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**SOLID WASTE AND RECYCLING PROGRAM
WASTE MANAGEMENT AND PREVENTION DIVISION
DEPARTMENT OF ENVIRONMENTAL CONSERVATION
AGENCY OF NATURAL RESOURCES
STATE OF VERMONT**

**PROCEDURE ADDRESSING REGULATED MEDICAL WASTE DEFINITIONS
AND THE HANDLING AND TREATMENT OF REGULATED MEDICAL WASTE**

**Original: June 2001
Amended: July 2018**

Section 1 Applicability

- (a) All health care facilities, licensed healthcare professionals, haulers, transfer facilities, treatment facilities, public properties hosting events, and mobile units are subject to the requirements of these rules.
- (b) As defined in Section 2, these rules utilize two major categories of regulated medical waste (RMW) generators:
 - (1) Large quantity generator, and
 - (2) Small quantity generator.

Section 2 Definitions and Acronyms**Definitions**

- (a) “Animal Infectious Waste” means animal carcasses, body parts, bedding, and other items from animals that the Department of Health or the Agency of Agriculture knows, or suspects are contaminated with organisms that can produce disease in humans and concludes that disposal by burial or other ordinarily acceptable means of disposing of the waste would not sufficiently reduce the risk of transmission of a disease to humans or other animals.
- (b) “Certification of Treatment” means a document issued and signed by the treatment facility operator or duly authorized person, certifying that RMW was treated in accordance with Section 3 Treatment Requirements.
- (c) “Cultures and Stocks of Infectious Agents” means cultures and stocks of infectious agents including:
 - (1) Cultures from medical and pathological laboratories;
 - (2) Cultures and stocks of infectious agents from research, industrial and educational laboratories;
 - (3) Discarded live and attenuated vaccines; and
 - (4) Culture dishes and devices used to transfer, inoculate, and mix cultures.
- (d) “Decontamination” means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

- (e) “General Medical Waste” means any waste generated that, once contaminated, does not meet the Other Potentially Infectious Materials definition. This includes bandages and dressings.
- (f) “Health Care Facilities” means hospitals, clinics, physician’s offices, school nurse or health rooms, long-term care facilities, hospice, dental practices, blood banks, veterinary hospitals, veterinary clinics, medical research facilities, and laboratories. Mobile medical units, such as mobile clinics and emergency response vehicles, and temporary treatment clinics are included in this definition.
- (g) “Home Generator” means any wastes generated from the use of medications, testing supplies, injectable medications, and waste saturated by bodily fluids generated in the private single- or multi-family residence. The waste items must be originally purchased and administered by the resident to be considered home generator waste. Refer to the EPA guidelines titled: *Community Options for Safe Needle Disposal* for proper handling and disposal. Any waste generated by licensed healthcare professionals or a trauma scene is RMW and excluded from this definition.
- (h) “Inaccessible” refers to treated RMW that have been decontaminated and are placed into a sealed container. Upon visual inspection the treated waste cannot be identified. It does not mean compaction or shredding without treatment.
- (i) “Infectious Substance” means a Division 6.2 material known or reasonably expected to contain a pathogen in accordance with 49 CFR 173.134.
- (j) “Licensed Healthcare Professional” means a person whose legally permitted scope of practice allows him or her to independently perform the activities required.
- (k) “Microbiological Waste” means cultures and stocks of infectious substances including cultures from medical and pathological laboratories; from research, industrial and education laboratories; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
- (l) “Needleless System” means a device that does not use needles for:
- (1) Collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;
 - (2) Administration of medication or fluids; or
 - (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Components of needleless systems may be disposed of in the municipal solid waste unless infectious agents have potential of being present.

(m) "Other Potentially Infectious Materials" (OPIM) means the following:

- (1) Semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- and HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV and HBV.

(n) "Pathological Waste" means human tissues, organs, and body parts that are removed during surgery, autopsy, obstetrical, or other medical or diagnostic procedures.

(o) "Pharmaceutical" means any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This includes, but is not limited to: dietary supplements, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals. Pharmaceuticals and used containers are covered under the Hazardous Waste program.

(p) "Regulated Medical Waste" (RMW) means that portion of waste generated in health care facilities as defined above requires special handling and treatment prior to disposal.

(1) The following types of solid waste are considered RMW:

- (A) Pathological and microbiological waste containing blood or OPIM;
- (B) Contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed;
- (C) Sharps;
- (D) Animal infectious waste;
- (E) Liquid or semi-liquid blood or OPIM;
- (F) Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; and
- (G) Other wastes not included above as determined by the Secretary.

(2) Exclusions. The following types of solid wastes are not considered RMW:

- (A) Waste that has been identified or characterized as hazardous waste based on the compounds listed in the *Vermont Hazardous Waste Management Regulations* (HWMR) Appendix 3, U or P (Acute) list [40 CFR 261.33, *Discarded Commercial Chemical Products, Off-Specification Species, Container Residues, and Spill Residues Thereof*] and is the sole active ingredient of the mixed formulation. The formulation may be hazardous if it exhibits any of the characteristics as described in §7-205, *Characteristic of Ignitability*, §7-206, *Characteristic of Corrosivity*, §7-207, *Characteristic of Reactivity*, and §7-208, *Characteristic of Toxicity*, as presented in the Vermont HWMR;
 - (B) Corpses, remains and anatomical parts that are for ceremonial interment or ceremonial cremation;
 - (C) Nasal secretions, sputum, tears, sweat, urine, and vomitus unless they contain visible blood;
 - (D) Teeth; and
 - (E) Medical waste generated in the home that has not been administered by a visiting licensed healthcare professional (see Home Generator definition).
- (q) “RMW Generator” means any person, whose act or process produces RMW or whose act first causes RMW to become subject to regulation.
- (1) Large Quantity RMW Generator: person that generates 50 pounds or more of RMW within a month.
 - (2) Small Quantity RMW Generator: person that generates less than 50 pounds of RMW within a month.
 - (3) Exclusion: any person that meets the definition of Home Generator.
- (r) “RMW Hauler” means a permitted solid waste commercial hauler that collects and transfers RMW to a consolidated point, transfer facility, or treatment facility.
- (s) “RMW Transfer Facility” means a certified management facility where RMW is collected, aggregated, sorted, stored, and/or processed for the purpose of subsequent transfer to a RMW treatment facility for treatment. A RMW Transfer Facility does not include facilities of medical waste generators employed for the purpose of consolidation or on-site treatment facilities.
- (t) “RMW Treatment Facility” means a certified facility that accepts, stores, and treats RMW. It includes mobile treatment units. Healthcare facilities that receive RMW from off-site generators that receive a fee or payment above the cost for this service may be operating as a commercial RMW

treatment facility. In addition, healthcare facilities that import RMW that exceeds the storage and treatment capacity of the host facility or accepts RMW from generators located outside of the host facility's network of medical offices and clinics may be operating as a commercial RMW treatment facility.

- (u) "Sanitization" means the process of becoming free from elements, such as filth or pathogens, that endanger health as by cleaning or disinfecting by cleansing to destroy or prevent growth of disease-carrying micro-organisms.
- (v) "Sharps" means any objects contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating the skin. This includes needles, scalpels, syringes, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Discarded unused sharps removed from the original packaging are also considered RMW.
- (w) "Sterilize" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
- (x) "Trace Chemotherapy Waste" means containers that held antineoplastics, i.e. empty vials, syringes, and intravenous bags. This waste includes any materials that are not overtly contaminated to include, but not limited to, gowns, goggles, gloves, tubing and wipes. This waste shall be handled separately from RMW.
- (y) "Treated Regulated Medical Waste" means treated RMW that has been decontaminated to at least the most stringent spore based on manufacturing standards or as otherwise specified, to substantially reduce, or eliminate its potential for causing disease.

Acronyms

HWMR	Hazardous Waste Management Regulations
OSHA	Occupational Safety and Health Administration

Section 3 RMW Handling, Treatment, and Disposal

- (a) Any person who generates RMW should complete the requirements of the *Procedure for Waste Minimization and Pollution Prevention Assessment*. These assessment materials should be maintained by the generator and available for reference and review by staff.
- (b) Any person who generates, treats, transports, transfers, or disposes of RMW must comply with the applicable section as identified in the following table:

<u>Entity</u>	<u>Applicable Portions of this Section</u>
Large Quantity Generator	Packaging: (c) Storage: (d)(2) to (7) Treatment: (e)(2) and (6)
Small Quantity Generator	Packaging: (c) Storage (d)(2) to (7) Treatment: (e) (3) to (6)
Generator who treat solely their own waste	Packaging: (c) Storage: (d) Treatment: (e)(1), (2) and (6) Also Solid Waste Management Rules §6-1404
Transporters	Transport.: (f)
Treatment facility	Storage: (d) Treatment: (e)(1), (2) and (6) Also Solid Waste Management Rules §6-1406
Transfer Facility	Packaging: (c) Storage: (d) Also Solid Waste Management Rules §6-1405
Landfill	Disposal: (g)

(c) RMW Packaging Requirements: Generators must comply with all U.S. Department of Transportation packaging regulations, 49 CFR 173.197 and OSHA regulations, 29 CFR 1910.1030.

(d) RMW Storage Requirements: Persons who store RMW must comply with the following requirements:

- (1) Waste received at a treatment or transfer facility must be date stamped or otherwise electronically identified as received as it is inventoried into the facility as soon as feasible, not to exceed eight hours.
- (2) The date of the first waste added will be visible on the containers. Containers will be considered in storage conditions after 30 days from the first waste added.

- (3) Waste must be stored under cover on an impervious surface in a manner and location that maintains the integrity of the packaging and prevents contact with water, precipitation, wind, and animals.
- (4) Storage areas dedicated to RMW must be secured to prevent unauthorized access.
- (5) Access to on-site storage areas must be limited to authorized personnel.
- (6) Areas used for the storage of RMW must be labeled with the universal warning sign or word to identify a "Universal Biohazard".
- (7) Treated and non-treated RMW must be maintained in a non-putrescent state such that there are no offsite odors.
- (8) Time limits for storage of untreated RMW, not including sharps, at a generator that serves as a consolidating point, transfer facility, or treatment facility may not exceed:

<u>Storage Conditions</u>	<u>From Date of receipt</u>
Room Temperature	up to 3 days
Refrigerated at < 40 F	up to 7 days
Frozen at < 0 F	up to 37 days

(e) **RMW Treatment Requirements**

(1) **Persons that treat RMW must meet the following criteria:**

- (A) Waste received at a treatment facility must be date stamped or otherwise electronically identified as received as it is inventoried into the facility as soon as feasible, not to exceed eight hours.
- (B) RMW must be treated by the following methods prior to disposal:
 - (i) Pathological waste shall be incinerated at either a certified RMW treatment facility or at a crematorium; and
 - (ii) **All other RMW shall be autoclaved or treated by an alternative treatment management method in accordance with an agreement for the proper disposal of the treated RMW at a certified disposal facility which has been approved by the Secretary.**

- (iii) Exceptions:
 - (I) Cultures and stocks must be treated in accordance with the requirements of 29 CFR §1910.1030;
 - (II) Blood and liquid wastes may be treated in a municipal wastewater treatment facility with the municipality's approval;
 - (III) Unused sharps in original packaging do not require treatment but may be disposed of as treated RMW. Once unused sharps are removed from the original packaging, they are considered RMW; and
 - (IV) All trace chemotherapy waste shall be incinerated or chemically neutralized.
- (iv) Treatment effectiveness must be demonstrated by one of the following methods:
 - (I) Manufacturer accepted maintenance and validation testing; or
 - (II) Other method with prior approval by the Secretary.
- (2) A Certification of Treatment (see Appendix), or a written alternative treatment management method approval, must accompany all treated waste offered for disposal and must provide the following information:
 - (1) Date treated;
 - (2) Name and address of treatment facility;
 - (3) Contact person;
 - (4) Method of treatment;
 - (5) Signature of operator or duly authorized person, certifying waste was treated to meet the manufacturer accepted decontamination; and
 - (6) Method used to render waste inaccessible, if applicable.
- (3) Used sharps should be placed in a container specifically manufactured for sharps with a secure top.
 - (1) For containers that come specifically with an immobilizing agent, follow the instructions to add the agent, wait the prescribed time to activate, then dispose of in

the municipal solid waste.

- (2) If container does not come with an immobilizing agent, follow the guidance provided by the EPA titled: *Community Options for Safe Needle Disposal*, or as may be amended.
- (3) The container should be closed securely with the screw cap or use strong tape, like duct tape, along the edges to prevent containers from opening.
- (4) All general medical waste should be placed in a separate container and disposed of in the municipal solid waste.
- (5) Potentially infectious bodily fluids should be contained with an absorbent material prior to disposal in the municipal solid waste.
- (6) Alternative Treatment Management Method Approval: All alternative treatment management methods must meet the manufacturer accepted decontamination and be approved by the Secretary.

(f) RMW Transport Requirements

- (1) Haulers of RMW must have a solid waste commercial hauler permit under the provisions of 10 V.S.A. §6607(a) and in accordance to Occupational Safety and Health Administration (OSHA) regulations, 29 CFR 1910.1030 and US Department of Transportation regulations, 49 CFR 173.197.
- (2) Haulers of treated RMW must have a Certificate of Treatment or a written alternative treatment management method approval in the vehicle during transportation.
- (3) Haulers shall not accept boxes which show evidence of leaking.
- (4) Haulers must complete delivery from a generator to a transfer facility, treatment facility or disposal facility within 72 hours or the next business day, whichever is later.

(g) RMW Disposal Requirements

- (1) Once RMW has been decontaminated, the treated RMW may be disposed of at a certified solid waste landfill.
- (2) Treated sharps rendered inaccessible may be mixed in with municipal solid waste.
- (3) A Certification of Treatment or a written alternative treatment management method approval:

- (1) Must accompany all treated waste offered for disposal.
- (2) Shall be maintained by all in-state landfills for a period of one year.

Section 4 RMW Generators with On-site Treatment and/or Serving as Consolidation Points

(a) Applicability Requirements:

- (1) Generators, except for facilities working with infectious agents at biosafety levels 3 or 4, may treat RMW on-site of the facility if the approved treatment equipment is available and the facility has been approved to treat RMW.
- (2) All facilities may not treat pharmaceuticals as part of the on-site treatment and must follow reverse distribution and other alternatives outlined in the *EPA Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities*.
- (3) The facility is required to have a RMW operational plan submitted for review and approval. The type of sanitization treatment methodology, such as autoclaving, will be explained in detail in the RMW operational plan.

(b) Generators with onsite treatment or that serve as consolidation points shall maintain and complete the following documentation and reporting requirements:

- (1) The large quantity generator will notify the Secretary when the agreement with the associate small quantity generators is established and will track all incoming waste.
- (2) The large quantity generator will have a written agreement with the small quantity generators on file at the facility.
- (3) In the case where the large quantity generator is in litigation, all records must be maintained throughout the litigation process.

(c) Small quantity generators that are participating in the large quantity generator on-site treatment and consolidation shall:

- (1) Be subject to all packaging labeling, hauling, and recordkeeping requirements. Generators must comply with all U.S. Department of Transportation packaging regulations, 49 CFR 173.197 and OSHA regulations, 29 CFR 1910.1030.
- (2) Be prohibited from shipping infectious agents at biosafety levels 3 or 4 to the consolidation and treatment facility.

Section 5 RMW Transfer Facility Certification

- (a) Application Requirements: The complete application for a RMW transfer facility or facility component must address requirements of the Solid Waste Management Rules. Additional information required within an application for a RMW transfer facility must include within the Facility Management Plan (FMP), at a minimum, the following:
- (1) Listing of the sources and quantities of RMW anticipated;
 - (2) Detailed description of the facility operations including:
 - (A) Unloading, weighing, monitoring, handling and storing practices;
 - (B) Methods to control contaminants potentially released into the air, soil or water;
 - (C) A prevention plan for the separation and proper management of hazardous waste and other prohibited materials;
 - (D) An agreement with a treatment facility to accept the RMW;
 - (E) A schedule for transfer of the RMW to a treatment facility adjusted as necessary to minimize odors from the waste;
 - (F) A prevention plan for detecting and managing radioactive wastes;
 - (G) A plan for educating generators and haulers regarding the type of RMW that is acceptable for storage and transfer at the facility;
 - (H) Engineering plans and specifications including: site plans showing the property boundaries, facility building dimensions, and waste storage area(s); and
 - (I) Other information deemed necessary by the Secretary to adequately review the application and protect public health and safety and the environment.

Section 6 RMW Treatment Facility Certification

- (a) Application Requirements: The complete application for a RMW treatment facility must address the Solid Waste Management Rules. Additional information required within an application for a RMW treatment facility includes:

- (1) A FMP which includes, at a minimum, the following:
 - (A) Listing of all treatment component(s) including:
 - (i) Detailed description of how each component operates;
 - (ii) Demonstration that the RMW, when treated, meets the manufacturer accepted decontamination; and
 - (iii) Appropriate operating parameters for the process, such as residence time, temperature, pressure, irradiation levels, and chemical concentrations.
 - (B) Listing of the sources and quantities of RMW anticipated;
 - (C) Detailed description of the facility operations including:
 - (i) Process flow diagram showing all aspects of RMW waste handling from receiving through offering for disposal including, but not limited to, unloading, weighing, monitoring, storing and treatment;
 - (ii) Start-up and, shut-down procedures;
 - (iii) Disinfection processes for reusable containers;
 - (iv) Facility hours of operation; and
 - (v) Methods to control the release of contaminants into the air, soil or water.
 - (vi) Facility must conform and comply with local wastewater discharge or publicly owned treatment works requirements and obtain wastewater and stormwater permits as necessary;
 - (vii) List and description of all permits required including any required for air and water discharges;
 - (viii) Description of the hauling process into and out of the facility;
 - (ix) Prevention plan for the separation and proper management of hazardous waste and other prohibited materials;
 - (x) Prevention plan for detecting and managing radioactive wastes;

- (xi) Plan for educating generators, venders and haulers regarding the type of RMW that is acceptable for treatment at the facility;
 - (D) Engineering plans and specifications including:
 - (i) Site plans showing the property boundaries, facility building dimensions, site topography, utilities, treatment unit(s) and layout;
 - (ii) Piping diagrams and connection details;
 - (iii) Cross-section views of the facility; and
 - (iv) Additional specifications for all equipment instrumentation and control centers;
 - (E) Description of the calibration and validation of component used to achieve treatment including:
 - (i) Manufacturer accepted indicator used with each load to verify the effectiveness of a specific RMW treatment device, and
 - (ii) Monthly manufacturer specified calibration and validation completed during standard operation conditions.
 - (F) Monitoring and maintenance plan for all treatment, pollution control and detection equipment;
 - (G) Agreement for the proper disposal of the treated RMW at a certified disposal facility; and
 - (H) Any other information deemed necessary by the Secretary to adequately review the application.
- (b) RMW is accompanied by a certification of treatment or written alternative treatment management method approval, may be disposed of at a certified municipal solid waste landfill disposal facility.

Effective Date

This Procedure is effective upon date of Signature and expires 5 years hence or when superseded by Rule.



July 10, 2018

Rebecca Ellis, Deputy Commissioner
Department of Environmental Conservation

Date

Appendix: Regulated Medical Waste Certificate of Treatment

TREATMENT FACILITY CONTACT INFORMATION

Individual Name: _____

Facility: _____

Address: _____

I certify that this regulated medical waste was treated to the manufacturer accepted standards using:

Specify the method of treatment, e.g. autoclave, incineration, etc.

TREATED REGULATED MEDICAL WASTE DESCRIPTION

Type(s) of Treated Regulated Medical Waste Includes: _____

Specify the type of waste treated, e.g. contaminated items, sharps, etc.

Estimated Amount of Treated Regulated Medical Waste: _____

Specify units of measure in pounds or cubic yards

Date of Treatment of Regulated Medical Waste: _____

Signature of Authorized Person

Print Name

Date

CERTIFICATE HANDLING INSTRUCTIONS

Regulated Medical Waste Treatment Facilities and Generators with On-site Treatment: This Certificate must be completed to accompany each pickup of treated regulated medical waste and must be provided to the transporter.

Regulated Medical Waste Transporters: This Certificate must be maintained in the vehicle during transport and be provided to the transfer station or landfill upon delivery.

Solid Waste Transfer Stations: This Certificate indicates that the solid waste in this container contains some treated regulated medical waste which has been rendered inaccessible. Please ensure that this Certificate is provided to the transporter of this solid waste for transfer to the landfill.

Landfill: This Certificate indicates that the solid waste in this container contains some treated regulated medical waste which has been rendered inaccessible. Please ensure that this Certificate is maintained for one year.