Regulated Medical Waste Management Regulations, 9 VAC 20-120
Amendment 3
Regulatory Advisory Panel (RAP) Meeting
August 20, 2019
Meeting Notes

Location: Bank of America Building
3rd Floor Conference Room
1111 East Main Street
Richmond, Virginia

Start: 10:02 a.m.
End: 2:57 p.m.

RAP Members Attending:
Tony Caswell, University of Virginia Health Systems
Cara Simaga, Stericycle
Morris Reece, Virginia Department of Health
Tim Torrez, SWANA & VWIA

RAP Members Absent:
Ann Germain, Healthcare Waste Insitute

DEQ Technical Support Staff:
Justin Williams, Land Protection and Revitalization Division Director
Leslie Beckwith, Office of Financial Responsibility and Waste Programs Director
Priscilla Rohrer, Solid Waste Compliance Coordinator
Kathryn Perszyk, Solid Waste Permit Coordinator
Debra Harris, Regulatory Affairs Planning and Policy Specialist

Others Attending:
Michele Payne, DEQ
Chris Bergin, Office of the Attorney General
Evan August, Curtis Bay

I. Agenda Item: Introductions, Welcome and Remarks (Justin Williams)
Discussion: Justin Williams welcomed everyone to the meeting and asked each person to introduce themselves. Mr. Williams remarked on the reasons why this amendment to the Regulated Medical Waste (RMW) Management Regulations (9VAC20-120) is needed and why we decided to use a Regulatory Advisory Panel (RAP) to assist with the amendment.

II. Agenda Item: Logistics (Leslie Beckwith)
Discussion: Leslie Beckwith provided the necessary logistics for the meeting and reviewed the agenda.

III. Agenda Item: Full Regulatory Process & Regulatory Advisory Panel Overview (Debra Harris)
Discussion: Debra Harris provided an overview of the full regulatory process which will be used for this amendment to 9VAC20-120. She also went over the guidelines for the RAP members regarding the rules for a public body and the importance of consensus.

IV. Agenda Item: Summary of NOIRA Comments Received (Debra Harris)
Discussion: Debra Harris handed out the comments that were submitted during the Notice of Intended Regulatory Action (NOIRA) public comment period (Attachment 1). She noted that the most frequent comments noted that the regulations were confusing, dated and needed to be updated to the current industry standards.

V. Agenda Item: Background & Summary of Proposed Changes (Priscilla Rohrer)
Discussion: Priscilla Rohrer presented the background and goals for this regulatory amendment. She noted that one of the initial triggers was the Ebola outbreak which led to a grant project to review the regulations. The results of the project included recommended revisions to the regulations. Ms. Rohrer then provided additional information on the goals of this amendment to streamline the regulations, clarify and update standards, improve permitting, and add requirements for highly infectious waste. A proposed outline was provided to the RAP members (Attachment 2) and reviewed. The requirements for transfer and treatment standards were discussed and proposed treatment facility requirements were reviewed. Ms. Rohrer provided the ideas for proposed permitting updates and noted that permits will still not be required for generators or transporters.

VI. Agenda Item: Overview of Topics for Consideration by RAP (Priscilla Rohrer)
Discussion: Priscilla Rohrer presented the topics that would be discussed with the RAP. These were identified subsequent to the grant project, as areas where additional input was necessary from a RAP. The discussion topics for RAP consideration are:

- RMW Definition and Exemptions
- Storage and Refrigeration
- Disinfection
- Ventilation
- Disposal of Treated Waste
- Highly Infectious Waste (Category A)

Ms. Rohrer then provided a brief overview on each of the topics.

The RAP took a lunch break from 11:07 a.m. until 12:19 p.m.

VII. Agenda Item: Topical Discussion #1 - RMW Definition and Exemptions (Priscilla Rohrer)
Discussion: Priscilla Rohrer began the discussion of what is RMW. She presented the existing definition of RMW and the list of specific RMWs. As part of this amendment the current RMW will be used but updates/revisions are needed. These include:

- Updating terminology – remove “discarded etiologic agents” and use “select agents and toxins”. This category is heavily regulated by the health department and federal agencies.
- Pathological waste may best be grouped with tissues and anatomical wastes. It was noted that in some states some pathological waste is exempted when in a fixative. The best management for “stabilized” waste (i.e., formalin fixed tissue) should be considered as disposal can be an issue if the definition is not clear.
- Animal wastes containing infectious agents that may be zoonotic are recommended to be RMW; however, there is an existing exemption when they are regulated by VDACS or USDA that dictate disposal (i.e., composting on site of bird carcasses infected with bird-flu). Disposal of animal carcasses was discussed in

general including what is done with rabid animals. The definition in the regulations relies on the intentionally infected animal waste. Ms. Rohrer noted that the intent is not to change how these animal waste are currently regulated and/or disposed. Clarification is needed.

Action Item: *Morris Reece will check on VDH authority and actions related to rabid animals and subsequent disposal of the carcasses and report back to the RAP.*

- Trauma and crime scene cleanup (TCS) wastes (not referring to wastes from trauma centers in hospitals) need clarity on what to do with this waste. A better definition for this waste and how to manage is needed. Michigan has some rules regarding TCS waste that may be helpful. Further review is needed.
- High risk or highly infectious waste (Category A). The Ebola issue was raised during the last outbreak. Management requirements of these types of high risk/infectious waste (HIW), also called Category A waste, is needed. This includes biohazard incident waste contaminated by releases of HIW.
- Biohazard incident waste. These are wastes contaminated by spills of infectious waste or HIW. It was noted that there is involvement of federal agencies regarding this category of RMW.

Leslie Beckwith summarized the RMW definition issue and asked if there were any other types of waste to be considered with this definition. It was noted that EPA's new pharmaceutical rule (effective in Virginia on August 23. 2019) will be dealing with many of the pharmaceuticals for management and disposal which are hazardous waste. It was noted that USP (United States Pharmacopeia) and OSHA may have more information to review as well. The RAP concurred that the proposed update defining RMW is in the right direction.

Ms. Rohrer continued with her presentation by presenting the exemptions. She noted that the plan is to retain all of the existing exemptions (9VAC20-120-130) and to consider if additional exemptions are needed. The additional exemptions that are being considered are:

- Cremains (ashes) human and animal
- Human remains provided to educational programs as gifts (i.e., donated remains)
- Human remains removed during medical procedures and retained by patient (if not a source of disease transmission).
- Lab samples, specimens and criminal evidence while they are in use. After use, proper disposal will be necessary.
- Tissue blocks embedded in paraffin, except those associated with prions. It was noted that prions will need a definition.
- Veterinary waste at a residence or farm, if generated by owner.

The RAP discussed the exemption issue as it pertains to urine. Urine normally is managed through a sewer system and, is therefore, excluded from the regulations. Additionally, urine is normally non-infectious; however, consideration of urine from chemo patients or those sickened by HIW may need to be considered. The RAP decided to consider this issue later.

The RAP took a break from 1:50 p.m. until 2:03 p.m.

Priscilla Rohrer presented the RAP with additional wastes to consider. These included:

- Unused or expired (uncontaminated) health care products and medical equipment, except sharps.
- Cosmetology wastes (piercing, nail, tattoo salons), except for sharps or unabsorbed blood or body fluids.
- Animal/plant wastes during construction/demolition projects when actions taken to avoid exposure (bat guano under bridges).

- Waste from routine food and drug testing.

The RAP concurred with the proposed list of exempted types of waste presented.

Ms. Rohrer presented an issue to be addressed regarding the reprocessing of used medical equipment/devices. These are used and contaminated medical equipment that are returned for cleaning, sterilization, or disinfecting for reuse. The proposed amendment would exempt these from RMW definition if packaged/transported in accordance with DOT requirements and reprocessed in accordance with FDA requirements. The RAP concurred with the exemption for reprocessed used medical equipment/devices.

Ms. Rohrer presented a recent issue regarding clean-up of blood and body fluid with solidifiers. These are normally sold in spill cleanup kits. The problem is that many of these kits do not fully absorb all of the fluids. As this doesn't meet the treatment standard, these types of waste will still be RMW in all patient-care settings and the RAP agreed. It was decided that an exemption could be proposed for solidified waste generated from spill cleanup in non-patient care settings (food service industry, retail, and businesses).

The issue of sharp collection facilities was presented to and then discussed by the RAP. It was decided that the name is confusing as they are not "facilities". A different name will be used in the amendment. The issue is the various convenience disposal boxes for household sharps disposal that are showing up at public areas such as bathrooms, airports, restaurants, parks, etc. The recommendation is that these "convenience box" collected sharps would be exempted from permit requirements provided that the sharps collected are packaged, labeled, and treated/disposed as RMW; however, the exemption would allow for storage for up to 30 days. The RAP concurred with the recommendation to exempt these boxes from permitting and require the collected sharps to be disposed as RMW with an extension to allow for up to 30-days for storage.

Ms. Rohrer presented other wastes for possible exemptions such as extracted teeth and saliva from dental procedures. It was noted that the amalgam standard of 40 CFR 441 was effective in Virginia. Other waste streams for consideration were urine unless contaminated by blood or from a patient with disease communicable through urine. The RAP agreed that both of these waste streams should be exempted. In addition, like urine, the RAP discussed saliva, feces, and vomit. The RAP concurred that these types of wastes should also be exempted unless contaminated by blood or known to be infectious by the health care professional in charge.

VIII. Agenda Item: Public Comment
Discussion: No further comment was provided.

IX. Agenda Item: Next Steps (Debra Harris)
Discussion: A next meeting date was not established. A doodle poll will be sent out with potential dates for the next RAP meeting.

Parking Lot
(These are topics/issues that the RAP decided to discuss further at a later date)

- Animal Wastes – how best to define in order to clarify proper management and not to dual regulate.
- Trauma and Crime Scene Waste – how to best define and manage this waste.
- Red Bags at Landfills – best management practices when these are found in a landfill setting (possible guidance issue).
- High Risk/Highly Infectious Waste (Category A) and Biohazard Incident Waste – management strategy for this waste with consideration of recent guidance and requirements from the Federal Government.

Attachment 1

NOIRA Public Comments Received

1. Commenter: Andrea Arredondo

Comment: The current RMW regulation is outdated, confusing, and hard to stay in compliance with. The RMW regulation needs to be updated to be more in line with current technologies, economic values, other regulations, and best management practices through clear and concise regulations. Additionally the regulation needs to better address smaller generators and healthcare facilities; as they have different objectives, waste generation processes, and economic status. The updating of this regulation will improve the over State-wide compliance efforts.

2. Commenter: Anne Germain, Healthcare Waste Institute, National Waste & Recycling Association

Comment: The Healthcare Waste Institute (HWI) of the National Waste & Recycling Association (NWRA) represents suppliers and service providers in the healthcare waste industry both in Virginia and on a national basis. We offer the follow with respect to the NOIRA on Virginia's regulated medical waste (RMW) regulations:

1. Regulations governing RMW are necessary to protect the public health, safety and welfare. Appropriate management of RMW ensures that it does not create a public health risk.
2. Should Virginia adopt regulations with reasonable changes, these regulations could benefit small businesses such as smaller healthcare facilities by providing potential costs savings and reducing compliance risk.
3. The current regulations are outdated, confusing and conflict with other regulations.

Therefore, we support making updates to the rule to make them clearer and easier to understand. Further, we would be interested in participating in the rulemaking process.

3. Commenter: Mary J Hayward, Old Dominion University

Comment: These regulations are due to be updated. While reading the draft, most of the obvious proposed changes look reasonable. However toward the end of the proposal, I do have concerns on the validation series of events, both from the standpoint of cost, efficiency, and wording of that proposed section.

4. Commenter: Cara Simaga, Stericycle, Inc.

Comment: We would like to address the following discussion points made in the NOIRA to further support the need for changes to the regulations found in 9VAC20-120.

(i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions;

Stericycle Response: The regulation is necessary for the protection of public health, safety, and welfare. Though the collection and management of RMW is not regulated at a federal level, almost all states have regulations to manage this waste stream. Many of those states have expanded on what is covered under their RMW regulations to include waste streams like pathological wastes, trace chemotherapy wastes, and non-RCRA pharmaceutical waste and we would encourage the Department to do the same. We would also recommend adding sections to the regulation regarding the management of wastes that are considered Category A infectious substances per DOT regulations. An example would be waste from patients with Ebola. Stericycle was involved in collection and management of Ebola patient waste in 2014 and we encourage all states to consider Category A wastes and potential situations generating these wastes in their regulations.

(ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law;

Stericycle response: We would disagree that the current regulation minimizes economic impact on small businesses. Making appropriate modifications to the regulations would however have a potentially minimizing effect on economic impact on small businesses. Though we are not a small business, we service customers/generators that are and some of the current regulation requirements increase our cost to do business, which can affect even small generators. Some parts of the regulation that impact us negatively include:

i. The numerous requirements for RMW transfer sites, including the requirement to be permitted if waste is stored on a trailer for more than 24 hours.
ii. The requirement to refrigerate waste after 7 days of storage.
iii. The requirement to shred treated RMW before landfilling.

(iii) is designed to achieve its intended objective in the most efficient, cost-effective manner;

Stericycle response: We have stated some of the reasons why we disagree that the current regulation is efficient and cost-effective above in (ii) but would like to include the following points as they have impacts on larger generators such as hospitals:

i. Many generators of large amounts of waste prefer the use of roll-off containers for storage and management of their wastes, however, due to the current storage regulations, these containers must be removed every 7 days, even if they are not full. This results in additional cost for the healthcare facilities.

ii. The limit on storage of RMW being only 200 gallons of waste; otherwise a permit is needed. This is an unclear requirement and is not a common way that waste storage is identified and managed in regulation. The 200 gallon limit seems arbitrary as this is not an amount referenced in other regulations.

(iv) is clearly written and easily understandable;

Stericycle response: The regulations are similar to other state regulations in that they reference solid waste regulations. It is understood that there is need to reference some solid waste regulations, but, the Department should consider creating one section for RMW regulations that contains all needed information, avoiding cross-references to solid waste regulations as much as possible, to make the regulations clear and easy to understand and comply with. We would also encourage limiting cross-referencing within the RMW regulation itself. We have included an attachment to these comments that lays out a proposed outline for how the regulations could be structured in order to avoid cross-referencing and to promote clarity on what parts apply to each regulated entity. These suggestions will assist the regulated community – generators, transporters, and treatment facilities, in understanding and compliance by providing all needed information in one clear and concise regulation.

(v) overlaps, duplicates, or conflicts with federal or state law or regulation;

Stericycle response: We appreciate that the regulations generally do not conflict with federal or state laws or regulations, especially DOT. However, we would like to point out two places where some conflict and/or confusion could occur:

i. The definition of "Etiologic Agents" references 42 CFR 72.3. This section of federal regulation no longer exists. If the Department wants to include a definition for similar agents, perhaps include 42 CFR Part 73 on Select Agents and Toxins.

ii. Parts of the regulation seem to pull from the federal Environmental Protection Agency's (EPA) hazardous waste regulations. For example, the terms "listed" and "characteristic" are used at times. These are terms used to define hazardous wastes that are found on lists (U, P, F, and K lists) and/or exhibit hazardous waste characteristics (ignitability, corrosivity, reactivity, toxicity). We would recommend not using the terms "listed" or "characteristic" in defining RMW.

(vi) is impacted by changes in technology, economic conditions, or other factors in the area affected by the regulation since the last review.

Stericycle response: We believe that changes in the industry and advancement of practices and technology merit changes in the regulations.

Finally, we recently received the NOIRA Agency Background Document which seeks comment on the following: (1) consideration of additional exemptions (2) appropriate storage and refrigeration requirements for generators and permitted facilities; (3) minimum requirements for disinfection following spills; (4) design considerations and operational requirements for RMW transfer stations and treatment facilities; (5) disposal standards for treated wastes; (6) operating parameters, validation, and periodic challenge testing for treatment technologies; (7) ideas to be considered in the development of this proposal; (8) the costs and benefits of the alternatives stated in this background document or other alternatives; (9) potential impacts of the regulation; and, (10) impacts of the regulation on farm and forest land preservation. Stericycle agrees that these items warrant further discussion and review and should be looked at as part of the regulatory review process. Stericycle would be willing to provide further details on these issues as well, however would like the opportunity for further discussion with the department before providing further comments.

5. Commenter: Jennifer L. Taylor, San-I-Pak, Inc.

Comment: San-I-Pak requests a slight modification to one of Virginia's medical waste management regulations. We believe that a change to the 'Permit-by-rule' requirements listed in 9VAC20-120-180 may help assist hospitals with their affordable healthcare goals. The eighth requirement: "*The facility will be operated by an individual certified by the Board of Waste Management Facility Operators.*" should be deleted, or changed to, "*The facility will be operated by an individual successfully trained per 9VAC20-120-1000 Operator Training.*" A requirement for licensing in this capacity is excessive and an unnecessary burden for hospitals, especially as such hospitals are already required to meet the Federal OSHA Blood Born Pathogen Standards (29 CFR 1910.1030) and the Federal DOT regulations (49 CFR § 173.197) governing such wastes. We believe that after reviewing the substantiating factors below, your agency will agree that this eighth requirement is no longer needed.

1. The licensing requirement is unique to Virginia. We are not aware of another regulatory agency in the country that requires an onsite treatment operator at a hospital to be licensed.
2. The Class III license also includes incinerators. We are not aware of a single incinerator in operation at a hospital in the state of Virginia.
3. This requirement is excessively burdensome for local hospitals, which are trying to keep communities healthy while simultaneously keeping patient costs down.
    a. There are only four (4) listed Training Suppliers in the state of Virginia, and two (2) of those are no longer offering such training. For the two (2) companies that state they are still available, there is not an option for on-line training. The two available companies also do not have any available classes listed on their websites. Hospitals are forced to send their employees for "personal training." The listed "training" for group classes are a minimum of $395 for each individual. Personal training may be at a much higher cost, and such training may not take place within a reasonable time period.
    b. The exam is only offered by one company, and the exam has to be taken in person at a facility. There is not an on-line option.
    c. Employee turnover at hospitals requires repeated licensing costs.
    d. Hospitals are forced to expend a minimum of $695 for the license, plus employee salaries and expenses for such offsite training and examination, and are also left with potentially unmanned posts at the hospitals while such tasks are completed.
4. 9VAC20-120-1000 Operator Training should be sufficient for the needs of DEQ. The objective is to make sure the facility is operating their treatment system correctly, and achieving inactivation of any potentially infectious waste.

Hospital waste objectives should be to eliminate the threat posed by infectious waste before it leaves a facility. We are confident that facility employee training, without the requirement to have staff members licensed, will successfully meet this target in a safe and effective manner.

Attachment 2

Proposed Outline for Amendment 3 of the Regulated Medical Waste Management Regulations

Part I Definitions
- Definitions

Part II General Information
- Purpose of Regulation
- Administration of Regulation
- Applicability of Regulations
- Prohibitions
- Enforcement and Appeal
- Public Participation and Information
- Relationship to Other Bodies of Regulations
- Identification of Regulated Medical Waste

Part III Standards for Regulated Medical Waste Management, Storage, and Transport
- General Handling and Generator Requirements
- Packaging and Labeling of Regulated Medical Waste
- Storage of Regulated Medical Waste
- Reusable Containers
- Management of Spills
- Transportation of Regulated Medical Waste
- Biohazard Incident Waste

Part IV Standards for Permitted Regulated Medical Waste Transfer Stations and Treatment Facilities
- General and Applicability
- Siting Requirements
- Design and Construction requirements
- Operation Requirements
- Treatment Standards
- Alternate Treatment Technology Approval Process
- Validation Testing
- Periodic Challenge Testing
- Disposal of Treated Waste
- Closure Requirements

Part V Permitting Requirements for Regulated Medical Waste Management Facilities
- Applicability
- Permits-by-rule and Emergency Permits
- Effect of the Permit
- Regulated Medical Waste Management Plan
- Recordkeeping and Reporting

Part VI Variance Application Procedures
- General
- Variances to Requirements
- Administrative Procedures