Chapter 900: BIOMEDICAL WASTE MANAGEMENT RULES

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facility without the modification, or may pose a significant risk which was not considered in the original application or is not addressed in the existing license.

RR. **Transfer facility.** "Transfer facility" means any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of biomedical waste are held during the normal course of transportation.

SS. **Transport.** "Transport" means the movement of biomedical waste from the point of its generation to any intermediate points and finally to its point of ultimate disposition. Movement of biomedical waste on the site where it is generated or on the site of a licensed biomedical waste transfer or treatment facility is not "transport."

TT. **Transporter.** "Transporter" means any person who transports biomedical waste in this state in any quantity, unless exempt from the requirements of this rule pursuant to Section 4 of this rule. The term includes, without limitation, individuals who own, lease or otherwise control conveyances in which biomedical waste is transported, operators of such conveyances, and businesses regardless of size and form of business organization, which engage in transportation of biomedical waste.

UU. **Transported Off-Site.** "Transported Off-Site" means to be transported from the point of generation to a biomedical waste transfer or treatment facility that is not on the generator's site.

VV. **Treatment.** "Treatment" means any method, technique, or process designed to change the biological character or composition of biomedical waste so as to eliminate or reduce its potential for causing disease.

WW. **Waste.** "Waste" means any useless, unwanted or discarded substance or material, whether or not such substance or material has any other or future use and includes any substance or material that is spilled, leaked, pumped, poured, emitted, emptied or dumped onto the land or into the water or ambient air.

7. Definition of Biomedical Waste

A. Identification of Biomedical Waste

The following wastes may contain human pathogens of sufficient virulence and in sufficient concentrations that exposure to them by a susceptible host could result in disease and are, therefore, biomedical wastes for the purposes of this rule.

(1) Discarded Human Blood, Blood Products, and Body Fluids: Discarded blood, serum, plasma, blood products, and body fluids. Body-fluids are defined as fluids which are generated or removed during surgery, autopsy, obstetrics, emergency care, or embalming and include cerebrospinal fluid, synovial fluid, pleural fluid; peritoneal fluid, pericardial fluid and amniotic fluid.

(2) Waste Saturated With Human Blood, Blood Products, or Body Fluids: These may include items such as sponges, surgical gloves and masks, drapes, aprons, dressings, disposable sheets and towels, underpads, plastic tubing, suction canisters, used syringes without needles and dialysis unit waste.

NOTE: The intent is to include waste which at the time of generation is soaked or dripping with human blood, blood products or body fluids. An example of material which may be included is a first change surgical dressing.

(3) Pathological Waste: Human tissues, organs, and anatomical parts including teeth, discarded from surgery, autopsy, obstetrical procedures, and laboratory procedures.

(4) Discarded Sharps Used In Patient, Animal, Cadaver Care or In Medical and Biomedical Research Laboratories: These include, but are not limited to, hypodermic needles, syringes, scalpel blades, suture needles, disposable razors, lancets, capillary tubes, Pasteur pipettes, broken glassware, IV tubing with needles attached, and dialysis bags with needles attached.

(5) Discarded cultures and stocks of infectious agents and the culture dishes and devices used to transfer, inoculate and mix cultures; discarded clinical specimens and the associated containers or vials; discarded biologicals; and waste from the production of biologicals and recombinant DNA research.

NOTE: The intent is to include discarded cultures and stocks of infectious agents that contain human pathogens of sufficient virulence and in sufficient concentration that exposure to it by a suscsptible host could result in disease.

(6) Discarded Carcasses, Body Parts, Bedding and Other Waste Generated By Research Facilities From Animals Containing Organisms or Agents Not Usual To The Normal Animal Environment And Which Are Pathogenic or Hazardous to Humans.

B. Cytotoxic Drugs, Chemotherapy Waste

The following wastes may be managed as biomedical waste for the purpose of this rule:

(1) Cytotoxic (antineoplastic) drugs not identified as hazardous wastes in Chapter 850 of the Department's regulations.

(2) Chemotherapy waste - All materials that have come in contact with, and have no more than trace amounts of, cytotoxic (antineoplastic) agents.

C. Exclusions

The following wastes are not biomedical waste for the purpose of this rule:

(1) Human remains. Human remains that are stored, transported or otherwise handled for the purpose of internment or cremation are not subject to the requirements of this rule.

(2) Urine and feces.

(3) Sludge and septage. Sludge means the semi-solid or liquid residual generated from a municipal, commercial or industrial wastewater treatment plant. Septage means waste,

refuse, effluent, sludge and any other materials from septic tanks, cesspools, or any other similar facilities.

(4) Water and wastewater samples. Wastes generated as a result of the routine screening of water and wastewater samples are not subject to the requirements of this rule.

8. Reference to Other Regulations

A. Solid waste as defined in 38 M.R.S.A. Section 1303-C(29) and in Section 6 of this rule shall be managed in accordance with the Department's Solid Waste Management Rules, Chapters 400-409.

NOTE: Incinerator ash, provided it is not hazardous by characteristic, is a special waste. Regulations governing the handling, storage and disposal of incinerator ash are specified in the Department's Solid Waste Management Rules, Chapter 400, *et seq.* Incinerator ash which meets hazardous waste characteristics, as defined in Chapter 850 of the Department's Hazardous Waste Management Rules, shall be managed as a hazardous waste.

B. Hazardous wastes as defined in 38 M.R.S.A. Section 1303-C(15) (with the exception of infectious and pathogenic wastes) and in Chapter 850 of the Department's rules shall be managed in accordance with the Department's Hazardous Waste Management Rules, Chapters 850, 851, 853-857.

NOTE: Some cytotoxic (antineoplastic) drugs are identified as hazardous waste in Chapter 850 of the Department's Hazardous Waste Management Rules.

C. Radioactive wastes as defined in Section 6(II) of this rule shall be managed in accordance with the rules of the U.S. Nuclear Regulatory Commission and the State of Maine Rules Relating to Radiation Protection.

D. Wherever another applicable rule or regulation conflicts with a requirement of this rule, the more restrictive requirement shall apply.

9. Prohibitions

A. The Department may not approve an application for a new commercial biomedical waste treatment facility unless at least 51% of the facility is owned by a licensed hospital or hospitals as defined in Title 22, section 328, subsection 14, or a group of hospitals that are licensed under Title 22 acting through a statewide association of Maine hospitals or a wholly owned affiliate of the association.

B. The Department does not permit the disposal of biomedical waste. Biomedical waste must be treated by an approved technology prior to being disposed of as a special waste.

C. A biomedical waste may not be mixed with hazardous wastes or radioactive waste.

D. Where a biomedical waste has been inadvertently or intentionally mixed with hazardous wastes or radioactive waste, all appropriate rules will apply to the management of the mixed waste. In

the facility until new approval is granted. Reapplications for approval must state the reasons why the facility was not begun within 2 years from the granting of the initial approval and the reasons why the applicant will be able to begin the activity within 2 years from the granting of a new approval, if granted. Reapplications for approval may include information submitted in the initial application by reference.

(16) Bid Specifications. A copy of this approval must be included in or attached to all contract bid specifications for the development.

(17) Contractor Copy. Work done by a contractor pursuant to this approval must not begin before the contractor has been given a copy of the license by the licensee.

F. Special Conditions

The Department may place special terms and conditions, , on any license issued under this rule. However, terms and conditions must address themselves to specifying particular means of satisfying minor or easily corrected problems, or both, relating to compliance with this rule and with all applicable statutes and must not substitute for or reduce the burden of proof on the applicant to affirmatively demonstrate to the Department that each of the applicable standards has been met.

G. Suspension or Revocation

(1) The Board may seek suspension or revocation of a license pursuant to 38 M.R.S.A. Section341-D(3).

(2) A licensee whose license has been revoked may not reapply for a license within one calendar year from the effective date of the revocation.

18. Standards for Treatment Facilities

A. Applicability of the Standards of the Site Location of Development Law

All new biomedical waste treatment facilities as well as substantial modifications to existing facilities are subject to the standards of the Site Location of Development Law, 38 M.R.S.A. § 484, which are incorporated herein by reference. The findings and conclusions required to be made for issuance of a permit under section 484 of the Site Location of Development Law must be made for issuance of a license under this rule.

B. Facility Location Criteria

(1) Environmental Performance Standards. All biomedical waste treatment facilities must be located, designed, constructed, altered, operated, maintained, and closed in a manner that will ensure protection of public health and welfare and the environment. Protection of health and welfare and the environment must include, but not be limited to:

(a) prevention of adverse effects on ground water quality;

(b) prevention of adverse effects on surface water quality;

(c) prevention of adverse effects on air quality; and

(d) prevention of adverse effects due to migration of waste constituents in the subsurface environment.

(2) Rebuttable Presumptions: All new biomedical waste treatment facilities as well as substantial modifications to existing facilities are subject to the following rebuttable presumptions governing facility location.

(a) A biomedical waste treatment facility located in the following areas is presumed to pose a serious threat to public health or welfare or to the environment such that a license for a facility cannot be issued. The presumption applies if:

(i) The facility or facility property overlies any portion of a significant surface or subsurface sand and gravel aquifer or its primary recharge zone or a high yield bedrock aquifer;

NOTE: Maps of significant sand and gravel aquifers are available from the Maine Geological Survey, Department of Conservation, Augusta.

(ii) The facility or facility property is located within 1,500 feet of any underground source of potable water for people;

(iii) The facility property is located on land defined as a wetland under statutes or regulations administered by the following Departments: Environmental Protection, Conservation (Land Use Regulation Commission-LURC), Inland Fisheries & Wildlife, Marine Resources or the State Planning office;

(iv) The facility or facility property is located within 100 feet of any 100 year flood plain or within 100 feet of the level of any actual documented flood of a greater magnitude;

(v) The facility or facility property is located such that it may pose a threat to the fisheries, wildlife or other natural resources of a sanctuary, refuge, preserve, state or federal park, designated wilderness area, critical area or fish hatchery;

(vi) The facility property is located within the boundaries of a state or federal park or designated wilderness area.

(b) An applicant seeking a license to establish, construct, alter or operate a biomedical waste treatment facility in such a location must overcome this presumption by clear and convincing evidence that the facility is unique in some way that allows for compliance with the intent of this rule.

C. General Design Standards

(1) Biomedical waste must be stored in conveyances or buildings that are leak-proof and equipped with locks.

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(2) If the treatment facility is not located at a medical facility, it must be enclosed by a chain link fence, at least six feet in height, and access will be controlled by a locking gate or an alternative Department approved security system that offers equivalent protection.

(3) The fence, conveyances or buildings must be posted with warning signs which indicate a potential biological hazard.

(4) All biomedical waste conveyances and buildings used primarily for the storage of biomedical waste and biomedical waste treatment areas must be located at least 50 feet from the facility property boundaries. In addition, storage and treatment areas must be located at least 300 feet from the nearest residence in existence at the time of application except that existing facilities which cannot meet the 300 foot requirement must locate treatment and storage areas as far as possible from the nearest residence in existence at the time of application.

(5) Provision must be made for the proper storage of biomedical waste prior to treatment, including the refrigeration of pathological waste, cultures, and animal carcasses and body parts.

D. Operating Standards

The following operational requirements apply to biomedical waste treatment facilities:

(1) The packaging, labeling, handling, and storage requirements specified in Sections 12(A), 12(B), 12(C), and 12(D) of this rule apply to biomedical waste treatment facilities.

(2) An operator of a biomedical waste treatment facility may not accept any biomedical waste that is not packaged and labeled in accordance with these rules and accompanied by a properly completed manifest except as provided for in Section 4 of this rule.

(3) The facility access gate and all biomedical waste conveyances and storage buildings must be closed except when loading or unloading wastes and will be locked whenever an operator is not in attendance at the facility.

(4) Pathological wastes, cultures, and discarded animal carcasses and body parts must be stored in refrigerated conveyances, or storage buildings in a frozen state.

(5) All areas used for the storage of biomedical waste must be maintained in a sanitary condition and must be designed to control or contain any spillage of such wastes.

(6) The on-site population of disease vectors must be controlled to protect public health.

(7) Biomedical waste may not be compacted or subjected to violent mechanical stress during transfer, storage or any time prior to final treatment and disposal.

E. Design Standards for Biomedical Waste Treatment Facilities

(1) The types, amounts (by weight and/or volume), and characteristics of all biomedical waste expected to be processed will be determined by survey.

(2) Facility design capacity must consid er such items as waste quantity and characteristics, variations in waste generation, equipment downtime, and availability of alternate storage, processing, or disposal capability.

(3) Facility systems and subsystems must be designed to assure standby capability in the event of breakdown.

(4) Audible signals must be provided to alert operating personnel of critical operating unit malfunctions.

F. Operating Standards for Biomedical Waste Treatment Facilities Using Non-Incineration Treatment Technologies

(1) Prior to accepting biomedical waste for treatment, the operator of a biomedical waste treatment facility using an approved treatment technology shall perform challenge testing using a Bacillus species spore specified by the Department to demonstrate that the technology can meet the standard specified in Section 19.

(2) Every 30 days, the licensee of a biomedical waste treatment facility using an approved non-incineration treatment technology shall perform challenge testing using a test organism prescribed by the Department. After 1 year of successful challenge tests, a licensee may request in writing to the Department for permission to reduce the frequency of challenge testing by demonstrating to the Department that an effective instrument calibration program is in place.

(3) The sharps portion of the biomedical waste stream may be required to ~~must~~ be rendered unrecognizable and shredded into pieces less than ¾ inch in diameter as a component of the treatment process and prior to removal from the facility. The remainder of the treated biomedical waste stream must be handled in a manner approved by the Department.

(4) All operating parameter records must be maintained for 3 years or until the resolution of any enforcement action, whichever is longer, and be available to a representative of the Department.

(5) Chemotherapy waste and pathological waste must not be treated in a non-incineration treatment unit. Chemotherapy waste and pathological waste may be stored at a treatment facility for a maximum of 30 days provided that the pathological waste is maintained in a frozen state.

(6) The facility will develop and implement a program to educate generators on the requirement for source segregation. The program will educate generators on what material must be managed as biomedical waste as well as the dangers and repercussions of shipping hazardous waste, universal waste, radioactive waste and other unauthorized waste to a biomedical waste treatment facility.

G. Closure

When plans are made for termination of a biomedical waste treatment facility, the Department must be notified in writing a minimum of 60 days prior to the proposed termination date. A plan

outlining the closing operation must be submitted to the Department for review and approval. The plan must demonstrate that the facility will be closed in a manner that will protect public health, safety and welfare and the environment.

A closure plan must include the following as a minimum:

(1) A description of how and when the facility will be closed including a schedule of closure.

(2) A description of how disposal and decontamination of equipment and structures will occur.

(3) The maximum inventory of waste in storage and treatment at any time during the life of the facility.

(4) A cost estimate for closure of the facility in accordance with the closure plan.

(5) Sufficient financial assurance for completion of closure activities.

(6) Liability insurance for sudden accidents.

(7) Provision for certification by the facility owner and an independent professional engineer that the facility was closed in accordance with the approved closure plan and that no biomedical waste or biomedical waste residues remain on site.

H. Manifests, Record Keeping and Reporting

(1) A biomedical waste treatment facility may not accept more than 50 pounds of biomedical waste from a biomedical waste generator or any quantity of biomedical waste from a transporter unless it is accompanied by a properly completed manifest.

A treatment facility operator shall, in the presence of the generator or transporter, complete the appropriate treatment facility portion of the manifest, including handwritten acceptance signature and date of acceptance, and immediately give a signed copy of the manifest to the generator or transporter, noting any discrepancies in manifest information.

(2) In instances where a facility accepts less than 50 pounds of waste from a generator, the facility must maintain a log of such receipts which includes, at a minimum, the following:

(a) The name, address and identification number of the treatment facility;

(b) The type and volume of waste received;

(c) The date of receipt of such waste;

(d) The name, location and identification number of the generator; and

(e) The signature of the person receiving the waste.

(3) The facility shall record on the manifest the date on which the shipment was received and accepted by the facility.

(4) The facility shall keep a copy of the completed manifest as part of the facility operating record and shall forward a completed copy to the generator within 35 days after the date the waste was accepted by the transporter.

(5) Retention of Records. Manifests, logs and operational records must be retained by the licensee for a period of not less than three (3) years. The period of retention of records is extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Department. These records must be available for inspection by the Department, upon request.

(6) Annual Report

The owner or operator of a biomedical waste treatment facility shall submit an annual report to the Department. The report must contain, at a minimum, the following information:

(a) Name, location and identification number of the facility.

(b) Sources, types and quantities of biomedical waste received.

(c) Method of treatment for each category of biomedical waste.

(d) Type and amount of specific wastes shipped from the facility.

(e) Name and location of treatment or disposal facility.

(f) Proof of liability insurance.

(g) A demonstration of financial capacity to construct, operate, maintain and close the facility.

(h) The facility shall report to the Department incidents whereby the facility has received hazardous, hazardous universal and radioactive wastes or other unauthorized wastes. The report must identify what steps were taken to prevent reoccurance.

(i) The facility shall report efforts to educate the generators on waste segregation.

19. Approval of Non-Incineration Treatment Technologies

A. Application Requirements

A person may apply to the Department for approval to use a biomedical waste treatment technology other than incineration, including, but not limited to, steam sterilization or microwaving. The application for this technology approval must include at a minimum the following information:

(1) The name, address, and business telephone number of the applicant;

(2) A description of the treatment method for which approval is sought;