Regulated Medical Waste Generator Inspections – An Inspector’s View Point

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13:1E-48.1 Comprehensive Regulated Medical Waste Management Act

- 13:1E-48.20 Enforcement; right to enter premises; counsel; violations; remedies; penalties, actions and injunctions
- The Department shall have the right to enter the premises of a generator, transporter or facility at any time in order to determine compliance with this act.
N.J.A.C. 7:26-3A.4(b)

- All records, reports, logs and tracking forms required to be made and/or kept in accordance with this subchapter shall be made available for inspection by the Department.
Rule of thumb

- To comply with these requirements always have someone available to provide the inspector access to the facility and the records.
What does an inspection entail?

- A regulated medical waste (rmw) generator inspection will typically be an inspection of the facility’s rmw generation areas and rmw storage areas.
- And an inspection of the rmw records for the past 3 years, which includes the rmw tracking forms and Annual Generator Reports.
See RMW Generator Checklist

*key points

- Did the RMW Generator ensure that all waste packaged in “Biohazard” labeled bags or bags with the universal biohazard symbol is managed as RMW for transport and disposal? [N.J.A.C. 7:26-3A.11(f)]
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.12(b)], is the rmw stored as follows:
  1. protected from water, rain and wind;
  2. refrigeration when necessary;
  3. lock the outdoor storage areas;
  4. limit access to authorized employees;
  5. protection from the animals, insects and rodents.
No protection from elements
Area outside and not locked
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.12(b), rmw shall be disposed of immediately if it becomes putrescent or emits any odors. And all rmw shall be disposed of within one year of the date of generation.

- As per N.J.A.C. 7:26-3A.12(c), facility shall ensure that any container that is being used to accumulate or store sharps is secured so that the contents are not accessible to any unauthorized persons.

***Biggest offender – over flow of sharps containers.
Unsecure – above the fill line and sticking out at the top
As per N.J.A.C. 7:26-3A.12(b), only use transporters that meet the requirements of N.J.A.C. 7:26-3A.27(c)... *Registered NJDEP Transporters.

As per N.J.A.C. 7:26-3A.16(h), a generator can accept home self-care medical waste for management. Generator must maintain a list of all persons, including name, address, and telephone number, and the dates and the number of the medical waste containers received.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.16(e), generators shall dispose of regulated medical waste only with a registered destination facility.
  - How does a generator ensure that their rmw is being disposed of properly through their transporters?
  - Review the manifests as they come back.
  - Ask for copies of the disposal/destination facility permits from your transporter and/or destination facility.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.8(a), register with the Department as a rmw generator and pay annual fees.
- As per N.J.A.C. 7:26-3A.8)a)1, register in the proper category.
- As per N.J.A.C. 7:26-3A.21(a)1, keep the copy of each tracking form required by N.J.A.C. 7:26-3A.19 (copy 1-generator copy and tracking form signed by the destination facility, intermediate handler or collection facility) for at least three years from the date the waste was accepted by the initial transporter.
As per N.J.A.C. 7:26-3A.12(b)

Generator shall submit annual generator reports to the Department for the period June 22 through June 21 of each calendar year by July 21 of each calendar year.

Generator retain copies of the generator reports for at least 3 years from the date that the report is due.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.19(d), generator shall complete the following information on the tracking form:
  1. Complete Boxes 1 through 15 of the tracking form for each shipment of rmw off-site;
  2. Sign and date the certification statement in Box 15 on the tracking form by hand;
  3. Obtain the handwritten signature of the initial transporter and date of acceptance on the tracking form in Box 16.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.22(b), generator shall submit a generator exception report to the Department if the generator had not received a completed copy of the tracking form signed by the owner or operator of the destination facility within 45 days of the date the waste was accepted by the initial transporter.

- As per N.J.A.C. 7:26-3A.22(c), generator shall keep a copy of the generator exception report for a period of at least 3 years.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.10(b), generator shall segregate rmw in containers according to:
  1. Sharps;
  2. Fluids (fluids greater than 20 cubic centimeters);
  3. Other regulated medical waste

- As per N.J.A.C. 7:26-3A.10(d), generator shall package, label, mark and manage as rmw all containers of solid waste and/or non regulated medical waste mixed with rmw.
Found at a solid waste transfer station. Mixed rmw.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.11(b), generators shall ensure that all regulated medical waste is placed in a container or containers that are:
  1. Rigid;
  2. Leak-resistant;
  3. Impervious to moisture;
  4. Sufficiently strong to prevent tearing or bursting under normal conditions of use and handling; and
  5. Sealed to prevent leakage during transport.
Can’t be leak resistant without a lid
OSHA Guidelines 29 CFR

- 1910.1030(d)(4)(iii)(B)(1)
  - Regulated waste shall be placed in containers which are:
    - Closable
    - Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping
    - Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.11(e), solid waste that is not being managed as regulated medical waste shall not be packaged for shipment inside a regulated medical waste container or in containers attached to, or part of, a regulated medical waste container.
Trash can being used for solid waste, but marked with a biohazard symbol
As per N.J.A.C. 7:26-3A.14(a), generator shall label each package of regulated medical waste and each individual container used at the specific location of initial generation immediately on use as either “Medical Waste” or “Infectious Waste” or display the universal biohazard symbol.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.15(a)1
  Outer container shall be marked with:
  1. generator’s name
  2. generator’s address
  3. transporter’s name
  4. transporter’s NJDEP registration number
  5. date of shipment
  6. identify contents as medical waste.
RMW Generator Checklist continued – key points

- As per N.J.A.C. 7:26-3A.15(a)2
  Inner containers, including sharps and fluid containers shall be marked with:
  1. generator’s name
  2. generator’s address
RMW Generator Checklist continued – key points
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There is an exemption under Title 49 Code of Federal Regulations: Transportation, PART 173.

173.197 Regulated medical waste.

(e) Inner packagings authorized for large packagings, carts, and BOPs. After September 30, 2003, inner packagings must be durably marked or tagged with the name and location (city and state) of the offeror, except when the entire contents of the Large Packaging, Cart, or BOP originates at a single location and is delivered to a single location.
Training, training, training....