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# Proposed Regulation
# Agency Background Document

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| **Agency name** | Virginia Waste Management Board |
| **Virginia Administrative Code (VAC) citation(s)** | 9VAC20-120 |
| **Regulation title(s)** | Regulated Medical Waste Management Regulations |
| **Action title** | Amendment 3 |
| **Date this document prepared** | November 21, 2019 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

## Brief Summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

The Regulated Medical Waste Management Regulations, 9VAC20-120, establish standards and procedures pertaining to regulated medical waste (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.

The purpose of this amendment is to streamline and clarify the requirements and modernize the standards for general handling and treatment of RMW based on current industry best management practices. This amendment includes a significant reorganization of the regulations; therefore, as it would be too cumbersome to do this as a revision, the decision was made to repeal Chapter 120 and to replace it with a new chapter, Chapter 121. This amendment clarifies the requirements for generators and permitted facilities, improves permitting procedures, includes best management practices for Category A Waste, and streamlines the regulations for ease of use while still protecting natural resources and human health.

In addition, a periodic review/small business impact review was conducted as part of this regulatory action. Please see the periodic review/small business impact review result section for additional information.

## Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.*

"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 United States Department of Transportation (USDOT) Hazardous Materials Regulations (HMR).

"Category A waste" means wastes that are contaminated with a Category A infectious substance and must be packaged and transported in accordance with the USDOT HMR or an applicable DOT special permit.

"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.

"Disinfection" means any procedure that involves the application of an antimicrobial agent (disinfectant) registered with the Environmental Protection Agency (EPA) that is consistent with its approved use in accordance with the manufacturer's instructions. Disinfection shall not be considered a form of treatment, and appropriate handling of disinfected materials, as well as health and safety precautions, shall still be required to achieve protection of public health and the environment.

"RMW" means Regulated Medical Waste

"RMW Transfer Station" means a regulated medical waste management facility where regulated medical waste is received for the purpose of its subsequent consolidation, over-packing, storage, trans-loading, or subsequent transfer to another regulated medical waste management facility for further processing, treatment, transfer, or disposal. Parking a vehicle containing regulated medical waste during transportation for 24 hours or more is considered a regulated medical waste transfer station.

"RMW Treatment Facility" means a regulated medical waste management facility where regulated medical waste is treated so that it no longer constitutes a threat to public health and the environment, and the waste is subsequently managed as solid waste.

"Sharps Drop Box" means a secure, tamper-proof sharps container for the temporary storage of only household sharps provided for the convenience of individual home generators who choose to transport their own household sharps to the collection point, and where collected sharps are packaged, labeled, and managed as regulated medical waste.

"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.

## Mandate and Impetus

*Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."*

During and after the 2014-2015 Ebola virus disease outbreak, 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 must be managed in accordance with more stringent handling, storage, transport, and treatment requirements than other types of regulated medical waste 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, DEQ relied on interim guidance from the Centers for Disease Control (CDC), EPA, USDOT, and other entities while working one-on-one with facilities to ensure that management would be protective of human health and the environment.

Following the Ebola virus disease outbreak, the CDC awarded the Virginia Department of Health (VDH) with a grant (Public Health and Emergency Preparedness (PHEP) Supplemental Funding for Ebola Preparedness and Response Activities) through the Hospital Preparedness Program and PHEP Cooperative Agreement. Under a Memorandum of Understanding (MOU), VDH administered grant funds to DEQ in 2016 to contract subject matter experts (SMEs) 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 SMEs 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 a NOIRA in 2018.

## Legal Basis

*Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.*

The legal basis for the Virginia Regulated Medical Waste Management Regulations (9VAC20-120) is the Virginia Waste Management Act (Chapter 14 of Title 10.1 of the Code of Virginia). Specifically, §10.1-1402 of the Code of Virginia authorizes the Board to supervise and control waste management activities in the Commonwealth and to promulgate regulations necessary to carry out its powers and duties.

## Purpose

*Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.*

The purpose of this amendment is to modernize the standards for general handling and treatment of RMW based on current industry best management practices. This regulatory action is necessary in order to update the requirements for RMW transfer stations and RMW treatment

facilities, provide clarity for the regulated universe, remove redundancies, and eliminate overlap with other regulations. The goals of this amendment are to clarify the requirements for generators and permitted facilities, improve permitting procedures, and streamline the regulations for ease of use while still protecting the health, safety, and welfare of citizens. Proposed validation and operating parameters for treatment technologies were evaluated during the regulatory development phase.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.*

These regulations are for the general handling, storage, transfer, treatment, and disposal of regulated medical waste. Rules for packaging, labeling and transporting RMW, as well as exemptions from regulation, are also included. Additional substantive revisions include:

- Providing conditional exemptions to encourage safe collection and proper management of specific types of regulated medical waste, such as sharps;
- Clarifying RMW storage requirements for generators and permitted facilities;
- Streamlining the permit structure and clarifying activities exempt from permitting;
- Specifying the siting, design, operation, recordkeeping, and reporting requirements of RMW transfer stations and treatment facilities;
- Requiring validation and periodic challenge testing for treatment technologies;
- Clarifying procedures for the management of Category A wastes;
- Improving the alternate treatment technology petition process; and
- Overall improvement of regulatory structure, procedures, and use.

## Issues

*Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

The primary advantage of this regulatory action is that the proposed regulation action will provide for clarity and certainty for the management and treatment of RMW. This is an advantage to the regulated community, the public, and the Commonwealth as proper management and treatment of RMW will provide protections for human health and the environment. In working with the Regulatory Advisory Panel (RAP) to develop the proposed regulations, the agency was careful to provide for greater clarity for those that implement the regulation. This proposed regulatory action should pose no disadvantages to the public or to the Commonwealth.

## Requirements More Restrictive than Federal

*Please identify and describe any requirement of the regulatory change that is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.*

There are no analogous regulations for the management of this subset of solid waste.

## Agencies, Localities, and Other Entities Particularly Affected

*Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact, which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

**Other State Agencies Particularly Affected:**

Public universities and state agencies (e.g. VDACS) with RMW treatment units are considered particularly affected by the proposed amendments to the regulation. There may be minor impacts on the Virginia Department of Health (VDH) and the Division of Consolidated Laboratory Services (DCLS) as potential generators of RMW. No other state agencies are known to be particularly impacted by these regulations.

**Localities Particularly Affected:**

No localities are known to be particularly impacted by these regulations. Localities will continue to have a role in local zoning decisions regarding siting of RMW transfer stations and treatment facilities.

**Other Entities Particularly Affected:**

RMW generators, RMW transfer stations, and RMW treatment facilities located in the Commonwealth are considered particularly affected by the proposed amendments to the regulation. However, as the regulations clarify the requirements, it is hoped that the proposed amendment will help generators and facilities that manage RMW to better understand the requirements that they must adhere to regarding RMW.

## Economic Impact

*Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.*

| **Impact on State Agencies** | |
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| *For your agency*: projected costs, savings, fees or revenues resulting from the regulatory change, including:<br>a) fund source / fund detail;<br>b) delineation of one-time versus on-going expenditures; and<br>c) whether any costs or revenue loss can be absorbed within existing resources | The state program is ongoing and may benefit from increased efficiencies; however, these are unpredictable at this time. |

**Impact on State Agencies**

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| *For other state agencies*: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures. | The regulation includes additional requirements subject to permitted RMW treatment facilities and transfer stations for installation of radiation detectors (one-time cost, if required and not already in place), new procedures for validation testing and improved procedures for challenge testing, which will have up-front costs with on-going expenditures. Several state agencies with permitted RMW treatment facilities already have radiation detectors in place and have previously participated in validation testing similar to the proposed protocols. The regulation allows captive regulated medical waste management facilities to demonstrate that a radiation detector is not required if the facility can certify that there is no potential for generation or management of radioactive materials or wastes onsite. |
| *For all agencies:* Benefits the regulatory change is designed to produce. | Changes to the regulation are intended to benefit RMW generators by streamlining and reorganizing the regulation for ease of use. Recodification of the regulation, consolidation of duplicative regulatory requirements, and updating to industry standards will greatly benefit program staff and regulated entities. The addition of Category A waste management requirements will better allow program staff to respond to the next Ebola or similar emerging disease outbreak. Adding validation procedures and improving periodic challenge testing requirements will help identify and correct any compliance issues with ineffective or failing treatment equipment sooner than would be expected under the existing regulation. |

**Impact on Localities**

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| Projected costs, savings, fees or revenues resulting from the regulatory change. | No net increase in costs to localities from the historical costs associated with this regulation are anticipated. |
| Benefits the regulatory change is designed to produce. | This amendment will clarify the role that localities have in local zoning decisions regarding siting of RMW transfer stations and treatment facilities. |

**Impact on Other Entities**

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| Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect. | Entities affected include RMW generators, RMW transfer stations, and RMW treatment facilities. |

**Impact on Other Entities**

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| Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:<br>a) is independently owned and operated and;<br>b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million. | There are currently fourteen permitted RMW transfer stations and treatment facilities in the Commonwealth: Four are located at state public universities; one at a VDACS lab; three at hospitals; and the remaining are privately owned, with only one facility possibly fitting the definition of a small business.<br><br>The regulation also affects the universe of RMW generators, which includes hospitals, doctor's offices, clinics, and other healthcare facilities as well as veterinary establishments, laboratories, research facilities, etc. The agency does not have an estimate of affected number of facilities under this category which likely includes a mix of small and large businesses. |
| All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:<br>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;<br>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;<br>c) fees;<br>d) purchases of equipment or services; and<br>e) time required to comply with the requirements. | For RMW generators, the proposed regulation includes additional requirements for the maintenance of records that may have an on-going administrative cost. The proposed regulation also allows for longer storage timeframes for RMW without refrigeration, providing cost savings for small RMW generators.<br><br>This action is not expected to have a significant economic impact on municipalities, individuals, small (or other) businesses, or other entities. The purpose of this amendment is to modernize the standards for general handling and treatment of RMW based on current industry best management practices; provide clarity for the regulated universe (both RMW generators and permitted facilities); remove redundancies and streamline the regulations for ease of use; eliminate overlap with other regulations; and improve permitting procedures while still protecting the health, safety, and welfare of citizens.<br><br>The majority of the changes come from reorganization of regulatory structure, removing redundancies, and eliminating overlap with other regulations. The reorganization clearly identifies what solid wastes are considered regulated medical wastes under the proposed regulation. In addition, the structure of the regulation is laid out so that RMW generators and RMW transfer stations and treatment facilities can easily find their applicable requirements. These improvements will result in a cost savings for both the department and the regulated community. |

**Impact on Other Entities**

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| | In improving permitting procedures for RMW treatment facilities, the option for an on-site permit-by-rule was removed. This will result in an increase in costs for onsite treatment facilities to compile additional submission documents for the permit application; however, the Department will receive better information on the onsite treatment units and can better ensure that RMW is treated effectively and appropriately. The permit changes for RMW transfer stations and treatment facilities also follow the permit format under the VSWMR regulations, standardizing the application and review procedures for permit staff.<br><br>Also following in the format of the VSWMR, the Operations Manual requirement from 9 VAC 20-120 is proposed to be replaced with a stand-alone Regulated Medical Waste Management Plan for RMW transfer stations and treatment facilities that includes a series of plans outlining waste acceptance, unauthorized waste control program, facility operations, RMW treatment (if applicable); emergency contingency and closure. The creation of a stand-alone plan that is not reviewed, as part of a permit application will reduce circumstances requiring permit modifications and will increase permitting efficiency reducing costs for both the department the regulated community. This plan should already exist in some form at existing permitted RMW facilities, but may need some tweaks to ensure all topic areas are addressed.<br><br>A periodic self-inspection requirement is also proposed for permitted RMW transfer stations and treatment facilities, which is consistent with the self-inspection requirement for other solid waste management facilities subject to the VSWMR. This will provide an additional opportunity for facilities to evaluate critical areas of operation to detect and address any potential deficiencies that could affect the proper management of RMW.<br><br>In modernizing the standards for general handling and treatment of RMW based on current industry best management practices, it is anticipated that RMW transfer stations and treatment facilities will incur some costs. New requirements include:<br>• Installation of a fixed radiation detector, if applicable and not already in place voluntarily<br>• Potential retrofits for facilities using cart tippers, slides, or conveyors to ensure that movement |

**Impact on Other Entities**

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| | 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)<br>• 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<br>• Enhanced periodic challenge testing requirements to prevent false positive readings and ensure effective treatment by achieving a 6 log 10 or greater reduction of the most appropriate biological indicator<br>These regulatory improvements will ensure that RMW is managed to prevent exposure and ensure that treatment is effective.<br><br>To off-set these potential cost increases, RMW transfer stations and treatment facilities may also benefit from cost-savings associated with the following regulatory changes:<br>• Removal of requirement to shred treated RMW;<br>• 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;<br>• Multiple options for the effective cleaning and disinfection of reusable containers; and<br>• Multiple options for packaging of treated RMW<br>• Removal of permit expirations after 10 years and required renewals; permits will now be valid for the life of the facility, consistent with permits issued under the VSWMR.<br><br>Also in modernizing the standards, procedures for management of Category A wastes were added to the regulation. These procedures will ensure that the program is prepared in response to the next Ebola or similar disease outbreak in the Commonwealth by having procedures for management of wastes clearly identified in regulation, which are consistent with new federal guidelines for management of Category A waste published in August 2019. In addition, the option for Emergency Permits will ensure that the program can properly oversee the handling, management, and treatment of Category A wastes in Virginia. |

**Impact on Other Entities**

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| Benefits the regulatory change is designed to produce. | The primary benefit of this regulatory change is the incorporation of modernized standards for general handling and treatment of RMW based on current industry best management practices. Clarified requirements for generators and permitted facilities along with improved permitting procedures will result in improved ease of use while ensuring the protection of health, safety, and welfare of citizens.<br><br>The addition of Category A waste management requirements will better allow the Commonwealth of Virginia to respond to the next Ebola or similar emerging disease outbreak requiring management of Category A waste by clarifying procedures for handling, storage, treatment, and disposal of this subset of RMW and improving consistency with management requirements under other state and federal agencies<br><br>This regulation also identifies additional waste streams that are exempt from management as regulated medical waste, which will benefit all generators of those types of wastes. |

## Alternatives

*Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.*

One alternative is to keep the current regulations. In that case, the existing regulation will continue to be cumbersome, disjointed, and outdated regarding technologies and best management practices for the treatment and management of RMW. The process for this regulatory action involved the use of a regulatory advisory panel and suggestions from this panel for protective and cost effective ideas were discussed and included where appropriate (e.g., the removal of shredding, stressing that treated RMW is a solid waste, removing outdated requirements and clarifying the process for generators, transfer, and treatment facilities).

## Regulatory Flexibility Analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.*

The proposed amendment includes the clarification and consolidation of compliance and reporting requirements; less stringent schedules for storage of regulated medical waste for generators of small quantities of RMW and following certain emergency cleanup activities; and

includes the establishment of consolidated operational performance standards. Exemptions of certain wastes from the requirement to be managed as regulated medical waste will benefit small businesses that generate those wastes identified.

## Periodic Review and Small Business Impact Review Report of Findings

*Indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable. In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, include 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 the 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.*

As part of the NOIRA, comments on a periodic review/small business impact review were requested to include information on whether the regulation: (i) is necessary for the protection of public health, safety, and welfare or for the economic performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; (iii) designed to achieve its intended objective in the most efficient, cost-effective manner; (iv) is clearly written and easily understandable; (v) overlaps, duplicates, or conflicts with federal or state law or regulation; and (vi) technology, economic conditions, or other factors have changed in the area affected by the regulation since the last review.

The following comments were received regarding the periodic review/small business impact review:

| Commenter | Factor | Comment |
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| Cara Simaga, Stericycle | (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; | 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; | 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: |

| Commenter | Factor | Comment |
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| | | 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.<br>ii. The requirement to refrigerate waste after 7 days of storage.<br>iii. The requirement to shred treated RMW before landfilling. |
| | (iii) is designed to achieve its intended objective in the most efficient, cost-effective manner; | 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:<br>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.<br>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; | 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; | 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:<br>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.<br>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. | We believe that changes in the industry and advancement of practices and technology merit changes in the regulations. |

| Commenter | Factor | Comment |
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| Anne Germain, Healthcare Waste Institute, National Waste & Recycling Association | | 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:<br>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.<br>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.<br>3. The current regulations are outdated, confusing and conflict with other regulations.<br>Therefore, we support making updates to the rule to make them more clear and easier to understand. |

Finally, as part of this amendment, the Board has considered: (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 the 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. An update the RMW management protocols is necessary as this regulation has not been through a full process revision since 2001/2002. The RMW regulations are still needed but do require updates to reduce the complexity of the regulation, to clarify the regulation, and to include the latest best management practices for RMW.

Based on the periodic review/small business comments received and the NOIRA comments received, an amendment of this regulation is necessary to address these comments. This amendment will attempt to address the issues raised and to provide a more cohesive, clearer, cost-effective and protective regulation for the management of RMW.

## Public Comment

*Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.*

During the NOIRA public comment period (5/6/2019 to 6/26/2019), five persons submitted comments on the RMW regulations under 9VAC20-120. The comments submitted were:

| Commenter | Comment | Agency response |
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| Andrea Arredondo | 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. | Recommendations accepted and taken under consideration during the drafting of the regulation. |

| Commenter | Comment | Agency response |
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| Anne Germain, Healthcare Waste Institute, National Waste & Recycling Association | 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:<br>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.<br>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.<br>3. The current regulations are outdated, confusing and conflict with other regulations.<br>Therefore, we support making updates to the rule to make them more clear and easier to understand. Further, we would be interested in participating in the rulemaking process. | Recommendations accepted and taken under consideration during the drafting of the regulation. |
| Mary J Hayward, Old Dominion University | 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. | Recommendations accepted and taken under consideration during the drafting of the regulation. |
| Cara Simaga, Stericycle, Inc. | 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.<br>(i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions;<br>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.<br>(ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law;<br>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 | Recommendations accepted and taken under consideration during the drafting of the regulation. |

| Commenter | Comment | Agency response |
|---|---|---|
| | 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:<br>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.<br>ii. The requirement to refrigerate waste after 7 days of storage.<br>iii. The requirement to shred treated RMW before landfilling.<br>(iii) is designed to achieve its intended objective in the most efficient, cost-effective manner;<br>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:<br>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.<br>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.<br>(iv) is clearly written and easily understandable;<br>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.<br>(v) overlaps, duplicates, or conflicts with federal or state law or regulation;<br>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:<br>i. The definition of “Etiologic Agents” references 42 CFR 72.3. This section of federal regulation no longer exists. If the Department | |

| Commenter | Comment | Agency response |
|---|---|---|
| | wants to include a definition for similar agents, perhaps include 42 CFR Part 73 on Select Agents and Toxins.<br>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.<br>(vi) is impacted by changes in technology, economic conditions, or other factors in the area affected by the regulation since the last review.<br>Stericycle response: We believe that changes in the industry and advancement of practices and technology merit changes in the regulations.<br>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. | |
| Jennifer L. Taylor, San-I-Pak, Inc. | 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. | Comment noted. Unfortunately, the requirement for the facility to be operated by a certified waste management facility operator is a statutory requirement, and therefore, cannot be changed. |

| Commenter | Comment | Agency response |
|---|---|---|
| | 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.<br>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.<br>3. This requirement is excessively burdensome for local hospitals, which are trying to keep communities healthy while simultaneously keeping patient costs down.<br>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.<br>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.<br>c. Employee turnover at hospitals requires repeated licensing costs.<br>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.<br>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.<br>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. | |

Additionally, seven people requested to be on the Regulatory Advisory Panel (RAP) during the NOIRA public comment period. All seven were chosen for the RAP; however, two withdrew from the RAP prior to the conclusion of the RAP process. The RAP process is further discussed in the *Details of Change* section.

## Public Participation

*Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.*

In addition to any other comments, the Board is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the Board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia.

Information may include: 1) projected reporting, recordkeeping and other administrative costs; 2) probable effect of the regulation on affected small businesses; and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Debra Harris, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218; phone (804) 698-4209; FAX (804) 698-419; email to Debra.Harris@deq.virginia.gov. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall website (http://www.townhall.virginia.gov). Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

## Detail of Changes

*Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.*
*If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change.*
*If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.*

A Regulatory Advisory Panel (RAP) was convened to assist with certain aspects of the proposed regulations. The discussion topics for the RAP were focused on areas where additional information and advice were needed. The topics for RAP consideration were:

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

The RAP had three meetings and the changes recommended from the RAP were incorporated into the proposed regulation. The RAP achieved consensus on the approach for each of the topics discussed (as noted above).

| **Current chapter-section number 9VAC20-120-** | **New chapter-section number, if applicable 9VAC20-121-** | **Current requirement** | **Change, intent, rationale, and likely impact of new requirements** |
|---|---|---|---|
| **Part I** | **Part I** | **Definitions** | **This part contains the definitions for terms used in this regulation.** |
| 10 | 10 | Definitions | Some definitions were clarified and several definitions were added to address Category A waste and enhanced procedures for validation and challenge testing. |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| **Part II & III** | **Part II** | **General Information** | **This part contains the authority for the regulation, purpose of chapter, prohibitions, enforcement policy, and the identification of regulated medical waste.** |
| 20 | N/A | Reserved | Deleted as not necessary. |
| 30 | 20 | Purpose of regulations | Explains the purpose of these regulations. Section was recodified. No other changes. |
| 40 | 30 | Administration of regulations | This section explains the statutory authority and also describes the role of the Waste Management Board and the Director. Section was recodified and revised to be consistent with the Solid Waste Management Regulations (VSWMR, 9 VAC 20-81). |
| 50 | 40 | Applicability of regulations | Explains the types of facilities and persons who are required to comply with these regulations. Deadline for existing permitted facilities to update their permits included. Section was recodified. |
| 60 | N/A | Severability | Deleted as not necessary. |
| N/A | 50 | Prohibitions | New Section. Added to clarify prohibitions regarding the management of regulated medical waste. Includes language from former 120-100.A, 160, & 300.B. Format mimics VSWMR. |
| N/A | 60 | Enforcement and appeal | New Section. Added to clarify enforcement procedure and to be consistent with the VSWMR language and format. |
| N/A | 70 | Public Participation and Information | New Section. Added to clarify public participation applicability. Format mimics VSWMR. |
| 70 | 80 | Relationship to Other Bodies of Regulation | Section 120-70 was recodified. References to federal regulations were updated. Added relationships for facilities managing select agents or toxins (replacement of etiological agents, former 120-230); radioactive materials (moved from 120-320); and Financial Assurance (moved from 120-190). |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| 80,<br>90,<br>100,<br>110,<br>130,<br>140,<br>150 | 90 | Identification of Regulated Medical Waste | Consolidation of sections 120-80, 90, 100, 110, 130, 140, and 150. RMW definition, examples, exemptions, and exclusions were previously spread throughout multiple sections of the regulation (former Part III) and have been consolidated into this section. Additional RMW examples and exemptions added based on frequent questions. |
| 120 | Deleted | Exemptions to the regulations | Section focuses on items that are not solid waste and exemptions are already addressed in VSWMR, 9 VAC 20-81-95. |
| **Part IV, V, & VI** | **Part III** | **Standards for Management of Regulated Medical Waste** | **This part describes the general handling, packaging and labeling, storage, spill management, and transportation of RMW applicable to all generators and handlers of RMW. Management of Category A RMW also included.** |
| 160 | Deleted | Permit required. | Section 160 is deleted here and included in 121-50.A. |
| 170 | Deleted | Exemptions from permitting | Section 170 is deleted here and included in 121-120 and 121-300.E. |
| 180 | Deleted | Persons qualifying for an on-site permit by rule | Section 180 is deleted here. Removing on-site permit by rule (PBR) option. PBR requirements applicable to all RMW transfer stations and treatment facilities are addressed in 121-310.A. |
| 190 | Deleted | Financial assurance requirements | Section 190 is deleted here. Reference to Financial Assurance regulations (9 VAC 20-70) added in 121-80. |
| 250,<br>300.A.,<br>300.C.,<br>310,<br>390,<br>470,<br>560 | 100 | General Handling and Generator Requirements | Consolidation of 120-250, 300.A., 300.C., 310, 390, 470, 560 to streamline and clarify the requirements applicable to all generators and handlers of RMW. Removed requirement to maintain records listed under 120-310.A. Added requirement applicable to cart tippers and conveyors. |
| 200,<br>210,<br>220,<br>240,<br>260.1 | 110 | Packaging and Labeling of Regulated Medical Waste | Consolidation of 120-200, 210, 220, 230 240, and 260.1 with minor changes to language for clarification of RMW packaging and labeling requirements. |
| 230 | Deleted | Etiological agents | Section 230 is deleted here. Reference to management of select agents or toxins (new term for etiological agents) added in 121-80 |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| 170,<br>330 - 380 | 120 | Storage of Regulated Medical Waste | Consolidation of 120-170, 330, 340, 350, 360, 370, 380. Per RAP consensus, the referenced storage limit was increased from 200 to 250 gallons and storage timeframes were changed:<br>• Generators of less than 250 gal/month shall be on a monthly pick-up schedule, maximum 45 day hold<br>• Generators of 250 gal/month or more shall be on a weekly pick-up schedule, maximum 10 day hold<br>• Transfer Stations may store up to 7 days unrefrigerated, maximum of 15 day hold<br>• Treatment Facilities shall treat or remove RMW on a weekly basis, maximum 10 day hold |
| 260<br>380 | 130 | Reusable Container Requirements | Consolidation of 120-260 & 380. Reusable cart cleaning standards revised per RAP information to provide flexibility while still maintaining minimum standards for disinfection. |
| 270<br>280 | 140 | Management of Spills of Regulated Medical Waste | Section was recodified and consolidated 120-270 & 280. Minor clarifications to existing requirements added. |
| 320 | Deleted | Management of radioactive materials | Section 320 is deleted here. Reference to management of radioactive materials added in 121-80 |
| 400 - 500 | 150 | Transportation of Regulated Medical Waste | Consolidation of 120-400, 410, 420, 430, 440, 450, 460, 470, 490, and 500. Additional requirements added to clarify that transporters must comply with the general handling requirements (new 121-100) as well as US DOT HMR requirements. All other sections recodified with minor changes. |
| N/A | 160 | Management of Category A Waste | New Section. Added requirements and best management practices for Category A Waste, referencing the federal guidance “Managing Solid Waste Contaminated with a Category A Infectious Substance” (see Documents incorporated by reference). |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| **Part VII, VIII & IX** | **Part IV** | **Standards for Regulated Medical Waste Transfer Stations and Treatment Facilities** | **This part describes the siting, design and construction, operation, and closure requirements for transfer and treatment facilities. Requirements specific to various RMW treatment methods included along with validation, challenge testing, and disposal of treated waste.** |
| 160, 690.A. | 200 | General and Applicability | Outlines applicability of this Part to all RMW Transfer Stations and Treatment Facilities and their need for a permit. Format revision similar to VSWMR for analogous solid waste management (non-disposal) facilities. |
| N/A | 210 | Siting Requirements | New Section. Incorporates siting criteria from the VSWMR applicable to all solid waste management (non-disposal) facilities for consistency. |
| N/A | 220 | Design and Construction Requirements | New Section. Incorporates design and construction criteria from the VSWMR applicable to all solid waste management (non-disposal) facilities for consistency. |
| 550, 610, 660 | Deleted | Compliance with other parts of this chapter | Sections 550, 610, & 660 deleted here. Requirement for RMW treatment facilities to comply with all other RMW general handling requirements included in 121-230. |
| N/A | 230 | Operation Requirements | New Section. Clarifies that all permitted RMW facilities must comply with the RMW general handling (new 121-100), packaging and labeling (new 121-110), storage (new 121-120), reusable carts (new 121-130), spill management (new 121-140) and transportation (new 121-150) requirements (consolidation of 120-550, 610, & 660). Adds requirements for operation in accordance with a Regulated Medical Waste Management Plan (see 121-330), implementation of a Control Program for Unauthorized Waste, use of radiation detection equipment, monthly self-inspections, and training consistent VSWMR criteria applicable to all solid waste management (non-disposal) facilities for consistency. |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| 300.A, 520, 530, 540, 580, 590, 630, 640 | 240 | Treatment Standards | Consolidation of RMW treatment standards found in former Parts VII, VIII, and IX. Operating parameters for autoclaves, microwaves, dry heat, and incineration updated to industry standards. New parameters added for alkaline hydrolysis. Chlorination standards removed; instead generic chemical treatment option allowed with alternate treatment technology approval. Additional requirements around use of biological indicators for equipment validation / challenge testing added. |
| 900, 910, 920, 930, 950 | 250 | Alternate Treatment Technologies | Consolidation and recodification of 120-900 through 950. Clarification that alternate treatment technologies are subject to general treatment standards (new 121-240). Updated spore inactivation requirement to 6 Log 10 reduction for alternate treatment technologies (consistent with updated treatment standards, 121-240). For alternate treatment technology method reviews, the words “petition” and “petitioner” have been replaced with “application” and “applicant” and department review steps for applications have been added. |
| N/A | 260 | Validation Testing | New Section. Section requires that all RMW treatment facilities perform equipment validation prior to beginning operation. Section outlines validation protocol to include number and location of biological indicators, process monitoring, reporting, and specifying when validation must be repeated. |
| 530.A.4, 590.2.a, 640.1.b. | 270 | Periodic Challenge Testing | Section was recodified. Also incorporates and updates treatment efficacy requirements from 120-530.A.4, 590.2.a, & 640.1.b. Clarifies requirements regarding number of biological indicators and recordkeeping. Updated challenge testing frequency to comport with hours of operation and added procedures for response following challenge testing failure. |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| 300.B, 540.C., 600, 650 | 280 | Disposal of Treated Waste | Consolidation of 120-300.B., 540.C., 600 and 650. Requirement for shredding of treated RMW removed. New requirement added, based on RAP consensus, for RMW treatment facilities to have written agreements with the solid waste transfer and disposal facilities to receive treated RMW. |
| 290, 730.D., 750 | 290 | Closure Requirements | Consolidation of 120-290, 730.D., and 750. Addresses need for permitted facilities to maintain a Closure Plan including procedures for waste removal and facility cleaning and disinfection at closure. Closure procedures from VSWMR applicable to analogous solid waste management (non-disposal) facilities added. |
| **Part X** | **Part V** | **Permitting of Regulated Medical Waste Facilities** | **This part outlines all of the requirements needed to obtain a permit by rule for a regulated medical waste management facility. It also clarifies the requirements of the required Regulated Medical Waste Management Plan as well as recordkeeping and reporting requirements of the permittee.** |
| 170, 180, 680, 690 | 300 | Applicability | Permit types and exemptions consolidated under new Part V. Added permit exemption for sharps drop boxes, RMW pre-treatment, sewage treatment systems, combustion of up to 10% by weight of RMW at a VSWMR permitted incinerator/waste to energy facility, and temporary RMW storage associated with emergency clean-up. |
| 180, 690, 710, 720 | 310 | Permits-by-rule and Emergency Permits | Removed on-site permit-by-rule (PBR) option; Clarify that all RMW Transfer Stations and Treatment Facilities are now required to have the same PBR. Removed Key Map, Near Vicinity Map, and adjacent property owner notification from PBR submission. Added requirements public participation and submission of certifications and documents to make the RMW PBR application consistent with the VSWMR PBR submission requirements. Per new 121-40.B., all existing on-site or off-site/full PBR holders will have to submit new PBR applications. |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| | | | Added Emergency Permit type. Intent is that an Emergency Permit may be issued for the storage, transfer, or treatment of Category A waste or other applicable situation. Language mimics Emergency Permit option in VSWMR. |
| 740 | 320 | Effect of the Permit | Section was recodified. Added procedure for the department to approve RMW treatment facilities to begin operations (e.g. receive RMW for treatment) following equipment validation per new 121-260. |
| 730 | 330 | Regulated Medical Waste Management Plan | Section was recodified. The Regulated Medical Waste Management Plan (RMWMP) replaces the previous narrative, Operations Manual, and Emergency Contingency Plan outlined in 120-730. The RMWMP will include the following:<br>• Waste Acceptance Plan;<br>• Unauthorized Waste Control Plan;<br>• Operations Plan;<br>• Treatment Plan (if applicable);<br>• Emergency Contingency Plan; and<br>• Closure Plan<br><br>On-site PBR holders were previously exempt from this requirement; as proposed, they will be required to develop and maintain a Regulated Medical Waste Management Plan. |
| 310, 540.B. & C., 590.2.b., 640.1.c., 760 | 340 | Recordkeeping and Reporting Required of a Permittee | Specifies recordkeeping and reporting requirements specific to RMW permitted facilities. Section was recodified and consolidates 120-310, 540.B & C, 590.2.b., 640.1.c, & 760. Removed requirement to maintain records listed under 310.A. Added requirements for submitting the annual Solid Waste Information and Assessment (SWIA) report, quarterly updates of Disclosure Statements, and maintenance of records regarding receipt of unauthorized waste and self-inspections. |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| 810 | deleted | Amendment of permits | Section 810 is deleted here. Revised wording from amendment to modification to be consistent with other DEQ programs. Procedures for temporary authorizations removed from regulation (not used). Procedures for permit modification included in 121-310.A.6. |
| 820 | deleted | Duration of permits | Deleted requirements for permit duration and renewal. Permits will be valid for the life of the facility, consistent with permits issued under the VSWMR. |
| 830 | Deleted | Existing facilities qualifications | Deleted section. Requirement for existing permitted facilities to submit new permit applications included in new 120-40. |
| **Part XI** | **Part VI** | **Variance Application Procedures** | **This part describes the procedures to follow when requesting a variance from this regulation. The words "petition" and "petitioner" have been replaced with "application" and "applicant".** |
| 840 | 400 | General (variances) | Section was recodified. Removed listed item regarding non-acceptance of variance to the definitions of regulated medical waste. Section 121-90 addresses process for demonstrating that a material meets an exemption from regulation as regulated medical waste. |
| 850, 860 | 410 | Variances to Requirements | Consolidation of 120-850 & 860. Section was recodified. No other changes made. |
| 870, 880, 890 | 420 | Administrative Procedures | Consolidation of 120-870, 880, & 890. Section was recodified. No other changes made. |
| 900 | Deleted | General (alternate treatment technology) | Section 900 is deleted here and included in 121-250.A. |
| 910 | Deleted | Criteria for microbial inactivation | Section 910 is deleted here and included in 121-250.B. |
| 920 | Deleted | Representative biological indicators | Section 920 is deleted here and included in 121-250.C. & D. |
| 930 | Deleted | Quantification of microbial inactivation | Section 930 is deleted here and included in 121-250.E. & F. |
| 940 | Deleted | Efficacy testing protocols | Section 940 is deleted here and included in 121-260. |
| 950 | Deleted | Technology approval process | Section 950 is deleted here and included in 121-250.G. |
| 960 | Deleted | Site approval process | Section 960 is deleted here and included in 121-260 and 121-330. |
| 970 | Deleted | User verification | Section 970 is deleted here and included in 121-270 |

| Current chapter-section number 9VAC20-120- | New chapter-section number, if applicable 9VAC20-121- | Current requirement | Change, intent, rationale, and likely impact of new requirements |
|---|---|---|---|
| 980 | Deleted | Small medical waste treatment devices | Section 980 is deleted. Per RAP consensus, separate requirements for small medical waste treatment devices were not needed. |
| 990 | Deleted | Waste residue disposal | Section 990 is deleted here. Information about alternate treatment technology waste residue is to be submitted with information required under 121-250. |
| 1000 | Deleted | Operator training | Section 1000 is deleted here. Requirements for training are addressed in 121-230.U. |
| FORMS | Forms | | Link to revised DISC-01, DISC-02, CERT-01, and RMWTP-01. Adding new RMW PBR application form. |
| N/A | Documents Incorporated by Reference | | Incorporating federal policy titled "Managing Solid Waste Contaminated with a Category A Infectious Substance." Document is referenced in new section 121-160. |

The changes to this regulation have been made to develop a more cohesive and technically up-to-date regulation. Many of the sections have remained the same except for recodification and other sections have been rearranged for clarity, conciseness, and efficiency.

## Family Impact

*In accordance with § 2.2-606 of the Code of Virginia, please assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

No impact on the institution of the family and family stability is anticipated with this regulatory action.