

REGISTRATION OF MEDICAL FACILITIES: GENERAL INFORMATION

1. BACKGROUND INFORMATION

38 M.R.S.A. _ 1319-0(3) requires the Board of Environmental Protection to adopt rules governing the management of biomedical waste, including registration of biomedical waste generators, to protect public health, safety and welfare and the environment. The Biomedical Waste Management Rules (Chapter 900 of the Department's rules) were adopted to implement the intent of the Legislature. The effective date of most provisions of the rule was January 1, 1991.

2. WHAT TYPES OF WASTE DOES THE RULE COVER?

38 M.R.S.A. _ 1303-C (1-A) defines biomedical waste as follows:

"Biomedical waste" means waste that may contain human pathogens of sufficient virulence and in sufficient concentrations that exposure to it by a susceptible human host could result in disease or that may contain cytotoxic chemicals used in medical treatment.

Section 7 of the rules identifies the following categories of waste subject to regulation:

1. Discarded human blood, blood products and body fluids;
2. Waste saturated with human blood, blood products, or body fluids;
3. Pathological waste;
4. Discarded sharps used in patient, animal or cadaver care or in medical and biomedical research laboratories;
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;
7. Cytotoxic (Antineoplastic) drugs not identified as hazardous waste in Chapter 850 of the Department's Regulations;
8. Chemotherapy Waste - All materials that have come in contact with, and have no more than trace amounts of, cytotoxic (antineoplastic) agents.

3. WHO MUST REGISTER?

Each medical facility that generates any amount of biomedical waste is required to register with the Department.

Section 6(Y) of the rule defines medical facility as follows:

"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.

Registration is by facility location. In instances where a medical practice has satellite offices, each location (address) must be registered. In the case of a group practice at a single location, the group practice must register (not each practitioner). In instances where separate medical practices are located within an office building, each practice must register.

Household generators of biomedical waste are not required to register with the Department. Section 5(U) of the rule defines household as follows:

"Household" means single and multiple residential dwellings and includes hotels, motels and boarding homes.

4. IS A BIOMEDICAL WASTE MANAGEMENT PLAN REQUIRED?

A medical facility which generates less than 50 pounds per month of biomedical waste is not required to prepare a written biomedical waste management plan. All other medical facilities are required to prepare such a plan. Plans need not be submitted to the Department but shall be available for inspection by a public safety officer or authorized representative of the Department.

5. WHERE DOES ONE REGISTER?

Facilities generating biomedical waste must register with:

Maine Department of Environmental Protection
Bureau of Remediation and Waste Management
17 State House Station
Augusta, Maine 04333-0017

6. WHAT IS THE REGISTRATION FEE?

The initial registration fee is fifty dollars (\$50) per facility. Checks should be made payable to: Hazardous Waste Fund - Biomedical Waste Account.

Annual Fee Requirement

In 2008 the Department instituted an annual registration fee. The fee has three levels. Those generating an average of ten pounds or less per month are assessed a \$25 annual fee. Those generating more than ten pounds per month but less than fifty pounds per month are assessed an annual fee of \$50. Those generating more than fifty pounds per month are assessed an annual fee of \$500. All annual fees are assessed on a calendar year.

NOTE: A medical facility must notify the Department in writing of a change in majority ownership, name, location, or operational status of a facility.

8. QUESTIONS AND ASSISTANCE

For assistance in answering questions regarding the Biomedical Waste Management Rules, call (207) 287-2651.