotherapeutic waste; general provisions); 25 Pa. Code § 284.513 (relating to transportation of infectious and chemotherapeutic waste; additional provisions); and 25 Pa. Code § 284.724 (relating to transportation limitations).

**§ 284.416. Marking of containers.**

(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.

**Cross References**

This section cited in 25 Pa. Code § 284.415 (relating to storage containers); and 25 Pa. Code § 284.724 (relating to transportation limitations).

**§ 284.417. Reuse of containers.**

(a) Nonrigid containers shall be managed as either infectious 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 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 waste may be reused if one of the following applies:

(1) The container has been decontaminated utilizing a Department-approved decontamination procedure.

(2) The surface of the container has been protected from direct contact with infectious waste.

(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 or chemotherapeutic waste incineration.**

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

(1) In an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building.

(2) On a pad that is no more permeable than  $1 \times 10^{-7}$  cm./sec.

(3) To prevent the release, dispersal or discharge of ash residue into the air, water or onto land.

(b) Ash residue 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).

**Cross References**

This section cited in 25 Pa. Code § 284.321 (relating to infectious waste monitoring requirements).

**§ 284.419. Storage and containment of processing residue from an infectious or chemotherapeutic waste processing facility.**

(a) Processing residue from infectious 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:

(1) Prevent the release, dispersal or discharge of processing residue into the air, water or onto land.

(2) Afford protection from animals, rain and wind.

(3) Prevent the development of a breeding place or food source for insects or rodents.

(4) Prevent the leakage of waste from the storage container.

(b) Processing residue from an infectious 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).

#### **Cross References**

This section cited in 25 Pa. Code § 284.321 (relating to infectious waste monitoring requirements).

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

#### **GENERAL**

Sec.

284.501. Scope.

#### **TYPES OF WASTE**

- 284.511. Transportation of ash residue from infectious or chemotherapeutic waste incineration.
- 284.512. Transportation of infectious and chemotherapeutic waste; general provisions.
- 284.513. Transportation of infectious and chemotherapeutic waste; additional provisions.
- 284.514. Transportation of processing residue from an infectious or chemotherapeutic waste facility.

#### **Cross References**

This subchapter cited in 25 Pa. Code § 284.2 (relating to permit-by-rule for infectious or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); and 25 Pa. Code § 284.631 (relating to basic limitations).

#### **GENERAL**

#### **§ 284.501. Scope.**

This subchapter sets forth the requirements for a person or municipality that collects and transports infectious or chemotherapeutic waste, ash residue from infectious or chemotherapeutic waste incineration and processing residue from an infectious 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 or chemotherapeutic waste incineration.**

(a) Ash residue from infectious 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 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.

(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.

**Cross References**

This section cited in 25 Pa. Code § 284.321 (relating to infectious waste monitoring requirements).

**§ 284.512. Transportation of infectious and chemotherapeutic waste; general provisions.**

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

(b) *Manner of transportation.* Infectious and chemotherapeutic waste shall be transported 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.

(c) *Containers.*

(1) Infectious and chemotherapeutic waste shall be transported in containers that are:

- (i) Rigid.
  - (ii) Leakproof.
  - (iii) Impervious to moisture.
  - (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.
- (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 of paragraph (1), infectious waste fluids—quantities greater than 20 cubic centimeters—and chemotherapeutic waste fluids shall be transported in containers that are:
- (i) Break resistant.
  - (ii) Tightly lidded or tightly stoppered.
- (4) Bags meeting the requirements of § 284.415 (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) Vehicles for transporting infectious or chemotherapeutic waste shall be noncompaction type vehicles.
- (f) Load compartments of vehicles holding infectious 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 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) Infectious waste may not be kept in an unrefrigerated transport vehicle for more than 48 hours. If the vehicle is refrigerated ( $\leq 7^{\circ}\text{C}$ ) or maintained at freezing temperatures ( $\leq -18^{\circ}\text{C}$ ), the in-transit storage period may not exceed 5 days.
- (h) Chutes may not be used by generators, processors or transporters to transfer infectious or chemotherapeutic waste at onsite or offsite locations.

#### Cross References

This section cited in 25 Pa. Code § 284.724 (relating to transportation limitations); and 25 Pa. Code § 285.201 (relating to scope).

**§ 284.513. Transportation of infectious and chemotherapeutic waste; additional provisions.**

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

(b) Vehicles for transporting infectious 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 and chemotherapeutic waste license number, if applicable.

(2) A placard or decal containing the phrase "infectious waste" or "chemotherapeutic waste," or both, 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). The placard or decal shall be capable of being read at a distance of 25 feet.

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

(1) An adequate amount of absorbent material.

(2) One gallon of hospital grade 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 (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.

(4) Two sets of protective overalls, gloves, boots, caps, goggles and masks. The protective garments shall be oversized or fitted for the vehicle operators.

(5) A first aid kit, boundary marking tape and other appropriate safety equipment.

(d) The surface of vehicles that have not been in direct physical contact with infectious 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.

**Cross References**

This section cited in 25 Pa. Code § 284.512 (relating to transportation of infectious and chemotherapeutic waste; general provisions).

**§ 284.514. Transportation of processing residue from an infectious or chemotherapeutic waste facility.**

(a) Processing residue from an infectious 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 or chemotherapeutic waste.

(c) A transporter may transport processing residue from infectious 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.

**Cross References**

This section cited in 25 Pa. Code § 284.321 (relating to infectious waste monitoring requirements).

**Subchapter G. TRANSPORTER LICENSING FOR INFECTIOUS AND CHEMOTHERAPEUTIC WASTE****GENERAL PROVISIONS**

- Sec.  
284.601. Scope.  
284.602. License requirement.  
284.603. Identification number.

**LICENSE APPLICATION REQUIREMENTS**

- 284.611. General application requirements.  
284.612. Vehicular liability insurance.

**LICENSE APPLICATION REVIEW**

- 284.621. Criteria for license issuance or denial  
284.622. Term of license.  
284.623. Conditions of licenses.  
284.624. License renewal.  
284.625. Public notice.

**OPERATIONAL REQUIREMENTS**

- 284.631. Basic limitations.
- 284.632. Infectious or chemotherapeutic waste discharges or spills.
- 284.633. Safety.
- 284.634. Annual report.

**BOND**

- 284.641. Bond requirements.
- 284.642. Release of bond.
- 284.643. Bond forfeiture.
- 284.644. Replacement of existing bond.
- 284.645. Preservation of remedies.

**Cross References**

This subchapter cited in 25 Pa. Code § 284.121 (relating to contents of general permits).

**GENERAL PROVISIONS****§ 284.601. Scope.**

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

**§ 284.602. License requirement.**

(a) Except as provided in subsection (b), a person or municipality may not transport infectious 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 or chemotherapeutic waste by generators.

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

(3) Transportation by a generator of less than 220 pounds per month of infectious or chemotherapeutic waste when transporting only the infectious or chemotherapeutic waste he generated if the manifesting requirements under § 284.701(b)(3) (relating to scope) are met.

(4) The transportation of infectious 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 or chemotherapeutic waste without first receiving an identification number. The number shall be one of the following:

- (1) An EPA identification number obtained under section 3010 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. § 6930).
- (2) An identification number obtained from the Department, if the identification number under paragraph (1) is not available.

**Cross References**

This section cited in 25 Pa. Code § 284.611 (relating to general application requirements).

**LICENSE APPLICATION REQUIREMENTS****§ 284.611. General application requirements.**

(a) An application for a license to transport infectious 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:

- (1) The applicant's identification number, as required by § 284.603 (relating to identification number).
- (2) The name, mailing address, place of business, business telephone number and 24-hour emergency telephone number of the applicant.
- (3) The average yearly total tonnage of infectious and chemotherapeutic waste picked up or delivered in this Commonwealth.
- (4) A nonrefundable application fee in the form of a check payable to the "Commonwealth of Pennsylvania" for \$500.
- (5) Information concerning terminal locations that will store infectious and chemotherapeutic waste in-transit.
- (6) An identification of interests and compliance history, as provided in §§ 271.124 and 271.125 (relating to identification of interests; and compliance information).
- (7) Collateral bond, as required by § 284.641 (relating to bond requirement).
- (8) Certificate of insurance, as required by § 284.612 (relating to vehicular liability insurance).
- (9) A contingency plan consistent with § 284.632 (relating to infectious or chemotherapeutic waste discharges or spills).

(c) An application for a license shall be certified by a responsible official of the applicant with a statement that the information contained in the application is true and correct to the best of the official's information and belief.

**§ 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 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 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.

(c) Insurance coverage provided under this section shall comply with the following:

(1) The insurance policy shall follow the standard commercial or comprehensive vehicular liability policy forms approved by the Insurance Department, and shall include coverage as specified in subsections (a) and (b).

(2) The insurance policy shall be issued by an insurer having a certificate of authority and a licensed agent authorized to transact the business of insurance in this Commonwealth by the Insurance Department. Insurance may be provided by an excess or surplus lines insurer approved by the Insurance Department.

(3) The full policy amount shall be applicable to each driver and vehicle authorized to operate under the license. There may be no proration of the policy amount of coverage among vehicles.

(4) The insurance policy shall provide that the insurer shall notify the Department by certified mail within 30 days whenever a substantive change is made in the policy, including policy amounts, scope of coverage, tail period, claims procedures, definitions of occurrences or claims or other provisions related to the requirements of this subchapter.

(d) The licensee shall maintain the insurance required by this section in full force and effect during the term of the license and renewals thereof.

(e) An applicant for a transporter license to transport infectious 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:

- (1) Commercial insurance as specified in this section.
- (2) Self-insurance allowed by Federal or State law.
- (3) Additional means approved by the Department.

(f) The amount of liability coverage for departments or agencies of the Commonwealth may not exceed the liability limits of 42 Pa.C.S. Chapter 85 (relating to matters affecting government units).

**Cross References**

This section cited in 25 Pa. Code § 284.611 (relating to general application requirements).

**LICENSE APPLICATION REVIEW**

**§ 284.621. Criteria for license issuance or denial.**

(a) A license application will not be approved unless the applicant affirmatively demonstrates to the Department's satisfaction that the following conditions are met:

(1) The license application is complete and accurate.

(2) The requirements of the act, the environmental protection acts and this title have been complied with.

(3) The compliance status of the applicant or a related party under section 503(c) and (d) of the act (35 P. S. § 6018.503(c) and (d)) does not require or allow license denial.

(b) The Department will deny a license application if the applicant fails to provide the Department with a bond consistent with this subchapter or fails to provide other required information within 120 days after the Department's written request.

**§ 284.622. Term of license.**

A license granted or renewed under this subchapter is valid for 2 years unless the Department determines that circumstances justify issuing a license for less than 2 years. The expiration date will be set forth in the license.

**Cross References**

This section cited in 25 Pa. Code § 284.624 (relating to license renewal).

**§ 284.623. Conditions of licenses.**

(a) The Department may place terms and conditions upon a license it deems necessary to protect public health, public safety and the environment, and to ensure compliance with the act, the environmental protection acts and this title.

(b) Except to the extent that the license states otherwise, the licensee shall conduct transportation activities as described in the approved application.

(c) A license to transport infectious and chemotherapeutic waste is nontransferable and nonassignable. A license applies to the licensee and its employees.

Leased or subcontracted drivers, and drivers 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 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.

**§ 284.625. Public notice.**

The Department will publish notice in the *Pennsylvania Bulletin* of the following:

- (1) Receipt of an application for a license under this subchapter.
- (2) Approval or denial of a license application under this subchapter.

### OPERATIONAL REQUIREMENTS

**§ 284.631. Basic limitations.**

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

- (1) The act, this article and other applicable regulations promulgated under the act, including Subchapter F (relating to collection and transportation).
- (2) The terms and conditions of the license, the environmental protection acts, this title and orders issued by the Department.

(b) A transporter shall allow authorized representatives of the Commonwealth, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to areas in which operations will be, are being or have been conducted.

**§ 284.632. Infectious or chemotherapeutic waste discharges or spills.**

(a) A copy of the most recently approved Transporter Contingency Plan (TCP) shall be carried on each transport vehicle at all times. Information in the TCP shall be kept current.

(b) In the event of a discharge or spill of infectious 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:

- (1) The name of the person reporting the spill or discharge.
- (2) The transporter's name, address, the Department-issued infectious and chemotherapeutic waste transporter license number and identification number.
- (3) The telephone number where the person reporting the spill or discharge can be reached.
- (4) The date, time and location of the spill or discharge.
- (5) The mode of transportation and type of transport vehicle.
- (6) A brief description of the accident.
- (7) For each waste involved in the spill:
  - (i) The name and identification number of the generators of the waste.
  - (ii) The estimated quantity of the waste spilled.

(c) If a discharge or spill of infectious 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 or manifests under this subchapter.

(d) A transporter shall:

(1) Clean up an infectious 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.

(2) File a complete report in writing concerning the incident with the Department's central office. The report shall include, at a minimum, a detailed description of the clean-up operation and the disposition of the waste, and the information required by subsection (a).

#### Cross References

This section cited in 25 Pa. Code § 284.611 (relating to general application requirements); and 25 Pa. Code § 284.633 (relating to safety).

### § 284.633. Safety.

A transporter of infectious 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 or chemotherapeutic waste discharges or spills).

**§ 284.634. Annual report.**

(a) A transporter shall submit to the Department's Central Office an annual report. The report shall be submitted by the end of March of each calendar year. The report shall be submitted on forms supplied by the Department.

(b) The annual report shall be based on the shipments of infectious 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 or chemotherapeutic waste.

(2) The weight or volume of each type of infectious or chemotherapeutic waste transported.

(3) When more than one transporter is used to transport a single shipment of infectious 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 and chemotherapeutic waste transportation on the hazardous waste transporter bond.

(b) *Approval by Department.* A license to transport infectious 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.

(c) *Amount of bond.*

(1) The bond shall be in an amount sufficient to assure that the licensee faithfully performs the requirements of the act, the Infectious and Chemothera

peutic Waste Law and regulations thereunder, the terms and conditions of the license, and Department orders issued to the licensee. The minimum amount of the bond is \$10,000.

(2) The Department may require additional bond amounts if the mode of transporting waste changes, or the Department determines additional bond amounts are necessary to meet the requirements described in paragraph (1).

(d) *Term of bond.* Liability under the bond shall contain at a minimum for the duration of the license, any renewals thereof and for 1 year after expiration, termination, revocation or surrender of the license. The 1-year extended period of liability includes, and shall be automatically extended for, an additional time period during which administrative or legal proceedings are pending involving a violation by the transporter of the act, the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license or Department orders issued to the licensee.

(e) *Collateral for transporter bonds.*

(1) The Department will accept the types of collateral for transporter bonds that are provided in § 271.322 (relating to general terms and conditions for collateral bonds).

(2) The terms and conditions for the bonds shall be as provided in §§ 271.322—271.325.

(3) A department or agency of the United States or the Commonwealth applying for a transporter license to transport infectious or chemotherapeutic waste shall satisfy the requirements of this section by filing a bond with the Department under this section, or by another means of financial assurance approved by the Department which satisfies the terms and conditions for bonds under § 271.313(b) (relating to forms, terms and conditions of the bond or trust). The Department may accept a bond executed by a transporter who is not the licensee, in lieu of a bond executed by the licensee, if the liability on the bond meets the requirements of this subchapter. The transporter may not accept waste or initiate operation prior to the approval by the Department of the financial assurances required by this section.

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

#### Cross References

This section cited in 25 Pa. Code § 284.611 (relating to general application requirements).

### § 284.642. Release of bond.

(a) Except as provided in subsection (b), the Department will release a transporter bond 1 year after the expiration or termination of a license upon written request of the licensee.

(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 or chemotherapeutic waste transportation.

(c) The release of a bond by the Department does not constitute a waiver or release of other liability provided in law, nor does it abridge or alter rights of action or remedies of a person or municipality presently or prospectively existing in equity or under criminal and civil common or statutory law.

#### Cross References

This section cited in 25 Pa. Code § 284.644 (relating to replacement of existing bond).

### § 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 or chemotherapeutic waste transportation.

(b) If the Department declares a bond forfeit, it will:

(1) Send written notification to the transporter of the Department's determination to declare the bond forfeit and the reasons for the forfeiture.

(2) Advise the transporter and surety of the right to appeal to the EHB under the Environmental Hearing Board Act (35 P. S. §§ 7511—7514).

(3) Proceed to collect on the bond as provided by applicable laws for the collection of defaulted bonds or other debts.

(c) If the Department declares a transporter bond forfeited, it will pay, or direct the State Treasurer to pay, the collateral funds into the Solid Waste Abatement Fund. If upon proper demand and presentation, the banking institution or other person or municipality which issued the collateral refuses to pay the Department the proceeds of a collateral undertaking, the Department will take appropriate steps to collect the proceeds.

### § 284.644. Replacement of existing bond.

(a) The Department may allow a transporter to replace an existing collateral bond with another collateral bond, if the liability which has accrued under the bond and against the transporter is incorporated into the replacement bond. The bond amount for this replacement bond will be determined under this subchapter, but may not be less than the amount of the existing bond.

(b) The Department will not release existing bonds until the transporter has submitted and the Department has approved acceptable replacement bonds. A replacement of bonds under this section does not constitute a release of bond under § 284.642 (relating to release of bond).

**§ 284.645. Preservation of remedies.**

Remedies provided or authorized by law for violation of statutes, including, but not limited to, the act, the applicable environmental protection acts, this title and the terms and conditions of permits or licenses, and orders of the Department, are expressly preserved. Nothing in this subchapter is an exclusive penalty or remedy for the violations. No action taken under this subchapter waives or impairs another remedy or penalty provided in law or equity.

**Subchapter H. MANIFESTING FOR INFECTIOUS AND  
CHEMOTHERAPEUTIC WASTE****GENERAL**

- Sec.  
284.701. Scope.  
284.702. Transfer facilities.  
284.703. Recordkeeping.

**GENERATOR RESPONSIBILITIES**

- 284.711. Use of manifest.  
284.712. Preparation of manifest.  
284.713. Generator's distribution of copies.  
284.714. Exception reporting.

**TRANSPORTER RESPONSIBILITIES**

- 284.721. Basic requirements.  
284.722. Preparation and use of manifest.  
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**FACILITY RESPONSIBILITIES**

- 284.731. Scope.  
284.732. Use of manifest.  
284.733. Distribution of copies.  
284.734. Significant discrepancies.

**Cross References**

This subchapter cited in 25 Pa. Code § 284.2 (relating to permit-by-rule for infectious or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); and 25 Pa. Code § 284.121 (relating to contents of general permits).

**GENERAL****§ 284.701. Scope.**

(a) Except as provided in subsections (b) and (c), this subchapter applies to a person or municipality that generates, transports, disposes or processes infectious or chemotherapeutic waste or processed infectious 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 or chemotherapeutic waste by generators.

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

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

(i) The generator only transports his own waste.

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

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

(B) The quantity of the waste transported and accepted by the processing or disposal facility.

(C) The date the waste is transported and accepted by the processing or disposal facility.

(iii) The generator carries and delivers a copy of this record 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 if the following are met:

(i) The package is sent to a permitted processing or disposal facility in this Commonwealth or to an out-of-State facility by certified mail, return receipt requested, indicating the name and address of the sender, the name of the addressee, the signature of the addressee, the date of delivery and the address where delivered or by utilizing an alternate tracking system approved in writing by the Department if applicable.

- (ii) The packaging meets the requirements of the United States Postal Service or other mail carriers.
- (iii) The generator maintains a log containing the following information:
  - (A) The weight of the waste transported.
  - (B) The date of shipment.
  - (C) The name and address of each processing or disposal facility to which the generator is shipping the waste by the United States Postal Service or other mail carrier.
- (5) The transportation by a generator of less than 220 pounds per month of infectious or chemotherapeutic waste that he generates and processes onsite, but which is recognizable waste, if the following are met:
  - (i) The generator records on a log or shipping paper the following information for each shipment:
    - (A) The name, address and telephone number of the generator of the waste.
    - (B) The quantity of the waste transported and accepted by the disposal facility.
    - (C) The name, address and telephone number of the transporter for each shipment of waste. If applicable, the log or shipping paper shall include the identification number of a licensed transporter.
    - (D) The date the waste is transported and accepted by the processing or disposal facility.
  - (ii) A copy of the log or record shall be carried and delivered to the disposal facility by the transporter for each shipment of waste.
- (6) The transportation through this Commonwealth of infectious or chemotherapeutic waste generated outside this Commonwealth and which is destined for processing or disposal outside this Commonwealth.
- (7) The transportation of processed infectious 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.

#### Cross References

This section cited in 25 Pa. Code § 284.2 (relating to permit-by-rule for infectious or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); 25 Pa. Code § 284.602 (relating to license requirement); 25 Pa. Code § 284.721 (relating to basic requirements); and 25 Pa. Code § 284.732 (relating to use of manifest).

### § 284.702. Transfer facilities.

(a) Infectious or chemotherapeutic waste or processed infectious 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.

(b) If infectious or chemotherapeutic waste or processed waste which is recognizable is transported to a transfer facility, the transfer facility shall be considered the designated facility for purposes of this subchapter. When the waste is 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 years from the date on which the report was required to be prepared. 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.

(a) A generator who transports, or offers for transportation, infectious or chemotherapeutic waste for offsite processing or disposal shall ensure proper segregation of infectious and chemotherapeutic waste from other types of waste and prepare a manifest according to the instructions supplied with the manifest. A processor who transports, or offers for transportation, processed infectious 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.

(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.**

(a) The generator shall provide the following information on each manifest before the offsite transportation of the manifested waste occurs:

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

- (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 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) 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) 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) Special instructions and information necessary for proper handling of the waste during transportation, processing, storage or disposal, if any.
- (8) The printed or typed name and handwritten signature of the generator's authorized representative, and the date of shipment.
- (9) 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.
  - (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.
  - (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.

#### Cross References

This section cited in 25 Pa. Code § 284.721 (relating to basic requirements).

**§ 284.713. Generator's distribution of copies.**

(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 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.

(2) Notify the Department's appropriate regional office by telephone within 1 business day of the status of the 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 the generator has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated processing or disposal facility within 35 days of the date the generator's waste was accepted by the initial transporter.

(c) The exception report shall include the following:

(1) A legible copy of the manifest for which the generator does not have confirmation of delivery.

(2) A cover letter signed by the generator or an authorized representative explaining the efforts taken to locate the waste shipment and the results of those efforts.

**TRANSPORTER RESPONSIBILITIES****§ 284.721. Basic requirements.**

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.**

(a) Before transporting infectious or chemotherapeutic waste or processed infectious 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.

(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 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) A transporter who delivers infectious or chemotherapeutic waste or processed recognizable waste to the designated processing or disposal facility shall:

(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.

(2) Retain copy 3 of the manifest according to the instructions supplied with the manifest.

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

(f) The transporter who delivers infectious or chemotherapeutic waste to another transporter shall:

(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 to the subsequent transporter.

(ii) The printed or typed name of the subsequent transporter and his handwritten signature.

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

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

**§ 284.723. Waste delivery.**

(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 or chemotherapeutic waste or processed infectious 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 or § 284.512 (relating to storage containers; and transportation of infectious and chemotherapeutic waste; general provisions).
- (2) The waste is not labeled or identified as required by § 284.416 (relating to marking of containers).
- (3) The number and type of containers and quantity of waste to be transported do not correspond with the number and type of containers and quantity of waste stated on the manifest.
- (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—284.734 (relating to use of manifest; distribution of copies; and significant discrepancies) apply to owners and operators of waste processing or disposal facilities that receive infectious or chemotherapeutic waste or processed infectious or chemotherapeutic waste that is recognizable from offsite sources.

**§ 284.732. Use of manifest.**

(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 or chemotherapeutic waste or processed infectious or chemotherapeutic waste that is recognizable from offsite sources unless the shipment is accompanied by a Pennsylvania manifest in accordance with 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.
  - (2) Note significant discrepancies in the information on the manifest, 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.
- (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.

#### Cross References

This section cited in 25 Pa. Code § 284.731 (relating to scope).

### § 284.733. Distribution of copies.

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.

#### Cross References

This section cited in 25 Pa. Code § 284.731 (relating to scope).

### § 284.734. Significant discrepancies.

(a) This section applies if there is a significant discrepancy in a manifest. A discrepancy is a difference between the quantity or type of waste designated on the manifest, and the quantity or type of waste a facility actually receives. A significant discrepancy occurs if one or more of the following apply:

- (1) There is a variation greater than 5% in weight, for bulk waste.
- (2) There is a variation in piece count, for batch waste.
- (3) There is a difference in waste type which can be discovered by inspection or waste analysis.

(b) If there is a significant discrepancy in a manifest, the owner or operator shall attempt to reconcile the discrepancy before the waste is processed or disposed at the facility or before the waste is accepted at a transfer facility. If the discrepancy is not resolved within 3 days of receipt of the waste, the owner or

operator shall immediately notify the appropriate regional office of the Department by telephone. Within 7 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.

**Cross References**

This section cited in 25 Pa. Code § 284.731 (relating to scope); and 25 Pa. Code § 284.732 (relating to use of manifest).

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