



STATE OF MAINE  
DEPARTMENT OF ENVIRONMENTAL PROTECTION

PAUL R. LEPAGE  
GOVERNOR

Memorandum

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ACTING COMMISSIONER

To: Board of Environmental Protection  
From: Ronald Dyer, Bureau of Remediation & Waste Management  
Subject: Adoption of Revisions to Code of Maine Regulations Chapter 900, Biomedical Waste Management Rules  
Date: July 21, 2011

I ask the board to adopt the revisions to Chapter 900, the Biomedical Waste Management Rules (The Rule). Attached for your review and consideration are the applicable sections of the proposed rule, the basis statement with the Department's response to comments and the actual comments.

Statutory and regulatory references

38 MRSA Sec. 1319-O (3)

Description of the rule

Chapter 900 was originally adopted in December 1989. The rule identified biomedical waste subject to regulation and required the registration of biomedical waste generators. The rule established packaging, labeling, handling, storage, transportation and treatment requirements. The rule also required the licensing of biomedical waste transporters, and transfer and treatment facilities. The rule specified siting, operating and reporting requirements and established a biomedical waste tracking or manifest system.

The rule was last revised in August 2008. Among the changes made were the elimination of obsolete biomedical waste incinerator standards and their replacement with non-incineration treatment standards for technologies such as autoclaving. Other changes included the classification of treated biomedical waste as a special waste requiring disposal in a licensed special waste landfill. In addition, the requirements of the Department's Chapter Two Rules concerning the Processing of Applications and Other Administrative Matters were incorporated into The Rule. Finally, US Postal Service Rules for the shipment of biomedical waste via the US Postal Service were also incorporated.

This current rulemaking was posted for a thirty day public comment on May 4, 2011. This comment period closed on June 3, 2011. The Department received a total of six comments. In addition, there were inquiries on how the proposed changes would impact operations and costs at regulated facilities, mostly hospitals. The comments, as well as the Department's responses are incorporated into the attached Basis Statement.

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The recommended revisions to the rule include:

- No longer requiring that the sharps portion of the treated biomedical waste stream be shredded prior to landfilling. Instead the Department retains the authority to require this on a case by case basis. Historically, shredding was considered a signature of treatment. In some technologies such as microwave and chemical treatment, it is an operational requirement to shred before treatment to create a uniform particle size. With the development of aggressive efficacy testing protocols for biomedical waste treatment technologies, including autoclaves, parameters can be developed to ensure that each cycle of biomedical waste is safely treated regardless of load density. Presently, the sharps portion of the biomedical waste stream is segregated by the generators. This segregation will continue.
- The insertion of a note in Section 7, clarifying which discarded cultures and stocks are considered biomedical waste and subject to regulation under the Maine Biomedical Waste Management Rules.
- A citation is corrected in three locations. Three references to a Section 19(10E) are referenced. This section does not exist. These citations are corrected to reference Section 19 of The Rule.

### **Issues**

The Department received no comments opposing the proposal that the sharps portion of the treated biomedical waste stream continue to be shredded prior to landfilling.

The Department received a few comments on the proposed insertion of a note in Section 7, the note clarifies which discarded cultures and stocks are considered biomedical waste subject to the requirements of the Maine Biomedical Waste Management Rules. Nonetheless, the Department commits to increased outreach and education to generators of this type of waste over the next year.

The Department's responses to these comments are contained in the draft Basis Statement.

### **Department recommendation**

I recommend the board adopt the proposed amendments to Chapter 900 as set forth in the enclosed draft.

### **Estimated time of presentation**

15 minutes