

**Summary of Public Comments and Responses to  
The Draft Changes to the Biomedical Waste  
Management Rules**

**June 2011**

**Basis Statement**

**Background and Description of the proposed rule changes:**

Chapter 900 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 requires all transporters and owners or operators of transfer and treatment facilities to obtain a license. The rule specifies siting, operating and reporting requirements and establishes a biomedical waste tracking or manifest system. The rule was adopted on December 18, 1989 and further revisions were adopted August 4, 2008.

On April 21, 2011 the Board of Environmental Protection (BEP) posted revisions to the Biomedical Waste Management Rules to a public comment period. The proposed revisions focused on two areas.

First, the Department has proposed to allow the disposal of treated sharps in a special waste landfill without being shredded. As part of this revision, treated biomedical waste would continue to be handled as a special waste to prevent commingling with solid waste. The Department received a request from Associated Health Resources to suspend the sharps portion of the biomedical waste stream treated at their licensed facility in Pittsfield, Maine. The reasons cited in the request were worker exposure to treated sharps and shredder downtime and associated maintenance costs due to shredder jams and shaft breakage. The Department proposed in the rule change that it have the option whether or not to mandate shredding of sharps.

Second, the Department more clearly defined which discarded cultures and stocks are a regulated biomedical waste. Since the rules were adopted in 1989, the Department has addressed the subject of what pathogens are capable of causing disease in humans and would therefore make these discarded cultures and stocks a regulated biomedical waste. The Department determined that the Bio-Safety Level One (BSL-1) criteria established by the Center for Disease Control (CDC) would be an appropriate criteria. Levels above BSL- 1 are considered biomedical waste. The issue of when a pathogen in discarded cultures and stocks is a biomedical waste was raised by the Board in the 2008 rulemaking. To address this concern, the long standing interpretation of utilizing BSL-1 criteria as the cutoff for biomedical waste was identified and discussed in an issue profile. During this current 2011 rulemaking, a note was placed in the rules to help further address this issue. This note read:

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

This note concerning discarded stocks and cultures produced few comments. Nonetheless, the Department commits to increased outreach and education to generators of this type of waste over the next year.

The public comment period closed on June 3, 2011. The Department received a total of six individual comments. The Department received many telephone calls seeking more information about the rulemaking but few comments were generated for the record. The majority of callers sought information as to what impact the change in sharps handling would have on their operations. One party noted that certain (CDC) (BSL-1) organisms are capable of causing disease in susceptible humans.

The following pages are a summary of the comments that were received during the written comment period. Each comment summary is followed by the Department's response to the comment. The comments and responses are organized by the appropriate section of the draft rules.

This document forms the written statement outlining the Department's basis for the adoption of the Biomedical Waste Management Rules.

**KEY TO COMMENTORS**

<b>CODE</b>	<b>ORGANIZATION AND NAME</b>	<b>REPRESENTING</b>
MHA	The Maine Hospital Association (Jeffery Austin)	The Maine Hospital Association is an advocacy group representing Maine's 39 hospitals
WM	Waste Management of Maine (Gordon R. Smith Attorney, Verrill Dana LLP)	Waste Management of Maine operates the Crossroads Landfill in Norridgewock
NORDX	NORDX (Crystal Sands Manager – QA, Regulatory Affairs, Safety)	NORDX
BC	Bates College (Raymond Potter Environmental Health & Safety Manager)	Bates College
MRH	Millinocket Regional Hospital (Betsey Kelley)	Millinocket Regional Hospital
JAX	Rebecca Lingenfelter	The Jackson Laboratory

## Comments Received and the Department's Response

### Section 7 (A) (5) – Definition of Biomedical Waste

#### **Comment #1:**

We suggest you provide a clarification for how processing of the exempt stocks/cultures should be achieved to meet the law, such as, onsite decontamination (e.g., autoclave) prior to disposal in regular trash.

We are in agreement that the BSL Level 1 organisms can be exempt from red bag with the appropriate treatment. Your wording explains what is necessary to include, but clarification and education on the exemptions would be helpful.

In a setting such as NorDX we will not segregate, but clearly in the education/academic arena this would be beneficial, and a very reasonable approach. (NORDX)

#### **Response to Comment #1:**

The Department agrees that further education and outreach with the various entities generating this type of waste will be beneficial to all parties and will organize that effort in the weeks ahead.

#### **Comment #2:**

Our past practice has been to autoclave all materials generated in our microbiology classes and laboratories and ship these materials via a licensed hazardous waste transporter to a licensed incineration site. Since our materials are almost exclusively level one biological wastes, this makes the rule change relevant to our procedures. We will be able to save the cost of sending autoclaved wastes to a licensed incinerator and dispose of them with our regular solid waste stream. In the unlikely event that any of our research projects generate waste in a higher biological waste level we would autoclave and ship to a licensed incinerator as we have in the past.

This rule change is logical, given the non-infectious nature of the materials involved. There will be no risk to the public as a result of this change and the cost savings to laboratories will help ensure sustainability in these increasingly difficult economic times. (BC)

#### **Response to Comment #2:**

The Department appreciates the general support for the proposed change expressed by this comment. Generally, most biomedical wastes are presently autoclaved. The exceptions are pathological wastes and trace chemotherapy wastes that are segregated from other biomedical wastes and incinerated. Transportation of biomedical waste is

provided by a Department licensed biomedical waste transporter. A reduction in the amount of biomedical waste shipped offsite for treatment will lower treatment costs.

**Comment # 3**

Some susceptible people could be adversely affected by some CDC Bio-Safety Level One organisms. (JAX)

**Response to Comment #3**

The Department recognizes that some members of the population are more susceptible to CDC-BSL1 level organisms, but the vast majority of the population is not. However it is an important consideration to address as part of the Department's its education and outreach efforts.

**Section 18 (F) (3) – Standards for Treatment Facilities**

**Comment # 4:**

Worker exposure due to shredding difficulties is our most important concern. The inherent risks of shredding equipment aside, the shredding operation is a problematic one with frequent jams necessitating work stoppage for the entire operation.

The result is that any treated waste in the hopper that is in queue to be shredded has to be manually removed to expose the shredder knives. (MHA)

**Response to Comment #4:**

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 the load density.

The Department agrees that workers are at risk of needlesticks during times when the hopper needs to be cleared for maintenance. Even though this material has been disinfected, needle sticks pose a significant psychological stigma as well as a physical injury threat.

In considering revisions to the shredding requirement, the Department evaluated the waste stream flow at the AHR facility as well as the operational protocols developed by Waste Management for the landfill. Waste Management officials indicated that they would prefer to receive this waste unshredded. There may be other situations that arise where landfill operators prefer that the sharps be shredded. There may also be situations where the Department may determine that sharps may need to be shredded such as where waste is not segregated at the landfill or where it will not be promptly covered. The

Department concluded that the rule should be revised to allow sharps to not be shredded, but that the shredding option should be retained for those situations where it is appropriate.

**Comment #5:**

Waste Management’s practice at its Norridgewock facility is to container and segregate sharps waste in an area of the landfill where future disturbance is prohibited. As such, sharps waste, whether or not it is shredded prior to arrival at the Waste Management facility, is in no danger of coming into contact with either employees or the public. (WM)

And,

Landfill operating protocols require operators to immediately bury the treated waste upon arrival to reduce worker exposure. This solves vector (bird) issues and also, environmental issues such as windblown waste. Furthermore, it allows workers to control the spread of the treated waste by localizing the load drop. (MHA)

**Response to Comment #5:**

The Department believes that Waste Management has the technical ability and experience to manage this waste stream safely from a human health perspective as well as an environmental perspective.

**General Comment**

**Comment #6:**

I see no issues with the changes proposed for Chapter 900.  
Looks like good clarification / improvement. (MRH)

**Response to Comment #6:**

The Department appreciates the support for the proposed changes expressed by this comment.