



pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION



Bureau of Waste Management

Update: Status of the Regulated Medical Waste Rulemaking

Solid Waste Advisory Committee

March 6, 2014

Timeline of Regulatory Package

- Proposed revisions published in the *Pennsylvania Bulletin* on August 24, 2013.
- Comment period closed on September 23, 2013. Comments were received from 5 commentators.
- Department is currently considering the comments received and revising the proposed regulation, as necessary.

Overview of Comments

- Definition of “Infectious Waste”
- Definition of “Used Sharps”
- Operating Requirements for Transfer Facilities
- Operating and Monitoring Requirements for Processing Facilities
- Segregation Requirements
- Storage Requirements

Overview of Comments

- Storage Container Requirements
- Marking of Containers
- Duration of Storage for Processors
- Transportation of Medical Waste
- Transporter Licensing
- Manifesting Requirements

Comments Received

Definition of Infectious Waste:

- Exclusion of agents classified as Biosafety Level 1 when generated by biologics facilities.
- Exclusion of empty containers generated by biologics facilities.
- Exclusion of cell lines that have not been exposed to infectious agents classified as Biosafety Levels 2-4 and used in biologics facilities.

Comments Received

Definition of Infectious Waste:

- Pathological Wastes: Hair, nails, extracted teeth, and preserved tissues are excluded from the definition of infectious waste.
- Clarification on whether items that are excluded from the category of pathological wastes are also excluded from the definition of infectious waste.

Comments Received

Definition of Used Sharps:

- Exclusion of plastic ware generated at biologics facilities
- Clarification on the interplay between the definitions of “sharps” versus “used sharps.”

Comments Received

Transfer Facilities – Operating Requirements:

- Clarification on the length of time a transfer station is allowed to hold regulated medical waste in a transport vehicle in §284.220.

Comments Received

Processing Facilities – Operating Requirements:

- Clarification on whether preserved tissues must be autoclaved.
- Reference for the annual autoclave validation requirements in §284.321(n)(3).

Comments Received

Processing Facilities – Monitoring Requirements (Section 284.321)

- Inclusion of additional paragraphs to apply only to certain biologics facilities and allow the use of alternative disinfection requirements applicable to the specific infectious agent used by the facility.

Comments Received

Processing Facilities – Autoclave Validation Requirements in Section 284.322

- Inclusion of an additional paragraph that applies only to certain biologics facilities and allows for development of alternative autoclave validation protocols designed for the specific agents present in the facility's waste.

Comments Received

Segregation Requirements:

- Exemption of biologics facilities from the requirement to segregate regulated medical waste and chemotherapeutic waste.

Comments Received

Storage Requirements

- Section 284.412(a)(4) is missing the required temperature threshold.

Maintains the waste in a non-putrescent state, using refrigeration (\leq $^{\circ}\text{C}$ or $\leq 45^{\circ}\text{F}$) . . .

Comments Received

Storage Requirements – Section 284.412(b)-(d)

- Clarification on the ventilation requirements for enclosed storage areas.
- Clarification on how the term “commingled” in §284.412 (c) applies to containers, storage facilities and vehicles.
- Clarification on when regulated medical, chemotherapeutic and municipal waste can be moved throughout a facility to an onsite processing or disposal facility (§284.412(d)).

Comments Received

Container Requirements – Sections 284.413-284.414

- Revise the container requirements to allow containers to be transported upright and leakproof on the sides and bottom.
- Clarification on whether containers can be marked with both “infectious waste” and “chemotherapeutic waste.”

Comments Received

Marking of Containers – Section 284.414

- Allow 2 years after the effective date of the final rulemaking to comply with new container marking requirements.
- Clarification on the requirement to mark containers with the date the container was filled.

Comments Received

Duration of Storage for Processors – Section 284.416

- Clarification on the length of time processors are allowed to store unrefrigerated waste.

Commingling of Waste – Section 284.512

- Clarification on the term “commingled” in subparagraph (e).

Comments Received

Transportation of Medical Waste – Section 284.513

- Allow 2 years after the effective date of the final rulemaking to comply with new placarding requirements.
- Clarification on whether vehicles can be marked with both “infectious waste” and “chemotherapeutic waste.”

Comments Received

Transportation of Medical Waste – Section 284.513

- Clarification on the requirement to clean, on a weekly basis, the surface of vehicles that have not been in direct physical contact with medical waste.

Comments Received

Transporter Licensing – Subchapter G

- Clarification on whether leased or subcontracted drivers may be used without prior written approval from DEP.
- Clarification on the requirement to report the amount of each type of regulated medical or chemotherapeutic waste transported in the transporters' annual report.

Comments Received

Transporter Licensing – Subchapter G

- Allow 2 years after the effective date of the final rulemaking to comply with new labeling requirements.
- Clarification on whether containers can be marked with both “infectious waste” and “chemotherapeutic waste.”

Comments Received

Manifest Requirements – General:

- Replace references to “manifest” with “log or shipping document.”

Use of Manifest – Section 284.732

- Clarification on whether electronic signatures are acceptable on shipping papers.

Comments Received

Manifest Requirements: Significant Discrepancies – Section 284.734

- Revise the section to allow transporters to reconcile discrepancies after processing and report unresolved discrepancies to DEP.

Next Steps

- Presentation of the final rulemaking to the SWAC is expected in late summer/early fall of 2014.
- Presentation of the final rulemaking to the EQB is expected in November 2014.
- Publication of the final rulemaking in the *Pennsylvania Bulletin* is expected in early spring of 2015.



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Questions?