Preamble

Regulated Medical and Chemotherapeutic Waste
[25 *Pa. Code* Chs. 271, 272, 273, 284, 285, 287, 288, and 299]

The Environmental Quality Board (Board) proposes to amend 25 *Pa Code* Chapters 271, 272, 273, 284, 285, 287, 288 and 299 (relating to Municipal Waste Management – General Provisions; Municipal Waste Planning; Municipal Waste Landfills; Infectious and Chemotherapeutic Waste; Storage, Collection and Transportation of Municipal Waste; Residual Waste Management – General Provisions; Residual Waste Landfills; and Storage and Transportation of Residual Waste) to read as set forth in Annex A. The proposed rulemaking would amend Chapter 271 to add and clarify terms and definitions in § 271.1 (relating to definitions) and Chapter 284 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 U.S. 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 U.S. Postal Service's program for shipping regulated medical waste through the U.S. Postal Service. The amendments proposed to Chapters 285 and 299 would revise signage requirements for transportation vehicles to be consistent with the recommended changes to Chapter 284. Finally, the amendments to Chapters 272, 273, 287, and 288 would replace all references to "infectious" 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 _____, 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, Program Development and Support Section, 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 proposal appears in Section J of this preamble. Persons with a disability may use the AT&T Relay Service by calling 1-800-654-5984 (TDD users) or 1-800-654-5988 (voice users). This proposal is available electronically

through the Department of Environmental Protection's (Department) website at www.depweb.state.pa.us (select Public Participation).

C. Statutory Authority

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

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 SWMA (35 P.S. §§ 6018.102 and 104), which 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 Infectious and Chemotherapeutic Waste Disposal Law (35 P.S. §§ 6019.1 - 6019.6), which at section 6019.4(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 law.

The Administrative Code of 1929 (71 P.S. §§ 510-1 - 510-27), which at section 1917-A (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), which grants the Board the power and duty to formulate, adopt, and promulgate such 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 amendments represent a comprehensive revision of the Commonwealth's existing infectious and chemotherapeutic waste regulations, which is necessary for several reasons.

First, since solid waste is not always generated, processed and disposed of within the Commonwealth, the revisions allow persons generating and managing infectious and chemotherapeutic waste to do so in a manner that complies with Pennsylvania 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." These amendments include revisions that would identify "infectious waste" as "regulated medical waste," making the terminology consistent with federal and other states' requirements. This 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 Pennsylvania requirements, federal requirements and the requirements imposed by other states.

Second, these amendments streamline the transportation and shipment requirements for regulated medical waste in several respects. The 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 Infectious and Chemotherapeutic Waste Law requires that any 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 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 amendments authorize the transportation of regulated medical waste through the U.S. Postal Service pursuant to the U.S. 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 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 U.S. Postal Service. This should provide generators, especially those generating small quantities of medical waste, with an alternative transportation and disposal option.

The 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 has required small generators to transport partial loads offsite, and thereby incur additional costs. The 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 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 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 the public health and safety or the environment.

These amendments also eliminate 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 the Commonwealth.

E. Summary of Regulatory Requirements

The following discussion outlines the regulatory requirements that have been affected by the proposed regulations 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" have been removed throughout Chapters 271, 272, 273, 284, 285, 287, 288, and 299 and replaced with "regulated medical waste." There is no substantive change in the definitions, other than minor amendments set forth in the following discussion on § 271.1. This shift in terminology will result in Pennsylvania's labeling requirements being consistent with federal and other states' requirements.

Section 271.1 – Definitions

The Board is proposing to amend certain terms and to 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. That reference has been replaced with "regulated medical waste."

The term "body fluids" has been revised to include saliva because saliva is a fluid that is capable of containing visible blood.

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

The definition for "environmental protection acts" has been revised by citing the relevant sections so that the formatting is consistent with the other citations.

The term "incineration" has been 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 term "regulated medical waste" is being defined in the amendments as "infectious waste," thereby incorporating the existing definition of "infectious waste." However, some changes have been made to the definition of "infectious waste" as described below:

- Pathological wastes will 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 now defined as infectious waste in the proposed regulation. The requirement that exposure to said pathogens must have occurred during research in order 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, which relates to regulated medical waste monitoring requirements. Therefore, the regulatory reference in subsection (iii)(F) under the definition of infectious waste has been corrected and now references § 284.321.

The term "mobile infectious waste processing facility" has been changed to "mobile regulated medical waste processing facility."

The term "regulated medical waste aggregation facility" has been added and is defined as a facility that accepts, aggregates or stores regulated medical waste.

The definition for "sharps" has been 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 has been removed. Razors are no longer required to be "disposable" to qualify as sharps.

Subchapter A. General Provisions

Section 284.1 – Scope

References to Chapter 283 (relating to resource recovery and other processing facilities) and Chapter 285 (relating to storage, collection and transportation of municipal waste) have been added.

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

The amendments to § 284.2 provide 6 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.

In order for autoclaves, incinerators, and steam superheated water disinfection operators to qualify for a permit-by-rule under paragraphs (a)(1)-(3), the facility must 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 must ensure that the processed waste is disposed or processed in a landfill or incinerator authorized to accept the waste. The operator of the facility must 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 paragraphs (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 required the waste to be vaporized, but the amendments have revised the language to "render the waste unrecognizable" since, by definition, autoclaves do not vaporize all liquid. Under paragraph (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 paragraph (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 such that no free liquids remain. The proposed regulations provide the Department with the authority to approve the use of other disinfectant-based products under this paragraph 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 at paragraph (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 at § 284.2(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 in a facility that has written approval from the Department to accept this type of waste. In addition, the generator must comply with the manifest requirements as set forth 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). Paragraph (c)(1) incorporates the amended citations that require

the facility to comply with the requirements in Chapter 284, 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).

For facilities operating under subsection (a), in addition to the current requirements, amendments to (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 paragraph (c)(8), for onsite autoclave facilities, "treated or processed regulated medical waste" is substituted for "processing residue" in the proposed regulation because "treated or processed regulated medical waste" more clearly describes waste that has not been rendered unrecognizable.

Paragraphs (c)(10) and (11) have been removed because these compliance criteria have been included in paragraphs (1)-(3) of proposed subsection (a).

Section 284.3 – Regulated medical waste aggregation facilities

This section has been added to establish a permit-by-rule for regulated medical waste aggregation facilities. The regulated medical waste aggregation facilities must comply with the generator standards in Subchapter E (relating to segregation and storage) 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.

Subchapter B. General Permits

Section 284.102 – Nature of a general permit; substitution for individual applications and permits

Regulatory references that no longer exist have been removed from § 284.102, and a clause has been added clarifying 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.

Section 284.111 – Application for general permit

A typographical error has been corrected: "employes" has been changed to "employees."

Section 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 has been removed from subsection (a).

Section 284.115 – Department-initiated general permits

"Departmental" has been replaced with "Department" in paragraph (c)(5) for clarity.

Section 284.116 – General permit renewal

Section 284.116 has been added to provide a procedure for renewing general permits. The section is based on the existing practices of the Department and has been added for clarity.

Section 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. Under the proposed regulation, the Department has eliminated determinations of applicability from the process of general permit issuance. Therefore, language regarding determination of applicability has been removed from paragraph (3) of § 284.121.

The requirement in paragraph (11) that processing residue be disposed of in a landfill has been removed and replaced with a requirement for processing residue to be managed in accordance with the Solid Waste Management Act to avoid potential conflicts.

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

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

Section 284.122 – Modification of certain requirements

In § 284.122 of the proposed regulation, the term "waiver" has been deleted from the section heading. The Department retains the ability to waive certain requirements where those requirements are inappropriate or otherwise not applicable to the applicant's proposed operation under a general permit. However, in such a 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 have been removed 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.

Section 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 relating to determinations of applicability has been removed from § 284.131.

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, § 284.132 is no longer necessary and has been removed from the proposed regulations.

Subchapter C. Transfer Facilities

Section 284.210 – Application requirements

A typographical error has been corrected in this section: The reference to sections "279.101 – 279.111 (relating to general requirements)" has been changed to "279.101 – 279.111 (relating to application requirements for transfer facilities)" to accurately reflect the name of the referenced sections.

Section 284.220 – Operating requirements

Section 284.220 has been revised to reference the sections in Chapter 279 that are applicable to operating requirements for transfer facilities.

Subchapter D. Processing Facilities

Section 284.320 – Operating requirements

Section 284.320 has been revised to reference the sections in Chapter 283 that are related to operating requirements for processing facilities.

Section 284.321 – Regulated waste monitoring requirements

Throughout the 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 proposed 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 contained in subsection (c).

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

Subsection (m) has been revised to state that an autoclave facility must comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.

Also, autoclave testing requirements have been added in subsection (n) to ensure that disinfection occurs under the proper operating conditions, with reference to § 284.322 (relating to autoclave validation testing requirements).

Section 284.322 – Autoclave validation testing requirements

Section 284.322 has been added to define the proper protocols and testing conditions that processors must 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 must 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.

Subchapter E. Segregation and Storage

Subchapter E has been 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 has relocated 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. Table 1 below summarizes the reorganization of sections in Subchapter E:

Table 1

Subject of Section	Location in Current Regulation	Location in 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**

Section 284.401 – Scope

The description of the reference to § 285.121 has been revised from "types of storage" to "containers" to correspond with the correct name of § 285.121.

Section 284.411 – Segregation

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. The name of proposed § 284.411 has been changed from "Sorting," currently located in § 284.412, to "Segregation."

In addition, the section has been changed 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).

Section 284.412 – Basic storage requirements

The sections of Subchapter E have been reorganized in accordance with Table 1 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) was revised to ensure segregation occurs first, and the temperature for refrigeration has been added in degrees Fahrenheit in paragraph (a)(4) for clarification.

Section 284.413 – Storage containers

The sections of Subchapter E have been reorganized in accordance with Table 1 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, has been removed in order to eliminate any possible conflicts with OSHA regulations or other workplace safety procedures.

Section 284.414 – Marking of containers

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. Throughout proposed § 284.414, "infectious waste" has been replaced with "regulated medical waste" with regards 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 one-year transition period after the effective date of the regulations 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 one 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.

Section 284.415 – Duration of storage of regulated medical waste for generators

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors.

Throughout § 284.415, language referring to "the date that waste was first placed in a container" has been changed to "to the date that the container was full or sealed" in order to be consistent with other sections of the proposed regulations. Therefore, under proposed § 284.415, 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 in § 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 has been removed from § 284.413 because the time periods for storage were difficult to interpret. Temperature standards for storage are now located in § 284.412. The requirement that putrescent waste be moved offsite within 24 hours has been changed to within 3 business days. The Department believes that the new amendments are more easily understood and provide generators sufficient storage times under typical operations, while maintaining the intent of the regulations.

Section 284.416 – Duration of storage of regulated medical waste for processors

The sections of Subchapter E have been reorganized in accordance with Table 1 to follow the path of waste as it is handled by generators and processors. Storage temperatures in proposed § 284.416 were modified slightly to correct errors in the existing text.

Section 284.417 – Reuse of containers

Current § 284.417 provides separate subsections addressing the reuse of nonfiberboard containers housing regulated medical waste versus chemotherapeutic waste. Proposed § 284.417 allows 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, has been removed, and subsection (c) has been modified to include chemotherapeutic waste.

Section 284.418 – Storage and containment of ash residue from regulated medical or chemotherapeutic waste incineration

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

Subchapter F. Collection and Transportation

Section 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.

Section 284.512 – Transportation of regulated medical and chemotherapeutic waste; general provisions

In paragraph (b)(4), a Fahrenheit equivalent has been added to clarify the temperature required to maintain waste in a non-putrescent state.

The prescriptive strength and weight limits for a corrugated fiberboard container in subparagraph (c)(1)(iv) have been removed and replaced with performance-based requirements that require containers to be of sufficient strength to prevent puncturing, tearing and bursting during transportation. Subparagraph (c)(1)(v) has been added to reference § 284.414, relating to marking of containers to ensure that the containers are marked properly for transportation.

Subsection (d) has been 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.

Subsection (e) has been added to clarify 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 has been 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.

Section 284.513 – Transportation of regulated medical and chemotherapeutic waste; additional provisions

The reference to OSHA regulations in paragraph (b)(2) has been corrected to accurately cite the applicable OSHA regulation relating to bloodborne pathogens and the standards for biohazard signage.

Paragraph (c) has been revised to state that portable disinfectants must be EPA-approved.

Subsection (e) has been deleted from proposed § 284.513 to remove potential conflicts with OSHA regulations or workplace safety procedures.

Section 284.514 – Transportation of processing residue from a regulated medical or chemotherapeutic waste facility

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

Subchapter G. Transporter Licensing for Regulated Medical and Chemotherapeutic Waste

Section 284.602 – License requirement

A grammatical error, "onside" instead of "onsite," has been corrected, and a minor clarification has been made to paragraph (b)(3).

Section 284.623 – Conditions of licenses

A grammatical error, "employes" instead of "employees," has been corrected.

Section 284.641 – Bond requirement

All subsections of § 284.641 in the current regulation are given a heading, except for subsection (f). Therefore, for consistency, "*Review of bonds*" has been added as the heading for subsection (f).

Subchapter H. Manifesting for Regulated Medical and Chemotherapeutic Waste

Section 284.701 – Scope

In the proposed regulations, logs or shipping papers, including electronic tracking systems, are recognized acceptable ways of tracking waste for manifesting purposes. Paragraph (b)(4) incorporates by reference the U.S. Postal Service's program for shipping regulated medical waste. Additional minor clarifications have been made throughout the section.

Section 284.702 – Transfer facilities

The subsections of § 284.702 have been renumbered for clarity. Language in former subsection (a) regarding the existing paper manifest tracking system has been removed 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) has been renumbered and rewritten for clarity, and a provision has been added to proposed paragraph (1), which requires the transfer facility to be permitted by the Department.

Section 284.703 – Recordkeeping

In proposed § 284.703, the subsection numbering has been removed. The record retention requirement in former subsection (a) has been reduced from 5 years to 2 years. Section 284.703 has been revised to 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 has been removed.

Section 284.711 – Use of manifest

Language regarding manifests has been removed because logs or shipping papers, including electronically based tracking systems, are acceptable standard business practices and are acceptable for compliance with the proposed regulation.

Section 284.712 – Preparation of manifest

Generators shall 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.

Paragraph (a)(10) has been removed from the proposed regulation 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.

Section 284.713 – Reserved

This section has been removed because the record or shipping log is not required to be distributed to the various parties as previously required.

Section 284.714 – Exception reporting

In 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 Infectious and Chemotherapeutic Waste Disposal Law. The time limit for the paperwork to be completed and transmitted to the proper entity has been extended from 20 days to 30 days based on the amount of time needed for industry practices.

Subsection (b) has been reworded for clarity.

Section 284.721 – Reserved

This section is now reserved because the provisions to satisfy the manifest requirements have been amended.

Section 284.722 – Preparation and use of manifest

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

Section 284.723 – Reserved

This section is now reserved because the provisions to satisfy the manifest requirements have been amended.

Section 284.724 – Transportation limitations

Regulatory citations have been changed to maintain accuracy with the proposed reorganization of Subchapter E. Information regarding copies of the manifests has been removed since this requirement will be satisfied by logs or shipping papers.

Section 284.731 – Scope

Section 284.733 has been reserved in the proposed regulation. Therefore, the reference to § 284.733 has been removed from § 284.731. Also, in proposed § 284.731, language regarding "owners" of waste processing facilities has been deleted since the owner of the facility may or may not be involved with the daily operations of the facility.

Section 284.732 – Use of manifest

Language regarding "owners" of waste processing facilities has been 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.

Section 284.733 – Reserved

This section is now reserved because the provisions to satisfy the manifest requirements have been amended.

Section 284.734 – Significant discrepancies

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

Section 285.218 – Signs on vehicles

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

F. Benefits, Costs and Compliance

Benefits

The proposed amendments simplify the labeling requirements to reduce costs and ensure consistency with the requirements of other states and the federal government. The new regulations 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 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. In order to avoid conflicts with OSHA requirements, duplicative requirements are eliminated by the amendment. The amendments will also provide another convenient shipping option by removing barriers to shipping waste through the mail where authorized by the U.S. Postal Service.

Compliance Costs

The proposed rulemaking provides a cost savings to the regulated community through:

- Providing consistency with the US 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.
- Reducing transportation costs for collection and processing.

Compliance Assistance Plan

The Department will assist the regulated community by developing fact sheets and continue 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 amendments 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 U.S. 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 Federal Pollution Prevention Act of 1990 established a national policy that promotes pollution prevention as the preferred means for achieving state environmental protection goals. DEP 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 assure 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 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 _____, 2013, the Department submitted a copy of the 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 after 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 postmarked by _____, 2013, (within 30 days of publication in the *Pennsylvania Bulletin*). 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 _____, 2013 (within 30 days following publication in the *Pennsylvania Bulletin*). 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 _____, 2013, (within 30 days of publication in the *Pennsylvania Bulletin*). A subject heading of the proposal 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.

MICHAEL L. KRANCER
Chairman
Environmental Quality Board