

Chapter 900: BIOMEDICAL WASTE MANAGEMENT RULES

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Chapter 900: BIOMEDICAL WASTE MANAGEMENT RULES

SUMMARY: The rule identifies biomedical waste subject to regulation; requires the registration of biomedical waste generators; and establishes packaging, labeling, handling, storage, transportation and treatment requirements. The rule does not establish disposal standards for biomedical waste because this rule defines treated biomedical waste as a special waste. The disposal of untreated biomedical waste is prohibited in this rule. The rule requires all transporters and owners or operators of transfer facilities and treatment facilities to obtain a license. The rule specifies siting, design, operating and reporting requirements and establishes a biomedical waste tracking or manifest system.

1. Legal Authority

This rule is authorized by and adopted under 38 M.R.S.A. Sections 341-D(1-B), 1303-C(34)(K) and 1319-O(3).

2. Preamble

It is the purpose of the Department of Environmental Protection, to provide effective controls for the management of biomedical waste so as to ensure the protection of public health, safety and welfare and the environment.

3. Applicability

This rule applies to all persons engaged in biomedical waste activity except as provided for in section 4 of this rule.

4. Exemptions**A. Household Generators**

This rule does not apply to household generators of biomedical waste except that sharps must be packaged in accordance with Section 12(A)(4) of this rule.

B. Small Quantity Generators

A medical facility which generates less than a total of 50 pounds of biomedical waste in any one month is exempt from the requirements of this rule for that month with the following exceptions:

- (1) The facility shall register in accordance with Section 11(A).
- (2) Discarded sharps, as defined in Section 7(A)(4), and discarded cultures and stocks of infectious agents, as defined in Section 7(A)(5), shall be packaged in accordance with Section 12(A), labeled in accordance with Section 12(B) and treated in accordance with Section 10.
- (3) Except as provided in (4) and (5) below, transport of biomedical waste shall be by a licensed biomedical waste transporter and accompanied by a four-part manifest unless the biomedical waste is taken by the generator to another medical facility or to a permitted biomedical waste transfer or treatment facility and the amount transported is less than 50 pounds.

- (4) The generator or an employee of the generator may transport sharps packaged in accordance with this rule to a licensed biomedical waste treatment facility or another medical facility that has volunteered to serve as a collection point for sharps if no more than 50 pounds of sharps are transported in one trip.

NOTE: The rule allows employees to generate biomedical waste off site at intermittent, temporary field collection points and transport it back to their facility. Included are blood drives, home health care providers and phlebotomists working at a temporary field location .

- (5) A generator of biomedical waste may send up to 50 pounds of properly packaged discarded sharps via the United States Postal Service to a licensed biomedical waste treatment facility. All generators are responsible for compliance with the packaging standards contained in Section 12 of the rules.

NOTE: The enabling legislation for the mailing of discarded sharps via the United States Postal Service (USPS) specified quantities of up to 50 pounds; however, USPS guidelines limit the amount to 35 pounds.

NOTE: For a medical facility to qualify for the small quantity exemption, all categories of biomedical waste identified in Section 7 must be considered and the total amount must be less than 50 pounds per month.

5. Responsibility of Generator

The generator of biomedical waste is responsible for the appropriate segregation, packaging, labeling, storage, handling, transport and treatment of biomedical waste it generated as required by this rule. A person may provide services to the generator of biomedical waste, including the appropriate packaging, labeling, storage, handling, transport and treatment of biomedical waste but it is the generator's responsibility to ensure that its biomedical waste is properly treated.

The generator must take all necessary steps to ensure that their biomedical waste does not contain hazardous waste, universal waste, radioactive waste or other unauthorized waste.

6. Definitions

- A. **Antineoplastic drug.** "Antineoplastic drug" means any of the group of cytotoxic drugs used in the treatment of cancer.
- B. **Biologicals.** "Biologicals" means preparations made from living organisms and their products, including serums, vaccines, antigens, and antitoxins.
- C. **Biomedical waste.** "Biomedical waste" means a waste that may contain human pathogens of sufficient virulence and in sufficient concentrations that exposure to it by a susceptible host could result in disease. Biomedical waste is further defined in Section 7 of this rule.
- D. **Biomedical waste activity.** "Biomedical waste activity" means the generation, handling, storage, transport, and treatment of biomedical waste.

- E. **Biomedical waste manifest.** "Biomedical waste manifest" means the form used for identifying the quantity, composition, and the origin, routing, and destination of biomedical waste during its transportation from the point of generation to the point of off-site treatment.
- F. **Board.** "Board" means Board of Environmental Protection.
- G. **Chemotherapy waste.** "Chemotherapy waste" means all materials that have come in contact with and have no more than trace amounts of cytotoxic/antineoplastic agents.
- H. **Commissioner.** "Commissioner" means the Commissioner of the Department of Environmental Protection.
- I. **Contaminated.** "Contaminated" means soiled or made inferior or potentially infectious through physical contact or mixture with a biomedical waste.
- J. **Conveyance.** "Conveyance" means any vehicle used for transportation on land, water or in the air. For the requirement that a transporter license be obtained, the term includes only the cargo-carrying portion of a conveyance. For the requirements of Section 14, the term includes the entire conveyance.
- K. **Cytotoxic drugs.** "Cytotoxic drugs" means drugs that are toxic to living cells.
- L. **Department.** "Department" means the Department of Environmental Protection, which includes the Commissioner and the Board.
- M. **Discharge.** "Discharge" means any spilling, leaking, pumping, pouring, emitting, emptying or dumping.
- N. **Disinfect.** "Disinfect" means to reduce the infectiousness of an object or material such that it poses virtually no risk of infection to those handling, or otherwise coming into contact with, the object or material.
- O. **Disposal.** "Disposal" means the discharge of untreated biomedical waste into or on any land or water so that the biomedical waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including ground waters. The Department prohibits the disposal of biomedical waste.
- P. **Existing facility.** "Existing facility" means a biomedical waste transfer facility in existence on December 18, 1989 or a facility holding an air emission license for a Class VI B incinerator on December 18, 1989.
- Q. **Flood plain.** "Flood plain" means the lowland and relatively flat areas adjoining inland and coastal waters, including flood prone areas of offshore islands, which are inundated by a flood that has 1% or greater chance of recurring in any year or a flood of a magnitude equaled or exceeded once in 100 years on the average.
- R. **Generator.** "Generator" means any person or medical facility whose act or process produces biomedical waste in any quantity.

- S. **Generated Off Site.** "Generated Off-Site" means biomedical waste accepted at a biomedical waste transfer or treatment facility that was not generated on-site.
- T. **Handle.** "Handle" means to store, transfer, collect, separate, salvage, process, reduce, recover, incinerate, treat or dispose of.
- U. **Hazardous waste.** "Hazardous waste" means material that is identified as hazardous waste under Chapter 850 of the Department's Hazardous Waste Management Rules.
- V. **Household.** "Household" means single and multiple residential dwellings and includes hotels, motels and boarding homes.
- W. **Incineration.** "Incineration" means a processing method using an engineered apparatus capable of withstanding heat and having as its purpose the efficient thermal oxidation and/or conversion of combustible material into noncombustible residues (ash) and product gases.
- X. **Infectious.** "Infectious" means caused by or capable of being communicated by invasion and multiplication of microorganisms in body tissues; having the potential to transmit disease.
- Y. **Infectious agent.** "Infectious agent" means a biological substance (such as a virus, bacterium or other biological organism) capable of causing disease or adverse health impacts in humans.
- Z. **Medical facility.** "Medical facility" means any place where biomedical waste is generated, including, but not limited to: hospitals, ambulatory surgical centers, emergency medical service providers, offices and mobile units of health care providers including doctors and dentists, nursing homes, medical diagnostic laboratories, blood centers, pharmaceutical companies, research laboratories, health agencies, diet or health care clinics, offices of veterinarians, veterinary hospitals, and funeral homes and mortuaries.
- AA. **M.R.S.A.** "M.R.S.A." means the Maine Revised Statutes Annotated.
- BB. **Municipality.** "Municipality" means a city, town, or plantation or unorganized township.
- CC. **Off-Site.** "Off-Site" describes a facility or area for the storage, handling or treatment of biomedical waste which is not on the generator's site (i.e., "on-site") or a facility or area which receives biomedical waste for storage or treatment which has not been generated "on-site" at that facility.
- DD. **On-Site.** "On-Site" means the activity in question is taking place or exists at the same site. Two or more contiguous pieces of property owned by the same generator or facility owner are a single site for the purposes of this definition.
- EE. **Operator.** "Operator" means any person who has care, charge or control of a biomedical waste transfer or treatment facility or conveyance. This person may be an agent, a lessee of the owner, or an independent contractor.
- FF. **Owner.** "Owner" means any person who alone or in conjunction with others owns a conveyance used for the transport of biomedical waste or the real property upon which is located a biomedical waste facility subject to these rules.

- GG. **Pathological waste.** "Pathological waste" means human tissues, organs, and anatomical parts including teeth, discarded from surgery, autopsy, obstetrical procedures, and laboratory procedures.
- HH. **Person.** "Person" means any individual, partnership, association, firm, company, corporation, department, agency, group, municipality, state, country, other governmental unit, or any other entity responsible in any way for an activity subject to these rules.
- II. **Radioactive waste.** "Radioactive waste" means any waste material which emits ionizing radiation spontaneously.
- JJ. **Saturated.** "Saturated" means thoroughly soaked or dripping. For the purposes of this rule the term "saturated" refers to a waste, which at the time of generation, is soaked or dripping with human blood, blood products or body fluids.
- KK. **Sharps.** "Sharps" means items which may cause puncture wounds or cuts including, but not limited to, hypodermic needles, syringes, scalpel blades, capillary tubes and lancets. Sharps are further identified in Section 7(A)(4) of this rule.
- LL. **Site.** "Site" means the same or geographically contiguous property which may be divided by a public or private right-of-way, provided that the entrance and exit between the properties is at a crossroads intersection and access is by crossing as opposed to going along the right-of-way. Noncontiguous properties owned by the same person but connected by a right-of-way which he or she controls and to which the public does not have access is also considered site property.
- MM. **Site Location Law.** "Site Location Law" means the Site Location of Development Law, 38 M.R.S.A. Section 481, *et seq.*
- NN. **Solid waste.** "Solid waste" as defined in 38 M.R.S.A. Section 1303-C(29) means useless, unwanted or discarded solid material with insufficient liquid content to be free flowing, including by way of example, and not by limitation to, rubbish, garbage, scrap materials, junk, refuse, inert fill material, and landscape refuse, but does not include hazardous waste, biomedical waste, septage or agricultural wastes.
- OO. **Special waste.** "Special waste" as defined in 38 M.R.S.A., Section 1303-C(34) means any solid waste generated by sources other than domestic and typical commercial establishments that exists in such an unusual quantity or in such a chemical or physical state, or any combination thereof, that may disrupt or impair effective waste management or threaten the public health, human safety or the environment and requires special handling, transportation and disposal procedures.
- PP. **Storage.** "Storage" means the containment of biomedical waste either on a temporary basis or for a period of years, in such a manner as not to constitute disposal of such wastes.
- QQ. **Substantial modification.** "Substantial modification" means any change in size, volume handled or operation of a licensed facility which may pose a risk to health, safety, welfare or the environment which is significantly different in kind or degree from that posed by the

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.
- (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 instances where there is a conflict between the requirements of the rules, the more stringent requirement will apply.
- E. A biomedical waste will be delivered only to another biomedical waste generating facility or to a licensed biomedical waste transfer or treatment facility.

10. Treatment Methods for Biomedical Waste

Biomedical waste must be treated as follows:

- A. Pathological waste must be incinerated, interred or treated by a treatment technology approved by the Department pursuant to Section 19.
- B. Discarded blood, blood products and body fluids must be (1) incinerated, (2) discharged through a sewer to a publicly owned treatment works (POTW), provided that it is discharged in accordance with the state's water quality laws and local ordinances, (3) discharged to a septic system, provided that the septic system is in compliance with state rules and standards and provided that it is discharged in compliance with local ordinances, or (4) treated in a licensed biomedical waste treatment facility using non-incineration technology approved by the Department pursuant to Section 19.
- C. All other biomedical waste must be incinerated or treated by a non-incineration treatment technology approved by the Department pursuant to Section 19.

NOTE: The Department recommends that discarded cultures and stocks of infectious agents, (see Section 7(A)(5) of these rules) to be transported off-site for treatment be pre-treated by steam sterilization to reduce the concentration of pathogens prior to packaging in accordance with Section 12(A) of this rule.

- D. All incineration of biomedical waste must be in a licensed biomedical waste incinerator.

11. Registration of Generators

A. Registration

- (1) Each medical facility which generates a biomedical waste shall register with the Department on forms available from the Department at least 30 days prior to the date such generation is expected to commence.
- (2) The Department will assign a biomedical waste generator registration number to each medical facility which registers with the Department and will notify each such facility in writing of such assigned registration number. Upon receiving such notification, the facility shall include the assigned registration number in or on manifests, labels affixed to packages of biomedical waste, and tags enclosed in each package of biomedical waste.
- (3) Facilities which generate biomedical waste shall notify the Department in writing within 30 days of a change in majority ownership, name, location or operational status of the facility.
- (4) The registration numbers assigned under this subsection are not transferable.
- (5) The initial registration fee will be \$50 per facility.
- (6) Biomedical waste generators will be assessed an annual fee based on the average amount of biomedical waste produced per month.

- (a) Generators producing less than 10 pounds per month will pay an annual fee of \$25.
- (b) Generators producing 10 pounds or more, but less than 50 pounds per month will pay an annual fee of \$50.
- (c) Generators producing 50 pounds or more per month will pay an annual fee of \$500.

B. Biomedical Waste Management Plan

- (1) Except as provided for in Section 4 of this rule, each medical facility which generates biomedical waste shall prepare a written biomedical waste management plan appropriate for the size and type of facility. Such plan must set forth policies and procedures consistent with these regulations for managing biomedical waste.
- (2) The biomedical waste management plan must include, at a minimum, the following:
 - (a) a description of the biomedical waste generated by the medical facility including type and volume of biomedical waste;
 - (b) a description of any biomedical waste handling procedures, in addition to those required by this rule, which are specific to that medical facility including such information as location of storage area, etc.;
 - (c) the treatment methods for each type of biomedical waste;
 - (d) personnel training procedures;
 - (e) spill containment and cleanup procedures and equipment; and
 - (f) the name, address, and telephone number of the person(s) responsible for biomedical waste management at the medical facility.
- (3) The medical facility shall certify, at the time of registration, that a biomedical waste management plan has been developed for the facility.
- (4) The medical facility biomedical waste management plan must be available for inspection by a public safety officer or authorized representative of the Department.

12. Standards for Generators

A. Packaging

Biomedical waste must be properly packaged to assure effective containment throughout the handling, storage, transport, and treatment processes.

- (1) Biomedical wastes, other than sharps and bulk liquids, must be packaged in bags which are impervious to moisture and have a strength sufficient to resist ripping, tearing or bursting under normal conditions of usage and handling.

- (2) All bags containing biomedical waste must be red in color and imprinted with the international biohazard symbol and the words "biomedical waste" or "infectious waste." Waste in red bags will be considered biomedical waste and must be managed as biomedical waste.
- (3) Bags must be sealed by forming a secure closure which results in a leak-resistant seal.
- (4) Discarded sharps must be segregated from other biomedical waste at the point of generation. Discarded sharps will be placed directly into leak-resistant, rigid, puncture-resistant containers without clipping or breaking. When full or in preparation to be sent for treatment, these containers will be taped closed or tightly lidded to preclude loss or leakage of contents. After proper packaging, sharps containers may be placed in biomedical waste bags referred to in Section 12 (A)(1) of these rules.

NOTE: An example of an acceptable container for storing discarded sharps at home is an empty rigid plastic bottle.

- (5) Discarded bulk blood and other liquids which is to be transported off-site will be packaged in tightly stoppered, unbreakable flasks or bottles or other appropriate containers.
- (6) All biomedical waste bagged in accordance with Section 12(A)(3), sharps containerized in accordance with Section 12(A)(4), and bulk liquids containerized in accordance with Section 12(A)(5) which are to be transported off-site must also be packaged for storage or handling by placement in disposable corrugated fiberboard boxes or equivalent rigid containers such as reusable pails, cartons, drums, or portable bins. The box or container must be leak-resistant or lined with a bag which is impervious to moisture and has a 200-pound burst strength as measured by the industry's Mullen test.
- (7) Reusable containers used for the handling of biomedical waste must be thoroughly washed and disinfected each time they are emptied unless the surfaces of the containers have been effectively protected from contamination by disposable liners, bags or other devices which are removed and disposed of with the waste. A red bag may not be enclosed in a bag of another color.
- (8) Reusable containers used for the handling of biomedical waste must not be used for containment of waste to be disposed of as non-biomedical waste or for any other purpose except after being disinfected.

B. Labeling

Biomedical waste to be transported off-site must be labeled immediately after packaging in accordance with Section 12(A)(6). The label must be securely attached to the outer layer of packaging and be clearly legible. Indelible ink will be used to complete the information on the label, and the label will be at least three inches by five inches in size. The following information must be included on the label:

- (1) The name, address, business telephone number, and registration number of the generator;
- (2) "Biomedical Waste" or "Infectious Waste" in large print;

- (3) "Refrigeration Required" in large print if pathological waste, cultures, or animal carcasses or body parts are included in the contents;
- (4) The name, address, business telephone number, and registration number of the person or persons to whose control the biomedical waste is to be transferred;
- (5) The international biohazard symbol; and
- (6) The date upon which the biomedical waste was packaged in accordance with Section 12(A)(6).

C. Handling

- (1) Packages of biomedical waste must be handled in a manner that does not impair the integrity of the packaging.
- (2) Trash chutes will not be used to transfer biomedical waste between locations where it is contained.
- (3) Compactors must not be used in the handling of biomedical waste. Biomedical waste in bags or other containers must not be subjected to compaction by any compacting device and must not be placed for storage or transport in a portable or mobile trash compactor.

D. Storage

- (1) Biomedical waste must be segregated from other wastes.
- (2) All on-site storage of containers of biomedical waste must be in a designated area away from general traffic flow patterns and, where possible, in a room reserved for this purpose. The manner of storage must prevent access to or contact with such waste by unauthorized persons.
- (3) Biomedical waste must be stored in a manner that preserves the integrity of the container and is not conducive to rapid microbial growth and/or putrefaction. Pathological waste, cultures, and discarded animal carcasses and body parts stored for more than 24 hours after packaging in accordance with Section 12(A)(3) must be refrigerated at a temperature of 45° F or below in a refrigerator or refrigerated space used only for biomedical waste.
- (4) All areas used for the storage of biomedical waste must be capable of being readily maintained in a sanitary condition.
- (5) All biomedical waste containers must be stored in a manner that allows access for inspection.
- (6) Biohazard signs must be posted wherever biomedical waste is stored or contained, including on storage rooms doors, refrigerators, bins and other containers.

E. Manifests and Record Keeping Requirements

- (1) Except as provided for in Section 4, the generator of biomedical waste that is to be transported off-site for treatment or disposal shall initiate a biomedical waste 4-part manifest available from the Department. Copy 4 of the biomedical waste manifest is to be retained by the generator; Copy 3, by the transporter; Copy 2, by the transfer or treatment facility; and Copy 1 is to be returned to the generator.
- (2) If the generator does not receive the completed manifest from the treatment facility within 35 days after the date the waste was accepted by the transporter, the generator shall report this fact to the Department.
- (3) Retention of Records. Manifests must be retained by the generator for a period of not less than 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 Commissioner. These records must be made available for inspection by the Department upon request.
- (4) The Department may approve electronic manifesting systems upon demonstration to the Department that the system meets EPA electronic manifest standards and provides an equal degree of regulatory oversight as the existing system. A paper copy must be provided to a generator upon request.

13. Licensing of Transporters**A. Applicability**

No person may transport biomedical waste without first obtaining a biomedical waste transporter license from the Department unless:

- (1) exempted pursuant to Section 4, or
- (2) the biomedical waste is moved in the site where it is generated or in the site of a license transfer or treatment facility.

B. Application Requirements

- (1) Application for a biomedical waste transporter license must be made on a form obtained from the Department.
- (2) All persons transporting biomedical waste shall apply to the Department at least 30 days prior to the date they wish to begin transporting biomedical waste and must obtain a license prior to transporting.
- (3) A transporter may apply for a license to cover himself as an operator and all conveyances which he or she either owns or leases for the purpose of biomedical waste transport. Where such an application is made and a single license issued, a license certificate must be obtained from the Department for the operator and for each conveyance covered by the license.

- (4) A transporter which is a business that engages in the transportation of biomedical waste may apply for a transporter license to cover all locations of the business; all conveyances owned, leased or otherwise controlled by the business and used for the transportation of biomedical waste; and all operators of such conveyances employed by the business. Where such an application is made and a single license issued, a license certificate must be obtained from the Department for each business location, each conveyance and each operator covered by the license. The requirements of this rule apply to the entire license and/or to the separate business locations and/or to the separate conveyances and/or to the separate operators covered by the license.
- (5) An applicant or licensee shall immediately notify the Department in writing of any change in circumstance or situation which changes or will change any information stated on his application.
- (6) The applicant must submit:
 - (a) Evidence of an applicant's history of compliance with laws, regulations and standards relating to environmental protection.

NOTE: For example, the Department will require the applicant to provide a list of all environmental licenses or permits previously obtained by the applicant in this, or any other, State as well as information pertaining to the status of those licenses or permits or to any related enforcement actions.

- (b) Records pertaining to the operation of motor vehicles.
 - (c) A certificate of liability insurance covering the licensed activity in an amount appropriate for the licensed activity and for the risk involved. In no event, however, may the limit of liability be less than \$1,000,000.
 - (d) A spill plan for the cleanup of discharges of biomedical waste that the applicant proposes to transport and evidence of the capability to carry out the plan.
 - (e) Any other information, including safety histories and training programs, which the Department deems to be necessary.
- (7) The application must be signed by:
 - (a) A principal executive officer of at least the level of vice president, if the applicant is a corporation.
 - (b) A general partner or a proprietor, if the applicant is a partnership or sole proprietorship.
 - (c) A principal executive officer or ranking elected official, if the applicant is a municipal, state, federal or other public agency.

- (8) The application fee schedule follows:
- (a) An application fee of \$100 must accompany each application for an initial or renewal license.
 - (b) If an applicant is applying for a license to cover more than one conveyance, and/or more than one operator and/or more than one business location, he or she must submit with the application an additional fee of \$50 for each additional conveyance, operator or business location.
 - (c) Application fees for additional conveyances, operators or business locations will be reduced to \$25 if the date of issuance of any license certificate is within six (6) months of the expiration date of the license.
 - (d) Application fees are non-refundable.
- (9) Application for renewal of a license must be made no sooner than ninety (90) days and no later than 30 days prior to the date of its expiration and will be made on forms provided by the Department. A copy of a prior application may, at the discretion of the Department, be submitted as the renewal application provided there has been no change in the information included therein or required by this rule. The applicant shall accompany the copy with a recent certificate of insurance, and a letter, signed and dated by the applicant, that states there have been no changes.

C. Decisions

The Department shall issue a biomedical waste transporter license whenever it finds that the applicant has satisfied all application requirements and has demonstrated the technical and financial ability to comply with the operating requirements and manifest and recordkeeping requirements of this section, all terms and conditions of the license, and all other requirements of this rule.

D. Terms

- (1) A license or renewal of a license granted under this rule is valid for one calendar year beginning with the date of issuance. Business location license certificates, conveyance license certificates and operator license certificates issued with the initial license or added thereafter as provided by this rule will also expire on the date the license expires.
- (2) A license under this rule is issued on the basis of information supplied in the application and is valid only so long as that information remains accurate. Where the Department has been notified of a change in the information, the license remains valid notwithstanding the change, so long as the licensee complies with any additional or different terms and conditions of the license necessitated by the changed information.
- (3) A license under this rule is issued only to and for the persons, conveyances, locations and activities specified in the license and is non-transferable. Operators who are no longer employed by the licensee and conveyances which are no longer owned, leased or otherwise controlled by the licensee are no longer covered by the license and must not be used to

transport biomedical waste. Any certificate issued to such operators or conveyances must be returned to the Department within 10 calendar days of the date of change.

- (4) A conveyance used to transport biomedical waste may be inspected at any time for compliance with its license and these rules, and for adequacy for safe transportation of biomedical waste. Inspection may be made by a public safety officer or any authorized representative of the Department. A conveyance found to be not in compliance with this rule or to be otherwise unsafe may not thereafter be operated except under the direction of a public safety officer or an authorized representative of the Department.

E. Standard Conditions

All transporter licenses issued under this rule are subject to the following standard conditions:

- (1) **Duty to Comply.** The licensee shall comply with all conditions of the license and these rules. Noncompliance with the license or rule constitutes a violation and is grounds for enforcement action, for license suspension or revocation, or for denial of any renewal application.
- (2) **Liability Insurance.** A licensee shall have liability insurance coverage in force at all times during the term of the license. The coverage must be appropriate for the licensed activity and for the risk involved. Under no circumstance may the amount of liability insurance in force be less than \$1,000,000.
- (3) **Local, State and Federal Permits.** A licensee shall hold all other local, state and federal permits, licenses and certifications required for the licensed activity and shall comply with all applicable local, state and federal laws and rules.
- (4) **Record Keeping.** A licensee shall comply with all applicable state and federal requirements regarding the use of a manifest and the maintenance of other required records.
- (5) **Duty to Ensure Safe Operation.** It is the duty of a licensee to ensure that the licensed activity is carried out safely and does not create a threat to public health or safety or the environment. A licensee shall ensure that all methods, equipment and personnel are adequate and capable to achieve this end.
- (6) **Inspection and Training Requirements.** A licensee shall comply with all state and federal inspection and training requirements as may from time to time be applied by law, rule or license condition to the licensed activity.
- (7) **Response to an Emergency.** A licensee agrees to provide to the Department and to public safety agencies all information necessary for response to emergency situations involving the licensed activity and agrees to assist the Department in obtaining compliance with this rule.
- (8) **Spill Plan.** The operator of a conveyance must be familiar with the spill plan for the conveyance and for the wastes in the conveyance which he or she is operating and shall be capable of carrying out the plan.

- (9) Discharge of Biomedical Waste. In the event of a discharge of biomedical waste in any amount, the licensee shall take immediate appropriate action to protect public health, safety and welfare and the environment, including immediate implementation of the approved spill plan, and shall immediately report the discharge to the Maine Department of Environmental Protection.
- (10) Duty to Mitigate. The licensee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with the license.
- (11) Duty to Reapply. If the licensee wishes to continue an activity regulated by the license after the expiration date of the license, the licensee must apply for and obtain a new license.

F. Special Conditions

The Department may place special conditions on any license issued under this rule. However, special conditions must address particular means of satisfying minor or easily corrected problems relating to compliance with this rule and with all applicable statutes and may 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 Department may seek suspension or revocation of a license pursuant to 38 M.R.S.A. Section 341-D(3).
- (2) Suspension or revocation may be sought as to any or all operators, conveyances or locations covered by the license.
- (3) Where a license covers more than one operator and/or conveyance and/or location and if two or more operator, conveyance and/or location licenses covered thereunder are suspended within a calendar year, the Department may seek revocation of the entire license.
- (4) The Department shall seek revocation of any license which is again suspended within 18 months of its prior suspension or revocation.
- (5) A licensee whose license has been revoked may not reapply for a license until the conditions or violations which led to the revocation have been eliminated.

14. Standards for Transporters

A. Operations

- (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 the transportation of biomedical waste.
- (2) Except as stated in Section 4 of this rule, biomedical waste shall only be transported from the point of generation by transporters who are licensed by the Department.

- (3) No person may transport or receive for transport any biomedical waste that is not packaged and labeled in accordance with these rules.
- (4) Conveyances that transport biomedical waste must include a cargo-carrying portion that must be closed and secured except when loading or unloading waste to prevent unauthorized access and exposure to wind and/or precipitation; must be designed and constructed so as to contain any spillage; must be cleaned and disinfected following leakage or spills; and must be cleaned and disinfected prior to using the conveyance for any other purpose.
- (5) The identity of the biomedical waste hauler and the international biohazard symbol must appear on three sides and the door of the cab of conveyances used to transport biomedical waste. The lettering of such identification must be clearly legible during daylight from a distance of 50 feet.
- (6) The transporter license certificate, or certified copy thereof obtained from the Department, must be available for inspection upon demand by any public safety officer or any authorized representative of the Department.
 - (a) A certificate covering an operator must be in his or her immediate possession while he or she is engaged in the transportation of biomedical waste.
 - (b) A certificate covering a conveyance must be with the conveyance while it is engaged in the transportation of biomedical waste.
 - (c) A certificate covering a business must be prominently displayed at each location of the business.
- (7) Vehicles used to transport biomedical wastes must carry an appropriate spill containment and clean up kit.
- (8) Biomedical waste must not be compacted or subjected to violent mechanical stress during transport.
- (9) Biomedical waste may not be transported in the same vehicle with other waste unless the biomedical waste is separately contained in rigid reusable containers or kept separate by barriers from other waste, or unless all of the waste is to be treated and disposed of as biomedical waste in accordance with this rule.

B. Manifests and Record Keeping

- (1) A transporter may not accept biomedical waste from a generator unless it is accompanied by a manifest with the generator portion completed, signed and dated by the generator.
- (2) A transporter shall in the presence of the generator or, for subsequent transporters, the prior transporter, complete the appropriate transporter 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 prior transporter, noting any discrepancies in manifest information.

- (3) Copy 4 of the 4-part biomedical waste manifest is to be retained by the generator; Copy 3, by the transporter; Copy 2, by the transfer or treatment facility; and Copy 1 is to be returned to the generator.
- (4) Retention of Records. Manifests must be retained by the licensed biomedical waste transporter 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 made available for inspection by the Department, upon request.

15. Licensing of Transfer Facilities

A. Applicability

- (1) No person may accept biomedical waste generated off-site for the purpose of temporary storage prior to transport to another licensed biomedical waste transfer or treatment facility without first obtaining a biomedical waste transfer facility license from the Department.
- (2) Exclusions. Generators of biomedical waste who accept less than a total of 100 pounds per month of biomedical waste from other generators for the purpose of temporary storage prior to transport to a licensed biomedical waste transfer or treatment facility are not transfer facilities for the purposes of this rule provided the waste accepted from off-site is stored with the receiving generator's biomedical waste and is managed in accordance with Sections 12(A), 12(B), 12(C), and 12(D) of this rule.

B. Application Requirements

- (1) Application for a biomedical waste transfer facility license will be made on a form obtained from the Department. The license application will be processed in accordance with Chapter 2 of the Department's rules.
- (2) Persons wishing to establish a transfer facility shall apply to the Department at least 60 days prior to the date they wish to begin operations.
- (3) An applicant or licensee shall immediately notify the Department in writing of any change in circumstance or situation which changes or will change any information stated on his or her application.
- (4) The applicant must submit:
 - (a) Evidence of the applicant's history of compliance with laws, regulations and standards relating to environmental protection.

NOTE: For example, the Department will require the applicant to provide a list of all environmental licenses or permits previously obtained by the applicant in this, or any other, State as well as information pertaining to the status of those licenses or permits or to any related enforcement actions.

- (b) A certificate of liability insurance covering the licensed activity in an amount appropriate for the licensed activity and for the risk involved. In no event, however, may the limit of liability be less than \$1,000,000.
 - (c) Any other information, including safety histories and training programs, which the Department deems to be necessary.
- (5) The applicant must demonstrate in his application sufficient financial capacity to construct, operate, maintain and close all aspects of the facility.
- (6) All property survey work must be signed and certified by a State of Maine Registered Land Surveyor.
- (7) All drawings, site plans and maps must be on sheets no smaller than 8½" x 11" and no larger than 30" x 40" and must be folded to a size of 8½" x 11" or smaller.
- (8) Biomedical Waste Management and Operations Plan
- (a) Each applicant for a biomedical waste transfer facility must submit a written biomedical waste management and operations plan. Such plan will set forth policies and procedures consistent with these rules for managing biomedical waste.
 - (b) The plan must include, at a minimum, the following:
 - (i) a description of the biomedical waste handled by the facility including type and volume of biomedical waste;
 - (ii) a detailed narrative explaining how the facility will operate, including, but not limited to, design capacity, a description of all biomedical waste storage areas and equipment specifications;
 - (iii) hours and days of operation of the facility and the number of conveyances delivering biomedical waste that are expected daily and that can be accommodated daily;
 - (iv) a general inspection schedule for the facility;
 - (v) a description of security procedures and equipment;
 - (vi) training procedures for personnel who handle biomedical waste;
 - (vii) emergency spill containment and cleanup procedures and equipment; and
 - (viii) the name, address, and telephone number of the person(s) responsible for biomedical waste management at the facility.
 - (c) The plan must be available for inspection at the facility by a public safety officer or authorized representative of the Department.

- (9) **Public Informational Meeting.** The applicant must hold a public informational meeting on the project. The purpose of the meeting is to provide information to the public and interested persons regarding the purpose of the project. The public informational meeting shall be held in the municipality or political jurisdiction where the project is to be located. The public notice of the application provided in accordance with Chapter 2 must identify the date, time and place of the public informational meeting.
- (10) **Access to the Site.** By filing an application for a license, the applicant agrees to provide authorized representatives of the Department with access to the facility site in order that the site may be evaluated for suitability as a biomedical waste transfer facility. Insofar as practical, access will be sought during normal business hours.
- (11) **Application Fee**
 - (a) At the time of filing, the applicant must remit an application fee of \$1,000 made payable to the Maine Hazardous Waste Fund.
 - (b) Application fees are required for an initial application, a renewal application, and an application for a license amendment seeking approval for a substantial modification to a facility or license.
 - (c) A refund of 50% of the fee will be made to an applicant who withdraws the application within 30 calendar days of its submission.
- (12) **Annual License Fee.** The licensee must remit an annual fee of \$500 upon the issuance of the license and on each anniversary date thereafter.

C. Decisions

The Department shall issue a biomedical waste transfer facility license whenever it finds that the applicant has satisfied all application requirements and has demonstrated the technical and financial ability to comply with the operating requirements and manifest and recordkeeping requirements of this section, all terms and conditions of the license, and all other requirements of this rule.

D. Terms

- (1) A license or renewal of a license granted under this rule is valid for 5 calendar years beginning with the date of issuance, but may be for a shorter time period if the Department deems it necessary in order to assure compliance with this rule.
- (2) A license under this rule is issued on the basis of information supplied in the application and is valid only so long as that information remains accurate.
- (3) A license under this rule is issued only to and for the persons, location and activities specified in the license unless a license transfer is approved in accordance with Department rules.

- (4) A biomedical waste transfer facility may be inspected at any time for compliance with its license and this rule. Inspection may be made by a public safety officer or any authorized representative of the Department.
- (5) The license may be modified, suspended or revoked by the Board pursuant to 38 M.R.S.A. Section 341-D(3).

E. Standard Conditions

All transfer facility licenses issued under this rule are subject to the following standard conditions.

- (1) The licensee shall not operate, construct or maintain a biomedical waste transfer facility other than as described in the application approved by the Department.
- (2) Relation of License to Application. A license issued under this rule is valid only as long as the information supplied in the application remains accurate. Approval of an application is dependent upon and limited to the proposals and plans contained in the application and supporting documents submitted and affirmed by the applicant. Any variation from the plans, proposals and supporting documents is subject to the review and approval of the Department prior to implementation.
- (3) Duty to Comply. The licensee shall comply with all conditions of the license and these rules. Noncompliance with the license or rule constitutes a violation of law and is grounds for enforcement action, for license suspension or revocation, or for denial of any renewal application.
- (4) Liability Insurance. A licensee shall have liability insurance coverage in force at all times. The coverage must be appropriate for the licensed activity and for the risk involved. Under no circumstance may the amount of liability insurance in force be less than \$1,000,000.
- (5) Local, State and Federal Permits. A licensee shall hold all other local, state and federal permits, licenses and certifications required for the licensed activity and will comply with all applicable local, state and federal laws and rules.
- (6) Record Keeping. A licensee shall comply with all applicable state and federal requirements regarding the use of a manifest and the maintenance of other required records.
- (7) Duty to Ensure Safe Operation. It is the duty of a licensee to ensure that the licensed activity is carried out safely and does not create a threat to public health or safety or the environment. A licensee shall ensure that all methods, equipment and personnel are adequate and capable to achieve this end.
- (8) Inspection and Training Requirements. A licensee shall comply with all state and federal inspection and training requirements as may from time to time be applied by law, rule or license condition to the licensed activity.

- (9) Response to an Emergency. A licensee agrees to provide to the Department and to public safety agencies all information necessary for response to emergency situations involving the licensed activity and agrees to assist the Department in obtaining compliance with this rule.
- (10) Discharge of Biomedical Waste. In the event of a discharge of biomedical waste in any amount, the licensee shall take immediate action to protect public health, safety and welfare and the environment, including immediate implementation of the spill containment and cleanup procedures contained in the approved biomedical waste management and operations plan, and shall immediately report the discharge to the Maine Department of Environmental Protection.
- (11) Duty to Mitigate. The licensee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with the license.
- (12) Duty to Reapply. If the licensee wishes to continue an activity regulated by the license after the expiration date of the license, the licensee must apply for and obtain a new license. Such application shall be made at least 6 months prior to the expiration of the license.
- (13) Duty to Provide Information. The licensee shall furnish to the Department, upon request, any information that the Department may require to determine compliance with the license and this rule. The licensee shall also furnish to the Department, upon request, copies of records required to be kept by the licensee and not otherwise required to be filed with the Department.

F. Special Conditions

The Department may place special conditions on any license issued under this rule. However, special conditions must address particular means of satisfying minor or easily corrected problems relating to compliance with this rule and with all applicable statutes and may 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

The Department may seek suspension or revocation of a license pursuant to 38 M.R.S.A. Section 341-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.

16. Standards for Transfer Facilities

A. Facility Location Criteria

- (1) Environmental Performance Standards. All biomedical waste transfer 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 includes, but is not 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) Siting Criteria. All new biomedical waste transfer facilities as well as substantial modifications to existing facilities are prohibited in the following areas:
- (a) Areas in which a risk to any underground source of potable water for people may be created. Location within 300 feet is presumed to pose a risk such that a license cannot be issued unless demonstrated otherwise to the Department's satisfaction;
 - (b) 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;
 - (c) 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;
 - (d) Areas in which 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 may be created; and
 - (e) Within the boundaries of a state or federal park or designated wilderness area.

B. Design Standards

- (1) Biomedical waste must be stored in conveyances or buildings that are leak-proof and equipped with locks.
- (2) If the transfer 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 alternate 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 must be located at least 50 feet from the facility property boundaries.
- (5) The operating area of the facility must be an impervious surface, such as asphalt or concrete, which must be kept entire.
- (6) The facility must have provisions for the packaging of biomedical waste in the event that repackaging is required because the integrity of the original container has been compromised.

Such re-packaging must be carried out in an enclosed space which is designed to contain any spillage of waste and prevent exposure to wind and precipitation.

C. Operating Standards

- (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 transfer facilities.
- (2) An operator of a biomedical waste transfer facility may not accept any biomedical waste that is not packaged and labeled in accordance with this rule and accompanied by a properly completed manifest except as provided for in Section 4 of this rule.
- (3) Biomedical waste may not be re-packaged unless the integrity of the original packaging has been compromised such that it can no longer contain the wastes.
- (4) Biomedical waste which was generated off-site may not be held at a transfer facility for more than one week (168 hours), except that:
 - (a) Pathological waste that is to be transferred off the site of the transfer facility for treatment may be stored up to 30 days provided it is frozen at a temperature of zero degrees Fahrenheit or below, and
 - (b) Trace chemotherapy waste and anti-neoplastic drugs as described in Section 7 (B) of this rule that are to be treated at another facility may also be stored for up to 30 days.

NOTE: The purpose of the above provision is to enable the efficient consolidation and movement of biomedical waste to the limited number of licensed treatment facilities for these portions of the waste stream requiring specialized treatment without risk to human health or the environment.

- (5) Pathological wastes, cultures, and discarded animal carcasses and body parts must be stored in refrigerated conveyances or storage buildings in a frozen state.
- (6) Biomedical waste may not be compacted or subjected to violent mechanical stress during transfer, storage or any time prior to final treatment.
- (7) 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.
- (8) The on-site population of disease vectors must be controlled to protect public health.
- (9) The facility access gate and all biomedical waste conveyances and storage buildings must be closed except when loading or unloading wastes and must be locked whenever an operator is not in attendance at the facility.
- (10) The biomedical waste transfer facility license or certified copy thereof obtained from the Department must be available for inspection upon demand by any public safety officer or any authorized representative of the Department.

D. Closure

A licensee who no longer accepts waste at a site shall remove all biomedical waste and biomedical waste residues to a facility licensed to handle the waste. Remaining conveyances, equipment, buildings and soil containing or contaminated with biomedical waste or biomedical waste residues must be disinfected or disposed of at a facility licensed to handle the waste. The licensee shall provide 60 days written notice to the Department prior to closure and shall submit to the Department, within 10 days of completion of closure, certification that closure was completed in accordance with this rule.

E. Manifests and Record Keeping

- (1) A transfer 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.
- (2) A transfer facility operator shall, in the presence of the generator or the transporter, complete the appropriate transfer 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.
- (3) The operator of a biomedical waste transfer facility that has accepted biomedical waste from a generator without a manifest because the quantity is less than 50 pounds shall maintain a log of all such wastes which includes, at a minimum, the following:
 - (a) The name, address and identification number of the transfer 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.
- (4) The transfer facility shall initiate a biomedical waste 4-part manifest available from the Department. In instances where the transfer facility initiates the manifest, Copy 4 of the biomedical waste manifest is to be retained by the transfer facility; Copy 3, by the transporter; Copy 2, by the transfer or treatment facility; and Copy 1 is to be returned to the transfer facility. If the transfer facility does not receive the completed manifest from the treatment facility within 35 days after the date the waste was accepted by the transporter, the transfer facility must report this fact to the Department.
- (5) Retention of Records. Manifests and logs must be retained by the licensed biomedical waste transfer facility for a period of not less than 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.

17. Licensing of Treatment Facilities

A. Applicability

No person may treat biomedical waste without first obtaining a biomedical waste treatment facility license from the Department.

NOTE: Both incineration and non-incineration treatment technologies are considered to be a method of treatment, not disposal. The Department will not issue a license for the disposal of untreated biomedical waste.

B. Application Requirements

- (1) Application for a biomedical waste treatment facility license must be made on a form obtained from the Department. The license application will be processed in accordance with Chapter 2 of the Department's rules. An applicant or licensee shall immediately notify the Department in writing of any change in circumstance or situation which changes or will change any information stated on his or her application.
- (2) Persons wishing to incinerate biomedical waste must apply to the Department for a biomedical waste treatment facility license pursuant to this rule and an air emission license pursuant to Chapter 115, Major and Minor Source Air Emission License Regulations. A solid waste incineration facility currently licensed under Chapter 403 of the Department's Solid Waste Management Rules must apply to the Department to amend its license to cover biomedical waste in accordance with this rule prior to accepting biomedical waste.
- (3) Persons wishing to treat biomedical waste utilizing a non-incineration treatment technology including, but not limited to, steam sterilization or microwaving, must obtain approval of the non-incineration treatment technology pursuant to Section 19 and a biomedical waste treatment facility license pursuant to this rule.
- (4) The Department will not accept an application for the disposal of untreated biomedical waste.
- (5) Biomedical Waste Management and Operations Plan
 - (a) Each biomedical waste treatment facility must submit a written biomedical waste management and operations plan. Such plan will set forth policies and procedures consistent with these rules for managing biomedical waste.
 - (b) The plan must include, at a minimum, the following:
 - (i) a description of the biomedical waste handled by the facility including type and volume of biomedical waste;
 - (ii) a detailed narrative explaining how the facility will operate, including, but not limited to, design capacity, equipment specifications, on site storage, and flow diagram schematics for all parts of the facility;

- (iii) total capacity and life expectancy of the facility, including calculations used to derive these data;
 - (iv) hours and days of operation of the facility and the number of conveyances delivering biomedical wastes that are expected daily and that can be accommodated daily;
 - (v) a general inspection schedule for the facility;
 - (vi) a description of security procedures and equipment;
 - (vii) training procedures for personnel who handle biomedical waste;
 - (viii) emergency spill containment and cleanup procedures and equipment; and
 - (ix) the name, address, and telephone number of the person(s) responsible for biomedical waste management at the facility.
- (c) The plan must be available for inspection at the facility by a public safety officer or authorized representative of the Department.
- (6) Treated Biomedical Waste Management Plan
- (a) In instances where the facility incinerates biomedical waste, the applicant must submit a plan for the storage, testing, removal and disposal of the incinerator ash.
 - (b) In instances where the facility treats biomedical waste using a non-incineration treatment technology approved pursuant to Section 19, the applicant must submit a plan for the storage, testing, removal and disposal of the treated waste and other residues, if any. The plan must demonstrate that the activity protects public health and safety and the environment and must provide for the following:
 - (i) the treated waste must meet the performance standards in Section 19 of this rule;
 - (ii) the wastes and treatment residues must be managed in a manner protective of human health and the environment;
 - (iii) all biomedical waste treated via a non-incineration treatment technology must be accompanied when shipped for disposal by a "Certificate of Destruction" certifying compliance with treatment performance standards as stated in Section 19;
 - (iv) the treated biomedical waste as a special waste must be handled, stored and disposed of as a special waste; and
 - (v) the plan must require a contract with a disposal facility licensed by the Department to accept special waste. The plan must also name all back up disposal facilities.
- (7) The applicant must submit evidence of the applicant's history of compliance with laws, regulations and standards relating to environmental protection and any other information,

including safety histories and training programs, which the Department deems to be necessary.

NOTE: For example, the Department may require the applicant to provide a list of all environmental licenses or permits previously obtained by the applicant in this, or any other, State as well as information pertaining to the status of those licenses or permits or to any related enforcement actions.

- (8) **The applicant must submit information regarding liability insurance coverage as follows:**
- (a) The applicant must submit with his application, and annually thereafter, proof of liability insurance against bodily injury or property damage. The level of coverage must be at least one million dollars per occurrence and two million dollars annual aggregate or such other financial guarantees which the Department determines are equivalent. The Department may require a higher minimum level of insurance coverage for a particular facility if it finds that, because of the design, operation or location of the facility, higher coverage is necessary to protect the public health, safety and welfare or the environment.
 - (b) All liability insurance coverage amounts must be exclusive of legal defense costs.
 - (c) A financial test may not be used in lieu of liability insurance nor may an owner or operator self-insure.
- (9) The applicant must demonstrate in his application sufficient financial capacity to construct, operate, maintain and close all aspects of the facility. Such demonstration shall be made on an annual basis.
- (10) All engineering designs, reports, plans and other technical engineering documents must be signed and certified by a registered professional engineer.
- (11) All geological work must be signed and certified by a State of Maine Certified Geologist, except that soils work may be signed and certified by a State of Maine Certified Soil Scientist.
- (12) All property survey work must be signed and certified by a State of Maine Registered Land surveyor.
- (13) All drawings, site plans and maps must be on sheets no smaller than 8½" x 11" and no larger than 30" x 40" and will be folded to a size of 8½" x 11" or smaller.
- (14) **Public Informational Meeting.** The applicant must hold a public informational meeting. The purpose of the meeting is to provide information to the public and interested persons regarding the purpose of the project. The public informational meeting will be held in the municipal or political jurisdiction where the project is to be located. The public notice of the application provided in accordance with Chapter 2 must identify the date, time and place of the public informational meeting.

(15) Access to the Site. By filing an application for a license, the applicant agrees to provide authorized representatives of the Department with access to the facility site in order that the site may be evaluated for suitability as a biomedical waste treatment facility. Insofar as practical, access will be sought during normal business hours.

(16) Application Fee

(a) At the time of filing, the applicant must remit an application fee made payable to the Maine Hazardous Waste Fund. The application fee is determined as follows:

- | | |
|---|---------|
| (i) for a facility which treats biomedical waste generated on-site or which treats no more than 15% on an annual average of biomedical waste generated off-site | \$3,500 |
| (ii) for all other facilities | \$5,000 |

(b) Application fees are required for an initial application, a renewal application, and any application for a license amendment seeking approval for a substantial modification to a facility or license.

(c) A refund of 50% of the fee will be made to an applicant who withdraws the application within 30 calendar days of its submission.

(17) Annual Fee. The licensee must remit an annual fee of \$1,000 upon the issuance of his license and on each anniversary date thereafter.

C. Decisions

The Department shall issue a biomedical waste treatment facility license whenever it finds that:

- (1) the applicant has satisfied all application requirements,
- (2) the proposed facility meets all siting and testing standards,
- (3) the proposed facility meets all standards of the Site Location of Development Law, and
- (4) the applicant has the financial and technical ability to construct, operate, maintain and close the facility in accordance with the operating, manifest and recordkeeping requirements of this section, all terms and conditions of the license, and all other requirements of this rule.

D. Terms

- (1) A license or renewal of a license granted under this rule is valid for 5 calendar years beginning with the date of issuance, but may be for a shorter time period if the Department deems it necessary in order to assure compliance with this rule.
- (2) A license under this rule is issued on the basis of information supplied in the application and is valid only so long as that information remains accurate.

- (3) A license under this rule is issued only to and for the persons, location and activities specified in the license unless a license transfer is approved in accordance with Department rules.
- (4) The biomedical waste treatment facility license or certified copy thereof obtained from the Department, must be available for inspection upon demand by any public safety officer or any authorized representative of the Department.
- (5) A biomedical waste treatment facility may be inspected at any time for compliance with its license and this rule. Inspection may be made by a public safety officer or any authorized representative of the Department.
- (6) The license may be modified, suspended or revoked by the Board pursuant to 38 M.R.S.A. Section 341-D(3).

E. Standard Conditions

All treatment facility licenses issued under this rule are subject to the following standard conditions:

- (1) The licensee must not operate, construct or maintain a biomedical waste treatment facility other than as described in the application approved by the Department.
- (2) **Relation of License to Application.** A license issued under this rule is valid only as long as the information supplied in the application remains accurate. Approval of an application is dependent upon and limited to the proposals and plans contained in the application and supporting documents submitted and affirmed by the applicant. Any variation from the plans, proposals and supporting documents is subject to the review and approval of the Department prior to implementation.
- (3) **Duty to Comply.** The licensee shall comply with all conditions of the license and these rules. Noncompliance with the license or rule constitutes a violation of law and is grounds for enforcement action, for license suspension or revocation, or for denial of any renewal application.
- (4) **Liability Insurance.** A licensee must have liability insurance coverage in force at all times. The coverage will be appropriate for the licensed activity and for the risk involved. Under no circumstance may the amount of liability insurance in force be less than \$1,000,000 per occurrence or \$2,000,000 in aggregate.
- (5) **Local, State and Federal Permits.** A licensee must hold all other local, state and federal permits, licenses and certifications required for the licensed activity and must comply with all applicable local, state and federal laws and rules.
- (6) **Record Keeping.** A licensee must comply with all applicable state and federal requirements regarding the use of a manifest or log and the maintenance of other required records.
- (7) **Duty to Ensure Safe Operation.** It is the duty of a licensee to ensure that the licensed activity is carried out safely and does not create a threat to public health or safety or the

environment. A licensee must ensure that methods, equipment and personnel are adequate and capable to achieve this end.

- (8) Inspection and Training Requirements. A licensee must comply with all state and federal inspection and training requirements as may from time to time be applied by law, rule or license condition to the licensed activity.
- (9) Response to an Emergency. A licensee agrees to provide to the Department and to public safety agencies all information necessary for response to emergency situations involving the licensed activity and agrees to assist the Department in obtaining compliance with this rule.
- (10) Discharge of Biomedical Waste. In the event of a discharge of biomedical waste in any amount, the licensee shall take immediate action to protect public health, safety and welfare and the environment, including the immediate implementation of the spill containment and cleanup procedures contained in the approved biomedical waste management and operations plan, and shall immediately report the discharge to the Maine Department of Environmental Protection.
- (11) Duty to Mitigate. The licensee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with the license.
- (12) Duty to Reapply. If the licensee wishes to continue an activity regulated by the license after the expiration date of the license, the licensee must apply for and obtain a new license. Such application must be made at least one year prior to the expiration of the license.
- (13) Duty to Provide Information. The licensee shall furnish to the Department, upon request, any information that the Department may require to determine compliance with the license and this rule. The licensee shall also furnish to the Department, upon request, copies of records required to be kept by the licensee and not otherwise required to be filed with the Department.
- (14) Prior to Construction. All preconstruction terms and conditions must be met before construction begins.
- (15) Construction/Operation within Two Years. If the construction or operation of the activity is not begun within 2 years, the approval will lapse and the applicant must reapply to the Department for a new approval. The applicant may not begin construction or operation of 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. Section 341-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.

(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 consider 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 be rendered unrecognizable and shredded into pieces less than $\frac{3}{4}$ 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 reoccurrence.
- (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;
- (3) A description of the amount and type of biomedical waste or wastes to which the proposed treatment would be applied, including the identification of potentially infectious agents contained, if known;
- (4) The basis for the request;
- (5) A demonstration of the effectiveness of the proposed alternate treatment method;

- (6) A demonstration that the alternate treatment method provides an equal degree of protection for the public and the environment; and
- (7) The application fee for non-incineration treatment technology approval:
- (a) At the time of filing, the applicant shall remit an application fee of \$1,000 made payable to the Maine Hazardous Waste Fund.
 - (b) A refund of \$500 will be made to an applicant who withdraws the application within 30 calendar days of submission.

B. Performance Standard

Any person seeking a license to operate a treatment facility using a non-incineration treatment technology must submit evidence to the Department that the technology will achieve the inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 99.9999% reduction or greater; and inactivation of *Bacillus stearothermophilus* spores and *Bacillus subtilis* spores at a 99.99% reduction or greater.

The applicant shall submit to the Department a plan for review and approval to perform initial challenge testing addressing waste load variables such as moisture content, waste density, waste packaging and sample placement within the waste load.

C. Approval

The Department will approve a non-incineration treatment technology for biomedical waste whenever it finds that the applicant has satisfied all application requirements and has demonstrated that the performance standard of this section will be met.

D. Facility License Required

A person that has obtained approval of a non-incineration treatment technology for biomedical waste must also obtain a biomedical waste treatment facility license prior to accepting biomedical waste for treatment.

E. Designation as Special Waste

Pursuant to its authority under 38 M.R.S.A. §1303-C(34)(K), the Board designates treated biomedical waste that results from non-incineration treatment technologies approved under this rule as special waste.

AUTHORITY: 38 M.R.S.A. §§ 341-D(1-B), 1303-C(34)(K) and 1319-0(3)

EFFECTIVE DATE: January 1, 1991

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