Virginia Department of Planning and Budget

Economic Impact Analysis

9 VAC 20-120 Regulated Medical Waste Management Regulations
Department of Environmental Quality
Town Hall Action/Stage: 5069 / 8858
February 13, 2020 (revised February 14, 2020)[1]

Summary of the Proposed Amendments to Regulation

The Virginia Waste Management Board (Board) proposes numerous changes to the *Regulated Medical Waste Management Regulations*, including how the chapter is organized. Due to the length and complexity of the proposed changes, instead of amending the current chapter the Board proposes to repeal chapter 9 VAC 20-120 and promulgate new chapter 9 VAC 20-121, keeping the name *Regulated Medical Waste Management Regulations*.

Significant changes include: 1) introducing best management practices for Category A Waste, 2) requiring that all regulated medical waste (RMW) transfer stations and treatment facilities submit new permit applications within six months of the effective date of the regulation, 3) eliminating the option for an on-site permit-by-rule, 4) eliminating expiration dates for permits and renewal requirements, 5) requiring the installation of a fixed radiation detector, 6) new specification requirements for cart tippers, slides, or conveyors, 7) new validation testing[2] requirements prior to operation of treatment systems or devices, 8) enhanced periodic challenge testing[3] requirements, 9) requiring periodic self-inspection of RMW treatment facilities, 10) requiring RMW generators to maintain shipping records, 11) eliminating requirement to shred treated RMW, 12) increasing flexibility for treatment facilities to establish operating parameters specific to the treatment unit and waste stream rather than defaulting to general regulatory

[1] Additional information was received and added on February 14, 2020.
[2] "Validation testing" means procedures conducted at the site of a regulated medical waste treatment facility prior to initial operation of a treatment system or device, the purpose of which is to demonstrate, through established operating parameters, the effective treatment of regulated medical waste.
[3] Challenge Testing" means periodic monitoring or testing of a regulated medical waste treatment device or system that employs the use of biological indicators to demonstrate continued, effective operation of the device or system.

performance standards for a particular treatment method, 13) increasing the allowed options for cleaning and disinfection of reusable containers, 14) increasing the allowed options for packaging of treated RMW, and 15) longer storage timeframes for RMW without refrigeration.

Background

The *Regulated Medical Waste Management Regulations* establish standards and procedures pertaining to RMW management, including permit requirements for the storage, transfer, treatment and disposal of RMW. Rules for packaging, labeling and transporting RMW, as well as exemptions from regulation, are also included. Standards for approved treatment processes are provided as well as provisions for establishing alternate treatment technologies.

During and after the 2014-2015 Ebola virus disease outbreak, the Department of Environmental Quality (DEQ) assisted healthcare facilities and other state and local agencies with planning for the management of Ebola-contaminated waste, which is considered a Category A waste. "Category A waste" means wastes that are contaminated with a Category A infectious substance and must be packaged and transported in accordance with the United States Department of Transportation (USDOT) Hazardous Materials Regulations (HMR) or an applicable USDOT special permit. "Category A infectious substance" means an infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to the substance occurs. Category A infectious substances are defined by 49 CFR 173.134 of the USDOT HMR.[4]

Category A waste must be managed in accordance with more stringent handling, storage, transport, and treatment requirements than other types of RMW in order to prevent the spread of highly infectious disease. The existing *Regulated Medical Waste Management Regulations* do not specifically address the management of Category A waste. Therefore, during the 2014-2015 Ebola virus disease outbreak DEQ relied on interim guidance from the Centers for Disease Control (CDC), the federal Environmental Protection Agency, USDOT, and other entities while working one-on-one with facilities to ensure that management would protect human health and the environment.

[4] See https://www.law.cornell.edu/cfr/text/49/173.134

Following the Ebola virus disease outbreak, the CDC awarded a grant to the Virginia Department of Health (VDH). Under a memorandum of understanding, VDH administered the grant funds to DEQ in 2016 to contract subject matter experts to perform a systematic review of the *Regulated Medical Waste Management Regulations* in order to identify existing regulatory gaps and propose revisions to address current industry best management practices for Category A waste and other types of RMW. The subject matter experts proposed changes to streamline RMW management requirements for generators and permitted facilities, update performance standards for treatment technologies, and clarify specific protocols for validation and periodic challenge testing. DEQ received a report with proposed regulatory revisions in 2017 and formed an internal RMW workgroup to evaluate the proposal prior to submitting the current action.

Estimated Benefits and Costs

Management of Category A waste

According to DEQ, no Category A waste has been known to be present in the Commonwealth, including during the Ebola virus disease outbreak. The proposed new regulation includes a section, 9 VAC 20-121-160, on the management of Category A waste. In addition to stating that, "Every effort shall be made to minimize the amount of Category A waste generated," the proposed section delineates the procedures to be followed if it is present. The proposed text does not introduce substantive cost, and is beneficial in that facilities would likely be more knowledgeable on how to most safely handle Category A waste if it is present.

Permits

The Board proposes to require that all RMW transfer stations and treatment facilities in Virginia submit new permit applications within six months of the effective date of the regulation. There are four RMW transfer stations and ten RMW treatment facilities in the Commonwealth. Each of these 14 entities would be required to pay a $390 permit fee. DEQ estimates that it would take each entity from 24 to 40 hours to assemble the information necessary to submit the application. The agency estimates that it would spend approximately 12 hours of staff time per permit application for review and processing. The Board believes that given the magnitude of proposed changes, a full review associated with permit application is necessary.

The current regulation includes a permitting option called on-site permit-by-rule. The Board proposes to eliminate this option, which would affect nine of the 14 permitted facilities.

As a result, these facilities would incur additional costs from the staff time needed to compile additional submission documents for the permit application. According to DEQ the facilities should already have all of the information needed to complete and submit the additional documents. The agency believes that by eliminating the on-site permit-by-rule option it would receive better information on treatment units. Improved information would allow DEQ to better ensure that RMW is treated effectively and appropriately, and thereby provide better protections for the public and consistency in permitting procedures for all fourteen facilities.

Under the current regulation, permits expire and need to be renewed every ten years. Under the proposed regulation, permits do not expire and do not need to be renewed. For each of the 14 RMW facilities and any other future RMW facilities, this would save $390 in fees and approximately 24 to 40 hours of staff time in application preparation every ten years. It would also save approximately 12 hours of DEQ staff time in application review and processing for each facility every ten years as well.

Other New Requirements

The proposed regulation requires that RMW transfer stations and treatment facilities have fixed radiation detectors in a location as close as practicable to the incoming waste loads and in proximity to monitor all waste prior to storage, transfer, or treatment. The fixed radiation detectors are not required at captive regulated medical waste management facilities[5] if the facility demonstrates that there is no potential for generation or management of radioactive materials or wastes. Radiation detectors cost from $6,000 to $8,000 for fixed devices depending on the configuration (floor mounted or door mounted).[6] According to DEQ, a number of permitted facilities (including at least two state university hospitals) have already installed fixed radiation detectors.

The proposed regulation includes new specification requirements for cart tippers, slides, or conveyors to ensure that movement of RMW is controlled to maintain the integrity of the RMW packaging (i.e. to avoid damage to packaging that could cause releases of RMW). Based on a DEQ survey of treatment facilities, modifications to existing cart tippers, if needed, may

[5] "Captive regulated medical waste management facility" means a regulated medical waste management facility that is located on property owned or controlled by the generator of all waste managed or disposed of at that facility.
[6] Source: DEQ

cost anywhere from a nominal maintenance charge (to adjust hydraulic pressure) up to $2,000 (to install a non-porous barrier).

"Validation testing" means procedures conducted at the site of a regulated medical waste treatment facility prior to initial operation of a treatment system or device, the purpose of which is to demonstrate, through established operating parameters, the effective treatment of regulated medical waste. The proposed regulation includes new validation requirements prior to operation, with criteria for when repeat validation is to occur (at least once every five years) to ensure treatment units are operating effectively. The additional costs for the initial validation include costs for four to 12 biological indicators for each of three validation test runs (at $3 to $4 per indicator) and approximately 8 hours of staff time to complete the testing (usually 30 to 90 minutes per test plus incubation time for biological indicators).[7] These are costs per treatment unit. Of the ten RMW treatment facilities in the Commonwealth, five have one unit ($36 to $144 in indicators and 8 hours of staff time), one has two units ($72 to $288 in indicators and 16 hours of staff time), two have three units ($108 to $432 in indicators and 24 hours of staff time), one has four units ($144 to $576 in indicators and 32 hours of staff time), and one has nine units ($324 to $1,296 in indicators and 72 hours of staff time).

"Challenge Testing" means periodic monitoring or testing of a regulated medical waste treatment device or system that employs the use of biological indicators to demonstrate continued, effective operation of the device or system. The proposed regulation includes enhanced periodic challenge testing requirements. The proposed enhanced challenge testing includes the costs of zero to three additional biological indicators ($3 to $4 per indicator) per month beyond the current requirement, depending on the volume of waste treated. The number of biological indicators required per month corresponds to the volume of waste treated per load. Staff time for performing challenge tests is not anticipated to be lengthened by the use of additional biological indicators.

The proposed regulation also requires that each facility conduct monthly inspections of all major aspects of facility operations necessary to ensure compliance with the regulation. Records of the self-inspections are required to be kept and be available for review. DEQ estimates that this would take one hour of one employee's time per month.

[7] Ibid

Not all generators of RMW are required to maintain records under the current regulation. The Board proposes to require that all RMW generators maintain records, including copies of all shipping papers, specifying the date of shipment, amount of waste removed from the site, and the names, addresses, and telephone numbers of the transporter and the destination facility receiving the shipment for treatment or disposal. Under both the current and proposed regulations, the records are to be kept for a minimum of three years following treatment or shipment.

All of these new requirements are intended to reduce risk to health and safety.

Other Eliminated Requirements or Increased Flexibility

The current regulation requires RMW waste to be shredded to indicate that it has been treated. According to DEQ, this is no longer necessary and the Board proposes to eliminate this requirement. Some facilities have already obtained a variance from the requirement. For those that still are shredding this change would be beneficial in that they will not be affected by down time or the repairs that are required by the shredding units, including the cost to replace blades and other components damaged by clogging. In addition, this would eliminate unnecessary safety and health risks posed to workers who repair shredders, which typically fail mid-cycle and could expose workers to pathogens from untreated RMW no longer contained in intact packaging.

The proposed regulation also introduces potential cost savings in time and materials by: a) increasing the flexibility for treatment facilities to establish operating parameters specific to the treatment unit and waste stream rather than defaulting to general regulatory performance standards for a particular treatment method, b) increasing the allowed options for cleaning and disinfection of reusable containers, c) increasing the allowed options for packaging of treated RMW, and d) allowing RMW to be stored for longer timeframes without refrigeration. All of the above were deemed safe, while potentially reducing costs.

Businesses and Other Entities Affected

The proposed amendments primarily affect the ten permitted RMW treatment facilities and the four permitted RMW transfer stations in the Commonwealth. RMW generators are also affected. The ten permitted RMW treatment facilities consist of four public universities, three hospitals, one state agency, one private laboratory, and one private treatment business. All four permitted RMW transfer stations are private entities. RMW generators include hospitals,

doctors' offices, dentists' offices, clinics, and other healthcare facilities as well as veterinary establishments, laboratories, research facilities, etc.

Adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. While the benefits to public health may be large, there would likely be some increases in net costs for some of the affected entities as described in the section above. Thus, adverse impact is indicated for this action.

Small Businesses[8] Affected:

Types and Estimated Number of Small Businesses Affected

Code of Virginia § 2.2-4007.04 defines small business as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million." One or two of the ten permitted RMW treatment facilities may qualify as a small business. Employment and revenue data is not available for those entities or the four permitted RMW transfer stations. Thus it is not known which if any qualify as a small business. Many, but not all of the healthcare facilities are likely small business, but specific data are not available.

Costs and Other Effects

The costs and other effects as described in the Estimated Benefits and Costs section of this report would apply to the affected entities that qualify as small businesses.

Alternative Method that Minimizes Adverse Impact

There are no clear alternative methods that both reduce adverse impact and meet the intended policy goals.

[8] Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Localities[9] Affected[10]

The proposed regulation affects all localities in that all localities have healthcare facilities. The 14 permitted RMW facilities are located in Arlington, Charlottesville, Chesterfield, Fairfax, Fredericksburg, Norfolk, Petersburg, Prince William, Richmond, Roanoke, Sandston, Sterling, and Warrenton. The proposed amendments do not introduce costs for local governments.

Projected Impact on Employment

The proposed changes associated with the repeal of 9 VAC 20-120 and promulgation of 9 VAC 20-121 are not likely to substantially affect total employment.

Effects on the Use and Value of Private Property[11]

The proposed changes associated with the repeal of 9 VAC 20-120 and promulgation of 9 VAC 20-121 increase some costs and reduce other costs for the two privately-owned permitted RMW treatment facilities and four privately-owned permitted RMW transfer stations. There would likely be some increase in net costs for some of these firms, which may moderately reduce their net value.

Legal Mandates

General: The Department of Planning and Budget has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the report should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5)the impact on the use and value of private property.

Adverse impacts: Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance within the 45-day period.

If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on

[9] "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

[10] § 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

[11] Private property is interpreted to include all private assets including private businesses.

affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.