PROPOSED RULEMAKING

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CHS. 1187 AND 1189]

Supplemental Ventilator Care Payment for Medical Assistance Nursing Facilities

The Department of Public Welfare (Department), under the authority of sections 201(2), 206(2), 403(b) and 443.1 of the Public Welfare Code (62 P. S. §§ 201(2), 206(2), 403(b) and 443.1), proposes to add § 1187.117 (relating to supplemental ventilator care payments) and amend § 1189.105 (relating to incentive payments) to read as set forth in Annex A.

Purpose of Proposed Rulemaking

The purpose of this proposed rulemaking is to change the Department's methods and standards for payment of Medical Assistance (MA) nursing facility services to offer a new category of supplemental payment to qualified MA nursing facilities effective July 1, 2012.

The proposed rulemaking is needed to address the financial impact that the implementation of the current Resource Utilization Group III (RUG-III) version 5.12 (RUG v. 5.12) resident classification system and the phase-out of the older RUG v. 5.01 is having on nursing facilities that care for a significant number of MA ventilator care residents.

Background

The Department is proposing to offer a new category of supplemental ventilator care payment to qualified MA nonpublic and county nursing facilities that provide medically necessary ventilator care for a significant portion of their MA-recipient resident population. The Department published a public notice announcing this proposed change at 42 Pa.B. 3824 (June 30, 2012). On September 27, 2012, the Department submitted State Plan Amendment (SPA) 12-030 regarding supplemental ventilator care payments to nonpublic and county nursing facilities to the Centers for Medicare and Medicaid Services (CMS). CMS approved the SPA on December 13, 2012.

Currently, the Department pays for nursing facility services provided to MA-eligible recipients in nonpublic nursing facilities at per diem rates that are computed using the case-mix payment system in Chapter 1187, Subchapter G (relating to rate setting). Beginning July 1, 2010, the payment methodology was changed to phase in, over a 3-year period, use of the RUG v. 5.12 classification system. Prior to July 1, 2010, RUG v. 5.01, an earlier version of the RUG-III classification system, was used.

The RUG-III classification systems were developed by the CMS to provide a patient-specific means of identifying the variable health care resources required to care for individuals with different needs by placing residents into groups based on their characteristics and clinical needs. Each group is then assigned a case-mix index (CMI) which is a numerical score intended to reflect the relative resource use of the average resident assigned to the group. See Chapter 1187, Appendix A (relating to resource utilization group index scores for case-mix adjustment in the nursing facility reimbursement system). A resident placed in a group which is assigned a higher CMI has greater needs and, therefore, requires more nursing resources than a resident in a group assigned a lower CMI. The data source used to classify each resident into a RUG-III group is the Federally-approved, Pennsylvania-specific minimum data set (MDS) assessment completed at a minimum upon admission and quarterly thereafter for each resident. Once each quarter (February 1, May 1, August 1 and November 1), the residents in the nursing facility's census are identified and the latest classifiable assessment is used to assign each resident to a RUG-III group. See §§ 1187.2 and 1187.33 (relating to definitions; and resident data and picture date reporting requirements). A facility average MA CMI is then calculated and used in the determination of each nonpublic nursing facility's per diem rate as specified in § 1187.96(a)(5) (relating to price- and rate-setting computations). In general, nursing facilities with a high facility average MA CMI receive a higher per diem rate because the residents in their care require more nursing resources.

Under § 1187.96, nursing facility case-mix per diem rates are a combination of a blended resident care rate, other resident-related rate, an administrative rate and a capital rate. The blended resident care rate uses a portion of both RUG-III versions as it phases in fully to RUG v. 5.12. For rate year 2010-2011, the resident care portion of the per diem rate was calculated using 75% of the RUG v. 5.01 resident care rate and 25% of the RUG v. 5.12 resident care rate. For rate year 2011-2012, the percent split was 50% and 50% and for rate year 2012-2013, the last year of the phase in, only 25% of the older RUG v. 5.01 resident care rate is used in the rate calculation.

Now that RUG v. 5.12 has been implemented and the phase-out of the older RUG v. 5.01 is nearing completion, the Department is addressing concerns regarding reimbursement of nursing facilities that serve ventilator care residents.

Although county nursing facilities do not have the same concerns relating to the CMI because their rates are calculated differently under Chapter 1189 (relating to county nursing facility services), the Department is nonetheless making the payment available to county nursing facilities to promote the growth of ventilator care. Making these additional funds available is part of the Department's ongoing efforts to ensure that MA recipients continue to receive access to medically necessary nursing facility services and that those services result in quality care that improves the lives of those who receive them.

Requirements

The Department is proposing to offer a new category of supplemental ventilator care payment under § 1187.117. The supplemental ventilator care payment will be calculated on a quarterly basis and paid to nursing facilities caring for a minimum of ten MA-recipient residents who receive medically necessary ventilator care, with at least 10% of the facility's MA-recipient resident population receiving medically necessary ventilator care. For those nursing facilities meeting both of the threshold criteria on the appropriate picture date, the total supplemental ventilator care payment will be the nursing facility's supplemental ventilator care per diem multiplied by the number of paid MA facility days and therapeutic leave days. If the Department grants a nursing facility a waiver to the 180-day billing requirement, the MA-paid days billed under the waiver and after the authorization date of the waiver will not be included in the calculation of the

supplemental ventilator care payment and the supplemental ventilator care payment amount will not be retroactively revised. Since this payment is a supplemental payment and not part of the case-mix per diem rates, it will not be subject to the budget adjustment factor under § 1187.96.

A nursing facility's supplemental ventilator care per diem would be calculated as follows: ((number of MA-recipient residents who receive medically necessary ventilator care ÷ total MA-recipient residents) × $69) × (the number of MA-recipient residents who receive medically necessary ventilator care ÷ total MA-recipient residents).

The maximum supplemental ventilator care per diem would be $69 for nursing facilities whose percent of MA-recipient residents who received medically necessary ventilator care to total MA-recipient residents equals 100%. This formula results in the provision of higher supplemental ventilator care payments to facilities with the highest percent of MA-recipient residents who received medically necessary ventilator care. These payments are based on the proportion of MA-recipients who received medically necessary ventilator care to total MA-recipient residents.

Affected Individuals and Organizations

This proposed rulemaking affects nonpublic and county nursing facilities enrolled in the MA Program.

Accomplishments and Benefits

This proposed rulemaking will benefit MA nursing facility residents in this Commonwealth by ensuring they will continue to have access to medically necessary nursing facility services and that those services result in quality care that improves the lives of those who receive them.

Fiscal Impact

This change will result in an estimated annual payment of $2.1 million in total funds ($0.956 million in State funds) in Fiscal Year 2012-2013.

Paperwork Requirements

There are no new or additional paperwork requirements. The CMI Report used to determine the number of MA-recipient residents who receive ventilator care is an existing report.

Effective Date

The effective date will be July 1, 2012.

Public Comment

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed rulemaking to Marilyn Yocum, Department of Public Welfare, Office of Long-Term Living, Bureau of Policy and Regulatory Management, P. O. Box 8025, Harrisburg, PA 17805-8025 within 30 calendar days after the date of publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Reference Regulation No. 14-535 when submitting comments.

Persons with a disability who require an auxiliary aid or service may submit comments using the Pennsylvania AT&T Relay Service at (800) 654-5984 (TDD users) or (800) 654-5988 (voice users).

Regulatory Review Act

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 14, 2013, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Human Services and the Senate Committee on Public Health and Welfare. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

BEVERLY D. MACKERETH,
Secretary

Fiscal Note: 14-535. (1) General Fund; (2) Implementing Year 2012-13 is $956,000; (3) 1st Succeeding Year 2013-14 is $956,000; 2nd Succeeding Year 2014-15 is $956,000; 3rd Succeeding Year 2015-16 is $956,000; 4th Succeeding Year 2016-17 is $956,000; 5th Succeeding Year 2017-18 is $956,000; (4) 2011-12 Program—$737,356,000; 2010-11 Program—$728,907,000; 2009-10 Program—$540,266,000; (7) Long-Term Care; (8) recommends adoption. Funds have been included in the budget to cover this increase.

Annex A

TITLE 55. PUBLIC WELFARE

PART III. MEDICAL ASSISTANCE MANUAL

CHAPTER 1187. NURSING FACILITY SERVICES

Subchapter H. PAYMENT CONDITIONS, LIMITATIONS AND ADJUSTMENTS

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

§ 1187.117. Supplemental ventilator care payments.

(a) A supplemental ventilator care payment will be made each calendar quarter, effective July 1, 2012, to nursing facilities subject to the following:

(1) To qualify for the supplemental ventilator care payment, the nursing facility shall satisfy both of the following threshold criteria on the applicable picture date:

(i) The nursing facility shall have a minimum of ten MA-recipient residents who receive medically necessary ventilator care.

(ii) The nursing facility shall have a minimum of 10% of their MA-recipient resident population receiving medically necessary ventilator care.

(2) Under paragraph (1), the percentage of the nursing facility's MA-recipient residents who require medically necessary ventilator care will be calculated by dividing the total number of MA-recipient residents who receive medically necessary ventilator care by the total number of MA-recipient residents. The result of this calculation will be rounded to two percentage decimal points.

(3) To qualify as an MA-recipient resident who receives medically necessary ventilator care, the resident shall be listed as an MA resident and have a positive response for the MDS item for ventilator use on the Federally-approved PA-specific MDS assessment listed on the nursing facility's CMI report for the applicable picture date.

(4) The number of total MA-recipient residents is the number of MA-recipient residents listed on the nursing facility's CMI report for the applicable picture date.

(5) The applicable picture dates and the authorization of a quarterly supplemental ventilator care payment are as follows:

Picture Dates	*Authorization Schedule*
February 1	September
May 1	December
August 1	March
November 1	June

(6) If a nursing facility fails to submit a valid CMI report for the picture date as provided under § 1187.33(a)(5) (relating to resident data and picture date reporting requirements), the facility cannot qualify for a supplemental ventilator care payment.

(b) A nursing facility's supplemental ventilator care payment is calculated as follows:

(1) The supplemental ventilator care per diem is ((number of MA-recipient residents who receive medically necessary ventilator care/total MA-recipient residents) × $69) × (the number of MA-recipient residents who receive medically necessary ventilator care/total MA-recipient residents).

(2) The amount of the total supplemental ventilator care payment is the supplemental ventilator care per diem multiplied by the number of paid MA facility and therapeutic leave days.

(c) If the Department grants a nursing facility a waiver to the 180-day billing requirement, then the MA-paid days that may be billed under the waiver and after the authorization date of the waiver will not be included in the calculation of the supplemental ventilator care payment. The Department will not retroactively revise the supplemental ventilator care payment amount.

(d) The paid MA facility and therapeutic leave days used to calculate a qualifying facility's supplemental ventilator care payment under subsection (b)(2) will be obtained from the calendar quarter that contains the picture date used in the qualifying criteria as described in subsection (a).

(e) The supplemental ventilator care payments will be made quarterly in each month listed in subsection (a).

CHAPTER 1189. COUNTY NURSING FACILITY SERVICES

Subchapter E. PAYMENT CONDITIONS, LIMITATIONS AND ADJUSTMENTS

§ 1189.105. Incentive payments.

* * * * *

(b) *Pay for performance incentive payment.* The Department will establish pay for performance measures that will qualify a county nursing facility for additional incentive payments in accordance with the formula and qualifying criteria in the Commonwealth's approved State Plan. For pay for performance payment periods beginning on or after July 1, 2010, in determining whether a county nursing facility qualifies for a quarterly pay for performance incentive, the facility's MA CMI for a picture date will equal the arithmetic mean of the individual CMIs for MA residents identified in the facility's CMI report for the picture date. An MA resident's CMI will be calculated using the RUG-III version 5.12 44 group values in Chapter 1187, Appendix A (relating to resource utilization group index scores for case-mix adjustment in the nursing facility reimbursement system) and the most recent classifiable assessment of any type for the resident.

(c) *Supplemental ventilator care payments.*

(1) A supplemental ventilator care payment will be made each calendar quarter, effective July 1, 2012, to county nursing facilities subject to the following:

(i) To qualify for the supplemental ventilator care payment, the county nursing facility shall satisfy both of the following threshold criteria on the applicable picture date:

(A) The county nursing facility shall have a minimum of ten MA-recipient residents who receive medically necessary ventilator care.

(B) The county nursing facility shall have a minimum of 10% of its MA-recipient resident population receiving medically necessary ventilator care.

(ii) For purposes of paragraph (1), the percentage of the county nursing facility's MA-recipient residents who require medically necessary ventilator care will be calculated by dividing the total number of MA-recipient residents who receive medically necessary ventilator care by the total number of MA-recipient residents. The result of this calculation will be rounded to two percentage decimal points.

(iii) To qualify as an MA-recipient resident who receives medically necessary ventilator care, the resident shall be listed as an MA resident and have a positive response for the MDS item for ventilator use on the Federally-approved PA-specific MDS assessment listed on the county nursing facility's CMI report for the applicable picture date.

(iv) The number of total MA-recipient residents is the number of MA-recipient residents listed on the county nursing facility's CMI report for the applicable picture date.

(v) The applicable picture dates and the authorization of a quarterly supplemental ventilator care payment are as follows:

Picture Dates	***Authorization Schedule***
February 1	**September**
May 1	**December**
August 1	**March**
November 1	**June**

(vi) If a county nursing facility fails to submit a valid CMI report for the picture date as provided under § 1187.33(a)(5) (relating to resident data and picture date reporting requirements), the facility cannot qualify for a supplemental ventilator care payment.

(2) A county nursing facility's supplemental ventilator care payment is calculated as follows:

(i) The supplemental ventilator care per diem is ((number of MA-recipient residents who receive medically necessary ventilator care/total MA-recipient residents) × $69) × (the number of MA-

recipient residents who receive medically necessary ventilator care/total MA-recipient residents).

(ii) The amount of the total supplemental ventilator care payment is the supplemental ventilator care per diem multiplied by the number of paid MA facility and therapeutic leave days.

(3) If the Department grants a county nursing facility a waiver to the 180-day billing requirement, the MA-paid days that may be billed under the waiver and after the authorization date of the waiver will not be included in the calculation of the supplemental ventilator care payment. The Department will not retroactively revise the supplemental ventilator care payment amount.

(4) The paid MA facility and therapeutic leave days used to calculate a qualifying facility's supplemental ventilator care payment under paragraph (2)(ii) will be obtained from the calendar quarter that contains the picture date used in the qualifying criteria as described in paragraph (1).

(5) The supplemental ventilator care payments will be made quarterly in each month listed in paragraph (1).

[Pa.B. Doc. No. 13-1584. Filed for public inspection August 23, 2013, 9:00 a.m.]

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CHS. 271, 272, 273, 284, 285, 287, 288 AND 299]

Regulated Medical and Chemotherapeutic Waste

The Environmental Quality Board (Board) proposes to amend Chapters 271, 272, 273, 284, 285, 287, 288 and 299 to read as set forth in Annex A.

The proposed rulemaking would amend Chapter 271 (relating to municipal waste management—general provisions) to add and clarify terms and definitions in § 271.1 (relating to definitions). The proposed rulemaking would amend Chapter 284 (relating to regulated medical and chemotherapeutic waste) to provide permits-by-rule for certain processors of regulated medical waste using autoclave, incineration, steam or superheated water, and chemical treatment techniques; generators of regulated medical waste processing small quantities of waste; transfer facilities; and organizations that generate regulated medical waste at multiple locations. The proposed amendments to Chapter 284 would also simplify testing requirements for autoclaves, provide flexibility in both the storage and transportation of regulated medical waste and chemotherapeutic waste, update practices for manifesting, recordkeeping, signage and disinfectant requirements, and delete provisions that are under the jurisdiction of the United States Occupational Safety and Health Administration (OSHA) to eliminate any potential inconsistencies. The amendments to Chapter 284 would also provide language that incorporates by reference the United States Postal Service's program for shipping regulated medical waste through the United States Postal Service. The amendments proposed to Chapters 285 and 299 (relating to storage, collection and transportation of municipal waste; and storage and transportation of residual waste) would revise signage requirements for transportation vehicles to be consistent with the recommended changes to Chapter 284. Finally, the proposed amendments to Chapters 272, 273, 287 and 288 would replace all references to "infectious" waste to "regulated medical" waste to be consistent with the recommended changes to Chapters 271 and 284.

This proposed rulemaking was adopted by the Board at its meeting on April 16, 2013.

A. *Effective Date*

This proposed rulemaking will be effective upon final-form publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information, contact Ali Tarquino Morris, Bureau of Waste Management, P. O. Box 69170, Rachel Carson State Office Building, Harrisburg, PA 17106-9170, (717) 783-2388; or Susan Seighman, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Information regarding submitting comments on this proposed rulemaking appears in Section J of this preamble. Persons with a disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposed rulemaking is available on the Department of Environmental Protection's (Department) web site at www.depweb.state.pa.us (select "Public Participation").

C. *Statutory Authority*

This proposed rulemaking is being made under the authority of the following statutes:

The Solid Waste Management Act (SWMA) (35 P. S. §§ 6018.101—6018.1003), which in section 105(a) (35 P. S. § 6018.105(a)) grants the Board the power and the duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the SWMA. Sections 102(4) and 104(6) of the SWMA (35 P. S. §§ 6018.102(4) and 104(6)) provide the Department with the power and duty to regulate the storage, collection, transportation, processing, treatment and disposal of solid waste to protect the public health, safety and welfare.

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 (ICWDL), which in section 4(b) (35 P. S. § 6019.4(b)) grants the Board the power and duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the ICWDL.

Section 1917-A of The Administrative Code of 1929 (71 P. S. § 510-17) authorizes and requires the Department to protect the people of this Commonwealth from unsanitary conditions and other nuisances, including any condition that is declared to be a nuisance by any law administered by the Department. Section 1920-A (71 P. S. § 510-20) of The Administrative Code of 1929 grants the Board the power and duty to formulate, adopt and promulgate rules and regulations as may be determined by the Board for the proper performance of the work of the Department.

D. *Background and Purpose*

The proposed rulemaking represents a comprehensive revision of the Commonwealth's existing infectious and chemotherapeutic waste regulations, which is necessary for several reasons.

Since solid waste is not always generated, processed and disposed of within this Commonwealth, the proposed

revisions allow persons generating and managing infectious and chemotherapeutic waste to do so in a manner that complies with Commonwealth law and is consistent with Federal requirements and the requirements of other states. Other states and the Federal government identify infectious waste as "regulated medical waste." This proposed rulemaking includes revisions that would identify "infectious waste" as "regulated medical waste," making the terminology consistent with Federal and other states' requirements. This proposed change in terminology will simplify the labeling requirements on containers that are used to collect, transport, process and dispose of the waste. Persons managing regulated medical waste will no longer need to ensure that Pennsylvania containers and labels are used and kept separate from those employed in other states. This uniform practice should reduce the costs borne by generators and other persons managing regulated medical waste because the same containers and labels could be used to satisfy Commonwealth requirements, Federal requirements and the requirements imposed by other states.

This proposed rulemaking streamlines the transportation and shipment requirements for regulated medical waste in several respects. The proposed amendments allow generators, transporters and those involved in storage, processing and disposal of regulated medical waste to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations instead of prescriptive and outdated paper manifests. A manifest is a document that accompanies a waste shipment and ensures that the waste being shipped is processed or disposed of in the manner intended by the generator. The ICWDL requires that a person who generates, transports, stores, processes or disposes regulated medical waste use a manifest to track waste through the shipping process to the disposal facility. The proposed amendments allow for the manifest requirement to be satisfied with a shipping paper, log or electronic tracking system that provides the required information, allowing the generator to track its waste in accordance with current industry practices. The flexibility added to this process should prove to be more efficient for all persons managing this waste stream.

In addition, the proposed amendments authorize the transportation of regulated medical waste through the United States Postal Service under the United States Postal Service's program and requirements for shipping medical waste. The existing regulations specifically provide that sharps from small quantity generators may be sent through the mail. However, the proposed amendments broaden this authorization to include other types of regulated medical waste in any amount or volume provided that certain conditions are satisfied, including the mailing standards and other relevant regulations of the United States Postal Service. This should provide generators, especially those generating small quantities of medical waste, with an alternative transportation.

The proposed amendments also encourage labor and fuel efficiency by removing certain storage and transportation restrictions. The existing regulations limit storage of regulated medical waste at the generation site for a maximum of 30 days from the date that waste was first placed into the container. This provision governing the duration of storage requires small generators to transport partial loads offsite, thereby incurring additional costs. The proposed amendments allow for generators to store regulated medical waste for up to 30 days from the date that the container is full or the date the generator seals the container, whichever occurs earlier. These proposed revisions provide the generator with more control over the length of time the waste may be stored onsite and promote more efficient business practices by reducing the need to transport partial loads, which will result in a cost savings for the generator.

Additionally, the proposed revisions allow haulers to transport containerized regulated medical waste and chemotherapeutic waste along with other wastes in the same vehicle. This will reduce the number of trips needed to transport waste from generators that have both regulated medical waste and other waste streams which require disposal, provided that the transportation can be done in a manner that does not adversely affect public health and safety or the environment.

The proposed amendments also delete provisions that relate to areas governed by OSHA. This removes the possibility that provisions may be inconsistent or duplicative of OSHA requirements but in no way affects the applicability of OSHA requirements to persons within this Commonwealth.

E. *Summary of Regulatory Requirements*

The following outlines the regulatory requirements that have been affected by the proposed rulemaking and describes the basis for the amendments.

There has been one global change to the regulations. "Regulated medical waste" has been added as a new term and is defined in § 271.1 as "infectious waste." Aside from the definition of "infectious waste" in § 271.1, all other references to "infectious waste" are proposed to be replaced with "regulated medical waste" throughout Chapters 271, 272, 273, 284, 285, 287, 288 and 299. There is no substantive change in the definitions other than minor amendments in the following discussion on § 271.1. This shift in terminology will result in the Commonwealth's labeling requirements being consistent with Federal and other states' requirements.

§ 271.1. Definitions

The Board is proposing to amend certain terms and add additional terms that assist in the identification of materials that are considered regulated medical or chemotherapeutic waste. The terms used to identify these classifications of waste include the following: "autoclave," "body fluids," "commercial regulated medical or chemotherapeutic waste facility," "disinfection," "general composting facility," "incineration," "infectious waste," "mobile regulated medical waste processing facility," "regulated medical waste," "regulated medical waste aggregation facility," "sharps," "special handling waste," "thermal processing" and "unrecognizable regulated medical waste." Of these terms, "autoclave," "disinfection," "general composting facility," "special handling waste," "thermal processing" and "unrecognizable regulated medical waste" include a reference to "infectious waste" within their definitions. This reference is proposed to be replaced with "regulated medical waste."

The definition of "body fluids" is proposed to be amended to include saliva because saliva is a fluid that is capable of containing visible blood.

The definition of "commercial regulated medical or chemotherapeutic waste facility" is proposed to be amended to eliminate redundancies and is rewritten for clarity.

The definition of "environmental protection acts" is proposed to be amended by citing the relevant sections so that the formatting is consistent with the other citations.

The definition of "incineration" is proposed to be added and is defined as the "act of reducing to ashes by combustion." "Incineration" has been added to the list of definitions to clarify its meaning throughout Chapter 271.

As indicated previously, the proposed definition of "regulated medical waste" is "infectious waste," thereby incorporating the existing definition of "infectious waste." The following changes are proposed to be made to the definition of "infectious waste":

• Pathological wastes do not include tissues that have been preserved in formaldehyde or any other approved preserving agents because preserved tissues do not exhibit the pathological characteristics of unpreserved tissues. Therefore, preserved tissues have been explicitly excluded from pathological wastes.

• Components of human blood and body fluid waste have been added. Soft plastic pipettes and plastic blood vials that have been used for blood transfusions will be considered human blood and body fluid waste. Also, tubing that is used to connect the intravenous bag to the patient has been added.

• Under the category for animal wastes, all animal waste known to have been exposed to zoonotic infectious agents or nonzoonotic human pathogens is defined as infectious waste in the proposed rulemaking. The requirement that exposure to these pathogens must have occurred during research for the animal wastes to fall subject to regulation has been removed.

• Used sharps are no longer limited to those generated at medical, research or industrial laboratories.

• Tissues and specimens that are being transported to or stored at a laboratory prior to laboratory testing will be excluded from infectious waste.

• Because regulated medical waste incineration is no longer covered under Chapter 283 (relating to resource recovery and other processing facilities), ash residue from the incineration of regulated medical waste will be regulated under § 284.321 (relating to regulated medical waste monitoring requirements). Therefore, the regulatory reference in subparagraph (iii)(F) is proposed to be corrected to § 284.321.

The term "mobile infectious waste processing facility" is proposed to be changed to "mobile regulated medical waste processing facility."

The proposed definition of "regulated medical waste aggregation facility" is defined as a "facility that accepts, aggregates or stores regulated medical waste."

The definition of "sharps" is proposed to be amended to clarify an existing ambiguity. Broken glass no longer has to have been in contact with pathogenic organisms to be considered sharps, as are syringes to which a needle is or can be attached. The phrase "with or without the attached needle, suture needles" is redundant and is proposed to be deleted. Razors are no longer required to be "disposable" to qualify as sharps.

§ 284.1. Scope

References to Chapters 283 and 285 are proposed to be added.

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

Proposed amendments to this section provide six permits-by-rule for qualifying processing facilities, which implement autoclaves, incinerators, steam and superheated water disinfection, onsite processing of blood and body fluids, short duration storage facilities and small quantity generators that process their own waste.

For autoclaves, incinerators and steam superheated water disinfection operators to qualify for a permit-by-rule under paragraphs (a)(1)—(3), the facility shall process at least 50% of its own regulated medical and chemotherapeutic waste and is limited to accepting not more than 50% of regulated medical waste for processing from small quantity generators. Facilities that process waste shall ensure that the processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste. The operator of the facility shall also provide the Department with the following: a notice of intention to operate under permit-by-rule; the name and address of the facility; a description of the processing activity; and the names and telephone numbers of the individuals responsible for operation of the processing facility.

More specifically, under subsection (a)(1) and (3), autoclave facilities and facilities with steam and superheated water disinfection may not process pathological or chemotherapeutic waste. However, these facilities may process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking. Existing regulations require the waste to be vaporized, but the proposed amendments state "render the waste unrecognizable" since, by definition, autoclaves do not vaporize all liquid. Under subsection (a)(2) a processing facility with an incinerator may process other municipal waste generated onsite if the resulting ash is managed as regulated medical or chemotherapeutic waste.

The permit-by-rule available under subsection (a)(4) is for onsite processing of liquid blood and body fluids using chemical treatment techniques that encapsulate or convert liquid blood or body fluids into solids or gels so that no free liquids remain. The proposed amendments provide the Department with the authority to approve the use of other disinfectant-based products under subsection (a)(4) if their effectiveness can be demonstrated. The processed regulated medical waste may be disposed at a municipal waste landfill provided that no free liquids remain in the processed waste, and the landfill has received written approval from the Department authorizing the disposal of this type of processed medical waste.

The permit-by-rule in subsection (a)(5) covers transfer facilities that temporarily store regulated medical or chemotherapeutic waste for up to 72 hours provided that the stored waste remains in its original packaging and is not putrescent.

The permit-by-rule in subsection (b) applies to generators that process and disinfect less than 220 pounds per month of regulated medical waste onsite, but do not render the waste unrecognizable. The generator shall dispose of the processed waste in a landfill or have the waste incinerated by a facility that has written approval from the Department to accept this type of waste. In addition, the generator shall comply with the manifest requirements in § 284.701(b)(5) (relating to scope).

Subsection (c) specifies the operating requirements for the permit-by-rule facilities identified in subsections (a)(1)—(4) and (b). Subsection (c)(1) incorporates the proposed citations that require the facility to comply with Chapter 284, Subchapters E and F (relating to segregation and storage; and collection and transportation) and Chapter 285.

For facilities operating under subsection (a), in addition to the current requirements, proposed amendments to subsection (c)(3)(i) require the written plan used to manage regulated medical waste generated at the facility to also contain the frequency of equipment calibration.

Under subsection (c)(8), for onsite autoclave facilities, "treated or processed regulated medical waste" is proposed to replace "processing residue" because "treated or processed regulated medical waste" more clearly describes waste that has not been rendered unrecognizable.

Subsection (c)(10) and (11) is proposed to be deleted because the compliance criteria have been included in the proposed subsection (a)(1)—(3).

§ 284.3. Regulated medical waste aggregation facilities

This proposed section establishes a permit-by-rule for regulated medical waste aggregation facilities. The regulated medical waste aggregation facilities must comply with the generator standards in Chapter 284, Subchapter E and only accept waste generated onsite or offsite by the operator of the aggregation facility, or waste generated in the same building or complex of buildings by physicians in their private practices or other medical personnel. The Department retains the ability to require an operator to obtain an individual permit, or take other appropriate action, if the generator is not in compliance or harms or presents a threat of harm to the health, safety or welfare of the people or the environment.

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

A reference to § 284.132 (relating to determination of applicability), which is proposed to be rescinded in this proposed rulemaking, is proposed to be deleted. A proposed clause clarifies that the Department can require a person or municipality authorized by a general permit to obtain an individual permit if a general permit is not available to conduct the specified activity.

§ 284.111. Application for general permit

A typographical error is proposed to be corrected ("employes" to "employees").

§ 284.112. Completeness review

The Department previously required that potential users of certain general permits obtain a determination of applicability from the Department prior to conducting the activity authorized by the general permit. The Department has since determined that a registration process for the issuance of general permits will be used, as opposed to a determination of applicability. Therefore, the language regarding the determination of applicability is proposed to be deleted from subsection (a).

§ 284.115. Department-initiated general permits

"Departmental" is proposed to be replaced with "Department" in subsection (c)(5) for clarity.

§ 284.116. General permit renewal

Proposed § 284.116 provides a procedure for renewing general permits. The section is based on the existing practices of the Department and is proposed to be added for clarity.

§ 284.121. Contents of general permits

The Department believes that a registration process will increase efficiency in the processing of general permits for both the applicant and the Department. The Department proposes to eliminate determinations of applicability from the process of general permit issuance. Therefore, language regarding determination of applicability is proposed to be deleted in paragraph (3).

The requirement in paragraph (11) that processing residue be disposed of in a landfill is proposed to be deleted and replaced with a requirement for processing residue to be managed in accordance with the SWMA to avoid potential conflicts.

In addition, a typographical error has been corrected in paragraphs (12) and (13) ("employes" to "employees" or "employee").

In paragraph (18), the prohibition of processing pathological waste or chemotherapeutic waste in an autoclave has been rewritten for clarity.

§ 284.122. Modification of certain requirements

The term "waiver" is proposed to be deleted from the section heading. The Department retains the ability to waive certain requirements when those requirements are inappropriate or otherwise not applicable to the applicant's proposed operation under a general permit. However, in this situation, the Department would modify the applicant's permit conditions to account for requirements that may not apply to the applicant's operation.

Provisions that limit the Department's flexibility to provide applicants with an effective permit are proposed to be deleted from subsection (b). These mandatory provisions relate to the Department's legal right to enter the permitted area, the identification of interested parties, compliance information, verification of the application, and the administration of civil penalties and enforcement actions. Removal of these mandatory provisions will allow the Department to use its discretion in issuing and modifying permits to provide the applicant with a permit that makes sense within the context of the applicant's proposed operation, while complying with the regulations that are in the best interest of the Commonwealth.

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

The Department is using a registration process, instead of a determination of applicability, to authorize an applicant's operation under a general permit. Therefore, language regarding determinations of applicability is proposed to be deleted from this section.

§ 284.132. Determination of applicability

The Department has determined that a registration process will be used for the issuance of general permits, instead of a determination of applicability. Therefore, this section is no longer necessary and is proposed to be rescinded.

§ 284.210. Application requirements

A typographical error is proposed to be corrected in this section. The reference to "§§ 279.101—279.111 (relating to general requirements)" is proposed to be changed to "§§ 279.101—279.111."

§ 284.220. Operating requirements

The proposed amendment to this section references the subchapters in Chapter 279 (relating to transfer facilities) that are applicable to operating requirements for transfer facilities.

§ 284.320. Operating requirements

The proposed amendment to this section references the subchapter in Chapter 283 that is related to operating requirements for processing facilities.

§ 284.321. Regulated medical waste monitoring requirements

Throughout this section, abbreviations of spore names have been spelled out for clarity and the nomenclature of "Bacillus stearothermophilus" has been updated to "Geobacillus stearothermophilus" to reflect its taxonomy in a new genus.

The current regulations require that microbiological analysis of a composite sample of the processing or ash residue be submitted to the Department quarterly. In the proposed amendment to subsection (b), the requirement to submit these microbiological analyses is reduced to annual submissions to be consistent with the schedule for submission of chemical analyses in subsection (c).

Subsection (f), regarding disinfection, is proposed to be amended to require that sterility indicators, analyzed to verify the effectiveness in the disinfection process, shall be placed within the load where disinfection is most difficult to achieve.

Subsection (m) is proposed to be amended to state that an autoclave facility shall comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.

Autoclave testing requirements are proposed to be added to subsection (n) to ensure that disinfection occurs under the proper operating conditions, with reference to § 284.322 (relating to autoclave validation testing requirements).

§ 284.322. Autoclave validation testing requirements

This proposed section defines the proper protocols and testing conditions that processors shall use to test their autoclaves. The requirements of the section ensure that proper performance criteria have been met and adequate disinfection is achieved. Generally, each autoclave shall be tested individually to establish its operating parameters prior to its first use and regularly thereafter. If a facility uses multiple autoclaves that are identical, an initial validation test may be performed on one of the autoclaves and the results used to establish the operating parameters of all identical autoclaves at the facility.

Chapter 284, Subchapter E. Segregation and storage

Subchapter E is proposed to be reorganized to mirror the steps taken by generators and processors when managing waste, starting with the segregation of waste through its storage. Since segregation by waste type is the first step taken by the generator in managing regulated medical and chemotherapeutic waste, the Department proposes to relocate the section regarding segregation so that it is the first section in Subchapter E following a description of the subchapter's scope. The order of management continues by next addressing basic storage requirements, followed by storage containers, marking of containers, duration of storage, reuse of containers, storage of ash residue and storage of processing residue. The following table summarizes the reorganization of sections in Subchapter E:

Subject of Section	*Current Regulation*	*Proposed Regulation*
Segregation	§ 284.412	§ 284.411
Basic storage requirements	§ 284.411	§ 284.412
Storage containers	§ 284.415	§ 284.413
Marking of containers	§ 284.416	§ 284.414
Duration of storage of waste for generators	§ 284.413	§ 284.415
Duration of storage of waste for processors	§ 284.414	§ 284.416
Reuse of containers	§ 284.417	§ 284.417
Storage of ash residue	§ 284.418	§ 284.418
Storage of processing residue	§ 284.419	§ 284.419

§ 284.401. Scope

The description of the references to §§ 285.111—285.115 and 285.121 is proposed to be deleted.

§ 284.411. Segregation

Subchapter E is proposed to be reorganized as shown in the previous table to follow the path of waste as it is handled by generators and processors. The proposed heading of § 284.411 is "segregation."

In addition, the section is proposed to be amended to state that regulated medical and chemotherapeutic waste be separated into the following three categories at the point of origin in the generating facility: (1) regulated medical waste, excluding pathological waste; (2) pathological waste; and (3) chemotherapeutic waste. Sharps that qualify as regulated medical waste may be placed in a chemotherapeutic waste sharps container under the proposed regulations. This section also contains requirements for bags used to store waste, which is discussed in § 284.413 (relating to storage containers).

§ 284.412. Basic storage requirements

Subchapter E is proposed to be reorganized as shown in the previous table to follow the path of waste as it is handled by generators and processors. Basic storage is the next logical step considered by generators and processors after the waste has been segregated.

Subsection (a) is proposed to be amended to ensure segregation occurs first, and the temperature for refrigeration has been added in degrees Fahrenheit in paragraph (a)(4) for clarification.

§ 284.413. Storage containers

Subchapter E is proposed to be reorganized as shown in the previous table to follow the path of waste as it is handled by generators and processors.

Subsection (f), regarding protective clothing for persons packaging regulated medical or chemotherapeutic waste, is proposed to be deleted to eliminate any possible conflicts with OSHA regulations or other workplace safety procedures.

§ 284.414. Marking of containers

Subchapter E is proposed to be reorganized as shown in the previous table to follow the path of waste as it is handled by generators and processors. Throughout § 284.414, "infectious waste" is proposed to be replaced with "regulated medical waste" with regard to marking containers, and the labeling requirements have been revised so that compliance is more convenient, while maintaining the intention of the regulations.

The proposed amendments provide a 1-year transition period after the effective date of the adoption of the final-form rulemaking for persons to comply with the new labeling requirements.

Also, containers will no longer be labeled with the date the waste was generated; instead, labels must include the date the container was full or the date the generator sealed the container. The exception to this rule is that roll-off containers need not be marked with the date, but a record of the date on which the roll-off was full or sealed must be maintained at the generating facility for at least 1 year.

In the proposed regulation, labeling requirements only apply when waste is transported offsite. For onsite transportation of waste within the same geographical property or facility, such as within a hospital campus, it is no longer necessary for generator and transporter information to be labeled on the containers.

Prescriptive size requirements for container labels have been replaced with performance-based requirements that ensure labeling is clearly legible.

§ 284.415. Duration of storage of regulated medical waste for generators

Subchapter E is proposed to be reorganized as shown in the previous table to follow the path of waste as it is handled by generators and processors.

Throughout this section, language referring to "the date that waste was first placed in a container" is proposed to be changed to "to the date that the container was full or sealed" to be consistent with other sections of the proposed rulemaking. Therefore, under this section, generators are required to mark the container with the date on which the container was full or the date that the container was sealed, as required under § 284.414 (relating to marking of containers), and generators may store regulated medical waste onsite for up to 30 days from the date the container was full or sealed. Language relative to freezing as a method to lengthen the duration of storage is proposed to be deleted from § 284.413 because the time periods for storage were difficult to interpret. Temperature standards for storage are proposed to be added to § 284.412 (relating to basic storage requirements). The requirement that putrescent waste be moved offsite within 24 hours has been changed to within 3 business days. The Department believes that the proposed amendments are more easily understood and provide generators sufficient storage times under typical operations while maintaining the intent of the regulations.

§ 284.416. Duration of storage of regulated medical waste for processors

Subchapter E is proposed to be reorganized as shown in the previous table to follow the path of waste as it is handled by generators and processors. Storage temperatures in this section are slightly amended to correct errors in the existing text.

§ 284.417. Reuse of containers

This section currently provides separate subsections addressing the reuse of nonfiberboard containers housing regulated medical waste versus chemotherapeutic waste. The proposed amendments to this section allow the same standards to apply for the reuse of nonfiberboard containers regardless of whether the container houses chemotherapeutic waste or regulated medical waste. Therefore, subsection (d), regarding the reuse of containers housing chemotherapeutic waste, is proposed to be deleted and proposed amendments to subsection (c) add chemotherapeutic waste.

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

Subsection (a)(2) is proposed to be clarified to indicate that ash residue must be stored on a pad to contain a spill or release of ash and facilitate clean-up.

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

Subsection (c) has been rewritten to more clearly state that ash from separate generators must be kept separate. Subsection (d) has been rewritten to more clearly state that municipal waste may be commingled with ash residue from regulated medical or chemotherapeutic waste incineration for transportation, provided that both come from the same generator.

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

In subsection (b)(4), a Fahrenheit equivalent is proposed to be added to clarify the temperature required to maintain waste in a nonputrescent state.

The prescriptive strength and weight limits for a corrugated fiberboard container in subsection (c)(1)(iv) is proposed to be deleted. Proposed subsection (c)(1)(v) references § 284.414, regarding marking of containers to ensure that the containers are marked properly for transportation.

Subsection (d) is proposed to be deleted because infectious waste, now labeled as regulated medical waste, and chemotherapeutic waste are required to be segregated into separate containers at the point of generation. Since these wastes are containerized and not commingled, the Department proposes to allow these containerized waste streams to be transported in the same vehicle and has removed the existing prohibition.

Proposed subsection (e) clarifies that, although regulated medical or chemotherapeutic waste may be transported in the same vehicle as municipal waste, it may not be commingled with municipal waste or transported in the same vehicle with residual waste.

In subsection (g), the transport time for regulated medical waste in an unrefrigerated vehicle is proposed to be increased from 48 to 72 hours provided the waste is not putrescent. This allows transporters to more easily comply with the regulations, provided the waste is not putrescent.

§ 284.513. Transportation of regulated medical and chemotherapeutic waste; additional provisions

The reference to OSHA regulations in subsection (b)(2) is proposed to be corrected to accurately cite the applicable OSHA regulation regarding bloodborne pathogens and the standards for biohazard signage.

Subsection (c) is proposed to be amended to state that portable disinfectants must be EPA approved.

Subsection (e) is proposed to be deleted to remove potential conflicts with OSHA regulations or workplace safety procedures.

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

Subsection (b) is proposed to be rewritten to more clearly state the requirement that processing residue from chemotherapeutic or regulated medical waste from separate generators shall be transported separately.

§ 284.602. License requirement

A grammatical error, "onside" instead of "onsite," is proposed to be corrected and a minor clarification is proposed to subsection (b)(3).

§ 284.623. Conditions of licenses

A grammatical error, "employes" instead of "employees," is proposed to be corrected.

§ 284.641. Bond requirement

A heading is proposed to be added for subsection (f).

§ 284.701. Scope

In the proposed amendments, logs or shipping papers, including electronic tracking systems, are recognized acceptable ways of tracking waste for manifesting purposes. Proposed amendments to subsection (b)(4) incorporate by reference the United States Postal Service's program for shipping regulated medical waste. Additional minor clarifications have been made throughout the section.

§ 284.702. Transfer facilities

This section is proposed to be renumbered for clarity. Language in current subsection (a) regarding the existing paper manifest tracking system is proposed to be deleted because shipping papers or logs, including electronic tracking systems, have become acceptable standard business practices for tracking the transportation and delivery of regulated medical and chemotherapeutic wastes. Subsection (b) is proposed to be renumbered as paragraph (2) and rewritten for clarity. Proposed paragraph (1) requires the transfer facility to be permitted by the Department.

§ 284.703. Recordkeeping

The record retention requirement in current subsection (a) is proposed to be reduced from 5 years to 2 years. Proposed amendments to this section clarify that the record is to be retained for 2 years from the date the record was prepared, and records shall be submitted to the Department upon request. Subsection (b) regarding manifests is obsolete and proposed to be deleted.

§ 284.711. Use of manifest

Language regarding manifests is proposed to be deleted because logs or shipping papers, including electronically based tracking systems, are acceptable standard business practices and are acceptable for compliance with the proposed amendments.

§ 284.712. Preparation of manifest

Generators will be required to create a log or shipping paper, which will qualify as a manifest, allowing the use of standard shipping procedures to track regulated medical waste during shipment through to its disposal.

Subsection (a)(10) is proposed to be deleted because, in accordance with proposed § 284.722(f) (relating to preparation and use of manifest), the generator will receive the shipping log back from the transporter after the waste has been delivered to the designated facility. Therefore, the designated facility no longer needs to be included in the original shipping log prepared by the generator.

§ 284.713. Generator's distribution of copies

This section is proposed to be rescinded because the record or shipping log is not required to be distributed to the various parties as previously required.

§ 284.714. Exception reporting

In proposed amendments to subsection (a), a log or shipping paper is to be received by the generator rather than a copy of a manifest since logs or shipping papers will satisfy the manifesting requirement under the proposed regulations and the ICWDL. The time limit for the paperwork to be completed and transmitted to the proper entity is proposed to be extended from 20 days to 30 days based on the amount of time needed for industry practices.

Subsection (b) is proposed to be reworded for clarity.

§ 284.721. Basic requirements

This section is proposed to be rescinded because the provisions to satisfy the manifest requirements are proposed to be amended.

§ 284.722. Preparation and use of manifest

The provisions regarding manifest copies are proposed to be deleted because logs or shipping papers, including electronic tracking systems, qualify as a manifest under the proposed amendments. The transporter shall ensure that processing facilities and generators have been provided with the relevant logs or shipping papers that are required.

§ 284.723. Waste delivery

This section is proposed to be rescinded because the provisions to satisfy the manifest requirements have been amended.

§ 284.724. Transportation limitations

Regulatory citations are proposed to be changed to maintain accuracy with the proposed reorganization of Chapter 284, Subchapter E. Information regarding copies of the manifests is proposed to be deleted since this requirement will be satisfied by logs or shipping papers.

§ 284.731. Scope

Section 284.733 (relating to distribution of copies) is proposed to be rescinded. Therefore, the reference to § 284.733 is proposed to be deleted from this section. Language regarding "owners" of waste processing facilities is proposed to be deleted since the owner of the facility may or may not be involved with the daily operations of the facility.

§ 284.732. Use of manifest

Language regarding "owners" of waste processing facilities is proposed to be deleted since the owner of the facility may or may not be involved with the daily operations of the facility. A log or shipping paper has been substituted for manifests to simplify documentation procedures.

§ 284.733. Distribution of copies

This section is proposed to be rescinded because the provisions to satisfy the manifest requirements are proposed to be amended.

§ 284.734. Significant discrepancies

In subsection (a)(2), a significant discrepancy is proposed to be defined as more than 1% variation in piece count for batch waste and more than 5% weight discrepancy for bulk waste. The time limits in subsection (b) are proposed to be changed from days to business days, allowing more flexibility for a resolution to be reached in the case of a dispute.

§ 285.218. Signs on vehicles

"Infectious or chemotherapeutic waste" has been replaced with "regulated medical or chemotherapeutic waste" throughout the proposed rulemaking. Therefore, required signage on transportation vehicles must also change. Signs on vehicles transporting regulated medical or chemotherapeutic waste must read "Regulated Medical/Chemotherapeutic Waste" under the proposed amendment.

F. *Benefits, Costs and Compliance*

Benefits

The proposed rulemaking simplifies the labeling requirements to reduce costs and ensure consistency with the requirements of other states and the Federal government. The proposed amendments would allow generators, transporters and those involved in storage and processing to use standard business documentation to demonstrate compliance with the regulations instead of the currently prescribed, outdated paper manifest. The proposed amendments also encourage labor and fuel efficiency by allowing haulers to transport regulated medical waste along with other wastes in the same vehicle and by allowing facilities more time to completely fill a vehicle before the vehicle must be placed into service. To avoid conflicts with OSHA requirements, duplicative requirements are proposed to be deleted. The proposed amendments also provide another convenient shipping option by removing barriers to shipping waste through the mail when authorized by the United States Postal Service.

Compliance Costs

The proposed rulemaking provides a cost savings to the regulated community through: providing consistency with the United States Department of Transportation and other states; reduced transportation cost for generators and transporters due to consolidation of waste in trucks; longer storage times for generators, meaning fewer waste pickups; and reducing transportation costs for collection and processing.

Compliance Assistance Plan

The Department will assist the regulated community by developing fact sheets and continuing to work with industry during program implementation. The Department's field staff will provide compliance assistance during routine facility permitting activities and inspections.

Paperwork Requirements

The proposed rulemaking should result in a reduction of paperwork requirements through the revised provisions for satisfying manifest requirements; the change in terminology from "infectious" to "regulated medical" waste ensures Pennsylvania signage and labeling requirements align with the requirements of the United States Department of Transportation and the requirements of other states; and the creation of permits-by-rule for qualifying facilities will eliminate the need to issue general or individual permits to those facilities.

G. *Pollution Prevention*

The Pollution Prevention Act of 1990 (42 U.S.C.A. §§ 13101—13109) establishes a National policy that promotes pollution prevention as the preferred means for achieving state environmental protection goals. The Department encourages pollution prevention, which is the reduction or elimination of pollution at its source, through the substitution of environmentally friendly materials, more efficient use of raw materials or the incorporation of energy efficiency strategies. Pollution prevention practices can provide greater environmental protection with greater efficiency because they can result in significant cost savings to facilities that permanently achieve or move beyond compliance.

This proposed rulemaking will continue to ensure that the citizens and the environment of this Commonwealth experience the advantages of a regulated medical waste regulatory program that is protective of public health and the environment. The proposed rulemaking encourages consolidation of waste for transportation, reducing the number of trips needed to transport waste and thereby reducing air emissions from transportation vehicles.

H. *Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 5, 2013, the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of comments, recommendations or objections raised.

J. *Public Comments*

Written comments. Interested persons are invited to submit comments, suggestions or objections regarding the proposed rulemaking to the Environmental Quality Board, P. O. Box 8477, Harrisburg, PA 17105-8477 (express mail: Rachel Carson State Office Building, 16th Floor, 400 Market Street, Harrisburg, PA 17101-2301). Comments submitted by facsimile will not be accepted. Comments, suggestions or objections must be received by the Board by September 23, 2013. Interested persons may also submit a summary of their comments to the Board. The summary may not exceed one page in length and must also be received by September 23, 2013. The one-page summary will be provided to each member of the Board in the agenda packet distributed prior to the meeting at which the final regulation will be considered.

Electronic comments. Comments may be submitted electronically to the Board at RegComments@pa.gov and must also be received by the Board by September 23, 2013. A subject heading of the proposed rulemaking and a return name and address must be included in each

transmission. If an acknowledgement of electronic comments is not received by the sender within 2 working days, the comments should be retransmitted to the Board to ensure receipt.

E. CHRISTOPHER ABRUZZO,
Acting Chairperson

Fiscal Note: 7-480. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE VIII. MUNICIPAL WASTE

CHAPTER 271. MUNICIPAL WASTE MANAGEMENT—GENERAL PROVISIONS

Subchapter A. GENERAL

§ 271.1. Definitions.

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

* * * * *

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

* * * * *

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

* * * * *

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

(i) **[Of the waste processed, less than 50% on a monthly average was generated onsite.**

(ii) Greater than 50% of the waste processed on a monthly average is not generated from entities that are wholly-owned by the owner of the waste processing facility.]

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

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

* * * * *

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

* * * * *

Environmental protection acts—The act, The Clean Streams Law (35 P. S. §§ 691.1—691.1001), the Municipal Waste Planning, Recycling and Waste Reduction Act **[(53 P. S. §§ 4001.101—4001.1904)] (53 P. S. §§ 4000.101—4000.1904)**, the Hazardous Sites Cleanup Act (35 P. S. §§ 6020.101—6020.1305), the Low-Level Radioactive Waste Disposal Act **[(35 P. S. §§ 7130.101—7130.906)] (35 P. S. §§ 7130.101—7130.905)**, the act of July 13, 1988 **(P. L. 525, No. 93)** (35 P. S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Disposal Law, the Air Pollution Control Act (35 P. S. §§ 4001—4015), the Surface Mining Conservation and Reclamation Act **[(52 P. S. §§ 1396.1—1396.31)] (52 P. S. §§ 1396.1—1396.19b)**, the Noncoal Surface Mining Conservation and Reclamation Act **[(35 P. S. §§ 3301—3326)] (52 P. S. §§ 3301—3326)**, the Dam Safety and Encroachments Act (32 P. S. §§ 693.1—693.27), and other State or Federal statutes relating to environmental protection or the protection of public health, including statutes adopted or amended after April 9, 1988.

* * * * *

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

* * * * *

Household hazardous waste—

(i) Waste generated by a household that could be chemically or physically classified as a hazardous waste under the standards of Article VII (relating to hazardous waste management).

(ii) For the purpose of this definition, the term "household" includes those places described as "households" in 40 CFR 261.4(b)(1) (relating to exclusions).

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

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

* * * * *

Infectious waste—

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

* * * * *

(B) *Pathological wastes.* Human pathological wastes, including tissues, organs and body parts and body fluids

that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth **or tissues that have been preserved with formaldehyde or other approved preserving agents**.

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

* * * * *

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

* * * * *

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

* * * * *

(F) *Used sharps.* Sharps that have been in contact with infectious agents or that have been used in animal or human patient care or treatment **[, at medical, research or industrial laboratories]**.

* * * * *

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

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

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

* * * * *

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

***Regulated medical waste*—Infectious waste.**

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

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

Unrecognizable **[** ***infectious*** **]** ***regulated medical*** *waste*—All components of the waste have been processed to produce indistinguishable and unusable pieces smaller than 3/4 of an inch, except that all sharps must be

smaller than 1/2 inch. The term does not mean compaction or encapsulation except through:

* * * * *

§ 271.2. Scope.

* * * * *

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

* * * * *

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

Subchapter B. GENERAL REQUIREMENTS FOR PERMITS AND PERMIT APPLICATIONS

REQUIREMENT

§ 271.101. Permit requirement.

* * * * *

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

* * * * *

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

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

* * * * *

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

* * * * *

EXISTING FACILITIES

§ 271.114. Transition period.

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

* * * * *

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

Subchapter E. CIVIL PENALTIES AND ENFORCEMENT

ENFORCEMENT

§ 271.421. Administrative inspections.

* * * * *

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

* * * * *

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

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

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

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

* * * * *

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

* * * * *

Subchapter G. RESIDUAL WASTE

GENERAL PROVISIONS

§ 271.601. Scope.

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

ADDITIONAL APPLICATION REQUIREMENTS

§ 271.611. Chemical analysis of waste.

* * * * *

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

Subchapter I. BENEFICIAL USE

SCOPE

§ 271.801. Scope.

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

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

* * * * *

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

§ 271.811. Authorization for general permit.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 272. MUNICIPAL WASTE PLANNING, RECYCLING AND WASTE REDUCTION

Subchapter C. MUNICIPAL WASTE PLANNING

PLAN CONTENT

§ 272.223. Description of waste.

* * * * *

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

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

* * * * *

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

* * * * *

Subchapter F. HOUSEHOLD HAZARDOUS WASTE COLLECTION, TRANSPORTATION AND MANAGEMENT

OPERATION OF PROGRAMS

§ 272.532. Limitations on acceptable waste.

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

* * * * *

(2) **[Infectious waste] Regulated medical**, except sharps.

* * * * *

CHAPTER 273. MUNICIPAL WASTE LANDFILLS

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

SPECIFIC WASTES

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

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

* * * * *

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

SPECIFIC WASTES

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

(a) **[Infectious] Regulated medical** waste may not be disposed **of** at a municipal waste landfill unless:

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

(2) Prior to initial disposal the landfill operator has obtained the necessary approval for disposal from the Department based on the application provided under § 273.411 (relating to processed **[infectious] regulated medical** and chemotherapeutic waste disposal).

* * * * *

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

Subchapter A. GENERAL PROVISIONS

GENERAL PROVISIONS

§ 284.1. Scope.

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

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

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

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

(i) Processing of pathological waste is prohibited.

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

(2) An onsite incineration facility that burns at least 50% of its own infectious or chemotherapeutic waste generated onsite and accepts offsite infectious or chemotherapeutic waste for incineration only from small quantity generators that generate less than 220 pounds per month of infectious or chemotherapeutic waste. This onsite incineration facility may process municipal waste generated onsite as long as the resulting ash is managed as processed infectious and chemotherapeutic waste.

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

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

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

(4) Onsite processing of liquid blood and body fluids using a glutaraldehyde-based or hypochlorite-based product that encapsulates or converts liquid blood or body fluids into solids or gels so that no free liquids remain. The Department may approve

the use of other disinfectant-based products under these provisions if their efficacy can be demonstrated. The processed infectious waste may be disposed of at a municipal waste landfill provided:

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

(ii) The landfill has received written approval from the Department authorizing disposal of the processed medical waste.

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

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

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

* * * * *

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

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

* * * * *

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

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

* * * * *

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

* * * * *

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

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

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

(i) The name and address of the facility.

(ii) A description of the processing activity.

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

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

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

* * * * *

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

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

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

§ 284.3. Regulated medical waste aggregation facilities.

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

(b) *Permit-by-rule for regulated medical waste aggregation facilities.* The operator of an aggregation facility may operate under a permit-by-rule. For the operation of a regulated medical 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 waste generated:

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

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

(c) *Noncompliance.* The Department may require the operator of an aggregation facility operated under permit-by-rule to apply for and obtain a permit, or take other

appropriate action, when the generator is not in compliance with the requirements for the permit-by-rule or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment.

Subchapter B. GENERAL PERMITS

GENERAL

§ 284.101. Authorization for general permits.

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

* * * * *

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

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

* * * * *

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

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

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

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

* * * * *

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

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

ISSUANCE OF A GENERAL PERMIT

§ 284.111. Application for general permit.

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

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

* * * * *

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

(3) An operation plan which contains the following:

* * * * *

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

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

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

* * * * *

(4) A contingency plan which provides procedures to be used for emergency situations including, at a minimum, spills of **[infectious] regulated medical** or chemotherapeutic waste and ruptures of containers containing

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

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

* * * * *

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

§ 284.112. Completeness review.

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

* * * * *

§ 284.113. Public notice and review period.

* * * * *

(b) The notice shall include:

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

* * * * *

§ 284.114. Approval or denial of an application.

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

* * * * *

§ 284.115. Department-initiated general permits.

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

* * * * *

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

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

* * * * *

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

* * * * *

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

§ 284.116. General permit renewal.

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

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

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

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

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

CONTENT OF GENERAL PERMITS AND **[WAIVERS] MODIFICATIONS**

§ 284.121. Contents of general permits.

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

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

* * * * *

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

* * * * *

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

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

* * * * *

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

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

* * * * *

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

[(i) Processing of pathological waste is prohibited.

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

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

* * * * *

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

REGISTRATION **[AND DETERMINATION OF APPLICABILITY]**

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

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

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

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

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

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

* * * * *

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

Subchapter C. TRANSFER FACILITIES

§ 284.201. Scope.

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

§ 284.210. Application requirements.

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

§ 284.220. Operating requirements.

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

Subchapter D. PROCESSING FACILITIES

§ 284.301. Scope.

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

§ 284.311. Plan for monitoring.

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

* * * * *

§ 284.320. Operating requirements.

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

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

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

* * * * *

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

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

(ii) The process shall be capable of inactivating **[B.] Geobacillus** stearothermophilus spores, **[B.] Bacillus** pumilus or **[B. subtilis] Bacillus atrophaeus** spores at a 4 log 10 reduction or greater.

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

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

(d) If the facility disinfects **[infectious] regulated medical** waste by means other than incineration or thermal processing, the operator shall perform a microbiological analysis of indicators removed from the pro-

cessed waste. The analysis shall be conducted at a minimum, every 40 hours during the operational life of the facility, unless otherwise provided in a permit. The analyses shall be made available to the Department upon request.

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

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

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

* * * * *

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

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

* * * * *

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

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

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

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

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

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

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

(n) Unless otherwise approved in writing by the Department, an operator of an autoclave facility shall employ the procedures in § 284.322 (relating to autoclave validation testing requirements) to validate the operating parameters and protocols of the processing equipment. These procedures shall be employed in the following circumstances:

(1) When a new autoclave is installed.

(2) When an autoclave is modified with respect to hardware, software, controls or ancillary equipment.

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

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

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

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

§ 284.322. Autoclave validation testing requirements.

Autoclave operating parameters 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 form the permitted operating parameters for the autoclave tested.

Subchapter E. **SEGREGATION AND** STORAGE

§ 284.401. Scope.

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

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

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

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

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

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

(4) Maintains the waste in a nonputrescent state, using refrigeration (≤7°C) or freezing (≤—18°C) when necessary.

(5) Prevents odors from emanating from the container.

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

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

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

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

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

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

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

(1) Regulated medical waste, excluding pathological waste.

(2) Pathological waste.

(3) Chemotherapeutic waste.

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

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

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

§ 284.412. **[Sorting] Basic storage requirements**.

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

(b) Infectious and chemotherapeutic waste may be stored together in the same container if approved in writing by the Department.

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

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

(1) Used sharps.

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

(3) Other infectious waste.

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

(1) Used sharps.

(2) Fluids.

(3) Other chemotherapeutic waste.

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

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

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

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

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

(4) Maintains the waste in a nonputrescent state, using refrigeration (≤°C or ≤45°F) or freezing (≤—18°C or ≤0°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. 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.

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

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

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

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

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

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

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

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

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

(1) Leakproof.

(2) Impervious to moisture.

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

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

(1) Rigid.

(2) Tightly lidded.

(3) Puncture resistant.

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

(1) Break resistant.

(2) Tightly lidded or tightly stoppered.

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

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

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

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

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

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

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

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

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

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

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

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

[If the waste processing facility is separate from the waste generating facility, infectious waste may not be stored at the waste processing facility for

more than the following periods unless other periods are approved in a permit:

(1) Seventy-two hours at a temperature ≤28°C.

(2) Seven days in a refrigerator at ≤7°C.

(3) Thirty days in a freezer at ≤—18°C.]

(a) For onsite or offsite transportation of regulated medical or chemotherapeutic waste, the following information must be provided on the outermost container:

(1) The words "chemotherapeutic waste" if chemotherapeutic waste is containerized.

(2) Until _____ (*Editor's Note*: The blank refers to 1 year after the effective date of adoption of this proposed rulemaking.), the words "infectious waste" or "regulated medical waste" if regulated medical waste is containerized.

(3) After _____ (*Editor's Note*: The blank refers to 1 year after the effective date of adoption of this proposed rulemaking.), the words "regulated medical waste" if regulated medical waste is containerized.

(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. If the container is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility and available for inspection by the transporter or Department for 1 year.

(b) For offsite transportation of regulated medical or chemotherapeutic waste, the following information must be provided on the outermost container:

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

(2) The name of the transporter and, if applicable, Department-issued regulated medical and chemotherapeutic waste transporter license number.

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

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

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

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

(1) Leakproof.

(2) Impervious to moisture.

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

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

(1) Rigid.

(2) Tightly lidded.

(3) Puncture resistant.

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

(1) Break resistant.

(2) Tightly lidded or tightly stoppered.

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

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

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

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

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

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

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

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

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

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

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

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

(f) With the exception of persons who work at a small quantity generator's operation, where less than 220 pounds of infectious and chemotherapeutic waste is generated per month, persons packag-

ing infectious or chemotherapeutic waste for offsite transportation shall wear:

(1) Protective overalls.

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

(a) Generators that store regulated medical waste onsite shall record on the container the date that the container was full or the date that the generator sealed the container, whichever occurs earlier. If the container is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility for 1 year.

(b) Regulated medical 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.

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

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

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

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

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

(2) The date the waste was generated.

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

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

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

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

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

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

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

(1) Seventy-two hours at a temperature ≤25°C or ≤77°F.

(2) Seven days in a refrigerator at ≤7°C or ≤45°F.

(3) Thirty days in a freezer at ≤—18°C or ≤0°F.

§ 284.417. Reuse of containers.

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

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

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

* * * * *

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

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

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

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

* * * * *

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

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

* * * * *

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

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

* * * * *

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

Subchapter F. COLLECTION AND TRANSPORTATION

GENERAL

§ 284.501. Scope.

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

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

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

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

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

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

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

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

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

* * * * *

(4) Maintains the waste in a nonputrescent state, using refrigeration (≤7°C **or ≤45°F**) or freezing (≤—18°C **or ≤0°F**) when necessary.

* * * * *

(c) *Containers.*

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

* * * * *

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

(v) Labeled in accordance with the requirements in § 284.414 (relating to marking of containers).

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

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

* * * * *

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

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

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

(e) ***Commingling of waste.*** **Regulated medical or chemotherapeutic waste may not be commingled with municipal waste or transported in the same vehicle as residual waste.**

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

(g) ***Refrigeration.*** **[Infectious] Regulated medical** waste may **[not]** be kept in an unrefrigerated transport vehicle for **[more than 48] up to 72** hours **provided the waste is not putrescent**. If the vehicle is refrigerated (≤7°C **or ≤45°F**) or maintained at freezing temperatures (≤—18°C **or ≤0°F**), the in-transit storage period may not exceed 5 days.

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

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

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

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

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

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

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

* * * * *

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

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

* * * * *

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

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

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

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

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

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

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

GENERAL PROVISIONS

§ 284.601. Scope.

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

§ 284.602. License requirement.

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

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

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

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

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

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

§ 284.603. Identification number.

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

* * * * *

LICENSE APPLICATION REQUIREMENTS

§ 284.611. General application requirements.

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

(b) The application shall contain the following:

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

§ 284.612. Vehicular liability insurance.

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

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

* * * * *

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

* * * * *

LICENSE APPLICATION REVIEW

§ 284.623. Conditions of licenses.

* * * * *

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

§ 284.624. License renewal.

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

OPERATIONAL REQUIREMENTS

§ 284.631. Basic limitations.

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

(d) A transporter shall:

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

* * * * *

§ 284.633. Safety.

A transporter of **[infectious] regulated medical** or chemotherapeutic waste shall provide adequate personnel training to ensure transport activities are conducted safely, in compliance with applicable laws and regula-

tions, and according to the contingency plan approved under § 284.632 (relating to **[infectious] regulated medical** or chemotherapeutic waste discharges or spills).

§ 284.634. Annual report.

* * * * *

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

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

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

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

BOND

§ 284.641. Bond requirement.

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

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

* * * * *

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

§ 284.642. Release of bond.

* * * * *

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

* * * * *

§ 284.643. Bond forfeiture.

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

* * * * *

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

GENERAL

§ 284.701. Scope.

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

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

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

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

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

* * * * *

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

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

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

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

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

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

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

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

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

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

§ 284.702. Transfer facilities.

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

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

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

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

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

§ 284.703. Recordkeeping.

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

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

GENERATOR RESPONSIBILITIES

§ 284.711. Use of manifest.

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

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

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

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

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

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

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

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

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

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

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

(iii) Copy 3 of the manifest is retained by the second transporter.

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

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

(3) A six-part manifest shall be used by a generator who designates three transporters.

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

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

(iii) Copy 3A of the manifest is retained by the second transporter.

(iv) Copy 3 of the manifest is retained by the third transporter.

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

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

(d) If the waste is to be processed or disposed outside this Commonwealth, the generator shall obtain the manifest from the destination state. If the destination state does not supply the manifest, the generator shall use the manifest format required by the Department.]

§ 284.712. Preparation of manifest.

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

* * * * *

(2) **[The total number of pages used to complete the manifest, counting the first page plus the number of continuation sheets, if any.**

(3)] Each transporter's company name, identification number, Pennsylvania **[infectious] regulated medical** and chemotherapeutic waste transporter license number and telephone number. **[If three transporters are designated by the generator, enter the third transporter's name, identification number, Pennsylvania infectious and chemotherapeutic waste transporter license number, telephone number and the words "Transporter 3 sign here," in the Special Handling Instruction Section.**

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) A generator located in this Commonwealth and designating a facility in a state that supplies the manifest shall provide information and distribute copies as required by the manifest in accord-

ance with instructions supplied with the manifest and retain one copy of the manifest.

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

§ 284.714. Exception reporting.

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

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

* * * * *

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

(c) The exception report shall include the following:

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

* * * * *

TRANSPORTER RESPONSIBILITIES

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

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

§ 284.722. Preparation and use of manifest.

(a) Before transporting **[infectious] regulated medical** or chemotherapeutic waste or processed **[infectious] regulated medical** or chemotherapeutic waste that is recognizable, the transporter shall **[print or type his name, sign and date the manifest, and, by the signature, acknowledge acceptance of the waste from the generator] provide the generator with a dated, handwritten signature of an authorized representative of the transporter acknowledging that the transporter has accepted the waste from the generator on the date of acceptance**.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Return the waste to the generator.

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

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

§ 284.724. Transportation limitations.

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

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

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

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

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

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

FACILITY RESPONSIBILITIES

§ 284.731. Scope.

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

§ 284.732. Use of manifest.

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

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

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

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

(3) **[Note the rejection in the discrepancy indication space, and sign and date the manifest in accordance with paragraph (1) if either partially or totally rejecting the waste.] Provide the transporter with a dated, handwritten signature from an authorized representative of the facility acknowledging that it has accepted the waste from the transporter on that date.**

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

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

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

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

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

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

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

§ 284.734. Significant discrepancies.

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

* * * * *

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

* * * * *

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

CHAPTER 285. STORAGE, COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE

Subchapter A. STORAGE OF MUNICIPAL WASTE

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE

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

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

* * * * *

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

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

§§ 285.141—285.145. (Reserved).

Subchapter B. COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE

GENERAL PROVISIONS

§ 285.218. Signs on vehicles.

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

* * * * *

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

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

* * * * *

TYPES OF WASTE

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

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

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

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

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

ARTICLE IX. RESIDUAL WASTE MANAGEMENT

CHAPTER 287. RESIDUAL WASTE MANAGEMENT—GENERAL PROVISIONS

Subchapter A. GENERAL

§ 287.1. Definitions.

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

* * * * *

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

* * * * *

§ 287.2. Scope.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 288. RESIDUAL WASTE LANDFILLS

Subchapter D. ADDITIONAL REQUIREMENTS FOR CLASS I RESIDUAL WASTE LANDFILLS

ADDITIONAL OPERATING REQUIREMENTS—GENERAL

§ 288.423. Minimum requirements for acceptable waste.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 299. STORAGE AND TRANSPORTATION OF RESIDUAL WASTE

Subchapter B. STANDARDS FOR COLLECTING AND TRANSPORTING OF RESIDUAL WASTE

GENERAL PROVISIONS

§ 299.220. Signs on vehicles.

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

* * * * *

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

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

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

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

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

* * * * *

[Pa.B. Doc. No. 13-1585. Filed for public inspection August 23, 2013, 9:00 a.m.]