

# Regulated Medical Waste Generator Inspections – An Inspector's View Point

Amy Scaffidi, Investigator I  
Bur. of Hazardous Waste & UST  
Compliance & Enforcement  
NJ Dept. of Environmental Protection

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Phone (609) 439-9651  
Fax (856) 614-3608

# History/Background on Regulated Medical Waste (RMW)



## Why, When, and How did New Jersey develop a regulated medical waste rule?

- Beach incidents of 1987 and 1988
- Economic impacts (*\$8 billion tourist industry*)
- *In August of 1988, New Jersey adopted a Special Medical Waste Rules which defined medical waste, created a 4 part tracking system, small quantity generator tracking exemption, record keeping, and summary reporting.*

## Why, When, and How did New Jersey develop a regulated medical waste rule? (continued)

- Signed on November 1, 1988, The EPA enacted the Medical Waste Tracking ACT (Mwta) of 1988. The Mwta defined medical waste and those wastes to be regulated, established a cradle to grave tracking system utilizing a generator initiated tracking form, required management standards for segregation, packaging, labeling and marking, and storage of the waste. This was followed by Federal EPA Regulations in June of 1989.

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

Adopted by NJ in March of 1989

- 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.

# What is Regulated Medical Waste?

- 7:26-3A.6 - Defines regulated medical waste as : “any solid waste, generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals...”

"Biologicals" means preparations made from living organisms and their products, including vaccines, cultures, etc.,intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto.

## There are 7 waste classes of Regulated Medical Waste

1. **Cultures and Stocks:** Infectious agents (humans), lab cultures, biological production wastes, live and attenuated vaccines (measles, mumps, rubella, polio), culture dishes..
2. **Pathological Wastes:** tissues, organs, body parts, body fluids that are removed during surgery or autopsy, specimens of body fluids and their containers, ...

## 7 Classes of RMW - continued

3. **Human Blood and Blood Products:** Liquid waste human blood; blood; items saturated and/or dripping with human blood; were saturated and/or dripping of blood, IV bags \*\*only if they have come into contact with blood or other regulated body fluid
4. **Sharps:** sharps that were used in animal or human patient care or treatment or in medical research, or industrial laboratories - hypodermic needles, syringes (with or w/o attached needle), scalpel blades, blood vials, culture dishes, broken or unbroken glass, culture dishes, \*\*acupuncture needles...
5. **Animal Waste:** contaminated animal carcasses, body parts, known to have been exposed to infectious agents during research that are infectious to humans.

## 7 waste classes of Regulated Medical Waste (continued)

6. **Isolation Wastes:** Biological waste and discarded material contaminated with blood excretion, secretions from humans who are isolated to protect others from highly communicable diseases or isolated animals known to be affected with such. Ex. Lassa Fever, small pox, viral hemorrhagic fevers... (list is compiled by CDC)
7. **Unused Sharps:** Unused, discarded sharps, that were intended to be used: hypodermic needles, suture needles, syringes, and scalpel blades

## When does rmw become considered non-rmw and just a solid waste???

- Treated rmw - means rmw that has been treated to substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed (N.J.A.C. 7:26-3A.5)
  - Autoclave but not destroyed/grinded – still rmw
- Destroyed rmw - means rmw that is no longer generally recognizable as rmw because all components of the waste have been ruined, torn apart, or mutilated to produce unrecognizable and unusable pieces smaller than 3-quarters of an inch...
  - Shredded/grinded with no autoclave and/or steam sterilization - still rmw
- Must have both requirements met - **TREATED AND DESTROYED TO BE CONSIDERED NO LONGER RMW.**

# Who is a medical waste generator?

- **“Generator”** – means any person, by site, whose act or process produces RMW as defined N.J.A.C. 7:26-3A.6 or whose act first causes a RMW to become subject to regulation. Examples of rmw generators are hospitals, clinics, doctor’s offices, dentists, veterinarians, etc.
- All medical waste generators shall register with the Department as a regulated medical waste generator and shall pay annual fees in accordance with the following: N.J.A.C. 7:26-3A(8)a. **NOTE: Fees were changed with update of regulations in 2009.**

Generators are divided according to the amount of waste generated, into the following five categories:

Generator Category	Pounds Per Year	Base Fee
1	less than 50	\$ 85.00
2	50-200	\$ 255.00
3	greater than 200-300	\$ 500.00
4	greater than 300-1,000	\$ 1,000.00
5	greater than 1,000	\$ 3,500.00

# Regulated Medical Waste? Or Not???

- Empty, used suction canister



# Regulated Medical Waste? Or Not???

- Not RMW
- Empty used suction canisters are not regulated. Only rmw if canister contained blood and/or body fluids removed during surgery/autopsy/medical procedure.

# Regulated Medical Waste? Or Not???

- Hygiene Products



# Regulated Medical Waste? Or Not???

- Not RMW
- Not unless that patient is generating class 6 rmw, isolation waste
- Generator can over-classify

Observed in a nursing home that the facility chose to over-classify razors and disposed of them in their sharps container.

# Regulated Medical Waste? Or Not???

- Used gowns, used gloves, used band-aides, used gauze/bandages that may have come into contact w/blood and other body fluid



# Regulated Medical Waste? Or Not???

- Not RMW
- Not unless items are saturated and dripping with blood.
- Not unless that patient is generating class 6 rmw, isolation waste

# Regulated Medical Waste? Or Not???

- E-coli grown for research. Then autoclaved.



Can it be thrown out as  
a solid waste?

# Regulated Medical Waste? Or Not???

- It is RMW
- It can only be thrown out as solid waste if it was treated and destroyed. AND the technology has to be approved by the NJDEP and DHSS.
- It is Waste Class 1 - Cultures and Stocks
- Wastes from the production of biologicals fall under rmw, does not have to be infectious.

# Sharp or non-sharp? (pictures are all rmw)

Glass  
pipettes



Syringes



# Sharp or non-sharp?

- Yes – sharp
- All syringes to which a needle can be attached (with or without the attached needle) and their components, including those from manufacturing research, manufacturing and marketing, pasteur pipettes, scalpel blades, blood vials, carpules, needles with attached tubing, acupuncture needles and culture dishes (regardless of presence of infectious agents).

# Sharp or non-sharp?

Plastic pipettes



Wooden stick applicators



# Sharp or non-sharps?

- Non-sharp.
- However, based on the experience and knowledge of your facility, these items may be needed to be disposed of as a sharp.
- ??? AND !!!!
- Inspector will not issue a violation based on the regulation.
- However, if your personnel (lab techs., environmental services, etc.) has determined that these items are a risk and are puncturing through the red bag and need to be in a puncture proof container, then act accordingly.

# 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.

TITLE 7. Environmental Protection  
CHAPTER 26. Solid Waste  
SUBCHAPTER 3A. Regulated Medical Waste

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.

## 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.**

## Over-flow of sharps



Unsecure – above the fill line and sticking out at the top



**Is the sharps container secured so that contents are not accessible to any unauthorized persons?**



**Think employee safety. Sharps container was high and on a corner shelf. Employees had a hard time reaching over to dispose of sharps. Inspection determined that there were sharps laying on top of container.**



**Sharps containers should not be used as a shelf.  
Potential Violation – could lead to container malfunction,  
over-flow of sharps, etc.**



## RMW Generator Checklist continued – key points

- 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.

## RMW Generator Checklist continued – key points

- 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. \*Exemption to generators who generate less than 200 lbs. of rmw per year. NO Annual Generator Report (AGR) required.

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



## Lids help keep the rmw in the container



# OSHA Guidelines 29 CFR

- **1910.1030(d)(4)(iii)(B)(1)**

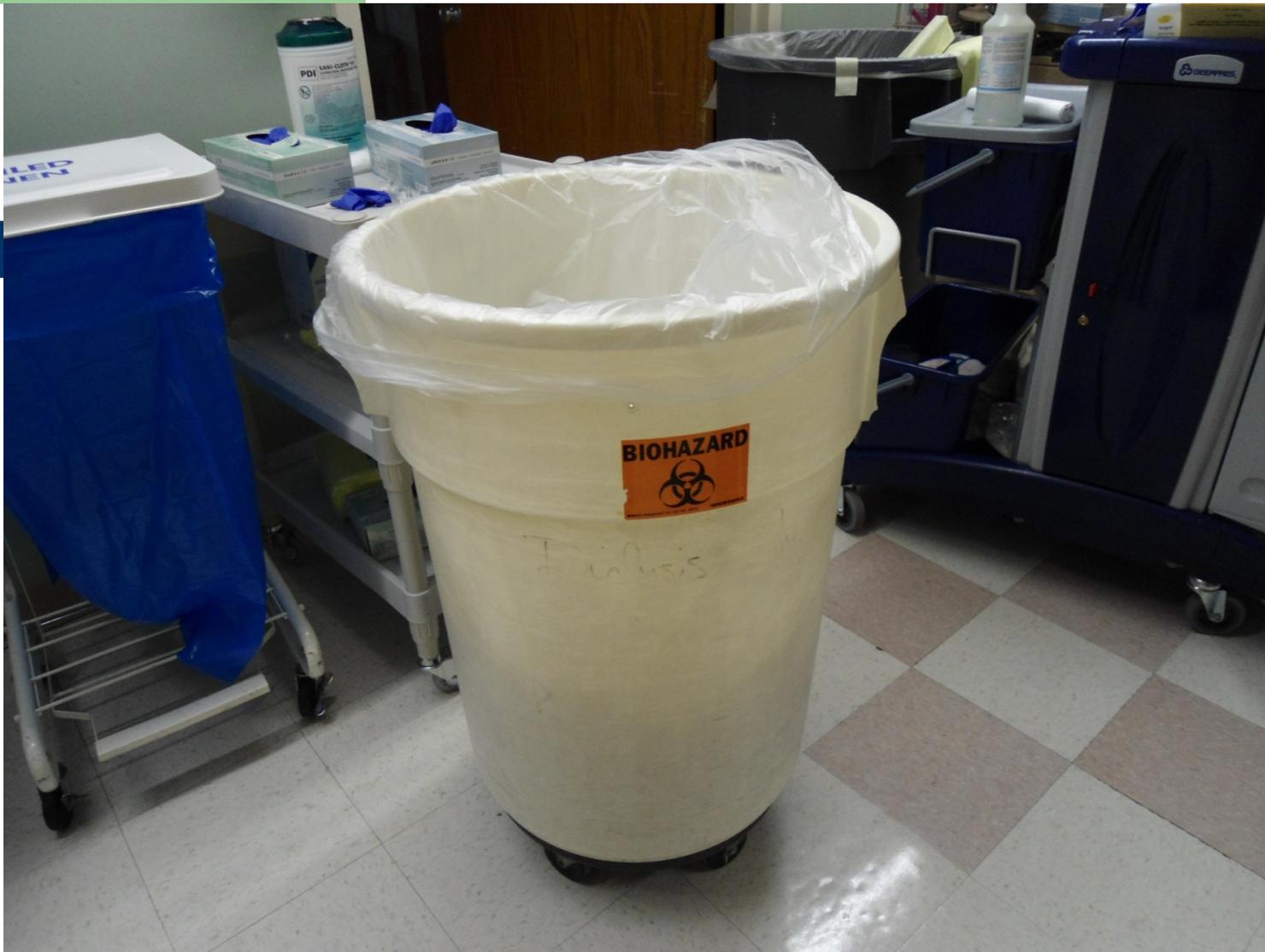
**Regulated waste shall be placed in containers which are:**

- **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



**Great idea! Two containers on one cart/tote, one for rmw and one for solid waste**



## RMW Generator Checklist continued – key points

- 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.



# Not the correct label...



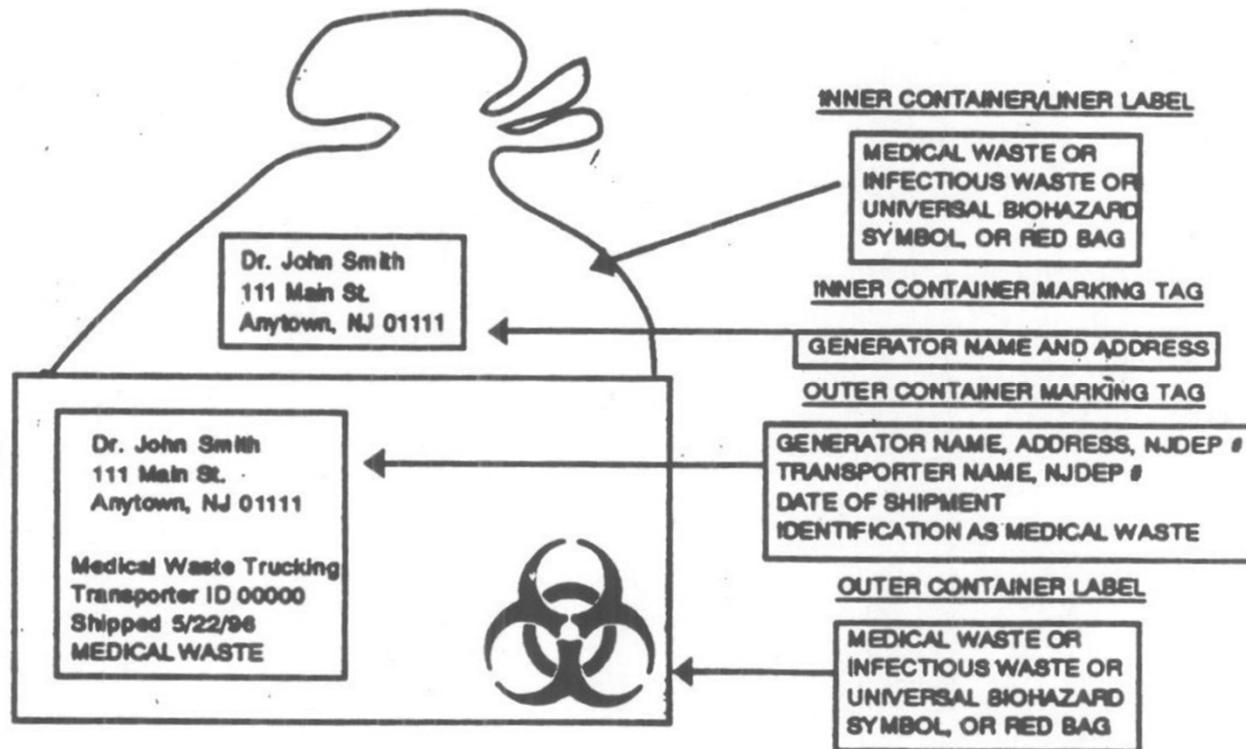
## RMW Generator Checklist continued – key points

- 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



# RMW Generator Checklist continued – key points

## HOWEVER

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.

# Exemptions to the rules

## 7:26-3A.17

- Generators of less than three cubic feet (50 pounds) of rmw per month that transport only their own rmw and home self care medical waste to another generator for storage or disposal are exempt from the requirements of N.J.A.C. 7:26-3A.16(d) and the requirements of N.J.A.C. 7:26-3A.27(c).  
  
\*Not required to be registered a rmw transporter, however you still need to complete a NJ RMW tracking forms and sign and date the certification statement in Box 15 on the tracking form by hand, and enter in Box 5 the words "Self-Transport"
- Generators that transport by the U.S. Postal Service rmw, classes 4 and 7 are exempt from the requirements N.J.A.C. 7:26-3A.16(d) if the generator generates less than 3 cubic feet (50 pounds) of rmw per month, and ship less than 50 lbs. per month. Generator must send package registered or certified mail, return receipt requested or priority mail AND fill out a rmw tracking form (see N.J.A.C. 7:26-3A.19).

## Exemptions to the rules – cont.

7:26-3A.17

- Generators of less than 500 pounds of rmw per year, excluding blood and body fluids disposed of in a municipal sewer system are exempt from the tracking requirements of N.J.A.C. 7:26-3A.19 provided (1) generators generate rmw within boundaries of a medical room operated by another registered generator generating rmw, such as a doctor or hospital (2) Each generator using the medical care room has a written agreement with the operator of the medical room providing that such operator will dispose of the generator's rmw.
- A generator that collects rmw from other generators, in the same building or in other buildings on the generator's property not divided by public roads is exempt from the requirements N.J.A.C. 7:26-3A.19

\*Not required to use a rmw tracking form.

# Training, training, training....

