RIDEM RESPONSE TO PUBLIC COMMENTS

Regarding Proposed Amendments to *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste in Rhode Island*

Public Notice Date: 11/25/2009
Public Hearing Date: Date: January 14, 2010 10:00 AM
Prepared: June 15, 2010
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RIDEM/Office of Waste Management

Explanation of Changes: The following pages contain the Department's response to the comments submitted on the above listed regulations. The Department considers the modifications made as a result of these comments to be minor, in that the changes either served to clarify the intent of the regulations or were updated to incorporate new information provided by commenters. The Department does not believe any of the changes altered the intent of the Draft Regulations.

Comment Letter #1- Edward Krisiunas, MT(ASCP), MPH, WNWN International

Mr. Krisiunas' comments relate to efficacy testing. The Proposed Regulations only made very minor changes to the efficacy testing requirements, Mr. Krisiunas points out that the science the *Regulations* were based on in 1994 (the STAAT report- State and Territorial Association on Alternate Treatment Technologies) has been refined and revised.

1. Section 5 Definition of Treatment and Section 15.7- Treatment Standards:

Comment: Mr. Krisiunas asserts that the requirement to reliably inactivate vegetative bacteria, fungi, viruses, parasites and mycobacterium at 6 log 10 reduction is unnecessary since bacterial spores and to a lesser degree mycobacterium are by nature much more resistant than the other microorganisms.

Response: Due to travel restrictions and personnel cutbacks the Department is much less active in the STAAT process than in the 1990's. As a result of the comment, the Department reviewed the 1998 STAAT 2 report and concurs that given its thermal and chemical resistance, vegetative spores such as *Bacillus stearothermophilus spores or Bacillus atrophaeus* are the accepted standards for these forms of treatment. As the STAAT 2 report makes it clear these are indicators of thermal and chemical treatment, the Department has kept the other microorganisms for other technologies. Sections 15.7 (e) and the definition of *Treatment* in Section 5 were modified as shown below:

15.7 (e) was modified as shown below:

(i) *Completely and reliably inactivate Bacillus stearothermophilus spores or Bacillus atrophaeus spores at a 4 Log_{10} reduction or greater; and*

(ii) Completely and reliably inactivate vegetative bacteria, fungi, viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater [this requirement is applicable to technologies not based on thermal and chemical treatment]; and

Also the definition of treatment was modified as shown below:

"Treatment" when used in the context of regulated medical waste management means any method, technique, or process designed to:

(1) Completely and reliably inactivate Bacillus stearothermophilus spores or Bacillus atrophaeus spores at a 4 Log_{10} reduction or greater.

(2) Technologies not based on thermal or chemical treatment must also demonstrate the ability to completely and reliably inactivate vegetative bacteria, fungi, viruses, parasites, and mycobacterium at a 6 Log_{10} reduction or greater; and

2. Various Sections Throughout Regulations:

Comment: Nomenclature of Bacillus stearothermophilus should be updated to *Geobacillus stearothermophilus* to reflect its taxonomy in a new genus. In a later correspondence, commenter supplied a peer reviewed scientific journal citation

*(*International Journal of Systematic and Evolutionary Microbiology, Vol 51, 433-446, Copyright © 2001).

Response: The Department has made the change globally throughout the *Regulations*.

3. Section 9.0 Reusable Containers:

Comment: There is no standard in the *Regulations* for determining if a reusable container is clean. A suggestion is made to use an ATP swabbing method to evaluate if reusable containers have been cleaned sufficiently.

Response: This comment brings up and important quality control and safety issue the Department had not considered. However, given the difficulty in revising regulations (this current revision is the first in 16 years) the Department is concerned about restricting a methodology that may change. Instead, the Department feels it is better to have broader language in the Regulations and make specific methodologies a part of permit conditions (that can be more flexible to evolving science and technology).

> 9.2 (b) *Any container used for the storage and/or transport of regulated medical waste and designated for reuse once emptied shall be decontaminated after each use. Decontamination can be accomplished by chemical disinfection, steam sterilization, thermal inactivation, or other suitable process that is appropriates both for the type of container to be decontaminated and for the type of contamination present. The facility or generator responsible for decontamination must submit sampling protocols and results to demonstrate the technology, as installed, is providing adequate decontamination.*

4. Section 12.4 (e) On-Site Steam Sterilization Standards:

Comment: Three spore strips should be required for each cart or bin of waste in an autoclave.

Response: The Department is not convinced that in all cases, testing each container, if the containers are identical is warranted. After considering the issue, the Department is concerned that this may provide an incentive for the facility to use fewer, larger containers to minimize analytical costs. Therefore the Department does not believe the change is warranted.

5. Section 12.4 (c) Steam Sterilization Standards

Comment: The requirement to loosen or removes caps and stoppers in medical waste is unlikely to be done and may present a safety hazard.

Response: The Department concurs and will delete the passage as shown below:

> *Regulated medical waste shall be steam sterilized in its primary container. The primary container shall be placed in the sterilization chamber so that sufficient space is provided between the chamber walls and the container to allow the steam to surround the container. The primary container shall be sealed loosely*

enough to allow the steam to penetrate the contents of the container, unless a self-venting bag is used. ~~*Caps and stoppers on bottles shall be loosened as well to facilitate steam penetration.*~~

6. Section 13.0 (d) Shipments of Sharps Through Common Courier Service

Comment: Requirements for shipping by the United State Post Office should reference the USPS Domestic Mail manual. Fedex and UPS will not accept Regulated Medical Waste.

Response: This issue was also raised in somewhat more detail by Jan Harris in Written Comment #3. See response to comment #3.

7. Section 15.7 Standards for Discharge of Medical Waste to Wastewater

Comment: Commenter questions if chemical disinfection needs to be demonstrated in this case the amount of organics can have a neutralizing effect on disinfection?

Response: We have discussed the issue with the state major sewer authority (Narragansett Bay Commission)**.** Currently the regulations require written approval of the appropriate sewer authority. We believe the specific requirements relative to organic loading of the waste should stay with the sewer authority and therefore the Regulations will not be modified.

Comment #2- Patricia Burke, DVM

(This commenter also gave verbal comments at hearing)

Dr. Burke's comments address both the Draft Medical Waste Regulations and Regulations and policies related to Animal Health. In light of the considerable expertise and experience Dr. Burke brings to these somewhat overlapping issues, the Office of Waste Management and the Office of Agriculture's Animal Health Unit have prepared the following response jointly to address these comments.

1. **Sections 2.3 and 7.2 Immunization Vials**

Comment: Immunizations vials should be exempt from the definition of Regulated Medical Waste.

Response: Agreed. This issue has been problematic with both humans and veterinarians and the Regulations have been amended to include a new exemption to clarify that commercially available vaccines vials that have not contacted blood are **not** Regulated Medical Waste.

2. **Section 2.3 and Appendix V- Highly Communicable Endemic Animal Diseases**

A general aspect of this comment is involved with the way carcasses and animal waste are dealt with in Appendix V (highly communicable endemic diseases). The comments detail how some of these requirements are unreasonably burdensome (such as dealing with large animals as regulated medical waste). After reviewing the comments, we concur and have extensively modified Appendix V in recognition that the method of post-mortem transmission (and therefore necessary precautions for handling carcasses) vary with the nature of the disease.

3. **Section 2.3- Definition of Regulated Medical Waste**

Comment: When regulations speak of body parts and bloods sponges, it should be clarified to be only from human blood, not animals. This waste is not much different from waste at slaughter houses.

Response: The Definition of Pathological Waste was changed to Human Pathological Waste to make this distinction clear. The Department also made a separate definition of animal pathological waste including only those animals affected with highly contagious diseases. We believe that the regulations as written will already exempt animal body parts unless they require special handling due to exposure to infectious agents.

4. **Disposal of Home Generated Sharps**

Comment: Has there been a change in how these are dealt with in the Regulations? Commenter is still advising people to securely package waste in a thick plastic container and dispose of it in the regular trash.

Response: There have been only minor changes. The Regulations now allow medical professionals to accept this waste from homeowners in the course of home health care. They also allow veterinarians to accept waste from wildlife rehabilitators.

However, in practice, the option for home users have narrowed significantly since the sharp smart program was discontinued in the Fall of 2009. Unless and until another program replaces sharp smart, commenter's advice is the only safe option for homeowners.

Comment #3- Jan Harris, MPH, BSDH, Sharps Compliance, Inc.

1. Section 13.2 (d)- Shipment of Medical Waste by Common Courier

Comment: The Commenter points out that UPS and Fedex do not accept Regulation Medical Waste for transport. Also, the rules as they are written, are not consistent with USPS requirements.

Response: The version of the *Regulations* that was issued for public notice did not propose changing these rules as the Department saw no need. The comment by Jan Harris brings forward information the Department was not aware of:

1. UPS and Fedex do not accept regulated medical waste for transport [RIDEM has confirmed this assertion is accurate]
2. USPS has updated its regulations for shipping medical waste since the *Regulations* were last updated. [RIDEM has confirmed this also]

In light of these issues, the Department feels the comment and the suggested solution are very reasonable. The regulations have been clarified as shown below to state that medical waste may only be shipped by the United State Postal Service and that shipping must be in accordance with Post Office Standards. Changes are shown below:

13.2 (d) ***Shipments of Sharps and Unused Sharps Through the U.S. Postal Service:*** *Small Quantity Generators who transport regulated medical waste (sharps and unused sharps) by the U.S. Postal Service are exempt from the requirement to use a transporter that has a Rhode Island Regulated Medical Waste Transporter Permit number provided that the following conditions are met:*

(1) The package is sent by first class or priority mail in accordance with section 10.17 (Infectious Substances) of the United State Postal Service Domestic Mail Manual.

(2) The generator compiles a shipment log and maintains the original shipping papers as required by Section 13.5 of these regulations;

Comment #4- Christopher J. M. Harwood MA, RBP, Brown University

1. Section 2.3- Definition of Regulated Medical Waste

Comment: Commenter points out that the distinction between Regulated Medical Waste Sharps and other kinds of sharps (like glassware and needles used in chemistry laboratories) is vague and asked for guidance on the issue.

Response: The point of defining hypodermic needles and other kinds of sharps as hazardous waste is that from a practical standpoint, whether a particular medical sharp has been used is nearly unknowable, forcing the handler to treat them as used and potentially infectious. The degree to which a chemical sharp (like a needle used for GC injection) resembles medical sharps is a judgment call. The Department would offer as a guidance that if a reasonable person were to be stuck by sharps in a load, would it be apparent the wound was from non-biological sharps? The Department would expect that if an inspector could readily tell waste was from a chemistry lab, then a victim stuck by the sharps could as well. Such a distinction could be made based on the nature of the generator (chemistry lab) or the nature of the waste (needles that were clearly not for medical use). Conversely, if sharps came from a facility that also generated Regulated Medical Waste but also generated waste from chemical processes that were indistinguishable from the medical waste sharps, it would be necessary to handle them all as regulated medical waste. The Department does not feel it would serve the interest of the public to put in rigid guidance to remove judgment from the process.

2. Section 5.0 Definitions

Comment: In section 5.0 entitled *Definitions,* regarding the definition for Destroyed Regulated Medical Waste, a clarification of the terminology "generally recognizable" would be very helpful in determinations of what is acceptable to the state of Rhode Island. The terminology as currently written is ambiguous and open to interpretation. We believe the regulations should either include a more definitive listing of items that would be considered RMW or some other clarification of this issue.

Response: The Department would concede the definition of “generally recognizable” is vague. The Department has added the following clarification that waste will be shredded such that the majority of waste is of a size of less than 1 inch and all sharps are ground to less than one half an inch to be unrecognizable.

3. Section 5.0 Definitions

Comment: For *Healthcare Professional*, commenter recommends that the term paramedic be changed to emergency medical technician, since paramedics are a subset of emergency medical technicians, and as written would exclude other levels of emergency medical technicians.

Response: The Department agrees and has made the change.

4. Section 12.4 (e) On-site Steam Sterilization Standards

Comment: Commenter recommends that spore testing be done in accordance with manufacturer specifications. In an organization such as theirs, placement of 3 samples of test organisms in each autoclave is impractical.

Response: While the Department understands the importance of operating the unit in accordance with the manufacturer's specification, we are not willing to make manufacturer's protocol the overriding authority regarding treatment standard. To do so would give an unfair advantage to systems with less stringent standards in the user's manuals. We would view's Brown University's situations as atypical and worthy of a specific variance request.

Comment #5- Brenda Bibb, New England Medical Waste Services

1. **Section 14.4(e)- Consolidation of Regulated Medical Waste**

Comment: Consolidating or Re-manifesting Waste to a New tracking form:

(1) The proposed change states that a transporter may re-manifest to a single tracking form all shipments less than 220 lbs.

As a transporter for small generators, most individual pick ups are under 50 lbs. When I bring a box truck load to Stericycle, they have requested that I consolidate all pick ups onto one tracking form. By doing this it would put me over the proposed weight limit for re-manifesting. I can fit 78 4.5cu boxes in my truck, 220 lbs is an average of only 5 boxes.

(2) With regard to the re-manifesting it indicates we need to send a copy of each tracking form received from the destination facility to the generator within 35 days.

This would create a quantity discrepancy because the volume picked up from the generator originally would be different than the volume brought to be disposed and listed on the new manifest. My suggestions would be to not limit the weight to re-manifest but to indicate any thing that has been re-manifested must be contained in a single load and can not be separated into, lets say two different truck loads.

As far as the tracking from brought to the destination facility, I would like to suggest, the medical waste tracking form be amended to have a section which states the waste has been reconsolidated by the transporter and a section for us to put the new tracking form number. As a transporter, I am accountable and the responsibility would be mine to keep a copy of the original medical waste tracking form with a copy of the consolidation log and the final destination tracking form.

Response: The Department has changed section 14.4(e) to allow consolidation for shipments on 1 vehicle. We have also modified the tracking form to create a field for re-manifesting of waste.

Comment: On page 37 f (4) you may need to define "Trailer" When I was working with Dave we ran into this because the "container" was separate entity from the truck.

Response: The Department feels that the term cargo carrying body is broad enough to define the cargo section of a straight truck or a trailer and that a special definition of trailer is not necessary.

Rhode Island Department of Environmental Management
Office of Waste Management

Summary of 2010 Changes to:
Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste in Rhode Island

Section	Description of Change
Changes Made Since Public Notice in 2010	
Misc	Change of Bacillus to Geobacillus in accordance with current nomenclature
2.3, 7.4, 7.5 and Appendix V	The definition of animal pathological waste, and the relevant appendices were changed to make more meaningful distinctions about how infected animals and animal remains should be handled.
2.3	An exemption to the definition of medical waste was added for containers for commercially available vaccines or other pharmaceuticals that do not have an attached needle, and that have not contacted blood or body fluid.
5	In definition of Health Care Professional paramedic was changed to emergency medical technician
5	Clarify definition of Treatment to include standards for those treatments not based on thermal or chemical disinfection.
9.2	Clarification that generator or facility must demonstrate effective decontamination of reusable containers
12.4	Removed requirement to loosen caps and stoppers on bottles.
13.5	Changed language regarding shipment of waste by post office to reflect current USPS standards.
14.4	Allow reconsolidation of waste within shipments in a vehicle instead of up to 200 lbs.
15.7	For thermal and chemical disinfection, define Geobacillus stearothermophilus and Bacillus atrophaeus as indicator organisms for treatment. For other technologies, must completely and reliably inactivate vegetative bacteria, fungi, viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater.

16.1	Effective date for requiring medical waste generators to register with the Department moved back to January of 2012 to allow time to create a program. Original date in Fiscal memo is January of 2011 but this was moved back given the time it took to finalize regulations
ORGINAL CHANGES PROPOSED IN NOVEMBER 2009	
CHANGES TO THE SCOPE OF DEFINITION OF REGULATED MEDICAL WASTE (RMW)	
2.3 (d)	Inclusion of sharps generated for cosmetic or training purposes in definition of RMW.
2.3 (e)	Addition of body art waste (tattoos and piercing) and hypodermic needles used for training to the definition of Regulated Medical Waste (RMW).
2.3 (h)	Inclusion in definition of medical waste of waste in medical waste container that is automatically a RMW.
2.3 (i) and 13.2	Inclusion of crime scene cleanup waste as RMW, with flexibility to allow them to bring waste to a central collection location without a transporter permit after notifying the Department.
2.3 (b)	Change name to animal **pathological** waste and include endemic communicable animal diseases (based on information supplied by Dr. Marshall, State Veterinarian).
2.3 (f)	Clarification of isolation waste to include foreign animal diseases or highly communicable zoonotic diseases (based on information supplied by Dr. Marshall, State Veterinarian).
OTHER SIGNIFICANT CHANGES TO THE REGULATIONS	
2.2	Scope and Authority amended to give the Director the right to impose a different standard of treatment on wastes associated with an outbreak of a highly communicable disease. This gives us the flexibility to responds to changes in threat (new diseases or changing threat of an existing disease). It could also allow new treatments and technologies to be used in fighting an outbreak.
2.3 (e)	In keeping with current practices developed by the Department of Health, isolation wastes are only RWM if they are contaminated with body fluids. However, the Director may add additional designation in connection with newly identified threats.
2.4	Clarify Household Medical Waste Exclusion to indicate that when Household Medical Waste is collected by a third party for disposal, it becomes a Regulated Medical Waste.
5.0	Refined the definition of Transportation to be off-site movement of medical waste along a public way.

8.3	Change storage time for RMW in vehicle to 7 days not including legal holidays instead of 48 continuous hours without including weekends.
12.4	Added that demonstration of efficacy must show uniformity of efficacy (within containers and within the load).
13.2	Elimination of small quantity generator report, clarification of self transport rules and consolidation of wastes on a single manifest.
13.2 (b) (i)	Change requirement to get a variance to self transport to requirement to get letter of authorization. Variance is not appropriate in this context of doing something that the regulations allow.
13.05 and others	Change requirement to keep tracking form from 3 years to 375 days in keeping with DOT ruling.
14.1 (b) (4)	Allow new exemption for DEM licensed wildlife rehabilitators to transport RMW to veterinarian that supervises them.
14.2	Deletion of presumptive incorporation of EPA rules that do not currently exist.
14.2	Addition of requirement that transporters must certify blood borne pathogen training of individuals authorized to handle RMW.
14.2	Restructuring of fee to make the following changes: Removal of requirement that both tractor and trailer have to have medical waste permit. The new regulations require only the power unit to be permitted. The Department feels that the requirement makes permitting unnecessarily complex and inconsistent with other states. Change of fee from $100 to $125 per vehicle to make above change (not requiring trailer permitting) revenue neutral. Inclusion of temporary ($25/month) permit for those wishing to only transport within a short period of time.
MISC FORMATTING AND OTHER MINOR CHANGES	
Misc	Reformat section number from format of 9.02 to format of 9.2 for ease of auto-numbering.
Misc	Deletion of requirement that all reporting must be done in pounds.
Misc	Correction of Bacillus subtilis to B. atrophaeus in keeping with revision of taxonomic classification.
Misc	Removal of footnotes from document.
4.04 (d)	Correct typo to say receives waste **from** generator.

5	Definition of medical waste tracking form revised to include digital forms.
5	Universal Biohazard Symbol references DOT as opposed to an appendix.
6.3	Require segregation and labeling of pathological waste.
14.2 (h)	Change to clarify procedure such that although vehicle permits are stilled renewed annually, company registration can be done every 3 years.
14.2	Require self inspection instead of Department inspection of vehicles.
14.4	Deletion of provisions allowing transporter to drop off waste without signature.
14.4	Clarification of procedures for consolidation of waste from different manifests onto one manifest.
14.5	Deletion of provisions to not require manifest on repackaged waste from SQG's. The provision creates a second document and is overly complicated.
14.12 (c)	Change requirement to prohibit storage of waste in vehicle longer than 1 week instead of requiring vehicle be parked for no more than 48 hours. The latter requirement cannot be enforced because moving the vehicle for 5 minutes resets the 48 hour clock.
14.13 (a), 14.14 (a) and 14.16	Delete presumptive incorporation to federal requirements that do not now exist.
14.14	Require reporting in electronic and not paper format.
14.16	Delete requirement to RCRA reporting not appropriate for this kind of waste.
15.3	Deletion from section 15.03 of requirement to mail back tracking form to generator.
17.01 (d)	Modified to delete word transporter which doesn't make any sense in that context.
Appendix IV	Update of current communicable diseases and re-evaluation of animal diseases in consultation with Agriculture.
Appendices V-VIII	Elimination of some appendices (transporter application, notification form) that are better left open for flexibility (and appropriate changes to their references).