Regulatory Analysis Form

(Completed by Promulgating Agency)

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INDEPENDENT REGULATORY REVIEW COMMISSION

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(1) Agency: Department of Environmental Protection

(2) Agency Number:

Identification Number: #7-480

IRRC Number: 3017

(3) PA Code Cite: 25 Pa Code Chapters 271, 272, 273, 284, 285, 287, 288, and 299

(4) Short Title: Regulated Medical and Chemotherapeutic Waste

(5) Agency Contacts (List Telephone Number and Email Address):

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(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
- ☐ Certification by the Governor
- ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Department of Environmental Protection's (Department) Bureau of Waste Management regulates and oversees the management and disposal of wastes that are generated from the diagnosis, treatment, immunization, or autopsy of human beings and animals.

This final-form rulemaking will bring Pennsylvania's regulated medical and chemotherapeutic waste provisions up to date and consistent with federal requirements. This regulation will:

- Change the terminology from "infectious waste" to "regulated medical waste";
- Exempt certain wastes generated by biologics facilities from the definitions of infectious waste and infectious agent based upon the federal classification of the waste;
- Clarify and streamline the storage, transportation and shipment requirements of regulated medical waste to recognize business practices, and encourage labor and fuel efficiency;
- Incorporate permits-by-rule for processing and treatment of regulated medical waste;
- Allow the use of standard business documentation, including electronic tracking systems, to record the proper processing and disposal of regulated medical waste;
- Allow the transportation of regulated medical waste through the U.S. Postal Service (USPS); and
- Eliminate provisions that relate to areas governed by the Occupational Safety and Health Association (OSHA) to avoid inconsistencies and duplication.

(8) State the statutory authority for the regulation. Include specific statutory citation.

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

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

The Infectious and Chemotherapeutic Waste Disposal Law, which at Section 6019.4(b), (35 P.S. § 6019.4(b)) grants the Board the power and duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the law and which at Section 6019.2(b) (35 P.S. § 6019.2(b)) provides the Department with the authority to review and revise regulations as necessary.

The Administrative Code of 1929 (71 P.S. §§ 510-1 - 510-27), which at Section 1917-A (71 P.S. § 510-17) authorizes and requires the Department to protect the people of this Commonwealth from unsanitary conditions and other nuisances, including any condition that is declared to be a nuisance by any law administered by the Department. Section 1920-A (71 P.S. § 510-20), which grants the Board the power and duty to formulate, adopt and promulgate such rules and regulations as may be determined by the Board for the proper performance of the work of the Department.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

This regulation is not mandated by any federal law or federal regulation.

This regulation is not mandated by, or related to, any federal or state court decision.

The Pennsylvania Infectious and Chemotherapeutic Waste Disposal Law requires a manifest system to track infectious and chemotherapeutic wastes.

Regulated medical and chemotherapeutic wastes are solid wastes under the Solid Waste Management Act and must be managed in accordance with the rules and regulations pursuant to that Act.

There are no deadlines associated with the regulations.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation of infectious waste (regulated medical waste) and chemotherapeutic waste is necessary to protect the overall health and safety of the public. Blood and bodily fluid have the ability to carry pathogenic organisms that can cause infections and diseases in humans or animals that come into contact with them. Chemotherapeutic drugs are inherently toxic substances. Their toxic effects can pose a threat to otherwise healthy individuals that come into contact with discarded medical devices or supplies used to administer drugs to patients for the treatment of cancer or contain residual amounts of chemotherapeutic substances.

Current regulations are not aligned with nationwide practices and place Pennsylvania at a disadvantage. New streamlined regulations will provide equivalent environmental protection with a more efficient process, which will benefit medical practitioners, medical facilities, transporters of and processors of regulated medical and chemotherapeutic waste (see number (15) for a breakdown of the number of facilities that will benefit). This rulemaking will allow an estimated 16,303 entities managing regulated medical and chemotherapeutic waste to better understand Pennsylvania's requirements and eliminate duplicative and other outdated requirements, as elaborated below:

Labeling

Currently, medical facilities in Pennsylvania are required to have two labels on their waste receptacles, one that reads "infectious waste" to comply with Pennsylvania regulations, and one that reads "regulated medical waste" to comply with Federal requirements. This final-form rulemaking will identify "infectious waste" as "regulated medical waste," making the terminology consistent with federal requirements and thus eliminating the need for two separate labels. This uniform practice should reduce the costs borne by waste generators and other persons managing regulated medical waste because the same containers and labels could be used to satisfy Pennsylvania requirements and the requirements imposed by federal agencies.

Storage

In Pennsylvania, medical facilities are currently required to seal medical waste disposal containers, such as boxes or bags, for disposal within 30 days of placing the first waste item in the container. This final-form rulemaking will allow generators to store regulated medical and chemotherapeutic waste for a longer time period: 30 days after the date the container is full or sealed, whichever occurs first. This will provide the generator with more control over the length of time the waste is stored on-site and promotes more efficient business practices by reducing the need to transport partially filled containers. This change encourages transporter labor savings and fuel efficiency, while maintaining the integrity of Pennsylvania's regulated medical waste management and disposal requirements.

Transportation and Shipping

The 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 the currently prescribed, but outdated, paper manifest. The rulemaking includes provisions 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. This provision will allow the generators and haulers to choose which tracking option is best to satisfy their compliance needs.

Additionally, the rulemaking allows authorized waste haulers, under certain conditions, to transport containerized regulated medical and chemotherapeutic wastes along with other containerized wastes in the same vehicle. This will reduce the number of trips needed to transport waste from generators that have both regulated medical and chemotherapeutic waste and other wastes requiring disposal, increasing fuel efficiency and reducing the hauling costs borne by the generators.

The rulemaking also allows the shipment of regulated medical waste through the USPS, in accordance with its program and requirements. Currently, sharps from small quantity generators may be sent through

the mail. This rulemaking will broaden the authorization to include other types of regulated medical waste, providing facilities more options for transporting their regulated medical waste to a processing or disposal site.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The Department is not aware of any provisions in the final-form rulemaking that are more stringent than federal requirements.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

The rulemaking reflects a global change in terminology from "infectious waste" to "regulated medical waste," which is consistent with how federal agencies identify this waste stream. By making the terminology consistent with federal requirements, containers used for collection, storage and transportation could be used, processed and reused without the need for any additional marking or labeling requirements. Additionally, the changes in the manifesting system should allow easier transport between states and decrease the amount of paperwork that generators and transporters would need to complete in order to comply with Pennsylvania's regulations. Rather than continuing to use a dedicated Department form and require that copies of that form accompany the waste shipment, the manifesting requirements can now be met with a generic shipping paper, log or electronic tracking system accompanying the waste stream, provided it includes all the required information.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The rulemaking is not expected to affect any other regulations of the Department.

The Department of Corrections and health centers operated by the Department of Health will be regulated under this final-form rulemaking. The benefits of the rulemaking will be realized by these facilities in the same manner that they will be realized by all generators, processors and transporters of regulated medical and chemotherapeutic waste (see numbers 15, 17 & 18).

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

In April of 2008, the Department conducted a Regulatory Review Meeting with representatives of the following groups: Stericycle, Inc., the nation's largest medical waste transportation and disposal company serving hospitals, dentist offices, long-term care facilities, medical laboratories, and physician's offices, including those that qualify as a small business; the American Red Cross; Thomas Jefferson University Hospital/Greater Philadelphia American Society Healthcare Environmental Services; Children's Hospital of Philadelphia; University of Pennsylvania Health System; University of Pennsylvania; Pugliese Associates; and Johnson & Johnson Pharmaceutical Research and Development.

In September of 2011, the Department's Solid Waste Advisory Committee (SWAC) considered the proposed amendments to these regulations and urged the Department to present them to the Environmental Quality Board for action.

In November of 2012, the Department presented this proposed rulemaking to the Department's Small Business Compliance Advisory Committee (SBCAC). The SBCAC is comprised of nine small business owners and other representatives from around the state, including the Department's Small Business Ombudsman. The committee voiced support for this rulemaking and wrote a letter of support, stating that these regulations will benefit small and rural health facilities by helping them to comply with regulatory requirements for management of regulated medical and chemotherapeutic waste.

The Department also contacted the Pennsylvania Medical Society, the Pennsylvania Dental Association, and the Pennsylvania Veterinary Medical Association regarding the proposed amendments. All were provided copies of the draft proposed rulemaking approved by the SWAC in 2011, as well as a summary of the proposed changes. The Department met with a representative of the Pennsylvania Medical Society on January 29, 2013, to discuss the regulatory changes proposed and additional opportunities for outreach to small businesses through the organization. In addition, the Department will continue to work with these organizations to provide outreach and support to doctors, dentists and veterinarians that will be subject to the final-form rulemaking.

Furthermore, the Department reached out randomly to a number of private medical facilities in an attempt to conduct the cost savings analysis for this regulation. These facilities include: Summit Health Chambersburg Hospital, Pinnacle Health Camp Hill Family Care, Phoenix Wellness Center, Mechanicsburg Family Dentistry, Cameron County Health Center, Cameron County Dental Center, Johnsonburg Dental Center, and Mountaintop Area Medical Center. All facilities expressed that the final-form rulemaking will benefit their operations. None of the facilities surveyed indicated that it would impact their regulated medical and chemotherapeutic waste disposal procedures negatively (see number 19).

The Department worked cooperatively with representatives of the impacted biologics facilities during the development of the final rulemaking and was able to incorporate revisions into the final rulemaking that satisfy the comments submitted on behalf of the biologics facilities while maintaining a high level of protection for public health and the environment.

On March 6, 2014, the SWAC reviewed the comments received on the proposed rulemaking, including the Department's proposed responses and possible revisions to the proposed regulations. SWAC provided constructive feedback on potential impacts the proposed amendments would have on municipal waste management facilities. The Department considered SWAC's concerns in developing the final rulemaking.

On June 5, 2014, SWAC discussed the final amendments. Although the SWAC did not have a quorum, of the eight members in attendance, all supported moving the rulemaking to the EQB for consideration and publication as final.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Types of facilities affected:
All generators, processors and transporters of regulated medical or chemotherapeutic waste currently regulated by the Department would be required to comply with the final-form rulemaking. Generators and processors of regulated medical and chemotherapeutic waste include providers of medical care, such as hospitals, physician offices, veterinary offices, home health care providers, nursing facilities, dentist offices, blood collection agencies, biologics facilities, laboratories, and research facilities.

The Department assumes that a portion of these affected facilities are small businesses, as defined in Section 3 of the Regulatory Review Act. This Act defines a small business in the medical industry based on the dollar amount of gross annual receipts generated by the business. This dollar amount is different for each type of facility. A facility that shows gross annual receipts less than the figures shown below is defined as a "small business" under the Regulatory Review Act.

- Hospital <$34.5 million gross annual receipts
- Waste Collection <$12.5 million
- Doctor's Office <$10 million
- Dentist Office <$7 million
- Veterinary Office <$7 million
- Nursing Home <$13.5 million
- Medical Lab <$13.5 million

Section 3 of the Regulatory Review Act defines a small business in the vaccine and biological manufacturing industry and the biotechnology research and development industry by the number of employees. A business that has fewer employees than the figures shown below is defined as a "small business" under the Regulatory Review Act.

- Biological Products Manufacturing <500 employees
- Research and Development in Biotechnology <500 employees

Number of facilities affected:
The Department estimates there are approximately 16,303 entities across Pennsylvania managing regulated medical and chemotherapeutic waste. These entities include generators, processors and transporters of regulated medical and chemotherapeutic waste. This estimation is based on the following data obtained from the Department's Bureau of Waste Management and Bureau of Radiation Protection, the Pennsylvania Department of Health, the Pennsylvania Department of Corrections, and the U.S. Census Bureau. In parenthesis is the accompanying 2012 NAICS code, along with the amount of gross annual receipts to indicate the threshold for small business consideration, as provided in the Regulatory Review Act.

Generators (16,232 total facilities)
According to the Department of Health, currently in Pennsylvania there are:

- 190 hospitals (622110; less than $35.5 million);
- 6,000 doctor's offices with in-house laboratories (621111; less than $10 million);
- 11 outpatient rehabilitation facilities (621498; less than $19 million);
- 95 outpatient physical therapy facilities (621498; less than $19 million);
- 64 rural health clinics (621111; less than $10 million);
- 13 birth centers (621410; less than $10 million);

- 5 pediatric extended care centers;
- 613 nursing home facilities (623110; less than $25.5 million);
- 272 renal dialysis centers (621492; less than $35.5 million);
- 188 intermediate care facilities;
- 106 psychiatric residential treatment facilities (622210; less than $35.5 million); and
- 340 independent laboratories (621511; less than $30 million).

The Department used data from the Bureau of Radiation Protection's licensing of X-Ray machines to obtain information on the number of the following businesses currently operating in Pennsylvania:

- 5,715 dentist offices (621210; less than $7 million);
- 556 podiatrist facilities (621391; less than $7 million);
- 918 chiropractor offices (621310; less than $7 million); and
- 867 veterinarian offices (541940; less than $7 million).

According to the Department of Corrections, in Pennsylvania there are:

- 26 state correctional institutions;
- 14 community corrections centers; and
- 70 county prisons.

According to the U.S. Census Bureau, as of 2011 in Pennsylvania, there were:

- 23 biological products manufacturing facilities (325414; less than 500 employees); and
- 146 biotechnology research and development facilities (541711; less than 500 employees)

NAICS code 325414 is titled "Biological Products (except Diagnostic) Manufacturing." All facilities utilizing this NAICS code are manufacturing facilities, including, but not limited to, manufacturers of agar culture media, allergens, allergenic extracts (except diagnostic substances), anti-venoms, vaccines, blood derivatives, and plasmas.

NAICS code 541711 is titled "Research and Development in Biotechnology." All facilities utilizing this NAICS code are research facilities, including, but not limited to, biotechnology research and development laboratories; services in biology, botany, agriculture, bacteriology, environmental science, food science, genetics, industrial research, medical sciences, and veterinary sciences biotechnology research and development laboratories; protein engineering research and experimental development laboratories; and recombinant DNA research and experimental development laboratories.

Based on the NAICS descriptions for biologics and biotechnology facilities, it is likely that a significant portion of the facilities listed are not generating regulated medical waste. Therefore the number of facilities affected by the final-form rulemaking is less than the total number of facilities classified under the two NAICS codes. In addition, even though biotechnology–related research may be conducted at hospitals, the U.S. Census Bureau does not classify hospitals within NAICS Code 541711. Hospitals are classified under NAICS Code 622110 (General Medical and Surgical Hospitals).

Processors

Currently, there are 25 facilities operating under permits issued by the Department to process infectious and chemotherapeutic waste. Of those 25 facilities, 11 are operating under a general permit; 11 are operating under an individual permit; and 3 are operating under a permit-by-rule. However, the number of processors operating in Pennsylvania is difficult to estimate because the term "processors" by

definition includes waste transfer facilities; facilities engaged in the disinfection, incineration, shredding, and encapsulation of regulated medical and chemotherapeutic waste, including those facilities which may operate under the permit-by-rule provisions of the regulations; as well as some generators, such as hospitals, doctors' offices, dentists' offices, veterinary practices and other patient care facilities that are processing their own waste. Therefore, there is some overlap between the number of generators of infectious and chemotherapeutic waste and the number of processors of those wastes, since in some instances the generators and the processors are the same entity.

Transporters
Currently, there are 46 transporters of infectious and chemotherapeutic waste licensed by the Department. For solid waste collection (NAICS 562111) the maximum gross annual receipts allowable by definition for a small business is $35.5 million.

Small Businesses:
Because the definition of a small business in the medical industry is based primarily on the gross annual receipts of the individual company, an exact number of small businesses affected by this regulation cannot be identified by the Department with any certainty. However, some assumptions and estimates can be made. The Department assumes that all 64 rural health facilities and most of the transporters qualify as small businesses. Of the other facilities, the Department assumes that a portion of each would qualify as a small business. Regardless of the amount shown in gross receipts each year, each facility will have more options for storage, transportation and disposal of their regulated medical and chemotherapeutic waste from this final-form rulemaking; thereby providing the regulated community with additional efficiencies that are not available under the existing regulations.

How they will be affected:
Terminology
By changing the terminology from "infectious waste" to "regulated medical waste," generators and transporters will no longer be required to have two labels on each waste container nor two signs on each truck in order to be compliant with both federal requirements and Pennsylvania requirements. This change in terminology will align Pennsylvania's regulations with federal requirements and reduce costs for this portion of the regulated community, particularly when waste is disposed of out-of-state.

Disposal and On-site Storage
Currently, generators of infectious and chemotherapeutic waste are required to seal and dispose of containers within 30 days of first placing waste in the container. Many generators have cited difficulty in keeping track of the date when waste was first placed in the container and have expressed frustration that they are required to dispose of and transport partially full bags and containers. This final-form rulemaking will allow generators to seal containers of regulated medical and chemotherapeutic waste when they are full and allow them to store the waste on-site for an additional 30 days after the container is full or sealed, whichever occurs first. This provision will reduce the costs borne by generators by eliminating the disposal of partially full containers.

Manifesting
The ability to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations will provide benefits to both generators and transporters of regulated medical and chemotherapeutic waste. Currently, a paper manifest is required to accompany the waste shipment to ensure that the waste is being disposed of in the manner intended by the generator. This is an

outdated method of waste tracking. This regulation will allow the generator and the transporter to utilize whichever system (shipping paper, log or electronic tracking) that works best for their needs.

Fuel Efficiency
Additionally, both generators and transporters of regulated medical and chemotherapeutic waste will benefit from the fuel efficiency achieved by being able to transport containerized regulated medical and chemotherapeutic waste along with other containerized waste in the same vehicle. Current regulations require infectious and chemotherapeutic waste to be transported in separate vehicles from municipal waste. This change will reduce the number of trips needed to transport waste from generators that have regulated medical and chemotherapeutic waste and other types of waste that require disposal, thus further reducing fuel costs.

Additional Options - Shipping
Currently, sharps from small quantity generators may be sent through the USPS's Medical Waste Program. This final-form rulemaking will allow generators to ship other types of regulated medical chemotherapeutic waste in any amount or volume through the USPS's Medical Waste Program, provided that certain conditions are satisfied, including mailing standards and other relevant USPS regulations. This provision is consistent with federal regulations and regulations of other states and will allow generators more options for disposing of their regulated medical waste.

Permits-by-rule for Processing Facilities
The final-form rulemaking will provide 7 permits-by-rule for qualifying processing facilities. Autoclaves, incinerators, and steam superheated water disinfection operators, along with regulated medical and chemotherapeutic waste aggregation facilities and certain transfer facilities, may qualify for permits-by-rule instead of having to obtain individual or general permits for processing. These permits-by-rule will allow facilities to operate under standard requirements contained in the regulations and will eliminate the need for these facilities to submit individual or general permit applications to the Department.

Biologics Facilities
The Department recognizes that improvements in practices and technologies employed in biologics facilities have increased the safety of vaccine viruses such that many vaccine agents that were once infectious have been attenuated to the point that they are no longer capable of being communicated by replication or invasion in healthy humans. The EPA, in its Medical Waste Tracking Act, has excluded from the definition of "cultures and stocks" those materials that do not pose an appreciable risk of causing disease, including materials classified as Biosafety Level 1 (BSL-1), citing the Centers for Disease Control's (CDC) *Biosafety in Microbial and Biomedical Laboratories* (BMBL), as guidance in determining what constitutes an "infectious agent." 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." An exception has been added to the definition of "infectious waste" for wastes generated by biologics facilities that have not come in contact with agents classified as BSL 2-4. Similar language has been included in the definition of "infectious agent," which excludes agents classified as BSL-1 by a biologics facility. This provides flexibility and cost savings for biologics facilities in managing their waste.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

See the "number of facilities affected" section in number (15) for a breakdown of the estimated 16,303 entities that will be affected by this final-form rulemaking. All generators, processors and transporters of regulated medical and chemotherapeutic waste will be required to comply with this rulemaking. These facilities are currently required to comply with the Department's regulations relating to infectious and chemotherapeutic waste. The final-form rulemaking does not increase the number of entities that have to comply with the Department's regulations.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The Department expects the final-form rulemaking to reduce the costs borne by all generators, processors and transporters of regulated medical or chemotherapeutic waste by allowing transporters to haul regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers prior to sending them for disposal. The rulemaking encourages labor and fuel efficiency and reduces costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations.

Other than biologics facilities, the Department expects the largest financial and economic benefit of the rulemaking to be realized by small medical facilities located in rural areas. Currently, these businesses must pay for the transportation of regulated medical and chemotherapeutic wastes and municipal wastes separately, meaning that two trips are necessary to regularly haul the facilities' wastes. In addition, small facilities must remove and dispose of containers of regulated medical and chemotherapeutic waste within 30 days of waste first being placed into the containers, resulting in many partially full containers being shipped for disposal. The rulemaking alleviates the requirement for wastes to be collected in two separate vehicles and allows businesses to completely fill containers of regulated medical and chemotherapeutic waste before they must be shipped off-site for disposal.

The final-form rulemaking allows generators, transporters and those involved in storage and processing of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking, to demonstrate compliance with the regulations instead of the currently prescribed and outdated method of a paper manifest. The rulemaking also provides an alternative transportation and disposal option for all medical facilities by allowing these facilities to ship waste through the mail where authorized by the USPS. The USPS allows small facilities to ship regulated medical waste based on need rather than on a prescribed regulatory frequency or schedule.

The rulemaking allows businesses to manage regulated medical and chemotherapeutic wastes more efficiently, while maintaining the equivalent level of protection to public safety and the environment that is currently realized under the existing regulations.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

No adverse effects are expected from the final-form rulemaking, while the benefits are numerous.

The benefits of this regulation involve increased flexibility for generators, processors and transporters of regulated medical and chemotherapeutic waste. These regulations create consistency with U.S. Department of Transportation requirements by changing the term "infectious waste" to "regulated

medical waste." The shift in terminology will simplify the labeling and signage requirements and reduce costs, in addition to ensuring consistency.

Generators will benefit from the flexibility of scheduling disposal of their medical waste as needed instead of on a prescribed disposal schedule. They will also be able to utilize shipping options through the USPS.

The final-form rulemaking encourages labor and fuel efficiency by allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle. Transporters will also benefit by eliminating unnecessary trips to rural parts of the state to pick up waste, as the final-form rulemaking will allow waste to be disposed of on an as-needed basis.

This final-form rulemaking will allow transporters of medical waste to use standard business documentation, including electronic tracking, to demonstrate compliance with regulations instead of the currently prescribed and outdated method of a paper manifest.

Qualifying processors will be able to utilize permits-by-rule instead of individual or general permits for their facilities.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Generators

The realized savings for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates, the frequency with which the waste is disposed and the contracted costs associated with disposing the waste. This will vary from generator to generator.

The Department reached out to different types of facilities to gauge the cost savings that each could expect from the regulation.

- *Biologics facilities (NAICS 325414):* The Department worked closely with Merck Sharp and Dohme Corporation (Merck) in response to the comments it provided on the proposed regulation. Merck expressed that the requirements in Pennsylvania were more stringent than in all the other states in which Merck has operations; this meant at least two main waste streams generated by their facility in Pennsylvania were still being handled as infectious waste, while in other states the same wastes could be managed in a less costly manner. For example, in one manufacturing process alone, Merck generates approximately 12,000 plastic bottles per week that were used to grow vaccine viruses; disposing of these bottles as infectious waste costs Merck over $2 million a year. As a result, this put Merck at a financial disadvantage. The Department was able to accommodate the requests of Merck and made several changes to the proposed regulation to provide more flexibility not only to Merck, but to all biologics facilities doing business in Pennsylvania, thereby providing these facilities with a savings in management and disposal costs.
- *Medium-sized hospital:* In conversations with Summit Health Chambersburg Hospital, a medium-sized hospital, it indicated to the Department that infectious and chemotherapeutic waste is picked up four times a week. Stericycle, Inc. (the waste hauler used) charges $35 per box,

whether it is full or not. Due to the volume of medical waste generated, a medium-sized hospital, such as Summit Health Chambersburg Hospital, is unable to waiver from this pickup schedule and therefore does not expect to see savings from the provisions included in the rulemaking.

- *Medium-sized physician's office:* Pinnacle Health Camp Hill Family Care indicated to the Department that, on average, two full boxes of infectious waste are transported for disposal every other week. Since its hauler charges a flat fee per box, and the facility generates enough waste that it does not dispose of partially full boxes, a medium-sized physician's office, such as Pinnacle Health Camp Hill Family Care, does not expect to see savings due to the provisions included in the rulemaking.

- *Small physician's office:* The Department spoke with Phoenix Wellness Center, a small physician's office, regarding management of its medical waste. This office has its transporter pick up infectious waste once a month, whether the box is full or not. Under the final-form rulemaking, it would be able to develop a schedule based on when its container is full, stretching out its pickup times and ensuring that all loads are full. If one box costs $35 a month and they stretch the pickup to every 2 months, they could save $210 a year ($35 x 6 months of eliminated half full pickups).

- *Dentist's office:* Most dentist offices do not generate as much infectious waste as a doctor's office, but are still required to comply with the regulations regarding this waste stream. According to Mechanicsburg Family Dentistry, who serves a large clientele, it has infectious waste picked up every four weeks. Sometimes the boxes are not completely full. Smaller generators, like dentists, will benefit from the provisions which allow generators to wait until the container is full before being required to seal and dispose of it. They will also have another option to mail it through the USPS Medical Waste Program as needed, instead of having a dedicated pickup schedule.

- *Rural Dentist Facility:* Cameron County Dental Center and Johnsonburg Dental Center, small dentist offices in rural areas, indicated to the Department that they have their infectious waste picked up every two months and pay $86.53 per pickup. These offices each spend $519.18 per year ($86.53 x 6 pickups) for infectious waste disposal. Under final-form rulemaking, each office could reduce its pickup schedule to every 6 months or longer, resulting in a savings of at least $346.12 each year. Both offices also expressed interest in utilizing the USPS Medical Waste Program for transportation to a processing or disposal site on an as-needed basis.

- *Rural Health Facility:* The Mountaintop Area Medical Center and Cameron County Health Center both spoke with the Department regarding the management of their infectious waste. Both stated that infectious waste is picked up every two months, regardless of whether the box is full. Pickup is offered once per month; however, the facilities do not generate enough infectious waste for a monthly schedule. The facilities each spend $86.53 per box, significantly more than other urban or suburban facilities. Rural facilities are expected to be some of the biggest beneficiaries of this regulation, based on their size (less regulated medical waste generated) and location (farther to drive for pickups). Through this rulemaking, they will have the additional option of shipping regulated medical waste through the USPS Medical Waste Program as needed, instead of having a dedicated pickup schedule.

Cost savings analysis per generator type:

- *Biologics facilities (NAICS 325414) :* Merck indicated in its comments to the Department that disposal of the approximately 12,000 plastic bottles generated in one of their manufacturing processes costs over $2 million per year; under the final-form rulemaking, this yearly cost would be greatly decreased, as these bottles will be able to be disposed in a less expensive manner. Combined with the savings that would also be realized for other waste streams generated at biologics facilities, the potential cost savings could exceed $2 million per year.

  Using the above assumptions, biologics facilities would collectively save ($2 million) x (23 facilities) = $46,000,000 per year.

- *Large and medium-sized hospital:* No additional costs, but no savings.

- *Medium-sized physician's office:* No additional costs, but no savings.

- *Small physician's office:* According to the above, a small physician's office will potentially save $210 per year. Based on estimates of the number of health facilities affected by the regulations (see number 15 for a breakdown of affected facilities), for this cost-savings analysis, the Department assumed that a total of 3,841 facilities would generate a similar amount of waste as the small physician's office identified above, and therefore, these facilities would realize similar cost-savings. The Department conservatively estimated that one-quarter of all physicians' offices would be considered small. (1,500 of the 6,000 doctors' offices with in-house laboratories (1/4 of all doctors' offices); all 556 podiatrist facilities; all 918 chiropractic facilities; and all 867 veterinary facilities).

  Using the above assumptions, small physicians' offices would collectively save ($210) x (3,841 facilities) = $806,610 per year.

- *Dentist's office:* According to the outreach conducted and described above, the Department conservatively estimated that 75% of all dentists' offices would generate a similar amount of waste as the small physicians' offices. Therefore, of the 5,715 dentists' offices currently operating in Pennsylvania (given in number 15), 4,286 offices are assumed to generate a quantity of medical waste similar to that generated by a small physician's office for the purpose of this cost analysis.

  Using the above assumptions, these dentists' offices would collectively save ($210) x (4,286 facilities) = $900,060 per year.

- *Rural Dentist's offices:* The Department conservatively estimated that 25% of all dentists' offices are rural dentist facilities. Therefore, of the 5,715 dentists' offices currently operating in Pennsylvania (given in number 15), 1,429 offices are assumed to generate a quantity of medical waste similar to that generated by a rural dentist facility for the purpose of this cost analysis.

  Using the above assumptions, these dentists' offices would collectively save ($346.12) x (1,429 facilities) = $494,605.48 per year.

- *Rural Health Facilities:* According to the above, a rural health facility will potentially save $346.12 per year. Based on estimates of the number of rural health clinics affected by the regulation (see number 15 for a breakdown of affected facilities), for this cost-savings analysis, the Department assumed that all 64 rural health clinics would realize the cost savings identified above for rural health facilities.

  Using the above assumptions, rural health facilities would collectively save ($346.12) x (64 facilities) = $22,151.68 per year.

Therefore, the total estimated annual savings for generators is approximately ($46,000,000) + ($806,610) + ($900,060) + ($494,605.48) + ($22,151.68) = $48,223,427.16.

Transporters

Currently, a generator must have a separate pick up of their infectious and chemotherapeutic waste at least every 30 days. Most transporters charge a flat fee based on number of boxes or weight of infectious and chemotherapeutic waste, not based on the number of times they visit a facility. Transporters will benefit from being able to make fewer trips, by picking up more waste on each trip. They will also benefit from being able to transport regulated medical and chemotherapeutic waste in the same vehicle as other wastes generated from the same facility.

According to Stericycle, Inc., increases in generator storage time will save an average of two unnecessary trips per transporter per week. That is approximately 100 trips per transporter per year.

(100 trips) x (46 transporters) = 4,600 unnecessary trips eliminated.

According to information obtained from transporters, a typical trip consists of 50 miles.

The average total transport cost (including labor) is approximately $80 per hour to operate a standard box truck. An average speed of 35 mph is used, resulting in a cost of approximately $2.30/mile.

The average total transport cost (including labor) for tractor/trailer shipments is $95.00 per hour. An average speed of 55 mph is used, resulting in a cost of approximately $1.75/mile.

Therefore, the average transportation cost is approximately $2 per mile.

Using the above assumptions, transporters would save ($2) x (50 miles) x (4600 trips) = $460,000 per year.

When added to the estimated annual savings for generators, the total estimated annual savings for generators and transporters is ($460,000) + ($48,223,427.16) = $48,683,427.16

Signs on transportation vehicles would need to be replaced within two years of the regulation taking effect. Most transporters have adequate signage already, as it is required in most of the surrounding states.

Assuming half of the transporters will need the signage update, and the cost is $500 to replace or add required signs, the regulated community will spend:

(1/2) x (46 transporters) x ($500) = $11,500.

See number (23) for a breakdown of the projected yearly savings versus costs of the final-form rulemaking.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Local government facilities, such as health centers and county prisons, are generators of medical waste, and therefore, said facilities will be subject to the final-form rulemaking. The savings realized for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates, the frequency with which the waste is disposed and the contracted costs associated with disposing the waste (see number 19).

These facilities will no longer need to use labels that satisfy differing federal regulations. Allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers and vehicles before it must be placed into service will reduce the overall costs of transportation and disposal. The final-form rulemaking encourages aggregation and consolidation of waste; encourages labor and fuel efficiency; reduces costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations; and allows the utilization of standard business documentation, such as electronic tracking, to show compliance with the regulations, instead of the outdated method of paper manifests.

The rulemaking is not expected to impose any additional regulatory costs on local governments.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

State government facilities, such as state-supported hospitals, local Department of Health facilities and the Department of Correction's state correctional facilities are generators of medical waste, and therefore, those facilities will be subject to the final-form rulemaking. The savings realized for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates the frequency with which the waste is disposed and the contracted costs associated with disposing the waste (see number 19).

These facilities will no longer need to use labels that satisfy differing federal regulations. Allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers and vehicles before it must be placed into service, will reduce the overall costs of transportation and disposal. The final-form rulemaking encourages aggregation and consolidation of waste; encourages labor and fuel efficiency; reduces costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations; and allows the utilization of standard business documentation, such as electronic tracking, to show compliance with the regulations, instead of the outdated method of paper manifests.

The rulemaking is not expected to impose any additional direct regulatory costs on state governments, except those nominal costs the Commonwealth will incur to provide training, outreach and technical assistance to the regulated community. It is not anticipated that any new staffing resources will be necessary.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

No additional legal, accounting or consulting procedures, nor additional reporting, recordkeeping or other paperwork are required for implementation of the regulation for the regulated community.

The final-form rulemaking allows generators and businesses involved in the transportation, storage and processing of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking, to demonstrate compliance with the regulations instead of the currently prescribed and outdated method of a paper manifest. The use of alternative documentation provides the Department with the same information contained in a paper manifest, while reducing the amount of paperwork required of regulated entities.

Paperwork will be reduced by the creation of permits-by-rule for qualifying facilities in the final-form rulemaking. The permits-by-rule will eliminate the need to issue individual or general permits to those facilities, reducing reporting, record keeping and paperwork submissions to the Department for those qualifying facilities, while reducing the amount of paperwork managed by the Department in authorizing the operation of facilities permitted-by-rule.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

The dollar amounts below are taken from number (19) above and rounded to whole dollar amounts. See number (19) above for a breakdown of the estimated costs and annual savings associated with the proposed rulemaking.

	Current FY Year	**FY +1 Year**	**FY +2 Year**	**FY +3 Year**	**FY +4 Year**	**FY +5 Year**
SAVINGS:	**$ 48.2 million**	**$ 48.2 million**	**$ 48.2 million**	**$ 48.2 million**	**$ 48.2 million**	**$ 48.2 million**
Regulated Community	$ 48.2 million	$ 48.2 million	$ 48.2 million	$ 48.2 million	$ 48.2 million	$ 48.2 million
Local Government						
State Government						
Total Savings	$ 48.2 million	$ 48.2 million	$ 48.2 million	$ 48.2 million	$ 48.2 million	$ 48.2 million
COSTS:						
Regulated Community	$ 11,500	0	0	0	0	0

Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	$ 11,500	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Environmental Program Management (#161-10382)	$28,881,000	$27,755,000	$24,965,000	$26,297,000
Environmental Protection Operations (#160-10381)	$78,021,000	$77,359,000	$74,547,000	$76,221,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The Department does not believe that this rulemaking will have any adverse impact on small businesses.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

There are no special provisions in the final-form rulemaking for any specific social or economic sectors. The largest financial and economic benefit of the rulemaking is expected to be realized by the small

medical facilities located in rural areas. Currently, these businesses must pay for the collection and transportation of regulated medical/chemotherapeutic wastes and municipal wastes separately, meaning that two trips are necessary to regularly haul the facilities' wastes. In addition, small facilities must remove and dispose of containers of regulated medical and chemotherapeutic waste within 30 days of wastes first being placed into the containers, resulting in many partially full containers being shipped for disposal. The final-form rulemaking allows businesses to completely fill containers of regulated medical and chemotherapeutic waste before they must be shipped off-site for disposal and alleviates the requirement for wastes to be collected in two separate vehicles. As a result, the final-form rulemaking will make compliance easier for these small facilities without reducing the level of protection to public health and the environment. All regulated facilities will be able to use the USPS program to ship regulated medical waste for disposal. That program provides an on-demand or as-needed approach for shipping regulated medical waste rather than a prescribed schedule.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No program alternatives were considered.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;

This final-form rulemaking will affect all generators, processors and transporters of regulated medical and chemotherapeutic waste, including small businesses. These regulations will allow all generators to store regulated medical and chemotherapeutic waste on-site for longer periods of time. They will be able to ship regulated medical and chemotherapeutic waste when their containers are full, instead of in accordance with a prescribed schedule. This will result in fewer pick-ups of partially full containers. These regulations provide permits-by-rule for processors and extend the amount of time processors can hold regulated medical and chemotherapeutic waste prior to processing. Generators and transporters will also be able to utilize standard business documentation, including electronic tracking or shipping logs, to demonstrate compliance with the regulations, instead of the currently prescribed, but outdated method of a paper manifest.

b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

There are no schedules or deadlines for compliance or reporting requirements except for all regulated facilities will be required to comply with the regulations, if approved.

c) The consolidation or simplification of compliance or reporting requirements for small businesses;

Compliance and reporting requirements were simplified for businesses that qualify for permits-by-rule including those considered small businesses. The final-form rulemaking allows these facilities to operate under a standard set of regulatory requirements that eliminate the need of a facility to apply for an individual or general permit. Regulatory compliance is further simplified in the rulemaking by allowing

generators and transporters to utilize standard business documentation, including electronic tracking or shipping logs, to track their waste disposal, instead of the currently prescribed, but outdated method of a paper manifest.

d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and

The final-form rulemaking provides 7 permits-by-rule for qualifying facilities, which allow these facilities to operate under a standard set of requirements without reducing the level of protection for public health or the environment.

e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Small businesses are not exempted from any of the requirements of this regulation. All businesses are given additional options for the transportation to a processing or disposal site of regulated medical and chemotherapeutic waste, such as utilizing the USPS Medical Waste Program.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The following article recommends the renaming of Bacillus stearothermophilus to Geobacillus stearothermophilus:

International Journal of Systematic and Evolutionary Microbiology, Vol 51, 433-446, Copyright © 2001

- A copy of the article is attached to this form. (Attachment 1)

The following article recommends the reclassification of bioindicator strains Bacillus subtilis DSM 675 and Bacillus subtilis DSM 2277 as Bacillus atrophaeus:

International Journal of Systematic and Evolutionary Microbiology *January 2001 51:35-7*

- A copy of the article is attached to this form. (Attachment 2)

The following link will redirect you to a publication by the United Nations, regarding health care waste, which recommends using mycobacteria only as an indicator of disinfection. According to the publication, Mycobacteria are the toughest to neutralize and therefore the best indicator:

http://gefmedwaste.org/downloads/Guidance%20on%20Microbiological%20Challenge%20Testing%20for%20Medical%20Waste%20Autoclaves-%20November%202010.pdf

- A copy of the publication is attached to this form. (Attachment 3)

The following link will redirect you to a fact sheet regarding steam autoclaves, written by the EPA. The fact sheet provides guidelines for bacterial reductions and temperature requirements:

http://www.epa.gov/osw/nonhaz/industrial/medical/mwpdfs/alt/autoclav.pdf

- A copy of the fact sheet is attached to this form. (Attachment 4)

(29) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: Summer 2013

B. The date or dates on which public meetings or hearings will be held: N/A

C. The expected date of promulgation of the proposed regulation as a final-form regulation: Spring 2014

D. The expected effective date of the final-form regulation: Fall 2014

E. The date by which compliance with the final-form regulation will be required: Fall 2014

F. The date by which required permits, licenses or other approvals must be obtained: N/A

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.

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Attorney General

By:
(Deputy Attorney General)

DATE OF APPROVAL

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Copy below is hereby certified to be true and correct copy of a document issued, prescribed or promulgated by:

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 7-480

DATE OF ADOPTION JULY 15, 2014

BY E Christopher Abruzzo

TITLE E. CHRISTOPHER ABRUZZO
CHAIRMAN

EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

Copy below is hereby approved as to form and legality
Executive or Independent Agencies

BY

JUL 16 2014
DATE OF APPROVAL

(Exec (Deputy General Counsel)
~~(Chief Counsel - Independent Agency)~~
(Strike inapplicable title)

☐ Check if applicable. No Attorney General Approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

Regulated Medical and Chemotherapeutic Waste

25 *Pa. Code,* Chapters 271, 272, 273, 284, 285, 287, 288, 299

NOTICE OF FINAL RULEMAKING
DEPARTMENT OF ENVIRONMENTAL PROTECTION
ENVIRONMENTAL QUALITY BOARD

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

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

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

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

A. Effective Date

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

B. Contact Persons

For further information, contact Ali Tarquino Morris, Bureau of Waste Management, P. O. Box 69170, Rachel Carson State Office Building, Harrisburg, PA 17106-9170, (717) 783-2388; or Susan Despot, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a

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

C. Statutory Authority

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

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

The act of July 13, 1988 (P. L. 525, No. 93) (35 P. S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Disposal Law (ICWDL), which in section 4(b) (35 P. S. § 6019.4(b)) grants the Board the power and duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the ICWDL.

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

D. Background and Summary

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

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

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

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

The amendments also encourage labor and fuel efficiency by removing certain storage and transportation restrictions. The existing regulations limit storage of regulated medical waste at the generation site for a maximum of 30 days from the date that waste was first placed into the container. The amendments allow for generators to store regulated medical and chemotherapeutic waste for up to 30 days from the date that the container is full or the date the generator seals the container, whichever occurs earlier. These revisions promote more efficient business practices by eliminating the requirement to transport lightly or partially filled containers every 30 days. These regulations allow generators to completely fill containers and only ship when necessary, which results in a cost savings for the generators.

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

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

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

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

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

E. Summary of Changes to the Proposed Rulemaking

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

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

§ 271.1. Definitions

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

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

- The category of "cultures and stocks" has been reformatted for clarity and amended to add the term "cell lines." Clarification on residues in emptied containers has also been added. In the final rulemaking, a determination is made on whether a container is empty by applying the criteria contained in 40 CFR § 261.7(b)(1) or (2).

- The proposed exclusion of certain preserved tissues from the category of "pathological wastes" was deleted in the final rulemaking.

- In the category of "animal wastes," the proposed deletion of the phrase "during research" was reinstated in the final rulemaking.

- The definitions of "sharps" and "used sharps" were combined in the final rulemaking. Used sharps are no longer limited to those generated at medical, research or industrial laboratories. The term now excludes broken or unbroken plasticware generated at biologics facilities where no agent in the waste is classified as BSLs 2-4 as determined by the protocols established in the most recent edition of the CDC's BMBL.

- Subparagraph (iii)(L) has been added to the exceptions provided under the definition of "infectious waste" and applies to wastes, mixtures of wastes and cell lines from biologics facilities that produce or conduct research and development of vaccines or other biologics, provided no agent in the waste is classified as BSLs 2-4 in accordance with the most recent edition of CDC's BMBL.

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

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

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

§ 271.101. Permit requirement

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

§ 271.114. Transition period

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

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

§ 272.532. Limitations on acceptable waste.

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

§ 273.511. Processed regulated medical waste disposal.

A typographical error was corrected in subsection (a).

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

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

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

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

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

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

§ 284.3. Regulated medical or chemotherapeutic waste aggregation facilities.

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

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

§ 284.111. Application for general permits.

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

§ 284.121. Contents of general permits.

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

§ 284.122. Waiver or modification of certain requirements.

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

In subsection (b), the proposed deletion of the phrase "waiver or" and the mandatory provisions relating to the Department's legal right to enter the permitted area, the identification of interested parties, compliance information, verification of the application, and the administration of civil penalties and enforcement actions were not adopted in the final rulemaking. Therefore, these provisions remain mandatory in the final rulemaking.

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

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

§ 284.230. Storage requirements.

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

§ 284.321. Regulated medical waste monitoring requirements.

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

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

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

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

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

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

§ 284.322. Autoclave validation testing requirements.

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

§ 284.411. Segregation.

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

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

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

§ 284.412. Basic storage requirements.

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

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

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

§ 284.413. Storage containers.

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

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

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

§ 284.414. Marking of containers.

Subsection (a) has been reworded for clarity.

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

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

In the final rulemaking, subsection (a)(6) was added to clarify that the requirement to label containers with the name, address and telephone number of the generator only applies when waste is transported off-site. For on-site transportation of waste within the same geographical property or facility (such as within a hospital campus), it is no longer necessary for generator and transporter information to be placed on the containers.

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

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

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

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

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

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

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

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

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

A typographical error was corrected in subsection (d).

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

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

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

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

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

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

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

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

§ 284.602. License requirement.

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

§ 284.623. Conditions of licenses.

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

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

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

Subchapter H. Tracking of regulated medical and chemotherapeutic waste.

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

§ 284.711. Use of logs and shipping papers.

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

§ 284.712. Preparation of log or shipping paper.

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

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

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

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

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

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

§ 284.731. Scope.

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

§ 284.732. Use of logs and shipping papers.

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

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

§ 299.220. Signs on vehicles.

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

F. *Summary of Comments and Responses on the Proposed Rulemaking*

General

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

§ 271.1. Definitions

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

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

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

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

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

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

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

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

§ 284.122. Contents of general permits.

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

§ 284.321. Regulated medical waste monitoring requirements.

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

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

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

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

§ 284.411. Segregation.

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

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

§ 284.412. Basic storage requirements.

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

§ 284.412. Basic storage requirements, and
§ 284.512. Transportation of regulated medical and chemotherapeutic waste; general provisions.

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

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

§ 284.413. Storage containers.

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

§ 284.414. Marking of containers,
§ 284.513. Transportation of regulated medical and chemotherapeutic waste; additional provisions, and
§ 284.724. Transportation limitations.

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

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

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

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

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

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

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

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

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

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

§ 284.623. Conditions of licenses.

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

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

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

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

§ 284.732. Use of logs and shipping papers.

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

§ 284.734. Significant discrepancies.

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

F. Benefits, Costs and Compliance

Benefits

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

Compliance Costs

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

Compliance Assistance Plan

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

Paperwork Requirements

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

G. Pollution Prevention

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

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

H. Sunset Review

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

I. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on August 5, 2013, the Department submitted a copy of this proposed rulemaking, published at 43 Pa. B. 4858 (August 24, 2013), to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Environmental Resources and Energy Committees, for review and comment.

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

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

J. Findings of the Board

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) This final rulemaking does not enlarge the purpose of the proposed rulemaking published at 43 Pa. B. 4858.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this preamble.

K. Order of the Board

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

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

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

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

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

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

E. CHRISTOPHER ABRUZZO
Chairperson

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION
PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION
Subpart D. ENVIRONMENTAL HEALTH AND SAFETY
ARTICLE VIII. MUNICIPAL WASTE
CHAPTER 271. MUNICIPAL WASTE MANAGEMENT—GENERAL PROVISIONS
Subchapter A. GENERAL

§ 271.1. Definitions.

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

* * * * *

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

* * * * *

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

* * * * *

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

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

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

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

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

* * * * *

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

* * * * *

Environmental protection acts—The act, The Clean Streams Law (35 P.S. §§ 691.1—691.1001), the Municipal Waste Planning, Recycling and Waste Reduction Act (53 P.S. §§ 4001.101—4001.1904), the Hazardous Sites Cleanup Act (35 P.S. §§ 6020.101—6020.1305), the Low-Level Radioactive Waste Disposal Act **[(35 P.S. §§ 7130.101—7130.906)] (35 P.S. §§ 7130.101—7130.905)**, the act of July 13, 1988 (35 P.S. §§ 6019.1—6019.6), known as the Infectious and Chemotherapeutic Waste Disposal Law, the Air Pollution Control Act (35 P.S. §§ 4001—4015), the Surface Mining Conservation and Reclamation Act **[(52 P.S. §§ 1396.1—1396.31)] (52 P.S. §§ 1396.1—1396.19b)**, the Noncoal Surface Mining Conservation and Reclamation Act **[(35 P.S. §§ 3301—3326)] (52 P.S. §§ 3301—3326)**, the Dam Safety and Encroachments Act (32 P.S. §§ 693.1—693.27), and other State or Federal statutes relating to environmental protection or the protection of public health, including statutes adopted or amended after April 9, 1988.

* * * * *

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

* * * * *

Household hazardous waste—

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

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

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

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

* * * * *

Infectious 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 *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~~]** **CULTURES** from medical and pathological laboratories**[~~;~~]**.

(II) **[~~cultures~~]** **CULTURES** and stocks of infectious agents**, AND CELL LINES THAT HAVE BEEN EXPOSED TO INFECTIOUS AGENTS** from research and industrial laboratories**[~~;~~]**.

(III) **[~~wastes~~]** **WASTES** from the production of biologicals**[~~;~~]**.

(IV) **[~~discarded~~]** **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) TO THE RESIDUE REMAINING IN THE CONTAINER[~~; and~~]**.

(V) **[~~culture~~]** **CULTURE** dishes, assemblies and devices used to conduct diagnostic tests or to transfer, innoculate 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**[~~ or tissues that have been preserved with formaldehyde or other approved preserving agents~~]**.

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

* * * * *

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

* * * * *

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

* * * * *

(F) *Used sharps.* **[~~Sharps~~]**

(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**[, at medical, research or industrial laboratories]**.

(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 NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) AS CODE 32514 – BIOLOGICAL PRODUCT (EXCEPT DIAGNOSTIC) MANUFACTURING OR CODE 541711 - RESEARCH AND DEVELOPMENT IN BIOTECHNOLOGY, WHERE NO AGENT IN THE WASTE IS CLASSIFIED AS BIOSAFETY LEVEL 2-4 AS DETERMINED BY THE PROTOCOLS ESTABLISHED IN THE MOST RECENT EDITION OF THE CENTERS FOR DISEASE CONTROL'S *BIOSAFETY IN MICROBIAL AND BIOMEDICAL LABORATORIES* (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED.

* * * * *

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

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

(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 NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (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 LEVEL 2-4 AS DETERMINED BY THE PROTOCOLS ESTABLISHED IN THE MOST RECENT EDITION OF THE CENTERS FOR DISEASE CONTROL'S *BIOSAFETY IN MICROBIAL AND BIOMEDICAL LABORATORIES* (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED.

* * * * *

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

* * * * *

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

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

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

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

(iii) Processes that melt plastics and fully encapsulate metallic or other **USED** sharps and seals where completely in a container that will not be penetrated by untreated **USED** sharps.

271.2. Scope.

* * * * *

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

* * * * *

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

Subchapter B. GENERAL REQUIREMENTS FOR PERMITS AND PERMIT APPLICATIONS

EXISTING FACILITIES

271.111. [Reserved].
271.112. [Reserved].
271.113. Closure plan.
271.114. **[~~Transition period~~]** **[RESERVED]**.

REQUIREMENT

§ 271.101. Permit requirement.

* * * * *

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

* * * * *

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

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

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

* * * * *

EXISTING FACILITIES

§ 271.114. [~~Transition period~~] (RESERVED).

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

~~(1) Municipal waste landfill.~~ **~~An application for a permit modification addressing the requirements of § § 273.133(a)(14) and 273.140(a) (relating to map and grid requirements; and radiation protection action plan) shall be filed by December 23, 2001.~~**

~~(2) Construction/demolition waste landfills.~~ **~~An application for a permit modification addressing the requirements of § § 277.133(a)(14) and 277.140 (relating to map and grid requirements and radiation protection action plan) shall be filed by December 23, 2001.~~**

~~(3) *Municipal waste transfer facility.* An application for a permit modification addressing the requirements of § § 279.103(a)(18) and 279.110 (relating to maps and related information; and radiation protection action plan) shall be filed by December 23, 2002.~~

~~(4) *Commercial municipal waste composting facility that will receive sewage sludge or unseparated municipal waste, or both.* An application for a permit modification addressing the requirements of § § 281.112(a)(20) and 281.119 (relating to maps and related information; and radiation protection action plan) shall be filed by June 23, 2001.~~

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

Subchapter E. CIVIL PENALTIES AND ENFORCEMENT

ENFORCEMENT

§ 271.421. Administrative inspections.

* * * * *

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

* * * * *

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

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

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

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

* * * * *

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

* * * * *

Subchapter G. RESIDUAL WASTE

GENERAL PROVISIONS

§ 271.601. Scope.

* * * * *

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

ADDITIONAL APPLICATION REQUIREMENTS

§ 271.611. Chemical analysis of waste.

* * * * *

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

Subchapter I. BENEFICIAL USE

SCOPE

§ 271.801. Scope.

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

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

* * * * *

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

§ 271.811. Authorization for general permit.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 272. MUNICIPAL WASTE PLANNING, RECYCLING AND WASTE REDUCTION

Subchapter C. MUNICIPAL WASTE PLANNING

PLAN CONTENT

§ 272.223. Description of waste.

* * * * *

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

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

* * * * *

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

* * * * *

Subchapter F. HOUSEHOLD HAZARDOUS WASTE COLLECTION, TRANSPORTATION AND MANAGEMENT

OPERATION OF PROGRAMS

§ 272.532. Limitations on acceptable waste.

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

* * * * *

(2) **[Infectious waste]** **Regulated medical WASTE**, **[~~except sharps~~]** **AND HYPODERMIC NEEDLES OR SYRINGES**.

* * * * *

CHAPTER 273. MUNICIPAL WASTE LANDFILLS

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

SPECIFIC WASTES

273.411. Processed **[infectious]** **regulated medical** or chemotherapeutic waste disposal.
273.412. Sewage sludge plan.

SPECIFIC WASTES

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

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

* * * * *

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

SPECIFIC WASTES

SPECIFIC WASTES

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

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

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

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

* * * * *

(d) **USED [~~Sharps~~] SHARPS AND UNUSED HYPODERMIC NEEDLES OR SYRINGES** shall be rendered **[~~unusable~~] INCAPABLE OF BEING REUSED** prior to disposal.

CHAPTER 284. [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

Subch. **Sec.**

Subchapter A. GENERAL PROVISIONS

GENERAL PROVISIONS

GENERAL PROVISIONS

§ 284.1. Scope.

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

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

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

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

(i) Processing of pathological waste is prohibited.

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

(2) An onsite incineration facility that burns at least 50% of its own infectious or chemotherapeutic waste generated onsite and accepts offsite infectious or chemotherapeutic waste for incineration only from small quantity generators that generate less than 220 pounds per month of infectious or

chemotherapeutic waste. This onsite incineration facility may process municipal waste generated onsite as long as the resulting ash is managed as processed infectious and chemotherapeutic waste.

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

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

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

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

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

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

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

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

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

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

(B) The name and address of the facility.

(C) A description of the processing activity.

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

(4) Onsite processing of liquid blood and body fluids using a glutaraldehyde-based or hypochlorite-based product that encapsulates or converts liquid blood or body fluids into solids or gels so that no free liquids remain. The Department may approve the use of other disinfectant-based products under these provisions if their efficacy can be demonstrated. The processed [~~infectious waste~~] 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 [~~medical waste~~] 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, [~~and it~~] is not putrescent, AND DOES NOT ATTRACT VECTORS.

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

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

(2) The generator shall comply with the **[~~manifest~~] 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)] (a)(1)-(4)** and (b) to operate under a permit-by-rule:

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

* * * * *

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

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

* * * * *

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

* * * * *

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

accordance with Subchapter H (relating to [~~manifesting for~~] TRACKING OF [infectious] regulated medical and chemotherapeutic waste).

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

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

(i) The name and address of the facility.

(ii) A description of the processing activity.

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

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

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

* * * * *

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

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

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

§ 284.3. Regulated medical 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 **[~~generator~~]** **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

ISSUANCE OF A GENERAL PERMIT

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

REGISTRATION [AND DETERMINATION OF APPLICABILITY]

GENERAL

§ 284.101. Authorization for general permits.

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

* * * * *

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

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

* * * * *

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

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

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

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

* * * * *

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

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

ISSUANCE OF A GENERAL PERMIT

§ 284.111. Application for general permit.

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

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

* * * * *

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

(3) An operation plan which contains the following:

* * * * *

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

* * * * *

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

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

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

* * * * *

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

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

* * * * *

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

* * * * *

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

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

* * * * *

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

§ 284.112. Completeness review.

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

* * * * *

§ 284.113. Public notice and review period.

* * * * *

(b) The notice shall include:

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

* * * * *

§ 284.114. Approval or denial of an application.

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

* * * * *

§ 284.115. Department-initiated general permits.

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

* * * * *

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

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

* * * * *

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

* * * * *

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

§ 284.116. General permit renewal.

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

(b) A permit renewal may include all persons or municipalities that have applied for renewal within the time period provided in subsection (a). A person or municipality that does not meet the time period provided 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 **[infectious]** **regulated medical** or chemotherapeutic waste eligible for coverage under the general permit.

* * * * *

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

* * * * *

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

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

appropriate.

* * * * *

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

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

(13) A requirement that individual **[employe]** **employee** training records be maintained at the processing facility.

* * * * *

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

[(i) Processing of pathological waste is prohibited.

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

§ 284.122. ŧWaiver or modification] [~~Modification~~] of certain requirements.

* * * * *

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

REGISTRATION [AND DETERMINATION OF APPLICABILITY]

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

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

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

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

(b) Registration **[or application]** requirements and time limits, if any, shall be set forth in the general

permit governing each category of processing **[infectious]** **regulated medical** or chemotherapeutic waste. The general permit shall also set forth the area or region within which each category of processing is allowed.

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

* * * * *

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

* * * * *

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

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

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

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

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

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

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

construed or understood to constitute grounds for a determination that the general permit applies to the proposed activity.

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

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

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

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

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

Subchapter C. TRANSFER FACILITIES

§ 284.201. Scope.

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

§ 284.210. Application requirements.

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

§ 284.220. Operating requirements.

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

§ 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 **[infectious]** **regulated medical** or chemotherapeutic waste. The requirements in this subchapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions).

§ 284.311. Plan for monitoring.

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

* * * * *

§ 284.320. Operating requirements.

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

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

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

* * * * *

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

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

(ii) The process shall be capable of inactivating **[B.]** **Geobacillus** stearothermophilus spores, **[B.]** **Bacillus**

pumilus or **[B. subtilis]** **Bacillus atrophaeus** spores at a 4 log 10 reduction or greater.

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

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

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

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

* * * * *

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

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

(p) FOR FACILITIES ENGAGED IN THE PRODUCTION OR RESEARCH AND DEVELOPMENT OF VACCINES OR OTHER BIOLOGICS THAT ARE CLASSIFIED UNDER THE NAICS AS CODE 325414 – BIOLOGICAL PROTOCOL (EXCEPT DIAGNOSTIC) MANUFACTURING AND WHO MEET THE FOLLOWING CRITERIA MAY UTILIZE THE ALTERNATE DISINFECTION REQUIREMENTS SPECIFIED IN PARAGRAPH (5) BELOW IN LIEU 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* (BMBL) EXISTING AT THE TIME THE WASTE IS GENERATED:

(1) UTILIZE ON-SITE PROCESSING FACILITIES AT WHICH AT LEAST 50% OF THE WASTE PROCESSED IS GENERATED ON-SITE.

(2) OPERATE IN ACCORDANCE WITH FDA GOOD MANUFACTURING PRACTICES (GMP)

OR GOOD LABORATORY PRACTICES (GLP).

(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 ONE 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 SHALL 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) OF THIS SECTION, MAY BE MANAGED, STORED, TRANSPORTED AND DISPOSED OF AS ORDINARY MUNICIPAL WASTE AND SHALL NOT BE SUBJECT TO ANY OF THE ADDITIONAL RESTRICTIONS OR REQUIREMENTS PERTAINING TO SPECIAL HANDLING WASTE OR REGULATED MEDICAL WASTE.

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

§ 284.322. Autoclave validation testing requirements.

Autoclave operating parameters must 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) IN LIEU 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 **[infectious] regulated medical** or chemotherapeutic waste, ash residue from **[infectious] regulated medical** or chemotherapeutic waste incineration and processing residue from **[an infectious] a regulated medical** or chemotherapeutic waste processing facility. The requirements in this chapter are in addition to the applicable requirements in Chapter 271 (relating to municipal waste management—general provisions) and the requirements in §§ 285.111—285.115 and 285.121 **[(relating to general; and types of storage)]**.

§ 284.411. [Basic storage requirements] Segregation.

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

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

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

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

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

(5) Prevents odors from emanating from the container.

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

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

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

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

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

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

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

(1) Regulated medical waste, excluding pathological waste.

(2) Pathological waste.

(3) Chemotherapeutic waste.

(b) Each category of waste segregated under subsection (a) shall be placed in a separate container, except USED sharps that qualify as regulated medical waste 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 [~~and yellow in color for chemotherapeutic 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 PERMIT-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. [Sorting] Basic storage requirements.

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

(b) Infectious and chemotherapeutic waste may be stored together in the same container if

approved in writing by the Department.

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

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

(1) Used sharps.

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

(3) Other infectious waste.

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

(1) Used sharps.

(2) Fluids.

(3) Other chemotherapeutic waste.

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

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

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

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

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

(4) Maintains the waste in a nonputrescent state, using refrigeration (<= 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. 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, [~~and~~] chemotherapeutic waste [~~and/~~] or municipal waste that has been sorted and separately containerized IN THE SAME LOCATION, INCLUDNG ON A CART [~~on the same cart for movement to an onsite processing or disposal facility. Chemotherapeutic waste may also be stored on the cart with municipal and regulated medical waste if it is sorted and separately containerized and if it is moved to an onsite incinerator.~~]

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

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

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

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

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

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

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

(a) Regulated medical [~~and~~] 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 [~~bag~~] 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. [Duration of storage of infectious waste for processors] Marking of containers.

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

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

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

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

(a) For onsite or offsite transportation of regulated medical or chemotherapeutic waste, [~~the following information must be provided on the outermost container:~~] THE OUTERMOST CONTAINERS OF REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE MUST BE LABELED WITH THE FOLLOWING:

(1) The words "chemotherapeutic waste" if chemotherapeutic waste is [~~containerized~~] PLACED IN THE CONTAINER.

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

(3) After _____ (*Editor's Note*: The blank refers to [~~1~~]2 [~~year~~] YEARS after the effective date of adoption of this proposed rulemaking.), the words "regulated medical waste" if regulated medical waste is [~~containerized~~] PLACED IN THE CONTAINER.

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

(5) The date the container was full or the date that the generator sealed the container, whichever occurs earlier. [~~If the containers of regulated medical and chemotherapeutic waste are placed is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility and available for inspection by the transporter or Department for 1 year.~~]

(6) THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE GENERATOR IF THE WASTE IS TRANSPORTED OFFSITE.

(b) [~~For offsite transportation of regulated medical or chemotherapeutic waste, the following information must be provided on the outermost container:~~] 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 name, address and telephone number of the generator.~~] THE WASTE IN THE VEHICLE

OR CONVEYANCE IS FROM A SINGLE GENERATOR;

(2) [~~The name of the transporter and, if applicable, Department-issued regulated medical and chemotherapeutic waste transporter license number.~~] THE VEHICLE OR CONVEYANCE IS TRANSPORTED OFF-SITE 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 REQUIREMENTS);

(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; AND

(5) THE OUTSIDE OF THE VEHCILE 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. [Storage containers] Duration of storage of regulated medical AND CHEMOTHERAPEUTIC waste for generators.

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

(1) Leakproof.

(2) Impervious to moisture.

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

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

(1) Rigid.

(2) Tightly lidded.

(3) Puncture resistant.

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

(1) Break resistant.

(2) Tightly lidded or tightly stoppered.

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

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

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

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

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

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

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

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

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

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

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

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

(f) With the exception of persons who work at a small quantity generator's operation, where less than 220 pounds of infectious and chemotherapeutic waste is generated per month, persons packaging infectious or chemotherapeutic waste for offsite transportation shall wear:

(1) Protective overalls.

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

(a) [~~Generators that store regulated medical waste onsite shall record on the container the date that~~

~~the container was full or the date that the generator sealed the container, whichever occurs earlier. If the container is a roll-off and the date is not recorded on the roll-off, a record of the date must be maintained at the generating facility for 1 year.~~

~~(b)~~] Regulated medical 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.

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

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

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

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

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

(2) The date the waste was generated.

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

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

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

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

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

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

If the waste processing facility is separate from the waste generating facility, regulated medical OR CHEMOTHERAPEUTIC waste may not be stored at the waste processing facility for more than the following periods unless other periods are approved in [a] THE FACILITY'S permit:

(1) Seventy-two hours at [~~a temperature <= 25 °C or <=77 °F~~] AMBIENT TEMPERATURE, UNLESS THE WASTE BECOMES PUTRESCENT OR ATTRACTS VECTORS.

(2) Seven days in a refrigerator at <= 7°C or <= 45°F, OR IF THE WASTE BECOMES PUTRESCENT OR ATTRACTS VECTORS.

(3) Thirty days in a freezer at <= -18°C or <= 0°F, OR IF THE WASTE BECOMES PUTRESCENT OR ATTRACTS VECTORS.

§ 284.417. Reuse of containers.

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

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

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

* * * * *

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

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

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

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

* * * * *

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

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

* * * * *

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

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

* * * * *

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

Subchapter F. COLLECTION AND TRANSPORTATION

TYPES OF WASTE

GENERAL

§ 284.501. Scope.

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

TYPES OF WASTE

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

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

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

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

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

waste from a generator may be commingled and transported with the generator's ash residue from regulated medical and chemotherapeutic waste incineration if the municipal waste and ash residue [is] ARE being transported separately from the waste of other generators.

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

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

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

* * * * *

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

* * * * *

(c) *Containers.*

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

* * * * *

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

(v) Labeled in accordance with the requirements in § 284.414 (relating to marking of containers), EXCEPT AS PROVIDED IN § 284.414(b) (RELATING TO MARKING OF CONTAINERS).

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

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

* * * * *

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

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

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

(e) ***Commingling of waste.*** **SEPARATELY CONTAINERIZED regulated medical or chemotherapeutic waste may [~~not~~] be [~~commingled~~] TRANSPORTED IN THE SAME VEHICLE with CONTAINERIZED municipal waste [~~or transported in the same vehicle as residual waste~~].**

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

(g) ***Refrigeration.*** **[Infectious]** **Regulated medical OR CHEMOTHERAPEUTIC** waste may **[not]** be kept in an unrefrigerated transport vehicle for **[more than 48]** **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 in-transit storage period may not exceed 5 days.

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

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

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

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

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

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

(3) UNTIL _____ *(EDITOR'S NOTE*: THE BLANK REFERS TO 2 YEARS AFTER THE EFFECTIVE DATE OF ADOPTION OF THIS PROPOSED RULEMAKING.), THE WORDS

"INFECTIOUS WASTE" OR "REGULATED MEDICAL WASTE" IF REGULATED MEDICAL WASTE IS BEING TRANSPORTED.

(4) AFTER _____ (*EDITOR'S NOTE*: THE BLANK REFERS TO 2 YEARS AFTER THE EFFECTIVE DATE OF ADOPTION OF THIS PROPOSED RULEMAKING.), THE WORDS "REGULATED MEDICAL WASTE" IF REGULATED MEDICAL WASTE IS BEING TRANSPORTED.

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

* * * * *

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

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

* * * * *

(d) The **CARGO AREA** **[~~surface~~]** of vehicles **USED FOR TRANSPORTING REGULATED MEDICAL OR CHEMOTHERAPEUTIC WASTE** that **[~~have~~]** **HAS** not been in direct physical contact with **[infectious]** **regulated medical** or chemotherapeutic waste shall be cleaned weekly. Drainage from the cleaning shall be discharged directly or through a holding tank to a sanitary sewer system or treatment facility.

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

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

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

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

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

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

OPERATIONAL REQUIREMENTS

GENERAL PROVISIONS

§ 284.601. Scope.

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

§ 284.602. License requirement.

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

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

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

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

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

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

§ 284.603. Identification number.

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

* * * * *

LICENSE APPLICATION REQUIREMENTS

§ 284.611. General application requirements.

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

(b) The application shall contain the following:

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

§ 284.612. Vehicular liability insurance.

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

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

* * * * *

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

* * * * *

LICENSE APPLICATION REVIEW

§ 284.623. Conditions of licenses.

* * * * *

(c) A license to transport **[infectious]** **regulated medical** and chemotherapeutic waste is nontransferable and nonassignable. A license applies to the licensee and its **[employes]** **employees**. Leased or subcontracted **[~~drivers~~]HAULERS**, and **[~~drivers~~]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 **[infectious]** **regulated medical** or chemotherapeutic waste after expiration of the current license term under § 284.622 (relating to term of license) shall file a complete application for license renewal on forms provided by the Department at least 90 days before the expiration date of the license. The application shall include a nonrefundable application fee in the form of a check payable to the "Commonwealth of Pennsylvania" for $500. The license renewal application will be reviewed by the Department in the same manner as a new application for a license under this subchapter.

OPERATIONAL REQUIREMENTS

§ 284.631. Basic limitations.

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

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

(d) A transporter shall:

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

* * * * *

§ 284.633. Safety.

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

§ 284.634. Annual report.

* * * * *

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

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

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

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

BOND

§ 284.641. Bond requirement.

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

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

payable to the Department on a form provided by the Department, and the bond has been approved by the Department.

* * * * *

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

§ 284.642. Release of bond.

* * * * *

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

* * * * *

§ 284.643. Bond forfeiture.

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

* * * * *

Subchapter H. [~~MANIFESTING FOR~~] TRACKING OF [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

GENERATOR RESPONSIBILITIES

284.711. Use of **[~~manifest~~] LOGS OR SHIPPING PAPERS.**
284.712. Preparation of **[~~manifest~~] LOGS OR SHIPPING PAPERS.**
284.713. **[Generator's distribution of copies] [Reserved].**
284.714. Exception reporting.

TRANSPORTER RESPONSIBILITIES

284.721. **[Basic requirements] [Reserved].**
284.722. Preparation and use of **[~~manifest~~] LOGS OR SHIPPING PAPERS.**
284.723. **[Waste delivey] [Reserved].**
284.724. Transportation limitations.

FACILITY RESPONSIBILITIES

284.731. Scope.

284.732. Use of **[~~manifest~~]** **LOGS OR SHIPPING PAPERS.**
284.733. **[Distribution of copies]** **[Reserved].**
284.734. Significant discrepancies.

GENERAL

§ 284.701. Scope.

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

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

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

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

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

* * * * *

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

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

* * * * *

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

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

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

* * * * *

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

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

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

* * * * *

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

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

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

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

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

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

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

§ 284.702. Transfer facilities.

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

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

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

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

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

§ 284.703. Recordkeeping.

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

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

GENERATOR RESPONSIBILITIES

§ 284.711. Use of [~~manifest~~] LOGS OR SHIPPING PAPERS.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 284.712. Preparation of [~~manifest~~] LOGS OR SHIPPING PAPERS.

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

* * * * *

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

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

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

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

(6)] (4) 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 Subchapter C (relating to hazardous materials regulations), if applicable.

[(7)] [(5)] [6] Special instructions and information necessary for proper handling of the waste during transportation, processing, storage or disposal, if any.

[(8)] [(6)] [7] The printed or typed name and handwritten signature of the generator's authorized representative, and the date of shipment.

[(9)] [(7)] [8] The printed or typed name and handwritten signature of the initial transporter's authorized representative, and the date of receipt.

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

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

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

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

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

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

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

(b) A generator located in this Commonwealth and designating a facility in a state that supplies the manifest shall provide information and distribute copies as required by the manifest in accordance with instructions supplied with the manifest and retain one copy of the manifest.

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

§ 284.714. Exception reporting.

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

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

* * * * *

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

(c) The exception report shall include the following:

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

* * * * *

TRANSPORTER RESPONSIBILITIES

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

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

§ 284.722. Preparation and use of [~~manifest~~] LOGS OR SHIPPING PAPERS.

(a) Before transporting **[infectious]** **regulated medical** or chemotherapeutic waste or processed **[infectious]** **regulated medical** or chemotherapeutic waste that is recognizable, the transporter shall

[print or type his name, sign and date the manifest, and, by the signature, acknowledge acceptance of the waste from the generator] **provide the generator with a dated[~~, handwritten~~] signature, INCLUDING, BUT NOT LIMITED TO, HANDWRITTEN, ELECTRONIC OR STAMPED SIGNATURES, [~~of~~] FROM an authorized representative of the transporter acknowledging that the transporter has accepted the waste from the generator on the date of acceptance.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 284.723. [Waste delivery] (Reserved).

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

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

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

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

(1) Return the waste to the generator.

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

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

§ 284.724. Transportation limitations.

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

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

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

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

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

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

FACILITY RESPONSIBILITIES

§ 284.731. Scope.

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

§ 284.732. Use of **[~~manifest~~]** **LOGS OR SHIPPING PAPERS.**

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

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

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

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

(3) **[Note the rejection in the discrepancy indication space, and sign and date the manifest in accordance with paragraph (1) if either partially or totally rejecting the waste.]** **Provide the transporter with a dated[, ~~handwritten~~] signature, 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.**

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

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

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

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

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

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

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

§ 284.734. Significant discrepancies.

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

* * * * *

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

* * * * *

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

CHAPTER 285. STORAGE, COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE

285.131. Storage and containment of ash residue from municipal waste incineration, including from **[infectious]** **regulated medical** or chemotherapeutic waste incineration.
285.132. [Reserved].
285.133. [Reserved].
285.134. Storage of sewage sludge in piles.

ADDITIONAL REQUIREMENTS FOR [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

285.141—285.145. [Reserved].
285.146. [Reserved].
285.147. [Reserved].
285.148. [Reserved].

Subchapter A. STORAGE OF MUNICIPAL WASTE

ADDITIONAL REQUIREMENTS FOR CERTAIN TYPES OF WASTE

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

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

* * * * *

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

ADDITIONAL REQUIREMENTS FOR [INFECTIOUS] REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

§§ 285.141—285.145. (Reserved).

Subchapter B. COLLECTION AND TRANSPORTATION OF MUNICIPAL WASTE

GENERAL PROVISIONS

§ 285.218. Signs on vehicles.

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

* * * * *

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

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

* * * * *

TYPES OF WASTE

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

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

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

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

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

ARTICLE IX. RESIDUAL WASTE MANAGEMENT

CHAPTER 287. RESIDUAL WASTE MANAGEMENT—GENERAL PROVISIONS

Subchapter A. GENERAL

§ 287.1. Definitions.

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

* * * * *

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

* * * * *

§ 287.2. Scope.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 288. RESIDUAL WASTE LANDFILLS

Subchapter D. ADDITIONAL REQUIREMENTS FOR CLASS I RESIDUAL WASTE LANDFILLS

ADDITIONAL OPERATING REQUIREMENTS—GENERAL

§ 288.423. Minimum requirements for acceptable waste.

* * * * *

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

* * * * *

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

* * * * *

CHAPTER 299. STORAGE AND TRANSPORTATION OF RESIDUAL WASTE

Subchapter B. STANDARDS FOR COLLECTING AND TRANSPORTING OF RESIDUAL WASTE

GENERAL PROVISIONS

§ 299.220. Signs on vehicles.

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

* * * * *

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

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

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

{(iii)} **[~~(ii)~~]** Residual waste shall be designated: Residual Waste.

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

* * * * *

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMENT AND RESPONSE DOCUMENT

REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE

25 *Pa. Code* Chapters 271, 272, 273, 284, 285, 287, 288, 299
43 *Pa.B.* 4858 (August 24, 2013)
Environmental Quality Board Regulation #7-480
(Independent Regulatory Review Commission #3017)

List of Commentators on the Proposed Rulemaking

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Comments and Responses

General Comments

1. **Comment:** Based on the number and significance of the issues raised by Merck and Sanofi Pasteur, we question the reasonableness of the requirements as they relate to biologics facilities, as well as the fiscal or economic impact, and the direct and indirect costs to the private sector. We ask EQB to consider the concerns of this segment of the regulated community, and to continue to engage the entire regulated community to allow for the opportunity to resolve as many concerns as possible prior to the submittal of the final-form regulation. We will review EQB's response as part of our consideration of whether the final-form regulation is in the public interest. (7)

   Response: This comment summarizes the comments of commentator 1 and is addressed through the individual responses to each of commentator 1's comments.

Specific Comments

§ 271.1 – Definitions

2. **Comment:** The activities conducted at facilities engaged in the R&D and/or production of vaccines and other biologics, herein after referred to as "biologics facilities," generate large quantities of cultures, containers and other wastes that have come into contact with vaccine components, such as live attenuated preparations of viruses, inactivated whole or subunit virions, purified recombinant proteins, or synthetic antigens. The current infectious and chemotherapeutic waste regulations define these materials as "infectious waste" because the materials have come in contact with "infectious agents," which is defined as "an organism, such as a virus or bacteria, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans." Recent technology improvements in vaccine manufacturing have increased the safety of vaccine viruses such that many vaccine agents that were once infectious have been attenuated to the point that they are no longer capable of being communicated by replication or invasion in healthy humans. In addition, biologics facilities are subject to stringent federal regulatory programs that do not apply to most hospitals and patient care facilities.

   The unique activities conducted at biologics facilities, the stringent federal regulatory programs that apply to development and production of biologics, the expertise of biologics facility scientists, and the well-characterized waste streams generated at these facilities support the adoption of regulatory provisions specific to their operations. Therefore, waste from biologics facilities that contains no biological agents classified above Biosafety Level 1 under Centers for Disease Control and Prevention and National Institutes of Health protocols should be exempted from the definition of regulated medical waste because it poses no appreciable risk of causing disease. Based on the foregoing, Merck and Sanofi Pasteur recommend that the following regulatory amendments be adopted:

25 Pa. Code § 271.1 is amended to add the following language to the definition of "infectious waste" (to be changed to "regulated medical waste"):

(iii) Exemptions: The term does not include the following:

. . . (L) Wastes or mixtures of wastes from facilities engaged in the production or research and development of vaccines or other biologics and 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, where no agent in the waste is classified as Biosafety Level 2-4 as determined by the protocols established in the most recent edition of the Centers for Disease Control's *Biosafety in Microbial and Biomedical Laboratories* (BMBL) existing at the time the waste is generated.

and

25 Pa Code § 271.1 is amended to add the following language to the definition of "infectious agent":

An organism, such as a virus or bacteria, that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans. **The 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.** (1)

Comment: Biosafety Level 1 agents are those that do not pose a risk of disease requiring special precautions or handling. We ask the EQB to explain why it is reasonable to include Biosafety Level 1 agents in the definition of *infectious waste,* as well as in the term *infectious agent.* (7)

Response: The department recognizes that improvements in practices and technologies employed in biologics facilities have increased the safety of vaccine viruses such that many vaccine agents that were once infectious have been attenuated to the point that they are no longer capable of being communicated by replication or invasion in healthy humans. The EPA, in its Medical Waste Tracking Act, has excluded from the definition of "cultures and stocks" those materials that do not pose an appreciable risk of causing disease, including materials classified as Biosafety Level 1 (BSL-1), citing the Centers for Disease Control's (CDC) *Biosafety in Microbial and Biomedical Laboratories* (BMBL), as guidance in determining what constitutes an "infectious agent." 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 department has accepted the regulatory additions proposed by the commentators. An exception has been added to the definition of "infectious waste" for wastes generated by biologics facilities that have not come in contact with

agents classified as BSL 2-4. Similar language has been included in the definition of "infectious agent," which excludes agents classified as BSL-1 by a biologics facility.

3. **Comment:** EQB proposes that *regulated medical waste* be defined as "infectious waste," thereby incorporating the existing definition of infectious waste. The use of two terms having the same definition has the potential to cause confusion among the public and regulated community. EQB should explain the need for and compelling public interest that justifies the use of the same definition for two terms, and how the benefits of using the two terms outweigh any adverse effects. (7)

   Response: The term "infectious waste" has been eliminated throughout the regulation and replaced with "regulated medical waste" to align Pennsylvania's container marking, vehicle signage and waste tracking regulations with federal requirements, which identify infectious waste as "regulated medical waste." Since solid waste is not always generated, processed and disposed of within the Commonwealth, the revisions allow persons generating and managing infectious and chemotherapeutic waste to do so in a manner that complies with Pennsylvania law and is consistent with federal requirements relating to container marking, vehicle signage and waste tracking. This change in terminology will simplify the labeling requirements on containers that are used to collect, transport, process, and dispose of the waste. Persons managing regulated medical waste will no longer need to ensure that Pennsylvania containers and labels are used and kept separate from those employed in other states. This uniform practice should reduce the costs borne by generators and other persons managing regulated medical waste because the same containers and labels can be used to satisfy Pennsylvania requirements and the requirements imposed by federal agencies.

   To avoid confusion within the medical industry, rather than eliminate the term "infectious waste" in § 271.1 and move all the language to the definition of "regulated medical waste," the Department chose to keep the infectious waste definition and simply define regulated medical waste as infectious waste. The Board believed that if the definition of "infectious waste" were to be eliminated, it would appear as though the Board was changing the scope of what is being regulated under a new term, "regulated medical waste," rather than just renaming the material for the purposes explained above. The department worked closely with representatives of the medical community during the development of the regulations that supported this approach. The department does not believe the industry will be confused by this action.

4. **Comment:** Under *infectious waste,* the language in Clause (i)(D) (relating to animal wastes) as amended is unclear. It appears that the word "during" should not be deleted, whereas the comma following the deleted language should be deleted. EQB should clarify the language in this clause. (7)

   Response: The department has corrected subparagraph (i)(D) in the final rulemaking to read, "*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, the production of biologicals, or testing of pharmaceuticals."

5. **Comment:** The large volume of plastics generated by biologics facilities should be exempted from the definition of "sharps" because they pose little risk of puncture and are not considered "sharps" in almost all other jurisdictions. Merck and Sanofi Pasteur recommend that an exemption for plasticware generated at biologics facilities be added to the definition of "used sharps," or alternatively that the definition of "sharps" be modified to exclude references to plasticware.

   Alternative 1 – Add the following language to the proposed definition of "used sharps" found in subsection (F) to the definition of "infectious waste" in 25 Pa. Code § 271.1:

   "Used sharps shall 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 North American Industrial Classification System (NAICS) as Code 32514 – Biological Product (except Diagnostic) Manufacturing or Code 541711 - Research and Development in Biotechnology."

   Alternative 2 – Modify the proposed definition of "sharps" to read as follows:

   "Sharps – 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, **glass** culture dishes, suture needles, **glass** slides, **glass** covers slips, and other broken or unbroken glass **[or plasticware]**." (1, 7)

   Response: The department combined the definitions of "sharps" and "used sharps" in the final rulemaking and has added the following language to the revised definition of "used sharps":

   Used sharps do 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 North American Industrial Classification System (NAICS) as Code 32514 – Biological Product (except Diagnostic) Manufacturing or Code 541711 - Research and Development in Biotechnology, where no agent in the waste is classified as Biosafety Level 2-4 as determined by the protocols established in the most recent edition of the Centers for Disease Control's *Biosafety in Microbial and Biomedical Laboratories* (BMBL) existing at the time the waste is generated.

6. **Comment:** The amended definitions in this Proposed Rulemaking are confusing:

   Under the definition of *Infectious Waste*:

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

Later, another definition was used:

Sharps-Broken glass **[that has been in contact with pathogenic organisms]**, hypodermic needles **[and]**, syringes to which a needle. . .

Why do you need two definitions for sharps if only used sharps are covered as regulated medical waste? Penn State University generates tons of broken glass each year in the form of reagent bottles, window glass, light bulbs and other such material.

Further clarification or a rewrite of the sharps definition to clarify this issue would be greatly appreciated. (2)

Response: The definitions being cited by the commentator are existing definitions in § 271.1, which were modified slightly in the proposed rulemaking. The department recognizes the need for clarification. Sharps are not managed differently from other municipal waste streams until after the sharps have come into contact with infectious agents or when used in animal or human patient care or treatment, and therefore, are classified as "used sharps" under the definition of "infectious waste." To eliminate confusion, the department has combined the definitions of "sharps" and "used sharps" in the final rulemaking.

7. **Comment:** The current definition of "infectious waste" as it pertains to cultures and stocks includes a category that reads as follows:

   ". . . discarded live and attenuated vaccines except for residue in emptied containers."

   The term lacks clarity in two respects. First it is unclear whether the exception modifies only the phrase "discarded live and attenuated vaccines" or whether the exception applies more broadly to other categories of cultures and stocks, including the category of "wastes from the production of biologicals." Second, the term "residue in empty containers" is not defined. The absence of a clear standard leaves biologics facilities at risk that their evaluation of whether a container has been sufficiently "emptied" to trigger the exemption will differ from the Department's evaluation. Other regulatory programs define an empty container more precisely. For example, the regulations adopted under the Resource Conservation and Recovery Act (RCRA) contain specific quantitative limits that can be used to determine whether a container is empty. The term "residue in empty containers" should be defined by borrowing the definition in the hazardous waste regulations, thereby providing clarity and certainty. Based on the foregoing, Merck and Sanofi Pasteur recommend that the following regulatory amendment be adopted:

   25 Pa. Code § 271.1 is amended to add the following language to the definition of "infectious waste" (to be changed to "regulated medical waste"):

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

   . . . (M) Wastes or mixtures of wastes from facilities engaged in the production or research and development of vaccines or other

biologics, and 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, that consist of empty containers as determined by applying the criteria in 40 CFR § 261.7 (b)(1) or (2) to regulated medical waste remaining in the container. (1, 7)

Response: The first issue raised by the commentators relates to whether the phrase "except for residues in emptied containers" applies only to "discarded live and attenuated viruses" or applies more broadly to other categories listed in subparagraph (i)(A) such as "wastes from the production of biologicals." After evaluating the manner in which categories of materials are listed in the existing language of subparagraph (i)(A), the department has determined that each category of subparagraph (i)(A) is separated by a semicolon. Since the categories "wastes from the production of biologicals" and "discarded live and attenuated viruses except for residues in emptied containers" are separated by a semicolon, the phrase "except for residue in emptied containers" would apply only to the category of discarded live and attenuated viruses. To clarify this, the Department has reformatted the list of categories under "cultures and stocks" in the final rulemaking.

The second issue raised by the commentators relates to the criteria applied to an empty container so that a generator of waste can determine whether a container has been sufficiently emptied, and therefore, excluded from the definition of "cultures and stocks" in subparagraph (i)(A). The department agrees with the commentators that clarification is needed and has added the following language to subparagraph (i)(A) under the definition of "infectious waste" in the final rulemaking:

> " . . . 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) to the residue remaining in the container . . ."

8. **Comment:** General Permit No. WMGI005 approves the processing of infectious waste generated in the production, research and development of pharmaceuticals when chemical and/or thermal inactivation is used. Among the types of wastes that the operator of the permitted facility may process are "cell lines from humans and primates." Cell lines are not capable of causing disease unless they are exposed to infectious agents. Neither the category of "cultures and stocks" nor any other category within the definition of infectious waste expressly mentions cell lines. Only cultures and stocks "of infectious agents and associated biologicals" fall within the definition of infectious waste because only those materials are capable of causing disease. The inclusion of cell lines in the general permit creates ambiguity regarding whether a cell line that has not been exposed to an infectious agent must be processed as infectious waste under the general permit. Based on the foregoing, Merck and Sanofi Pasteur recommend that the following regulatory amendment be adopted:

> 25 Pa. Code § 271.1 is amended to add the following language to the definition of "infectious waste" (to be changed to "regulated medical waste"):

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

(N) Cell lines that have not been exposed to infectious agents classified as Biosafety Levels 2-4 as determined by the protocols established in the most recent edition of Centers for Disease Control's Biosafety in Microbial and Biomedical Laboratories (BMBL) existing at the time the waste is generated.

Alternatively, the Department may simply wish to resolve this ambiguity in the general permit by changing "cell lines from humans and primates" to "cell lines from humans and primates that have been exposed to infectious agents classified as Biosafety Levels 2-4 as determined by the protocols established in the most recent edition of Centers for Disease Control's *Biosafety in Microbial and Biomedical Laboratories* (BMBL) existing at the time the waste is generated." (1, 7)

Response: The department understands that cell lines are not capable of causing disease unless they are exposed to infectious agents and that the definition of infectious waste does not expressly address cell lines. To alleviate the ambiguity created by the inclusion of the term "cell lines" in General Permit No. WMGI005, the department has included "cell lines" in the exception applying to biologics facilities in subparagraph (iii)(L) in the final rulemaking and the definition of "cultures and stocks" in subparagraph (i)(A) of the definition of "infectious waste." Both changes clarify that only cell lines that have been exposed to infectious agents classified as Biosafety Levels 2-4 will fall within the definition of "infectious waste."

9. **Comment:** Section 271.1 of the proposed rulemaking defines "pathological wastes" as follows:

(i)(B) *Pathological wastes.* Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery, autopsy, other medical procedures or laboratory procedures. The term does not include hair, nails or extracted teeth **or tissues that have been preserved with formaldehyde or other approved preserving agents**.

Clarification Requested: If these materials are no longer considered pathological waste are they still considered regulated medical waste? Would they be permitted to be placed in autoclaves or in the solid waste? Concern has been raised that while some pathological waste (e.g. prepared slide specimens) may not be of concern, other materials such as full body parts (e.g. legs, arms, etc.) will be more recognizable creating issues at landfills and formalin/formaldehyde preservatives may volatilize during autoclaving which could be harmful to healthcare waste workers. Perhaps there may be a way to better define what types of tissues would be acceptable. (3, 4, 5, 7)

Response: The department has deleted the proposed addition to the definition of "pathological waste" in the final rulemaking. Therefore, preserved tissues will remain subject to the definition of "pathological waste," unless the tissues meet the exception provided in subparagraph (iii)(B) of the definition of "infectious waste," and must be managed as "regulated medical waste" as set forth in the final rulemaking. The department does not recommend that preserved tissues be processed using an autoclave if a risk of volatizing preservatives exists or presents a threat to worker safety.

Human anatomical remains that do not meet the exception provided in subparagraph (iii)(B) of the definition of "infectious waste" must be incinerated prior to disposal at a landfill in accordance with § 273.511(b).

§ 284.111 – Application for general permit

10. **Comment:**
In § 284.111(b)(3)(viii) EQB should replace the reference to "infectious" waste with the proposed "regulated medical" waste. For clarity and consistency, EQB should ensure that all references to "infectious" waste throughout the regulation are updated as intended. (7)

Response: The term "infectious" has been replaced with the words "regulated medical" in § 284.111(b)(3)(viii) of the final rulemaking.

§ 284.122 – Waiver or modification of certain requirements

11. **Comment:** In subsection (b), EQB is proposing to delete several currently mandatory provisions relating to the legal right of the Department 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. EQB states that these mandatory provisions limit the Department's flexibility to provide applicants with an effective permit. EQB's explanation for this change is insufficient to show how the deletion of these provisions is in the public interest. EQB should explain in detail how protection of the public health, safety and welfare would not be impacted by the deletion of each of these provisions. For example, why is it in the public interest for the Department to waive its legal right to enter the permitted area? (7)

Response: The proposed deletion will not be adopted, and the existing language of § 284.122(b) will remain unchanged in the final rulemaking. The legal right of the department 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 will remain mandatory provisions of the regulations.

§ 284.220 – Operating requirements

12. **Comment:** In § 284.220, relating to operating requirements for transfer facilities, clarification is requested on the allowable time a transfer facility may hold waste on-site prior to processing. Other sections of the regulations refer to now a consistent 72 hours for holding time of waste. Would transfer stations be permitted to hold waste for 72 hours as well or would there be different requirements as under Chapter 279, Subchapters A and C?

Recommendation: Add a section, § 284.230 – Storage time requirements. This section can specify the 72 hour requirement to be consistent with § 284.512 (g) – ". . Regulated medical waste may be kept in an unrefrigerated transport vehicle for up to 72 hours provided the waste is not putrescent." (3, 4, 5)

Response: As suggested by the commentator, the department has added § 284.230 (relating to storage requirements for transfer facilities) to clarify that transfer facilities may store regulated medical or chemotherapeutic waste for up to 72 hours provided that it is in the original packaging, is not putrescent, and does not attract vectors.

§ 284.321 – Regulated medical waste monitoring requirements

13. **Comment:** Section 284.321(m) requires an autoclave facility to comply with all applicable requirements and is prohibited from processing pathological waste or chemotherapy waste. Under the proposed amendment to the definition of pathological waste, those materials which have been in preservatives would no longer be considered pathological waste. Does the department intend then that those materials may be autoclaved or would they not be required to be treated at all (see definition of Pathological Waste clarification request above)? (3, 4, 5)

    Response: The department has deleted the proposed addition to the definition of "pathological waste" in the final rulemaking. Therefore, preserved tissues will remain subject to the definition of "pathological waste," unless the tissues meet the exception provided in subparagraph (iii)(B) of the definition of "infectious waste," and must be managed as "regulated medical waste" as set forth in the final rulemaking. See the response to comment 9. Human anatomical remains that do not meet the exception provided in subparagraph (iii)(B) of the definition of "infectious waste" must be incinerated prior to disposal at a landfill in accordance with § 273.511(b).

14. **Comment:** Section 284.321(n)(3) requires an autoclave facility to validate the autoclave operation and at a frequency specified by the manufacturer, but no less than 1 year. It is not typical that autoclave processes are "validated" regularly. They are typically validated at the start up or during process change (such as the desire to increase the weight processed, change in equipment etc.). Is there a specific reference to the need for annual validations of equipment? (3, 4, 5, 7)

    Response: The department has reorganized § 284.321(n) in the final rulemaking and revised the language to require validation of the autoclave operation at a frequency specified by the manufacturer of the autoclave. The requirement to repeat the autoclave validation procedure annually has been removed from the final rulemaking.

15. **Comment:** Under § 284.321(n)(4), certain procedures are to be employed when a "significant change" occurs or a "problem is evident." Neither of these phrases sets a clear compliance standard for the regulated community. EQB should define these phrases, or provide examples of what is meant by them. (7)

Response: To assist the regulated community in complying with § 284.321(n), the department has reorganized and revised the language of this section. The following language has been incorporated in § 284.321(n) of the final rulemaking:

(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.

16. **Comment:** The disinfection, monitoring, validation, and disposal requirements in §§ 284.321 and 284.322 of the proposed regulations should be simplified for the wastes generated at biologics manufacturing facilities that utilize expert biosafety committees and consultants. Waste generated by manufacturers of vaccines or other biologics differs significantly from wastes generated by medical providers, which serves as the focus for the regulations. Unlike medical providers, biologics manufacturers employ procedures mandated by governmental agencies and standard industry practices to produce well-characterized biologics free of adventitious agents. They also establish methods specific to the biological agent to effectively decontaminate any waste in contact with the agent. These procedures include.

    1. Operating in accordance with FDA good manufacturing practices ("GMP") or good laboratory practices ("GLP").
    2. Employing trained technicians to review decontamination cycle data to confirm that kill requirements have been met.
    3. Establishing and implementing maintenance and calibration programs for decontamination equipment.
    4. Defining the methods and minimum parameters for biological kill of the infectious agents in the waste stream.
    5. Qualifying the decontamination processes to achieve the minimum parameters for kill.
    6. Implementing biosafety programs that are appropriate for the decontamination operation performed and the Biosafety Level of the infectious agents in the waste stream and that may include, among other things, practices, techniques and secondary biocontainment systems to capture any accidental discharges.
    7. Employing a qualified Institutional Biosafety Committee constituted in accordance with CDC/NIH guidelines and/or whose membership includes a biosafety professional certified by the American Biological Safety Association or the American Society for Microbiology, to review and approve the decontamination method for each specific infectious agent. In lieu of the Institutional Biosafety Committee a

contractor with the same qualifications may be given the authority and responsibility to approve a specific decontamination.

The central role of the biologics manufacturer's Institutional Biosafety Committee in designing biosafety procedures specific to each vaccine or other biologic produced on-site results in use of sound science to establish a controlled operation and environment.

Merck and Sanofi Pasteur propose that Pennsylvania's regulated medical waste regulations grant these expert Institutional Biosafety Committees authority and responsibility to approve the decontamination process, method and associated monitoring and validation requirements for each specific infectious agent at the facility in lieu of submitting an application to the Department for approval.

Merck and Sanofi Pasteur further propose that where the Institutional Biosafety Committee at a biologics facility determines that an outside certified contractor possesses special expertise concerning the appropriate decontamination procedures for waste from production of a specific vaccine or other biologic, the biologics manufacturer be authorized to rely on the judgment of the certified scientist who would then accept the responsibility for approval of the specific decontamination process. The American Biological Safety Association and the American Society for Microbiology currently offer certifications for biosafety professionals. When the Institutional Biosafety Committee seeks the special expertise of a professional certified by one of these organizations, the specific disinfection requirements specified by the expert and relied upon by the biologics manufacturer should be given the same effect as requirements developed by the Committee.

The stated objectives of the proposed amendments to Chapter 284 include providing permits-by-rule for certain processors of regulated medical waste using autoclave, incineration, steam or superheated water and chemical treatment techniques and simplifying testing requirements for autoclaves. Preamble at 4858. By incompletely addressing the concerns of manufacturers of vaccines and other biologics, the proposed amendments do no fully meet these objectives. For captive processing facilities disinfecting waste produced at the biologics production site, the expertise, infrastructure, technology and protocols of biologics manufacturers support adopting disinfection methods and monitoring, validation and waste handling and disposal regulatory provisions specific to their unique activities.

Based on the foregoing, Merck and Sanofi Pasteur recommend that the following regulatory additions to §§ 284.321 and 284.322 be adopted:

284.321(p): 1. Applicability. This subsection applies to vaccine or other biologic manufacturers classified under the North American Industrial Classification System (NAICS) as Code 325414 – Biological Protocol (except Diagnostic) Manufacturing, and who (i) utilize on-site processing facilities at which at least 50% of the waste processed is generated on-site, (ii) operate in accordance with FDA good manufacturing practices (GMP) or good laboratory practices (GLP), (iii) employ a production process where the infectious biological agents are

known and well characterized, inactivation criteria are determined and bioburden is measured and controlled including screening for objectionable organisms, and (iv) specify and approve the decontamination process, method and monitoring and validation procedures for ach specific infectious agent in its waste by (1) establishing and utilizing an Institutional Biosafety Committee constituted in accordance with CDC/NIH 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 and/or (2) 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").

2. Alternative Disinfection Requirements: Vaccine or other biologic manufacturers satisfying the applicability conditions in subsection (p)(1) may employ the following regulated medical waste disinfection procedures in lieu of the requirements in the other subsections of the § 284.321 to process waste containing an infectious agent classified as Biosafety Level 2 or below.

(1) 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 and/or independent Certified Biosafety Professional consistent with CDC and NIH guidelines and/or scientifically accepted protocols.

(2) 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 facility's Institutional Biosafety Committee and/or independent Certified Biosafety Professional as appropriate for the specific biological agent present in the waste. The procedures for demonstrating the efficacy of the inactivation operations shall be set forth in standard operating procedures and/or other written procedures maintained at the facility.

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

284.321(q): With the exception of used sharps, which remain subject to the additional requirements that this Chapter imposes on used sharps, regulated medical waste that is generated by manufacturers of vaccines and other biologics who satisfy the applicability criteria of subsection 284.321(p)(1) and decontaminated in accordance with the procedures specified in subsection 284.321(p)(2), may be managed, stored, transported and disposed of as ordinary municipal or residual waste and shall not be subject to any of the additional restrictions or requirements pertaining to special handling waste or regulated medical waste.

284.322(8): In lieu of the temperature, residence time and other requirements of this section 284.322, manufacturers of vaccines or other biologics who satisfy the applicability criterion of subsection 264.321(p)(1) may establish and validate autoclave operating parameters and residence time based upon the requirements determined by the manufacturer's Institutional Biosafety Committee and/or independent Certified Biosafety Professional as necessary to achieve the required disinfection under § 284.321(p)(2) for the specific infectious agent and /or biologic present in the wastes. (1)

Comment: The commentators state that these provisions are unnecessarily onerous when applied to the well-characterized waste streams from biologics facilities, and they raise concerns related to the impact of this section on biologics facilities. We ask EQB to explain how these provisions are reasonable and necessary for biologics facilities.

Is the temperature requirement for autoclaves reasonable for all entities who must comply, including biologics facilities where the waste is known to contain only a well-characterized vaccine or other biologic that is inactivated at a much lower temperature than that proposed? EQB should explain how the requirement is reasonable for all regulated entities. (7)

Response: The department recognizes that the wastes generated by biologics facilities that are engaged in the manufacturing of vaccines are unlike the wastes generated at hospitals, clinics and patient care facilities. The waste generated from a vaccine production process consists of a single infectious agent that is a known, well-characterized component of a vaccine or other biologic. In addition, biologics facilities are subject to additional standards imposed by federal governmental agencies that ensure a high level of protection for public health and safety. Therefore, the department has added subsections (p) and (q) to § 284.321, and paragraph (8) to § 284.322 to incorporate the recommendations of the commentators and allow biologics facilities who employ the more stringent practices required by governing federal agencies to utilize alternate disinfection protocols when disinfecting infectious waste prior to processing or disposal that are specific to the infectious agent or organism present in the facility's waste.

§ 284.411 - Segregation

17. **Comment:** The proposed rulemaking would require segregation of wastes as follows:

Section 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 sharps container.

This proposed rule does not account for the manner in which biologics facilities engaged in R&D generate waste or the safety of their on-site disposal processes. Pharmaceutical and vaccine compound research often involves the intentional combination of infectious and chemotherapeutic agents. The need to conduct research by combining infectious and chemotherapeutic agents renders it infeasible to segregate those materials when discarded. The requirement that regulated medical waste be segregated from chemotherapeutic waste should not apply to biologics facilities that combine infectious agents and chemotherapeutic material as part of their R&D activities.

Based on the foregoing, Merck and Sanofi Pasteur recommend that the following subsection be added to the proposed amendment to § 284.411:

(c) Facilities engaged in the production or research and development of vaccines or other biologics, and 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, are exempt from the requirement under the subsection (a) to segregate regulated medical waste and chemotherapeutic waste. (1, 7)

Response: The regulations do not require that mixtures of infectious and chemotherapeutic agents be un-mixed when discarded. Subparagraph (iii)(K) in the definition of "infectious waste" states, "[m]ixtures of materials identified in subparagraph (i) and chemotherapeutic waste shall be managed as chemotherapeutic waste in accordance with this article." Therefore, infectious waste and chemotherapeutic waste may be mixed, provided that the mixture is managed entirely as chemotherapeutic waste. In the scenario described by the commentators, any mixture of infectious and chemotherapeutic agents must simply be managed as chemotherapeutic waste when discarded. Therefore, the language proposed by the commentators was not included in the final rulemaking.

The department has added language to § 284.411 to allow flexibility in the management of chemotherapeutic waste in instances where the waste is processed on-site by 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 requirement to use different colored bags for regulated medical and chemotherapeutic waste when the waste is processed on-site, since this requirement is only necessary when bags of chemotherapeutic waste are transported to an off-site processing facility where they are handled by workers who are unfamiliar with the contents.

§ 284.412 – Basic storage requirements

18. **Comment:** Section 284.412(a)(4), states that waste that is awaiting transport to a processing facility must be stored in a manner that "maintains the waste in a non-putrescent state, using refrigeration (<=°C or <=45°) or freezing (<=18°C or <=0°F) when necessary." The temperature for C needs to be included <=7C. (3, 4, 5, 7)

    Response: The temperature for refrigeration in degrees Celsius has been included in the final rulemaking.

19. **Comment:** Section 284.412(b), states that "enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste must be constructed of finish materials that are impermeable and capable of being readily maintained in a sanitary condition. Exhaust air from storage areas must be ventilated to minimize human exposure." Ventilation requirements are too generic or broad. Would recommend that the department consider deleting last sentence and replacing it with the following:

    > "Containers in enclosures must be maintained in a closed upright position when not in use in the storage areas to minimize exposure and vectors." (3, 4, 5)

    Response: The commentators are citing existing regulatory language that was relocated from § 284.411(b) to § 284.412 (b) in the proposed rulemaking. The department has incorporated language similar to that suggested by the commentators into § 284.412(b) of the final rulemaking. However, the statement, "[e]xhaust air from storage areas must be ventilated to minimize human exposure," was maintained in the final rulemaking. The department believes that it is important to ensure that some ventilation in waste storage areas is required. In addition, the language cited by the commentators is existing regulatory language and has never been identified as problematic in the implementation of this paragraph.

20. **Comment:** Subsection (c) of 284.412 states, "regulated medical and chemotherapeutic waste may not be commingled with other waste. Confusing. Recommend "Regulated medical and chemotherapeutic waste may not be commingled with other waste in the same container." This would clarify what we understand may be the intention of the department based on the Summary of Regulatory Requirements. The distinction is that other wastes may be stored together or near each other so long as they are not commingled in the same container. Is this correct? (3, 4, 5)

    Response: The department is using the dictionary definition of "commingled" in § 284.412(c). As the commentators suggest, the intent of the department is to allow other wastes to be stored in the same area as regulated medical and chemotherapeutic waste, but prevent the mixing of unconsolidated municipal waste with unconsolidated regulated medical or chemotherapeutic waste in the same container. To clarify, the department has modified § 284.412(c) to incorporate the language suggested by the commentators.

21. **Comment:** Section 284.412(d) states that "the generator may store regulated medical and municipal waste that has been sorted and separately containerized on the same cart for movement to an onsite processing or disposal facility. Chemotherapeutic waste may also be stored on the cart with municipal and regulated medical waste if it is sorted and separately containerized and if it is moved to an onsite incinerator." There are several on-site treatment facilities in the state but there are not many on-site incinerators. It may be better stated for the generators if they are intending to treat on-site or are bringing waste to a centralized storage area to prepare waste for segregation and proper packing for off-site treatment. (3, 4, 5)

    Response: The language cited by the commentators refers to existing regulatory language that was relocated from § 284.411 to § 284.412 in the proposed rulemaking. Chemotherapeutic waste must be incinerated in order to be disposed of at a municipal waste landfill. Therefore, the provisions for regulated medical waste in § 284.412(d) were written differently than those pertaining to chemotherapeutic waste. For clarity, the department has revised the paragraph in the final rulemaking to allow regulated medical and chemotherapeutic waste that has been sorted and separately containerized to be stored in the same location as municipal waste, including on a cart.

§ 284.413 – Storage Containers

22. **Comment:** Under 284.413, I recommend adding the following language shown in bold type below:

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

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

    (2) A storage container filled with infectious waste may be stored in a refrigeration unit for up to 30 days from **the date waste was first placed in the container. Change to: from the date the container was filled or sealed, whichever comes first.**

    (3) A storage container of infectious waste that has been filled within 30 days **from the date waste was first placed in the container** may be frozen immediately for up to **90 days from the date waste was first placed in the container. Change both to: from the date the container was filled or sealed, whichever comes first.** (6)

    Response: The commentator is citing language that was deleted in the proposed rulemaking. The recommendations made by the commentator were included in § 284.415 of the proposed rulemaking and are adopted in the final rulemaking.

23. **Comment:** Section 284.413(a)(1) requires that regulated medical and chemotherapeutic waste be placed in containers that are leak-proof. Federal DOT requires that the final container for shipping

be leak-proof, however a new regulation passed in 2012 and implemented in the spring of 2013 allows for the transport of sharps containers which are not themselves leakproof to be transported in racks which maintain them upright for transport. Most sharps containers are not leak-proof, however are closed and overpacked prior to transport. The language in the OSHA Bloodborne Pathogens 1910.1030(d)(4)(iii)(A)(1)(ill) regulations states that containers must be leak-proof on sides and bottom. We would recommend that the section be modified to read "Leak-proof on sides and bottom and maintained upright." (3, 4, 5)

Response: The department has revised § 284.413(a)(1) to state that containers must be leak-proof on the sides and bottom and maintained in an upright position.

§ 284.414 – Marking of containers

24. **Comment:** Section 284.414 allows 1 year after the effective date of adoption of the proposed rulemaking to change the labels on containers from "infectious waste" to "regulated medical waste." Will it be a violation if both regulated medical waste and infectious waste are noted on the container – meaning wording would be added to reusable or single use containers in order to ensure compliance? Would the department be willing to extend the time frame for coming into compliance with the rule to 2 years? This would ensure that the existing inventory of single use containers (cardboard boxes), which are currently labeled "infectious waste" are used prior to the deadline for implementation of the new labeling requirements and that the inventory of reusable containers, which are given generators to collect waste are able to be collected and re-labeled prior to the deadline for implementation of the new labeling requirements. Based on the fact that generators will be able to hold waste on site longer (30 days after the container is full or closed to be shipped versus 30 days after the first time waste was put into the container) we want to make sure that the containers are fully rotated through the operating facilities to change appropriate markings. (3, 4, 5, 7)

    Response: The department does not consider it a violation of the regulations for both the words "regulated medical waste" and "infectious waste" to appear on containers. The department has incorporated a 2-year transition period for marking of containers in the final rulemaking, as suggested by the commentators.

25. **Comment:** Section 284.414 (a)(5) requires that the date the container was full or the date that the generator sealed the container, whichever occurs earlier, be marked on the outermost container for transportation. This is difficult to control for transporters or processing facilities which take waste from generators. We would like to request that it be clear that this is a generator responsibility. § 284.724 (a)(2) specifies that transporters may not accept or transport regulated medical waste if the waste is not properly labeled per this section. If there are customer loaded trailers, this may make it impossible for transporters to know that all containers have the date. Would recommend that either this section make it clear this is a generator requirement or that the requirement for the transporter or facility operator be exempt from this specific labeling provision. (3, 4, 5, 7)

Response: The department has revised this section to include labeling provisions that apply when waste from a single generator is placed in a vehicle or conveyance, including a roll-off, provided that the vehicle or conveyance is transported off-site every 30 days. This amendment provides flexibility by allowing generators and transporters under certain conditions to label the vehicle or conveyance with required information in lieu of labeling each individual container inside the vehicle or conveyance. The amendment aligns Pennsylvania's container marking requirements with the regulations imposed by the U.S. Department of Transportation regarding marking of containers for the transportation of regulated medical and chemotherapeutic waste.

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

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

26. **Comment:** Section 284.416 specifies that the processing facility can maintain the waste on site for 72 hours without refrigeration for waste over 77F. Does this mean once the waste is accepted on site? Most processing facilities do not necessarily have air conditioning for the processing floor. Processing facility temperatures can fluctuate. Under the current rule there is no temperature requirement to maintain waste on site. Is this for waste that is being "stored" or would the department consider waste which is being off loaded "in process"? Recommend modifying subparagraph § 284.416(1) to read as follows:

> "Seventy-two hours at ambient temperature. Should the waste become putrescent or create a concern for vectors, it must be refrigerated immediately and then must be maintained as specified under § 284.416(2) or (3)." (3, 4, 5)

Response: The department has incorporated language similar to that suggested by the commentators into the final rulemaking to allow processors of regulated medical or chemotherapeutic waste to store waste for 72 hours at ambient temperature, unless it becomes putrescent or attracts vectors.

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

27. **Comment:** In subparagraph (c)(iv), EQB is deleting strength and weight requirements on corrugated fiberboard containers. We ask EQB to explain how this amendment to the regulation adequately protects the public health, safety and welfare. (7)

Response: The department 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 department believes that a general performance standard, such as that provided in § 284.512(c)(1)(iv)(relating to transportation of regulated medical and chemotherapeutic waste; general provisions) and § 284.413(a)(relating to storage containers), is sufficient. This standard requires that containers being used 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. Containers made of alternative materials, such as plastics or metal, also may be used to transport regulated medical and chemotherapeutic waste. However, there are no standard strength and weight limits for these types of containers that could be referenced in this regulation. The department believes that it is necessary for this regulation to address all types of containers and has provided a consistent performance standard for all types.

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 department 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 department's regulations, where it is useful to provide the regulated industry flexibility in compliance and where industry standards evolve over time.

28. **Comment:** Section 284.512(e), relating to transportation of regulated medical and chemotherapeutic waste; general provisions, states, "regulated medical or chemotherapeutic waste may not be commingled with municipal waste or transported in the same vehicle as residual waste." Does this mean in the same container or could you have for example non-RCRA pharmaceutical waste (which is currently municipal waste) in separate containers but on the same vehicle? Is the idea that you could not have a roll off that had all the waste together? (3, 4, 5, 7)

Response: The department is using the dictionary definition of "commingled" in proposed § 284.512(e). The intent of the department is to allow regulated medical or chemotherapeutic waste to be transported in the same vehicle as municipal waste, but prevent the mixing of unconsolidated municipal waste with unconsolidated regulated medical or chemotherapeutic waste. To clarify, the department has revised § 284.512(e) in the final rulemaking to state, "[s]eparately containerized regulated medical or chemotherapeutic waste may be transported in the same vehicle with containerized municipal waste."

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

29. **Comment:** Section 284.513(b) requires that vehicles transporting regulated medical or chemotherapeutic waste be identified with a placard or decal containing the phrase "regulated medical waste" or "chemotherapeutic waste." Would like to request a transition period similar to the container labeling to be able to change the marking of transport vehicles. Most vehicles have "infectious waste" today and would be required to be changed which may take some time. Would it be permitted to provide the same 1 year transition period or potentially 2 years (as requested in the comments above). Also would it be improper or considered a violation if both markings were on the vehicle? (3, 4, 5, 7)

    Response: The department does not consider it a violation of the regulations for both the words "regulated medical waste" and "infectious waste" to appear on vehicles. The department has incorporated a 2-year transition period for marking of transportation vehicles in the final rulemaking, as suggested by the commentators.

30. **Comment:** Section 284.513(d), requires that the surface of vehicles that have not been in direct physical contact with regulated medical or chemotherapeutic waste shall be cleaned weekly. Why would all surfaces of vehicles which HAVE NOT been in contact with contamination be required to be cleaned weekly? Also is it the intent of this regulation that all surfaces would be required to be cleaned? Could there be language included to be clear about the cargo area or interior area of the trucks? Not all trucks may be cleaned on all surfaces weekly (roof or undercarriage especially in the winter months). (3, 4, 5)

    Response: The department has revised § 284.513(d) to specify that the cargo area of vehicles transporting regulated medical or chemotherapeutic waste must be cleaned weekly to ensure that the surfaces of vehicles which are most likely to become contaminated with infectious or chemotherapeutic agents are cleaned on a routine basis.

§ 284.623 – Conditions of licenses

31. **Comment:** Section 284.623(c), relating to condition of licenses, states that leased or subcontracted drivers who provide equipment, have no authority to operate under the licensee's license without prior written approval from the Department. Some transporters use subcontracted or contracted drivers (meaning they are temporary drivers hired from temporary labor agencies for example) and they would be working under the authority of the waste company. Would it be more clear to specify that "Leased or subcontracted haulers, and haulers who provide equipment . . ." in this section? Doing so would clarify that it is not an individual driver who is a temporary employee who cannot operate under the licensee's license but rather another company to which the license cannot be transferred? (3, 4, 5)

    Response: The department has replaced the word "drivers" with "haulers" in § 284.623(c), as suggested by the commentators.

§ 284.624 – Annual report

32. **Comment:** Section 284.634(b)(2), relating to annual report, requires that the weight or volume of each regulated medical or chemotherapeutic waste transported be included in the annual report. However, the requirements for tracking the "type" of regulated medical waste will be eliminated by the change in the manifesting requirements. It would be recommended that the annual report identify the total amount of waste incinerated versus what was treated by alternative technologies. It is not clear what the department is trying to achieve. If the goal is to ensure wastes which must be incinerated are being properly identified and diverted to incineration, then there must be some way to identify that. The manifest will no longer provide that information. We recommend that § 284.414(b)(2) be revised to the following language:

    "The weight or volume of regulated medical waste, pathological waste or chemotherapeutic waste transported." (3, 4, 5)

    Response: In the final rulemaking, the department has reinstated the language proposed for deletion at § 284.712(a)(5) into § 284.712(a)(4) of the final rulemaking, which requires the generator to include a waste code on the log or shipping papers to represent the type of waste being transported. 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 at facilities authorized to accept the waste.

§ 284.724 – Transportation limitations

33. **Comment:** Section 284.724(a)(2) states that a transporter may not accept regulated medical or chemotherapeutic waste that is recognizable if the waste is not labeled or identified as required by § 284.414 (relating to marking of containers). Will it be a violation if both regulated medical waste and infectious waste are noted on the container – meaning wording would be added to reusable or single use containers in order to ensure compliance? Would the department be willing to extend the time frame for coming into compliance with rule to 2 years? This would ensure that the existing inventory of single use containers (cardboard boxes), which are currently labeled "infectious waste" are used prior to the deadline for implementation of the new labeling requirements and that the inventory of reusable containers, which are given generators to collect waste are able to be collected and re-labeled prior to the deadline for implementation of the new labeling requirements. Based on the fact that generators will be able to hold waste on-site longer (30 days after the container is full or close to be shipped versus 30 days after the first time waste was put into the container) we want to make sure that the containers are fully rotated through the operating facilities to change appropriate markings.

This is difficult to control for transporters or processing facilities which take waste from generators. We would like to request that it be clear that this is a generator responsibility. Section 284.724(a)(2) specifies that transporters may not accept or transport regulated medical waste if the waste is not properly labeled per this section. If there are customer-loaded trailers this may make it impossible for transporters to know that all containers have the date. Would recommend that either this section make it clear this is a generator requirement or that the requirement for the transporter or facility operator be exempt from this specific labeling provision. (3, 4, 5, 7)

Response: The department does not consider it a violation of the regulations for both the words "regulated medical waste" and "infectious waste" to appear on containers. The department has incorporated a 2-year transition period for marking of containers in the final rulemaking, as suggested by the commentators.

The department has revised § 284.414 to include labeling provisions that apply when waste from a single generator is placed in a vehicle or conveyance, including a roll-off, provided that the vehicle or conveyance is transported off-site every 30 days. This amendment provides flexibility by allowing generators and transporters under certain conditions to label the vehicle or conveyance with required information in lieu of each individual container inside the vehicle or conveyance. The amendment aligns Pennsylvania's container marking requirements with the regulations imposed by the U.S. Department of Transportation regarding marking of containers for the transportation of regulated medical and chemotherapeutic waste.

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

§ 284.732 – Use of logs and shipping papers

34. **Comment:** The PADEP has done a great job in changing the manifesting requirements. This provides added flexibility and compliance with federal regulations for the shippers (generators), the haulers and processing facilities. There are some sections that still refer to "manifest" or requirements for "properly completed manifest." We would recommend to be consistent that these documents continue to be referred to as a "log or shipping document." (3, 4, 5)

Response: The department has changed all references to "manifests" to "logs or shipping papers" in the final rulemaking, including section headings.

35. **Comment:** Section 284.732(b)(3) requires that the receiving facility provide the transporter of waste with a dated, handwritten signature from an authorized representative of the facility acknowledging that it has accepted the waste from the transporter on that date. Would the department be willing to accept a stamp of the signature from the authorized representative at the facility? (3, 4, 5)

    Response: The department has amended §§ 284.732(a) and 284.732(b)(3) to include electronic signatures or the stamped signature of an authorized representative as an acceptable means of acknowledging the receipt of waste on logs or shipping papers.

36. **Comment:** Section 284.734(b) states that "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." This is a very difficult section. For operators who are transporting the waste, they may not know that there is a discrepancy until it reaches a processing facility. The processing facility is often offloading at the same time that it is processing the waste through. This would mean that under certain circumstances the waste will have already been processed before the discrepancy was clearly identified. The processing facility should make every attempt to identify with the generator what happened (especially because the generator-loaded trailers can be off considerably by piece count just due to improper loading procedures). Would not recommend that the waste be held from processing.

    We would offer the following change/addition:

    If there is a significant discrepancy in the logs or shipping papers the operator shall:

    (i) Notify the generator within 3 business days if the waste was a customer loaded trailer;

    (ii) Notify the transporter within 3 business days to identify to the transporter of the discrepancy when the waste is from multiple generators or a single generator in a load.

    (iii) The transporter is required to ensure reconciliation of the load and must report any unresolved discrepancies to the department within 7 business days of being notified of the discrepancy. (3, 4, 5)

    Response: The department recognizes that the circumstance described by the commentators is possible. However, if the quantity of waste unloaded from a vehicle or trailer does not match the quantity of waste specified on the log or shipping papers, it is unrealistic that the discrepancy could be reconciled if the waste has been processed and is no longer available for evaluation. The department 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

commentators was not included, and the amendments to § 284.734(b), as proposed, were adopted in the final rulemaking.

Comments on Regulatory Analysis Form (RAF)

37. **Comment:** In its response to the RAF, EQB cites various numbers in terms of how many entities are affected by the regulation. For example:
    - In response to #10, EQB states there are an estimated 16,063 generators.
    - In response to #15, EQB states that the regulation will affect generators, processors and transporters.
    - Also in response to #15, EQB states that 42 transporters will be affected.
    - In response to #16, EQB estimates 16,063 entities will be affected by the regulation.

    Also, it is unclear to us, based on our review of the RAF, whether EQB includes processors in the total.

    We understand through our discussion with the Department that quantifying the number of affected entities is challenging, but we ask EQB to revise its response to the RAF to ensure that, as accurately as possible, all types of entities impacted by the regulation are counted and considered in EQB's response to each question. (7)

    Response: The department recognizes that it failed to include biologics facilities when considering the proposed rulemaking. In its revisions to the RAF, the department included information relating to the biologics facilities that are impacted by the rulemaking.

    The number of processors operating in Pennsylvania is difficult to obtain because the term "processors" by definition includes waste transfer facilities, facilities engaged in the disinfection, incineration, shredding, and encapsulation of regulated medical and chemotherapeutic waste, including those facilities which may operate under the permit-by-rule provisions of the regulations, as well as some generators, such as hospitals, doctors' offices, dentists' offices, veterinary practices and other patient care facilities that are processing their own waste. Therefore, there is some overlap between the number of generators of regulated medical and chemotherapeutic waste and the number of processors of those wastes, since in some instances the generators and the processors are the same entity. In consideration of the foregoing, the department has revised its response to the RAF; provided its best estimate of the number of processors in the commonwealth; and to the best of its ability ensured that all types of entities impacted by the regulation are counted and considered in response to each question.

Comments on Preamble

38. **Comment:** In § 271.1 regarding the definition of *infectious waste,* EQB states: "Also, tubing that is used to connect the intravenous bag to the patient has been added." It does not appear that this

language regarding tubing has, in fact, been added to the definition of *infectious waste*. We ask EQB to review the definition and ensure that it has been amended as intended. (7)

Response: The term "tubing" was added to the preamble in error. The pertinent parts of the preamble have been updated.

39. **Comment:** In § 284.711, relating to use of manifest, EQB states that language regarding manifests is proposed to be deleted and replaced with logs or shipping papers. For clarity and consistency, EQB should consider whether deleting the word "manifest" from the titles of relevant sections would improve clarity of the regulation. Likewise, commentators state that some sections of the regulation still refer to manifests. For clarity and consistency, EQB should ensure that references to manifests are updated as intended. (7)

    Response: The department has changed all references to "manifests" to "logs or shipping papers" in the final rulemaking, including the titles of sections, and the relevant sections of the preamble have been updated.

pennsylvania
DEPARTMENT OF ENVIRONMENTAL
PROTECTION

July 25, 2014

David Sumner
Executive Director
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17120

Re: Final Rulemaking: Regulated Medical and Chemotherapeutic Waste (#7-480)

Dear Mr. Sumner:

Pursuant to Section 5.1(a) of the Regulatory Review Act, please find enclosed the Regulated Medical and Chemotherapeutic Waste final rulemaking for review and comment by the Independent Regulatory Review Commission (IRRC). The Environmental Quality Board (EQB) adopted the final rulemaking at its July 15, 2014 meeting.

The enclosed final-form rulemaking includes comprehensive amendments to the Commonwealth's existing infectious and chemotherapeutic waste regulations. Pennsylvania's current infectious and chemotherapeutic waste regulations are not aligned with nationwide practices and therefore place Pennsylvania at a disadvantage. This rulemaking makes Pennsylvania's requirements for regulated medical and chemotherapeutic waste consistent with federal requirements. This rulemaking also eliminates duplicative and other outdated requirements, thereby streamlining the regulations. These amendments enhance compliance and support cost effective business practices among generators, transporters and processors of regulated medical and chemotherapeutic waste in Pennsylvania.

The rulemaking modifies existing terminology so that medical waste is identified under Pennsylvania regulation in a manner consistent with federal requirements. With the revision in terminology, the labeling requirements for medical waste have been simplified, thereby reducing costs and ensuring consistency with the requirements of other states and the federal government. In addition, the rulemaking provides seven new permits-by-rule for qualifying processors of medical waste and allow generators, transporters and those involved in storage and processing to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations in lieu of the currently prescribed, outdated paper manifest. The rulemaking also encourages labor and fuel efficiency by allowing generators to completely fill containers prior to shipment, allowing haulers to transport regulated medical waste with other wastes in the same vehicle, and by allowing transporters more time to completely fill a vehicle before that vehicle must be placed into service. Finally, the rulemaking allows the shipment of regulated medical waste through the mail where authorized by the U.S. Postal Service.

All generators, processors and transporters of regulated medical or chemotherapeutic waste currently regulated by the Department of Environmental Protection (Department or DEP) are required to comply with this final-form rulemaking. Generators and processors include providers of medical care such as hospitals, physician offices, veterinary offices, home health care, nursing home facilities, blood collection agencies, laboratories and research facilities. Approximately 16,303 generators of infectious and chemotherapeutic waste are affected by this rulemaking. As of May 14, 2014, there were 46 transporters of infectious and chemotherapeutic waste licensed by DEP and 25 processors of infectious and chemotherapeutic waste operating under permits authorized by DEP.

DEP conducted extensive outreach in the development of this rulemaking, consulting with Stericycle, Inc. (the nation's largest medical waste transportation and disposal company), the Pennsylvania Medical Society, the Pennsylvania Dental Association, the Pennsylvania Veterinary Medical Association, the American Red Cross, Johnson & Johnson Pharmaceutical Research and Development, and a representative selection of hospitals, dentist offices, long-term care facilities, medical laboratories and physician's offices in Pennsylvania.

DEP also consulted with two of its advisory committees in the development of this rulemaking. In September of 2011, the Solid Waste Advisory Committee (SWAC) considered the proposed amendments to the regulations and encouraged DEP to present them to the EQB for action. In November of 2012, the proposed rulemaking was presented to the Small Business Compliance Advisory Committee (SBCAC). SBCAC provided a letter of support for this rulemaking, stating these revised regulations will benefit small and rural health facilities by helping them to comply with regulatory requirements. On March 6, 2014, SWAC reviewed the comments received on the proposed amendments, including DEP's responses and possible revisions to the proposed regulations. On June 5, 2014, SWAC endorsed moving the final amendments to the EQB for consideration as a final-form rulemaking.

The proposed rulemaking was adopted by the EQB on April 16, 2013 and was published in the *Pennsylvania Bulletin* for public comment on August 24, 2013, where notice of a 30-day public comment period was provided. The Board received comments from seven commentators including: Warren Glass law firm on behalf of Merck Sharp and Dohme Corporation (Merck) and Sanofi Pasteur, Inc.; Pennsylvania State University; Stericycle, Inc.; OnSite Sterilization, LLC; Environmental Industry Associations' Healthcare Waste Institute, Inc.; Pennsylvania Department of Corrections, Bureau of Health Care Services; and the Independent Regulatory Review Commission. DEP worked cooperatively with representatives of Merck during the development of the final rulemaking and was able to incorporate provisions that satisfy the comments submitted on behalf of the biologics facilities while maintaining a high level of protection for public health and the environment. All comments, responses, and changes that were incorporated into the final-form rulemaking are included in the comment and response document that accompanies this final rulemaking.

The Department will provide assistance as necessary to facilitate IRRC's review of the enclosed final-form rulemaking under Section 5.1(e) of the Regulatory Review Act.

Please contact me by e-mail at ledinger@pa.gov or by telephone at 717.783.8727 if you have any questions or need additional information.

Sincerely,

Laura Edinger

Laura Edinger
Regulatory Coordinator

Enclosures

0120-FM-PY0011 8/2006

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION
OFFICE OF POLICY

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 7-480 Regulated Medical and Chemotherapeutic Waste

SUBJECT:

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Regulation with Notice of Proposed Rulemaking Omitted
- ☐ 120-day Emergency Certification of the Attorney General
- ☐ 120-day Emergency Certification of the Governor
- ☐ Delivery of Tolled Regulation
  a. ☐ With Revisions b. ☐ Without Revisions

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2014 JUL 25 AM 9:48

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
7-25-14	Mary Seiger	Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Rep. Ron Miller
7-25-14	Jerri L Kolb	Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Rep. Greg Vitali
7-25-14	Patti Gilroy	Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator Gene Yaw
7-25-14	Richard Cox	Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY Senator John Yudichak
7/25/14	K. Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 4920

SUBJECT:

AGENCY: DEPARTMENT OF ENVIRONMENTAL PROTECTION

TYPE OF REGULATION

- ☐ Proposed Regulation
- ☒ Final Regulation
- ☐ Final Regulation with Notice of Proposed Rulemaking Omitted
- ☐ 120-day Emergency Certification of the Attorney General
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7-25-14		Majority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
7-25-14		Minority Chair, HOUSE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
7-25-14		Majority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
7-25-14		Minority Chair, SENATE COMMITTEE ON ENVIRONMENTAL RESOURCES & ENERGY
		INDEPENDENT REGULATORY REVIEW COMMISSION
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