RULES AND REGULATIONS

Title 25—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) amends Chapters 271, 272, 273, 284, 285, 287, 288 and 299 to read as set forth in Annex A.

The final-form 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-form 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 amendments to Chapter 284. Finally, the amendments to Chapters 272, 273, 287 and 288 replace all references to "infectious" waste with "regulated medical" waste to be consistent with amendments to Chapters 271 and 284.

This final-form rulemaking was adopted by the Board at its meeting on July 15, 2014.

A. Effective Date

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

B. Contact Persons

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C. Statutory Authority

This final-form 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 of The Administrative Code of 1929 (71 P. S. § 510-20) 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-form 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-form 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-form 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 final-form regulations allow generators to completely fill containers and only ship when necessary, which results in a cost savings for the generators.

The amendments 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 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 former infectious and chemotherapeutic waste regulations defined 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 inva-

sion 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 so 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 United States Environmental Protection Agency in the Medical Waste Tracking Act of 1988 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 (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 BSLs 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 BSLs 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 amended in the final-form 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 299.

§ 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 RMRI.

In the final-form 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-form 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-form rulemaking, a determination is made on whether a container is empty by applying the criteria in 40 CFR 261.7(b)(1) or (2) (relating to residues of hazardous waste in empty containers).
- The proposed exclusion of certain preserved tissues from the category of "pathological wastes" was deleted in the final-form rulemaking.
- In the category of "animal wastes," the proposed deletion of "during research" was reinstated in the final-form rulemaking.

- The definitions of "sharps" and "used sharps" were combined in the final-form 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 "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-form rulemaking.

§ 271.101. Permit requirement

Subsection (b)(5) is amended in this final-form rule-making to change "facility" to "facilities."

§ 271.114. Transition period

The former regulation established a time frame 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 rescinded.

§ 272.532. Limitations on acceptable waste

Subsection (a)(2) is amended in this final-form rule-making 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 is corrected in subsection (a).

Subsection (d) is reworded for clarity and unused hypodermic needles or syringes are added.

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

In subsection (a)(4), "infectious waste" and "medical waste" have been replaced with "liquid blood and body fluids" for clarity. Subsection (a)(4)(iii) has 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-form rulemaking.

In subsection (b)(2), the term "manifest" has been changed to "log and shipping paper" to mirror the changes made to \$ 284.701(b)(5) (relating to scope).

Subsection (c)(8) was amended in the final-form rule-making to delete "manifested" and "manifesting" to reflect the changes made to the heading of Chapter 284, Subchapter H (relating to tracking of regulated medical and chemotherapeutic waste).

§ 284.3. Regulated medical or chemotherapeutic waste aggregation facilities

Chemotherapeutic waste has been added throughout this section, including the section's heading, to maintain consistency with the amendments to the definition of "regulated medical and chemotherapeutic waste aggregation facilities" in § 271.1.

In subsection (c), "generator" has been replaced with "operator" for clarity.

§ 284.111. Application for general permit

In subsection (b)(3)(viii), "infectious" has been changed to "regulated medical" in accordance with the changes that have been applied uniformly throughout the final-form rulemaking.

§ 284.121. Contents of general permits

In paragraph (8), "manifest" has been changed to "log or shipping paper" in accordance with the changes that have been applied uniformly across the final-form rule-making. "Manifesting for" has been replaced with "tracking of" to maintain consistency with the changes made to the heading of Chapter 284, 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-form rulemaking.

In subsection (b), the proposed deletion of "waiver or" and the mandatory provisions regarding 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-form rulemaking. Therefore, these provisions remain mandatory.

§ 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 § 284.2(a)(5) (relating to permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements) for transfer facilities operating under a permit-by-rule and the changes applied uniformly to the final-form rulemaking.

§ 284.321. Regulated medical waste monitoring requirements

In subsection (g), "after disinfection" has been deleted for clarity.

Subsection (n) was reorganized and revised in the final-form rulemaking to require autoclave validation at a frequency specified by the manufacturer of the autoclave.

Language was added to subsection (n)(2) to clearly state when the autoclave validation procedure shall be performed.

Proposed subsection (n)(3) was deleted in the final-form 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 deleted from the final-form rulemaking.

Proposed subsection (n)(4) was deleted to eliminate the ambiguity of the phrases "significant change" and "problem is evident." Specific language regarding when the autoclave validation procedure shall be performed was added to subsection (n)(2) in the final-form 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) (relating to regulated medical waste monitoring requirements) 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 onsite.

§ 284.412. Basic storage requirements

Language has been added to subsection (b) to clarify that containers in enclosures shall 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-form 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.

Final-form subsection (a)(2) and (3) extends 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-form rulemaking.

The proposed language in subsection (a)(5) regarding 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-form 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 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 placed on the containers.

Subsection (b) was added to the final-form 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 subsection (b) must be satisfied and include the requirement that the waste is from a single generator and the vehicle or conveyance is transported offsite 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 provisions) 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.

Proposed subsection (a) was deleted because the language duplicates the requirement of § 284.414(a)(5) and (b)(4) (relating to marking of containers).

§ 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 immediately transported offsite if it becomes putrescent or attracts vectors has also been added.

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

§ 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 \S 284.414(b) 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 deleted from the final-form rulemaking.

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-form rulemaking.

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

In subsection (b), "or conveyances" has been added to maintain consistency with other transportation requirements referenced throughout Articles VIII and IX (relating to municipal waste; and residual waste management).

Subsection (b)(3) and (4) was 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 shall 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), "manifesting" has been changed to "log and shipping paper" in accordance with the changes that have been applied uniformly across the final-form rulemaking.

§ 284.623. Conditions of licenses

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

Chapter 284, Subchapter H. Tracking of regulated medical and chemotherapeutic waste

In the final-form 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, "manifesting for" has been replaced with "tracking of" in the heading of Chapter 284, Subchapter H.

§ 284.711. Use of logs or shipping papers

The reference to "manifest" in the section heading was replaced with "logs or shipping papers" in accordance with changes made uniformly to the final-form rulemaking.

§ 284.712. Preparation of logs or shipping paper

The reference to "manifest" in the section heading was replaced with "logs or shipping papers" to maintain consistency with the change in terminology that has been applied uniformly to the final-form rulemaking.

Subsection (a)(5) was proposed to be deleted. The intent of this paragraph was added to the final-form rulemaking as subsection (a)(4) to require generators and transport-

ers 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-form rulemaking.

In subsection (c), "manifest" has been replaced with "logs or shipping papers" to reflect the change made to the heading 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-form 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.

Language requiring a log or shipping paper to also be delivered to a subsequent transporter has been added to subsection (e).

§ 284.731. Scope

"Manifest" has been changed to "logs and shipping papers" in accordance with changes that have been applied uniformly to the final-form rulemaking.

§ 284.732. Use of logs or shipping papers

The reference to "manifest" in the section heading was replaced with "logs or shipping papers" to maintain consistency with the change in terminology that has been applied uniformly to the final-form 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-form rulemaking to maintain consistency with the signage requirements in § 285.218 (relating to signs on vehicles).

F. Summary of Comments and Responses on the Proposed Rulemaking

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, seven commentators provided comments to the Board on the proposed rulemaking, including the Independent Regulatory Review Commission (IRRC). The comments received on the proposed rulemaking are summarized in this section and are addressed in a Comment and Response Document which is available from the Department.

General

Several commentators suggested that all references to "manifests" be replaced with "logs or shipping papers" for consistency, including references in section headings. The Board replaced "manifest" with "logs or shipping papers" throughout Article VIII in the final-form rulemaking.

§ 271.1. Definitions

Commentators representing biologics facilities provided pertinent information on their unique activities, asserting that biologics facilities are highly regulated by the United States Food and Drug Administration, the CDC and the National Institutes of Health, 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 final-form rulemaking. The Department worked cooperatively with representatives of the impacted biologics facilities during the development of the final-form rulemaking and was able to incorporate revisions into the final-form 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 so 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 shall follow biosafety guidelines set forth by the CDC and the National Institutes of Health 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, 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 BSLs 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 BSLs 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 incorporated the criteria of 40 CFR 261.7(b)(1) or (2) in the final-form 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 volatize during autoclaving, processing these materials can pose a threat to worker safety. In response to these comments, the Board did not adopt the proposed amendments in the final-form 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 proposed to be amended slightly in the proposed rulemaking. The commentator noted 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-form rulemaking.

§ 284.122. Waiver or modification of certain requirements

In response to a question submitted by IRRC concerning the proposed deletion of language in § 284.122 (relating to waiver or modification of certain requirements) regarding 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 amendment, thereby withdrawing the amendment to this section. The requirements of § 284.122 will remain mandatory provisions.

§ 284.321. Regulated medical waste monitoring requirements

Several commentators requested revisions to or clarification of § 284.321. Commentators requested the deletion 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-form rulemaking, the Board did not adopt the proposed language requiring an annual autoclave validation and deleted proposed § 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 \S 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-form rulemaking, the Board deleted proposed \S 284.321(n)(4) and added language to \S 284.321(n)(2) to clarify for the regulated community when the autoclave validation testing requirements of \S 284.322 (relating to autoclave validation testing requirements) shall 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 provided flexibility for biologics facilities to utilize alternate disinfection techniques in the final-form rulemaking, provided that certain criteria are met. These additional provisions are in §§ 284.321(p) and (q) and 284.322(8).

§ 284.411. Segregation

Commentators representing biologics facilities also expressed that under proposed § 284.411(a) (relating to segregation), regulated medical (infectious) and chemotherapeutic wastes shall 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-form rulemaking relieving biologics facilities engaged in this 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 shall simply be managed as chemotherapeutic waste when discarded. Therefore, the exception proposed by the commentator was not adopted in the final-form rulemaking.

To address the concerns raised by commentators regarding the segregation requirements of § 284.411(a), the Board added language to § 284.411 to allow flexibility for facilities that are processing chemotherapeutic waste onsite 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 onsite processing of chemotherapeutic waste since those requirements are only necessary when chemotherapeutic waste is transported to an offsite 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 in the final-form rulemaking, to that recommended by the commentators, 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

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

Commentators expressed that the use of "commingled" in proposed § 284.412(c) and § 284.512(e) (relating to transportation of regulated medical and chemotherapeutic waste; general provisions) may cause confusion for the regulated community. The language of the proposed rule-making may be construed in different ways and does not clearly address whether regulated medical or chemothera-

peutic 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 revised § 284.412(c) in the final-form rulemaking to state that regulated medical and chemotherapeutic waste may not be commingled with other wastes in the same container. Likewise, the Board revised § 284.512(e) in the final-form 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 onsite, the Board revised § 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 of § 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 the Pennsylvania requirements with United States Department of Transportation requirements regarding the transportation of regulated medical or chemotherapeutic waste. Therefore, the Board adopted the change in the final-form rulemaking.

§ 284.414. Marking of containers

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

§ 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 of § 284.414 and § 284.724(a)(2) (relating to transportation limitations), and vehicle signage requirements of § 284.513(b), respectively, be extended from 1 year, as provided in the proposed rulemaking, to 2 years. The Board adopted the extended transition period in the final-form rulemaking to provide generators and transporters with 2 years from the effective date of this final-form 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 offsite every 30 days. This amendment provides flexibility by allowing generators and transporters under certain conditions to label the vehicle or conveyance with required information instead of labeling each individual container inside the vehicle or conveyance. The amendment aligns the Pennsylvania container marking requirements with the regulations imposed by the United States 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 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, when 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-form rulemaking, the Board amended § 284.513(d) to specify that the cargo area of vehicles used to transport regulated medical or chemotherapeutic waste shall 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 (relating to duration of storage of regulated medical and chemotherapeutic waste for processors) 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-form rule-making.

§ 284.512. Transportation of regulated medical and chemotherapeutic waste; general 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 §§ 284.413(a) and 284.512(c)(1)(iv), 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 not standard strength and weight limits for nonfiberboard 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 amended § 284.623(c) (relating to conditions of licenses) in the final-form rule-making 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.

§ 284.634. Annual report

§ 284.712. Preparation of logs or shipping papers

Commentators noted that in § 284.634(b)(2) (relating to annual report) the quantity of each type of regulated medical or chemotherapeutic waste shall 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 proposed to be deleted in § 284.712(a)(5) (relating to preparation of logs or shipping papers). Therefore, the Board added the language from § 284.712(a)(5) to § 284.712(a)(4) in the final-form 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 or shipping papers

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

§ 284.734. Significant discrepancies

Several commentators who represented the waste transportation industry recommended revisions to § 284.734(b) (relating to significant discrepancies) 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 shall attempt to reconcile the discrepancy prior to processing or disposing of the waste. The Board recognizes that there are instances when 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-form rulemaking.

F. Benefits, Costs and Compliance

Benefits

The final-form 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 of regulated medical and chemotherapeutic waste 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-form rulemaking provides a cost savings to the regulated community through: providing consistency with the United States Department of Transportation; reduced transportation costs 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-form 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. 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 final-form 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 final-form 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 the notice of proposed rulemaking, published at 43 Pa.B. 4858, to IRRC and 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-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on September 17, 2014, 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 September 18, 2014, and approved the final-form rulemaking.

J. Findings

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-form 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

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 by adding §§ 284.3, 284.116, 284.230 and 284.322, by deleting §§ 271.114, 284.132, 284.713, 284.721, 284.723 and 284.733 and by amending §§ 271.1, 271.2, 271.101, 271.103, 271.421, 271.601, 271.611, 271.801, 271.811, 272.223, 272.532, 273.411, 273.511, 284.13, 284.201, 284.102, 284.111—284.115, 284.121, 284.131, 284.201, 284.210, 284.220, 284.301, 284.311, 284.320, 284.321, 284.401, 284.411—284.419, 284.501, 284.511—284.623, 284.624, 284.631—284.634, 284.641—284.642, 284.623, 284.701—284.703, 284.711, 284.712, 284.714, 284.722, 284.724, 284.731, 284.732, 284.734, 285.131, 285.218, 285.221, 287.1, 287.2, 288.423 and 299.220 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(*Editor's Note*: Section 271.114, which was proposed to be amended in the proposed rulemaking published at 43 Pa.B. 4858, is rescinded in Annex A. The addition of § 284.230 was not included in the proposed rulemaking. The amendment to § 284.122 included in the proposed rulemaking has been withdrawn by the Board.)

- (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 $Pennsylvania\ Bulletin$.

DANA K. AUNKST, Acting Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 44 Pa.B. 6306 (October 4, 2014).)

Fiscal Note: Fiscal Note 7-480 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE VIII. MUNICIPAL WASTE CHAPTER 271. MUNICIPAL WASTE MANAGEMENT—GENERAL PROVISIONS

Subchapter A. GENERAL

§ 271.1. Definitions.

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

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

* * * * *

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

* * * * *

Commercial establishment—An establishment engaged in nonmanufacturing or nonprocessing business, including, but not limited to, stores, markets, office buildings, restaurants, shopping centers and theaters.

Commercial regulated medical or chemotherapeutic waste facility—A facility that processes regulated medical or chemotherapeutic waste under either of the following conditions:

- (i) The facility does not generate any of the regulated medical or chemotherapeutic waste that it processes.
- (ii) If the facility generates the regulated medical or chemotherapeutic waste that it processes, the amount of waste on a monthly average that is generated onsite and offsite by wholly-owned generators of the facility is less than 50% of the waste that it processes.

Community activities—Events sponsored in whole or in part by a municipality, or conducted within a municipality and sponsored privately, which include, but are not limited to, fairs, bazaars, socials, picnics and organized sporting events that will be attended by 200 or more individuals per day.

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

Household hazardous waste—

- (i) Waste generated by a household that could be chemically or physically classified as a hazardous waste under the standards of Article VII (relating to hazardous waste management).
- (ii) For the purpose of this definition, the term "household" includes those places described as "households" in 40 CFR 261.4(b)(1) (relating to exclusions).

Incineration—The act of reducing to ashes by combustion.

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

Incorporating—Injecting sludge beneath the surface of the soil or mixing sludge with the surface soil.

Industrial establishment—An establishment engaged in manufacturing or processing, including, but not limited to, factories, foundries, mills, processing plants, refineries, mines and slaughterhouses.

Infectious agent—

- (i) 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.
- (ii) The term does not include agents classified as Biosafety Level 1 by a facility engaged in the production or research and development of vaccines or other biologics classified under the North American Industrial Classification System (NAICS) as Code 325414—Biological Product (except Diagnostic) Manufacturing or Code 541711—Research and Development in Biotechnology, as determined by the protocols established in the most recent edition of the Centers for Disease Control's (CDC) Biosafety in Microbial and Biomedical Laboratories (BMBL) existing at the time the waste is generated.

Infectious waste—

- (i) General. Municipal and residual waste which is generated in the diagnosis, treatment, immunization or autopsy of human beings or animals, in research pertaining thereto, in the preparation of human or animal remains for interment or cremation, or in the production or testing of biologicals, and which falls under one or more of the following categories:
- (A) Cultures and stocks. Cultures and stocks of infectious agents and associated biologicals, including the following:
 - (I) Cultures from medical and pathological laboratories.
- (II) Cultures and stocks of infectious agents, and cell lines that have been exposed to infectious agents from research and industrial laboratories.
 - (III) Wastes from the production of biologicals.
- (IV) Discarded live and attenuated vaccines except for residue in emptied containers, as determined by applying the criteria in 40 CFR 261.7(b)(1) or (2) (relating to

- residues of hazardous waste in empty containers) to the residue remaining in the container.
- (V) Culture dishes, assemblies and devices used to conduct diagnostic tests or to transfer, inoculate and mix cultures.
- (B) Pathological wastes. Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth.
 - (C) Human blood and body fluid waste.
 - (I) Liquid waste human blood.
 - (II) Blood products.
 - (III) Items saturated or dripping with human blood.
- (IV) Items that were saturated or dripping with human blood that are now caked with dried human blood, including serum, plasma and other blood components, which were used or intended for use in patient care, specimen testing or the development of pharmaceuticals.
- (V) Intravenous bags that have been used for blood transfusions, including soft plastic pipettes and plastic blood vials.
- (VI) Items, including dialysate, that have been in contact with the blood of patients undergoing hemodialysis at hospitals or independent treatment centers.
- (VII) Items saturated or dripping with body fluids or caked with dried body fluids from persons during surgery, autopsy, other medical procedures or laboratory procedures
- (VIII) Specimens of blood products or body fluids, and their containers.
- (D) Animal wastes. Contaminated animal carcasses, body parts, blood, blood products, secretions, excretions and bedding of animals that were known to have been exposed to zoonotic infectious agents or nonzoonotic human pathogens during research, production of biologicals, or testing of pharmaceuticals.
- $\left(E\right)$ Isolation wastes. Biological wastes and waste contaminated with blood, excretion, exudates or secretions from:
- (I) Humans who are isolated to protect others from highly virulent diseases.
- (II) Isolated animals known or suspected to be infected with highly virulent diseases.
 - (F) Used sharps.
- (I) Broken glass, hypodermic needles, syringes to which a needle is or can be attached, razors, pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, culture dishes, suture needles, slides, cover slips, and other broken or unbroken glass or plasticware that have been in contact with infectious agents or that have been used in animal or human patient care or treatment.
- (II) The term does not include broken or unbroken plasticware generated at facilities engaged in the production or research and development of vaccines or other biologics and classified under the NAICS as Code 325414—Biological Product (except Diagnostic) Manufacturing or Code 541711—Research and Development in Biotechnology, where no agent in the waste is classified as Biosafety Levels 2—4 as determined by the protocols established in the most recent edition of the CDC's BMBL existing at the time the waste is generated.

- (ii) Mixtures.
- (A) The term also includes materials identified under subparagraph (i) that are mixed with municipal and residual waste, including disposable containers.
- (B) The term also includes mixtures of materials identified in subparagraph (i) with quantities of radioactive waste not subject to regulation.
- (iii) Exceptions. The term does not include the following:
 - (A) Wastes generated as a result of home self-care.
- (B) Human corpses, remains and anatomical parts that are intended for interment or cremation, or are donated and used for scientific or medical education, research or treatment.
- (C) Etiologic agents being transported for purposes other than waste processing or disposal under the requirements of the United States Department of Transportation (49 CFR 171.1—171.26 (relating to general information, regulations, and definitions)), the Department of Transportation (67 Pa. Code Part I) and other applicable shipping requirements.
- (D) Samples of regulated medical waste transported offsite by Commonwealth or United States government enforcement personnel during an enforcement proceeding.
- (E) Body fluids, tissues, specimens or biologicals that are being transported to or stored at a laboratory prior to laboratory testing.
- (F) Ash residue from the incineration of materials identified in subparagraphs (i) and (ii) if the incineration was conducted in accordance with § 284.321 (relating to regulated medical waste monitoring requirements). The ash residue shall be managed as special handling municipal waste.
- (G) Reusable or recyclable containers or other nondisposable materials, if they are cleaned and disinfected, or if there has been no direct contact between the surface of the container and materials identified in subparagraph (i). Laundry or medical equipment shall be cleaned and disinfected in accordance with the United States Occupational Safety and Health Administration requirements in 29 CFR 1910.1030 (relating to bloodborne pathogens).
- (H) Soiled diapers that do not contain materials identified in subparagraph (i).
- (I) Mixtures of hazardous waste subject to Article VII and materials identified in subparagraph (i) shall be managed as hazardous waste and not regulated medical waste.
- (J) Mixtures of materials identified in subparagraph (i) and regulated radioactive waste shall be managed as radioactive waste in accordance with applicable Commonwealth and Federal statutes and regulations, including § 236.521 (relating to minimum requirements for classes of waste).
- (K) Mixtures of materials identified in subparagraph (i) and chemotherapeutic waste shall be managed as chemotherapeutic waste in accordance with this article.
- (L) Wastes, mixtures of wastes or cell lines from facilities engaged in the production or research and development of vaccines or other biologics and classified under the NAICS as Code 325414—Biological Product (except Diagnostic) Manufacturing or Code 541711—Research and Development in Biotechnology, where no agent in the waste is classified as Biosafety Levels 2—4 as determined

by the protocols established in the most recent edition of the CDC's BMBL existing at the time the waste is generated.

Institutional establishment—An establishment engaged in service, including, but not limited to, hospitals, nursing homes, orphanages, schools and universities.

* * * * *

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

* * * * *

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

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

Regulated medical waste—Infectious waste.

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

* * * * *

Sewage sludge—Liquid or solid sludges and other residues from a municipal sewage collection and treatment system; and liquid or solid sludges and other residues from septic and holding tank pumpings from commercial, institutional or residential establishments. The term includes materials derived from sewage sludge. The term does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator, grit and screenings generated during preliminary treatment of sewage sludge at a municipal sewage collection and treatment system, or grit, screenings and nonorganic objects from septic and holding tank pumpings.

Site—The area where municipal waste processing or disposal facilities are operated. If the operator has a permit to conduct the activities, and is operating within the boundaries of the permit, the site is equivalent to the permit area.

* * * * *

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

* * * * *

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

* * * * *

Unrecognizable regulated medical waste—All components of the waste have been processed to produce indistinguishable and unusable pieces smaller than 3/4 inch, except that all used sharps must be smaller than 1/2 inch. The term does not mean compaction or encapsulation except through:

- (i) Processes such as thermal treatment or melting, during which disinfection and destruction occur.
- (ii) Processes such as shredding, grinding, tearing or breaking, during or after disinfection occurs.
- (iii) Processes that melt plastics and fully encapsulate metallic or other used sharps and seals waste completely in a container that will not be penetrated by untreated used sharps.

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§ 271.2. Scope.

- (a) This chapter specifies certain general procedures and rules for persons who operate municipal waste management facilities. This chapter, together with Chapters 273, 275, 277, 279, 281, 283, 284 and 285, specifies the Department's requirements for municipal waste processing, disposal, transportation, collection and storage.
- (b) Management of the following types of residual waste is subject to this article instead of Article IX (relating to residual waste management), and shall be regulated as if the waste is municipal waste, regardless of whether the waste is a municipal waste or residual waste.
- (1) Construction/demolition waste, except construction/demolition waste with greater than 4 ppm PCBs.
 - (2) Regulated medical and chemotherapeutic waste.
 - (3) Leaf waste and grass clippings.
- (4) Waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material.
- (c) Management of the following types of waste is subject to Article IX instead of this article, and shall be regulated as if the waste is residual waste, regardless of whether the waste is municipal waste or residual waste:
 - (1) Water supply treatment plant sludges.
 - (2) Waste oil that is not hazardous waste.
 - (3) Waste tires and auto fluff.
 - (4) Contaminated soil.
 - (5) Used asphalt.
 - (6) Dredged material.
- (d) The disposal, processing, storage and transportation at a municipal waste management facility of the following types of special handling waste is subject to the applicable additional requirements for the disposal, processing, storage and transportation of these wastes in Article IX, and shall be regulated as if the waste is residual waste, regardless of whether the waste is municipal waste or residual waste:
 - (1) Friable asbestos containing waste.
 - (2) PCB containing waste.

Subchapter B. GENERAL REQUIREMENTS FOR PERMITS AND PERMIT APPLICATIONS REQUIREMENT

§ 271.101. Permit requirement.

- (a) Except as provided in subsection (b), a person or municipality may not own or operate a municipal waste disposal or processing facility unless the person or municipality has first applied for and obtained a permit for the facility from the Department under the requirements of this article.
- (b) A person or municipality is not required to obtain a permit:
- (1) For the use or application of agricultural waste in normal farming operations, unless the proposed use or application of the waste may cause pollution to air, water or other natural resources of this Commonwealth.
- (2) For a source separation and collection program for recycling municipal waste, or for dropoff points, or collection or processing centers for source separated recyclable materials.
- (3) For the use as clean fill of the following materials if they are separate from other waste:
- (i) Uncontaminated soil, rock, stone, gravel, unused brick and block and concrete.
- (ii) Waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material.
- (4) For the use of waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material if the waste is not hazardous. A person managing waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material, shall implement best management practices. The Department will prepare a manual for the management of waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material which identifies best management practices and may approve additional best management practices on a caseby-case basis. If a person fails to implement best management practices for managing waste from land clearing, grubbing and excavation, including trees, brush, stumps and vegetative material, the Department may require compliance with the disposal, composting, processing and storage operating requirements of this chapter and Chapters 281, 283 and 285 (relating to composting facilities; resource recovery and other processing facilities; and storage, collection and transportation of municipal waste).
- (c) Subsection (b) does not relieve a person or municipality of the requirements of an applicable environmental protection act or an applicable regulation promulgated under it. Notwithstanding subsection (b), the Department may require a person or municipality to apply for, and obtain, an individual or general solid waste permit, or take other appropriate action, when the person or municipality is conducting a solid waste activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.
- § 271.103. Permit-by-rule for municipal waste processing facilities other than for regulated medical or chemotherapeutic waste; qualifying facilities; general requirements.
- (a) *Purpose*. Facilities and activities described in this section shall be deemed to have a municipal waste permit by rule if the following general requirements are met:

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EXISTING FACILITIES

§ 271.114. (Reserved).

Subchapter E. CIVIL PENALTIES AND ENFORCEMENT ENFORCEMENT

§ 271.421. Administrative inspections.

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- (c) The Department, its employees and agents intend to conduct inspections under the act of:
- (1) Facilities for the agricultural utilization of sewage sludge operating under a permit issued under Chapter 275 (relating to land application of sewage sludge) or a beneficial use order issued prior to January 25, 1997, at least two times per year.
- (2) Municipal waste processing facilities other than resource recovery facilities, which process or incinerate regulated medical or chemotherapeutic waste, at least two times per year.
- (3) Municipal waste processing facilities other than resource recovery facilities, which do not process or incinerate regulated medical or chemotherapeutic waste, at least once per year.
- (4) Hospitals where regulated medical or chemotherapeutic waste is generated, at least two times per year.
- (5) Locations other than hospitals where regulated medical or chemotherapeutic waste is generated, at least once per year.
- (6) Facilities subject to permit-by-rule under § 271.102 (Reserved) at least once per year.
- (7) Facilities and beneficial use areas subject to permitby-rule under § 271.103 (relating to permit-by-rule for municipal waste processing facilities other than for regulated medical or chemotherapeutic waste; qualifying facilities; general requirements), a general permit for beneficial use or processing, or both, under Subchapter I (relating to beneficial use), or a permit for the land application of sewage sludge under Subchapter J (relating to beneficial use of sewage sludge by land application), at least once per year.

Subchapter G. RESIDUAL WASTE GENERAL PROVISIONS

§ 271.601. Scope.

- (a) This subchapter applies to municipal waste processing or disposal facilities that apply to receive residual waste for processing or disposal. Section 271.611 (relating to chemical analysis of waste) also applies to an application for a general permit for the beneficial use or processing of municipal waste under Subchapter I (relating to beneficial use). This subchapter does not apply to:
- (1) Transfer facilities except as otherwise required in writing by the Department.
- (2) The disposal at permitted municipal waste landfills of residual waste from a person or municipality that generates a total quantity of 2,200 pounds or less of residual waste per generating location in each month, if the application demonstrates to the Department's satisfaction that the waste is not hazardous.
- (3) The disposal at permitted municipal waste landfills of an individual type of residual waste from a person or municipality that generates a total of 2,200 pounds or

- less of that type of residual waste per generating location in each month, if approved by the Department in writing.
- (b) The requirements of this subchapter are in addition to the application and operating requirements in this article.
- (c) The Department may require analyses under this subchapter for special handling waste other than sewage sludge, regulated medical waste, chemotherapeutic waste and ash residue from a resource recovery facility.

ADDITIONAL APPLICATION REQUIREMENTS

§ 271.611. Chemical analysis of waste.

* * * * *

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

Subchapter I. BENEFICIAL USE SCOPE

§ 271.801. Scope.

- (a) This subchapter sets forth requirements for general permits for the processing and beneficial use of municipal waste, except as follows:
- (1) This subchapter does not set forth requirements for general permits for the processing or beneficial use of regulated medical or chemotherapeutic waste.
- (2) This subchapter does not set forth requirements for general permits for the beneficial use of sewage sludge by land application, except as provided in § 271.821(b)(6) (relating to application for general permit). A general or individual permit for the beneficial use of sewage sludge not mixed with residual waste will be issued only under Subchapter J (relating to beneficial use of sewage sludge by land application).
- (b) An operation that is approved under this subchapter does not require an individual processing or disposal permit under this article. The requirements of Subchapters A—G and Chapters 273, 277, 279, 281, 283 and 285 are applicable to the extent required in § 271.832 (relating to waiver and modification of requirements).

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

§ 271.811. Authorization for general permit.

- (a) Under §§ 271.812 and 271.821—271.825, the Department may issue general permits on a regional or Statewide basis for a category of processing when processing is necessary to prepare the waste for beneficial use, or for a category of beneficial use, or both, of municipal waste, if the following are met:
- (1) The wastes included in the category are generated by the same or substantially similar operations and have the same or substantially similar physical character and chemical composition. If wastes are not the same or substantially similar and are blended for use, the blend shall be consistently reproduced with the same physical character and chemical composition.

- (2) The wastes included in the category are proposed for the same or substantially similar beneficial use or processing operations.
- (3) The activities in the category can be adequately regulated utilizing standardized conditions without harming or presenting a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth. The Department will not issue a general permit if the use of the waste as an ingredient in an industrial process or as a substitute for a commercial product presents a greater harm or threat of harm than the use of the produce or ingredient which the waste is replacing.
- (b) The Department may issue a general permit upon its own motion under § 271.825 (relating to Department initiated general permits) or upon an application from a person or municipality under §§ 271.821—271.824.
- (c) The Department may modify, suspend, revoke, issue or reissue a general permit or coverage under a general permit under this subchapter as it deems necessary to prevent harm or the threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.
- (d) The Department may modify, suspend, revoke, issue or reissue a general permit or coverage under a general permit under this subchapter as it deems necessary to prevent violation of or interference with the laws or solid waste management plans of any state, county or municipality.
- (e) The Department may issue a general permit for processing combinations of municipal and residual wastes when processing is necessary to prepare a waste for beneficial use, or for beneficial use of combinations of municipal and residual wastes, or both, under this article or Article IX (relating to residual waste management), whichever the Department determines is appropriate. The Department will determine which article is appropriate based on factors including whether the facility is captive or noncaptive, and the proportions of municipal and residual wastes. A general permit for processing or beneficial use of combinations of sewage sludge and residual waste will be issued only under this subchapter.
- (f) The requirements in this subchapter that apply to municipal waste also apply to residual waste when residual waste is mixed with municipal waste.
- (g) The Department will not issue a general permit under this subchapter for the following:
- (1) A municipal waste landfill, the use of municipal waste to fill open pits from coal or noncoal mining, or the use of municipal waste solely to level an area or bring the area to grade unless construction activity is completed on the area promptly after placement of the waste.
- (2) A facility or activity which should be covered under the individual permitting process required in this article because of its size and potential to affect the environment adversely or because of its relationship to municipal waste management plans.
- (3) The processing or beneficial use of regulated medical or chemotherapeutic waste.
- (4) The beneficial use of sewage sludge by land application for sewage sludge that is not mixed with residual waste.
- (5) The use of a waste for construction or operations at a resource recovery facility or disposal facility.

CHAPTER 272. MUNICIPAL WASTE PLANNING, RECYCLING AND WASTE REDUCTION

Subchapter C. MUNICIPAL WASTE PLANNING PLAN CONTENT

§ 272.223. Description of waste.

- (a) The plan shall describe and explain the origin, content and weight or volume of municipal waste currently generated within the county's boundaries, and the origin, content and weight or volume of municipal waste that will be generated within the county's boundaries during the next 10 years. The plan shall also include a statement of the county or other geographical area for which the plan is prepared.
- (b) In describing the content of waste, the plan shall specifically address sewage sludge (including septage), regulated medical and chemotherapeutic waste, ash from resource recovery facilities, construction/demolition waste other than waste from demolition of an industrial site and other municipal waste.
- (c) In describing the origin of waste, the plan shall provide:
- (1) An estimate of the number of residential, commercial, municipal and institutional establishments, and community activities within the county, for municipal waste other than the special handling wastes specifically addressed in this subsection.
- (2) An inventory of public and private sewage treatment plants, including mobile homes, restaurants and hotels, and an inventory of septage haulers serving the county, for sewage sludge (including septage).
- (3) An inventory of hospitals in the county, and a representative sampling of different medical specialists, such as clinics, doctors, dentists, funeral directors and veterinarians, for regulated medical and chemotherapeutic waste
- (4) An inventory of the facilities serving the county, for ash from resource recovery facilities.
- (5) An estimate of the amount of construction/demolition waste currently generated within the county's boundaries and that will be generated within the county's boundaries during the next 10 years; and an estimate of the amount of construction/demolition waste that is currently recycled and that could be recycled during the next 10 years.
- (d) In describing the weight or volume of waste, the plan shall provide:
- (1) A total waste generation estimate for the planning area derived from best available National studies, sampling data from similar counties or other reliable information, for municipal waste other than special handling waste described in subsection (c).
- (2) Sampling or survey data for the planning area, or other reliable information, for the special handling waste described in subsection (c).
- (3) A detailed analysis, for each type of waste, of the extent to which recycling currently reduces the weight or volume of waste that requires processing or disposal, and the extent to which waste reduction or recycling will reduce the weight or volume of waste that will require processing or disposal within the next 10 years. If less than 35% of the weight or volume of waste will be recycled or reduced, the plan shall contain a detailed justification.

- (e) The plan may also, at the discretion of the county, specifically address one or more of the following:
 - (1) Waste tires.
 - (2) Household hazardous waste.
- (3) Leaf waste, yard waste and other waste suitable for composting.
 - (4) Bulk items from community cleanup days.
- (5) Other components of municipal waste not described in this section.

Subchapter F. HOUSEHOLD HAZARDOUS WASTE COLLECTION, TRANSPORTATION AND MANAGEMENT

OPERATION OF PROGRAMS

§ 272.532. Limitations on acceptable waste.

- (a) The following wastes may not be accepted at a collection event:
 - (1) Radioactive material.
- (2) Regulated medical waste, and hypodermic needles or syringes.
 - (3) Explosives.
- (b) An eligible entity may not deposit more than 1,000 kilograms (2,200 pounds) of waste at an individual collection event. The collection contractor shall weigh waste received at a collection event to ensure that no entity deposits more than 1,000 kilograms of waste at an individual collection event. A sponsor may lower the maximum amount of waste that may be deposited by an eligible entity.

CHAPTER 273. MUNICIPAL WASTE LANDFILLS

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

SPECIFIC WASTES

§ 273.411. Processed regulated medical or chemotherapeutic waste disposal.

- (a) An application for the disposal of processed regulated medical or chemotherapeutic waste shall contain necessary plans and specifications showing how the applicant will comply with § 273.511 or § 273.512 (relating to processed regulated medical waste disposal; and chemotherapeutic waste), or both, whichever is applicable.
- (b) The application, on a form provided by the Department, shall contain the following information:
- (1) The name and location of the generator of the waste.
- (2) A description of the origin and content of the waste, its containerization and the expected volume and frequency of waste disposal at the facility.
- (3) A description of the facility where the waste will be disinfected prior to disposal, including its name and location. For a permitted processing facility that is not operating under a permit by rule under Chapter 271, Subchapter B (relating to general requirements for permits and permit applications), the applicant shall provide the permit number.
- (4) A description of the processing methods to be used for each type of waste, including, when necessary, schematic drawings.

- (5) A description of the containers to be used for storage during collection and during movement within the facility, including the length of storage.
- (6) A description of the alternatives to be used if the processing equipment is inoperable, and the procedures to be used for storage of the waste if it cannot be promptly processed.
- (7) A description of handling and safety measures that will be employed for each type of waste, including personal protection and safety as well as modifications to the operational safety plan that are required.
- (8) If disinfection will be employed, a description of the monitoring and quality assurance program to ensure proper disinfection.
- (9) A description of modifications to an existing processing facility that are required to process the waste, including drawings.
- (10) A certification indicating that the waste to be disposed is noninfectious. The certification shall include the method of processing, indicator test results and testing frequency.

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

SPECIFIC WASTES

§ 273.511. Processed regulated medical waste disposal.

- (a) Regulated medical waste may not be disposed of at a municipal waste landfill unless:
- (1) The waste has been disinfected in accordance with § 284.321 (relating to regulated medical waste monitoring requirements).
- (2) Prior to initial disposal the landfill operator has obtained the necessary approval for disposal from the Department based on the application provided under § 273.411 (relating to processed regulated medical or chemotherapeutic waste disposal).
- (3) The waste being received has been disinfected by a permitted processing facility.
- (b) Waste consisting of human anatomical remains, including human fetal remains, may not be disposed at municipal waste landfills unless the waste has first been incinerated at a permitted waste processing facility.
- (c) Body fluids and animal body fluids may be disposed by discharge into a permitted sewage treatment system that provides a minimum of secondary treatment in accordance with local, Federal and State requirements, including The Clean Stream Law (35 P.S. §§ 691.1—691.1001).
- (d) Used sharps and unused hypodermic needles or syringes shall be rendered incapable of being reused prior to disposal.

CHAPTER 284. REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

Subchapter A. GENERAL PROVISIONS GENERAL PROVISIONS

§ 284.1. Scope.

This chapter sets forth application and operating requirements for a person or municipality that operates a regulated medical or chemotherapeutic waste facility. The requirements in this chapter are in addition to the applicable requirements in Chapters 271, 283 and 285

(relating to municipal waste management—general provisions; resource recovery and other processing facilities; and storage, collection and transportation of municipal waste).

- § 284.2. Permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements.
- (a) The following processing facilities for regulated medical and chemotherapeutic waste will be deemed to have a municipal waste processing permit under this article if the following requirements in this subsection and subsection (c) are met:
- (1) A processing facility with an autoclave if the following requirements are met:
- (i) The facility processes at least 50% of its own regulated medical waste. The facility may not accept more than 50% of regulated medical waste for disinfection from small quantity generators that generate less than 220 pounds per month.
- (ii) The facility does not process pathological waste or chemotherapeutic waste.
- (iii) The facility may additionally process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.
- (iv) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.
- (v) The operator of the facility provides notice to the Department that includes the following:
 - (A) An intention to operate under permit-by-rule.
 - (B) The name and address of the facility.
 - (C) A description of the processing activity.
- (D) The names and telephone numbers of the individuals responsible for operation of the processing facility.
- (2) A processing facility with an incinerator if the following requirements are met:
- (i) The facility processes at least 50% of its own regulated medical or chemotherapeutic waste. The facility may not accept more than 50% of regulated medical or chemotherapeutic waste for disinfection from small quantity generators that generate less than 220 pounds per month.
- (ii) The facility may process other municipal waste generated onsite if the resulting ash is managed as processed regulated medical or chemotherapeutic waste.
- (iii) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.
- (iv) The operator of the facility provides notice to the Department that includes the following:
 - (A) An intention to operate under permit-by-rule.
 - (B) The name and address of the facility.
 - (C) A description of the processing activity.
- (D) The names and telephone numbers of the individuals responsible for operation of the processing facility.
- (3) A processing facility with steam and superheated water disinfection if the following requirements are met:
- (i) The facility processes at least 50% of its own regulated medical waste. The facility may not accept

- more than 50% of regulated medical waste for disinfection from small quantity generators that generate less than 220 pounds per month.
- (ii) The facility does not process pathological waste or chemotherapeutic waste.
- (iii) The facility may additionally process regulated medical waste to render the waste unrecognizable by processes such as thermal treatment, melting, encapsulation, shredding, grinding, tearing or breaking.
- (iv) The processed waste is disposed of or processed in a landfill or incinerator authorized to accept the waste.
- (v) The operator of the facility provides notice to the Department that includes the following:
 - (A) An intention to operate under permit-by-rule.
 - (B) The name and address of the facility.
 - (C) A description of the processing activity.
- (D) The names and telephone numbers of the individuals responsible for operation of the processing facility.
- (4) Onsite processing of liquid blood and body fluids using a glutaraldehyde-based or hypochlorite-based product that encapsulates or converts liquid blood or body fluids into solids or gels so that no free liquids remain. The Department may approve the use of other disinfectant-based products under these provisions if their efficacy can be demonstrated. The processed liquid blood and body fluids may be disposed of at a municipal waste landfill provided:
 - (i) No free liquids remain in the processed waste.
- (ii) The landfill has received written approval from the Department authorizing disposal of the processed liquid blood and body fluids.
- (iii) The facility does not process chemotherapeutic waste.
- (5) Transfer facilities that temporarily store regulated medical or chemotherapeutic waste for less than 72 hours provided the stored waste remains in its original packaging, is not putrescent and does not attract vectors.
- (b) Generators that process and disinfect less than 220 pounds per month of regulated medical waste onsite and render the waste unrecognizable will be deemed to have a municipal waste processing permit under this article if the requirements under subsection (c) are met. Generators that process and disinfect less than 220 pounds per month of regulated medical waste onsite without rendering the waste unrecognizable will be deemed to have a municipal waste processing permit under this article if the following requirements under this subsection and subsection (c) are met:
- (1) The generator shall dispose of the processed waste in a landfill or have the waste incinerated in a facility that has written approval from the Department to accept this type of waste.
- (2) The generator shall comply with the log and shipping paper requirements in § 284.701(b)(5) (relating to scope).
- (c) The following requirements shall be met by facilities identified in subsections (a)(1)—(4) and (b) to operate under a permit-by-rule:
- (1) The facility complies with Subchapters E and F (relating to segregation and storage; and collection and transportation) and Chapter 285 (relating to storage, collection and transportation of municipal waste).

- (2) The facility has necessary permits under the environmental protection acts, and is operating in accordance with the environmental protection acts and the regulations promulgated thereunder, the terms and conditions of permits and orders of the Department.
- (3) The operator maintains at the facility in a readily accessible place the following information:
- (i) For a processing facility identified in subsection (a), a written plan for managing regulated medical waste generated at the facility, including waste handling, equipment operation and maintenance, processing method, disinfection monitoring procedures including quality assurance procedures, frequency of calibration and a description of how noninfectious waste is managed to prevent commingling.
- (ii) For processing facilities subject to a permit-by-rule, daily records of the weight or volume of the waste that is processed, the method and location of disposal facilities for wastes from the processing facility, and waste handling problems and emergencies.
- (4) Processing does not have an adverse effect on public health, safety, welfare or the environment.
- (5) The waste is disinfected in accordance with § 284.321 (relating to regulated medical waste monitoring requirements).
- (6) Disinfection occurs before or during processing of the waste.
- (7) A log is maintained for each disinfection unit and is made available to the Department upon request. The log shall record the following:
 - (i) The date, time and operator for each use.
 - (ii) The dates and results of calibration.
- (iii) The postdisinfection color reading of temperature sensitive tape and the results of biological indicator spore testing, in accordance with § 284.321 for steam disinfection facilities.
- (iv) Results of ash testing which utilizes a methodology approved by the Department, for incineration facilities.
- (8) Remaining waste is managed in accordance with the act and the regulations promulgated thereunder. For onsite autoclave facilities that do not render the waste unrecognizable, the treated or processed regulated medical waste shall be transported in accordance with Subchapter H (relating to tracking of regulated medical and chemotherapeutic waste).
- (9) For incineration facilities, an air quality permit shall be obtained as required under the Air Pollution Control Act (35 P. S. §§ 4001—4015).
- (d) Chapter 271, Subchapter E (relating to civil penalties and enforcement) is applicable to facilities subject to permit-by-rule.
- (e) Notwithstanding a provision in this section to the contrary, a facility will not be deemed to have a permit-by-rule if it causes or allows violations of the environmental protection acts, the regulations promulgated thereunder, the terms or conditions of a permit issued by the Department, or an order issued by the Department, or causes a public nuisance. A facility that is subject to permit-by-rule is not required to apply for a permit under this article, if that facility operates in accordance with this section.
- (f) The requirements under Chapter 271, Subchapter D (relating to financial assurances requirements) that relate

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

§ 284.3. Regulated medical or chemotherapeutic waste aggregation facilities.

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

Subchapter B. GENERAL PERMITS GENERAL

§ 284.101. Authorization for general permits.

- (a) In accordance with this subchapter, the Department may issue general permits on a regional or Statewide basis for a category of mobile or stationary regulated medical waste processing facilities or stationary chemotherapeutic waste processing facilities if the Department determines the following:
- (1) The processing facilities and the waste to be processed in the category are substantially similar.
- (2) The processing facilities in the category can be adequately regulated utilizing standard conditions without harming or presenting a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.
- (3) The processing facilities in the category will comply with the requirements established in the permit and with the standards and requirements for design, construction, operation, maintenance and monitoring in Chapter 283 (relating to resource recovery and other processing facilities) and Subchapter D (relating to processing facilities).
- (b) The Department may issue a general permit upon its own motion under § 284.115 (relating to Department-initiated general permits) or upon an application from a person or municipality under §§ 284.111—284.114.
- (c) The Department may issue a general permit for the mixing of disinfection products with regulated medical waste to perform processing.
- (d) The Department may issue a general permit for the processing of mixtures of the same types of waste that are regulated medical or residual wastes.

- (e) The Department may modify, suspend, revoke or reissue general permits under this subchapter as it deems necessary to prevent harm or the threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.
- (f) The Department will not issue a general permit for a commercial regulated medical or chemotherapeutic waste processing facility, including commercial incinerators

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

- (a) When the Department issues a general permit for a regulated medical or chemotherapeutic waste processing facility on either a regional or Statewide basis, persons or municipalities who intend to process regulated medical or chemotherapeutic waste in accordance with the terms and conditions of the general permit may do so without filing an individual application for, and first obtaining, an individual permit.
- (b) The use of an applicable general permit shall satisfy the requirement to obtain a permit in § 271.101 (relating to permit requirement) if the following are met:
- (1) The processing activities are conducted in accordance with the terms and conditions of the applicable general permit.
- (2) The person or municipality conducting the processing activities is authorized to operate under the general permit at the time that the Department issued the general permit or under the applicable general permit in accordance with § 284.133 (relating to registration).
- (c) Notwithstanding subsections (a) and (b), the Department may require a person or municipality authorized by a general permit to apply for, and obtain, an individual permit if a general permit is not available to conduct an activity, when the person or municipality is not in compliance with the conditions of a general permit or is conducting an activity that harms or presents a threat of harm to the health, safety or welfare of the people or the environment of this Commonwealth.

ISSUANCE OF A GENERAL PERMIT

§ 284.111. Application for general permit.

- (a) A person or municipality may apply to the Department for the issuance of a general permit for a specific category of processing of regulated medical or chemotherapeutic waste.
- (b) An application for the issuance of a general permit for processing regulated medical or chemotherapeutic waste shall be submitted on a form prepared by the Department and shall contain the following:
 - (1) A description of the waste.
- (2) A characterization of the waste as either regulated medical or chemotherapeutic.
 - (3) An operation plan which contains the following:
- (i) A description of the proposed processing activity and equipment.
- (ii) A description of the method proposed to receive regulated medical or chemotherapeutic waste which ensures the waste is handled separately from other solid waste until processing and disposal, and that prevents unauthorized persons from having access to or contact with the waste.

- (iii) A description of the procedure for managing containers which arrive in a leaking condition, which includes whether the waste is processed immediately, repacked or rejected.
- (iv) A description of the method proposed to unload and process regulated medical or chemotherapeutic waste, limiting the number of persons handling the waste and minimizing the possibility of exposure of that waste to employees and the public using or visiting the facility.
- (v) A description of the method proposed for disinfecting emptied, reusable regulated medical waste containers, transport vehicles and facility equipment which are known or suspected to be contaminated with regulated medical waste.
- (vi) A description of the method proposed for handling and disposal of regulated medical or chemotherapeutic waste containers which cannot be reused.
- (vii) A description of reuse of containers if the surfaces of the containers have been protected from direct contact with chemotherapeutic waste.
- (viii) A description of the means by which provisions will be made to require the use of clean gloves and clean uniforms along with other protective clothing to provide protection of employees against exposure to regulated medical or chemotherapeutic waste.
- (ix) A description of the means by which provisions will be made to require decontamination of a person having had bodily contact with regulated medical or chemotherapeutic waste while handling that waste at the facility.
- (x) A description of the method proposed to quantify, on a weight basis, the maximum amount of regulated medical or chemotherapeutic waste to be stored and processed each month.
 - (xi) A schedule of the operating hours of the facility.
- (xii) A description of the method proposed to assure that regulated medical or chemotherapeutic waste received at the facility is consistent with § 283.201 (relating to basic limitations).
- (xiii) A description of periodic testing using biological indicators which demonstrate effective disinfection of the waste, in accordance with § 284.321 (relating to regulated medical waste monitoring requirements).
- (xiv) A description of closure activities which are proposed to be carried out upon cessation of operations, in accordance with § 283.272 (relating to cessation of operations).
- (xv) A description of how the processing residue will be managed.
- (xvi) A description of how aerosols will be minimized and controlled during processing activities.
- (4) A contingency plan which provides procedures to be used for emergency situations including, at a minimum, spills of regulated medical or chemotherapeutic waste and ruptures of containers containing the waste. The plan shall include procedures for cleanup and disinfection of spill area, protection of personnel, disposal of spill residue and repackaging of the waste. The plan shall also include a description of an alternative waste handling system during periods when the proposed facility is not in operation, including procedures to be followed in the case of equipment breakdown. Alternate waste handling procedures may include use of standby equipment, extension of

operating hours and contractual agreements for diversion of regulated medical or chemotherapeutic waste to other facilities.

- (5) A personnel training plan which describes the hiring of equipment operators and the training of personnel involved in the handling and processing of regulated medical or chemotherapeutic waste. The plan shall include a detailed explanation of the operation and contingency plans.
- (c) A nonrefundable fee in the form of a check payable to the "Commonwealth of Pennsylvania" for \$1,000 shall accompany the application.
- (d) The application requirements in subsection (b) may be waived or modified for the mixing of disinfection products with regulated medical waste to perform processing.

§ 284.112. Completeness review.

- (a) After receipt of an application for the issuance of a general permit, the Department will determine whether the application is administratively complete. For purposes of this subchapter, an application is administratively complete if it contains the necessary analyses, fees, documents and information, regardless of whether the analyses, fees, documents and information would be sufficient for the issuance of the permit.
- (b) If the application is not administratively complete, the Department will return it to the applicant, within 60 days of receipt of the application. A written statement of the specific analyses, fees, documents or information that are required to make the application administratively complete will accompany an application which is returned.
- (c) The Department will deny the application if the applicant fails to provide the analyses, fees, documents and information within 90 days of receipt of the notice in subsection (b).

§ 284.113. Public notice and review period.

- (a) The Department will publish notice of receipt of an application for a general permit in the *Pennsylvania Bulletin* when the Department determines that the application is administratively complete.
 - (b) The notice shall include:
- (1) A brief description of the waste and the category of processing of regulated medical or chemotherapeutic waste which is identified in the application as a candidate for a general permit.
- (2) The Department's address and telephone number at which interested persons or municipalities may obtain further information and review a copy of the application for the general permit.
- (3) A brief description of the procedures for public comment on the general permit application.
- (4) A statement that interested persons or municipalities may submit comments to the Department within 60 days of the publication of the notice, and may recommend conditions upon, revisions to, approval or disapproval of the general permit application.
- (c) The Department may hold a public meeting or public hearing on the application for a general permit.
- (d) Upon issuance of a general permit, the Department will place a notice in the *Pennsylvania Bulletin* of the availability of the general permit. If a county has made recommendations to the Department concerning condi-

tions, revisions or disapproval of the permit during the 60-day comment period, and the Department has overridden the recommendations, the Department will publish its justification for overriding the recommendations in the *Pennsylvania Bulletin*.

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

§ 284.114. Approval or denial of an application.

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

- (1) The application for the general permit is accurate and complete.
- (2) The applicant has complied with the requirements of §§ 284.101, 284.102 and 284.111—284.113.
- (3) The proposed processing activities will be conducted in a manner that will not harm or present a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth through exposure to constituents of the waste during the processing activities and afterwards.

§ 284.115. Department-initiated general permits.

- (a) The Department may issue or modify a general permit for a category of processing of regulated medical or chemotherapeutic waste upon its own motion in accordance with this section.
- (b) At least 60 days prior to the issuance or modification of a general permit under this section, the Department will publish a notice in the *Pennsylvania Bulletin* of intent to issue or modify a general permit under this section
- (c) The notice required by subsection (b) will include the following:
- (1) A clear and specific description of the category of processing of regulated medical or chemotherapeutic waste eligible for coverage under the proposed general permit.
- (2) The standards in § 284.101(a) (relating to authorization for general permits), and a brief description of the reasons for the Department's determination that the category of processing is eligible for coverage under a general permit in accordance with these standards.
- (3) A brief description of the terms and conditions of the proposed general permit.
- (4) A brief description of the procedures for public comment on the general permit in accordance with this subchapter.
- (5) The Department address and telephone number at which interested persons or municipalities may obtain further information and review a copy of the proposed general permit.
- (6) A statement that interested persons or municipalities may submit comments to the Department within 60 days of the publication of the notice and may recommend conditions upon, revisions to, and approval or disapproval of the proposed general permit.
- (d) The Department may hold a public meeting or public hearing on the proposed general permit or proposed modification to the general permit.

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

§ 284.116. General permit renewal.

- (a) A person or municipality that plans to process regulated medical or chemotherapeutic waste after the expiration of the term in the general permit shall file notice to the Department of intent to continue operating under the permit at least 180 days before the expiration date of the permit. The notice must include updated registration information on forms provided by the Department, a check payable to the "Commonwealth of Pennsylvania" for \$250 and any suggested changes to the terms or conditions of the permit.
- (b) A permit renewal may include all persons or municipalities that have applied for renewal within the time period provided in subsection (a). A person or municipality that does not meet the time period in subsection (a) shall be required to register under a renewed general permit.
- (c) At least 120 days prior to the permit expiration, the Department will provide public notice of the permit renewal along with an update of the terms or conditions in accordance with the public notice requirements of § 284.115 (relating to Department-initiated general permits.)
- (d) General permits will be renewed for a maximum term of 10 years.
- (e) If the Department is unable to reissue the general permit prior to its expiration date, the Department may extend the term of a general permit for a period not to exceed 1 year for any permittee that is operating in compliance with the terms and conditions of the general permit and the environmental statutes and regulations of the Commonwealth.

CONTENT OF GENERAL PERMITS AND WAIVERS OR MODIFICATIONS

§ 284.121. Contents of general permits.

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

- (1) A clear and specific description of the category of processing of regulated medical or chemotherapeutic waste eligible for coverage under the general permit.
- (2) The standards in § 284.101(a) (relating to authorization for general permits) and a brief explanation of the reasons for the Department's determination that the category of processing is eligible for coverage under the general permit in accordance with the standards in § 284.101(a).
- (3) A specification of registration requirements established in accordance with § 284.131 (relating to authorization for persons or municipalities to be included in a general permit) and the fee imposed on registrants for coverage under the general permit.
- (4) An effective date, and a fixed permit term, which may not exceed 10 years from the effective date. If the Department renews a general permit, the term may not exceed the term of the original permit.
- (5) A set of terms and conditions governing the construction, operation, maintenance, inspection and monitoring of the processing activities covered by the general permit as are necessary to assure compliance with this act, this article and the environmental protection acts.

- (6) A requirement that persons or municipalities who conduct activities authorized by the general permit shall allow authorized representatives of the Commonwealth, without advance notice or a search warrant, upon the presentation of appropriate credentials, and without delay, to have access to areas in which the activities covered by the general permit will be, are being or have been conducted to ensure compliance with the act and the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations promulgated thereunder and a permit, license or order issued by the Department under the act.
- (7) A requirement that the activities authorized by the general permit will not harm or present a threat of harm to the health, safety or welfare of the people or environment of this Commonwealth.
- (8) A requirement that waste be accompanied by a properly completed log or shipping paper, in accordance with Subchapter H (relating to tracking of regulated medical and chemotherapeutic waste).
- (9) A requirement that waste be delivered by a licensed transporter in accordance with Subchapter G (relating to transporter licensing for regulated medical and chemotherapeutic waste), when appropriate.
- (10) A requirement that the processing facility operate in accordance with local, State and Federal requirements.
- (11) A requirement that the processing residue be managed in accordance with the Solid Waste Management Act (35 P.S. §§ 6018.101—6018.1003) and the regulations promulgated thereunder.
- (12) A requirement that an up-to-date list of names, addresses and telephone numbers of employees that have been designated by the permittee to respond to emergencies at the processing facility be maintained at the facility.
- (13) A requirement that individual employee training records be maintained at the processing facility.
- (14) A requirement for use of additional indicators selected by the Department to monitor the disinfection process.
- (15) A requirement that daily records of the weight or volume of the waste processed, the method and location of disposal facilities for wastes from the processing facility and waste handling problems and emergencies be maintained for 3 years.
- (16) A requirement that a log be maintained for each disinfection unit for 3 years that records the following:
 - (i) The date, time and operator for each use.
 - (ii) The dates and results of calibration.
 - (iii) The results of biological indicator spore testing.
- (iv) Other information that the Department may require relating to the disinfection process.
 - (17) Requirements for closure.
- (18) A prohibition against processing pathological waste or chemotherapeutic waste in an autoclave.

REGISTRATION

- § 284.131. Authorization for persons or municipalities to be included in a general permit.
- (a) A person or municipality is authorized to operate under a general permit if the person or municipality has

registered in accordance with the terms of the general permit and the requirements of this subchapter.

- (b) Registration requirements and time limits, if any, will be set forth in the general permit governing each category of processing regulated medical or chemotherapeutic waste. The general permit will also set forth the area or region within which each category of processing is allowed.
 - (c) At a minimum, the registration must include:
- (1) The name, address and location of the person or municipality conducting the activity covered under the general permit.
- (2) A description of the waste, including a characterization of the waste as either regulated medical or chemotherapeutic, that will be processed in accordance with the general permit.
- (3) A description of the proposed method of processing of the waste.
- (4) The name or number of the general permit being utilized for the activity.
- (5) A demonstration that the activities which the person or municipality intends to conduct are authorized by the general permit.
- (6) A signed and notarized statement by the person or municipality conducting the activity authorized by the general permit, on a form prepared by the Department, which states that the person or municipality agrees to accept the conditions imposed by the general permit for processing of regulated medical or chemotherapeutic waste under the general permit.
- (d) A person or municipality that registers for coverage under a general permit shall submit a copy of the registration to each municipality in which the processing activity will be located. The submission shall occur at the same time that the person or municipality files the registration with the Department.

§ 284.132. (Reserved).

Subchapter C. TRANSFER FACILITIES

§ 284.201. Scope.

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

§ 284.210. Application requirements.

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

§ 284.220. Operating requirements.

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

§ 284.230. Storage requirements.

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

Subchapter D. PROCESSING FACILITIES

§ 284.301. Scope.

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

§ 284.311. Plan for monitoring.

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

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

§ 284.320. Operating requirements.

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

§ 284.321. Regulated medical waste monitoring requirements.

- (a) A person or municipality that disinfects regulated medical waste shall monitor the waste to ensure the following:
- (1) For thermal processing or incineration, the absence of anaerobic or aerobic bacterial growth in a composite sample of processing residue or ash.
- (2) For other disinfection processes, both of the following are met:
- (i) The process shall be capable of inactivating mycobacteria at a 6 log 10 reduction or greater.
- (ii) The process shall be capable of inactivating Geobacillus stearothermophilus spores, Bacillus pumilus or Bacillus atrophaeus spores at a 4 log 10 reduction or greater.
- (b) The operator of a facility that incinerates or thermally processes regulated medical waste shall submit to the Department a microbiological analysis of a composite sample of the processing or ash residue on forms provided by the Department, at a minimum, annually during the life of the facility.
- (c) The operator of a facility that incinerates regulated medical waste shall submit to the Department, at least annually during the life of the facility, a chemical analysis of composite samples of the ash residue on forms provided by the Department.
- (d) If the facility disinfects regulated medical waste by means other than incineration or thermal processing, the operator shall perform a microbiological analysis of indicators removed from the processed waste. The analysis shall be conducted, at a minimum, every 40 hours during the operational life of the facility, unless otherwise provided in a permit. The analyses shall be made available to the Department upon request.
- (e) Unless the Department approves another indicator or test in writing, the following indicators shall be used to establish and verify the following processes:

- (1) For autoclaving, spores of Geobacillus stearothermophilus.
- (2) For dry heat, gas or chemical disinfection, spores of Bacillus atrophaeus variety niger (globigii). Ethylene oxide may not be used for gas disinfection.
 - (3) For ionizing radiation, spores of Bacillus pumilus.
- (f) Indicators used for methods of disinfection other than incineration or thermal processing shall be located prior to disinfection at a point within the load where disinfection will be most difficult to achieve.
- (g) Regulated medical waste will be considered to be infectious unless one of the following has occurred:
- (1) For disinfection processes other than incineration or thermal processing, the indicator spores are determined by microbiological analysis to have been destroyed in accordance with subsection (a).
- (2) For incineration or thermal processing using a test other than an indicator spore, a microbiological analysis determines that disinfection has occurred in accordance with subsection (a).
- (h) The operator of the disinfection facility shall so certify that the requirements of subsection (a) have been met on a form provided by the Department.
- (i) Ash or other processing residue shall be stored in accordance with § 284.418 or § 284.419 (relating to storage and containment of ash residue from regulated medical or chemotherapeutic waste incineration; and storage and containment of processing residue from a regulated medical or chemotherapeutic waste processing facility).
- (j) Ash or other processing residue shall be transported in accordance with § 284.511 or § 284.514 (relating to transportation of ash residue from regulated medical or chemotherapeutic waste incineration; and transportation of processing residue from a regulated medical or chemotherapeutic waste facility).
- (k) Compactors, grinders or similar devices may not be used to reduce the volume of regulated medical waste before the waste has been rendered noninfectious. If the volume reduction device is within a continuous, enclosed disinfection process and part of one processing system, then the reduction device may be used.
- (l) The operator of a regulated medical waste processing facility shall dispose of ash or other processing residue from the facility in a landfill that has been approved by the Department to accept the waste, if the waste is disposed in this Commonwealth.
- (m) An autoclave facility shall comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapeutic waste.
- (n) Unless otherwise approved in writing by the Department, an operator of an autoclave facility shall employ the procedures in § 284.322 (relating to autoclave validation testing requirements) to validate the operating parameters and protocols of the processing equipment. These procedures must be employed at an on-going frequency specified by the manufacturer of the autoclave and in the following circumstances:
 - (1) When a new autoclave is installed.
- (2) When an autoclave is modified, repaired or has experienced a malfunction with respect to hardware, software, controls or ancillary equipment.

- (o) The facility shall maintain a record of the autoclave validation testing protocols and procedures.
- (p) For facilities engaged in the production or research and development of vaccines or other biologics that are classified under the North American Industrial Classification System as Code 325414—Biological Protocol (except Diagnostic) Manufacturing and who meet the following criteria may utilize the alternate disinfection requirements specified in paragraph (5) instead of the requirements of subsections (a)—(o) to process waste containing an infectious agent classified as Biosafety Level 2 or below, as determined by the protocols established in the most recent edition of the Centers for Disease Control's Biosafety in Microbial and Biomedical Laboratories existing at the time the waste is generated:
- (1) Utilize onsite processing facilities at which at least 50% of the waste processed is generated onsite.
- (2) Operate in accordance with United States Food and Drug Administration good manufacturing practices or good laboratory practices.
- (3) Employ a production process where the infectious agents or biological, or both, are known and well characterized, inactivation criteria are determined and bioburden is measured and controlled including screening for objectionable organisms.
- (4) Specify and approve the decontamination process, method and monitoring, and validation procedures for each specific infectious agent in its waste by either of the following:
- (i) Establishing and utilizing an Institutional Biosafety Committee constituted in accordance with the Centers for Disease Control and the National Institute of Health guidelines or composed in whole or in part of a panel of experts, a member of which is a biosafety officer certified by the American Biological Safety Association or the American Society for Microbiology or equivalent.
- (ii) Retaining a contractor certified by the American Biological Safety Association or the American Society for Microbiology who accepts responsibility for the process, method and procedures that the contractor specified and approves (Independent Certified Biosafety Professional).
- (5) The alternate disinfection process must be conducted as follows:
- (i) Disinfection shall be conducted by inactivating all waste material in accordance with the practices, methods and minimum parameters for biological kill established by the facility's Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, consistent with the Centers for Disease Control and the National Institute of Health guidelines or scientifically accepted protocols, or both.
- (ii) Efficacy of the inactivation operations shall be demonstrated through review of decontamination cycle data by trained technicians or other testing methods or studies specified by the Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, as appropriate for the specific infectious agent or biologic, or both, present in the waste. The procedures for demonstrating the efficacy of the inactivation operations must be set forth in standard operating procedures or other written procedures maintained at the facility, or both.
- (iii) Preventative maintenance and calibration programs for decontamination equipment consistent with generally accepted industry standards as specified by the

Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, shall be established and routinely implemented.

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

§ 284.322. Autoclave validation testing requirements.

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

- (1) For facilities with one autoclave or multiple autoclaves that are not identical, each autoclave must have an initial validation test that establishes its operating parameters.
- (2) For facilities with multiple autoclaves that are identical, one autoclave may have an initial validation test that establishes the operating parameters for all identical autoclaves at that facility.
- (3) Autoclaves shall be tested using the manufacturer's recommended vacuum pulse plan, operating temperature, operating pressure and residence time at the maximum weight and with the most difficult heat transfer challenge anticipated with the indicators located where disinfection would be most difficult to achieve.
- (4) If multiple vacuum pulse plans, residence times, temperatures and pressures are recommended, the autoclave shall be tested to validate its performance at each recommended vacuum pulse plan, residence time, temperature and pressure. If a test fails, more stringent operating parameters shall be used incrementally until a satisfactory test and set of operating parameters is determined.
- (5) Autoclave operating parameters must be validated to achieve a minimum of 250°F or 121°C measured at a point where disinfection would be most difficult to achieve.
- (6) The residence time required to achieve a 6 log 10 reduction of mycobacteria and a 4 log 10 reduction of Geobacillus stearothermophilus spores for the level of heat transfer challenge selected shall be the residence time set into that autoclave's controls.
- (7) The vacuum pulse plan, residence time, operating temperature and operating pressure established in the validation test will form the permitted operating parameters for the autoclave tested.
- (8) Instead of the temperature, residence time and other requirements of this section, manufacturers of vaccines or other biologics who satisfy the applicability criterion of § 284.321(p) (relating to regulated medical waste monitoring requirements) may establish and validate autoclave operating parameters and residence time based upon the requirements determined by the Institutional Biosafety Committee or Independent Certified Biosafety Professional, or both, as necessary to achieve the required disinfection under § 284.321(p)(5)(ii) for the specific infectious agent or biologic, or both, present in the wastes.

Subchapter E. SEGREGATION AND STORAGE § 284.401. Scope.

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

§ 284.411. Segregation.

- (a) Regulated medical waste and chemotherapeutic waste shall be segregated at the point of origin at the generating facility into the following three categories:
- (1) Regulated medical waste, excluding pathological waste.
 - (2) Pathological waste.
 - (3) Chemotherapeutic waste.
- (b) Each category of waste segregated under subsection (a) shall be placed in a separate container, except used sharps that qualify as regulated medical waste may be placed in a chemotherapeutic waste used sharps container.
- (c) When bags are used as containers to segregate the waste, the bags must be fluorescent orange, orange-red or red in color for regulated medical waste or pathological waste
- (d) When bags are used as containers to segregate the waste, the bags must be yellow in color for chemotherapeutic waste, unless the chemotherapeutic waste is processed onsite in an incinerator that operates in accordance with § 284.2 (relating to permits-by-rule for regulated medical or chemotherapeutic waste processing facilities; qualifying facilities; general requirements) or in accordance with a permit authorized by the Department.
- (e) When bags are used to segregate and store the waste, the requirements of § 284.413 (relating to storage containers) must be satisfied.

§ 284.412. Basic storage requirements.

- (a) After regulated medical and chemotherapeutic waste has been segregated and collected for transportation to an onsite or offsite processing facility, the waste shall be stored and contained in a manner that:
- (1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers, and provides protection from water, rain and wind.
- (2) Prevents the spread of regulated medical waste or chemotherapeutic agents.
- (3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.
- (4) Maintains the waste in a nonputrescent state, using refrigeration ($<= 7^{\circ}\text{C}$ or $<= 45^{\circ}\text{F}$) or freezing ($<= -18^{\circ}\text{C}$ or $<= 0^{\circ}\text{F}$) when necessary.
 - (5) Prevents odors from emanating from the container.
- (6) Prevents unauthorized access to the waste. As part of this requirement, the following shall be met:
- (i) Enclosures and containers used for storage of regulated medical or chemotherapeutic waste shall be secured to deny access to unauthorized persons.

- (ii) Enclosures and containers shall be marked with prominent warning signs indicating the storage of regulated medical or chemotherapeutic waste.
- (b) Enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste must be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Containers located in enclosures used for the storage of regulated medical or chemotherapeutic waste must be maintained in compliance with § 284.413 (relating to storage containers) and in a manner that minimizes human exposure and vectors. Exhaust air from storage areas must be ventilated to minimize human exposure.
- (c) Regulated medical and chemotherapeutic waste may not be commingled with other waste in the same container.
- (d) The generator may store regulated medical waste, chemotherapeutic waste or municipal waste that has been sorted and separately containerized in the same location, including on a cart.

§ 284.413. Storage containers.

- (a) Regulated medical or chemotherapeutic waste shall be placed in containers that are:
- (1) Leakproof on the sides and bottom and maintained in an upright position.
 - (2) Impervious to moisture.
- (3) Sufficient in strength to prevent puncturing, tearing or bursting during storage.
- (b) In addition to the requirements of subsection (a), used sharps shall be placed in containers that are:
 - (1) Rigid.
 - (2) Tightly lidded.
 - (3) Puncture resistant.
- (c) In addition to the requirements of subsection (a), regulated medical waste fluids in quantities greater than 20 cubic centimeters and chemotherapeutic waste fluids shall be placed in containers that are:
 - (1) Break resistant.
 - (2) Tightly lidded or tightly stoppered.
- (d) When bags are used as the only container, double or multiple bagging shall be employed and the following requirements shall be met:
 - (1) Upon packaging, the bags shall be securely tied.
- (2) The bags must be constructed of material of sufficient single thickness strength to meet the following:
- (i) The ASTM Standard D1709, Test Method for Impact Resistance of Polyethylene Film by the Free Falling Dart Method, with an impact resistance of 165 grams or greater (Method A).
- (ii) The ASTM Standard D1922, Propagation Tear Resistance of Plastic Film and Thin Sheeting by Pendulum Method, with a tearing resistance, parallel and perpendicular to the length of the bag of 480 grams.
- (iii) If the standards in subparagraphs (i) and (ii) are modified by ASTM, the standard that is in effect on the date of manufacture of the bags shall be applied.
- (3) Bags must include one of the following certifications indicating that the ASTM standards have been met:

- (i) Each bag must contain a printed certification by the manufacturer.
- (ii) The manufacturer may issue a certification letter to the regulated medical or chemotherapeutic waste generator and print a certification on each packaged lot of the bags.
- (4) Bags must have sufficient seam strength that is at least equal in resistance to tearing and equally impermeable as the other portions of the bag.
- (5) Bags must be fluorescent orange, orange-red or red in color for regulated medical waste and yellow in color for chemotherapeutic waste and contain colorants that are organic pigments with no heavy metal content.

§ 284.414. Marking of containers.

- (a) For onsite or offsite transportation of regulated medical or chemotherapeutic waste, the outermost containers of regulated medical or chemotherapeutic waste must be labeled with the following:
- (1) The words "chemotherapeutic waste" if chemotherapeutic waste is placed in the container.
- (2) Until November 8, 2016, the words "infectious waste" or "regulated medical waste" if regulated medical waste is placed in the container.
- (3) After November 8, 2016, the words "regulated medical waste" if regulated medical waste is placed in the container.
- (4) The universal biohazard symbol that conforms to the design in 29 CFR 1910.1030(g)(1)(i)(B) (relating to bloodborne pathogens) and the word "BIOHAZARD."
- (5) The date the container was full or the date that the generator sealed the container, whichever occurs earlier.
- (6) The name, address and telephone number of the generator if the waste is transported offsite.
- (b) The requirements of subsection (a) do not apply if the outermost container is a vehicle or conveyance, including a roll-off, and all of the following are satisfied:
- (1) The waste in the vehicle or conveyance is from a single generator.
- (2) The vehicle or conveyance is transported offsite for processing or disposal every 30 days.
- (3) The vehicle or conveyance complies with the requirements of § 284.513 (relating to transportation of regulated medical and chemotherapeutic waste; additional provisions).
- (4) The outside of the vehicle or conveyance displays the information required in subsection (a)(5), except when a record of the date the vehicle or conveyance is full or sealed, whichever occurs earlier, is maintained by the generator and available for inspection by the transporter or Department for 1 year.
- (5) The outside of the vehicle or conveyance displays the information required in subsection (a)(6).
- (c) Nonwall-mounted used sharps containers storing regulated medical waste must have fluorescent orange, orange-red or red markings and chemotherapeutic waste must have yellow markings. The markings must sufficiently identify the waste as regulated medical or chemotherapeutic waste.
- (d) The information required under this section must be clearly legible and produced with indelible ink in a color that contrasts with the color of the container, such

as black. If a label is used to provide the information, the label must be securely attached to the container.

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

- (a) Regulated medical or chemotherapeutic waste may not be stored for longer than 30 days from the date that the storage container is full or sealed by the generator, whichever occurs earlier.
- (b) If the regulated medical or chemotherapeutic waste becomes putrescent during the storage period identified in subsection (a), the waste shall be moved offsite within 3 business days for processing or disposal.

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

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

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

§ 284.417. Reuse of containers.

- (a) Nonrigid containers shall be managed as either regulated medical or chemotherapeutic waste based upon the contents of the container. These containers may not be reused.
- (b) Corrugated fiberboard containers used for storage of regulated medical or chemotherapeutic waste may be reused if the surface of the container has been protected from direct contact with the waste.
- (c) A rigid, nonfiberboard container used for the storage of regulated medical waste or chemotherapeutic waste may be reused if one of the following applies:
- (1) The container has been decontaminated utilizing a Department-approved decontamination procedure.
- (2) The surface of the container has been protected from direct contact with regulated medical and chemotherapeutic waste, as applicable.

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

- (a) Ash residue from regulated medical or chemotherapeutic waste incineration shall be stored in accordance with the following:
- (1) In an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building.
- (2) On a pad for collecting a spill or release of ash that is no more permeable than 1×10^{-7} cm./sec.
- (3) In a manner to prevent the release, dispersal or discharge of ash residue into the air, water or onto land.
- (b) Ash residue may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

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

- (a) Processing residue from regulated medical or chemotherapeutic waste processing facilities shall be stored in an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building, to:
- (1) Prevent the release, dispersal or discharge of processing residue into the air, water or onto land.
 - (2) Afford protection from animals, rain and wind.
- (3) Prevent the development of a breeding place or food source for insects or rodents.
- (4) Prevent the leakage of waste from the storage container.
- (b) Processing residue from a regulated medical or chemotherapeutic waste processing facility may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

Subchapter F. COLLECTION AND TRANSPORTATION GENERAL

§ 284.501. Scope.

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

TYPES OF WASTE

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

- (a) Ash residue from regulated medical or chemotherapeutic waste incineration shall be wetted immediately prior to loading, and shall remain wetted during transportation and unloading at a municipal waste landfill to prevent the dispersal of ash residue.
- (b) Ash residue from regulated medical or chemotherapeutic waste incineration shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.
- (c) A generator's ash residue from regulated medical or chemotherapeutic waste incineration shall be transported separately from the ash residue of other generators.
- (d) Municipal waste from a generator may be commingled and transported with the generator's ash residue from regulated medical and chemotherapeutic waste incineration if the municipal waste and ash residue are being transported separately from the waste of other generators.

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

(a) General. This section sets forth general requirements for a person or municipality that transports regulated medical or chemotherapeutic waste. Section 284.513

(relating to transportation of regulated medical and chemotherapeutic waste; additional provisions) sets forth additional provisions relating to the transportation of the waste.

- (b) Manner of transportation. Regulated medical and chemotherapeutic waste shall be transported in a manner that:
- (1) Maintains the integrity of the containers, prevents the leakage or release of waste from the containers and provides protection from water, rain and wind.
- (2) Prevents the spread of infectious or chemotherapeutic agents.
- (3) Affords protection from animals and does not provide a breeding place or a food source for insects or rodents.
- (4) Maintains the waste in a nonputrescent state, using refrigeration (<= 7°C or <= 45°F) or freezing (<= -18°C or <= 0°F) when necessary.
 - (5) Prevents odors from emanating from the container.
 - (6) Prevents unauthorized access to the waste.
 - (c) Containers.
- (1) Regulated medical and chemotherapeutic waste shall be transported in containers that are:
 - (i) Rigid.
 - (ii) Leakproof.
 - (iii) Impervious to moisture.
- (iv) Sufficient in strength to prevent puncturing, tearing or bursting during transportation.
- (v) Labeled in accordance with the requirements in $\S~284.414$ (relating to marking of containers), except as provided in $\S~284.414$ (b).
- (2) In addition to the requirements of paragraph (1), used sharps shall be transported in containers that are tightly lidded.
- (3) In addition to the requirements of paragraph (1), regulated medical waste fluids—quantities greater than 20 cubic centimeters—and chemotherapeutic waste fluids shall be transported in containers that are:
 - (i) Break resistant.
 - (ii) Tightly lidded or tightly stoppered.
- (4) Bags meeting the requirements of § 284.413 (relating to storage containers) may be used to meet the requirements of this subsection that containers be leak-proof and impervious to moisture.
- (d) Types of vehicles. Vehicles for transporting regulated medical or chemotherapeutic waste shall be noncompaction type vehicles.
- (e) Commingling of waste. Separately containerized regulated medical or chemotherapeutic waste may be transported in the same vehicle with containerized municipal waste.
- (f) Cleaning of vehicles. Load compartments of vehicles holding regulated medical or chemotherapeutic waste for transportation shall be constructed of materials that are impermeable and easily cleaned. Surfaces of vehicles that have been in direct physical contact with regulated medical or chemotherapeutic waste, because of a leak in a bag or container or because of another reason, shall be decontaminated as soon as possible after unloading.

- (g) Refrigeration. Regulated medical or chemotherapeutic waste may be kept in an unrefrigerated transport vehicle for up to 72 hours provided the waste is not putrescent and does not attract vectors. If the vehicle is refrigerated (<= 7°C or <= 45°F) or maintained at freezing temperatures (<= -18°C or <= 0°F), the intransit storage period may not exceed 5 days.
- (h) *Chutes*. Chutes may not be used by generators, processors or transporters to transfer regulated medical or chemotherapeutic waste at onsite or offsite locations.

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

- (a) This section sets forth additional requirements for the transportation of regulated medical and chemotherapeutic waste. This section does not apply to vehicles used by a generator of less than 220 pounds of regulated medical and chemotherapeutic waste per month for transporting the generator's own waste.
- (b) Vehicles or conveyances for transporting regulated medical or chemotherapeutic waste shall be identified on the two sides and back of the cargo compartment with the following:
- (1) The transporter's Department-issued regulated medical and chemotherapeutic waste license number, if applicable.
- (2) A placard or decal containing the phrase "regulated medical waste" or "chemotherapeutic waste," or both, as applicable, and the universal biohazard symbol that conforms to the design shown in the United States Occupational Safety and Health Administration's regulations at 29 CFR 1910.1030(g)(1)(i)(B) (relating to bloodborne pathogens).
- (3) Until November 8, 2016, the words "infectious waste" or "regulated medical waste" if regulated medical waste is being transported.
- (4) After November 8, 2016, the words "regulated medical waste" if regulated medical waste is being transported.
- (c) A vehicle used for transporting regulated medical or chemotherapeutic waste shall contain, in a readily accessible place, a portable decontamination and spill containment unit, including at a minimum the following:
 - (1) An adequate amount of absorbent material.
- (2) One gallon of EPA-approved disinfectant in an appropriate applicator.
- (3) Fifty fluorescent orange, orange-red, or red or yellow, or both, plastic bags that meet the requirements of § 284.413 (relating to storage containers). The bags shall be accompanied by seals and appropriate labels, and shall be large enough to overpack any container normally transported in the vehicle.
- (4) Two sets of protective overalls, gloves, boots, caps, goggles and masks. The protective garments shall be oversized or fitted for the vehicle operators.
- (5) A first aid kit, boundary marking tape and other appropriate safety equipment.
- (d) The cargo area of vehicles used for transporting regulated medical or chemotherapeutic waste that has not been in direct physical contact with regulated medical or chemotherapeutic waste shall be cleaned weekly. Drainage from the cleaning shall be discharged directly or through a holding tank to a sanitary sewer system or treatment facility.

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

- (a) Processing residue from a regulated medical or chemotherapeutic waste facility shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.
- (b) A transporter shall transport processing residue from regulated medical or chemotherapeutic waste for each generator separately from other generators.
- (c) A transporter may transport processing residue from regulated medical or chemotherapeutic waste that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.

Subchapter G. TRANSPORTER LICENSING FOR REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

GENERAL PROVISIONS

§ 284.601. Scope.

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

§ 284.602. License requirement.

- (a) Except as provided in subsection (b), a person or municipality may not transport regulated medical or chemotherapeutic waste unless the person has first obtained a license from the Department in accordance with this subchapter.
 - (b) This subchapter does not apply to the following:
- (1) Onsite movement of regulated medical or chemotherapeutic waste by generators.
- (2) Onsite movement of regulated medical or chemotherapeutic waste by operators of permitted regulated medical or chemotherapeutic waste management facilities.
- (3) Transportation by a generator of less than 220 pounds per month of regulated medical or chemotherapeutic waste when transporting only the generator's own regulated medical or chemotherapeutic waste if the log and shipping paper requirements under § 284.701(b)(3) (relating to scope) are met.
- (4) The transportation of regulated medical or chemotherapeutic waste generated outside this Commonwealth destined for processing or disposal outside this Commonwealth.

§ 284.603. Identification number.

- A person or municipality subject to this chapter may not transport regulated medical or chemotherapeutic waste without first receiving an identification number. The number shall be one of the following:
- (1) An EPA identification number obtained under section 3010 of the Resource Conservation and Recovery Act of 1976 (42 U.S.C.A. § 6930).
- (2) An identification number obtained from the Department if the identification number under paragraph (1) is not available.

LICENSE APPLICATION REQUIREMENTS

§ 284.611. General application requirements.

(a) An application for a license to transport regulated medical or chemotherapeutic waste shall be submitted to

- the Department, in writing, on forms provided by the Department. An application for a license shall be accompanied by information, specifications and other data required by the Department to determine compliance with this subchapter.
 - (b) The application shall contain the following:
- (1) The applicant's identification number, as required under § 284.603 (relating to identification number).
- (2) The name, mailing address, place of business, business telephone number and 24-hour emergency telephone number of the applicant.
- (3) The average yearly total tonnage of regulated medical and chemotherapeutic waste picked up or delivered in this Commonwealth.
- (4) A nonrefundable application fee in the form of a check payable to the "Commonwealth of Pennsylvania" for \$500.
- (5) Information concerning terminal locations that will store regulated medical and chemotherapeutic waste intransit.
- (6) An identification of interests and compliance history, as provided in §§ 271.124 and 271.125 (relating to identification of interests; and compliance information).
- (7) Collateral bond, as required under § 284.641 (relating to bond requirement).
- (8) Certificate of insurance, as required under § 284.612 (relating to vehicular liability insurance).
- (9) A contingency plan consistent with § 284.632 (relating to regulated medical or chemotherapeutic waste discharges or spills).
- (c) An application for a license shall be certified by a responsible official of the applicant with a statement that the information contained in the application is true and correct to the best of the official's information and belief.

§ 284.612. Vehicular liability insurance.

- (a) The application shall include a certificate of insurance issued by an insurance company authorized to do business in this Commonwealth, certifying that the applicant has comprehensive vehicular liability insurance in force covering the operation of vehicles and associated regulated medical and chemotherapeutic waste transportation activities.
- (b) The certificate of insurance shall expressly document coverage for property damage and bodily injury to third parties. The insurance coverage shall include coverage for the cost of cleaning up a regulated medical or chemotherapeutic waste spill, and damages arising from the spill. Minimum insurance coverage shall be \$500,000 annual aggregate, exclusive of claims administration and legal defense costs.
- (c) Insurance coverage provided under this section shall comply with the following:
- (1) The insurance policy shall follow the standard commercial or comprehensive vehicular liability policy forms approved by the Insurance Department, and shall include coverage as specified in subsections (a) and (b).
- (2) The insurance policy shall be issued by an insurer having a certificate of authority and a licensed agent authorized to transact the business of insurance in this Commonwealth by the Insurance Department. Insurance may be provided by an excess or surplus lines insurer approved by the Insurance Department.

- (3) The full policy amount shall be applicable to each driver and vehicle authorized to operate under the license. There may be no proration of the policy amount of coverage among vehicles.
- (4) The insurance policy shall provide that the insurer shall notify the Department by certified mail within 30 days whenever a substantive change is made in the policy, including policy amounts, scope of coverage, tail period, claims procedures, definitions of occurrences or claims, or other provisions related to the requirements of this subchapter.
- (d) The licensee shall maintain the insurance required by this section in full force and effect during the term of the license and renewals thereof.
- (e) An applicant for a transporter license to transport regulated medical or chemotherapeutic waste which is a department or an agency of the United States or of the Commonwealth may fulfill the requirements under this section by means of one or more of the following:
 - (1) Commercial insurance as specified in this section.
 - (2) Self-insurance allowed by Federal or State law.
 - (3) Additional means approved by the Department.
- (f) The amount of liability coverage for departments or agencies of the Commonwealth may not exceed the liability limits of 42 Pa.C.S. Chapter 85 (relating to matters affecting government units).

LICENSE APPLICATION REVIEW

§ 284.623. Conditions of licenses.

- (a) The Department may place terms and conditions upon a license it deems necessary to protect public health, public safety and the environment, and to ensure compliance with the act, the environmental protection acts and this title.
- (b) Except to the extent that the license states otherwise, the licensee shall conduct transportation activities as described in the approved application.
- (c) A license to transport regulated medical and chemotherapeutic waste is nontransferable and nonassignable. A license applies to the licensee and its employees. Leased or subcontracted haulers, and haulers who provide equipment, have no authority to operate under the licensee's license without prior written approval from the Department.

§ 284.624. License renewal.

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

OPERATIONAL REQUIREMENTS

§ 284.631. Basic limitations.

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

- (1) The act, this article and other applicable regulations promulgated under the act, including Subchapter F (relating to collection and transportation).
- (2) The terms and conditions of the license, the environmental protection acts, this title and orders issued by the Department.
- (b) A transporter shall allow authorized representatives of the Commonwealth, without advance notice or a search warrant, upon presentation of appropriate credentials, and without delay, to have access to areas in which operations will be, are being or have been conducted.

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

- (a) A copy of the most recently approved Transporter Contingency Plan (TCP) shall be carried on each transport vehicle at all times. Information in the TCP shall be kept current.
- (b) In the event of a discharge or spill of regulated medical or chemotherapeutic waste during transportation, the transporter shall take appropriate immediate action to protect the health and safety of the public and the environment, in accordance with its approved TCP. The transporter shall also immediately telephone the Department and the affected municipality, and provide the following information:
- (1) The name of the person reporting the spill or discharge.
- (2) The transporter's name, address, the Departmentissued regulated medical and chemotherapeutic waste transporter license number and identification number.
- (3) The telephone number where the person reporting the spill or discharge can be reached.
 - (4) The date, time and location of the spill or discharge.
- (5) The mode of transportation and type of transport vehicle.
 - (6) A brief description of the accident.
 - (7) For each waste involved in the spill:
- (i) The name and identification number of the generators of the waste.
 - (ii) The estimated quantity of the waste spilled.
- (c) If a discharge or spill of regulated medical or chemotherapeutic waste occurs during transportation, and if the immediate removal of the waste is necessary to protect public health and safety or the environment, the Department may authorize the removal of the waste to a selected receiving facility by transporters who do not have identification numbers, licenses, logs or shipping papers under this subchapter.
 - (d) A transporter shall:
- (1) Clean up a regulated medical or chemotherapeutic waste discharge or spill that occurs during transportation or take action that may be required or approved by the Department so that the discharge or spill no longer presents a hazard to public health, public safety or the environment.
- (2) File a complete report in writing concerning the incident with the Department's Central Office. The report shall include, at a minimum, a detailed description of the clean-up operation and the disposition of the waste, and the information required by subsection (a).

§ 284.633. Safety.

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

§ 284.634. Annual report.

- (a) A transporter shall submit to the Department's Central Office an annual report. The report shall be submitted by the end of March of each calendar year. The report shall be submitted on forms supplied by the Department.
- (b) The annual report shall be based on the shipments of regulated medical or chemotherapeutic waste during the previous calendar year, and shall include the following:
- (1) The name, location, telephone number and permit identification number of each processing or disposal facility to which the transporter delivered regulated medical or chemotherapeutic waste.
- (2) The weight or volume of each type of regulated medical or chemotherapeutic waste transported.
- (3) When more than one transporter is used to transport a single shipment of regulated medical or chemotherapeutic waste from the generator to the processing or disposal facility, only the first transporter is required to submit information for that shipment on the annual report.

BOND

§ 284.641. Bond requirement.

- (a) General. The applicant shall provide the Department a bond, secured by collateral as specified by this section and which bond is conditional upon compliance by the licensee with the requirements of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1— 6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license and Department orders issued to the licensee. The bond shall be consistent with, and subject to, the requirements of this section. The amount, duration, form, conditions and terms of the bond will be specified by the Department. An additional bond amount will not be required of applicants that are also licensed hazardous waste transporters during the term of license or renewal thereof under this subchapter if the applicant or licensee submits a bond endorsement, including an increase in the amount of the bond of a minimum of \$10,000, to the Department that includes liability for regulated medical and chemotherapeutic waste transportation on the hazardous waste transporter bond.
- (b) Approval by Department. A license to transport regulated medical or chemotherapeutic waste will not be issued by the Department before the applicant for the license has filed a collateral bond payable to the Department on a form provided by the Department, and the bond has been approved by the Department.
 - (c) Amount of bond.
- (1) The bond shall be in an amount sufficient to assure that the licensee faithfully performs the requirements of the act, the Infectious and Chemotherapeutic Waste Law and regulations thereunder, the terms and conditions of the license, and Department orders issued to the licensee. The minimum amount of the bond is \$10,000.

- (2) The Department may require additional bond amounts if the mode of transporting waste changes, or the Department determines additional bond amounts are necessary to meet the requirements described in paragraph (1).
- (d) Term of bond. Liability under the bond shall contain at a minimum for the duration of the license, any renewals thereof and for 1 year after expiration, termination, revocation or surrender of the license. The 1-year extended period of liability includes, and shall be automatically extended for, an additional time period during which administrative or legal proceedings are pending involving a violation by the transporter of the act, the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license or Department orders issued to the licensee.
 - (e) Collateral for transporter bonds.
- (1) The Department will accept the types of collateral for transporter bonds that are provided in § 271.322 (relating to general terms and conditions for collateral bonds).
- (2) The terms and conditions for the bonds shall be as provided in §§ 271.322—271.325.
- (3) A department or agency of the United States or the Commonwealth applying for a transporter license to transport regulated medical or chemotherapeutic waste shall satisfy the requirements of this section by filing a bond with the Department under this section, or by another means of financial assurance approved by the Department which satisfies the terms and conditions for bonds under § 271.313(b) (relating to forms, terms and conditions of the bond or trust). The Department may accept a bond executed by a transporter who is not the licensee, instead of a bond executed by the licensee, if the liability on the bond meets the requirements of this subchapter. The transporter may not accept waste or initiate operation prior to the approval by the Department of the financial assurances required by this section.
- (f) Review of bonds. Bonds will be reviewed for legality and form according to established Department procedures.

§ 284.642. Release of bond.

- (a) Except as provided in subsection (b), the Department will release a transporter bond 1 year after the expiration or termination of a license upon written request of the licensee.
- (b) The Department will not release a bond if the transporter is in violation of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Law, regulations thereunder, the terms and conditions of the license or Department orders issued to the licensee, whether or not the violation results from regulated medical or chemotherapeutic waste transportation.
- (c) The release of a bond by the Department does not constitute a waiver or release of other liability provided in law, nor does it abridge or alter rights of action or remedies of a person or municipality presently or prospectively existing in equity or under criminal and civil common or statutory law.

§ 284.643. Bond forfeiture.

(a) The Department will declare a bond forfeit if the transporter is in violation of the act, the act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste

Law, regulations thereunder, the terms and conditions of the bond, the terms and conditions of the license or Department orders issued to the licensee, whether or not the violation results from regulated medical or chemotherapeutic waste transportation.

- (b) If the Department declares a bond forfeit, it will:
- (1) Send written notification to the transporter of the Department's determination to declare the bond forfeit and the reasons for the forfeiture.
- (2) Advise the transporter and surety of the right to appeal to the EHB under the Environmental Hearing Board Act (35 P. S. §§ 7511—7516).
- (3) Proceed to collect on the bond as provided by applicable laws for the collection of defaulted bonds or other debts.
- (c) If the Department declares a transporter bond forfeited, it will pay, or direct the State Treasurer to pay, the collateral funds into the Solid Waste Abatement Fund. If upon proper demand and presentation, the banking institution or other person or municipality which issued the collateral refuses to pay the Department the proceeds of a collateral undertaking, the Department will take appropriate steps to collect the proceeds.

Subchapter H. TRACKING OF REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE GENERAL

§ 284.701. Scope.

- (a) Except as provided in subsection (b), this subchapter applies to a person or municipality that generates, transports, disposes or processes regulated medical or chemotherapeutic waste or processed regulated medical or chemotherapeutic waste that is recognizable.
- (b) This subchapter does not apply to a person or municipality for the following activities:
- (1) Onsite movement of regulated medical or chemotherapeutic waste by generators.
- (2) Onsite movement of regulated medical or chemotherapeutic waste by operators of permitted regulated medical or chemotherapeutic waste management facilities.
- (3) Transportation by a generator who generates less than 220 pounds per month of regulated medical and chemotherapeutic waste if the following are met:
 - (i) The generator only transports his own waste.
- (ii) The generator records on a log or shipping paper the following information for each shipment:
- (A) The name, address and telephone number of the generator of the waste.
- (B) The quantity of the waste transported and accepted by the processing or disposal facility.
- (C) The date the waste is transported and accepted by the processing or disposal facility.
- (iii) The generator carries and delivers a copy of this log or shipping paper with the waste shipment to the offsite processing or disposal facility.
- (4) The transportation of regulated medical waste if the following are met:
- (i) The package is sent to a permitted processing or disposal facility in this Commonwealth or to an out-of-State facility by certified mail, return receipt requested, indicating the name and address of the sender, the name

- of the addressee, the signature of the addressee, the date of delivery and the address where delivered or by utilizing an alternate tracking system approved in writing by the Department if applicable.
- (ii) The mailing standards of the United States Postal Service in 39 CFR 211.2 (relating to regulations of the Postal Service) and incorporated by reference into this chapter authorize the package to be mailed.
- (iii) The package is mailed in compliance with United States Postal Service regulations.
- (iv) The generator maintains a log or shipping paper containing the following information:
 - (A) The weight of the waste transported.
 - (B) The date of shipment.
- (C) The name and address of each processing or disposal facility to which the generator is shipping the waste by the United States Postal Service or other mail carrier.
- (5) The transportation by a generator who generates and processes onsite less than 220 pounds per month of regulated medical or chemotherapeutic waste, which is recognizable waste, if the following are met:
 - (i) The generator only transports its own waste.
- (ii) The generator records on a log or shipping paper the following information for each shipment:
- (A) The name, address and telephone number of the generator of the waste.
- (B) The quantity of the waste transported and accepted by the disposal facility.
- (C) The name, address and telephone number of the transporter for each shipment of waste. If applicable, the log or shipping paper shall include the identification number of a licensed transporter.
- (D) The date the waste is transported and accepted by the processing or disposal facility.
- (iii) A copy of the log or shipping paper shall be provided to the disposal facility by the transporter for each shipment of waste.
- (6) The transportation through this Commonwealth of regulated medical or chemotherapeutic waste generated outside this Commonwealth that is destined for processing or disposal outside this Commonwealth.
- (7) The transportation of processed regulated medical or chemotherapeutic waste to a disposal facility if the waste has been rendered unrecognizable.

§ 284.702. Transfer facilities.

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

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

§ 284.703. Recordkeeping.

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

GENERATOR RESPONSIBILITIES

§ 284.711. Use of logs or shipping papers.

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

§ 284.712. Preparation of logs or shipping papers.

- (a) The generator shall create a log or shipping paper of the following information and provide it to the transporter before the offsite transportation of the waste
- (1) The name, mailing address and telephone number of the generator.
- (2) Each transporter's company name, identification number, Pennsylvania regulated medical and chemotherapeutic waste transporter license number and telephone number.
- (3) The number of containers, types of containers and the total quantity of the waste by weight or volume.
- (4) One of the following regulated medical or chemotherapeutic waste code numbers for each waste type, as appropriate:
 - (i) A100 for regulated medical waste.
- (ii) A200 for processed regulated medical waste that is recognizable.
 - (iii) A300 for chemotherapeutic waste.
- (5) The United States Department of Transportation proper shipping name, hazard class and identification number (UN or NA) for each waste identified by 49 CFR Subtitle B, Chapter I, Subchapter C (relating to hazard-ous materials regulations), if applicable.
- (6) Special instructions and information necessary for proper handling of the waste during transportation, processing, storage or disposal, if any.
- (7) The printed or typed name and handwritten signature of the generator's authorized representative, and the date of shipment.
- (8) The printed or typed name and handwritten signature of the initial transporter's authorized representative, and the date of receipt.
- (b) An authorized representative of the generator shall ensure that a legible log or shipping paper has been completed.
- (c) After the offsite transportation of the waste, the generator shall receive from the transporter and maintain as a record the log or shipping paper prepared by the transporter in accordance with § 284.722(f) (relating to preparation and use of logs or shipping papers).

§ 284.713. (Reserved).

§ 284.714. Exception reporting.

- (a) A generator that does not receive a log or shipping paper indicating the designated facility that received its waste within 30 days of the date the generator's waste was accepted by the initial transporter shall:
- (1) Contact the transporter or the operator of the designated facility, or both, to determine the status of the shipment.
- (2) Notify the Department's appropriate regional office by telephone within 1 business day of the status of the shipment.
- (b) If the generator has not received a log or shipping paper indicating the designated facility that received its waste from the transporter within 35 days of the date the generator's waste was accepted by the initial transporter, the generator shall notify the Department's appropriate regional office by telephone and submit an exception report to the Department's Central Office.
 - (c) The exception report shall include the following:
- (1) A record of the waste for which the generator does not have confirmation of delivery.
- (2) A cover letter signed by the generator or an authorized representative explaining the efforts taken to locate the waste shipment and the results of those efforts.

TRANSPORTER RESPONSIBILITIES

§ 284.721. (Reserved).

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

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

provide the operator of the designated facility or subsequent transporter with a log or shipping paper containing the following information:

- (1) The name, mailing address and telephone number of the generator for each container of waste.
- (2) The number of containers, types of containers and the total quantity of the waste by weight or volume for each generator.
- (f) After the waste has been transported to the designated facility, the transporter shall provide the generator with a log or shipping paper containing the following information:
- (1) The name, mailing address and telephone number of each designated facility that received each container of the generator's waste.
- (2) The number of containers, types of containers and the total quantity of the waste by weight or volume received by each designated facility.
- (3) The date that each designated facility received each container of the generator's waste.
- (4) Acknowledgment from the designated facility that it accepted each container of the generator's waste.

§ 284.723. (Reserved).

§ 284.724. Transportation limitations.

- (a) A transporter may not accept or transport a shipment of regulated medical or chemotherapeutic waste or processed regulated medical or chemotherapeutic waste that is recognizable if:
- (1) The waste is in containers or packaging which appear to be leaking, damaged or otherwise in violation of § 284.413 or § 284.512 (relating to storage containers; and transportation of regulated medical and chemotherapeutic waste; general provisions).
- (2) The waste is not labeled or identified as required under § 284.414 (relating to marking of containers).
- (3) The number and type of containers and quantity of waste to be transported do not appear to correspond with the number and type of containers and quantity of waste stated in the generator's log or shipping paper at the time of acceptance by the transporter.
- (b) A transporter shall ensure that the waste shipment complies with applicable United States Department of Transportation regulations and 67 Pa. Code Part I (relating to Department of Transportation).

FACILITY RESPONSIBILITIES

§ 284.731. Scope.

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

§ 284.732. Use of logs or shipping papers.

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

- (1) Examine the records of the transporter.
- (2) Note significant discrepancies in the log or shipping paper of the generator and transporter, as defined in § 284.734 (relating to significant discrepancies).
- (3) Provide the transporter with a dated signature, including, but not limited to, handwritten, electronic or stamped signatures, from an authorized representative of the facility, acknowledging that it has accepted the waste from the transporter on that date.

§ 284.733. (Reserved).

§ 284.734. Significant discrepancies.

- (a) This section applies if there is a significant discrepancy in the logs or shipping papers of the generator and transporter. A discrepancy is a difference between the quantity or type of waste designated in the log or shipping paper, and the quantity or type of waste a facility actually receives. A significant discrepancy occurs if one or more of the following apply:
- (1) There is a variation greater than 5% in weight, for bulk waste.
- (2) There is a variation in piece count, for batch waste, excluding 1% variation for generator-loaded trailers.
- (3) There is a difference in waste type which can be discovered by inspection or waste analysis.
- (b) If there is a significant discrepancy in the logs or shipping papers, the operator shall attempt to reconcile the discrepancy before the waste is processed or disposed of at the facility or before the waste is accepted at a transfer facility. If the discrepancy is not resolved within 3 business days of receipt of the waste, the operator shall immediately notify the appropriate regional office of the Department by telephone. Within 7 business days of receipt of the waste, the operator shall also send a letter to the regional office describing the discrepancy and attempts to reconcile it.

CHAPTER 285. STORAGE, COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE

Subchapter A. STORAGE OF MUNICIPAL WASTE ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE

- § 285.131. Storage and containment of ash residue from municipal waste incineration, including from regulated medical or chemotherapeutic waste incineration.
- (a) Ash residue from municipal waste incineration, including from regulated medical or chemotherapeutic waste incineration, shall be stored in accordance with the following:
- (1) In an enclosed container, which may include a properly tarped container, or in an enclosed area, which may include an adequately ventilated building.
- (2) On a pad that is no more permeable than 1 x 10^{-7} cm./sec.
- (3) To prevent the release, dispersal or discharge of ash residue into the air, water or onto land.
- (b) Ash residue from a regulated medical or chemotherapeutic waste incinerator may be commingled with other municipal waste if the commingled waste is from one generator and if storage of the commingled waste is in accordance with subsection (a).

ADDITIONAL REQUIREMENTS FOR REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

§§ 285.141—285.145. (Reserved).

Subchapter B. COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE GENERAL PROVISIONS

§ 285.218. Signs on vehicles.

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

- (1) The sign shall include the name and business address of the person or municipality that owns the vehicle or conveyance.
- (i) The name shall be the actually and commonly recognized name of the person or municipality. Abbreviations or acronyms are permissible if they do not obscure the meaning.
- (ii) The address shall include the city, state and five digit zip code for the principal place of business for the person or municipality.
- (2) The sign shall include the specific type of solid waste transported by the vehicle or conveyance.
- (i) Regulated medical or chemotherapeutic waste shall be designated: Regulated Medical/Chemotherapeutic Waste
- (ii) Other municipal waste shall be designated: Municipal Waste.
- $\left(\mathrm{iii} \right)$ Residual waste shall be designated: Residual Waste.
- (iv) Mixed municipal and residual waste shall be designated: Municipal/Residual Waste.
- (3) The sign shall have lettering that is 6 inches in height. The lettering shall be placed on the roll-off box or trailer. If available space for lettering on the trailer or roll-off box is so limited that all letters cannot be 6 inches in height, the lettering shall be as close to 6 inches as possible. The required information shall be clearly visible and easily readable.
 - (4) The sign may be permanent or detachable.

TYPES OF WASTE

§ 285,221. Transportation of ash residue from municipal waste incineration and from regulated medical or chemotherapeutic waste incineration.

- (a) Ash residue from municipal waste incineration and from regulated medical or chemotherapeutic waste incineration shall be wetted immediately prior to loading, and shall remain wetted during transportation and unloading at a municipal waste landfill, to prevent the dispersal of ash residue.
- (b) Ash residue from regulated medical or chemotherapeutic waste incineration shall be transported in an enclosed or covered vehicle to prevent dispersal of the residue.
- (c) A transporter shall transport separately each generator's ash residue from regulated medical or chemotherapeutic waste.
- (d) A transporter may transport ash residue from a regulated medical or chemotherapeutic waste incinerator that is commingled with other municipal waste if the commingled waste is from one generator and the waste is transported separately from another generator's waste.

ARTICLE IX. RESIDUAL WASTE MANAGEMENT

CHAPTER 287. RESIDUAL WASTE MANAGEMENT—GENERAL PROVISIONS

Subchapter A. GENERAL

§ 287.1. Definitions.

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

* * * * *

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

* * * * *

§ 287.2. Scope.

- (a) This chapter specifies general procedures and rules for persons or municipalities who generate, manage or handle residual waste. This article specifies the Department's requirements for residual waste processing, disposal, transportation, collection and storage.
- (b) Management of the following types of residual waste is subject to Article VIII (relating to municipal waste) instead of this article, and shall be regulated as if the waste is municipal waste regardless of whether the waste is a municipal waste or residual waste:
- (1) Construction/demolition waste, as defined in § 271.1 (relating to definitions).
- (2) Regulated medical and chemotherapeutic waste. The terms shall have the same meaning for residual waste as set forth in \S 271.1.

* * * * *

CHAPTER 288. RESIDUAL WASTE LANDFILLS Subchapter D. ADDITIONAL REQUIREMENTS FOR CLASS I RESIDUAL WASTE LANDFILLS

ADDITIONAL OPERATING REQUIREMENTS— GENERAL

§ 288.423. Minimum requirements for acceptable waste.

* * * * *

- (b) A person or municipality may not dispose of municipal waste or special handling waste at a Class I residual waste landfill, except that the Department may, in the permit, approve the storage or disposal of the following types of waste generated by the operator:
 - (1) Industrial lunchroom or office waste.
- (2) Special handling waste, other than sewage sludge, regulated medical or chemotherapeutic waste, waste oil or ash residue from the incineration of municipal waste.

* * * * *

CHAPTER 299. STORAGE AND TRANSPORTATION OF RESIDUAL WASTE

Subchapter B. STANDARDS FOR COLLECTING AND TRANSPORTING OF RESIDUAL WASTE

GENERAL PROVISIONS

§ 299.220. Signs on vehicles.

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

- (1) The sign shall include the name and business address of the person or municipality that owns the vehicle or conveyance.
- (i) The name shall be the actually and commonly recognized name of the person or municipality. Abbreviations or acronyms are permissible if they do not obscure the meaning.
- (ii) The address shall include the city, state and five digit zip code for the principal place of business for the person or municipality.
- (2) The sign shall include the specific type of solid waste transported by the vehicle or conveyance.
- (i) Regulated medical or chemotherapeutic waste shall be designated: Regulated Medical/Chemotherapeutic waste.
- (ii) Other municipal waste shall be designated: Municipal Waste.
- (iii) Residual waste shall be designated: Residual Waste.
- (iv) Mixed municipal and residual waste shall be designated: Municipal/Residual Waste.
- (3) The sign shall have lettering that is 6 inches in height. The lettering shall be placed on the roll-off box or trailer. If available space for lettering on the trailer or roll-off box is so limited that all letters cannot be 6 inches in height, the lettering shall be as close to 6 inches as possible. The required information shall be clearly visible and easily readable.
 - (4) The sign may be permanent or detachable.

[Pa.B. Doc. No. 14-2307. Filed for public inspection November 7, 2014, 9:00 a.m.]

Title 58—RECREATION

GAME COMMISSION
[58 PA. CODE CH. 141]
Hunting and Trapping; Big Game

To effectively manage the wildlife resources of this Commonwealth, the Game Commission (Commission), at its September 23, 2014, meeting amended § 141.42 (relating to parties hunting big game) by deleting the voided roster requirement text.

The final-form rulemaking will not have an adverse impact on the wildlife resources of this Commonwealth.

The authority for the final-form rulemaking is 34 Pa.C.S. (relating to Game and Wildlife Code) (code).

Notice of proposed rulemaking was published at 44 Pa.B. 5212 (August 2, 2014).

1. Purpose and Authority

On January 27, 2014, the act of November 27, 2013 (P. L. 1148, No. 103) (Act 103) became effective. Act 103 amended section 2324 of the code (relating to parties hunting big game) to eliminate the roster requirement and remove the Commission's authority to establish roster requirements. The Commission amends § 141.42 by deleting the voided roster requirement text.

Section 2102(a) of the code (relating to regulations) provides that "[t]he commission shall promulgate such regulations as it deems necessary and appropriate concerning game or wildlife and hunting or furtaking in this Commonwealth, including regulations relating to the protection, preservation and management of game or wildlife and game or wildlife habitat, permitting or prohibiting hunting or furtaking, the ways, manner, methods and means of hunting or furtaking, and the health and safety of persons who hunt or take wildlife or may be in the vicinity of persons who hunt or take game or wildlife in this Commonwealth." The amendments to § 141.42 are adopted under this authority.

2. Regulatory Requirements

The final-form rulemaking amends § 141.42 by deleting the voided roster requirement text.

3. Persons Affected

Persons wishing to hunt big game within this Commonwealth will be affected by the final-form rulemaking.

4. Comment and Response Summary

There were no official comments received regarding the final-form rulemaking.

5. Cost and Paperwork Requirements

The final-form rulemaking should not result in additional cost or paperwork.

6. Effective Date

The final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin* and will remain in effect until changed by the Commission.

7. Contact Person

For further information regarding the final-form rule-making, contact Thomas P. Grohol, Director, Bureau of Wildlife Protection, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797, (717) 783-6526.

Findings

The Commission finds that:

- (1) Public notice of intention to adopt the administrative amendment adopted by this order has been 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 the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.
- (2) The adoption of the amendments of the Commission in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

Order

The Commission, acting under the authorizing statute, orders that:

- (a) The regulations of the Commission, 58 Pa. Code Chapter 141, are amended by amending § 141.42 to read as set forth at 44 Pa.B. 5212.
- (b) The Executive Director of the Commission shall certify this order and 44 Pa.B. 5212 and deposit them with the Legislative Reference Bureau as required by law.
- (c) This order shall become effective upon final-form publication in the $Pennsylvania\ Bulletin$.

R. MATTHEW HOUGH, Executive Director

Fiscal Note: Fiscal Note 48-367 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 14-2308. Filed for public inspection November 7, 2014, 9:00 a.m.]

GAME COMMISSION [58 PA. CODE CH. 147] Special Permits; Falconry

To effectively manage the wildlife resources of this Commonwealth, the Game Commission (Commission), at its September 23, 2014, meeting amended §§ 147.101 and 147.103 (relating to definitions; and classes) to make it clear that in the regulations the term "hybrid" applies to all offspring of species listed in 50 CFR 10.13 (relating to list of migratory birds).

The final-form rulemaking will not have an adverse impact on the wildlife resources of this Commonwealth.

The authority for the final-form rulemaking is 34 Pa.C.S. (relating to Game and Wildlife Code) (code).

Notice of proposed rulemaking was published at 44 Pa.B. 5213 (August 2, 2014).

1. Purpose and Authority

The United States Fish and Wildlife Service (Service) recently amended the definition of "hybrid" in 50 CFR 21.3 (relating to definitions) to include any bird that results from a cross of genetic material between two separate taxa when one or both are listed in 50 CFR 10.13. See 78 FR 65576 (November 1, 2013). This revision clarified that "hybrid" includes any bird resulting from propagation when only one parent is defined as a migratory bird. The previous definition required both parents to be defined as a migratory bird. The previous definition created difficulties due to its inconsistency with the Service's longstanding interpretation of the same term under the Migratory Bird Treaty Act (16 U.S.C.A. §§ 703—712) as requiring only one parent to be defined as a migratory bird. The Commission amended §§ 147.101 and 147.103 to make it clear that in the regulations "hybrid" applies to all offspring of species listed in 50 CFR 10.13. Adoption of this amendment will maintain the Commonwealth's necessary compliance with the applicable Federal regulations concerning falconry to continue this program in this Commonwealth.

Section 2901(b) of the code (relating to authority to issue permits) provides that "the commission may, as deemed necessary to properly manage the game or wild--

life resources, promulgate regulations for the issuance of any permit and promulgate regulations to control the activities which may be performed under authority of any permit issued." The amendments to §§ 147.101 and 147.103 are adopted under this authority.

2. Regulatory Requirements

The final-form rulemaking amends §§ 147.101 and 147.103 to make it clear that "hybrid" applies to all offspring of species listed in 50 CFR 10.13.

3. Persons Affected

Persons wishing to engage in falconry activities within this Commonwealth will be affected by the final-form rulemaking.

4. Comment and Response Summary

There were no official comments received regarding the final-form rulemaking.

5. Cost and Paperwork Requirements

The final-form rulemaking should not result in additional cost or paperwork.

6. Effective Date

The final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin* and will remain in effect until changed by the Commission.

7. Contact Person

For further information regarding the final-form rule-making, contact Thomas P. Grohol, Director, Bureau of Wildlife Protection, 2001 Elmerton Avenue, Harrisburg, PA 17110-9797, (717) 783-6526.

Findings

The Commission finds that:

- (1) Public notice of intention to adopt the administrative amendments adopted by this order has been 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 the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.
- (2) The adoption of the amendments of the Commission in the manner provided in this order is necessary and appropriate for the administration and enforcement of the authorizing statute.

Order

The Commission, acting under the authorizing statute, orders that:

- (a) The regulations of the Commission, 58 Pa. Code Chapter 147, are amended by amending §§ 147.101 and 147.103 to read as set forth at 44 Pa.B. 5213.
- (b) The Executive Director of the Commission shall certify this order and 44 Pa.B. 5213 and deposit them with the Legislative Reference Bureau as required by law.
- (c) This order shall become effective upon final-form publication in the *Pennsylvania Bulletin*.

R. MATTHEW HOUGH, Executive Director

Fiscal Note: Fiscal Note 48-368 remains valid for the final adoption of the subject regulations.

 $[Pa.B.\ Doc.\ No.\ 14\text{-}2309.\ Filed\ for\ public\ inspection\ November\ 7,\ 2014,\ 9\text{:}00\ a.m.]$

PENNSYLVANIA GAMING CONTROL BOARD [58 PA. CODE CHS. 421a, 421b, 439a,

464a, 465a, 481a, 501a, 503a, 503b, 513a, 603a AND 633a 1

Gaming Junket Enterprises, Accounting and Internal Controls, Compulsive and Problem Gambling, Self-Exclusion, Underage Gaming, Equipment, Blackjack

The Pennsylvania Gaming Control Board (Board), under the general authority in 4 Pa.C.S. § 1202(b)(15) and (30) (relating to general and specific powers) and the specific authority in 4 Pa.C.S. §§ 1207(2), (5), (8) and (9), 1212, 13A02(2), 13A26(c), 1509, 1516, 1518(a)(13) and 1602, rescinds Chapters 421b and 503b and amends Chapters 421a, 439a, 464a, 465a, 481a, 501a, 503a, 513a, 603a and 633a to read as set forth in Annex A.

Purpose of the Final-Form Rulemaking

This final-form rulemaking will transition two statements of policy on advertising and jackpot credit meter payouts (former Chapters 421b and 503b) into regulations, allow for the conditional licensure of gaming junket enterprises, amend the procedure for removal from the exclusion list for individuals whose period of voluntary exclusion has concluded and add an additional pay table to an already existing side wager in Blackjack.

Explanation of the Final-Form Rulemaking Advertising

Section 421a.6 is rescinded as these requirements properly belong in Chapter 501a (relating to compulsive and problem gambling requirements). These provisions are moved to § 501a.7 (relating to advertising). Additionally, the statements of policy in Chapter 421a are rescinded and the requirements are also moved to § 501a.7. Section 501a.7 provides requirements regarding the gambling assistance message that must be on gaming related advertising.

Conditional licensure for gaming junket enterprises

The Board added provisions to § 439a.6b (relating to conditional licenses) for a conditional license awarded to gaming junket enterprises provided that certain criteria are satisfied including the following: agreements between a slot machine licensee and gaming junket enterprise are submitted to the Board; the gaming junket enterprise is licensed or otherwise credentialed in good standing in a gaming jurisdiction that the Board has determined has licensing standards that are as comprehensive and thorough and provide similar safeguards as those required under 4 Pa.C.S. Part II (relating to gaming); and the applicant has passed a preliminary criminal history review.

Internal controls

In § 465a.20 (relating to personal check cashing), provisions are added prohibiting a licensee or an entity certified or registered with the Board that is operating within a licensed facility from accepting checks made payable to an individual such as Social Security, unemployment, public assistance checks, and the like. Notwithstanding the prohibition, a licensee may cash a payroll check of one of its employees or a check issued to a patron by the licensee. This provision is added as an employee convenience and to allow a licensee to cash its own check made payable to a patron who won a jackpot payout.

The prohibition on check cashing that was moved into 465a.20 was previously in § 501a.6. Section 501a.6 is

rescinded as the provisions more logically belong in Chapter 465a (relating to accounting and internal controls). Cross-references to § 501a.6 are deleted from § 465a.20 and §§ 465a.21 and 465a.22 (relating to wire transfers; and cash equivalents).

Section 465a.26(b)(2) (relating to jackpot and credit meter payouts) formerly required that two individuals be present to sign off on a jackpot payout more than \$1,200 but less than \$9,999.99. The final-form rulemaking allows operators to utilize only one individual instead of two for credit meter payouts less than \$5,000 provided that both the facility's casino management system and the central control computer system are fully operational. This should reduce the number of personnel required to sign off on a majority of jackpot payouts that occur on a daily basis.

Diversity

Chapter 481a (relating to diversity) is amended to reflect that the Bureau of Small Business Opportunities (formerly the Bureau of Minority and Women's Business Enterprises) verifies that a business is minority or women's business enterprise. Amendments to § 481a.6 (relating to diversity reviews) reflect that Board staff conducts diversity reviews, not audits. This technical revision was made for consistency with 4 Pa.C.S. § 1212(b) (relating to diversity goals of board).

Compulsive and problem gambling

As previously mentioned, the advertising requirements formerly in § 421a.6 and Chapter 421b are now included in § 501a.7.

A definition of "advertising" is added to § 501a.1 (relating to definitions).

Former language in § 501a.2(i) (relating to compulsive and problem gambling plan) reiterated the requirements already specified in subsections (g) and (h). This redundant language is deleted and a cross-reference is added.

Section 501a.3(b) (relating to employee training program) is added to require that training materials be updated annually to include the most current research on responsible and problem gambling. The remaining subsections are renumbered.

A signage requirement is added to § 501a.5 (relating to signage requirements) to reflect the statutory mandate in 4 Pa.C.S. § 1509(c) (relating to compulsive and problem gambling program). Former subsection (b) is deleted as advertising requirements are now addressed in § 501a.7.

Self-exclusion

The Board has amended the provisions associated with self-exclusion in Chapter 503a (relating to self-exclusion). In § 503a.1 (relating to definitions), language is added to the definitions of "fully executed gaming transaction" and "self-exclusion list" to reflect that gaming activity may also be conducted in locations off the gaming floor. The same language is be added throughout Chapter 503a to reflect this change. A definition of "gaming activity" is added and the definition of "gaming related activity" is amended in § 503a.1.

In § 503a.2 (relating to request for self-exclusion), the cross-reference in subsection (c) is corrected.

In subsection (e)(5), language is added specifying that a self-excluded individual's gambling winnings will be subject to confiscation to support compulsive and problem gaming programs. Confiscation is consistent with 4 Pa.C.S. § 1516(a) (relating to list of persons self excluded from gaming activities). The confiscation of winnings language is also included in the waiver individuals are required to sign to be placed on the exclusion list as specified in subsection (e)(6)(iii).

Section 503a.4(a) (relating to duties of slot machine licensees) is amended for clarity and to delete unnecessary language. Final-form subsection (a)(6) (formerly subsection (a)(7)) formerly required licensees to disseminate self-exclusion program materials but did not provide guidelines for licensees to ensure compliance. This paragraph is amended to require licensees to "make available" information on the self-exclusion program. This amendment is consistent with § 609a.12(f) (relating to duties of certificate holders), regarding the voluntary credit suspension program.

In subsection (e), redundant language is deleted and replaced with a cross-reference to the submission and approval process in subsections (c) and (d).

The former process for individuals whose term of voluntary exclusion has concluded is amended in § 503a.5 (relating to removal from self-exclusion list). Formerly, once an individual's period of exclusion has concluded (those with a 1-year or 5-year term), the individual can schedule an appointment and at the appointment time submit a Request for Removal Form. The individual is then required to schedule another appointment and return a second time to sign the form. Requiring individuals to come back to the Board's Harrisburg office or a regional office in Pittsburgh, Conshohocken and Scranton on two separate occasions can present substantial challenges to those individuals who live some distance from a Board office. Therefore, individuals whose term of voluntary exclusion has expired will be required to schedule only one appointment to be removed from the voluntary list once their period of exclusion has ended. Additionally, the Office of Compulsive and Problem Gambling may now approve an alternative location to complete the removal process if circumstances, such as geographical distance, warrant the use of an alternative location. Alternative locations can be discussed with the Director of the Office of Compulsive and Problem Gambling when the self-excluded individual schedules an appointment to be removed from the list.

In subsection (d), the time period for the Board and licensees to remove the name of a self-excluded person is amended from 5 to 15 business days. After an individual completes the process to be removed from the self-exclusion list, the Board will update the database, provide notice to the licensees and the licensees shall update their in-house databases. Based on the Board's experience to date, 15 business days will provide adequate time to the Board and slot machine licensees to complete the administrative process of removing the individual's information from all databases. This additional time should also ensure that individuals who have completed the removal process are not inadvertently ejected from a licensed facility and charged with criminal trespass.

Section 503a.7 (relating to disclosure of information related to persons on the self-exclusion list) specifies the type of general information that the Board may disclose publicly. In accordance with 4 Pa.C.S. § 1516(d), detailed information, including whether a specific individual is on the self-exclusion list, is deemed confidential and will not be publically disclosed.

Underage gaming

Amendments to Chapter 513a (relating to underage gaming) add additional requirements to ensure the exclusion of underage individuals from gaming and gaming

related activities. Slot machine licensees are required to train their employees and establish procedures to identify underage individuals, refuse gaming related activities to minors, including check cashing and to notify the onsite casino compliance representatives and the Pennsylvania State Police if an underage individual is discovered on the gaming floor or areas off the gaming floor where contests or tournaments are conducted.

In § 513a.4 (relating to signage requirements), the underage prohibition language is updated to add specificity on the type of activity that an underage individual is prohibited from engaging in and to reflect that gaming activity now includes the play of not only slot machines but also table games.

Table gaming equipment

Section 603a.12 (relating to dice; physical characteristics) requires that dice used in an automated Sic Bo must be a 0.625 inch cube with ball edge corners. These size specifications ensure a proper tumble of the dice in the automated Sic Bo shaker and are consistent with industry standards.

Blackjack

A payout table is added to § 633a.13(k) (relating to payout odds; payout limitation) for winning Three Card Poker wagers.

Additional Revisions

The following additional revisions were made in the final-form rulemaking.

Conditional junket enterprise licenses

A minor revision was made to § 439a.6b(a)(1) to delete the reference to specific names of applications associated with a gaming junket enterprise license that are required to be completed as there are additional applications, beyond those referenced, that may be required depending on the corporate structure of the junket enterprise.

For example, a majority of the junket enterprises that have applied for a license with the Board are sole proprietors and would therefore be required to complete a junket enterprise application and a permit application. However, if a junket enterprise is not a sole proprietor but is a subsidiary of a company that owns 20% or more of the junket enterprise, the junket enterprise's holding company would also be required to complete an application, the Gaming Junket Enterprise Private Holding Company Form.

The first page of the Gaming Junket Enterprise Application lists the various applications associated with the Junket Enterprise License and under what circumstances each of the applications are required to be completed.

Slot machine tournaments

In \S 464a.2(e)(1) (relating to conduct of a slot machine tournament), the cross-references to Chapter 421b and \S 421a.6 are deleted and replaced with a cross-reference to \S 501a.7.

Check cashing

Language is added to § 465a.20(g) for consistency with 4 Pa.C.S. § 1516(b), which requires licensed gaming entities to establish procedures designed to deny self-excluded persons access to check cashing privileges. Subsection (h) is added which to hold a company contracted to act on the licensee's behalf to the same standards as those applicable to the licensee.

Removal from self-exclusion list

In the proposed rulemaking, language was proposed to be added to §§ 503a.2 and 503a.5 allowing an individual who had signed up for lifetime exclusion from all gaming activities to petition the Board for removal from the exclusion list only after 10 years had elapsed. At this time, the Board decided to withdraw the amendments so those who signed up for lifetime exclusion remain on the list permanently.

Comment and Response Summary

Notice of proposed rulemaking was published at 43 Pa.B. 2152 (April 20, 2013) with a 30-day public comment period. During the comment period, the Board received comments from Greenwood Gaming and Entertainment, d/b/a Parx Casino (Parx). On June 19, 2103, the Independent Regulatory Review Commission (IRRC) also submitted comments.

Parx specifically commented on the provisions associated with advertising that were being transitioned from statements of policy into regulation. Parx objected to the proposed language in § 501a.7(e)(3) which would require that for video and television advertisements, the gambling assistance message be displayed at 2% for the entire length of the advertisement. Parx suggested alternative language which would require that the gambling assistance message be displayed at 2% only from the moment the advertisement mentions the casino name or displays a gambling image to the end of the advertisement, for at least 25% of the total length of time for that advertisement.

The Board recognizes that the purpose of advertising is to get the audience's attention and convince or prompt people into action to visit the casino and enjoy its amenities, including gambling. While the Board appreciates advertising a casino's positive attributes and that for most individuals, visiting a casino is entertainment that does not lead to problem gambling. The reality is that for some individuals gambling is an addiction, the social effects of which impact not only the individual with the gambling problem but also his family, friends and coworkers. It is an issue that the Board takes seriously.

Consistent with the objectives of 4 Pa.C.S. Part II, the Board recognizes its duty to protect the public through the regulation and policing of activities involving gaming and to take into consideration the public interest of the citizens of this Commonwealth and the social effects of gaming in any decision or order of the Board. See 4 Pa.C.S. § 1102(1) and (10) (relating to legislative intent). The General Assembly also acknowledged in 4 Pa.C.S. § 1102(13) that authorization of gaming requires the Commonwealth to take steps to increase awareness of compulsive and problem gambling. One effective way to increase awareness of problem gambling, and that treatment for the disease is available, is through the dissemination of the gambling assistance message on all advertising promoting gambling.

While it is unclear to the Board how the 2% print containing the gambling assistance message at the bottom of a television advertisement would negate an advertising campaign in which the message does not make reference that a casino is what is being advertised or which one is being promoted, the Board agrees to provide operators with an option. Operators can display the gambling assistance message for either the entire length of the advertisement or from the time gaming activity is displayed or the casino's name is referenced to the end of the advertisement. If an operator elects to utilize this

option, the gambling assistance must also appear, at 8%, on a screen shot for the last 3 seconds of the advertisement. While the Board appreciates the operator's suggestion that the message be displayed at least 25% of the advertisement, the Board does not believe that amounts to enough time to make the assistance message visible at 2%. A screen shot for 3-second at 8% at the end of the advertisement would be more prominently visible and would equate to 20% of a 15-second advertisement or 10% of a 30-second advertisement regardless of how long gaming activity was displayed. The Board believes this to be a fair compromise while still consistent with the objectives of 4 Pa.C.S. Part II.

At IRRC's suggestion, the Board deleted the definition of "underage individual" from § 513a.1 (relating to definitions) as the term is not used within Chapter 513a.

Affected Parties

Slot machine licensees, gaming junket enterprises and individuals who are currently on the voluntary self-exclusion list or may request placement on the list will be affected by this final-form rulemaking.

Fiscal Impact

Commonwealth. The Board does not expect that this final-form rulemaking will have fiscal impact on the Board or any other Commonwealth agency. Updates to internal control procedures or training materials regarding compulsive and problem gambling submitted by licensees will be reviewed by existing Board staff.

Political subdivisions. This final-form rulemaking will not have fiscal impact on political subdivisions of this Commonwealth.

Private sector. Slot machine licensees will be required to comply with the requirements in this final-form rule-making and may need to submit updated internal control procedures and training materials regarding compulsive and problem gambling. Most licensees have already been complying with requirements in the statements of policy on advertising. Therefore, it is not anticipated that this final-form rulemaking will have a negative fiscal impact on the licensees.

With respect to the amendment to the number of individuals required for jackpot credit meter payouts, the licensees may see a slight cost savings as licensees will only need one individual instead of two to perform a majority of the credit meter payouts during the gaming day.

General public. This final-form rulemaking will not have fiscal impact on the general public.

Paperwork Requirements

If a certificate holder selects different options for the play of table games, the certificate holder will be required to submit an updated rules submission reflecting the changes. These forms are available and submitted to the Board electronically.

Additionally, licensees will be required to update their compulsive and problem gambling training annually to include current research and information. This information is submitted electronically to the Director of the Office of Compulsive and Problem Gambling.

Effective Date

The final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on April 5, 2013, the Board submitted a copy of the notice of proposed rulemaking, published at 43 Pa.B. 2152, to IRRC and the Chairpersons of the House Gaming Oversight Committee and the Senate Community, Economic and Recreational Development Committee 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-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on September 17, 2014, 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 September 18, 2014, and approved the final-form rulemaking.

Findings

The Board finds that:

- (1) Public notice of intention to adopt these amendments 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 the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.
- (2) The final-form rulemaking is necessary and appropriate for the administration and enforcement of 4 Pa.C.S. Part II.

Order

The Board, acting under 4 Pa.C.S. Part II, orders that:

(1) The regulations of the Board, 58 Pa. Code Chapters 421a, 421b, 439a, 464a, 465a, 481a, 501a, 503a, 503b, 513a, 603a and 633a, are amended by adding §§ 439a.6b, 501a.7 and 503a.7, deleting §§ 421a.6, 421b.1—421b.4, 501a.6 and 503b.1 and amending §§ 464a.2, 465a.20—465a.23, 465a.26, 465a.29, 481a.3, 481a.6, 501a.1—501a.3, 501a.5, 503a.1, 503a.2, 503a.4—503a.6, 513a.1, 513a.3, 513a.4, 603a.12 and 633a.13 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(*Editor's Note*: The amendment to § 464a.2 was not included in the proposed rulemaking published at 43 Pa.B. 2152.)

- (2) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.
- (3) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

WILLIAM H. RYAN, Jr., Chairperson

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 44 Pa.B. 6306 (October 4, 2014).)

Fiscal Note: Fiscal Note 125-168 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 58. RECREATION

PART VII. GAMING CONTROL BOARD Subpart B. LICENSING, PERMITTING, CERTIFICATION AND REGISTRATION

CHAPTER 421a. GENERAL PROVISIONS

§ 421a.6. (Reserved).

CHAPTER 421b. (Reserved)

§§ 421b.1—421b.4. (Reserved).

CHAPTER 439a. JUNKET ENTERPRISES

- § 439a.6b. Conditional licenses.
- (a) The Board may grant an applicant for a gaming junket enterprise license a conditional license to conduct junkets in this Commonwealth. To be eligible to obtain a conditional gaming junket enterprise license, the applicant shall:
- (1) Submit completed gaming junket enterprise applications, including the nonrefundable application fees, as posted on the Board's web site, and pass a preliminary review.
- (2) Submit agreements entered into between the slot machine licensee and the gaming junket enterprise or representative.
- (3) Be licensed or credentialed, in good standing, to arrange or negotiate the terms of a gaming junket in a jurisdiction in the United States or Canada that the Board has determined has licensing standards that are as comprehensive and thorough and provide similar adequate safeguards as those required under the act.
- (4) Pass a preliminary review of the applicant's criminal history.
- (5) Agree, in writing, that the grant of permission to conduct business with a conditional license does not create a right to continue to conduct business and that the Bureau of Licensing may rescind, at any time, the conditional licensure granted to the applicant, with or without prior notice to the applicant, if the Bureau of Licensing is notified that the suitability of the applicant is at issue or the applicant fails to cooperate in the application process.
- (b) If the Office of Enforcement Counsel issues a Notice of Recommendation for Denial to an applicant that has received a conditional gaming junket enterprise license, the Bureau of Licensing may rescind the conditional license. If the conditional license is rescinded, the gaming junket enterprise shall cease conducting business by the date specified in the notice of the rescission sent to the conditional licensee.
- (c) If the conditional license is rescinded, the Bureau of Licensing will notify the holder of the conditional license and the slot machine licensee by registered mail that:
- (1) Permission for the conditional licensee to conduct business has been rescinded.
- (2) The slot machine licensee shall cease conducting business with the gaming junket enterprise by the date specified in the notice.
- (d) Pending a hearing on the Notice of Recommendation for Denial, the conditional licensee may not seek or conduct new business in this Commonwealth.
- (e) The slot machine licensee shall investigate the background and qualifications of the applicant for a

gaming junket enterprise license with whom the slot machine licensee intends to have a relationship or enter into a contractual agreement.

- (f) The slot machine licensee has an affirmative duty to avoid agreements or relationships with persons applying for a gaming junket enterprise license whose background or association is injurious to the public health, safety, morals, good order and general welfare of the people of this Commonwealth or who threaten the integrity of gaming in this Commonwealth.
- (g) The slot machine licensee has a duty to inform Board staff of an action by an applicant for or holder of a gaming junket enterprise license which the slot machine licensee believes would constitute a violation of the act or this part.

Subpart E. SLOT MACHINES AND ASSOCIATED EQUIPMENT

CHAPTER 464a. SLOT MACHINE TOURNAMENTS § 464a.2. Conduct of a slot machine tournament.

* * * * *

- (e) Advertising to promote a slot machine tournament must, at a minimum:
- (1) Comply with the advertising requirements in § 501a.7 (relating to advertising).
- (2) Contain information on who is eligible to participate.
- (3) Include a copy of the slot machine tournament rules or state how a copy of the rules may be obtained.

CHAPTER 465a. ACCOUNTING AND INTERNAL CONTROLS

§ 465a.20. Personal check cashing.

- (a) Checks made payable to an individual, including Social Security, unemployment insurance, disability, public assistance and payroll checks, may not be cashed by a slot machine licensee or entity certified or registered with the Board that is operating within the licensed facility. Notwithstanding the prohibition, a slot machine licensee may cash the payroll check of one of its employees or a check issued to a patron by the slot machine licensee. Personal checks accepted by a slot machine licensee which enable a patron to take part in gaming must be:
- (1) Drawn on a commercial bank, savings bank, saving and loan association or credit union and payable on demand.
 - (2) Drawn for a specific amount.
- (3) Made payable to the slot machine licensee or entity certified or registered with the Board that is operating within the licensed facility.
 - (4) Currently dated, but not postdated.

* * * * *

(g) Prior to accepting personal checks, each slot machine licensee shall establish a comprehensive system of internal controls applicable to the acceptance of personal checks. The internal controls shall be submitted to and approved by the Board under § 465a.2 (relating to internal control systems and audit protocols). The internal controls submitted by the slot machine licensee must address procedures for complying with § 503a.4(a)(4) (relating to duties of slot machine licensees) and this section including the dollar limitation per gaming day contained in subsection (b)(6).

(h) An entity certified or registered with the Board that is cashing checks on behalf of a licensee within a licensed facility shall comply with the requirements in subsections (a)—(f).

§ 465a.21. Wire transfers.

(a) A slot machine licensee may accept a wire transfer on behalf of a patron to enable the patron to take part in gaming. A wire transfer accepted by a slot machine licensee shall be recorded in the slot machine licensee's cage accountability no later than the next gaming day.

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§ 465a.22. Cash equivalents.

- (a) The requirements in this section are not applicable to gaming chips or plaques.
- (b) Prior to accepting cash equivalents for gaming purposes, a slot machine licensee shall establish a comprehensive system of internal controls addressing the acceptance and verification of cash equivalents. The internal controls shall be submitted to and approved by the Board under § 465a.2 (relating to internal control systems and audit protocols).
- (c) The internal control procedures developed and implemented by the slot machine licensee under subsection (a) must include:
- (1) A requirement that cage employees perform the specific verification procedures required under the issuer of each cash equivalent accepted. The slot machine licensee shall retain adequate documentation evidencing the verification of each cash equivalent.
- (2) A requirement that cage employees examine each cash equivalent for counterfeiting, forgery or alteration.
- (3) When a slot machine licensee elects to incorporate into its verification procedures a level of reliance on previously accepted cash equivalents, the procedures must articulate the general parameters governing the reliance.
- (4) Criteria for cage supervisor involvement in the verification process.
- (5) Procedures for verifying any patron signature on the cash equivalent. Signature verification must be accomplished in accordance with the signature verification procedures in § 465a.20 (relating to personal check cashing). The slot machine licensee shall retain adequate documentation evidencing how each signature was verified.

§ 465a.23. Customer deposits.

- (a) At the request of a patron, a slot machine licensee may hold cash, value chips, plaques, funds accepted by means of personal check in accordance with § 465a.20 (relating to personal check cashing) or wire transfer in accordance with § 465a.21 (relating to wire transfers) or cash equivalents accepted in accordance with § 465a.22 (relating to cash equivalents) for a patron's subsequent use at the licensed facility. For the purposes of this section, after complying with this chapter for acceptance and verification, noncash items shall be considered converted to cash and deposited as cash for credit to the patron in a customer deposit account maintained in the cage.
- (b) Prior to agreeing to hold a patron's cash, value chips, plaques, funds accepted by means of personal check in accordance with § 465a.20 or wire transfer in accordance with § 465a.21 or cash equivalents accepted in accordance with § 465a.22 for a patron's subsequent use

- at the licensed facility, each slot machine licensee shall establish a comprehensive system of internal controls addressing the receipt and withdrawal of a customer deposit. The internal controls shall be submitted to and approved by the Board under § 465a.2 (relating to internal control systems and audit protocols).
- (c) The internal control procedures developed and implemented by the slot machine licensee under subsection (b) must include:
- (1) A requirement that customer deposits be accepted at the cage.
- (2) A requirement that customer deposits be withdrawn by the patron at the cage, gaming table or upon receipt of a written request for withdrawal whose validity has been established.
- (3) A requirement that the patron receive a receipt for any customer deposit accepted reflecting the total amount deposited, the date of the deposit and the signature of the cage employee accepting the customer deposit.
- (4) Procedures for verifying the identity of the patron at the time of withdrawal. Signature verification shall be accomplished in accordance with the signature verification procedures under § 465a.20. The slot machine licensee shall maintain adequate documentation evidencing the patron identification process and how the signature was verified.

§ 465a.26. Jackpot and credit meter payouts.

* * * * *

- (b) The internal control procedures must, at a minimum, include:
- (1) The use of a two-part electronically generated jackpot/credit meter payout slip created by a slot attendant or slot supervisor or higher slot operations department employee, verifying the winning wager or winning combination of characters or a code corresponding to the winning combination of characters on the slot machine or fully automated electronic gaming table and the amount of the jackpot or credit meter payout based on the observed winning wager or winning combinations.
- (2) A requirement that if the jackpot or credit meter payout on a slot machine is equal to or between \$1,200 and \$9,999.99, a security department member or a slot operations department member other than the preparer shall sign the jackpot/credit meter payout slip verifying the winning combination of characters or a code corresponding to the winning combination of characters on the slot machine, the amount of the jackpot or credit meter payout and the payment of the jackpot or credit meter payout to the patron. Notwithstanding the forgoing, if the licensee's slot or casino management system can independently verify a jackpot or credit meter payout, only the preparer is required to sign the jackpot/credit meter payout slip for payouts less than or equal to \$4,999.99 provided that the slot machine licensee's internal control reflect the following:
- (i) If the slot machine licensee's slot or casino management system or the central control computer system are not fully operational, or when overrides or adjustments are required, two individuals shall verify a jackpot or credit meter payout that is equal to or between \$1,200 and \$9,999.99 as specified in this paragraph.
- (ii) Jackpot payouts that are equal to or greater than \$1,200 shall be accompanied by the issuance of a W-2G Form.

- (3) A requirement that if the jackpot or credit meter payout is equal to or between \$10,000 and \$24,999.99 on a slot machine, or between \$5,000 and \$24,999.99 on a fully automated electronic gaming table, a security department member, a slot supervisor or other employee holding the same or greater level of authority than a slot supervisor shall sign the jackpot/credit meter payout slip verifying the winning wager or winning combination of characters or a code corresponding to the winning combination of characters on the slot machine or fully automated electronic gaming table, the amount of the jackpot or credit meter payout, and the payment of the jackpot or credit meter payout to the patron. If the two-part electronically generated jackpot/credit meter payout slip required under paragraph (1) is created by a slot supervisor or higher slot operations department employee, the verification required by this paragraph may be completed by a slot attendant, security department member, a slot supervisor or other employee holding the same or greater level of authority as a slot supervisor.
- (4) A requirement that if the jackpot or credit meter payout on a slot machine or fully automated electronic gaming table is \$25,000 or more, a slot supervisor or other employee holding the same or greater level of authority as a slot supervisor shall sign the jackpot/credit meter payout slip verifying the winning wager or winning combination of characters or a code corresponding to the winning combination of characters on the slot machine or fully automated electronic gaming table, the amount of the jackpot or credit meter payout, and the payment of the jackpot or credit meter payout to the patron. If the two-part electronically generated jackpot/credit meter payout slip required under paragraph (1) is created by a slot supervisor or higher slot operations department employee, the verification required by this paragraph may be completed by a slot attendant, security department member, a slot supervisor or other employee holding the same or greater level of authority as a slot supervisor.
- (5) A requirement that the following information be on all two-part electronically generated jackpot/credit meter payout slips:
- (i) The date and time of the jackpot or credit meter payout.
- (ii) The asset number of the slot machine or fully automated electronic gaming table on which the jackpot or credit meter payout was registered.
- (iii) The winning wager or winning combination of characters constituting the jackpot or a code corresponding to the winning combination of characters constituting the jackpot.
- (iv) The type of win (that is, progressive, jackpot or credit meter payout).
- (v) The amount that is to be paid to the winning patron. This amount may, at the slot machine licensee's discretion, be rounded up to the nearest whole dollar.
- (vi) A unique number generated by the slot monitoring system.
- (vii) The signature or, if the slot accounting system has approved controls for access to the system, the electronic authorization of the preparer.
- (viii) The signature or, if the slot accounting system has appropriate controls for access, the electronic authorization of the witness when the amount is equal to or greater than \$1,200, except as provided in paragraph (2).
- (ix) The signature or identification code of the cashier providing the funds to the preparer, if applicable.

- (6) A requirement that the two-part electronically generated jackpot/credit meter payout slip not be susceptible to any changes or deletion from the slot monitoring system by any personnel after preparation.
- (7) A requirement that whenever a winning patron is paid directly by a slot attendant's imprest fund, a two-part manual jackpot/credit meter payout slip is completed that contains the following information:
- (i) The date and time of the jackpot or credit meter payout.
- (ii) The asset number of the slot machine or fully automated electronic gaming table on which the jackpot or credit meter payout was registered.
- (iii) The winning wager or winning combination of characters constituting the jackpot or a code corresponding to the winning combination of characters constituting the jackpot.
- (iv) The type of win (that is, progressive, jackpot or credit meter payout).
- (v) The amount paid to the winning patron. This amount may, at the slot machine licensee's discretion, be rounded up to the nearest whole dollar.
- (vi) The signature and Board-issued credential number of the preparer.
- (vii) The signature and Board-issued credential number of the witness when the amount is equal to or greater than \$1,200, except as provided in paragraph (2).

- (a) Automated teller machines may be placed at any location within a licensed facility. Automated teller machines that offer credit card advances may not be placed on the gaming floor.
- (b) An automated teller machine must have a label on the top and front of the automated teller machine that displays a unique identification number of the automated teller machine. The labels must have white lettering on a black background or another color combination approved by the Bureau of Casino Compliance, may not be easily removed and must be easily visible to the surveillance department. The label on the top of the automated teller machine must be at least 1.5 inches by 5.5 inches and the label on the front of the automated teller machine must be at least 1 inch by 2.5 inches.
- (c) A slot machine licensee may utilize an automated teller machine that also contains an automated gaming voucher redemption machine, an automated coupon redemption machine or bill breaker provided that the machine complies with § 465a.34 (relating to automated gaming voucher and coupon redemption machine accounting controls).
- (d) Automated teller machines located within a licensed facility may not accept Pennsylvania Access/Electronic Benefits Transfer Cards.

Subpart G. MINORITY AND WOMEN'S BUSINESS ENTERPRISES

CHAPTER 481a. DIVERSITY

§ 481a.3. Diversity participation.

(a) The list of the minority and women's business enterprises that are verified by the Bureau of Small Business Opportunities of the Department of General Services under 62 Pa.C.S. Part I (relating to Common-

- wealth Procurement Code) may be used by a regulated entity to establish the eligibility of an enterprise as a minority or women's business enterprise for the purpose of promoting and ensuring minority and women's business participation.
- (b) It is the responsibility of the regulated entity to verify that a minority or women's business enterprise that is not verified by the Bureau of Small Business Opportunities of the Department of General Services is a minority or women's business enterprise as defined in 4 Pa. Code § 58.302 (relating to definitions).

§ 481a.6. Diversity reviews.

- (a) Onsite diversity reviews may be performed on an annual basis or at the discretion of Board staff to ensure compliance with this chapter.
- (b) Advanced written notice will be provided to a regulated entity prior to the conduct of an onsite diversity review by Board staff.

Subpart I. COMPULSIVE AND PROBLEM GAMBLING

CHAPTER 501a. COMPULSIVE AND PROBLEM GAMBLING REQUIREMENTS

§ 501a.1. Definitions.

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

Advertisement—Gaming related marketing materials including a notice or communication by a licensee, certified or registered entity or its agent to the public through signs, billboards, broadcasts, publications, mail, e-mail, text message, tweet or other means of dissemination.

OCPG—The Office of Compulsive and Problem Gambling.

§ 501a.2. Compulsive and problem gambling plan.

- (a) An applicant for a slot machine license shall submit a compulsive and problem gambling plan for review at the time of submission of the application. The plan must, at a minimum, contain the elements listed in subsection (d).
- (b) The compulsive and problem gambling plan of an applicant for a slot machine license that has been approved to receive a slot machine license must be approved by the Director of OCPG. An applicant for a slot machine license who has been approved to receive a slot machine license will be notified in writing of any deficiencies in the plan and may submit revisions to the plan to the Director of OCPG. A slot machine licensee may not commence operations until the Director of OCPG approves the plan.

* * * * *

- (f) The Board may provide the plan submitted by the slot machine licensee to the Department of Health for its use in administering the act. The Department of Health may provide comments and recommendations to the OCPG and the licensee relating to the plan.
- (g) A slot machine licensee shall submit amendments to the compulsive and problem gambling plan to the Director of OCPG for review and approval at least 30 days prior to the intended implementation date of the amendments. The slot machine licensee may implement the amendments on the 30th calendar day following the

filing the amendments unless the slot machine licensee receives a notice under subsection (h) objecting to the amendments.

- (h) If during the 30-day review period the Director of OCPG determines that the amendments may not promote the prevention of compulsive and problem gambling or assist in the proper administration of responsible gaming programs, the Director of OCPG may, by written notice to the slot machine licensee, object to the amendments. The objection will:
- (1) Specify the nature of the objection and, when possible, an acceptable alternative.
- (2) Direct that the amendments not be implemented until approved by the Director of OCPG.
- (i) When amendments have been objected to under subsection (h), the slot machine licensee may submit revised amendments for review in accordance with subsections (g) and (h).

§ 501a.3. Employee training program.

- (a) The employee training program required under § 501a.2(d)(5) (relating to compulsive and problem gaming plan) must include instruction in the following:
- (1) Characteristics and symptoms of compulsive behavior, including compulsive and problem gambling.
- (2) The relationship of compulsive and problem gambling to other addictive behavior.
- (3) The social and economic consequences of compulsive and problem gambling, including debt, treatment costs, suicide, criminal behavior, unemployment and domestic issues
- (4) Techniques to be used when compulsive and problem gambling is suspected or identified.
- (5) Techniques to be used to discuss compulsive and problem gambling with patrons and advise patrons regarding community, public and private treatment services.
- (6) Procedures designed to prevent serving alcohol to visibly intoxicated gaming patrons.
- (7) Procedures designed to prevent persons from gaming after having been determined to be visibly intoxicated.
- (8) Procedures for the dissemination of written materials to patrons explaining the self-exclusion program.
- (9) Procedures for removing an excluded person, an underage individual or a person on the self-exclusion list from a licensed facility including, if necessary, procedures that include obtaining the assistance of appropriate law enforcement personnel.
- (10) Procedures for preventing an excluded person or a person on the self-exclusion list from being mailed any advertisement, promotion or other target mailing no later than 5 business days after receiving notice from the Board that the person has been placed on the excluded person or self-exclusion list.
- (11) Procedures for preventing an individual under 21 years of age from receiving any advertisement, promotion or other target mailing.
- (12) Procedures to prevent an excluded person, an individual under 21 years of age or a person on the self-exclusion list from having access to or from receiving complimentary services, or other like benefits.

- (13) Procedures to prevent an excluded person, an individual under 21 years of age or a person on the self-exclusion list from cashing checks.
- (b) Training and training materials shall be updated annually and include current research and information on responsible and problem gambling.
- (c) Training for employees shall be conducted by a person with specialized knowledge, skill, training and experience in responsible gaming employee training programs as part of the employee's orientation.
- (d) Employees who have received training shall be certified by the slot machine licensee under § 501a.2(d)(6) upon completion of the training.
- (e) Employees are required to receive periodic reinforcement training at least once every calendar year starting with the year following the year in which the employee was hired. The date of the reinforcement training shall be recorded in each employee's personnel file.
- (f) Employees shall report suspected or identified compulsive or problem gamblers to a designated key employee or other supervisory employee.
- (g) The identity of an individual suspected of known compulsive or problem gambling shall be confidential except as provided under § 503a.3(f) (relating to self-exclusion list) and section 1516(d) of the act (relating to list of persons self excluded from gaming activities).
- (h) Slot machine licensees may collaborate with a person with specialized knowledge, skill, training and experience in responsible gaming employee training programs to develop an in-house or Internet-based employee training program to provide the training and reinforcement training required under this chapter.

§ 501a.5. Signage requirements.

Under section 1509(c) of the act (relating to compulsive and problem gambling program), each slot machine licensee shall post at least 20 signs that include a gambling assistance message that complies with \S 501a.7(d) (relating to advertising). The complete text of the sign shall be submitted for approval to the Director of OCPG utilizing the process contained in \S 501a.2(g) (relating to compulsive and problem gambling plan). The signs must be prominently posted at the following locations:

- (1) Within 50 feet of each entrance and exit of the facility.
- (2) Above or below the cash dispensing opening on all automated teller machines, automated gaming voucher and coupon redemption machines, and other machines that dispense cash to patrons in the licensed facility.

§ 501a.6. (Reserved).

§ 501a.7. Advertising.

- (a) A licensee, certified or registered entity, or its agent may not employ or contract with an individual or entity to persuade or convince a person to engage in gaming or play a specific slot machine or table game while on the gaming floor of a licensed facility.
- (b) A licensee, certified or registered entity, or its agent shall discontinue as expeditiously as possible the use of a particular advertisement upon receipt of written notice that the OCPG has determined that the use of the particular advertisement in, or with respect to, this Commonwealth could adversely impact the public or the integrity of gaming.

- (c) Advertisements used by a licensee, certified or registered entity, or its agent may not:
 - (1) Contain false or misleading information.
- (2) Fail to disclose conditions or limiting factors associated with the advertisement.
- (3) Use a font, type size, location, lighting, illustration, graphic depiction or color obscuring conditions or limiting factors associated with the advertisement or the statement required under subsection (d).
- (d) Advertisements must contain a gambling assistance message that is similar to one of the following:
- (1) If you or someone you know has a gambling problem, help is available. Call (toll free telephone number).
- (2) Gambling Problem? Please call (toll free telephone number).
- (3) Gambling Problem? Call (toll free telephone number).
- (e) The complete text of the gambling assistance message and the font to be used for the statement, if it has not been previously approved, shall be submitted to the Director of OCPG for approval utilizing the process in § 501a.2(g) (relating to compulsive and problem gambling plan) and comply with the following:
- (1) For signs, direct mail marketing materials, posters and other print advertisements, the height of the font used for the gambling assistance message must be the greater of:
- (i) The same size as the majority of the text used in the sign, direct mail marketing material, poster or other print advertisement.
- (ii) Two percent of the height or width, whichever is greater, of the sign, direct mail marketing material, poster or other print advertisement.
- (2) For billboards, the height of the font used for the gambling assistance message must be at least 5% of the height or width, whichever is greater, of the face of the billboard.
- (3) For video and television, the gambling assistance message must be visible for either:
- (i) The entire time the video or television advertisement is displayed. The height of the font used for the gambling assistance message must be at least 2% of the height or width, whichever is greater, of the image that will be displayed.
- (ii) From the first time a table game, table game device, slot machine, associated equipment or casino name is displayed or verbally referenced, and on a dedicated screen shot visible for at least the last 3 seconds of the video or television advertisement. If the licensee elects to utilize this option, the height of the font used for the gambling assistance message displayed:
- (A) During the advertisement must be at least 2% of the height or width, whichever is greater, of the image that will be displayed.
- (B) On the dedicated screen shot must be at least 8% of the height or width, whichever is greater, of the image that will be displayed.
 - (4) For web sites, including social media sites:
- (i) The gambling assistance message must be posted on each webpage or profile page and on a gaming related advertisement posted on the webpage or profile page.

- (ii) The height of the font used for the gambling assistance message must be at least the same size as the majority of the text used in the webpage or profile page.
- (iii) For advertisements posted on the webpage or profile page, the height of the font used for the gaming assistance message must comply with paragraph (1).

CHAPTER 503a. SELF-EXCLUSION

§ 503a.1. Definitions.

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

Fully executed gaming transaction—An activity involving a slot machine, table game or associated equipment which occurs on the gaming floor of a licensed facility or in areas off the gaming floor where contests or tournaments are conducted which results in an individual obtaining any money or thing of value from, or being owed any money or thing of value by, a slot machine licensee or slot system operator.

Gaming activity—The play of slot machines or table games including play during contests, tournaments or promotional events.

Gaming related activity—An activity related to the play of slot machines or table games including applying for player club memberships or credit, cashing checks, or accepting a complimentary gift, service, promotional item or other thing of value at a licensed facility.

OCPG—Office of Compulsive and Program Gambling.

Self-excluded person—A person whose name and identifying information is included, at the person's own request, on the self-exclusion list maintained by the Board.

Self-exclusion list—A list of names and identifying information of persons who, under this chapter, have voluntarily agreed to be:

- (i) Excluded from the gaming floor and areas off the gaming floor where gaming activity is conducted.
- (ii) Excluded from engaging in all gaming related activities at a licensed facility.
- (iii) Prohibited from collecting any winnings or recovering any losses resulting from gaming activity.

Winnings—Any money or thing of value received from, or owed by, a slot machine licensee or slot system operator as a result of a fully executed gaming transaction

§ 503a.2. Request for self-exclusion.

- (a) A person requesting placement on the self-exclusion list shall submit, in person, a completed Request for Voluntary Self-exclusion from Gaming Activities Form to the Board. The submission may be made by scheduling an appointment at the Board's Harrisburg office, one of the Board's other offices or at a licensed facility. To make an appointment, a person may contact the OCPG at (717) 346-8300.
- (b) A request for self-exclusion must include the following identifying information:
 - (1) Name, including any aliases or nicknames.
 - (2) Date of birth.
 - (3) Address of current residence.
 - (4) Telephone number.

- (5) Social Security number, when voluntarily provided in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C.A. § 552a).
- (6) Physical description of the person, including height, weight, gender, hair color, eye color and any other physical characteristic that may assist in the identification of the person.
- (c) The information provided in subsection (b) shall be updated by the self-excluded person within 30 days of a change. Updated information shall be submitted on a Change of Information Form to the following address. A copy of the form can be obtained by calling the OPCG at (717) 346-8300 or by writing to:

PENNSYLVANIA GAMING CONTROL BOARD

OFFICE OF COMPULSIVE AND PROBLEM GAMBLING P. O. BOX 69060 HARRISBURG, PA 17106-9060

- (d) The length of self-exclusion requested by a person must be one of the following:
 - (1) One year (12 months).
 - (2) Five years.
 - (3) Lifetime.
- (e) A request for self-exclusion must include a signed release which:
- (1) Acknowledges that the request for self-exclusion has been made voluntarily.
- (2) Certifies that the information provided in the request for self-exclusion is true and accurate.
- (3) Acknowledges that the individual requesting self-exclusion is a problem gambler.
- (4) Acknowledges that a person requesting a lifetime exclusion is prohibited from requesting removal from the self-exclusion list and that a person requesting a 1-year or 5-year exclusion will remain on the self-exclusion list until a request for removal under § 503a.5 (relating to removal from self-exclusion list) is approved.
- (5) Acknowledges that if the individual is discovered on the gaming floor, in areas off the gaming floor where gaming activity is conducted or engaging in gaming related activities at any licensed facility, that the individual will be subject to removal and arrest for criminal trespass under 18 Pa.C.S. § 3503 (relating to criminal trespass) and the individual's winnings will be subject to confiscation and remittance to support compulsive and problem gambling programs.
- (6) Releases, indemnifies, holds harmless and forever discharges the Commonwealth, the Board and all slot machine licensees from claims, damages, losses, expenses or liability arising out of, by reason of or relating to the self-excluded person or to any other party for any harm, monetary or otherwise, which may arise as a result of one or more of the following:
- (i) The failure of a slot machine licensee to withhold gaming privileges from or restore gaming privileges to a self-excluded person.
- (ii) Otherwise permitting or not permitting a self-excluded person to engage in gaming activity in a licensed facility while on the list of self-excluded persons.
 - (iii) Confiscation of the individual's winnings.

- (f) Self-exclusions for 1 year or 5 years remain in effect until the period of self-exclusion concludes and the person requests removal from the Board's self-exclusion list under § 503a.5.
- (g) A person submitting a self-exclusion request shall present a valid government-issued photo identification containing the person's signature and photograph when the person submits the request.
- (h) A person requesting self-exclusion under this chapter shall have a photograph taken by the Board, or agent thereof, upon acceptance of the request to be on the list.

§ 503a.4. Duties of slot machine licensees.

- (a) A slot machine licensee shall train its employees and establish procedures to:
- (1) Identify a self-excluded person when present on the gaming floor, in areas off the gaming floor where gaming activity is conducted or engaging in gaming related activities and, upon identification, immediately notify the following persons:
- (i) Employees of the slot machine licensee whose duties include the removal of self-excluded persons.
- (ii) Casino compliance representatives at the licensed facility.
 - (iii) The Pennsylvania State Police.
- (2) Refuse wagers from and deny gaming privileges to a self-excluded person.
- (3) Deny gaming related activities, gaming junket participation and other similar privileges and benefits to a self-excluded person.
- (4) Ensure that self-excluded persons do not receive, either from the slot machine licensee or any agent thereof, gaming junket solicitations, targeted mailings, telemarketing promotions, player club materials or other promotional materials relating to gaming activities at its licensed facility as required under § 501a.3(a)(10) (relating to employee training program).
- (5) Comply with \S 503a.3(d) (relating to self-exclusion list).
- (6) Make available to patrons written materials explaining the self-exclusion program.
- (b) A slot machine licensee shall submit a copy of its procedures and training materials established under subsection (a) to the Director of OCPG for review and approval at least 30 days prior to initiation of gaming activities at the licensed facility. The slot machine licensee will be notified in writing of any deficiencies in the procedures and training materials and may submit revisions to the procedures and training materials to the Director of OCPG. A slot machine licensee may not commence operations until the Director of OCPG approves the procedures and training.
- (c) A slot machine licensee shall submit amendments to the procedures and training materials required under subsection (b) to the Director of OCPG for review and approval at least 30 days prior to the intended implementation date of the amendments. The slot machine licensee may implement the amendments on the 30th calendar day following the filing of the amendments unless the slot machine licensee receives a notice under subsection (d) objecting to the amendments.
- (d) If during the 30-day review period the Director of OCPG determines that the amendments to the procedures and training materials may not promote the prevention of

gaming by self-excluded individuals or assist in the proper administration of the self-exclusion program, the Director of OCPG may, by written notice to the slot machine licensee, object to the amendments. The objection will:

- (1) Specify the nature of the objection and, when possible, an acceptable alternative.
- (2) Direct that the amendments not be implemented until approved by the Director of OCPG.
- (e) When the amendments to the procedures and training materials have been objected to under subsection (d), the slot machine licensee may submit revised amendments in accordance with subsections (c) and (d).
- (f) A slot machine licensee shall post signs at all entrances to a licensed facility indicating that a person who is on the self-exclusion list will be subject to arrest for trespassing under 18 Pa.C.S. § 3503 (relating to criminal trespass) if the person is on the gaming floor, in areas off the gaming floor where gaming activity is conducted or engaging in gaming related activities in the licensed facility. The text and font size of the signs shall be submitted for approval to the Director of OCPG under the procedures specified in subsection (b).
- (g) The list of self-excluded persons is confidential, and any distribution of the list to an unauthorized source constitutes a violation of the act.
- (h) Under section 1516 of the act (relating to list of persons self excluded from gaming activities), slot machine licensees and employees thereof may not be liable for damages in any civil action, which is based on the following:
- (1) Failure to withhold gaming privileges from or restore gaming privileges to a self-excluded person.
- (2) Permitting or not permitting a self-excluded person to gamble.
- (3) Good faith disclosure of the identity of a self-excluded person to someone, other than those authorized by this chapter, for the purpose of complying with this chapter.
- (i) A slot machine licensee shall report the discovery of a self-excluded person on the gaming floor, in areas off the gaming floor where gaming activity is conducted or engaging in gaming related activities to the Director of OCPG within 24 hours.

§ 503a.5. Removal from self-exclusion list.

- (a) For individuals who are self-excluded for 1 year or 5 years, upon the conclusion of the period of self-exclusion, the individual may request removal from the self-exclusion list by scheduling an appointment with the OCPG at (717) 346-8300. At the scheduled appointment time, the individual requesting removal shall submit, in person, a completed Request for Removal from Voluntary Self-Exclusion Form as required under subsections (b) and (c). With an appointment, removal from the list may be conducted at the Board's Harrisburg office, one of the Board's regional offices or other location approved by the OCPG
- (b) A Request for Removal from Voluntary Self-Exclusion Form must include:
- (1) The identifying information specified in § 503a.2(b) (relating to request for self-exclusion).
- (2) The signature of the person requesting removal from the self-exclusion list indicating acknowledgment of the following statement:

- "I certify that the information that I have provided above is true and accurate. I am aware that my signature below constitutes a revocation of my previous request for self-exclusion, and I authorize the Board to permit all slot machine licensees of the Commonwealth of Pennsylvania to reinstate my gaming privileges at licensed facilities."
- (c) A person submitting a Request for Removal from Voluntary Self-Exclusion Form shall be required to present a valid government-issued photo identification containing the person's signature when the form is submitted during the person's scheduled appointment.
- (d) Within 15 business days after the Request for Removal from Voluntary Self-Exclusion Form is accepted by Board staff, the OCPG will delete the name of the individual from the self-exclusion list and notify each slot machine licensee of the removal. An individual who was removed from the voluntary self-exclusion list may not enter the gaming floor, areas off the gaming floor where contests or tournaments are conducted or engage in gaming related activities for 15 business days from the date Board staff accepts the request to be removed from the voluntary self-exclusion list or may be subject to arrest for trespassing under 18 Pa.C.S. § 3503 (relating to criminal trespass).

§ 503a.6. Exceptions for individuals on the selfexclusion list.

The prohibition against allowing self-excluded persons to be on the gaming floor or in areas off the gaming floor where gaming activity is conducted does not apply to an individual who is on the self-exclusion list if all of the following apply:

- (1) The individual is carrying out the duties of employment or incidental activities related to employment.
- (2) The slot machine licensee's security department and the Board's office located at the licensed facility have received prior notice.
- (3) Access to the gaming floor or areas off the gaming floor where gaming activity is conducted is limited to the time necessary to complete the individual's assigned duties.
- (4) The individual does not otherwise engage in any gaming activities.

§ 503a.7. Disclosure of information related to persons on the self-exclusion list.

- (a) The Board may periodically release to the public demographics and general information regarding the self-exclusion list such as the total number of individuals on the list, gender breakdown and age range.
- (b) The Board may make selected data available, upon request, for the limited purpose of assisting in the proper administration of responsible gaming programs.
- (c) The Board will not disclose identifying information or confirm or deny the existence of an individual's name on the Board's voluntary self-exclusion list.

CHAPTER 503b. (Reserved)

§ 503b.1. (Reserved).

Subpart J. EXCLUSION OF PERSONS CHAPTER 513a. UNDERAGE GAMING

§ 513a.1. Definitions.

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

Fully executed gaming transaction—An activity involving a slot machine, table game or associated equipment which occurs on the gaming floor of a licensed facility or in areas off the gaming floor where contests or tournaments are conducted and which results in an individual obtaining any money or thing of value from, or being owed any money or thing of value by, a slot machine licensee

OCPG—The Office of Compulsive and Problem Gambling.

Winnings—Any money or thing of value received from, or owed by, a slot machine licensee as a result of a fully executed gaming transaction.

§ 513a.3. Responsibilities of licensees, permittees, registrants and certification holders.

- (a) A person holding a license, permit, certification or registration issued by the Board is prohibited from permitting or enabling an individual to engage in conduct that violates § 513a.2(a), (b), (c) or (d) (relating to exclusion requirements).
- (b) The slot machine licensee shall train its employees and establish procedures to:
- (1) Identify and remove individuals who are less than 21 years of age and not otherwise authorized to be in the licensed facility as provided in § 513a.2(a).
- (2) Immediately notify the casino compliance representatives at the licensed facility and the Pennsylvania State Police when an individual less than 21 years of age is discovered on the gaming floor, in areas off the gaming floor where gaming activity is conducted or engaging in gaming related activities.
- (3) Refuse wagers from and deny gaming privileges to an individual less than 21 years of age.
- (4) Deny check cashing privileges, player club memberships, extensions of credit, complementary goods and services, junket participation, and other similar privileges and benefits to an individual less than 21 years of age.
- (5) Ensure that individuals less than 21 years of age do not receive, either from the slot machine licensee or an agent thereof, junket solicitations, targeted mailing, telemarketing promotions, player club membership materials or other promotional materials relating to gaming activities.
- (c) Slot machine licensees shall establish procedures to prevent violations of this chapter and submit a copy of the procedures to the Director of OCPG 30 days prior to initiation of gaming activities at the licensed facility. A slot machine licensee will be notified in writing of any deficiencies in the plan and may submit revisions to the plan to the Director of OCPG. The slot machine licensee may not commence operations until the Director of OCPG approves its procedures. Amendments to these procedures must be submitted to and approved by the Director of OCPG prior to implementation.

- (d) A slot machine licensee may be subject to Board imposed administrative sanctions if a person engages in conduct that violates § 513a.2(a), (b), (c) or (d) at its licensed facility. Under § 513a.2(e), winnings obtained by a slot machine licensee from or held on account of a person under 21 years of age shall be remitted to the Board to support compulsive and problem gambling programs of the Board.
- (e) A person holding a license, permit, registration or certification issued by the Board who violates a provision of this chapter may be held jointly or severally liable for the violation.

§ 513a.4. Signage requirements.

A slot machine licensee shall post signs that include a statement that is similar to the following: "It is unlawful for any individual under 21 years of age to enter or remain in any area where slot machines or table games are operated. It is unlawful for any individual under the age of 21 to wager, play or attempt to play a slot machine or table game. Individuals violating this prohibition will be removed and may be subject to arrest and criminal prosecution." The complete text of the sign shall be submitted to and approved by the Director of OCPG as part of the procedures required under § 513a.3(b) (relating to responsibilities of licensees, permittees, registrants and certification holders). The signs shall be prominently posted within 50 feet of each entrance and exit of the gaming floor.

Subpart K. TABLE GAMES CHAPTER 603a. TABLE GAME EQUIPMENT

§ 603a.12. Dice; physical characteristics.

(c) Dice used in the table game of Sic Bo must comply with subsection (a) except each die used in an automated Sic Bo shaker must be formed in the shape of a cube 0.625 inch on each side with ball edge corners.

CHAPTER 633a. BLACKJACK

§ 633a.13. Payout odds; payout limitation.

* * * * *

(k) The certificate holder shall pay out winning Three Card Poker Wagers at odds in one of the following pay tables selected by the certificate holder in its Rules Submission filed in accordance with § 601a.2:

Hand			Payt	able A	1	$Paytable\ B$
Straight Flush Three-of-a-kind				9 to 1 9 to 1	_	30 to 1 20 to 1
Straight				9 to 1	L	10 to 1
Flush	*	*	*	9 to 1	Į.	5 to 1

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