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**SOLID WASTE MANAGEMENT PROGRAM
WASTE MANAGEMENT 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**

June, 2001

PROCEDURE ADDRESSING REGULATED MEDICAL WASTE

Prior to September 30, 1998, the Vermont Hazardous Waste Management Regulations (HWMR) listed “infectious waste” as a Vermont regulated hazardous waste. Infectious waste was defined in the Vermont HWMR as “a waste capable of producing an infectious disease. For a waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease.” The definition contained a list of wastes that had to be managed as a hazardous waste when “the presence of an infectious disease was known or when exposure to or contamination by pathogens was known to have occurred.”

Wastes generated in the medical industry consist of a wide variety of materials, ranging from office paper, packaging and food wastes to sharps, chemotherapeutic and pathological wastes. Although the vast majority of the industry’s wastes are considered regular solid waste, a small percentage of the waste requires special handling and treatment prior to disposal in order to protect public health, safety, and the environment. In this procedure, these materials are referred to as Regulated Medical Waste (“RMW”).

Solid Waste Program staff have consulted with a number of health care professionals, organizations, and regulators both within Vermont and nationally to better understand the nature of the medical waste stream. Based on these discussions, the term Regulated Medical Waste has been adopted to identify the wastes subject to special handling and treatment. The definition of RMW includes the majority of components currently listed in the definition of “infectious wastes” at §6-201 of the Vermont Solid Waste Management Rules effective January 15, 1999 (“SWMR”). However, this definition is not limited to wastes produced where the presence of an infectious disease is known or when exposure to or contamination by pathogens is known to have occurred.

The Solid Waste Program is adopting this procedure to promote the proper management of RMW. Section 1 establishes definitions for the terms used. Section 2 addresses Waste Minimization and Pollution Prevention. All RMW generators are encouraged to perform an RMW assessment. Section 3 sets forth requirements for the handling, treatment and disposal of RMW. Section 4 lists information to be included in any application for certification of an RMW transfer or treatment facility. Under this procedure RMW disposed in Vermont landfills is regulated in the same manner as “infectious waste” under § 6-802(b) of the SWMR.

SECTION 1 DEFINITIONS RELATING TO REGULATED MEDICAL WASTE

I. INTRODUCTION

The following definitions supplement definitions in 10 V.S.A. §6602, §6-201 of the SWMR, and other Solid Waste Management Facility Procedures adopted by the Secretary of the Agency of Natural Resources.

II. DEFINITIONS

BioSafety Level (BSL) is the combination of laboratory practice and techniques, safety equipment and facility design and construction appropriate to the infectious agent handled as defined by the CDC publication “Biosafety in Microbiological and Biomedical Laboratories”, 4th Edition, May 1999 or as may be amended.

Certification of Treatment is a document issued and signed by the treatment facility operator or duly authorized person, certifying that RMW was treated in accordance with the approved procedures for the method used. A sample Certification of Treatment form is included in Appendix A.

Challenge Testing is a method used to verify the effectiveness of a specific RMW treatment device using a biological indicator during standard operating conditions.

Discrete Disposal Facilities means all facilities other than diffuse disposal facilities that are used for the disposal of solid waste.

Disinfection is the reduction in level of microbial contamination.

Inaccessible means RMW that has been treated to the Treatment Standard and is placed into a sealed container and plaster-like medium so that it is no longer usable. Upon visual inspection the waste cannot be identified. It does not mean compaction or shredding.

Infectious Agent is a pathogen in sufficient virulence and quantity so that exposure to it by a susceptible host could result in an infectious disease.

Person means any individual, partnership, company corporation association, unincorporated association, joint venture, trust municipality, the state of Vermont or any agency, department or subdivision of the state, federal agency, or any other legal or commercial entity.

Regulated Medical Waste (RMW) means that portion of waste generated in the medical industry which requires special handling and treatment prior to disposal.

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

- (1) Pathological Waste: Human tissues, organs, and body parts that are removed during surgery, autopsy, obstetrical, or other medical or diagnostic procedures.

- (2) Human blood, blood products and other body fluids: which were generated in either patient care, testing and laboratory analysis or the development of pharmaceuticals, including but not limited to:
 - (A) All liquid waste human blood and blood products such as serum plasma and other blood components;
 - (B) Other potentially infectious liquid body fluids, including cerebrospinal fluid, synovial, pleural, peritoneal and amniotic fluid; not including nasal secretions, sputum, tears, sweat, urine, and vomitus unless they contain visible blood; and
 - (C) Items saturated or dripping with blood or with potentially infectious body fluids and those caked with dried blood or with potentially infectious dried body fluids.
- (3) Cultures and stocks of infectious agents: Cultures and stocks of infectious agents including cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research, industrial and educational laboratories; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
- (4) Sharps: objects that are capable of cutting or penetrating the skin and inducing subdermal inoculation of an infectious agent. This includes needles, Pasteur pipettes, scalpel blades and other items derived from human and animal patient care, blood banks, laboratories, mortuaries and research facilities. Discarded unused sharps are also considered RMW.
- (5) Animal Waste: animal carcasses, body parts, bedding, and other items from animals that are known or suspected by either the Department of Health or the Department of Agriculture of being contaminated with organisms that can produce disease in humans and that disposal by burial or other ordinarily acceptable means would not sufficiently reduce the risk of transmission of a disease to humans or other animals.
- (6) Chemotherapy waste: any non-hazardous material containing cytotoxic/antineoplastic agents (agents toxic to cells) and/or antineoplastic agents (agents that inhibit or prevent the growth and spread of tumors or malignant cells) during the preparation, handling and administration of such agents. This waste includes, but is not limited to, masks, gloves, gowns, empty IV tubing bags and vials, and other contaminated materials.
- (7) Infectious isolation waste: biological waste and discarded materials contaminated with blood, body fluids, excretion, exudates or secretions from humans who are isolated to protect others from dangerous communicable diseases.
- (8) Biotechnological by-product effluents: any discarded preparation made from genetically altered living organisms (excluding plants) and their products.
- (9) Other: wastes not included above as determined by the Secretary.

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

- (1) Waste that has been identified or characterized as hazardous waste based on the compounds listed in the Vermont HWMR Appendix 3, U or P (Acute) list (40 CFR261.33) 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 Ignitability, §7-206 Corrosivity, §7-207 Reactivity, §7-208 Toxicity as presented in the Vermont HWMR.
- (2) Corpses, remains and anatomical parts that are for ceremonial interment or ceremonial cremation.
- (3) Teeth.
- (4) RMW generated in the home that has not been administered by a visiting health care service. See Appendix B for Suggested Safe Handling Practices.
- (5) Police evidence that is held for more than one year in sealed packages.

RMW Generator is a person who produces RMW.

RMW Transfer Facility means a solid waste management facility where RMW is collected, aggregated, sorted, stored and/or processed for the purpose of subsequent transfer to an RMW treatment facility for treatment.

RMW Treatment Facility means a facility that accepts, stores and treats RMW. It includes mobile treatment units.

STAATT Report (“STAATT”) is a report produced by the State and Territorial Association on Alternative Treatment Technologies, entitled “Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies”, dated April 1994, or as may be amended.

Sterilization is the complete elimination or destruction of all forms of microbial life, including highly resistant bacterial endospores.

Treated RMW is RMW that has been treated to the Treatment Standard or as otherwise specified, to substantially reduce, or eliminate its potential for causing disease.

Treatment Standard means to disinfect to a 6 Log₁₀ probability of a survivor in a standard load of treated RMW.

SECTION 2 WASTE MINIMIZATION AND POLLUTION PREVENTION**I. INTRODUCTION**

Under both state and federal law, waste minimization and pollution prevention are the first priority for managing wastes. Waste minimization and pollution prevention is the practice that results in the maximum feasible reduction of the total volume of RMW generated; the reduction of the toxicity of the RMW, or both. It includes practices that reduce the use of hazardous and non-hazardous materials, energy, water, or other resources as well as those that protect natural resources through conservation or more efficient use.

Practices that are considered waste minimization and pollution prevention include recycling, source separation, product substitution, and the use of less toxic materials. All RMW generators are asked to consider performing a waste minimization and pollution prevention assessment for their facility.

II. RMW ASSESSMENT

A Waste Minimization and Pollution Prevention Assessment (RMW Assessment) reviews the types and amounts of RMW generated at a facility and recommends waste minimization and pollution prevention strategies for eliminating or reducing the amount or toxicity of these wastes. An RMW Assessment describes, to the extent applicable to the facility, the items listed below:

- (a) The name of the individual (s) responsible for the management of RMW.
- (b) RMW composition analysis, identifying types and amounts of RMW generated.
- (c) Waste streams of particular concern such as mercury and PVC plastics.
- (d) Current method(s) for management of RMW
 - (1) Use of on-site or off-site autoclave.
 - (2) Use of on-site or off-site incineration.
 - (3) Use of sanitary landfills, crematories or other disposal sites.
- (e) The feasibility of substituting non-toxic or less toxic materials for products containing toxic materials.
- (f) Purchasing strategies and opportunities to eliminate or reduce packaging waste, product toxicity, and the consumption of non-renewable resources.
- (g) Set and implement goals for waste minimization and pollution prevention; set and implement internal waste management policies.
- (h) Educate and train employees to comply with waste management policies and goals.

The RMW Assessment is a voluntary assessment.

SECTION 3 HANDLING, TREATMENT & DISPOSAL OF REGULATED MEDICAL WASTE

I. INTRODUCTION

This section sets forth requirements for the packaging, storage, treatment, transport and disposal of RMW for persons that generate and otherwise manage this waste. Persons regulated under this Procedure must also comply with all other State and Federal regulations.

II. REQUIREMENTS

(a) Applicability

Any person who generates, treats, transports, transfers or disposes of RMW must comply with the applicable section of this Procedure as identified in the following table:

Entity	Applicable Subsection
Generator	II(b), II(c)(2)(3)(4)(5)(6)
Generator who treat solely their own waste	II(c)(2)(3)(4)(5)(6), II(d)(2)(3)(4)
Transporters	II(f)
Treatment facility	II(c), II(d)
Transfer Facility	II(c)
Discrete Disposal Facility	II(g)

(b) Packaging Requirements

Generators must comply with all U.S. Department of Transportation packaging regulations. In addition, generators must meet the following:

- (1) All containers must be labeled with the name and address of the generator.
- (2) Containers shall not be leaking when shipped.
- (3) Bulk containers, such as roll-off containers, are not permitted for transport of untreated RMW.

(c) 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 upon receipt at the facility.
- (2) Waste must be stored in a manner and location that maintains the integrity of the packaging and prevents contact with water, precipitation, wind, and animals.
- (3) Storage areas must be locked to prevent unauthorized access.
- (4) Access to on-site storage areas must be limited to authorized personnel.
- (5) Areas used for the storage of RMW must be labeled to identify a "Universal Biohazard".
- (6) Treated and non-treated RMW must be maintained such that there are no offsite odors.
- (7) Time limits for storage of untreated RMW, at a transfer, storage or treatment facility may not exceed:

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

(d) Treatment Requirements

Persons that treat RMW must meet the following criteria:

- (1) Waste received at a treatment facility must be date stamped upon receipt at the facility.
- (2) RMW must be treated to the Treatment Standard by the following methods prior to disposal:
 - (A) Pathological waste shall be incinerated at either a certified RMW treatment facility or at a crematorium;

- (B) All other RMW shall be
 - (i) autoclaved; or,
 - (ii) treated by an alternative treatment method in accordance with Section III(f) which has been approved by the Secretary.
- (C) Exceptions:
 - (i) Cultures and stocks must be treated in accordance with the CDC Biosafety in Microbiological and Biomedical Laboratories, March 1999, or as amended;
 - (ii) Blood and liquid wastes may be treated in a municipal waste water treatment facility with the municipality's approval, or as other RMW in (d)(2)(B) above;
 - (iii) Unused sharps in original packaging do not require treatment.
Note: unused sharps may be disposed of as treated RMW; and,
 - (iv) All non-hazardous chemotherapy waste shall be incinerated or chemically neutralized.
- (3) Treatment effectiveness must be demonstrated by one of the following methods:
 - (A) Challenge testing and continuous monitoring;
 - (B) Other method with prior approval by the Secretary.
- (4) A Certification of Treatment must accompany all treated waste offered for disposal and must provide the following information (for sample form, see Appendix A):
 - (A) Date treated;
 - (B) Name and address of treatment facility;
 - (C) Contact person;
 - (D) Method of treatment;
 - (E) Signature of operator or duly authorized person, certifying waste was treated to meet the Treatment Standard;
 - (F) Method used to render waste inaccessible, if applicable.

(e) **Alternative Treatment Method Approval**

All alternative treatment methods must meet the Treatment Standard using the Process for Approving Medical Waste Treatment Technologies in Section 3 of STAATT.

(f) **Transport Requirements**

- (1) Transporters of RMW, that meet the definition of a commercial hauler, must have a solid waste transporter permit under the provisions of 10 V.S.A. §6607(a).
- (2) Transporters must ensure compliance with the packaging requirements in section II(b).

- (3) Transporters of treated RMW must have a Certificate of Treatment in the vehicle during transportation.
- (4) Transporters shall not accept boxes which show evidence of leaking.

(g) **Disposal Requirements**

- (1) Once RMW has been treated to the Treatment Standard, the treated RMW may be disposed of at a certified solid waste discrete disposal facility in accordance with the requirements set forth in §6-802(b) of the SWMR.
- (2) Treated sharps rendered inaccessible may be mixed in with municipal solid waste.
- (3) A Certification of Treatment must accompany all treated waste offered for disposal.
- (4) Certification of Treatment shall be maintained by all in-state landfills for a period of one year.

SECTION 4 TREATMENT AND TRANSFER FACILITY CERTIFICATION APPLICATION REQUIREMENTS

I. INTRODUCTION

Persons that wish to operate a RMW treatment or transfer facility must obtain a solid waste management facility certification as required by 10 V.S.A. §6605 and the Vermont Solid Waste Management Rules, effective January 15, 1999, (“Rules”). This section identifies certification application requirements which are in addition to the requirements in the Rules.

II. RMW TRANSFER FACILITY

An application for a RMW transfer facility or facility component must address Subchapters 3, 5, 9,10 and 12 of the SWMR. Additional information required by the Solid Waste Program in an Application for a RMW transfer facility must include:

- (a) A Facility Management Plan which includes, at a minimum, the following information:
 - (1) A listing of the sources and quantities of RMW anticipated.
 - (2) A 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.
 - (3) A plan for the separation and proper management of hazardous waste.
 - (4) An agreement with a treatment facility to accept the RMW.
 - (5) A schedule for transfer of the RMW to a treatment facility adjusted as necessary to minimize odors from the waste.
 - (6) A plan for detecting and managing radioactive wastes.
 - (7) A plan for educating generators and haulers regarding the type of RMW that is acceptable for storage and transfer at the facility.
- (b) Engineering plans and specifications including: site plans showing the property boundaries, facility building dimensions, and waste storage area(s).
- (c) Other information deemed necessary by the Secretary to adequately review the application.

III. RMW TREATMENT FACILITY

An application for a RMW treatment facility must address Subchapters 3, 5, 6, 7, 9 and 10 of the SWMR. Additional information required by the Solid Waste Program in an Application for a RMW treatment facility will include:

- (a) A Facility Management Plan which includes, at a minimum, the following information:
 - (1) A listing of all treatment component(s) including:
 - (A) a detailed description of how each component operates;
 - (B) a demonstration that the RMW when treated meets the treatment standard; and,
 - (C) appropriate operating parameters for the process, such as residence time, temperature, pressure, irradiation levels and chemical concentrations.
 - (2) A listing of the sources and quantities of RMW anticipated.
 - (3) A detailed description of the facility operations including:
 - (A) 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;
 - (B) start-up and, shut-down procedures;
 - (C) disinfection processes for reusable containers;
 - (D) facility hours of operation; and,
 - (E) methods to control the release of contaminants into the air, soil or water.
 - (4) A description of the utility requirements including:
 - (A) estimates of the quantity of water used for cooling, including that which may be recycled;
 - (B) characterization and estimates of the treatment facility's wastewater production including the process water to be treated as hazardous waste or intended to be discharged from the treatment facility.
 - (5) A list and description of all permits required including any required for air and water discharges.
 - (6) A description of the hauling process into and out of the facility.
 - (7) A plan for the separation and proper management of hazardous waste.
 - (8) A plan for detecting and managing radioactive wastes.
 - (9) A plan for educating generators, vendors and haulers regarding the type of RMW that is acceptable for treatment at the facility.

- (b) Engineering plans and specifications including:
 - (1) site plans showing the property boundaries, facility building dimensions, site topography, utilities, treatment unit(s) and layout.
 - (2) piping diagrams.
 - (3) cross-section views of the facility.
- (c) Specifications for all equipment instrumentation and control centers.
- (d) A description of the challenge testing program.
- (e) A monitoring and maintenance plan for all treatment, pollution control and detection equipment.
- (f) A agreement for the proper disposal of the treated RMW at a certified disposal facility.
- (g) Any other information deemed necessary by the Secretary to adequately review the application.

Effective date

This Procedure is effective 60 days from date of Signature.

Signature

Canute Dalmasse, Commissioner
Department of Environmental Conservation

Date

Appendix A
Certification of Treatment

Name of Person or Facility Performing Treatment _____

Address: _____

I certify that this Regulated Medical Waste was treated to the Treatment Standard using:

Specify the method of treatment used, i.e. autoclave, incineration, etc.

The type(s) of Regulated Medical Waste Treated includes: _____

Specify the type of waste, e.g. sharps, cultures and stocks, etc.

Estimated Amount of Regulated Medical Waste Treated: _____ lbs.
Or _____ cubic yards

Date of Treatment: _____

Signature of Authorized Person

Print Name

Date _____

If the waste is to be considered inaccessible, identify the method used to make the waste inaccessible.

Regulated Medical Waste Treatment Facilities and Generators That Treat Regulated Medical Waste

This certification of treatment must be completed for each load of treated regulated medical waste and must be provided to the transporter.

Transporters

This certification of treatment must be maintained in the vehicle during transport and be provided to the transfer station or to the disposal facility upon delivery.

Transfer Stations

If you receive this Certificate of Treatment with a load of solid waste, the solid waste contains some treated Regulated Medical Waste which has been rendered inaccessible. Please ensure that this Certification of Treatment is provided to the transporter of the solid waste which contains the treated Regulated Medical Waste.

Appendix B

Guidance for the Proper Disposal of Home Generated Regulated Medical Waste

Introduction

Home Generated RMW (HGRMW) includes wastes generated from the use of medications, testing supplies, injectable medications and waste generated in long term care or hospice. These wastes are purchased and administered by the resident. Many of these wastes would be considered RMW if generated in a healthcare facility. Proper handling and disposal methods for these wastes are critical to minimize risks to public health and safety and to the environment.

Section 1 Applicability

This Guidance is applicable to all HGRMW, as specified in Section 1, II(RMW Definition)(b)(4). Waste generated by home health care professionals is RMW and must be handled and treated in accordance with the Procedure Addressing Medical Waste Definitions And The Handling And Treatment of Medical Waste.

Section 2 Handling and Disposal of HGRMW

- (a) Sharps should be placed in a hard plastic, opaque container, such as a detergent bottle.
- (b) Containers may be placed in the regular house hold trash.
- (c) All other medical waste, such as bandages, dressings etc. should be placed in a separate container and disposed of in the regular house hold trash.