

REGULATED MEDICAL WASTE *GENERATOR FACT SHEET*

(Revised November 2013)

THE NEW JERSEY REGULATED MEDICAL WASTE PROGRAM IS A COMPREHENSIVE MANAGEMENT SYSTEM THAT PROVIDES FOR THE PROPER AND SAFE TRACKING, ON SITE CONTROL, COLLECTION AND DISPOSAL OF MEDICAL WASTES BY USING A SPECIAL TRACKING FORM TOGETHER WITH SPECIFIC PACKAGING, MARKING, LABELING, REPORTING AND OTHER REQUIREMENTS.

**REPORT ALL INCIDENTS CONCERNING RELEASES OF RMW BY CALLING
THE NJDEP 24-HOUR EMERGENCY HOTLINE AT
1-877-WARNDEP (1-877-927-6337)**

BACKGROUND

A comprehensive, cradle-to-grave, regulated medical waste (RMW) management program was developed by the New Jersey Department of Environmental Protection (NJDEP) under New Jersey's Comprehensive Regulated Medical Waste Management Act (N.J.S.A. 13:1E-48 et seq.), with the assistance of the Department of Health (DOH). Procedures for the proper processing, transportation, and ultimate disposal of RMW are listed in the New Jersey Administrative Code, Title 7, Chapter 26, Subchapter 3A, (N.J.A.C. 7:26-3A). Guidelines for general procedures in other medical situations may be found in the DOH Hospital Licensure Manual, Section 306 and in the Occupational Safety and Health Administration Instructions (CPL 2-2.44).

The Regulated Medical Waste Fact sheets are publications of the Solid and Hazardous Waste Management Program (SHWMP), Bureau of Landfill and Hazardous Waste Permitting. These fact sheets are designed only as information guides, to be read in conjunction with the New Jersey RMW regulations. All persons are responsible for compliance with the RMW Regulations at N.J.A.C. 7:26-3A et seq.

Information regarding the access to the New Jersey Comprehensive Regulated Medical Waste Management Act (N.J.S.A. 13:1E-48.1 et seq.) and the New Jersey medical waste regulations (N.J.A.C. 7:26-3A) is available from the Department's Office of Legal Affairs' webpage at http://www.nj.gov/dep/legal/get_rule.htm The RMW regulations are found at pages 26-139 through 26-156.18. As an alternative to purchasing the regulations, access to an unofficial version of the regulations is made available from the Department's webpage at <http://www.nj.gov/dep/dshw/resource/rules.html>. New Jersey RMW tracking forms, reporting forms, and technical assistance with regulatory interpretations may be obtained from Mail Code: 401-02C, NJDEP, SHWMP, Bureau of Landfill and Hazardous Waste Permitting, P.O. Box 420, Trenton, NJ 08625-0420 or by calling (609) 984-6985 during normal business hours.

COPIES OF REGULATIONS & FORMS

WHAT IS REGULATED MEDICAL WASTE (N.J.A.C. 7:26-3A.6)

RMW is defined as any solid waste, generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, that is not excluded or exempted under N.J.A.C. 7:26-3A.6(b) and that is listed or meets any waste characterization criteria described in the table at N.J.A.C. 7:26-3A.6(a). Refer to the rule for excluded waste (N.J.A.C. 7:26-3A.6(b)).

“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).

“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 three-quarters of an inch, except that all sharps must be smaller than one-half inch. It does not mean compaction or encapsulation except through:

1. Processes such as thermal treatment or melting, during which treatment and destruction occur;
2. Processes such as shredding, grinding, tearing, or breaking, during which only destruction takes place; or
3. Processes that melt plastics and fully encapsulate metallic or other sharps in the melted plastic and, in addition, the resulting metal plastic mass must be completely sealed in a secondary puncture-proof container that will not be opened or penetrated by undestroyed sharps in any circumstance of handling.

REGULATED MEDICAL WASTE TABLE – WASTE CLASS & DESCRIPTION

1. Cultures & Stocks

Cultures and stocks of infectious agents and associated biologicals, including: culture from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate and mix cultures.

2. Pathological Waste

Human pathological waste, including tissues, organs and body parts, and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.**

**Regulated body fluids means liquids emanating or derived from humans and limited to blood; amniotic; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; and semen and vaginal secretions (N.J.A.C. 7:26-3A.5)

3. Human Blood & Blood Products

Liquid waste human blood; blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags (only if they have come into contact with blood or other regulated body fluid), soft plastic pipettes and plastic blood vials are also included in this category.

4. Sharps

Sharps that were used in animal or human patient care or treatment or in medical research, or industrial laboratories, including sharp or potentially sharp if broken items such as, but not limited to hypodermic needles, 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, and cultured dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware (ie. used slides and cover slips) that were in contact with infectious agents

5. Animal Waste

Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

6. Isolation Wastes

Biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect other from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

7. Unused Sharps

The following unused, discarded sharps that were intended to be used: hypodermic needles, suture needles, syringes, and scalpel blades.

N.J.A.C. 7:26-3A.6(b)4 excludes residues from treatment and destruction processes once RMW has been both treated and destroyed. RMW that is treated but not destroyed, or destroyed but not treated, is still considered RMW.

**WHO IS A
MEDICAL WASTE
GENERATOR?
(N.J.A.C. 7:26-3A.5)**

“Generator” means any person, by site, whose act or process produced RMW as defined in N.J.A.C. 7:26-3A.6 or whose act first causes a RMW to become subject to regulation. Noncontiguous properties owned or operated by the same person are separate sites and in the case where more than one person (for example, doctors with separate medical practices) are located in the same building and office, each individual business entity is a separate generator for the purposes of this subchapter. However, household utilizing home self-care exclusively are not generators.

**USE OF THE
NJDEP RMW
TRACKING FORM**

The New Jersey medical waste regulations require all medical waste generators, transporters, intermediate handlers and destination facilities to track RMW, no matter how small the amount generated. Each generator shipping RMW off site is responsible for initiating the New Jersey RMW Tracking Form. Each person in the chain of custody (handling process) of RMW assumes the responsibility for getting the waste to the proper destination facility for treatment, destruction, or disposal.

Portions of the New Jersey RMW Tracking Form must be completed by the RMW generators, transporters, intermediate handlers, and by the destination or disposal facilities. (N.J.A.C. 7:26-3A.19, 3A.31, 3A.39, and 3A.41)

In additional, RMW generated in New Jersey but transported for disposal in another state, which prints and requires use of its own tracking form, must also be report on that state’s tracking form. (N.J.A.C. 7:26-3A.19(a))

GENERATOR REQUIREMENTS

Assistance with waste classification can be obtained from NJDEP’s Bureau of Landfill and Hazardous Waste Permitting at (609) 984-6985 or the Department of Health’s Division of Environmental and Occupational Health Services at (609) 826-4941.

**REGISTRATION
AND FEES**

All medical waste generators, no matter how small the amount produced, with the exception of home self-care medical waste, must register with the NJDEP and pay the appropriate fees (N.J.A.C. 7:26-3A.8(a)). For information on medical waste generator registration, please call (609) 984-3448.

**SEGREGATION
OF WASTE**
(N.J.A.C. 7:26-3A.10)

Generators must segregate RMW intended for transport off site, to the extent practicable, prior to placement in containers. *Generators must segregate RMW into:

1. Sharps (Classes 4 and 7 as defined at N.J.A.C. 7:26-3A.6(a)) including sharps containing residual fluids;
2. Fluids (quantities greater than 20 cubic centimeters); and
3. Other RMW.

*If waste other than RMW is placed in the same container(s) as RMW then the generator must package, label, and mark the container and its entire contents according to the RMW rule requirements at N.J.A.C. 7:26-3A.11, 3A.14, and 3A.15.

STORAGE
(N.J.A.C. 7:26-3A.12)

Any person who stores RMW prior to treatment or disposal on-site or for transport off site must:

1. Store the RMW in a manner and location that maintains the integrity of the packaging and provides protection from the elements;
2. Maintain the RMW in a nonputrescent state using refrigeration if necessary;
3. Lock any outdoor storage areas containing RMW to prevent unauthorized access;
4. Limit access to on site storage areas only to authorized employees;
5. Store the RMW in a manner that provides protection from animals and does not provide a breeding place or a food source for insects and rodents;
6. Disposal of RMW immediately if it becomes putrescent; and
7. Store RMW for no longer than one year.

PACKAGING
(N.J.A.C. 7:26-3A.11)

Generators must ensure that all RMW is placed in 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;
5. Sealed to prevent leakage during transport;
6. Puncture resistant for packaging sharps and sharps with residual fluids; and
7. Break-resistant and tightly lidded or stoppered for packaging fluids (quantities greater than 20 cubic centimeters).
8. Solid waste that is not managed as RMW shall not be packaged for shipment inside a RMW container or in containers attached to, or part of an RMW container.

* Oversized RMW need not be placed in containers (N.J.A.C. 7:26-3A.11(d)).

**TRANSPORTATION
OF RMW USING
A MEDICAL WASTE
TRANSPORTER**

Generators must use only medical waste transporters, who are registered with Solid Waste Compliance and Enforcement and who possess a Certificate of Public Convenience and Necessity (N.J.A.C. 7:26-3A.27) from the NJDEP. Contact Solid Waste Compliance and Enforcement at (609) 292-7081. (N.J.A.C. 7:26-3A.16(d))*

**Exemption: N.J.A.C. 7:26-3A.17(a): Generators of less than 3 cubic feet (50 pounds) of RMW per month who transport only their own RMW to another generator for storage or disposal are exempt from transporter registration requirements provided: (1) the RMW is transported by the generator or authorized employee in a vehicle with a gross weight of less than 8,000 pounds, owned by the generator or authorized employee; (2) the original generation point and the storage point or disposal facility are located in New Jersey; and (3) the generator completes a New Jersey Tracking Form in accordance with (N.J.A.C. 7:26-3A.19(e)).*

**Exemption: N.J.A.C. 7:26-3A.17(b): Generators who transport Class 4 and Class 7 RMW (sharps and unused sharps) through US Postal Service do not need to use a registered medical waste transporter if: 1. the generator generates less than three cubic feet (5) pounds) RMW per month and ships less than 3 cubic feet (50 pounds) of RMW per shipment, 2. the package is sent registered or certified mail, return receipt requested (indicating the person to which the package is sent, signature of sender, date, and address where delivered) or Priority Mail; 3. the generator shall retain the original mailing receipt and returned registered or certified mail receipt, or in case of Priority Mail, a hard copy of the electronic delivery confirmation (containing at least the name, address, city, state, and zip code of the facility, date of delivery and amount of RMW delivered) attached to the generator copy of the tracking form; and 4. the generator shall comply with tracking form requirements at N.J.A.C. 7:26-3A.19.*

**LABELING AND
MARKING**

Transporters may not accept any shipment of RMW from a generator unless the outer surface of the container is properly labeled and marked in accordance with N.J.A.C. 7:26-3A-14 and 3A.15 (N.J.A.C. 7:26-3A.28(a))

Labeling refers to the destination of the contents as “medical waste” or “infectious waste”. Labeling means each generator must, prior to offering for transport off site, label each container of untreated RMW with a water-resistant label affixed to or printed on the outside of the container. The label shall include the words “Medical Waste”, or “Infectious Waste”, or display the universal biohazard symbol. Containers of treated medical waste or red plastic bags used as inner packaging are not required to be labeled (N.J.A.C. 7:26-3A.14(a)1).

Marking refers to the use of a name and address. Treated RMW is required to be marked (N.J.A.C. 7:26-3A(a)2). Marking means the generator, including an intermediate handler must mark the outermost surface of the outer container of RMW prepared for shipment with a water-resistant identification tag containing the generator’s or intermediate handler’s name and address, the transporter’s name and NJDEP solid waste registration number, date of shipment, and identification of the contents as RMW (N.J.A.C. 7:26-3A.15(a)1).

TRACKING FORM

Each New Jersey RMW Tracking Form contains 6 copies to be distributed as follows: (N.J.A.C. 7:26-3A.19)

- Copy 6 Generator copy – retained by generator
- Copy 3, 4 & 5 Transporter copy - retain by transporter
- Copy 2 Destination Facility Copy – retained by destination facility owner/operator
- Copy 1 Generator copy – mailed to generator by destination facility

- a. The generator completes items 1 through 15, including signing the certification at item 15;

- b. The transporter verified the quantity, notes any discrepancies in item 23, and completes and signs item 16;
- c. The generator removed copy 6 and keeps it; and
- d. The transporter retains copies 3, 4, 5 and delivers the waste to the approved destination facility.

RESPONSIBILITIES

Generators must complete the generator portion of the tracking form and sign the certification. A licensed medical waste transporter may complete the generator section of the tracking form, but it is the generator who is ultimately responsible for ensuring the information is accurate. All RMW that is shipped off the site of generation must be accompanied by a properly completed tracking form. Certification should be completed at the time that the RMW is picked up by the licensed transporter (N.J.A.C. 7:26-3A.19).

RECORDKEEPING

Retain a copy of each tracking form for at least three years from the date the waste was accepted by the initial transporter unless the Department specifically requires an additional retention period (N.J.A.C. 7:26-3A.21(a)1).

**RECEIPT BY
DESTINATION
FACILITY**

If a copy of the completed tracking form is not received from the destination facility within 35 days of acceptance of waste by the initial transporter, the generator must contact the transporter or facility to determine the status of the tracked waste (N.J.A.C. 7:26-3A.22(a)).

EXCEPTION REPORT

If a signed copy of the tracking form **is not** received from the destination facility within 45 days of acceptance of the waste by the transporter, the generator must submit a Generator Exception Report (N.J.A.C. 7:26-3A.22(b)) to:

New Jersey Department of Environmental Protection
Bureau of Solid Waste Compliance & Enforcement
Mail Code 09-01
P.O. Box 420
Trenton, NJ 08625-0420

The Exception Report must be postmarked on or before the 46th day and include:

- 1. A legible copy of the original tracking form for which the generator does not have confirmation; and
- 2. A cover letter signed by the generator explaining the efforts taken and the results to locate the RMW.

A copy of the Exception Report must be kept for at least 3 years from the date of the report.

ANNUAL REPORTS

Generators of more than 200 pounds of RMW during the period of June 22 (previous year) through June 21(current year) must complete and submit an Annual Generator Report (forms are provided by the NJDEP) to the Department by July 21st of each calendar year unless the Department specifically changes the reporting or filing date (N.J.A.C. 7:26-3A.21(d)).

**GENERATOR WITH
ON SITE
INCINERATOR
OPERATING LOG**

Generators of RMW with on-site incinerators must keep a Generator On-Site Incinerator Operating Log at their facility that includes: date, duration and quantity (in pounds) of the incineration cycle, the quantity of ash generated and transported off site, including dates of transport and identification of the transporter and disposal facility (N.J.A.C. 7:26-3A.25(a))

**GENERATOR
WITH ON SITE
INCINERATORS
THAT ACCEPT
RMW FROM
OTHER
GENERATORS**

Generators of RMW with on site incinerators that accept RMW from other generators must maintain information on: the date of waste acceptance, the origin and quantity of the RMW, and the signature of the individual accepting the waste. (N.J.A.C. 7:26-3A.25(b). Generators must also register with the NJDEP and declare their intent to operate on a commercial or non-commercial basis. Addition information on registration as a disposal facility may be obtained by calling (609) 984-6985.

**GENERATOR
WITH ON SITE
INCINERATORS
REPORTS
(N.J.A.C. 7:26-
3A.26)**

Generators of RMW with on-site incinerators must submit annual intermediate handler and Destination Facility reports on or before July 30 of each calendar year covering the period of July 1 (previous year) through June 30 (current year). The report shall be submitted to the NJDEP at the following address:

Mail Code: 401-02C
New Jersey Department of Environmental Protection
Solid and Hazardous Waste Management Program
Bureau of Landfill and Hazardous Waste Permitting
P.O. Box 420
Trenton, NJ 08625-0420
Phone (609) 984-6985

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