

# CHAPTER 284. REGULATED MEDICAL 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); the 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); amended under the Solid Waste Management Act (35 P. S. § § 6018.101—6018.1003); 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 Disposal Law; and sections 1917-A and 1920-A of The Administrative Code of 1929 (71 P. S. § § 510-17 and 510-20), 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

Sec.

[284.1.](#) Scope.

[284.2.](#) Permit-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.

[284.3.](#) Regulated medical or chemotherapeutic waste aggregation facilities.

### GENERAL PROVISIONS

#### § 284.1. Scope.

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

#### Source

The provisions of this § 284.1 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (317353).

#### **§ 284.2. Permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.**

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

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

(ii) The landfill has received written approval from the Department authorizing disposal of the processed liquid blood and body fluids.

(iii) The facility does not process chemotherapeutic waste.

(5) Transfer facilities that temporarily store regulated medical or chemotherapeutic waste for less than 72 hours provided the stored waste remains in its original packaging, is not putrescent and does not attract vectors.

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

deemed to have a municipal waste processing permit under this article if the following requirements under this subsection and subsection (c) are met:

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

(2) The generator shall comply with the log and shipping paper requirements in § 284.701(b)(5) (relating to scope).

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

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

(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 regulated medical waste generated at the facility, including waste handling, equipment operation and maintenance, processing method, disinfection monitoring procedures including quality assurance procedures, frequency of calibration and a description of how noninfectious waste is managed to prevent commingling.

(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 regulated medical 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 that do not render the waste unrecognizable, the treated or processed regulated medical waste shall be transported in accordance with Subchapter H (relating to tracking of regulated medical and chemotherapeutic waste).

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

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

#### Source

The provisions of this § 284.2 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (317354) and (273291) to (273303).

#### Cross References

This section cited in 25 Pa. Code § 284.411 (relating to segregation).

### **§ 284.3. Regulated medical or chemotherapeutic waste aggregation facilities.**

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

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

- (1) Comply with the generator standards in Subchapter E (relating to segregation and storage).
- (2) Only accept the following regulated medical or chemotherapeutic waste generated:
  - (i) Onsite or offsite by the operator of the aggregation facility.
  - (ii) By physicians in their independent practices or other medical personnel within the same building or complex of buildings.
- (c) *Noncompliance.* The Department may require the operator of an aggregation facility operated under permit-by-rule to apply for and obtain a permit, or take other appropriate action, when the operator is not in compliance with the requirements for the permit-by-rule or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment.

#### Source

The provisions of this § 284.3 adopted November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021.

## Subchapter B. GENERAL PERMITS

### GENERAL

Sec.

- [284.101.](#) Authorization for general permits.
- [284.102.](#) Nature of a general permit; substitution for individual applications and permits.

### ISSUANCE OF A GENERAL PERMIT

- [284.111.](#) Application for general permit.
- [284.112.](#) Completeness review.
- [284.113.](#) Public notice and review period.
- [284.114.](#) Approval or denial of an application.
- [284.115.](#) Department-initiated general permits.
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## CONTENT OF GENERAL PERMITS AND WAIVERS OR MODIFICATIONS

- [284.121.](#) Contents of general permits.  
[284.122.](#) Waiver or modification of certain requirements.

## REGISTRATION

- [284.131.](#) Authorization for persons or municipalities to be included in a general permit.  
[284.132.](#) [Reserved].  
[284.133.](#) Registration.

## GENERAL

### § 284.101. Authorization for general permits.

(a) In accordance with this subchapter, the Department may issue general permits on a regional or Statewide basis for a category of mobile or stationary regulated medical 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 regulated medical waste to perform processing.

(d) The Department may issue a general permit for the processing of mixtures of the same types of waste that are regulated medical 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 regulated medical or chemotherapeutic waste processing facility, including commercial incinerators.

#### **Source**

The provisions of this § 284.101 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273293).

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

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

(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 § 284.133 (relating to registration).

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

#### **Source**

The provisions of this § 284.102 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273294).

## **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 regulated medical or chemotherapeutic waste.

(b) An application for the issuance of a general permit for processing regulated medical 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 regulated medical 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 regulated medical or chemotherapeutic waste which ensures the waste is handled separately from other solid waste until processing and disposal, and that prevents unauthorized persons from having access to or contact with the waste.

(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 regulated medical 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 regulated medical waste containers, transport vehicles and facility equipment which are known or suspected to be contaminated with regulated medical waste.

(vi) A description of the method proposed for handling and disposal of regulated medical 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 regulated medical or chemotherapeutic waste.

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

(x) A description of the method proposed to quantify, on a weight basis, the maximum amount of regulated medical 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 regulated medical 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 regulated medical 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 regulated medical or chemotherapeutic waste and ruptures of containers containing the waste. The plan shall include procedures for cleanup and disinfection of spill area, protection of personnel, disposal of spill residue and repackaging of the waste. The plan shall also include a description of an alternative waste handling system during periods when the proposed facility is not in operation, including procedures to be followed in the case of equipment breakdown. Alternate waste handling procedures may include use of standby equipment, extension of operating hours and contractual agreements for diversion of regulated medical or chemotherapeutic waste to other facilities.

(5) A personnel training plan which describes the hiring of equipment operators and the training of personnel involved in the handling and processing of regulated medical 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 regulated medical waste to perform processing.

#### **Source**

The provisions of this § 284.111 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial apges (273294) to (273296).

#### **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, 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.

(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).

#### **Source**

The provisions of this § 284.112 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273296).

#### **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 regulated medical 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.

#### **Source**

The provisions of this § 284.113 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273297).

#### **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 regulated medical 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.

#### Source

The provisions of this § 284.114 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273297) to (273298).

#### 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 regulated medical 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) will include the following:

(1) A clear and specific description of the category of processing of regulated medical 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 Department 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.

#### Source

The provisions of this § 284.115 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273298).

#### Cross References

This section cited in 25 Pa. Code § 284.101 (relating to authorization for general permits); and 25 Pa. Code § 284.116 (relating to general permit renewal).

#### § 284.116. General permit renewal.

(a) A person or municipality that plans to process regulated medical or chemotherapeutic waste after the expiration of the term in the general permit shall file notice to the Department of intent to continue operating under the permit at least 180 days before the expiration date of the permit. The notice must include updated registration information on forms provided by the Department, a check payable to the “Commonwealth of Pennsylvania” for \$250 and any suggested changes to the terms or conditions of the permit.

(b) A permit renewal may include all persons or municipalities that have applied for renewal within the time period provided in subsection (a). A person or municipality that does not meet the time period in subsection (a) shall be required to register under a renewed general permit.

(c) At least 120 days prior to the permit expiration, the Department will provide public notice of the permit renewal along with an update of the terms or conditions in accordance with the public notice requirements of § 284.115 (relating to Department-initiated general permits.)

(d) General permits will be renewed for a maximum term of 10 years.

(e) If the Department is unable to reissue the general permit prior to its expiration date, the Department may extend the term of a general permit for a period not to exceed 1 year for any permittee that is operating in compliance with the terms and conditions of the general permit and the environmental statutes and regulations of the Commonwealth.

#### Source

The provisions of this § 284.116 adopted November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021.

## **CONTENT OF GENERAL PERMITS AND WAIVERS OR MODIFICATIONS**

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

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

- (1) A clear and specific description of the category of processing of regulated medical 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 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 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 log or shipping paper, in accordance with Subchapter H (relating to tracking of regulated medical and chemotherapeutic waste).

(9) A requirement that waste be delivered by a licensed transporter in accordance with Subchapter G (relating to transporter licensing for regulated medical 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 managed in accordance with the Solid Waste Management Act (35 P. S. § § 6018.101—6018.1003) and the regulations promulgated thereunder.

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

(13) A requirement that individual employee 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 prohibition against processing pathological waste or chemotherapeutic waste in an autoclave.

### **Source**

The provisions of this § 284.121 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273299) to (273300).

**§ 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**

**§ 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 the person or municipality has registered in accordance with the terms of the general permit and the requirements of this subchapter.

(b) Registration requirements and time limits, if any, will be set forth in the general permit governing each category of processing regulated medical or chemotherapeutic waste. The general permit will also set forth the area or region within which each category of processing is allowed.

(c) At a minimum, the registration must 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 regulated medical 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 regulated medical or chemotherapeutic waste under the general permit.

(d) A person or municipality that registers for coverage under a general permit shall submit a copy of the registration 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 with the Department.

#### Source

The provisions of this § 284.131 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273300) to (273301).

#### Cross References

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

### § 284.132. [Reserved].

#### Source

The provisions of this § 284.132 reserved November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273301) to (273303).

### § 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.
- [284.230.](#) Storage requirements.

### **§ 284.201. Scope.**

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

#### **Source**

The provisions of this § 284.201 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273304).

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

An application to operate a transfer facility shall comply with § § 279.101—279.111.

#### **Source**

The provisions of this § 284.210 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273304).

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

A person or municipality that operates a transfer facility shall comply with Chapter 279, Subchapters A and C (relating to general; and operating requirements for transfer facilities).

#### **Source**

The provisions of this § 284.220 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273304).

### **§ 284.230. Storage requirements.**

A transfer facility may store regulated medical or chemotherapeutic waste for up to 72 hours provided that the stored waste remains in its original packaging, is not putrescent and does not attract vectors.

#### **Source**

The provisions of this § 284.230 adopted November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021.

## **Subchapter D. PROCESSING FACILITIES**

Sec.

- [284.301.](#) Scope.
- [284.310.](#) Application requirements.
- [284.311.](#) Plan for monitoring.
- [284.320.](#) Operating requirements.
- [284.321.](#) Regulated medical waste monitoring requirements.
- [284.322.](#) Autoclave validation testing 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 regulated medical or chemotherapeutic waste. The requirements in this

subchapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions).

#### **Source**

The provisions of this § 284.301 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273304).

#### **§ 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 regulated medical waste shall contain a plan, including necessary designs, procedures and test protocols on forms provided by the Department, for meeting the requirements of § 284.321 (relating to regulated medical 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.

#### **Source**

The provisions of this § 284.311 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273304) and (281971).

#### **§ 284.320. Operating requirements.**

A person or municipality that operates a processing facility shall comply with Chapter 283, Subchapter C (relating to operating requirements).

#### **Source**

The provisions of this § 284.320 corrected July 20, 2001, effective March 3, 2001, 31 Pa.B. 3942; amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (281971).

#### **§ 284.321. Regulated medical waste monitoring requirements.**

(a) A person or municipality that disinfects regulated medical 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 mycobacteria at a 6 log 10 reduction or greater.
  - (ii) The process shall be capable of inactivating *Geobacillus stearothermophilus* spores, *Bacillus pumilus* or *Bacillus atrophaeus* spores at a 4 log 10 reduction or greater.
- (b) The operator of a facility that incinerates or thermally processes regulated medical waste shall submit to the Department a microbiological analysis of a composite sample of the processing or ash residue on forms provided by the Department, at a minimum, annually during the life of the facility.
- (c) The operator of a facility that incinerates regulated medical waste shall submit to the Department, at least annually during the life of the facility, a chemical analysis of composite samples of the ash residue on forms provided by the Department.
- (d) If the facility disinfects regulated medical waste by means other than incineration or thermal processing, the operator shall perform a microbiological analysis of indicators removed from the processed waste. The analysis shall be conducted, at a minimum, every 40 hours during the operational life of the facility, unless otherwise provided in a permit. The analyses shall be made available to the Department upon request.
- (e) Unless the Department approves another indicator or test in writing, the following indicators shall be used to establish and verify the following processes:
  - (1) For autoclaving, spores of *Geobacillus stearothermophilus*.
  - (2) For dry heat, gas or chemical disinfection, spores of *Bacillus atrophaeus* 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 within the load where disinfection will be most difficult to achieve.
- (g) Regulated medical waste will be considered to be infectious 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 regulated medical or chemotherapeutic waste incineration; and storage and containment of processing residue from a regulated medical or chemotherapeutic waste processing facility).
- (j) Ash or other processing residue shall be transported in accordance with § 284.511 or § 284.514 (relating to transportation of ash residue from regulated medical or chemotherapeutic waste incineration; and transportation of processing residue from a regulated medical or chemotherapeutic waste facility).
- (k) Compactors, grinders or similar devices may not be used to reduce the volume of regulated medical waste before the waste has been rendered noninfectious. If the volume reduction device is within a continuous, enclosed disinfection process and part of one processing system, then the reduction device may be used.
- (l) The operator of a regulated medical waste processing facility shall dispose of ash or other processing residue from the facility in a landfill that has been approved by the Department to accept the waste, if the waste is disposed in this Commonwealth.
- (m) An autoclave facility shall comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.
- (n) Unless otherwise approved in writing by the Department, an operator of an autoclave facility shall employ the procedures in § 284.322 (relating to autoclave validation testing requirements) to validate the operating parameters and protocols of the processing equipment. These procedures must be employed at an on-going frequency specified by the manufacturer of the autoclave and in the following circumstances:
- (1) When a new autoclave is installed.
  - (2) When an autoclave is modified, repaired or has experienced a malfunction with respect to hardware, software, controls or ancillary equipment.
- (o) The facility shall maintain a record of the autoclave validation testing protocols and procedures.
- (p) For facilities engaged in the production or research and development of vaccines or other biologics that are classified under the North American Industrial Classification System as Code 325414—Biological Protocol (except Diagnostic) Manufacturing and who meet the following criteria may utilize the alternate disinfection requirements specified in paragraph (5) instead of the requirements of subsections (a)—(o) to process waste containing an infectious agent classified as Biosafety Level 2 or below, as determined by the protocols established in the most recent edition of the Centers for Disease Control's *Biosafety in Microbial and Biomedical Laboratories* existing at the time the waste is generated:
- (1) Utilize onsite processing facilities at which at least 50% of the waste processed is generated onsite.

(2) Operate in accordance with United States Food and Drug Administration good manufacturing practices or good laboratory practices.

(3) Employ a production process where the infectious agents or biological, or both, are known and well characterized, inactivation criteria are determined and bioburden is measured and controlled including screening for objectionable organisms.

(4) Specify and approve the decontamination process, method and monitoring, and validation procedures for each specific infectious agent in its waste by either of the following:

(i) Establishing and utilizing an Institutional Biosafety Committee constituted in accordance with the Centers for Disease Control and the National Institute of Health guidelines or composed in whole or in part of a panel of experts, a member of which is a biosafety officer certified by the American Biological Safety Association or the American Society for Microbiology or equivalent.

(ii) Retaining a contractor certified by the American Biological Safety Association or the American Society for Microbiology who accepts responsibility for the process, method and procedures that the contractor specified and approves (Independent Certified Biosafety Professional).

(5) The alternate disinfection process must be conducted as follows:

(i) Disinfection shall be conducted by inactivating all waste material in accordance with the practices, methods and minimum parameters for biological kill established by the facility's Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, consistent with the Centers for Disease Control and the National Institute of Health guidelines or scientifically accepted protocols, or both.

(ii) Efficacy of the inactivation operations shall be demonstrated through review of decontamination cycle data by trained technicians or other testing methods or studies specified by the Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, as appropriate for the specific infectious agent or biologic, or both, present in the waste. The procedures for demonstrating the efficacy of the inactivation operations must be set forth in standard operating procedures or other written procedures maintained at the facility, or both.

(iii) Preventative maintenance and calibration programs for decontamination equipment consistent with generally accepted industry standards as specified by the Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, shall be established and routinely implemented.

(q) With the exception of used sharps, which remain subject to the additional requirements of this chapter, regulated medical waste that is generated by manufacturers of vaccines and other biologics who satisfy the criteria of subsection (p)(1)—(4) and decontaminated in accordance with the procedures specified in subsection (p)(5), may be managed, stored, transported and disposed of as ordinary municipal waste and is not subject to any of the additional restrictions or requirements pertaining to special handling waste or regulated medical waste.

## Source

The provisions of this § 284.321 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (281971) to (281972).

## Cross References

This section cited in 25 Pa. Code § 271.1 (relating to definitions); 25 Pa. Code § 273.511 (relating to processed regulated medical waste disposal); 25 Pa. Code § 284.2 (relating to permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); 25 Pa. Code § 284.111 (relating to application for general permit); 25 Pa. Code § 284.311 (relating to plan for monitoring); and 25 Pa. Code § 284.322 (relating to autoclave validation testing requirements).

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

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

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

§ 284.321(p) (relating to regulated medical waste monitoring requirements) may establish and validate autoclave operating parameters and residence time based upon the requirements determined by the Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, as necessary to achieve the required disinfection under § 284.321(p)(5)(ii) for the specific infectious agent or biologic, or both, present in the wastes.

#### **Source**

The provisions of this § 284.322 adopted November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021.

#### **Cross References**

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

## **Subchapter E. SEGREGATION AND STORAGE**

Sec.

[284.401.](#) Scope.

[284.411.](#) Segregation.

[284.412.](#) Basic storage requirements.

[284.413.](#) Storage containers.

[284.414.](#) Marking of containers.

[284.415.](#) Duration of storage of regulated medical and chemotherapeutic waste for generators.

[284.416.](#) Duration of storage of regulated medical and chemotherapeutic waste for processors.

[284.417.](#) Reuse of containers.

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

[284.419.](#) Storage and containment of processing residue from a regulated medical or chemotherapeutic waste processing facility.

#### **Cross References**

This subchapter cited in 25 Pa. Code § 284.2 (relating to permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); and 25 Pa. Code § 284.3 (relating to regulated medical or chemotherapeutic waste aggregation facilities).

### **§ 284.401. Scope.**

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

#### **Source**

The provisions of this § 284.401 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273307).

### **§ 284.411. Segregation.**

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

- (1) Regulated medical waste, excluding pathological waste.
- (2) Pathological waste.
- (3) Chemotherapeutic waste.

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

(c) When bags are used as containers to segregate the waste, the bags must be fluorescent orange, orange-red or red in color for regulated medical waste or pathological waste.

(d) When bags are used as containers to segregate the waste, the bags must be yellow in color for chemotherapeutic waste, unless the chemotherapeutic waste is processed onsite in an incinerator that operates in accordance with § 284.2 (relating to permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements) or in accordance with a permit authorized by the Department.

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

#### **Source**

The provisions of this § 284.411 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273307) to (273308).

## **§ 284.412. Basic storage requirements.**

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

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

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

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

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

(5) Prevents odors from emanating from the container.

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

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

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

(b) Enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste must be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Containers located in enclosures used for the storage of regulated medical or chemotherapeutic waste must be maintained in compliance with § 284.413 (relating to storage containers) and in a manner that minimizes human exposure and vectors. Exhaust air from storage areas must be ventilated to minimize human exposure.

(c) Regulated medical and chemotherapeutic waste may not be commingled with other waste in the same container.

(d) The generator may store regulated medical waste, chemotherapeutic waste or municipal waste that has been sorted and separately containerized in the same location, including on a cart.

### **Source**

The provisions of this § 284.412 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273308).

**§ 284.413. Storage containers.**

(a) Regulated medical or chemotherapeutic waste shall be placed in containers that are:

- (1) Leakproof on the sides and bottom and maintained in an upright position.
- (2) Impervious to moisture.
- (3) Sufficient in strength to prevent puncturing, tearing or bursting during storage.

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

- (1) Rigid.
- (2) Tightly lidded.
- (3) Puncture resistant.

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

- (1) Break resistant.
- (2) Tightly lidded or tightly stoppered.

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

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

(2) The bags must be constructed of material of sufficient single thickness strength to meet the following:

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

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

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

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

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

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

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

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

### **Source**

The provisions of this § 284.413 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273309).

### **Cross References**

This section cited in 25 Pa. Code § 284.411 (relating to segregation); 25 Pa. Code § 284.412 (relating to basic storage requirements); 25 Pa. Code § 284.512 (relating to transportation of regulated medical and chemotherapeutic waste; general provisions); 25 Pa. Code § 284.513 (relating to transportation of regulated medical and chemotherapeutic waste; additional provisions); and 25 Pa. Code § 284.724 (relating to transportation limitations).

### **§ 284.414. Marking of containers.**

(a) For onsite or offsite transportation of regulated medical or chemotherapeutic waste, the outermost containers of regulated medical or chemotherapeutic waste must be labeled with the following:

(1) The words “chemotherapeutic waste” if chemotherapeutic waste is placed in the container.

(2) Until November 8, 2016, the words “infectious waste” or “regulated medical waste” if regulated medical waste is placed in the container.

(3) After November 8, 2016, the words “regulated medical waste” if regulated medical waste is placed in the container.

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

(5) The date the container was full or the date that the generator sealed the container, whichever occurs earlier.

(6) The name, address and telephone number of the generator if the waste is transported offsite.

(b) The requirements of subsection (a) do not apply if the outermost container is a vehicle or conveyance, including a roll-off, and all of the following are satisfied:

(1) The waste in the vehicle or conveyance is from a single generator.

(2) The vehicle or conveyance is transported offsite for processing or disposal every 30 days.

(3) The vehicle or conveyance complies with the requirements of § 284.513 (relating to transportation of regulated medical and chemotherapeutic waste; additional provisions).

(4) The outside of the vehicle or conveyance displays the information required in subsection (a)(5), except when a record of the date the vehicle or conveyance is full or sealed, whichever occurs earlier, is maintained by the generator and available for inspection by the transporter or Department for 1 year.

(5) The outside of the vehicle or conveyance displays the information required in subsection (a)(6).

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

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

#### **Source**

The provisions of this § 284.414 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273309).

#### **Cross References**

This section cited in 25 Pa. Code § 284.512 (relating to transportation of regulated medical and chemotherapeutic waste; general provisions); and 25 Pa. Code § 284.724 (relating to transportation limitations).

#### **§ 284.415. Duration of storage of regulated medical and chemotherapeutic waste for generators.**

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

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

#### **Source**

The provisions of this § 284.415 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273309) to (273311).

#### **§ 284.416. Duration of storage of regulated medical and chemotherapeutic waste for processors.**

If the waste processing facility is separate from the waste generating facility, regulated medical or chemotherapeutic waste shall be immediately moved offsite if the waste becomes putrescent or attracts vectors during the storage period and may not be stored at the waste processing facility for more than the following periods unless other periods are approved in the facility's permit:

- (1) Seventy-two hours at ambient temperature, unless the waste becomes putrescent or attracts vectors.
- (2) Seven days in a refrigerator at  $\leq 7^{\circ}\text{C}$  or  $\leq 45^{\circ}\text{F}$ , unless the waste becomes putrescent or attracts vectors.
- (3) Thirty days in a freezer at  $\leq -18^{\circ}\text{C}$  or  $\leq 0^{\circ}\text{F}$ , unless the waste becomes putrescent or attracts vectors.

#### **Source**

The provisions of this § 284.416 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (373311).

#### **§ 284.417. Reuse of containers.**

- (a) Nonrigid containers shall be managed as either regulated medical or chemotherapeutic waste based upon the contents of the container. These containers may not be reused.
- (b) Corrugated fiberboard containers used for storage of regulated medical or chemotherapeutic waste may be reused if the surface of the container has been protected from direct contact with the waste.
- (c) A rigid, nonfiberboard container used for the storage of regulated medical waste or chemotherapeutic 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 regulated medical and chemotherapeutic waste, as applicable.

#### **Source**

The provisions of this § 284.417 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273311) to (273312).

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

(a) Ash residue from regulated medical 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 for collecting a spill or release of ash that is no more permeable than  $1 \times 10^{-7}$  cm./sec.

(3) In a manner 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).

#### **Source**

The provisions of this § 284.418 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273312).

#### **Cross References**

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

#### **§ 284.419. Storage and containment of processing residue from a regulated medical or chemotherapeutic waste processing facility.**

(a) Processing residue from regulated medical or chemotherapeutic waste processing facilities shall be stored in an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building, 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 a regulated medical or chemotherapeutic waste processing facility may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

#### **Source**

The provisions of this § 284.419 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273312) to (273313).

#### **Cross References**

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

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

### **GENERAL**

**Sec.**  
[284.501.](#) Scope.

### **TYPES OF WASTE**

- [284.511.](#) Transportation of ash residue from regulated medical or chemotherapeutic waste incineration.
- [284.512.](#) Transportation of regulated medical and chemotherapeutic waste; general provisions.
- [284.513.](#) Transportation of regulated medical and chemotherapeutic waste; additional provisions.
- [284.514.](#) Transportation of processing residue from a regulated medical or chemotherapeutic waste facility.

#### **Cross References**

This subchapter cited in 25 Pa. Code § 284.2 (relating to permits-by-rule for regulated medical 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 regulated medical or chemotherapeutic waste, ash residue from regulated medical or chemotherapeutic waste incineration and processing residue from a regulated medical or chemotherapeutic waste processing facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions) and the requirements in §§ 285.211—285.219 (relating to general provisions).

#### **Source**

The provisions of this § 284.501 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273313).

## **TYPES OF WASTE**

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

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

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

(c) A generator's ash residue from regulated medical or chemotherapeutic waste incineration shall be transported separately from the ash residue of other generators.

(d) Municipal waste from a generator may be commingled and transported with the generator's ash residue from regulated medical and chemotherapeutic waste incineration if the municipal waste and ash residue are being transported separately from the waste of other generators.

#### **Source**

The provisions of this § 284.511 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273314).

## Cross References

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

### **§ 284.512. Transportation of regulated medical and chemotherapeutic waste; general provisions.**

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

(b) *Manner of transportation.* Regulated medical 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  $\leq 45^{\circ}\text{F}$ ) or freezing ( $\leq -18^{\circ}\text{C}$  or  $\leq 0^{\circ}\text{F}$ ) when necessary.

(5) Prevents odors from emanating from the container.

(6) Prevents unauthorized access to the waste.

(c) *Containers.*

(1) Regulated medical 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.

(v) Labeled in accordance with the requirements in § 284.414 (relating to marking of containers), except as provided in § 284.414(b).

(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 requirements of paragraph (1), regulated medical 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 § 284.413 (relating to storage containers) may be used to meet the requirements of this subsection that containers be leakproof and impervious to moisture.

(d) *Types of vehicles.* Vehicles for transporting regulated medical or chemotherapeutic waste shall be noncompaction type vehicles.

(e) *Commingling of waste.* Separately containerized regulated medical or chemotherapeutic waste may be transported in the same vehicle with containerized municipal waste.

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

(g) *Refrigeration.* Regulated medical or chemotherapeutic waste may be kept in an unrefrigerated transport vehicle for up to 72 hours provided the waste is not putrescent and does not attract vectors. If the vehicle is refrigerated ( $\leq 7^{\circ}\text{C}$  or  $\leq 45^{\circ}\text{F}$ ) or maintained at freezing temperatures ( $\leq -18^{\circ}\text{C}$  or  $\leq 0^{\circ}\text{F}$ ), the in-transit storage period may not exceed 5 days.

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

### Source

The provisions of this § 284.512 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273313) to (273315).

### 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 regulated medical and chemotherapeutic waste; additional provisions.**

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

(b) Vehicles or conveyances for transporting regulated medical or chemotherapeutic waste shall be identified on the two sides and back of the cargo compartment with the following:

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

(2) A placard or decal containing the phrase "regulated medical waste" or "chemotherapeutic waste," or both, as applicable, and the universal biohazard symbol that conforms to the design shown in the United States Occupational Safety and Health Administration's regulations at 29 CFR 1910.1030(g)(1)(i)(B) (relating to bloodborne pathogens).

(3) Until November 8, 2016, the words "infectious waste" or "regulated medical waste" if regulated medical waste is being transported.

(4) After November 8, 2016, the words "regulated medical waste" if regulated medical waste is being transported.

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

(1) An adequate amount of absorbent material.

(2) One gallon of EPA-approved disinfectant in an appropriate applicator.

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

(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 cargo area of vehicles used for transporting regulated medical or chemotherapeutic waste that has not been in direct physical contact with regulated medical or chemotherapeutic waste shall be cleaned weekly. Drainage from the cleaning shall be discharged directly or through a holding tank to a sanitary sewer system or treatment facility.

### Source

The provisions of this § 284.513 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273316) to (273317).

### Cross References

This section cited in 25 Pa. Code § 284.414 (relating to marking of containers); and 25 Pa. Code § 284.512 (relating to transportation of regulated medical and chemotherapeutic waste; general provisions).

### **§ 284.514. Transportation of processing residue from a regulated medical or chemotherapeutic waste facility.**

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

(b) A transporter shall transport processing residue from regulated medical or chemotherapeutic waste for each generator separately from other generators.

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

### Source

The provisions of this § 284.514 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273317).

### Cross References

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

# **Subchapter G. TRANSPORTER LICENSING FOR REGULATED MEDICAL 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.](#) Regulated medical or chemotherapeutic waste discharges or spills.
- [284.633.](#) Safety.
- [284.634.](#) Annual report.

## BOND

- [284.641.](#) Bond requirement.
- [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 regulated medical or chemotherapeutic waste.

#### Source

The provisions of this § 284.601 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273318).

### § 284.602. License requirement.

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

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

- (1) Onsite movement of regulated medical or chemotherapeutic waste by generators.
- (2) Onsite movement of regulated medical or chemotherapeutic waste by operators of permitted regulated medical or chemotherapeutic waste management facilities.
- (3) Transportation by a generator of less than 220 pounds per month of regulated medical or chemotherapeutic waste when transporting only the generator's own regulated medical or chemotherapeutic waste if the log and shipping paper requirements under § 284.701(b)(3) (relating to scope) are met.
- (4) The transportation of regulated medical or chemotherapeutic waste generated outside this Commonwealth destined for processing or disposal outside this Commonwealth.

#### Source

The provisions of this § 284.602 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273318).

### § 284.603. Identification number.

A person or municipality subject to this chapter may not transport regulated medical 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.

#### **Source**

The provisions of this § 284.603 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273319).

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

(b) The application shall contain the following:

(1) The applicant's identification number, as required under § 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 regulated medical 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 regulated medical 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 under § 284.641 (relating to bond requirement).

(8) Certificate of insurance, as required under § 284.612 (relating to vehicular liability insurance).

(9) A contingency plan consistent with § 284.632 (relating to regulated medical 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.

#### Source

The provisions of this § 284.611 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273319) to (273320).

### **§ 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 regulated medical and chemotherapeutic waste transportation activities.

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

(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 regulated medical or chemotherapeutic waste which is a department or an agency of the United States or of the Commonwealth may fulfill the requirements under this section by means of one or more of the following:

- (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).

#### **Source**

The provisions of this § 284.612 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273320) to (273321).

#### **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 regulated medical and chemotherapeutic waste is nontransferable and nonassignable. A license applies to the licensee and its employees. Leased or subcontracted haulers, and haulers who provide equipment, have no authority to operate under the licensee's license without prior written approval from the Department.

#### **Source**

The provisions of this § 284.623 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273321) to (273322).

### **§ 284.624. License renewal.**

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

#### **Source**

The provisions of this § 284.624 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273322).

**§ 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 regulated medical 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.

**Source**

The provisions of this § 284.631 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273322).

**§ 284.632. Regulated medical 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 regulated medical or chemotherapeutic waste during transportation, the transporter shall take appropriate immediate action to protect the health and safety of the public and the environment, in accordance with its approved TCP. The transporter shall also immediately telephone the Department and the affected municipality, and provide the following information:

- (1) The name of the person reporting the spill or discharge.
- (2) The transporter's name, address, the Department-issued regulated medical 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 regulated medical or chemotherapeutic waste occurs during transportation, and if the immediate removal of the waste is necessary to protect public health and safety or the environment, the Department may authorize the removal of the waste to a selected receiving facility by transporters who do not have identification numbers, licenses, logs or shipping papers under this subchapter.

(d) A transporter shall:

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

(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).

#### **Source**

The provisions of this § 284.632 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273322) to (273323).

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

### Source

The provisions of this § 284.633 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273323).

### § 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 regulated medical or chemotherapeutic waste during the previous calendar year, and shall include the following:

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

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

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

### Source

The provisions of this § 284.634 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273324).

### 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), known 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 will 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 regulated medical and chemotherapeutic waste transportation on the hazardous waste transporter bond.

(b) *Approval by Department.* A license to transport regulated medical or chemotherapeutic waste will not be issued by the Department before the applicant for the license has filed a collateral bond payable to the Department on a form provided by the Department, and the bond has been approved by the Department.

(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 Chemotherapeutic 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 regulated medical 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, instead 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) *Review of bonds.* Bonds will be reviewed for legality and form according to established Department procedures.

**Source**

The provisions of this § 284.641 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273324) to (273325).

### **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 regulated medical 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.

### **Source**

The provisions of this § 284.642 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273325) to (273326).

### **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 regulated medical 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—7516).

(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.

#### **Source**

The provisions of this § 284.643 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273326).

#### **§ 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. TRACKING OF REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE**

## GENERAL

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- [284.733.](#) [Reserved].
- [284.734.](#) Significant discrepancies.

### Cross References

This subchapter cited in 25 Pa. Code § 284.2 (relating to permits-by-rule for regulated medical 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 subsection (b), this subchapter applies to a person or municipality that generates, transports, disposes or processes regulated medical or

chemotherapeutic waste or processed regulated medical or chemotherapeutic waste that is recognizable.

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

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

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

(3) Transportation by a generator who generates less than 220 pounds per month of regulated medical 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 log or shipping paper with the waste shipment to the offsite processing or disposal facility.

(4) The transportation of regulated medical 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 mailing standards of the United States Postal Service in 39 CFR 211.2 (relating to regulations of the Postal Service) and incorporated by reference into this chapter authorize the package to be mailed.

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

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

(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 who generates and processes onsite less than 220 pounds per month of regulated medical or chemotherapeutic waste, which is recognizable waste, if the following are met:

(i) The generator only transports its own waste.

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

(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.

(iii) A copy of the log or shipping paper shall be provided to the disposal facility by the transporter for each shipment of waste.

(6) The transportation through this Commonwealth of regulated medical or chemotherapeutic waste generated outside this Commonwealth that is destined for processing or disposal outside this Commonwealth.

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

#### **Source**

The provisions of this § 284.701 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273328) to (273330).

#### **Cross References**

This section cited in 25 Pa. Code § 284.2 (relating to permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements); 25 Pa. Code § 284.602 (relating to license requirement); and 25 Pa. Code § 284.732 (relating to use of logs or shipping papers).

### **§ 284.702. Transfer facilities.**

Regulated medical waste, chemotherapeutic waste or processed regulated medical or chemotherapeutic waste that is recognizable may be transported to or from a transfer facility in accordance with the following:

- (1) The transfer facility is permitted by the Department.
- (2) If transported to a transfer facility, the transfer facility shall be considered the designated facility for purposes of this subchapter.
- (3) If transported from the transfer facility to a processing or disposal facility, the transfer facility shall be considered the generator and the processing or disposal facility shall be considered the designated facility for purposes of this subchapter.

#### **Source**

The provisions of this § 284.702 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273330).

### **§ 284.703. Recordkeeping.**

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

#### **Source**

The provisions of this § 284.703 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273330).

## **GENERATOR RESPONSIBILITIES**

### **§ 284.711. Use of logs or shipping papers.**

A generator who transports, or offers for transportation, regulated medical or chemotherapeutic waste for offsite processing or disposal shall ensure proper segregation of regulated medical and chemotherapeutic waste from other types of waste and prepare a log or shipping paper as required under this subchapter. A processor who transports, or offers for transportation, processed regulated medical or chemotherapeutic waste that is recognizable for offsite disposal shall be considered a generator for purposes of this subchapter.

#### **Source**

The provisions of this § 284.711 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273330) to (273331).

**§ 284.712. Preparation of logs or shipping papers.**

(a) The generator shall create a log or shipping paper of the following information and provide it to the transporter before the offsite transportation of the waste occurs:

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

(2) Each transporter's company name, identification number, Pennsylvania regulated medical and chemotherapeutic waste transporter license number and telephone number.

(3) The number of containers, types of containers and the total quantity of the waste by weight or volume.

(4) One of the following regulated medical or chemotherapeutic waste code numbers for each waste type, as appropriate:

(i) A100 for regulated medical waste.

(ii) A200 for processed regulated medical waste that is recognizable.

(iii) A300 for chemotherapeutic waste.

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

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

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

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

(b) An authorized representative of the generator shall ensure that a legible log or shipping paper has been completed.

(c) After the offsite transportation of the waste, the generator shall receive from the transporter and maintain as a record the log or shipping paper prepared by the transporter in accordance with § 284.722(f) (relating to preparation and use of logs or shipping papers).

**Source**

The provisions of this § 284.712 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273331) to (273332).

**§ 284.713. [Reserved].**

**Source**

The provisions of this § 284.713 reserved November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273333).

**§ 284.714. Exception reporting.**

(a) A generator that does not receive a log or shipping paper indicating the designated facility that received its waste within 30 days of the date the generator's waste was accepted by the initial transporter shall:

(1) Contact the transporter or the operator of the designated facility, or both, to determine the status of the shipment.

(2) Notify the Department's appropriate regional office by telephone within 1 business day of the status of the shipment.

(b) If the generator has not received a log or shipping paper indicating the designated facility that received its waste from the transporter within 35 days of the date the generator's waste was accepted by the initial transporter, the generator shall notify the Department's appropriate regional office by telephone and submit an exception report to the Department's Central Office.

(c) The exception report shall include the following:

(1) A record of the waste 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.

**Source**

The provisions of this § 284.714 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273333).

**TRANSPORTER RESPONSIBILITIES**

**§ 284.721. [Reserved].**

**Source**

The provisions of this § 284.721 reserved November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273333).

**§ 284.722. Preparation and use of logs or shipping papers.**

- (a) Before transporting regulated medical or chemotherapeutic waste or processed regulated medical or chemotherapeutic waste that is recognizable, the transporter shall provide the generator with a dated signature, including, but not limited to, handwritten, electronic or stamped signatures, from an authorized representative of the transporter acknowledging that the transporter has accepted the waste from the generator on the date of acceptance.
- (b) The transporter shall ensure that the log or shipping paper required under subsections (c) and (d) accompanies the waste shipment.
- (c) A transporter who delivers regulated medical or chemotherapeutic waste or processed recognizable waste to the designated processing or disposal facility shall create a log or shipping paper containing the following information:
  - (1) The date that each container of waste was delivered to a designated facility.
  - (2) The name and address of the designated facility for each container of waste.
- (d) The transporter who delivers regulated medical or chemotherapeutic waste to another transporter shall create a log or shipping paper containing the following information:
  - (1) The date that each container of waste was delivered to the subsequent transporter.
  - (2) The name and address of the subsequent transporter that received each container of waste.
- (e) At the time the waste is delivered to the designated facility or subsequent transporter, the transporter shall provide the operator of the designated facility or subsequent transporter with a log or shipping paper containing the following information:
  - (1) The name, mailing address and telephone number of the generator for each container of waste.
  - (2) The number of containers, types of containers and the total quantity of the waste by weight or volume for each generator.
- (f) After the waste has been transported to the designated facility, the transporter shall provide the generator with a log or shipping paper containing the following information:

- (1) The name, mailing address and telephone number of each designated facility that received each container of the generator's waste.
- (2) The number of containers, types of containers and the total quantity of the waste by weight or volume received by each designated facility.
- (3) The date that each designated facility received each container of the generator's waste.
- (4) Acknowledgment from the designated facility that it accepted each container of the generator's waste.

#### **Source**

The provisions of this § 284.722 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273334).

#### **Cross References**

This section cited in 25 Pa. Code § 284.712 (relating to preparation of logs or shipping papers).

### **§ 284.723. [Reserved].**

#### **Source**

The provisions of this § 284.723 reserved November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273334) to (273335).

### **§ 284.724. Transportation limitations.**

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

- (1) The waste is in containers or packaging which appear to be leaking, damaged or otherwise in violation of § 284.413 or § 284.512 (relating to storage containers; and transportation of regulated medical and chemotherapeutic waste; general provisions).
- (2) The waste is not labeled or identified as required under § 284.414 (relating to marking of containers).
- (3) The number and type of containers and quantity of waste to be transported do not appear to correspond with the number and type of containers and quantity of waste stated in the generator's log or shipping paper at the time of acceptance by the transporter.

(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).

#### **Source**

The provisions of this § 284.724 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273335).

## **FACILITY RESPONSIBILITIES**

### **§ 284.731. Scope.**

Sections 284.732 and 284.734 (relating to use of logs or shipping papers; and significant discrepancies) apply to operators of waste processing or disposal facilities that receive regulated medical or chemotherapeutic waste or processed regulated medical or chemotherapeutic waste that is recognizable from offsite sources.

#### **Source**

The provisions of this § 284.731 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273335).

### **§ 284.732. Use of logs or shipping papers.**

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

(b) The operator of the designated facility shall:

(1) Examine the records of the transporter.

(2) Note significant discrepancies in the log or shipping paper of the generator and transporter, as defined in § 284.734 (relating to significant discrepancies).

(3) Provide the transporter with a dated signature, including, but not limited to, handwritten, electronic or stamped signatures, from an authorized representative of the facility, acknowledging that it has accepted the waste from the transporter on that date.

#### **Source**

The provisions of this § 284.732 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273335) to (273336).

## **Cross References**

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

### **§ 284.733. [Reserved].**

#### **Source**

The provisions of this § 284.733 reserved November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial page (273336).

### **§ 284.734. Significant discrepancies.**

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

(1) There is a variation greater than 5% in weight, for bulk waste.

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

(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 the logs or shipping papers, the operator shall attempt to reconcile the discrepancy before the waste is processed or disposed of at the facility or before the waste is accepted at a transfer facility. If the discrepancy is not resolved within 3 business days of receipt of the waste, the operator shall immediately notify the appropriate regional office of the Department by telephone. Within 7 business days of receipt of the waste, the operator shall also send a letter to the regional office describing the discrepancy and attempts to reconcile it.

#### **Source**

The provisions of this § 284.734 amended November 7, 2014, effective November 8, 2014, 44 Pa.B. 7021. Immediately preceding text appears at serial pages (273336) to (273337).

## **Cross References**

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

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