

# **COMMENT AND RESPONSE DOCUMENT**

## **PROPOSED REGULATED MEDICAL AND CHEMOTHERAPEUTIC WASTE REGULATIONS (#7-480)**

**JULY 1, 2014**

## 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 biologics.” 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 biologics” 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 biologics” 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 volatilizing 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 not 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 each 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 ( $\leq 0^{\circ}\text{C}$  or  $\leq 45^{\circ}$ ) or freezing ( $\leq 18^{\circ}\text{C}$  or  $\leq 0^{\circ}\text{F}$ ) when necessary.” The temperature for C needs to be included  $\leq 7^{\circ}\text{C}$ . (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)(iii) 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.