

**NOTICE OF FINAL RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
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) by this order amends Chapters 271, 272, 273, 284, 285, 287, 288 and 299 to read as set forth in Annex A.

The final rulemaking amends Chapter 271 (relating to municipal waste management—general provisions) to add and clarify terms and definitions in § 271.1 (relating to definitions). The final rulemaking amends 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 that are processing small quantities of waste; transfer facilities; and organizations that generate regulated medical waste at multiple locations. The amendments to Chapter 284 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 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 to Chapters 285 and 299 (relating to storage, collection and transportation of municipal waste; and storage and transportation of residual waste) 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 replace all references to "infectious" waste to "regulated medical" waste to be consistent with the recommended changes to Chapters 271 and 284.

This final rulemaking was adopted by the Board at its meeting on _____.

A. Effective Date

These amendments will go into effect upon publication in the *Pennsylvania Bulletin* as final rulemaking.

B. Contact Persons

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disability may use the AT&T Relay Service, (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This final rulemaking is available on the Department of Environmental Protection's (Department) web site at www.dep.state.pa.us (select "Public Participation").

C. Statutory Authority

This final 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 Summary

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

The federal government identifies infectious waste as "regulated medical waste." This final rulemaking includes revisions that identify "infectious waste" as "regulated medical waste," making the terminology consistent with federal requirements. This change in terminology simplifies the labeling requirements on containers that are used to collect, transport, process and dispose of the waste for persons managing regulated medical waste across multiple jurisdictions. This uniform practice reduces the costs borne by generators and other persons managing regulated medical waste because the same containers and labels can be used to satisfy federal and Commonwealth requirements.

This final rulemaking streamlines the transportation and shipment requirements for regulated medical and chemotherapeutic waste in several respects. The amendments allow generators, transporters and those involved in storage, processing and disposal of regulated medical and chemotherapeutic 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 of regulated medical or chemotherapeutic 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 is more efficient for all persons managing this waste stream.

In addition, the amendments authorize the transportation of regulated medical waste 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 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 provides generators, especially those generating small quantities of medical waste, with an alternative method for transporting and disposing of medical waste.

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. The amendments allow for generators to store regulated medical and chemotherapeutic 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 promote more efficient business practices by eliminating the requirement to transport lightly or partially filled containers every 30 days. These regulations allow generators to completely fill containers and only ship when necessary, which results in a cost savings for the generators.

The revisions allow haulers to transport containerized regulated medical waste and chemotherapeutic waste along with other containerized wastes in the same vehicle. This reduces 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 amendments 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.

Finally, in response to public comments, the Department has made several revisions to accommodate the unique activities conducted at facilities engaged in the research and

development or production of vaccines and other biologics, hereinafter referred to as “biologics facilities.” Biologics facilities generate large quantities of cultures, containers and other wastes that have come into contact with vaccine components, such as live attenuated preparations of viruses, inactivated whole or subunit virions, purified recombinant proteins, or synthetic antigens. The current infectious and chemotherapeutic waste regulations define these materials as “infectious waste” because the materials have come in contact with “infectious agents,” which is defined as “an organism, such as a virus or bacteria, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.”

The Department recognizes that improvements in practices and technologies employed in biologics facilities have increased the safety of vaccine viruses such that many vaccine agents that were once infectious have been attenuated to the point that they are no longer capable of being communicated by replication or invasion in healthy humans. The Department also recognizes that the wastes generated by biologics facilities are unlike the wastes generated at hospitals, clinics and patient care facilities, and biologics facilities are subject to additional standards imposed by federal governmental agencies that ensure a high level of protection for public health and safety. The Environmental Protection Agency (EPA) in its Medical Waste Tracking Act has excluded from regulation as regulated medical waste those materials that do not pose an appreciable risk of causing disease, including materials classified as Biosafety Level 1 (BSL-1), citing the Centers for Disease Control’s (CDC) *Biosafety in Microbial and Biomedical Laboratories* (BMBL), as guidance in this determination. The CDC defines BSL-1 as, “the basic level of protection and is appropriate for agents that are not known to cause disease in normal, healthy humans.” Therefore, the Board amended the definitions of “infectious agents” and “infectious waste” in § 271.1 to exclude agents classified as BSL-1 by a biologics facility and wastes, mixtures of wastes and cell lines from biologics facilities where no agent in the waste is classified as Biosafety Levels 2-4 as determined by the CDC’s BMBL. In addition, plasticware generated by biologics facilities that has not been in contact with agents classified as Biosafety Levels 2-4 as determined by the CDC’s BMBL has been excluded from the category “used sharps” in the definition of “infectious waste.”

E. Summary of Changes to the Proposed Rulemaking

The following outlines the regulatory requirements that have been modified in the final rulemaking and describes the basis for the amendments.

The term “sharps” has been deleted and its provisions incorporated into the definition of “used sharps” under the definition of “Infectious waste.” All references to “sharps” have been replaced with “used sharps” throughout Chapters 271, 272, 273, 284, 285, 287, 288 and 289.

§ 271.1. Definitions

The definition of “infectious agent” has been amended to exclude agents classified as BSL-1 by a biologics facility as determined by the protocols in the CDC’s BMBL.

In the rulemaking, the definition of "regulated medical waste" is "infectious waste," and thereby incorporates the existing definition of "infectious waste." The following changes have been made to the definition of "infectious waste" in the final rulemaking:

- The category of “cultures and stocks” has been reformatted for clarity and amended to add the term “cell lines.” Clarification on residues in emptied containers has also been added. In the final rulemaking, a determination is made on whether a container is empty by applying the criteria contained in 40 CFR § 261.7(b)(1) or (2).
- The proposed exclusion of certain preserved tissues from the category of “pathological wastes” was deleted in the final rulemaking.
- In the category of “animal wastes,” the proposed deletion of the phrase “during research” was reinstated in the final rulemaking.
- The definitions of “sharps” and “used sharps” were combined in the final rulemaking. Used sharps are no longer limited to those generated at medical, research or industrial laboratories. The term now excludes broken or unbroken plasticware generated at biologics facilities where no agent in the waste is classified as BSLs 2-4 as determined by the protocols established in the most recent edition of the CDC’s BMBL.
- Subparagraph (iii)(L) has been added to the exceptions provided under the definition of “infectious waste” and applies to wastes, mixtures of wastes and cell lines from biologics facilities that produce or conduct research and development of vaccines or other biologics, provided no agent in the waste is classified as BSLs 2-4 in accordance with the most recent edition of CDC’s BMBL.

The term "regulated medical waste aggregation facility" has been renamed to “regulated medical and chemotherapeutic waste aggregation facility,” and the definition of the term has been amended to include facilities that accept, aggregate or store chemotherapeutic waste.

The definition of "sharps" has been incorporated into the category of “used sharps” under the definition of “infectious waste.”

The reference to “sharps” in the definition of “unrecognizable regulated medical waste” has been changed to “used sharps” in the final rulemaking.

§ 271.101. Permit requirement

Subsection (b)(5) was amended in the final rulemaking to change “facility” to “facilities.”

§ 271.114. Transition period

In the existing regulation, this section establishes a timeframe for waste disposal facilities authorized to operate under a permit that was issued by the Department prior to December 23, 2000, to comply with radioactive material monitoring and detection requirements which became

effective on December 23, 2000. These facilities were required to modify their permits in accordance with this section by December 23, 2002. All the dates provided for compliance with this section have passed. Therefore, the section is no longer necessary and has been reserved in the final rulemaking.

§ 272.532. *Limitations on acceptable waste.*

Subsection (a)(2) was amended in the final rulemaking to specify that regulated medical waste, hypodermic needles and syringes may not be accepted at a household hazardous waste collection event.

§ 273.511. *Processed regulated medical waste disposal.*

A typographical error was corrected in subsection (a).

Subsection (d) was reworded for clarity, and unused hypodermic needles or syringes were added.

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

In subsection (a)(4), the terms “infectious waste” and “medical waste” have been replaced with “liquid blood or body fluids” for clarity. Subparagraph (iii) has also been added to clarify that chemotherapeutic waste may not be processed under this subsection.

In subsection (a)(5), a requirement to maintain regulated medical and chemotherapeutic waste in a manner that does not attract vectors was added for consistency with other changes made uniformly throughout the final rulemaking.

In subsection (b)(2), the term “manifest” has been changed to “log and shipping paper” to mirror the changes made to the title of § 284.701(b)(5) (relating to scope).

Subsection (c)(8) was amended in the final rulemaking to remove “manifested” and “manifesting” to reflect the changes made to the title of Subchapter H.

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

Chemotherapeutic waste has been added throughout the section, including the section’s title, to maintain consistency with the changes made to the definition of “regulated medical and chemotherapeutic waste aggregation facilities” in § 271.1.

In subsection (c), the term “generator” has been replaced with “operator” for clarity.

§ 284.111. *Application for general permits.*

In subparagraph (b)(3)(viii), the term “infectious” has been changed to “regulated medical” in accordance with the changes that have been applied uniformly throughout the final rulemaking.

§ 284.121. *Contents of general permits.*

In paragraph (8), the term “manifest” has been changed to “log or shipping paper” in accordance with the changes that have been applied uniformly across the rulemaking, and the words “manifesting for” has been replaced with “tracking of” to maintain consistency with the changes made to the title of Subchapter H.

§ 284.122. *Waiver or modification of certain requirements.*

The phrase “waiver or modification” in the section heading has been reinstated in the final rulemaking.

In subsection (b), the proposed deletion of the phrase “waiver or” and the mandatory provisions relating 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 were not adopted in the final rulemaking. Therefore, these provisions remain mandatory in the final rulemaking.

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

In subsection (c), “must” has been added to correct a typographical error.

§ 284.230. *Storage requirements.*

This section has been added to clarify that a transfer facility may store regulated medical or chemotherapeutic waste for up to 72 hours provided that the waste remains in its original packaging, is not putrescent, and does not attract vectors. This section maintains consistency with the provisions in § 284.2(a)(5) for transfer facilities operating under a permit-by-rule and the changes applied uniformly to the final rulemaking.

§ 284.321. *Regulated medical waste monitoring requirements.*

In subsection (g), the phrase “after disinfection” has been deleted for clarity.

Subsection (n) was reorganized and revised in the final rulemaking to require autoclave validation at a frequency specified by the manufacturer of the autoclave, and language was added to subsection (n)(2) to clearly state when the autoclave validation procedure must be performed.

Subsection (n)(3) was deleted in the final rulemaking because the requirement to repeat the autoclave validation procedure at a frequency specified by the manufacturer of the autoclave was

incorporated into subsection (n). The requirement to repeat the autoclave validation procedure annually was removed from the final rulemaking.

Subsection (n)(4) was deleted to eliminate the ambiguity of the phrases “significant change” and “problem is evident.” Specific language relating to when the autoclave validation procedure must be performed was added to subsection (n)(2) in the final rulemaking.

Alternate disinfection requirements for biologics facilities that produce or conduct research and development of vaccines have been established in subsections (p) and (q) to allow these facilities, under certain conditions, to utilize alternate disinfection protocols that are specific to the infectious agent or organism present in a facility’s waste.

§ 284.322. Autoclave validation testing requirements.

Paragraph (8) was added to allow biologics facilities that satisfy the requirements of § 284.321(p) to establish and validate autoclave operating parameters and residence times based on the requirements determined by the institutional biosafety committee or independent certified biosafety professional, or both, which are specific to the infectious agent or organism present in a facility’s waste.

§ 284.411. Segregation.

The term “used” has been added to subsection (b) to be consistent with changes made to the definition of “sharps” and “used sharps” in § 271.1.

Provisions for bags storing chemotherapeutic waste have been moved from subsection (c) to subsection (d) and “pathological waste” has been added to subsection (c).

Subsection (d) has been added to include requirements for bags storing chemotherapeutic waste and provide flexibility in the colored bag requirements for generators who process chemotherapeutic waste on-site.

§ 284.412. Basic storage requirements.

Language has been added to subsection (b) to clarify that containers in enclosures must be maintained in accordance with § 284.413 (relating to storage containers) and in a manner that minimizes human exposure and vectors.

Subsection (c) has been amended to clarify that regulated medical or chemotherapeutic waste may not be commingled with other wastes in the same container.

For clarity, subsection (d) was revised in the final rulemaking to allow regulated medical and chemotherapeutic waste that has been sorted and separately containerized to be stored in the same location as municipal waste, including on a cart.

§ 284.413. *Storage containers.*

In subsection (a), “and” has been replaced with “or.”

Language has been added to subsection (a)(1) to clarify that containers holding regulated medical or chemotherapeutic waste must be leakproof on the sides and bottom and maintained in an upright position.

In subsection (d)(2), “bag” has been replaced with “bags.”

§ 284.414. *Marking of containers.*

Subsection (a) has been reworded for clarity.

Subsections (a)(2) and (3) of the final rulemaking extend the transition period for generators and transporters to comply with the revised container marking requirements from 1 year to 2 years after the effective date of the final rulemaking.

The proposed language in subsection (a)(5) relating to a record of the date on which a roll-off was full or sealed to be maintained at the generating facility was moved to subsection (b)(4).

In the final rulemaking, subsection (a)(6) was added to clarify that the requirement to label containers with the name, address and telephone number of the generator only applies when waste is transported off-site. For on-site 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 placed on the containers.

Subsection (b) was added to the final rulemaking to allow a vehicle or conveyance to serve as the outermost container of regulated medical or chemotherapeutic waste for labeling purposes, rather than labeling each container within the vehicle or conveyance. However, the conditions in (b)(1)-(5) must be satisfied and include the requirement that the waste is from a single generator and the vehicle or conveyance is transported off-site every 30 days. Subsection (b)(3) was added to specify that the requirements of § 284.513 (relating to transportation of regulated medical and chemotherapeutic waste; additional requirements) apply if the outermost container of regulated medical or chemotherapeutic waste is a vehicle or conveyance, including a roll-off.

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

The section heading and language throughout the section have been amended to clarify that the requirements also apply to chemotherapeutic waste.

Subsection (a) was deleted because the language duplicates the requirement of § 284.414(a)(5) and (b)(4).

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

The section heading and language throughout the section have been amended to clarify that the requirements also apply to chemotherapeutic waste.

The storage temperatures in paragraph (1) have been deleted and replaced with “ambient temperature.” Language requiring the waste to be refrigerated or frozen if it becomes putrescent or attracts vectors has also been added.

The storage temperature in paragraph (2) was also added to correct an error in the proposed text.

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

A typographical error was corrected in subsection (d).

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

A cross reference to § 284.414(b) (relating to marking of containers) has been added to subsection (c)(1)(v).

Subsection (e) clarifies that separately containerized regulated medical or chemotherapeutic waste may be transported in the same vehicle as containerized municipal waste. For clarity, proposed language prohibiting transportation of regulated medical or chemotherapeutic waste in the same vehicle with residual waste has been removed from the final regulation.

In subsection (g), chemotherapeutic waste and a requirement that wastes may not attract vectors has been added to maintain consistency with other changes that have been made uniformly in the final rulemaking.

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

In subsection (b), the phrase “or conveyances” has been added to maintain consistency with other transportation requirements referenced throughout Articles VIII and IX.

Subsections (b)(3) and (4) were added to establish a transition period for transporters to comply with the required signage for vehicles transporting regulated medical waste.

Subsection (d) has been revised to clarify that the cargo area of vehicles transporting regulated medical or chemotherapeutic waste must be cleaned weekly to ensure that the surfaces of vehicles which are most likely to become contaminated with infectious agents are cleaned on a routine basis.

§ 284.602. *License requirement.*

In subsection (a)(3), the term “manifesting” has been changed to “log and shipping paper” in accordance with the changes that have been applied uniformly across the proposed and final rulemaking.

§ 284.623. *Conditions of licenses.*

In subsection (c), the word “drivers” has been replaced with “haulers” for clarity and to accommodate industry’s current business practices.

§ 284.632. *Regulated medical or chemotherapeutic waste discharges or spills.*

In subsection (c), the term “manifests” has been changed to “logs or shipping papers” in accordance with the changes that have been applied uniformly to the final rulemaking.

Subchapter H. Tracking of regulated medical and chemotherapeutic waste.

In the final rulemaking, logs or shipping papers, including electronic tracking systems, are recognized as acceptable ways of tracking shipments of regulated medical or chemotherapeutic waste. For clarity, the words “Manifesting for” have been replaced with “Tracking of” in the title of Subchapter H.

§ 284.711. *Use of logs and shipping papers.*

The reference to “manifest” in the section heading was replaced with “logs and shipping papers” in accordance with changes made uniformly to the final rulemaking.

§ 284.712. *Preparation of log or shipping paper.*

The reference to “manifest” in the section heading was replaced with “logs and shipping papers” to maintain consistency with the change in terminology that has been applied uniformly to the final rulemaking.

The proposed deletion of subsection (a)(5) has been returned to the final rulemaking in subsection (a)(4) to require generators and transporters of regulated medical or chemotherapeutic waste to use waste codes on logs or shipping papers. The applicable waste codes have been added in the final rulemaking.

In subsection (c), the term “manifest” has been replaced with “logs and shipping papers” to reflect the change made to the title of § 284.722.

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

The reference to “manifest” in the section heading was replaced with “logs and shipping papers” in accordance with changes that have been applied uniformly to the final rulemaking.

The use of electronic signatures or a stamped signature of an authorized representative has been added to subsection (a) as acceptable means of acknowledging that waste has been accepted on logs or shipping papers.

§ 284.731. Scope.

The term “manifest” has been changed to “logs and shipping papers” in accordance with changes that have been applied uniformly to the final rulemaking.

§ 284.732. Use of logs and shipping papers.

The reference to “manifest” in the section heading was replaced with “logs and shipping papers” to maintain consistency with the change in terminology that has been applied uniformly to the final rulemaking.

The use of electronic signatures or a stamped signature of an authorized representative on logs or shipping papers has been added to subsection (b)(3) as acceptable means of acknowledging that waste has been accepted.

§ 299.220. Signs on vehicles.

The proposed deletion of subparagraph (2)(i) was not adopted in the final rulemaking to maintain consistency with the signage requirements in § 285.218.

F. Summary of Comments and Responses on the Proposed Rulemaking

General

Several commentators suggested that all references to “manifests” be replaced with “logs or shipping papers” for consistency, including references to those terms in section headings. The Board has replaced the term “manifest” with “logs or shipping papers” throughout Article VIII in the final rulemaking.

§ 271.1. Definitions

The proposed rulemaking was adopted by the Board on April 16, 2013, and published at 43 Pa. B. 4858 (August 24, 2013). During the comment period, 7 commentators provided comments to the Board on the proposed rulemaking, including the Independent Regulatory Review Commission (IRRC).

Commentators representing biologics facilities provided pertinent information on their unique activities, asserting that biologics facilities are highly regulated by the U.S. Food and Drug Administration, CDC and National Institutes of Health (NIH), which impose stringent requirements and mandate practices to ensure the purity and safety of vaccine products. Therefore, commentators recommended amendments that would include provisions which are applicable only to biologics facilities and afford biologics facilities consideration of their unique circumstances.

In its comments on the proposed rulemaking, IRRC asked the Board to consider the reasonableness of the requirements as they relate to biologics facilities, as well as the fiscal or economic impact of the rulemaking. The Department has worked cooperatively with representatives of the impacted biologics facilities during the development of the final rulemaking and was able to incorporate revisions into the final rulemaking that satisfy the comments submitted on behalf of the biologics facilities and maintain a high level of protection for public health and the environment.

The Board recognizes that improvements in practices and technologies employed in biologics facilities have increased the safety of vaccine viruses such that many vaccine agents that were once infectious have been attenuated to the point that they are no longer capable of being communicated by replication or invasion in healthy humans. Furthermore, biologics facilities must follow biosafety guidelines set forth by the CDC and NIH, which require the facilities to classify infectious agents into one of four biosafety levels based on the risk that the agents pose. According to the CDC's guidelines, Biosafety Level 1 (BSL-1) agents are those that do not pose a risk of disease and do not require special handling or precautions, and therefore, do not warrant additional management requirements that are imposed on materials subject to the definition of "infectious waste." In response to the comments received, the Board amended the definitions of "infectious agents" and "infectious waste" in § 271.1 to exclude agents classified as BSL-1 by a biologics facility and wastes, mixtures of wastes and cell lines from biologics facilities where no agent in the waste is classified as Biosafety Levels 2-4 as determined by the CDC's BMBL. In addition, plasticware generated by biologics facilities that has not been in contact with agents classified as Biosafety Levels 2-4 as determined by the CDC's BMBL has been excluded from the category "used sharps" in the definition of "infectious waste."

In response to questions raised by commentators concerning how the Board defines "residue in emptied containers," in the definition of "infectious waste" under the category of "cultures and stocks," the Board has incorporated the criteria of 40 CFR § 261.7(b)(1) or (2) in the final rulemaking to determine whether or not a container is empty.

Several commentators expressed that the proposed exclusion in the category of "pathological wastes" under the definition of "infectious waste" required clarification on whether preserved tissues, if excluded from the category "pathological wastes," would also be excluded from the definition of "infectious waste," and therefore, considered municipal waste for waste management purposes. Commentators also questioned whether autoclave facilities can process preserved tissues under the proposed rulemaking, since those items would no longer be considered pathological wastes. Since agents used to preserve tissues can volatilize during autoclaving, processing such materials can pose a threat to worker safety. In response to these

comments, the Board did not adopt the proposed changes in the final rulemaking, and therefore, preserved tissues will remain subject to the definition of “pathological wastes.”

The Board received a comment on the definitions of “sharps” and “used sharps,” which are existing definitions that were modified slightly in the proposed rulemaking. The commentator notes that having two definitions is confusing since only “used sharps” are managed as regulated medical waste, and “sharps” are managed in the same manner as other municipal waste. Therefore, the definition of “sharps” was combined into the category of “used sharps” under the definition of “infectious waste” in the final rulemaking.

§ 284.122. Contents of general permits.

In response to a question submitted by IRRC concerning the proposed deletion of language in § 284.122, relating to the legal right of the Department to enter the permitted area, the identification of interested parties, compliance information, verification of an application, and the administration of civil penalties, the Board did not adopt the proposed deletion, and the requirements of § 284.122 will remain mandatory provisions in the final rulemaking.

§ 284.321. Regulated medical waste monitoring requirements.

Several commentators requested revisions or clarification to § 284.321. Commentators requested the removal of the proposed requirement of § 284.321(n)(3) to repeat the autoclave validation procedure at least once per year, citing that it is not standard industry practice to regularly validate an autoclave. In the final rulemaking, the Board did not adopt the proposed language requiring an annual autoclave validation and deleted § 284.321(n)(3). However, the Board maintained the requirement to repeat the autoclave validation procedure at an ongoing frequency specified by the manufacturer of the autoclave in § 284.321(n).

In its comments on the proposed rulemaking, IRRC expressed that in § 284.321(n)(4), use of the phrase “when a significant change in the waste stream occurs or a problem is evident” does not set clear compliance standards for the regulated community and asked the Board to define the phrases or provide examples. In the final rulemaking, the Board deleted § 284.321(n)(4) and added language to § 284.321(n)(2) to clarify for the regulated community when the autoclave validation testing requirements of § 284.322 must be performed.

A commentator representing biologics facilities requested that additional provisions be added to §§ 284.321 and 284.322 to allow biologics facilities to employ alternate disinfection protocols that are specific to the infectious agents present in the waste generated. IRRC also expressed that the disinfection requirements of the proposed rulemaking may be unnecessarily onerous when applied to the waste streams of biologics facilities, and asked the Board to explain how the provisions are reasonable and necessary for biologics facilities. Recognizing that the wastes generated from a vaccine manufacturing process consist of a single infectious agent that is a known, well-characterized component of a vaccine or other biologic, and biologics facilities are subject to additional standards imposed by federal governmental agencies that ensure a high level of protection for public health and safety, the Board has provided flexibility for biologics

facilities to utilize alternate disinfection techniques in the final rulemaking, provided that certain criteria are met. These additional provisions are found in §§ 284.321(p)-(q) and 284.322(8).

§ 284.411. Segregation.

Commentators representing biologics facilities also expressed that under the proposed rulemaking in § 284.411(a), regulated medical (infectious) and chemotherapeutic wastes must be segregated when discarded. Biologics facilities conduct research by intentionally combining infectious and chemotherapeutic agents, making it unfeasible to segregate those materials when discarded. The commentators requested that an exception be provided in the final rulemaking, relieving biologics facilities engaged in such research from the requirement to segregate regulated medical and chemotherapeutic waste. However, the regulations do not require that mixtures of infectious and chemotherapeutic agents be separated from each other when discarded. Rather, mixtures of infectious and chemotherapeutic waste must simply be managed as chemotherapeutic waste when discarded. Therefore, the exception proposed by the commentator was not adopted in the final rulemaking.

To address the concerns raised by commentators regarding the segregation requirements of § 284.411(a), the Board has added language to § 284.411 to allow flexibility for facilities that are processing chemotherapeutic waste on-site in a captive incinerator operating in accordance with the permit-by-rule provisions in § 284.2, or in accordance with a permit authorized by the Department. The additional language alleviates the prescriptive colored bag requirements for on-site processing of chemotherapeutic waste since those requirements are only necessary when chemotherapeutic waste is transported to an off-site processing facility where it is handled by workers who are unfamiliar with its contents.

§ 284.412. Basic storage requirements.

Several commentators who represented transporters of regulated medical and chemotherapeutic waste submitted comments regarding § 284.412, relating to basic storage requirements. Existing regulatory language addressing requirements for enclosures used for the storage of regulated medical and chemotherapeutic waste was relocated from § 284.411(b) to § 284.412(b) in the proposed rulemaking. Commentators expressed that the statement in proposed § 284.412(b) requiring exhaust air from storage areas to be ventilated to minimize human exposure is too broad and recommended that the statement be replaced with, “Containers in enclosures must be maintained in a closed upright position when not in use in the storage areas to minimize exposure and vectors.” The Board adopted language similar to that recommended by the commentators in the final rulemaking, but the Board did not eliminate the requirement to ventilate exhaust air from the storage area, as suggested by the commentators. The Board believes that it is important to ensure that some ventilation in waste storage areas is required and that the requirement has not been problematic in the implementation of this provision.

§ 284.412. Basic storage requirements, and

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

Commentators expressed that the use of term “commingled” in proposed §§ 284.412(c) and 284.512(e) may cause confusion for the regulated community. The language of the proposed rulemaking may be construed in different ways and does not clearly address whether regulated medical or chemotherapeutic waste may be stored near or transported with other types of waste provided that it does not become commingled in the same container. The intention of the Department is to allow other wastes to be stored in the same area and transported in the same vehicle as regulated medical and chemotherapeutic wastes, but prevent the mixing of unconsolidated regulated medical or chemotherapeutic wastes with unconsolidated municipal waste in the same container. For clarity, the Board has modified § 284.412(c) in the final rulemaking to state that regulated medical and chemotherapeutic waste may not be commingled with other wastes in the same container. Likewise, the Board has revised § 284.512(e) in the final rulemaking to state that separately containerized regulated medical and chemotherapeutic waste may be transported in the same vehicle as containerized municipal waste.

In response to questions raised by commentators concerning the manner in which generators may move regulated medical, chemotherapeutic and municipal waste on-site, the Board revised the language of § 284.412(d) to clarify that sorted and separately containerized regulated medical or chemotherapeutic waste may be stored in the same location, including on a cart.

§ 284.413. Storage containers.

Several commentators who represented the waste transportation industry requested that the container requirements at § 284.413(a)(1) be revised to require containers of regulated medical or chemotherapeutic waste to be leakproof on the sides and bottom only provided that the containers are maintained in an upright position. The modification will align Pennsylvania’s requirements with U.S. Department of Transportation requirements regarding the transportation of regulated medical or chemotherapeutic waste. Therefore, the Board adopted the change in the final rulemaking.

§ 284.414. Marking of containers,

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

§ 284.724. Transportation limitations.

Several commentators representing transporters of regulated medical and chemotherapeutic waste requested that the transition period for compliance with the amended container marking requirements at §§ 284.414 and 284.724(a)(2), and vehicle signage requirements at § 284.513(b), respectively, be extended from 1 year, as provided in the proposed rulemaking, to 2 years. The Board has adopted the extended transition period in the final rulemaking to provide generators and transporters with 2 years from the effective date of the rulemaking to appropriately mark all containers and vehicles.

Commentators questioned whether the requirement in § 284.414(a)(5) to label containers of regulated medical or chemotherapeutic waste with the date the container is full or sealed, whichever occurs earlier, is the responsibility of the generator or the transporter and expressed that § 284.724(a)(2) specifies that transporters may not accept waste that is not properly labeled. The commentators note that when trailers are loaded by the generator, the transporter may not be able to inspect all the containers to ensure compliance with § 284.724(a)(2). Section § 284.414 was revised to include labeling provisions that apply when waste from a single generator is placed in a vehicle or conveyance, including a roll-off, provided that the vehicle or conveyance is transported off-site every 30 days. This amendment provides flexibility by allowing generators and transporters under certain conditions to label the vehicle or conveyance with required information in lieu of labeling each individual container inside the vehicle or conveyance. The amendment aligns Pennsylvania's container marking requirements with the regulations imposed by the U.S. Department of Transportation regarding marking of containers for the transportation of regulated medical and chemotherapeutic waste.

When the waste in a vehicle or conveyance is not from a single generator, the Board believes that the responsibility for marking containers in accordance with § 284.414 is belongs to the generator and the transporter. The transporter should, to the extent possible, ensure that containers of regulated medical or chemotherapeutic waste are labeled in accordance with this section prior to transporting the containers and refuse to accept waste that is not properly labeled. The Board recognizes that in some cases, where the generator preloads trailers of waste, it is impractical for the transporter to inspect containers that are located in portions of the trailer which are not amenable to inspection. However, the Board expects generators to ensure that containers are labeled in accordance with § 284.414 to the extent that visual inspection of the containers is possible.

Several commentators requested clarification on the requirement of § 284.513(d) to clean surfaces of vehicles that have not been in direct physical contact with regulated medical or chemotherapeutic waste on a weekly basis. In the final rulemaking, the Board has amended § 284.513(d) to specify that the cargo area of vehicles used to transport regulated medical or chemotherapeutic waste must be cleaned weekly to ensure that the vehicle surfaces which are most likely to be contaminated with infectious or chemotherapeutic agents be cleaned on a routine basis.

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

Several commentators requested that the temperature range given in § 284.416 for storing unrefrigerated regulated medical or chemotherapeutic waste be replaced with a general standard that waste may be stored for 72 hours at ambient temperature, provided that the waste is not putrescent and does not attract vectors. The Board adopted the requested language in the final rulemaking.

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

In its comments on the proposed rulemaking, IRRC asked the Board to explain how the proposed deletion of strength and weight requirements on corrugated fiberboard containers in § 284.512(c)(1)(iv) is protective of public health, safety and welfare. The Board does not believe that the regulations must contain a standard prescriptive strength or weight limit for corrugated fiberboard containers to transport regulated medical and chemotherapeutic waste. Rather, the Board believes that a general performance standard, such as that provided in §§ 284.512(c)(1)(iv) and 284.413(a) is sufficient. This standard requires that containers being used to transport regulated medical and chemotherapeutic waste be “[s]ufficient in strength to prevent puncturing, tearing or bursting during transportation.”

The amendments to § 284.512(c)(1)(iv) eliminate prescriptive strength and weight limits for corrugated fiberboard containers since those limits only apply to corrugated fiberboard containers, but waste may be transported in other types of containers, such as plastics or metal. However, there are no standard strength and weight limits for non-fiberboard containers that could be referenced in this regulation. The Board believes that it is necessary for this regulation to address all types of containers and has provided a consistent performance standard for each type.

Furthermore, the inclusion of prescriptive requirements for fiberboard containers does not guarantee that the performance standard will be satisfied. Even if the prescriptive standards were followed, the containers may still be punctured, torn or burst through mishandling, misuse or other circumstances during the handling of these containers. The Board believes that general performance requirements provide a clear standard for transporters and will eliminate any uncertainty that may result in an enforcement action. In addition, this type of performance standard is commonly used in the Board’s regulations, where it is useful to provide the regulated industry flexibility in compliance and where industry standards evolve over time.

§ 284.623. Conditions of licenses.

At the request of commentators representing the waste transportation industry, the Board has amended § 284.623(c) in the final rulemaking to clarify that a license to transport regulated medical and chemotherapeutic waste may not be transferred to subcontracted haulers and haulers who provide their own equipment without prior written approval of the Department. The amendment allows transporters authorized by the Department to transport regulated medical and chemotherapeutic waste to utilize temporary or subcontracted drivers without obtaining prior written approval from the Department.

*§ 284.624. License renewal, and
§ 284.712. Preparation of logs and shipping papers.*

Commentators noted that in § 284.624(b)(2), the quantity of each type of regulated medical or chemotherapeutic waste must be included in the transporter’s annual report. However, the requirement to track the type of waste being transported on logs or shipping papers was deleted

from § 284.712(a)(5) in the proposed rulemaking. Therefore, the Board has reinstated the language from § 284.712(a)(5) to § 284.712(a)(4) in the final rulemaking, maintaining the requirement for generators to include the type of waste being transported on logs or shipping papers. By including the waste code on the logs or shipping papers, transporters may continue to include this information in their annual reports, and the Department is able to ensure that regulated medical and chemotherapeutic wastes are processed or disposed of at facilities authorized to accept the waste.

§ 284.732. Use of logs and shipping papers.

At the request of several commentators, the Board has included the use of electronic and stamped signatures as acceptable forms of acknowledging that waste has been received on logs or shipping papers in § 284.732(b)(3) of the final rulemaking.

§ 284.734. Significant discrepancies.

Several commentators who represented the waste transportation industry recommended revisions to § 284.734(b) regarding the manner in which significant discrepancies between the quantity of waste shipped and the quantity of waste listed on the log or shipping paper are handled. In the proposed rulemaking, when a significant discrepancy exists, the processor must attempt to reconcile the discrepancy prior to processing or disposing of the waste. The Board recognizes that there are instances where the waste is being processed as it is off-loaded, and therefore, operators at the processing facility may not realize that a discrepancy exists until some or all of the waste has been processed. However, if the waste is no longer available for evaluation, it is unrealistic that the discrepancy could be reconciled. The Board believes that once a discrepancy is identified by the processor, processing of the waste should be stopped, and the remaining waste should be held while the processor attempts to reconcile the discrepancy with the generator. Therefore, the language suggested by the commentator was not included, and the amendments to § 284.734(b), as proposed, were adopted by the Board in the final rulemaking.

F. Benefits, Costs and Compliance

Benefits

The rulemaking simplifies the labeling requirements to reduce costs and ensure consistency with Federal requirements. The amendments 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. To avoid conflicts with OSHA requirements, duplicative requirements are deleted. The 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 final rulemaking provides a cost savings to the regulated community through: providing consistency with the United States Department of Transportation; reduced transportation cost for generators and transporters due to consolidation of waste in trucks; longer storage times for generators, meaning fewer waste pickups; reduced waste management and disposal costs for biologics facilities; and reduced 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 final 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 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 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 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, published at 43 Pa. B. 4858 (August 24, 2013), to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees, for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the House and Senate Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final rulemaking, the Department has considered all comments from IRRC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _____, the final-form rulemaking was deemed approved by the House and Senate Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, and approved the final-form rulemaking.

J. Findings of the Board

The Board finds that:

- (1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law and all comments were considered.
- (3) This final rulemaking does not enlarge the purpose of the proposed rulemaking published at 43 Pa. B. 4858.
- (4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this preamble.

K. Order of the Board

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapters 271, 272, 273, 284, 285 287, 288, and 299, are amended to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

E. CHRISTOPHER ABRUZZO,
Chairperson