Comments of the Independent Regulatory Review Commission

Environmental Quality Board Regulation #7-480 (IRRC #3017)

Regulated Medical and Chemotherapeutic Waste

October 23, 2013

We submit for your consideration the following comments on the proposed rulemaking published in the August 24, 2013 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Environmental Quality Board (EQB) to respond to all comments received from us or any other source.

1. **Determining whether the regulation is in the public interest; Economic or fiscal impacts; Direct and indirect costs to the Commonwealth or private sector; Reasonableness of requirements.**

EQB states in the Preamble that the proposed regulation represents a comprehensive revision of Pennsylvania's existing infectious and chemotherapeutic waste regulations. In developing this proposed regulation, EQB consulted with several advisory committees and met and communicated with members of the regulated community. Merck Sharp and Dohme Corp. (Merck) and Sanofi Pasteur Inc. (Sanofi Pasteur) commented on the regulation, asserting that biologics facilities, a segment of the regulated community, were excluded from providing input on the proposed regulation. We met with Department of Environmental Protection (Department) staff who acknowledged that while they did not meet with this segment of the regulated community during the drafting process, staff is in communication with Merck and Sanofi Pasteur and is considering the issues raised in their comments.

Merck and Sanofi Pasteur assert that biologics facilities are highly regulated by the U.S. Food and Drug Administration, which imposes stringent requirements and mandates practices to ensure the purity and safety of vaccine products. According to Merck and Sanofi Pasteur, biologics facilities assiduously follow the Centers for Disease Control and Prevention (CDC) biosafety guidelines, which require companies to classify infectious agents present at their facilities into one of four biosafety levels based on the risk that the agents pose. Biosafety Level 1 agents are those that do not pose a risk of disease requiring special precautions or handling. The crux of the comments submitted by Merck and Sanofi Pasteur is that infectious wastes containing only Biosafety Level 1 agents should not be treated as ordinary municipal or residual waste.

Merck and Sanofi Pasteur request EQB amend the regulation, taking into consideration the CDC classification of Biosafety Level 1 agents and the unique activities conducted at biologics facilities. Specifically, Merck and Sanofi Pasteur raise concerns regarding:

- The need to exempt Biosafety Level 1 agents from the definition of *regulated medical waste* because these agents pose no appreciable risk of causing disease;
- The need to exempt the large volume of plastics generated by biologics facilities from the definition of *sharps* because they pose little risk of puncture and are not considered sharps in almost all other jurisdictions;
- The need to define "residue in empty containers";
- The need to clarify the term "cell lines";
- The need to exempt certain biologics facilities from the requirement to segregate regulated medical waste from chemotherapeutic waste; and
- The need to simplify disinfection, monitoring, validation and disposal requirements for certain biologics manufacturing facilities.

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.

2. Section 271.1. Definitions. – Protection of the public health, safety and welfare; Clarity; Reasonableness of requirements.

Infectious waste

In order to use terminology that is consistent with other states and the Federal government, EQB is amending the regulation to identify *infectious waste* as *regulated medical waste*. 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.

As noted in comment 1, Biosafety Level 1 agents are those that do not pose a risk of disease requiring special precautions or handling. We ask 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*.

Commentators note that under Clause (i)(A) (relating to cultures and stocks) the definition of *cultures and stocks* uses the undefined term "residue in emptied containers." Commentators request that EQB provide clarity to the regulated community by incorporating the Resource and Conservation and Recovery Act (RCRA) definition of empty containers into this regulation.

Commentators request that certain emptied containers meeting the RCRA criteria be exempt from the definition of *infectious waste*. We ask EQB to address this clarity concern for the regulated community, or to explain why clarification is not needed.

Commentators further request that certain cell lines that have not been exposed to infectious agents classified as Biosafety Levels 2-4 be exempt from the definition of *infectious waste*. We ask EQB to explain why it is reasonable to include these cell lines in the definition of *infectious waste.*

Also, under Clause (i)(B) (relating to pathological wastes), EQB is proposing to exempt tissues preserved with formaldehyde from the definition of *pathological waste*. Several commentators express confusion over what type of waste this tissue will be considered after the regulation takes effect. Could this confusion among the regulated community affect protection of the public health, safety and welfare? EQB should address this concern or clarify its intent by revising the definition.

Used sharps

We ask EQB to explain the reasonableness of including plasticware generated at biologics facilities in the definition of *used sharps*.

3. Section 284.122. Modification of certain requirements. – Determining whether the regulation is in the public interest; Protection of the public health, safety and welfare.

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?

4. Section 284.321. Regulated medical waste monitoring requirements. – Economic or fiscal impacts; Clarity; Need for the regulation; Reasonableness of requirements; Implementation procedures.

General

Commentators state the following provisions are appropriate when the specific biological composition of the waste is unknown:

- Proposed amendments to Paragraph (a)(2) related to disinfection;

- The monitoring provisions in Subsection (d); and
- Existing regulations referencing this section (Sections 273.411 and 273.511 require Departmental approval for the disposal at a municipal landfill of waste disinfected in accordance with Section 284.321.).

Correspondingly, these commentators state that these provisions are unnecessarily onerous when applied to the well-characterized waste streams from biologics facilities, and 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.

Annual validation

Paragraph (n)(3) requires the regulated community to validate existing systems at a frequency specified by the manufacturer, but not less than one year. This appears to be a new requirement for the regulated community. Is it possible that a manufacturer requires its product to be validated at a frequency that is greater than one year? If so, EQB should explain why it is reasonable to implement a more stringent timeframe than a manufacturer has set. Will this new requirement have economic or fiscal impacts on the regulated community?

Threshold for procedures

Under Paragraph (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.

5. Section 284.322. Autoclave validation testing requirements. – Reasonableness of the requirements.

EQB proposes to set new requirements for autoclave operating parameters. Commentators question the reasonableness of the minimum temperature requirements in Section (5). Is this temperature requirement reasonable for all entities who must comply, including biologic 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.

6. Section 284.411. Segregation. – Clarity, feasibility and reasonableness of the regulation.

Commentators raise concerns that the nature of the work conducted at biologics facilities makes it infeasible to segregate the waste according to EQB's proposed regulation. Commentators further assert that in some cases segregation is unnecessary if the waste is processed and kept entirely on-site. EQB should explain how the proposed regulation is feasible and reasonable for biologics facilities, particularly for facilities where the waste is kept entirely on-site, or amend the regulation to address these concerns.

7. Section 284.414. Marking of containers. – Protection of the public health, safety and welfare; Clarity and lack of ambiguity; Reasonableness of requirements; Implementation procedures.

General

This section addresses the types of information required to be marked on the outermost container; however, we do not see where this section, or any other section of the regulation, states explicitly who is responsible for complying with the requirements of this section. While it is implied that this section applies to generators (particularly in Paragraph (a)(5) which references the date that the generator sealed the container), for the protection of the public health, safety and welfare, we ask EQB to clarify in the final-form regulation who bears responsibility for complying with requirements for marking of containers, thereby ensuring lack of ambiguity.

Implementation timeframe

In Paragraph (a)(3), EQB provides a one-year timeframe for the regulated community to comply with the new requirements for marking containers. Commentators express concern about having sufficient time to use their existing inventory of containers, particularly given that the proposed regulation would extend the length of time that a generator is permitted to hold waste. We agree and ask EQB to review the proposed implementation procedures in light of this concern and consider the reasonableness of extending the implementation timeframe.

Commentators pose a related concern regarding whether having both "infectious waste" and "regulated medical waste" marked on a container would be a violation after the implementation timeframe cited in Paragraph (a)(3). We agree that EQB should clarify for the regulated community whether this would be a violation.

8. Section 284.512. Transportation of regulated medical and chemotherapeutic waste; general provisions. – Protection of the public health, safety and welfare; Clarity; Implementation procedures.

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.

We also ask EQB to consider amending this section to clarify how roll-offs are impacted. For example, in Subsection (e) (relating to commingling of waste), how does the requirement that regulated medical or chemotherapeutic waste may not be transported in the same vehicle as residual waste affect the transportation of roll-offs?

9. Section 284.513. Transportation of regulated medical and chemotherapeutic waste; additional provisions. – Clarity; Reasonableness of requirements; Implementation procedures.

Paragraph (b)(2) requires that vehicles transporting regulated medical or chemotherapeutic waste shall be identified with a placard or decal containing the phrase "regulated medical waste" or "chemotherapeutic waste," or both, as applicable. Commentators request that EQB provide an implementation timeframe. We agree that providing the regulated community a period of time to become compliant is reasonable, and ask EQB to revise the final-form regulation accordingly.

Similar to the concern noted above in Section 284.414 (a)(3), commentators express concern as to whether identifying a vehicle with both "infectious waste" and "regulated medical waste" would be a violation. We agree that EQB should clarify for the regulated community whether this would be a violation.

10. Section 284.724. Transportation limitations. – Protection of the public health, safety and welfare; Clarity and lack of ambiguity.

Paragraph (a)(2) states that a transporter may not accept or transport a shipment of regulated medical or chemotherapeutic waste or processed regulated medical or chemotherapeutic waste if the waste is not labeled or identified as required by Section 284.414 (relating to marking of containers). Commentators suggest that it may be impossible for transporters to verify that all marking requirements are met on containers which a generator has pre-loaded onto a trailer. These commentators question whether in a scenario such as this, transporters would be in violation of this paragraph. In light of the ambiguity regarding responsibility for marking of containers addressed in comment 7, we agree that this could be a point of concern for the regulated community. For the protection of the public health, safety and welfare, we ask EQB to clarify in the final-form regulation who bears responsibility for complying with transportation limitations.

11. Miscellaneous clarity.

Regulatory Analysis Form (RAF)

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.

Preamble regarding Section 271.1 (relating to definitions)

EQB states regarding the definition of *infectious waste*: "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.

Preamble regarding Section 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.

Section 271.1. Definitions.

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.

Section 284.111. Application for general permit.

In (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.

Section 284.412. Basic storage requirements.

The Celsius temperature equivalent to 45°F should be added to Paragraph (a)(4).