



Periodic Review / Retain Regulation Agency Background Document

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| Agency name | Virginia Waste Management Board |
| Virginia Administrative Code (VAC) citation | 9VAC20-120 |
| Regulation title | Regulated Medical Waste Management Regulations |
| Document preparation date | June 11, 2014 |

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 14 (2010) and 58 (1999).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., agency, board, or person.

Section 10.1-1402 of the Code of Virginia authorizes the Virginia Waste Management Board to promulgate and enforce regulations necessary to carry out its powers and duties and the intent of the chapter and federal law. Section 10.1-1408.1 prohibits any person from operating a sanitary landfill or other facility for the disposal, treatment or storage of nonhazardous solid waste without a permit from the Director. Regulated medical waste is a type of solid waste.

In addition to the general authority of the Board, the General Assembly directed the Virginia Waste Management Board to adopt regulations governing the management of regulated medical waste. The directive is set forth in enactment clause 4 of Chapters 751, 773 and 774 of the 1992 Acts of Assembly, as amended by Chapter 721 of the 1993 Acts of Assembly.

In response to this authority and directive, the Virginia Waste Management Board has adopted Regulated Medical Waste Management Regulations, (9 VAC 20- 120-10, et seq.).

Alternatives

Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were

rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

One alternative is to incorporate the requirements of the regulated medical waste regulations into the Virginia Solid Waste Management Regulations (VSWMR). None of the comments received recommended this action and at this at time it appears that incorporating these regulations in the VSWMR may not be less burdensome on the regulated community.

Public comment

Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

| Commenter | Comment | Agency response |
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| Andrea Arredondo | <p>One minor suggestion regarding the definition of "storage" = >200 gallons of waste. There often seems to be confusion (between inspectors and "storage facilities") of how to calculate the 200 gallons; also there is some confusion as to whether the calculation is actual waste stored or potential to store waste. Sounds like it should be simple - but this has been a point of contention for a few facilities.</p> <p>Additionally, typically medical waste is not calculated/tracked, by RMW industry standards, in gallons. It is calculated or tracked in pounds or tons. Has DEQ considered changing the units of waste to be more inline with industry standards?</p> <p>Section 810 - Amendment of permits only addresses temporary authorizations; but does not address permanent permit amendments. This regulation should, at least, reference PBR amendments in 9VAC20-81, in order to provide guidance for amendments submission and approvals.</p> | <p>Thank you for your comment on the Virginia Regulated Medical Waste Regulations. The Department is not taking a regulatory action as a result of this periodic review. However, the Department will be convening a stakeholder group to discuss potential changes regarding these regulations to focus on increasing clarity and on other possible changes that should be considered for the on-site storage and treatment of regulated medical waste. If you wish to be notified when the opportunity to participate in the stakeholder group is announced, please notify Justin Williams at Justin.Williams@deq.virginia.gov</p> |
| Steve Hilliker, MBA, San-I-Pak, Inc. | <p>Section 180 - Permit by rule</p> <p>A permit by rule regulation generally enables hospitals to easily manage their medical waste onsite. Virginia's regulation is unique in that it requires operators of the equipment to go through a state licensing program. No other state in the country has this requirement for onsite medical waste treatment. We have one client who removed their onsite treatment system due to this requirement. They would get an operator licensed only to have that operator leave the hospital for other employment. We feel this requirement is a duplication of effort and unnecessary. First, the training for an "autoclave" license also requires training on an incinerator. There are no incinerators for medical waste in Virginia. (US EPA HMIWI report, http://www.epa.gov/ttnatw01/129/hmiwi/epa453b10001_hmiwi.pdf) Second, the training outline lists items that are all monitored by</p> | <p>Thank you for your comment on the Virginia Regulated Medical Waste Regulations. The Department is not taking a regulatory action as a result of this periodic review. However, the Department will be convening a stakeholder group to discuss potential changes regarding these regulations to focus on increasing clarity and on other possible changes that should be considered for the on-site storage and treatment of regulated medical waste. If you wish to be notified when the</p> |

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| | <p>several departments within the hospital for compliance with Joint Commission, OSHA and Department of Health. Finally, proper operation of a specific brand of treatment system will be different. Most equipment manufacturers offer training as part of the purchase. I think this portion of the regulation can be replaced with the requirement that the treatment system is operated and maintained to manufacturer recommendations. The generator is responsible for ensuring that their system meets or exceeds state requirements for efficacy. This requirement can be verified through the operations records already required to be maintained for 3 years.</p> <p>The entire Part VII of the regulation can be eliminated. Based on the Clean Air Act requirements, there are less than 20 hospitals still using incineration. As of the 2010 update from the EPA, there are none in Virginia. To address the potential desire to install an incinerator, you can make it the prerogative of the Director to approve any installation. One of the requirements for applying for a permit should be meeting all EPA Clean Air requirements.</p> <p>Section 600 - Disposal of treated wastes</p> <p>Any efforts to expand the number of facilities that can receive treated medical waste would be appreciated. As stated earlier, we would like to encourage generators to manage their RMW onsite. A significant part of that is the final disposition of the waste. If the only acceptance facility is several hours away, a generator is less likely to treat onsite, even if it is the right thing to do for their facility.</p> | <p>opportunity to participate in the stakeholder group is announced, please notify Justin Williams at Justin.Williams@deq.virginia.gov . The commenter suggested removing the requirement for operators to complete a state licensing program for onsite treatment. The state licensing requirement is a statutory requirement and must be included in the regulation.</p> |
| <p>Don Nuss, Stericycle, Inc.</p> | <p>After comprehensive review of 9VAC20-120, Stericycle believes that the entire regulation has many areas that should be revisited and reviewed. In many areas, Stericycle recommends changes so that the regulation is current with today's terminology, advancement in electronic documentation/media, consistent with current federal regulation (more specifically Federal DOT Pipeline Hazardous Materials Safety —PMSA) and addresses treatment/storage procedures that have evolved and improved over the many years since this regulation was originally written. Listed below are those sections which we recommend be reviewed and changed in some capacity.</p> <p>9VAC20-120-10. Definitions. 9VAC20-120-70. Relationship to other bodies of regulation 9VAC20-120-90. Materials rendered nonregulated. 9VAC20-120-150. Lists of controlled regulated medical wastes. 9VAC20-120-170. Exemptions from permitting. 9VAC20-120-200. Responsibility for packaging and labeling. 9VAC20-120-220. Labeling requirements. 9VAC20-120-270. Spill containment and cleanup kit.</p> | <p>Thank you for your comment on the Virginia Regulated Medical Waste Regulations. The Department is not taking a regulatory action as a result of this periodic review. However, the Department will be convening a stakeholder group to discuss potential changes regarding these regulations to focus on increasing clarity and on other possible changes that should be considered for the on-site storage and treatment of regulated medical waste. If you wish to be notified when the opportunity to participate in the stakeholder group is announced, please notify Justin Williams at Justin.Williams@deq.virginia.gov</p> |

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| | <p>9VAC20-120-280. Containment and cleanup procedures. 9VAC20-120-310. Recordkeeping requirements. Part V Special requirements for storage facilities 9VAC20-120-330. Application. 9VAC20-120-360. Temperature control and storage period 9VAC20-120-400. Application. 9VAC20-120-450. Packaging and labeling. 9VAC20-120-530. Performance standards 9VAC20-120-540. Analysis and management of the ash product; procedure; results and records; disposition of ash; ash storage. 9VAC20-120-590. Performance standards. 9VAC20-120-600. Disposal of treated wastes. 9VAC20-120-640. Performance standards. 9VAC20-120-690. Applicability; exemptions from permit requirements; off-site permits by rule; experimental facility permits; variances. 9VAC20-120-830. Existing facilities qualifications. 9VAC20-120-910. Criteria for microbial inactivation.</p> | |
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An informal advisory group was not formed for the purpose of assisting in the periodic review.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

The regulation is necessary for the protection of public health, safety and welfare. The requirements for proper management and disposal of regulated medical waste assist with protecting the public from the hazards associated with regulated medical waste. The regulation is clearly written and easily understandable.

Result

Please state that the agency is recommending that the regulation should stay in effect without change.

The agency is recommending the regulation be retained.

The agency will be convening a stakeholder group to discuss potential changes regarding these regulations to focus on increasing clarity and on other possible changes that should be considered for the on-site storage and treatment of regulated medical waste.

Small business impact

In order to minimize the economic impact of regulations on small business, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

In order to continue to protect the public from risks associated with regulated medical waste the regulation needs to be retained. The regulations currently include reduced requirements for a "limited small clinic" many of which may meet the definition of a small business. This allows limited small clinics to have reduced requirements for storage areas based on the weekly volume of the waste handled by the facility as well as the total volume stored. These provisions should reduce the economic impact on some small businesses regulated by this regulation. Additionally, these regulations allow for a permit-by-rule for on-site treatment which is a more streamlined permitting process for those small businesses who treat their own regulated medical waste.

The comments submitted by the public indicated that there are some areas in which the regulation may need to be clarified or simplified. One commenter indicated that they supported removing the requirement for operators to complete a state licensing program for onsite treatment, stating this requirement was unique to Virginia. However, the state licensing requirement is a statutory requirement. The commenter suggested replacing this requirement with a requirement that the treatment system be operated and maintained according to manufacturer specifications. A commenter also asked that the agency consider expanding the number of facilities that can receive treated regulated medical waste.

The regulation can be seen as complex since it does contain specific standards that must be met concerning the treatment of regulated medical waste. The regulations however need to contain specific requirements for the proper treatment of regulated medical waste to ensure that the waste is appropriately handled and treated to prevent the spread of disease.

The regulations are part of a series of regulations that regulate the medical community and those handling regulated medical waste. The Virginia Department of Health (VDH), the Virginia Department of Labor and Industry (DOLI) and federal Occupational Safety and Health Administration (OSHA) also regulate the activities of the medical community. These regulations have been created to avoid any conflicts with the requirements of VDH, DOLI, and OSHA. These regulations contain requirements for the storage, treatment and disposal of regulated medical waste.

These regulations were revised in 2013 (removal of transporter registration requirement), 2011 (update of citations needed to be consistent with amendment of 9VAC20-81), and 2002. Since that time technology has advanced, which has changed the breakdown of which technologies are being used to treat regulated medical waste. The use of incineration to treat regulated medical waste has been replaced with other treatment technologies.

The agency is retaining the regulation. The agency will be convening a stakeholder group to discuss potential changes regarding these regulations. The stakeholder group would focus on increasing clarity within the regulation and on other possible changes that should be considered for the on-site storage and treatment of regulated medical waste.

Family impact

Please provide an analysis of the regulation's impact on the institution of the family and family stability.

This regulation does not have an adverse impact on the institution of the family and family stability. It requires regulated medical waste to be properly stored, treated, and disposed of, thus protecting families from the risks associated with regulated medical waste.