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DEPARTMENT OF ENVIRONMENTAL PROTECTION

Bureau of Waste Management

Update: Status of the Regulated Medical Waste Rulemaking

Solid Waste Advisory Committee

June 5, 2014

Timeline of Regulatory Package

- DEP has considered all comments received and made revisions to the rulemaking where necessary.
- DEP has developed the draft final regulatory package and supporting documents.
- SWAC reviews draft final rulemaking.

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Comments / Responses

Definition of Infectious Agents:

- Commentator requested an exclusion for agents classified as Biosafety Level 1 by a biologics facility.
- An exclusion was added to the definition of "infectious agents."

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Comments / Responses

Definition of Infectious Wastes – Cultures and stocks:

- Commentators requested clarification on what defines a residue in an empty container.
- The criteria of 40 CFR §261.7(b)(1) or (2) was incorporated for determining whether a container is empty.
- The category *cultures and stocks* was reorganized for clarity.

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Comments / Responses

Definition of Infectious Wastes – Pathological Wastes:

- Commentators requested clarification on whether items that are excluded from the category of pathological wastes are also excluded from the definition of infectious waste.
- The proposed exclusion of preserved tissues has been deleted from the final-form rulemaking.

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Comments / Responses

Definition of Infectious Waste – Used Sharps:

- Commentators requested:
  - Exclusion of plasticware generated by biologics facilities.
  - Clarification on “sharps” versus “used sharps.”

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Comments / Responses

Definition of Infectious Waste – Used Sharps:

- The definitions of “sharps” and “used sharps” were combined in the final-form rulemaking.
- References to “sharps” were updated to “used sharps” throughout Article IX.
- An exception was added for plasticware generated by biologics facilities that are not classified as Biosafety Levels 2-4.

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Comments / Responses

Definition of Infectious Waste – Exceptions:

- Commentators requested an exception be added for wastes, mixtures of wastes and cell lines generated by biologics facilities that are not classified as Biosafety Levels 2-4.
- The exception was added at subparagraph (iii)(L) of the definition of infectious waste.

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Comments / Responses

§284.220 – Operating Requirements for Transfer Facilities:

- Commentators requested clarification on the length of time a transfer station is allowed to hold regulated medical waste in an unrefrigerated transport vehicle.
- A new section, §284.230 (Storage requirements) , has been added in the final-form rulemaking to provide clarification for transfer facility storage times. Transfer facilities can store waste for up to 72 hours, but the waste must:
    - Remain in its original packaging
    - Not be putrescent
    - Not attract vectors

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Comments / Responses

§§284.321 and 284.322 – Monitoring and Autoclave Validation Requirements

- Commentators requested inclusion of additional paragraphs to allow the use of alternative disinfection methods for biologics facilities.
- The additions were added at §§284.321(p) and 284.322(q).
- §284.321(n) was also modified for clarity in the final-form rulemaking.

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Comments / Responses

§284.411 – Segregation Requirements:

- Commentators requested an exemption from the requirement to segregate regulated medical and chemotherapeutic waste for biologics facilities.
- The suggested language was not included in the final-form rulemaking. Mixtures of regulated medical and chemotherapeutic waste must be managed entirely as chemotherapeutic waste.

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Comments / Responses

§284.412(b) – Storage Requirements

- Commentators suggested deleting:

  "Exhaust air from storage areas must be ventilated to minimize human exposure."

  And replacing with:

  "Containers located in enclosures used for the storage of regulated medical or chemotherapeutic waste must be maintained in a closed, upright position when not in use to minimize exposure and vectors."

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Comments / Responses

§284.412(b) – Storage Requirements

- Most of the commentators' suggested language was added to §284.412(b), but the existing language relating to exhaust air was also maintained.

"Enclosures at a waste generating or processing facility that are used for the storage of regulated medical or chemotherapeutic waste . . . Containers located in enclosures used for the storage of regulated medical or chemotherapeutic waste must be maintained in compliance with § 284.413 and in a manner that minimizes human exposure and vectors. Exhaust air from storage areas must be ventilated to minimize human exposure."

Comments / Responses

§284.412(b) – Storage Requirements

- The commentators' suggested language that pertained to maintaining containers in a "closed, upright position when not in use" was not added.
- The storage requirements in § 284.413 (relating to *storage containers)* have been cross-referenced to allow waste containers to be closed/sealed in a manner determined by the operator, as long as it's in a manner that minimizes human exposure and vectors.

Comments / Responses

§284.412(c) – Storage Requirements

- The commentators requested clarification on how the term “commingled” applies to containers, storage facilities and vehicles.
- §284.412(c) was amended to:

  “Regulated medical and chemotherapeutic waste may not be commingled with other waste in the same container.”

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Comments / Responses

§284.412(d) – Storage Requirements

- Commentators requested clarification on the manner in which regulated medical, chemotherapeutic and municipal waste can be moved throughout a facility.
- The paragraph was modified to read:

  "The generator may store regulated medical waste, chemotherapeutic waste or municipal waste that has been sorted and separately containerized in the same location, including a cart."

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Comments / Responses

§284.413 – Storage Containers

- Commentators requested that the container requirements allow containers to be leak-proof on the sides and bottom only, provided that they are maintained upright.
- The suggested language was incorporated into the final-form rulemaking.

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Comments / Responses

§284.414 - Marking of Containers

- This section was revised to clarify labeling requirements for regulated medical waste or chemotherapeutic waste that is containerized and placed in a vehicle or conveyance, including a roll-off.
- A vehicle or conveyance can be the outermost container if both of the following criteria are met:
  - The waste in the vehicle or conveyance is from a single generator
  - The vehicle or conveyance is transported off-site for processing or disposal every 30 days

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Comments / Responses

§284.414 - Marking of Containers

- Labeling requirements can be applied to the outside of a vehicle or conveyance if it is considered to be the outermost container.
- If the date that a vehicle or conveyance is filled or sealed is not recorded on the vehicle or conveyance, the generator must maintain a record of this date at the generating facility and make it available upon request to the transporter and the Department during an inspection.

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Comments / Responses

§284.416 – Duration of Storage for Processors

- Commentators requested clarification on the temperature requirement for storing unrefrigerated waste.
- The suggested language was incorporated in §284.416. In the final-form rulemaking, processors may store waste for:
  - 72 hours at ambient temperature, unless the waste become putrescent or attracts vectors.

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Comments / Responses

§284.512(e) – Commingling of Waste

- Commentators requested clarification on the term “commingled.”
- The paragraph was revised to state:

  “Separately containerized regulated medical or chemotherapeutic waste may be transported in the same vehicle with containerized municipal waste.”

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Comments / Responses

§284.513 – Transportation; additional provisions

- Commentators requested clarification regarding which vehicle surfaces must be cleaned on a weekly basis.
- The final-form rulemaking specifies that the cargo area of vehicles used for transporting medical waste must be cleaned weekly.

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Comments / Responses

Transporter Licensing – Subchapter G

- Commentators requested clarification on whether leased or subcontracted drivers may be used without prior written approval from DEP.

- §284.623(c) was revised to specify that licenses may not be transferred to leased or subcontracted haulers, rather than drivers.

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Comments / Responses

Tracking of Medical Waste – Subchapter H

- Commentators noted that the requirement to track the type of waste on logs or shipping papers was deleted from the proposed rulemaking, but it was not deleted from the requirements for annual reports.
- The proposed deletion at §284.712(a)(5) was re-added in the final-form rulemaking, requiring the type of waste to be tracked on logs or shipping papers.

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Comments / Responses

Tracking of Medical Waste – Subchapter H

- Commentators requested that electronic signatures or stamps be acceptable for use on shipping papers in §284.732.
- Electronic signatures and stamped signatures have been specifically included in the final-form rulemaking to §§ 284.732 and 284.722, which previously required handwritten signatures.

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Comments / Responses

Tracking of Medical Waste – Subchapter H

- Commentators requested that the requirement to hold waste from processing while attempting to reconcile discrepancies be deleted from §284.734.
- The suggested revision was not adopted in the final-form rulemaking.

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Other Changes to Final-Form Rulemaking

- Deletion of §271.114 (relating to transition period).
- Extension of transition period for marking of containers and vehicles to two years.
- All references to “manifest” were replaced with “log or shipping papers.”

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Next Steps

- Present final-form rulemaking to EQB in July 2014.
- Regulation presented to IRRC in September 2014.
- Publish final rulemaking in October 2014.

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Questions?