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Final Regulation
Agency Background Document

Agency name	Virginia Waste Management Board
Virginia Administrative Code (VAC) Chapter citation(s)	9VAC20-120(repeal) 9VAC20-121(new)
VAC Chapter title(s)	Regulated Medical Waste Management Regulations
Action title	Amendment 3
Date this document prepared	September 21, 2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

"DCLS" means the Division of Consolidated Laboratory Services.

"EPA" means the U.S. Environmental Protection Agency.

"FDA" means the Food & Drug Administration.

"DPOR" means the Department of Professional and Occupational Regulation.

"PBR" means Permit by Rule.

"RAP" means a Regulatory Advisory Panel.

"RMW" means Regulated Medical Waste.

"SWIA" means Solid Waste Information and Assessment.

"US DOT" means the U.S. Department of Transportation.

"VDACS" means the Virginia Department of Agriculture and Consumer Services.

"VDH" means the Virginia Department of Health.

"WMFO" means the Waste Management Facility Operator.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

At the October 28, 2022, Board meeting the Virginia Waste Management Board took final action to adopt a new Regulated Medical Waste Management Regulation (9VAC20-121) and to repeal the existing Regulated Waste Management Regulation (9VAC20-120). The regulatory action is to be effective as provided in the Administrative Process Act.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

There are no changes to the mandate for this regulation.

Legal Basis

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

The promulgating agency for this regulation is the Virginia Waste Management Board.

The legal basis for this regulation 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

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

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.

Currently, Virginia has 16 permitted regulated medical waste management facilities that have transfer stations or that treat regulated medical waste. Permitted facilities are listed in Attachment A (RMW Treatment Facilities) and Attachment B (RMW Transfer Stations).

Issues

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

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

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

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, 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. A listing of permitted RMW treatment facilities is attached (Attachment A).

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 more easily find the requirements that apply to them and to have a better understanding of the requirements that they must adhere to regarding RMW.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in EO 19 and the ORM procedures, 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, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (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. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

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.

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 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 the technology, economic conditions, or other factors have changed in the area affected by the regulation. An update to the RMW protocols is necessary as this regulation has not been through a full process revision since 2001/2002. The RWM 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. Comments received and the recommendations accepted and taken under consideration during the drafting of the regulation are listed below.

Commenter	Factor	Comment
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: i. The numerous requirements for RMW transfer sites, including the requirement to be permitted if waste is stored on a trailer for more than 24 hours. ii. The requirement to refrigerate waste after 7 days of storage. iii. The requirement to shred treated RMW before landfilling.
	(iii) is designed to achieve its intended objective in the most efficient, cost-effective manner;	We have stated some of the reasons why we disagree that the current regulation is efficient and cost-effective above in (ii) but would like to include the following points as they have impacts on larger generators such as hospitals: i. Many generators of large amounts of waste prefer the use of roll-off containers for storage and management of their wastes, however, due to the current storage regulations, these containers must be removed every 7 days, even if they are not full. This results in additional cost for the healthcare facilities. ii. The limit on storage of RMW being only 200 gallons of waste; otherwise a permit is needed. This is an unclear requirement and is not a common way that waste storage is identified and managed in regulation. The 200 gallon

Commenter	Factor	Comment
		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: i. The definition of “Etiologic Agents” references 42 CFR 72.3. This section of federal regulation no longer exists. If the Department wants to include a definition for similar agents, perhaps include 42 CFR Part 73 on Select Agents and Toxins. ii. Parts of the regulation seem to pull from the federal Environmental Protection Agency’s (EPA) hazardous waste regulations. For example, the terms “listed” and “characteristic” are used at times. These are terms used to define hazardous wastes that are found on lists (U, P, F, and K lists) and/or exhibit hazardous waste characteristics (ignitability, corrosivity, reactivity, toxicity). We would recommend not using the terms “listed” or “characteristic” in defining RMW.
	(vi) is impacted by changes in technology, economic conditions, or other factors in the area affected by the regulation since the last review.	We believe that changes in the industry and advancement of practices and technology merit changes in the regulations.
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: 1. Regulations governing RMW are necessary to protect the public health, safety and welfare. Appropriate

Commenter	Factor	Comment
		management of RMW ensures that it does not create a public health risk. 2. Should Virginia adopt regulations with reasonable changes, these regulations could benefit small businesses such as smaller healthcare facilities by providing potential costs savings and reducing compliance risk. 3. The current regulations are outdated, confusing and conflict with other regulations. Therefore, we support making updates to the rule to make them more clear and easier to understand.

Public Comment

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

Commenter	Comment	Agency response
Bryce Lindley, Staunton, VA	My concern after reviewing the revised regulations is that the regulations were revised by a Regulatory Advisory Panel (RAP) that may have been encompassed of individuals that may gain personal benefit from the regulations as written (potentially in violation of § 2.2-3103. Prohibited conduct). This panel, if it is the same as the one listed at https://www.dpor.virginia.gov/Boards/WMFO/, seems to be designed to have a perception of a Conflict of Interest. Though I believe that the Board of Waste Management meant to just get advice from select members of the community, they may be getting advice from individuals that may receive direct or indirect compensation for the prevalence of off-site treatment and transportation of waste and/or direct or indirect compensation for providing training to local businesses for the Waste Management Facility Operator license. *§ 54.1-2210. Board for Waste Management Facility Operators; membership; terms.The Board for Waste Management Facility Operators shall consist of seven members appointed by the Governor as follows: a representative from the Department of Environmental Quality, a representative from a local government that owns a sanitary landfill, a representative from a local government that owns a waste management facility other than a sanitary landfill, a representative of a private owner of a sanitary landfill, a representative of a private owner of a waste management facility other than a sanitary landfill, and two citizen*	Per 9VAC20-11-70 B of the Public Participation Guidelines regulation, the agency shall determine when a regulatory advisory panel (RAP) shall be appointed and the composition of the RAP. The agency director determines who is appointed to the RAP based on professional specialization or technical assistance per 9VAC20-11-70 A. Anyone may ask to be appointed to the RAP, but appointment is not guaranteed and is at the pleasure of the agency director. The Regulatory Advisory Panel for this regulatory amendment, the Board for Waste Management Facility Operators, and the Virginia Waste Management Board are three different entities. No change has been made to the regulation in

	members, one of whom shall be a representative of a commercial waste generator. No owner shall be represented by more than one representative or employee. The terms of Board members shall be four years, except that vacancies shall be filled for the unexpired term. No member shall serve more than two consecutive four-year terms. I hope that after reading the below, the Board of Waste Management makes the appropriate amendments to the revised regulations to ensure that the regulations make sense, and that any Board decisions do not advance the perception of a conflict of interest.	response to this comment.
Bryce Lindley, Staunton, VA	The new regulations seem arbitrary and capricious, and are above and beyond industry standard. I would like to see certain regulations changed to ensure that any and all infectious waste is treated at its source, per industry best practice, to prevent its dangerous reintroduction back into our communities. I would think that the average citizen of Virginia would prefer the same. Numerous Federal agencies have defined or tried to define regulated medical waste. The EPA states, "Medical waste is a subset of wastes generated at health care facilities, such as hospitals, physicians' offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories. Generally, medical waste is healthcare waste that that may be contaminated by blood, body fluids or other potentially infectious materials and is often referred to as regulated medical waste." The CDC states that certain medical waste should be targeted for proper waste disposal processes - "Health-care facility medical wastes targeted for handling and disposal precautions include microbiology laboratory waste (e.g., microbiologic cultures and stocks of microorganisms), pathology and anatomy waste, blood specimens from clinics and laboratories, blood products, and other body-fluid specimens.2 Moreover, the risk of either injury or infection from certain sharp items (e.g., needles and scalpel blades) contaminated with blood also must be considered." Medical waste is primarily regulated by state environmental and health departments. EPA has not had authority, specifically for medical waste, since the Medical Waste Tracking Act (MWTA) of 1988 expired in 1991. As such, the state of Virginia's Waste Management Board is trying to revise its regulations to try to provide a safe environment for its populace. Best practices guidelines state that on-site treatment is preferred[1]. On-site treatment decreases the chance that infectious waste gets re-introduced into the community. On-site treatment, generally performed and supervised by the industry experts – medical professionals – that are already mandated to comply	The Board appreciates the comment, but determines that the general permitting and operational requirements for onsite treatment of regulated medical waste as written in the proposed regulations are necessary to protect the health, safety and welfare of the public. No change has been made to the regulation in response to this comment. Portions of this comment relating to operator licensing and pre-treatment vacuum requirements are consistent with the next two comments, which have been addressed separately.

	with Federal OSHA Blood Born Pathogen Standards (29 CFR 1910.1030) and the Federal DOT regulations (49 CFR § 173.197) governing such wastes – do not need additional state regulations that try to prevent hospitals from completing their missions - to participate in activities to protect and promote the health of the public. The regulations, as currently written, heavily deter onsite treatment. Not only do the regulations require hospitals to get a license to operate an on-site waste treatment system, they include an odd, never before seen, triple stage pre-vacuum requirement for steam sterilization. I fear that certain parts of these regulations may have been written in this fashion with malicious intent. By deterring on-site treatment, facilities will be required to transport their waste off site, and be forced to pay 3 to 5 times more for waste disposal. Municipal solid waste usually costs a facility less than $0.10 per pound to dispose. Regulated medical waste that requires off site treatment and transport can be charged as much as $0.80 per pound. The average cost of on-site RMW treatment system averages $0.07 to $0.11 per pound, saving the facilities from $0.22 to $0.60 per pound. These cost savings only increase the longer the on-site treatment system is used and the more waste that is treated. At a facility where the RMW poundage can be 2,826,560 lbs per year the facility will need to spend approximately $490,000 per year for off-site waste disposal versus $87,000 per year for an on-site waste treatment system. This is an added $403,000 per year that a hospital in a pandemic should not be forced to pay!	
Bryce Lindley, Staunton, VA	Virginia is the ONLY state in the U.S. that requires hospitals to have a license to run a commercial incinerator or autoclave (Class III), per 9VAC20-121-300. This license is expensive, very hard to attain, requires education in equipment that the hospital will not be using (incinerators), and it requires the employees to leave the hospital facility during a pandemic to try to attain this “privilege”. The Board of Waste Management excluded certain treatment systems from this license requirement, but seemed to fail to take into consideration all available treatment systems and the ramifications of requiring certain industries and easily operated systems in the licensing requirement. The definition of a commercial incinerator or autoclave cannot be found by the average person because the Department of Professional and Occupational Regulation isn’t capable of even keeping its website updated. The link found at [DPOR’s Waste Management Facility Operator Candidate Information Bulletin] to the “training materials’ is not available. Some of the listed entities that the Board claims are to provide training are no longer in business or	Industrial and domestic sewage discharges are regulated under other laws and regulations. Solid waste incinerators, thermal treatment facilities, and waste to energy facilities require a solid waste management facility permit under the Virginia Solid Waste Management Regulations, 9VAC20-81, and solid waste management facilities are required to operate under the supervision of a licensed WMFO as required by §10.1-1408.2 of the Code of Virginia. The requirement for the facility to be operated by a licensed waste management facility

	no longer offer the training. There is only one company still claiming to provide such training. Hospitals cannot afford to lose one employee during a pandemic, much less lose an employee for days on training for easily attained information. Manufacturers of needed equipment will come on sight to ensure that operators know how to operate their systems and will provide industry standard training. The Class III license also includes training for incinerators. Not only is there not a single incinerator in operation at a hospital in the state of Virginia, but why should a hospital know how to operate a system that they aren't using? These superfluous requirements do not seem justified or reasonable. The revised regulations added a new definition just for generators that treat their own waste on site - captive regulated medical waste management facilities; and as such, can easily exempt these specially defined facilities. The revised regulations have already proven that certain treatment systems can be exempted – the RAP board exempted treatment systems used to treat industrial or domestic sewage discharges, and permitted solid waste incinerators, thermal treatments, or waste to energy facilities with combustion of up to 10% by weight of regulated medical waste under 9VAC20-121-300(E.). By exempting these systems, the Board has proven that some systems can and should be exempted from this permit process. The Attorney General also verified that the Board has the authority to amend its regulations (per Christopher E. Bergin, Jr.'s letter dated December 19, 2019). The Board can ensure that these same facilities are still safely treating on-site be re-instituting 9VAC20-120-1000 - Operator Training.	operator (WMFO) is a statutory requirement (§10.1-1408.2 of the Code of Virginia). Changes to the Code of Virginia can only be accomplished through action by the Virginia General Assembly. In addition, 18VAC155-20-110.A.3 of the Department of Professional and Occupational Regulation's WMFO Regulations (which is not part of this regulatory amendment) requires individuals operating a facility regulated under the Regulated Medical Waste Management Regulations to hold a Class III license. State law does not provide DEQ or the Virginia Waste Management Board with the authority to revise licensing criteria or examination procedures for waste management facility operators. Under §54.1-2211 of the Code of Virginia, the Board for Waste Management Facility Operators promulgates regulations and standards for the training and licensing of operators. The Board for WMFO also approves training providers. No change has been made to the regulation in response to this comment.
Bryce Lindley, Staunton, VA	9VAC20-121-240 (C.)(3.) requires a vacuum autoclave to fully evacuate the air three times. Why does a pre-vacuum sterilizer require a minimum of three cycles? This isn't found in any other regulation or description in the U.S. What scientific reason was used to include a three-cycle pre-vacuum stage? Some autoclaves, such as a Tuttnauer, state that they have pulses of vacuum[2], but I've never seen a 3-cycle vacuum stage. This	Pulling multiple vacuums prior to the residence phase of the treatment cycle conditions the waste and its packaging to ensure that all portions of the waste in the treatment unit receive

	regulation needs to be amended, as it seems to refer to a type of sterilization system that does not exist. 9VAC20-121-240 (C.)(3.) *For vacuum autoclaves, pre-vacuum cycles shall be conducted such that all system air is fully evacuated ~~a minimum of three times~~ at the beginning of each treatment cycle and held with all air evacuated to ensure adequate steam exposure throughout the waste.*	adequate steam exposure. Adequate steam exposure ensures that minimum temperatures necessary for effective treatment are achieved in all portions of the waste in the treatment unit. The text has been revised to require a minimum of two pre-vacuums, unless based on the results of validation testing additional vacuum is needed for certain waste or packaging types.
Bryce Lindley, Staunton, VA	Easy solutions exist to correct these regulation errors – the Board can delete the minimum 3 times for the pre-vacuum cycle from 9VAC20-121-240 (C.)(3.), exempt captive regulated medical waste management facilities *or* on-site regulated medical waste treatment systems that treat less than 500 pounds per load from a license requirement under 9VAC20-121-300, and remove individuals from the Board or RAP that create a perception of a conflict of interest.	The Board appreciates the comment, but determines that the general permitting and operational requirements for onsite treatment of regulated medical waste as written in the proposed regulations are necessary to protect the health, safety and welfare of the public. No change has been made to the regulation in response to this part of the comment. Portions of this comment relating to pre-treatment vacuum requirements, operator licensing, and RAP membership are consistent with previous comments, which have been addressed separately.
Bryce Lindley, Staunton, VA	My final “fear” is that the regulations could be considered so capricious and expensive that healthcare professionals could bypass the regulations all together by claiming that none of their waste is capable of producing an infectious disease in humans. As 9VAC20-121-90 gives them the legal means to do this – by allowing them to make the ultimate decision as to what they “suspect” might produce an infectious disease – they could in essence decrease their expenses by claiming that 100% of their waste is non-infectious and just municipal waste.	Even if a solid waste is not suspected by the health care professional in charge of being capable of producing an infectious disease in humans, the waste is still regulated medical waste if it is identified in the list of wastes under 9VAC20-121-90 B 2, unless specifically excluded or exempted by subsection

		C or D of 9VAC20-121-90. No change has been made to the regulation in response to this comment.
Marianna Denny, Fauquier County Environmental Services	**Response to RMW changes, specifically home sharps** Fauquier County Environmental Services will be negatively impacted by proposed changes to the Regulated Medical Waste Management chapter of the Virginia Administrative Code, specifically proposed additions contained in 9VAC20-121-10 "Definitions," 9VAC20-121-90 "Identification of regulated medical waste" and 9VAC20-121-300 "Applicability." In September 2018, Fauquier County Environmental Services began implementation of a home sharps collection program, with approval from DEQ Northern Region staff and the local office of the Virginia Department of Health. This program was conceived due to repeated sharps injuries within County staff, particularly recycling sorting staff, caused by improperly disposed home sharps in recycling material at the County's residential recycling facility. The program is designed to provide a convenient and accessible way for Fauquier County residents to dispose of home sharps in a safe manner, and keep them out of the larger waste and recycling stream. In order for the program to be affordable to the County, and to prevent an increased financial burden to County taxpayers, the resulting home sharps were allowed by DEQ to be disposed of directly into the working face of Fauquier County's sanitary MSW landfill, PN 575. The collection and disposal of home sharps is carried out in an organized and safe fashion, with program specifics previously approved by DEQ. Fauquier County Environmental Services has also developed and implemented a department-specific Exposure Control Plan in consultation with Katherine West, BSN, MSEd, CIC. We are only collecting home sharps directly from only Fauquier County residents at our facilities, and in-person screening of each deposit (required by the program) allows us to be certain we are not accepting sharps from business entities. After implementation of the sharps collection program in late 2018, sharps injuries among Environmental Services staff dropped by 50% in 2019, and to zero in 2020. In 2021, Environmental Services had only one possible sharps-related injury, the specific source of injury being undetermined, and there have been zero sharps-related injuries in 2022 to date. There have been no reported hazards to staff or the public related to disposal of collected home sharps in the sanitary landfill's working face. Under the proposed additions to the regulations, there is a newly defined "sharps drop box" in the proposed	The Board appreciates the suggestion, but determines that the requirements as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.

	9VAC20-121-10 “Definitions”, which is “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.” Under this definition, the residential collection points operated by Fauquier County Environmental Services would be defined as sharps drop boxes. We have no objection to this definition, save for the last line “where collected sharps are packaged, labeled and managed as regulated medical waste.” This line of the proposed regulation would negatively impact our program, as it would trigger all other requirements of the regulated medical waste regulations in regard to our collection, transport and disposal of home sharps.	
Marianna Denny, Fauquier County Environmental Services	The proposed draft of 9VAC20-121-90 “Identification of regulated medical waste” also negatively impacts our program. Previously, home sharps were largely exempt from regulation. Under this draft of 9VAC20-121-90, both subsection B.2.d. (“This also includes sharps generated through veterinary practice, acupuncture needles, and household sharps collected in a sharps drop box”) and D.2. (“Household sharps centrally collected in a sharps drop box shall be managed as regulated medical waste in accordance with 9VAC20-121-300 E 1”) home sharps collected in a sharps drop box are specifically designated as regulated medical waste, triggering the requirements outlined in the proposed 9VAC20-121-300 “Applicability.”	The Board appreciates the suggestion, but determines that the requirements as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Marianna Denny, Fauquier County Environmental Services	The proposed draft of 9VAC20-121-300 “Applicability” also negatively impacts our program. Under 9VAC20-121-300 E.1.a-c, we may collect home sharps in a sharps drop box at our residential collection facilities, but “must comply with the general handling, packaging and labeling, storage, reusable container, spill cleanup, transportation, and Category A waste management requirements for regulated medical waste outlined in Part III (9VAC20-121-100 et seq.) of this chapter,” with the further restriction in that same subsection that “Collected sharps shall be treated or disposed of as regulated medical waste in accordance with this chapter. Untreated sharps shall not be recycled or disposed of in a solid waste landfill or other solid waste management facility.”	The Board appreciates the suggestion, but determines that the requirements as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Marianna Denny, Fauquier County Environmental Services	The proposed regulations as outlined above will effectively eliminate Fauquier County Environmental Services’ ability to continue operating our home sharps collection program. It will no longer be financially viable, and will place an undue burden on the County’s taxpayers as it would require a significant budget increase to comply with the new requirements. This program has been highly successful in providing a needed resource for residents in a largely rural area	The Board appreciates the suggestion, but determines that the requirements as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made

	with few options for safe home sharps disposal. It has been very effective in reducing sharps injuries amongst our staff. We believe that our system as currently operating is no less protective of human health and the environment than residents legally disposing of individual or packaged home sharps mixed in household solid wastes. In actuality, we feel that our system is more protective, as we ensure that home sharps are directly disposed of in our landfill's working face using specific safety procedures, rather than having household sharps interspersed in waste that is collected by widely varying methods, dumped on our MSW transfer station tipping floor, and shipped out to another landfill via public roads. In the view of Fauquier County Environmental Services, this regulatory change will only serve to increase health and safety risks to our staff and others, as unmanaged home sharps are highly likely to be improperly and unsafely disposed. We would propose several options for changes to the draft regulations in question: 1. Create a separate category for a permitted solid waste facility that would allow it to directly operate sharps drop boxes at such facilities, with the caveat that only home sharps would be disposed of in the associated permitted facility. This should include a permitted sanitary landfill, but could be expanded to include a permitted MSW transfer station should DEQ agree. Our program would not be affected by this expansion, but we can see the potential utility of this for other localities. 2. Eliminate or modify the last line of 9VAC20-121-300 E.1.c. that states "Untreated sharps shall not be recycled or disposed of in a solid waste landfill or other solid waste management facility," to allow for disposal of home sharps as outlined in the previous bullet point. 3. Provide for a process to apply for an exemption or variance to the proposed regulation that would allow Fauquier County Environmental services or other localities to obtain said exemption/variance, if we are able to show a significant benefit to public health and access to needed services, combined with little to no risk to health or the environment.	in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-10.** The definition of "autoclave" is incorrect. Consistent with the definition of "autoclave" in other states, the definition should not include the term "sterilization." Autoclaving is not intended to achieve sterile conditions; rather it renders materials noninfectious through steam at high temperature and pressure. Stericycle proposed text: "Autoclave" means a wet thermal ~~sterilization~~ process that uses saturated steam under a specified amount of pressure for a specified exposure time and at a specific temperature.	The Board agrees with this comment, and the text has been revised to remove the word "sterilization" and replace it with the word "treatment."

Cara Simaga, Stericycle, Inc.	**9VAC20-121-10.** Although Stericycle makes best efforts to use EPA-registered disinfectants, they are not always readily available (such as during public health crises like the COVID-19 pandemic). Stericycle requests that DEQ remove the language requiring use of an EPA registered disinfectant or add language allowing flexibility or other disinfectant options so that appropriate disinfection can occur when EPA-registered disinfectants are not readily available. Stericycle proposed text: "Disinfection" means any procedure that involves the application of an antimicrobial agent (disinfectant) ~~registered with 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.	The Environmental Protection Agency (EPA) and the Food & Drug Administration (FDA) regulate the labeling and sale of disinfectants in the United States. In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and FDA regulates those used on critical or semi-critical medical devices. EPA has a process to register disinfectant products, including those that are considered "hospital grade" disinfectants. In March 2020, EPA introduced a temporary regulatory amendment to address supply chain disruptions for disinfectants effective against Coronavirus. These temporary regulatory flexibilities allowed the use of non-registered disinfectants during the early days of the pandemic. In September 2021, EPA announced termination of the temporary amendment due to the stabilization of the supply chain, and compliance with the permanent requirements is required by September 2022. The Board would expect EPA to exercise similar options in the future if supply chain disruptions occur again. No changes have been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-10.** Pharmaceutical waste should be removed from the definition of "unauthorized waste." Incineration at a hospital, medical, and infectious waste incinerator (HMIWI) is a strongly recommended treatment option for non-hazardous pharmaceutical waste. Allowing customers to make use of this	The Board agrees that pharmaceutical waste, trace chemotherapeutic waste, and pathological waste may not be considered unauthorized

	technology reduces the likelihood that pharmaceutical waste will be sewered, a practice that can increase the presence of harmful chemicals in drinking water. Trace chemotherapeutic wastes (such as contaminated gloves), and pathological wastes (such as human tissue) are considered medical waste in many jurisdictions, and are routinely handled by medical waste treatment facilities today. If medical waste treatment facilities are prohibited from accepting these wastes, healthcare facilities may face difficulty in identifying suitable vendors for that waste stream. Stericycle proposed text: "Unauthorized waste" means waste that is not authorized by the department to be managed by a regulated medical waste management facility. Examples are dependent upon the treatment technology and permit but may include ~~chemotherapeutic, pathological, pharmaceutical,~~ radioactive, chemical, hazardous, or other wastes.	waste across the board at all regulated medical waste management facilities. However, it is possible for each of these waste types to be an example of unauthorized waste at a particular regulated medical waste facility based on the facility's site-specific treatment technology and permit. The definition has been clarified to emphasize that examples of unauthorized waste may vary from site to site.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-40(B).** Facilities with existing permits should not be required to submit new permit applications within six months after the new regulations take effect. Rather, existing facilities should be required to demonstrate compliance by the time that their existing permits come up for renewal. This change would ease the regulatory burden of the new regulations, better accord with expectations of regulated parties who may not be required to renew their permits for several more years, and more evenly spread DEQ's workload in that it will not be flooded with unnecessary or duplicative permit applications immediately following finalization of the proposed rule. Stericycle proposed text: All existing regulated medical waste management facilities must comply with this chapter. ~~Existing f~~Facilities~~, including those~~ with an existing permit, must demonstrate compliance ~~submit a complete permit application (insert date six months after the effective date of this regulation) to come into compliance~~ with this chapter~~.~~ by their next permit renewal date.	The time frame for existing facilities to submit updated permit applications to come into compliance with the new regulations has been extended from 6 months to 18 months. The regulatory text has also been revised to clarify that permit applications for existing facilities will not need to include public participation unless the updated application includes changes that result in a different type of facility (e.g. change from transfer to treatment facility or change from captive to non-captive facility). As part of this amendment, the permit procedures for all types of facilities have been made more consistent, and the regulation no longer distinguishes "on-site" PBRs from "offsite" PBRs. In addition, on-site PBRs did not previously require a 10-year renewal. Therefore a set timeframe for submittal of PBR applications by all existing facilities has been outlined in the

		regulation. The Board agrees that a six month time frame may be impractical or difficult for facilities; therefore the timeframe for submittal of the application is extended to 18 months. The extended time frame will also allow DEQ time to provide training and compliance assistance.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-90(C)(8).** The proposed language is overly broad. Stericycle recommends adding language to clarify that not all used health care products and "contaminated" medical devices or equipment are regulated as medical wastes, but rather only those that meet the specific criteria for the identification of RMW laid out in 9VAC20-121-90(B). Stericycle proposed text: The following materials are not solid wastes or regulated medical wastes . . . 8. Used health care products and reusable medical devices, being returned to a manufacturer or third party for reprocessing (cleaning and disinfecting or sterilizing) and reuse if packaged and labeled in accordance with 49 CFR 173.134(b)(12)(ii)(A) through (D) and reprocessed in accordance with applicable U.S. Food and Drug Administration requirements. Used health care products and contaminated medical devices or equipment <u>that meet either of the two criteria of 9VAC20- 121-90(B)</u> being sent offsite for recycling or disposal are regulated medical waste and shall be managed in accordance with this chapter. These items do not include reusable carts or containers used in the management of regulated medical waste, which shall be managed in accordance with 9VAC20-121-130.	The Board agrees with this comment, and the text has been clarified.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-90(C)(10).** Through the use of the word "shall," this proposed regulation appears to *require* the disposal of paraffin blocks as solid waste, not as RMW. Stericycle requests that DEQ use permissive language, changing "shall" to "may," to allow the incineration of paraffin blocks as RMW, which is a current common practice. Stericycle proposed text: The following materials are not solid wastes or regulated medical wastes: 10. Tissue blocks of organs or tissues (except those associated with prions) that have been fixed in paraffin or similar embedding materials for cytological or histological examinations. Once these items are no longer needed for their intended purpose, they ~~shall~~ <u>may</u> be managed as solid waste.	The Board agrees with this comment, and the text has been clarified.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-90(D)(1)(a).** The proposed language has the unintended consequence of prohibiting disposal of autoclave-treated RMW. Packaging remains intact	The Board agrees with the comment, and the text has been clarified.

	during autoclaving. For example, RMW that goes into an autoclave in a red bag will come out of the autoclave as treated waste, but still in the same red bag. This treated red bag waste is—and should be—disposed of as solid waste. To the extent the proposed regulation requires the waste to be packaged differently when it is removed from the autoclave because it has become "treated waste," it is unworkable. The regulation should be clarified to prohibit *re*-packaging of treated waste as RMW or this provision should be deleted in its entirety. Stericycle proposed text: a. Treated waste that was once regulated but is no longer regulated medical waste shall not be re-packaged as regulated medical waste. ~~Solid waste packaged as regulated medical waste is regulated medical waste.~~	
Cara Simaga, Stericycle, Inc.	**9VAC20-121-90(D)(2).** Stericycle supports this addition to the RMW regulations. In particular, Stericycle supports the treatment of home healthcare waste as RMW, as it reduces the likelihood that such items end up untreated in municipal sewers or landfills. Medical waste generated by health care professionals, including hospice care providers, can sometimes include pharmaceutical waste. Allowing home health care professionals to potentially utilize one service provider for all of these waste streams further helps facilitate proper disposal practices. (See also Stericycle's comments to proposed section 9VAC20-121-10, above). Stericycle proposed text: ~~The following solid wastes are not regulated medical wastes for purpose of this chapter: …2. Household waste, including household sharps.~~ A person shall not knowingly place household sharps waste in any container used for the collection of solid waste or recyclable materials. Household sharps waste shall be placed in a~~n opaque,~~ leak proof, puncture resistant container that is closed~~,~~ and tightly sealed~~, and labeled for home use before being mixed with other solid wastes or disposed~~. Household sharps waste ~~may be placed in U.S. Food and Drug Administration cleared sharps containers if specifically designed and labeled for home use. Household sharps containers shall be labeled "HOUSEHOLD SHARPS – DO NOT RECYCLE" or "HOME GENERATED SHARPS – DO NOT RECYCLE" printed in large legible text and permanent ink. Household sharps centrally collected in a sharps drop box~~ shall be managed as regulated medical waste in accordance with 9VAC20-121-300 E 1. Medical waste generated by a health care professional administering care in a household is regulated medical waste and must be managed in accordance with this chapter.	The Board appreciates the suggestion, but determines that the requirements as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-100(B).** The generator is the entity that can safely segregate RMW. Segregation of RMW from other types of waste and by treatment method should	The Board agrees with part of the comment. The text has been clarified to

	be clearly identified as an obligation of the generator. The generator should have the option to comingle solid waste, such as personal protective equipment (PPE) and non-hazardous pharmaceuticals, with RMW, and to overmanage that waste as RMW. Stericycle proposed text: All generators must identify and segregate ~~R~~regulated medical waste ~~shall be identified and segregated~~ from other waste, including radioactive waste, hazardous waste, and other solid waste, at the point of origin or as soon as practicable after generation, except that solid waste may be combined with regulated medical waste. If solid waste is combined with medical waste, it shall be managed as regulated medical waste. All generators must also segregate ~~. If practical,~~ regulated medical waste ~~shall also be segregated~~ based on the anticipated treatment method.	emphasize that the generator is the entity responsible for identifying and segregating regulated medical waste. Regarding the remainder of the comment, the Board appreciates the suggestion, but determines that the remainder of the requirements as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. When a generator intends to over-manage solid waste as regulated medical waste, the solid waste shall be packaged as regulated medical waste. No change has been made in response to this part of the comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-110(B).** Stericycle supports this proposed provision. This language helps to clarify that generators are ultimately responsible for the packaging and labeling of RMW. Stericycle proposed text: *No changes – Stericycle supports this provision.*	The Board thanks the commenter for their support.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-110(D)(5)(a).** The labeling of RMW is regulated by the US Department of Transportation (DOT), under its Hazardous Materials Regulations (HMR), 49 CFR Parts 171- 180, and the Occupational Safety and Health Administration (OSHA), under its bloodborne pathogens regulations, 29 CFR § 1910.1030. State regulations regarding the labeling of federally regulated materials are preempted if they are not "substantively the same" as the HMR. *See* 49 USC § 5125; 49 CFR § 171(f). To the extent that the requirements imposed by the proposed regulations are not "substantively the same" as the HMR, they are preempted, and should be deleted from the proposed regulations. Additionally, DEQ should remove the proposed labeling requirements as indicated because complying with a patchwork of state-by-state labeling requirements is costly, unnecessarily burdensome and inefficient. Moreover, RMW handlers should be given the flexibility to move away from traditional paper labels in order to improve both sustainability and efficiency (for example, by	The Board appreciates the suggestion, but determines that the requirements as written in the proposed regulations are sufficient to protect the health, safety, and welfare of the public. The labeling requirements as written are for onsite management of regulated medical waste prior to transport. Regulated medical waste must still be packaged and labeled in accordance with the US DOT Hazardous Materials Regulations in order to be transported. In addition, nothing in the

	transitioning to use of barcodes and other electronic means of tracking). Stericycle proposed text: All regulated medical waste packaging shall be labeled in accordance with the U.S. Department of Transportation Hazardous Materials Regulations at 49 CFR Parts 171 through 180, as applicable, and 29 CFR 1910.1030. ~~The label shall be securely attached to or printed on packaging. The label may be a tag or sticker securely affixed to the package. Permanent ink shall be used to complete the information on the label. The label and the information provided on the label must be clearly legible. The following information shall be included: a. The name, address, and business telephone number of the generator. For hospitals, the label shall identify the specific department or lab where the waste originated;~~	proposed regulation prevents the use of barcodes in addition to meeting the minimum labeling requirements for onsite management of regulated medical waste. No change has been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-120(D)(4).** Stericycle generally supports this proposed provision, however the language requiring records to be maintained in accordance with 9VAC20-121-340 should be removed as significant portions of 9VAC20-121- 340 are inapplicable to transfer facilities. Stericycle proposed text: All regulated medical waste shall be stored in accordance with the following timeframes: 4. Regulated medical waste transfer stations shall store unrefrigerated regulated medical waste onsite for no more than seven calendar days. All regulated medical waste stored for more than seven calendar days must be refrigerated and stored in an ambient temperature between 35°F and 45°F (2°C and 7°C). No regulated medical waste shall be stored onsite for more than a total of 15 calendar days. ~~Records shall be maintained in accordance with 9VAC20-121-340.~~	While the Board agrees that 9VAC0-121-340 contains recordkeeping requirements for all types of facilities, transfer stations would only be required to maintain records associated with the types of activities performed on site, such as records associated with receiving and shipping waste materials. The term “as applicable” has been added to the regulatory text to clarify that facilities are responsible to maintain records as applicable for their type of operation.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-120(D)(5).** Stericycle recommends adding language that allows transfer stations and treatment facilities to track the length of time RMW is accumulated onsite by means of a “log.” This is a standard, accepted industry practice in Virginia and other states. Stericycle proposed text: All regulated medical waste shall be stored in accordance with the following timeframes: 5. Regulated medical waste transfer stations and treatment facilities shall clearly demonstrate the length of time that regulated medical waste is accumulated onsite by marking the outer packaging in permanent ink or maintaining an inventory, log, barcode, or other recordkeeping system.	The Board agrees with the comment, and the text has been clarified.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-140(B).** The proposed language regarding spill containment and cleanup kit requirements should be removed or amended. RMW handlers should be given the flexibility to tailor their	The Board appreciates the suggestion, but determines that the requirement as written in

	equipment and kits to their own needs based on their own practices, facilities, and the waste they typically handle, rather than using a one-size-fits-all approach. Stericycle proposed text: Anyone handling regulated medical waste shall maintain a spill containment and cleanup kit onsite within the vicinity of any area where regulated medical waste is managed, and the location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting regulated medical wastes are required to carry a spill containment and clean up kit in the vehicle whenever regulated medical wastes are conveyed. ~~A spill containment and cleanup kit shall consist of at least the following items: 1. Material designed to absorb spilled liquids, and the amount of absorbent material shall be that having a capacity, as rated by the manufacturer, of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in the area for which the kit is provided or 10 gallons, whichever is less; 2. In a sprayer capable of dispersing its charge in a mist and a stream at a distance, at least one gallon of an EPA-registered hospital grade disinfectant effective against mycobacteria, unless it can be demonstrated than an alternate EPA-registered disinfectant is protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected; 3. Enough red plastic bags to double enclose at least 150% of the maximum load managed (up to a maximum of 500 bags) that meet the applicable requirements of 49 CFR Part 173, including the ASTM 125 pound drop test for filled bags (D959) or an exemption approved by the U.S. Department of Transportation and are accompanied by seals and labels. These bags shall be large enough to overpack any box or container normally used for regulated medical waste management by that generator, handler, or facility; 4. Appropriate personal protective equipment, such as puncture and leak resistant gloves, safety glasses or face shield, protective coveralls or bib, protective footwear, and mask or respiratory protection as needed; and 5. For vehicles only, a first aid kit, fire extinguisher, boundary marking tape, lights, and other appropriate safety equipment.~~	the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-140(C)(4).** As noted above, although Stericycle makes best efforts to use EPA-registered disinfectants, they are not always readily available. Stericycle requests that DEQ remove the language requiring use of an EPA-registered disinfectant or add language allowing flexibility or other disinfectant options so that appropriate disinfection can occur when EPA-registered disinfectants are not readily available.	The Environmental Protection Agency (EPA) and the Food & Drug Administration (FDA) regulate the labeling and sale of disinfectants in the United States. In general, EPA regulates

	Stericycle proposed text: Following any spill or release of regulated medical waste or its discovery, the following procedures shall be implemented: … 4. Clean and disinfect all areas and materials having been contacted by regulated medical waste using a ~~an EPA-registered~~ hospital grade disinfectant effective against mycobacteria in accordance with manufacturer's label instructions, unless it can be demonstrated that an alternate ~~EPA-registered~~ disinfectant is protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected.	disinfectants and sterilants used on environmental surfaces, and FDA regulates those used on critical or semi-critical medical devices. EPA has a process to register disinfectant products, including those that are considered "hospital grade" disinfectants. In March 2020, EPA introduced temporary regulatory amendment to address supply chain disruptions for disinfectants effective against Coronavirus. These temporary regulatory flexibilities allowed the use of non-registered disinfectants during the early days of the pandemic. In September 2021, EPA announced termination of the temporary amendment due to the stabilization of the supply chain, and compliance with the permanent requirements is required by September 2022. The Board would expect EPA to exercise similar options in the future if supply chain disruptions occur again. No changes have been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-150(E).** The requirement to limit access control to persons specifically designated to manage RMW is unnecessary as long as the waste cargo, itself, is secured. Stericycle recommends amending the language to add greater flexibility to this requirement, while still ensuring the safety and security of the RMW. Stericycle proposed text: All vehicles and equipment used in the transportation of regulated medical waste must have access controls ~~that limits access to those persons specifically designated to manage regulated medical waste,~~ and the cargo carrying body must be secured except when loading and unloading.	The Board appreciates the suggestion, but determines that the requirement as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-150(J).** As noted above, although Stericycle makes best efforts to use EPA-registered	The Environmental Protection Agency (EPA)

	disinfectants, they are not always readily available. Stericycle requests that DEQ remove the language requiring use of an EPA-registered disinfectant or add language allowing flexibility or other disinfectant options so that appropriate disinfection can occur when EPA-registered disinfectants are not readily available. Stericycle proposed text: All vehicles and equipment used to transport regulated medical waste must be thoroughly cleaned and disinfected before being used for any other purpose and prior to any transfer of ownership. Disinfection shall include using a ~~an EPA-registered~~ hospital grade disinfectant effective against mycobacteria in accordance with manufacturer's label instructions, unless it can be demonstrated that an alternate ~~EPA-registered~~ disinfectant is protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected. Any areas of vehicles or equipment that are visibly contaminated, or that become contaminated as a result of a spill must be immediately decontaminated in accordance with 9VAC20-121-140.	and the Food & Drug Administration (FDA) regulate the labeling and sale of disinfectants in the United States. In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and FDA regulates those used on critical or semi-critical medical devices. EPA has a process to register disinfectant products, including those that are considered "hospital grade" disinfectants. In March 2020, EPA introduced temporary regulatory amendment to address supply chain disruptions for disinfectants effective against Coronavirus. These temporary regulatory flexibilities allowed the use of non-registered disinfectants during the early days of the pandemic. In September 2021, EPA announced termination of the temporary amendment due to the stabilization of the supply chain, and compliance with the permanent requirements is required by September 2022. The Board would expect EPA to exercise similar options in the future if supply chain disruptions occur again. No changes have been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-160(B)(4), (5).** As noted above, although Stericycle makes best efforts to use EPA-registered disinfectants, they are not always readily available. Stericycle requests that DEQ remove the language requiring use of an EPA-registered disinfectant or add language allowing flexibility or other disinfectant options so that appropriate disinfection can occur when EPA-registered disinfectants are not readily available.	The Environmental Protection Agency (EPA) and the Food & Drug Administration (FDA) regulate the labeling and sale of disinfectants in the United States. In general, EPA regulates

	Stericycle proposed text: 4. Category A waste shall not be conveyed in reusable carts or containers unless the containers are subsequently cleaned and disinfected in accordance with 9VAC20-121-130 using a ~~an EPA-registered~~ disinfectant appropriate for the type of Category A waste managed and materials being disinfected. 5. All spills of Category A waste shall be cleaned and disinfected in accordance with 9VAC20-121-140 using a ~~an EPA-registered~~ disinfectant appropriate for the type of Category A waste managed and the materials being disinfected.	disinfectants and sterilants used on environmental surfaces, and FDA regulates those used on critical or semi-critical medical devices. EPA has a process to register disinfectant products, including those that are considered "hospital grade" disinfectants. In March 2020, EPA introduced temporary regulatory amendment to address supply chain disruptions for disinfectants effective against Coronavirus. These temporary regulatory flexibilities allowed the use of non-registered disinfectants during the early days of the pandemic. In September 2021, EPA announced termination of the temporary amendment due to the stabilization of the supply chain, and compliance with the permanent requirements is required by September 2022. The Board would expect EPA to exercise similar options in the future if supply chain disruptions occur again. No changes have been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-220(A).** The requirements in this section should not universally apply to RMW transfer stations. Several of the requirements—including a water supply and a bermed pavement or liquid retaining lip—may be impracticable for transfer stations, which according to the proposed regulatory definition can include even parked vehicles transporting RMW. Moreover, as the agency noted, radiation detectors can cost between $6,000 and $8,000, plus periodic maintenance and calibration costs. It is unnecessarily costly and burdensome to require this equipment at all RMW transfer facilities. Stericycle proposed text: The design and construction of all regulated medical waste ~~transfer stations or~~	The Board appreciates the suggestion, but determines that the requirement as written in the proposed regulations are necessary to protect the health, safety and welfare of the public. No change has been made in response to this comment.

	treatment facilities shall be governed by the standards set forth in this section. These facilities shall have: …	
Cara Simaga, Stericycle, Inc.	**9VAC20-121-230(E).** As noted above, although Stericycle makes best efforts to use EPA-registered disinfectants, they are not always readily available. Stericycle requests that DEQ remove the language requiring use of an EPA-registered disinfectant or add language allowing flexibility or other disinfectant options so that appropriate disinfection can occur when EPA-registered disinfectants are not readily available. Stericycle proposed text: All facilities that manage reusable carts or containers for regulated medical waste shall comply with the requirements of 9VAC20-121-130 and maintain onsite an adequate water supply and sufficient quantity of detergent and ~~EPA-registered~~ disinfectant or other approved materials, as applicable.	The Environmental Protection Agency (EPA) and the Food & Drug Administration (FDA) regulate the labeling and sale of disinfectants in the United States. In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and FDA regulates those used on critical or semi-critical medical devices. EPA has a process to register disinfectant products, including those that are considered "hospital grade" disinfectants. In March 2020, EPA introduced temporary regulatory amendment to address supply chain disruptions for disinfectants effective against Coronavirus. These temporary regulatory flexibilities allowed the use of non-registered disinfectants during the early days of the pandemic. In September 2021, EPA announced termination of the temporary amendment due to the stabilization of the supply chain, and compliance with the permanent requirements is required by September 2022. The Board would expect EPA to exercise similar options in the future if supply chain disruptions occur again. No changes have been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-230(K)(4).** The timeframe proposed here is too short and overly burdensome. For certain categories of unauthorized waste, it can take substantially longer than 10 days to identify and	The number of days that unauthorized waste is allowed to remain on site is consistent with other

	contract with an appropriate vendor for removal and/or management of the waste. Stericycle recommends allowing at least 30 days to remove unauthorized waste that has been appropriately separated from the RMW and stored. Stericycle proposed text: Any unauthorized waste accepted by the owner or operator shall be managed in accordance with applicable federal or state laws and regulations. The facility must carefully store the waste in a designated storage area within the facility separate from untreated regulated medical waste and treated regulated medical waste. Unauthorized waste that has been segregated and stored shall be adequately secured and contained to prevent leakage or contamination to the environment. The facility shall have the unauthorized waste removed or properly managed as soon as practicable, but no later than ~~10~~ 30 calendar days after discovery or an alternate timeframe as approved by the department for certain waste types. Handling and management of the unauthorized waste, including segregation, removal, and transportation, shall be by a person authorized to manage such waste and shall be transferred, treated, or disposed of at a permitted waste management facility approved to receive it.	limitations on the storage of untreated waste in other parts of the regulation. In addition, the facility owner/operator's unauthorized waste plan should anticipate the types of unauthorized wastes it could receive and have general plans in place for managing those wastes. The Board will retain the 10-day limitation but amend the proposed text to provide for the opportunity for a permittee to request an extension of up to 30 days.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-230(V)(1-6).** The language requiring training on challenge testing for all facility operators should be removed. Challenge testing training is not generally necessary or considered an industry best practice for all personnel. Stericycle proposed text: Prior to managing regulated medical waste or using process equipment, and at least annually, within one year from the date of the last training, the facility shall provide all operators with training on the procedures for managing regulated medical waste specific to the transfer or treatment process used, including: 1. General handling of regulated medical waste and use of personal protective equipment; 2. Packaging, labeling, and storage of regulated medical waste; 3. Cleaning and disinfection of reusable containers; 4. Facility housekeeping and management of spills; 5. Overall process and mechanical operation of any equipment used, including operation of any treatment units ~~and procedures for conducting periodic challenge testing~~; and 6. Emergency contingency plan procedures, in case of system failure or other emergency.	The Board agrees and regulatory text was modified to limit training on treatment equipment and challenge testing to treatment facility operators.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-240(B)(1).** Stericycle recommends that the proposed regulations require segregation of pathological waste and trace chemotherapy waste, as well as specific treatment processes for each of these waste streams. In addition, Stericycle recommends adding language to the proposed rule requiring generators to segregate and label this waste to help ensure proper treatment and handling procedures are	The proposed regulation requires generators of regulated medical waste to identify and segregate wastes. In addition, the regulation references the applicability of other regulations. No changes

	utilized. Many medical waste treatment facilities already routinely accept pathological and trace chemotherapy waste - those waste streams should be removed from the definition of "unauthorized waste" and instead DEQ should add these segregation and treatment requirements. (See also Stericycle's comments to proposed section 9VAC20-121-10, above). Stericycle proposed text: "Pathological waste" means all tissues, organs, limbs, products of conception, and other body parts removed from the whole body, including but not limited to: (1) tissues; organs; secretions; excretions; blood; bodily fluids; body parts; or body parts removed during surgery, autopsy, or other medical procedure (with the exception of human teeth), and (2) contaminated animal tissue, including animal carcasses, organs, and body parts, that have been exposed to pathogens in research, were used in the production of biologicals or the in vivo testing of pharmaceuticals, or that died of a known or suspected infectious disease. Pathological waste: The secondary container used for pathological waste shall be labeled with the word "Pathological Waste" or "PATH" or other label approved by the Department. Labels shall be placed on the lid and all sides of the container so as to be readily visible from all directions. "Trace chemotherapy waste" means waste contaminated through contact with, or having previously contained, chemotherapeutic agents, including but not limited to gloves; disposable gowns; towels or wipes; intravenous solution bags and attached tubing that are empty. Trace chemotherapy waste: The secondary container used for chemotherapy waste shall be labeled with the word "Chemotherapy Waste" or "CHEMO" or other label approved by the Department. Labels shall be placed on the lid and all sides of the container so as to be readily visible from all directions. Sharps waste contaminated through contact with, or having previously contained, chemotherapeutic agents shall be placed in a sharps container labeled in accordance with the above requirements. Generators shall segregate and label waste according to type (including pathological, trace chemotherapy, and non-hazardous pharmaceutical wastes) to facilitate the appropriate and effective ~~The~~ treatment method and operating parameters ~~shall be appropriate and effective~~ for the type of waste being managed.	have been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-240(B)(16).** This proposed requirement is impracticable. Given the materials and volume involved, it is not possible to keep all carts and containers (including autoclave carts/bins) completely clear of treated waste residuals between cycles. Small amounts of film plastics often melt onto the insides of	The Board agrees with the comment, and the text has been revised.

	autoclave carts during the treatment process. It is not feasible to remove this melted plastic. Stericycle requests that DEQ remove this requirement or amend the language to allow for a more practicable maintenance plan and/or a de minimis amount of residual material that will nonetheless not affect the equipment's performance. Stericycle proposed text: ~~Reusable treatment carts and containers (such as autoclave carts) shall be clean and free of treated waste residuals before reuse.~~	
Cara Simaga, Stericycle, Inc.	**9VAC20-121-240(C)(1).** The best method for determining efficacy is through validation testing. Establishing operating parameters in the absence of such testing does not guarantee efficacy. The term "a large quantity of liquid" is impractically vague. "Large quantity" is not defined. Even if the term were to be defined, a treatment facility cannot—and for safety reasons should not—open containers of RMW to attempt to quantify the amount of liquid present in any particular autoclave cart/bin. Stericycle proposed text: All autoclaves shall be operated at ~~100% saturated steam conditions at a minimum operating temperature of 250°F (121°C) at no less than 15 pounds per square inch of gauge pressure. Autoclaves shall maintain the minimum operating temperature and pressure for an uninterrupted cycle of 90 minutes. Alternate~~ <u>appropriate</u> combinations of operating temperatures, pressures, and cycle times <u>that have been</u> ~~may be~~ demonstrated through validation testing to achieve a reliable and complete kill of all microorganisms in regulated medical waste at design capacity. ~~Longer steam sterilization times are required when a load contains a large quantity of liquid.~~	The Board agrees validation testing is needed to demonstrate the efficacy of treatment for various operating temperatures, pressures and cycle times, but still determines the provided example of operating conditions does not prevent alternate operating conditions. The text has been reworded to require autoclave operation at conditions that are demonstrated through site-specific validation testing to achieve reliable and effective treatment of the waste stream, instead of requiring a standard set of autoclave operating conditions. Minimum temperature and pressure are still specified based on accepted industry practice. As to the statement regarding liquids in the loads, the facility should be familiar with the regulated medical waste being treated to know if there are liquids, without having to open bags of regulated medical waste. This statement was added to reiterate that wet loads may require longer cycle times to achieve effective treatment. The regulatory

		text has been revised for clarification.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-280(D)(1-3).** The provision requiring specific language in contracts between RMW treatment facilities and solid waste transfer and disposal facilities should be removed. Although Stericycle understands and respects the state's authority to require RMW treatment facilities to send treated waste to appropriate transfer facilities and end disposal locations, the terms of the agreements between these entities are private contracting matters outside to scope of DEQ's regulatory authority. Moreover, for RMW companies such as Stericycle, that operate in multiple states, state-by-state regulations that dictate specific contract terms are unmanageable. Stericycle proposed text: ~~The regulated medical waste treatment facility shall have a written agreement with each permitted solid waste management facility that will transfer, store, or dispose of the treated waste. The agreement shall specify and include the following: 1. A description of how the treated waste will be packaged and transported to each solid waste management facility, including the types and colors of bags or containers used, and any special labeling if applicable; 2. The type of regulated medical waste treated, treatment method, and name, address, and telephone number of the treatment facility; and 3. The name, address, and telephone number of any transfer stations or other intermediate facilities or locations where the treated waste will be transferred or temporarily stored prior to transport to a permitted solid waste disposal facility.~~	The intent of the regulation was to make sure regulated medical waste treatment facilities coordinate with the waste management facilities handling the treated waste so they are familiar with the treatment process and wastes that will be received in order to distinguish between treated and untreated waste. Regulatory text has been changed to require the treatment facility to provide a treated waste disposal plan to receiving waste management facilities and document the distribution of the plan.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-290(A)(1).** As noted above, although Stericycle makes best efforts to use EPA-registered disinfectants, they are not always readily available. Stericycle requests that DEQ remove the language requiring use of an EPA-registered disinfectant or add language allowing flexibility or other disinfectant options so that appropriate disinfection can occur when EPA-registered disinfectants are not readily available. Stericycle proposed text: When a unit that has been used for regulated medical waste management is to cease operations involving regulated medical waste, the unit and all related equipment, structures, and surfaces shall be thoroughly cleaned and disinfected. Cleaning shall be conducted with detergent and water. At a minimum, disinfection shall include using <u>a</u> ~~an EPA-registered~~ hospital grade disinfectant effective against mycobacteria in accordance with manufacturer's label instructions, unless it can be demonstrated to the satisfaction of the department that an alternate ~~EPA-registered~~ disinfectant will be protective of human health and the environment and is appropriate for the type of regulated medical waste managed and surfaces being disinfected.	The Environmental Protection Agency (EPA) and the Food & Drug Administration (FDA) regulate the labeling and sale of disinfectants in the United States. In general, EPA regulates disinfectants and sterilants used on environmental surfaces, and FDA regulates those used on critical or semi-critical medical devices. EPA has a process to register disinfectant products, including those that are considered "hospital grade" disinfectants. In March 2020, EPA introduced temporary regulatory amendment to address

		supply chain disruptions for disinfectants effective against Coronavirus. These temporary regulatory flexibilities allowed the use of non-registered disinfectants during the early days of the pandemic. In September 2021, EPA announced termination of the temporary amendment due to the stabilization of the supply chain, and compliance with the permanent requirements is required by September 2022. The Board would expect EPA to exercise similar options in the future if supply chain disruptions occur again. No change has been made in response to this comment.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-300(C)(2).** This threshold for a new permit-by-rule is overly broad and unworkably vague, as it does not provide regulated entities any metrics for understanding what the department would consider to be a "substantial" change in design or process. Stericycle proposed text: A new permit-by-rule is required when there is: ~~Any change in design or process of a regulated medical waste management facility that will, in the opinion of the department, result in a substantially different type of facility.~~	The Board has revised the text to provide additional regulatory text to clarify what would constitute a new PBR facility as opposed to a PBR modification as discussed in 9VAC20-121-310 A 6.
Cara Simaga, Stericycle, Inc.	**9VAC20-121-340(G), (H).** The requirements in these sections are vague in that they appear to apply to treatment facilities and generators respectively, but do not state this explicitly. Stericycle proposes adding these clarifications. Stericycle proposed text: G. If a treatment facility receives regulated medical waste ~~is received~~ from offsite, the treatment facility shall maintain records ~~shall be maintained~~ for three years following receipt of the waste and shall include the date of receipt, name of each offsite generator, transporter, type and quantity (weight or volume) of waste received, and dates of subsequent treatment onsite or shipment offsite. The treatment facility shall maintain a signed certificate, contract, or equivalent document for each load or inclusive of all loads received from offsite in which the generator affirms that the load does not contain hazardous waste or radioactive materials, unless the facility is permitted to receive those types of wastes.	The Board determines that the requirements as written are sufficient and meant to apply to any facility receiving or shipping waste as applicable, whether they are a treatment facility or transfer station. No change has been made to the regulation in response to this comment.

	H. If regulated medical waste is shipped or transferred offsite, the generator facility shall maintain records, including copies of all shipping papers, specifying the date of shipment, type, and quantity (weight or volume) of waste removed from the site and the names, addresses, and telephone numbers of both the transporters and the destination facility receiving the shipments for treatment or disposal.	
Cara Simaga, Stericycle, Inc.	Additionally, Stericycle supports DEQ's removal of the requirement to shred treated RMW. Shredding is not necessary prior to disposal and adds additional expense and complication.	The Board thanks the commenter for their support.
Anne Germain, and Darrel K. Smith, Healthcare Waste Institute of the National Waste & Recycling Association (NWRA HWI)	Section 9VAC20-121-40 Applicability Part B of this section requires that all existing regulated medical waste management facilities must submit a complete permit application within six months after the effective date of this regulation to come into compliance with this chapter. While HWI members support many of the changes in the regulations, we do not support the requirement for a new application to be submitted by existing facilities with current permits. Rather, we recommend that existing permittees be instead required to comply with the new regulations upon permit renewal.	The regulatory text has been clarified to outline what permit applications for existing facilities will need to include. Public participation will not be required for existing facilities to comply with the regulations unless the updated application includes changes that result in a different type of facility (e.g. change from transfer to treatment facility or change from captive to non-captive facility). The time frame for PBR application submittal is also extended to 18 months. As part of this amendment, the permit procedures for all types of facilities have been made more consistent, and the regulation no longer distinguishes "on-site" PBRs from "offsite" PBRs. In addition, on-site PBRs did not previously require a 10-year renewal. Therefore, a set timeframe for submittal of PBR applications by all existing facilities has been outlined in the regulation. The Board determines that a six month time frame may be impractical or difficult for facilities; therefore, the timeframe for submittal of the application is

		extended to 18 months. The extended time frame will also allow DEQ time to provided training and compliance assistance.
Anne Germain, and Darrel K. Smith, NWRA HWI	Section 9VAC20-121-120. Storage of regulated medical waste. HWI supports requirements to limit storage of regulated medical waste. However, the storage time for small generators is very limited. We recommend increasing the storage time to 90 days. In addition, we recommend that onsite storage for both RMW treatment facilities and transfer stations be ten days.	The Board determines the proposed storage requirements for small generators (less than 250 gallons) is reasonable and protective. Additionally, treatment facilities may store RMW for no more than 10 days, and transfer stations may store RMW up to 15 days provided waste is refrigerated after seven days. No change has been made in response to this comment.
Anne Germain, and Darrel K. Smith, NWRA HWI	Section 9VAC20-121-240. Treatment standards. B.16 of this section requires that reusable treatment containers (autoclave bins) be clean and free of residuals before reuse. Often when being treated small amount of film plastics will melt onto the insides of the containers. Cleaning methods do not remove this melted plastic. We recommend that the language be modified to provide consideration for this de minimum material.	The Board agrees with the comment, and the text has been revised.
Anne Germain, and Darrel K. Smith, NWRA HWI	Section 9VAC20-121-240. Treatment standards. C.1 of this section requires specific temperature, pressure and time for autoclave operations with alternate combinations permitted based on demonstration through validation testing. The 90 minute cycle at 250 degrees F is significantly longer and much cooler than typical. We suggest instead requiring validation testing to determine the appropriate operations parameters for each treatment facility.	The Board agrees that validation testing is critical to demonstrate appropriate operating parameters (temperature, pressure, and cycle times) for effective treatment of regulated medical waste. The text has been revised to clarify; however, minimum operating criteria for temperature and pressure in accordance with standard accepted industry practice has been left in the regulations.
Anne Germain, and Darrel K. Smith, NWRA HWI	Section 9VAC20-121-240. Treatment standards. C.3 of this section requires a minimum of three pre-vacuum cycles to be conducted. Typically, there are three vacuum cycles are conducted: once at the beginning, once at the end of the pre-heat cycle and a final time at the end of the final heat cycle. However,	Pulling multiple vacuums prior to the residence phase of the treatment cycle conditions the waste and its packaging to ensure that all portions

	there are not three “pre”-vacuum cycles. We suggest removing the prefix “pre” from the language.	of the waste in the treatment unit receive adequate steam exposure. Adequate steam exposure ensures that minimum temperatures necessary for effective treatment are achieved in all portions of the waste in the treatment unit. The text has been revised to require a minimum of two pre-vacuums, unless (based on the results of validation testing), additional vacuum is needed for certain waste or packaging types.
Curtis Knisley	9VAC20-121-40 Applicability, Paragraph B. The cost involved with re-permitting were in the $10,000-$20,000 range, just for the engineering firm to certify the facility, format and submit the application. This is an extremely high cost for small medical waste transporters with a small transfer station. The only change in our permit would seem to be the addition of radiation detectors. This brings me to my next concern.	As part of this amendment, the permit procedures for all types of facilities have been made more consistent, and the regulation no longer distinguishes “on-site” PBRs from “offsite” PBRs. The Board determines that updating permit-by-rule applications are necessary to ensure compliance with the new regulations and to protect the health, safety and welfare of the public. The regulatory text has been revised to give more time to existing permitted facilities (i.e. eighteen months instead of the proposed six months after the regulation becomes effective) to submit updated permit applications to come into compliance with the new regulation.
Curtis Knisley	9VAC20-121-220 Design and construction requirements, Number 12. Ludlum Radiation Monitoring Systems were running about $11,000.00 in 2020. With inflation I am sure that price has climbed to close to $15,000.00. Installation is not included in the cost but, would run at least another $5,000.00. For transfer stations that only accept waste	The Board determines that any non-captive regulated medical waste facility (i.e. facilities that receive waste from offsite), should be equipped with radiation

	from customers, whose businesses they are familiar with, through transporter collection, radiation monitors seem like an unnecessary burden. I could understand if the medical waste transfer station was accepting waste from haulers that were not associated with the transfer station.	detectors to ensure that unauthorized (radioactive) waste is not received unknowingly. No changes were made in response to this comment.
Curtis Knisley	Another issue not addressed in the regulations is the difficulty in finding licensed operators. Since the Board of Waste Management Facility Operators went to a closed book test, very few individuals have been able to pass the test, leaving a shortage of operators. Many had hoped that the requirement for Medical Waste Transfer Station Operators, to be licensed, would be going away. In most Medical Waste Transfer Stations containers are not even opened, just transferred from collection vehicles to long-haul trailers. The license requirement, (as long as the Board of Waste Management Facility Operators continues to not allow open book tests) for Medical Waste Transfer Stations may end up being the reason transfer stations begin to close.	The requirement for the facility to be operated by a licensed waste management facility operator (WMFO) is a statutory requirement (§10.1-1408.2 of the Code of Virginia). Changes to the Code of Virginia can only be accomplished through action by the Virginia General Assembly. In addition, 18VAC155-20-110.A.3 of the Department of Professional and Occupational Regulation's WMFO Regulations (which is not part of this regulatory amendment) requires individuals operating a facility regulated under the Regulated Medical Waste Management Regulations to hold a Class III license. State law does not provide DEQ or the Virginia Waste Management Board with the authority to revise licensing criteria or examination procedures for waste management facility operators. Under §54.1-2211 of the Code of Virginia, the Board for Waste Management Facility Operators promulgates regulations and standards for the training and licensing of operators. No change has been made to the regulation in response to this comment.

Sharon L. Baumann, Department of Defense (DoD)	**1. 9VAC20-121-10 Definitions, Hazardous Material** **Comment:** The DoD is concerned that the definition does not fully encompass the U.S. Department of Transportation definition of hazardous material and may result in confusion to the reader. **Discussion:** The U.S. Department of Transportation definition of hazardous material is more definitive and descriptive. **Recommendation:** The following revision to the definition of a "Hazardous Material" is provided for consideration in order to provide clarity. **Recommended Definition:** "Hazardous material" means a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and is designated as hazardous under section 5103 of the Federal hazardous materials transportation law (49 U.S.C. 5103).	The Board appreciates the suggestion, but determines that the definition as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Sharon L. Baumann, DoD	**2. 9VAC20-121-10 Definitions, Sharps** **Comment:** The DoD is concerned that the definition, as written, is more inclusive than needed for protection of human health for the discard of unused sharps contained in its original inner and outer packaging. **Discussion:** Including discarded unused sharps contained in its original inner and outer packaging subjects these items to the Regulated Medical Waste regulations that provide no additional protection of human health. The industry standard for treating sharps is autoclaving, followed by placement in landfills. Excluding unused sharps from 9VAC20-121-10 would maintain consistency with the Department of Transportation's definition of sharps in 49 CFR 173.134(a)(6). **Recommendation:** The following revision to the definition of "Sharps" is provided for consideration along with the regulatory citation, 49 CFR 173.134(a)(6): **Recommended Definition:** "Sharps" means needles, scalpels, knives, lancets, syringes with attached needles, suture needles, pasteur pipettes, broken glass, broken rigid plastic, and similar items having a point or sharp edge or that are likely to cause percutaneous injury or break during transportation and result in a point or sharp edge that may puncture or compromise the integrity of the container. Discarded unused sharps contained in its original liner and outer packaging are excluded from this definition. 49 CFR 173.134(a)(6) Sharps means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. Sharps includes needles, syringes, scalpels, broken glass, culture slides, culture dishes,	The Board agrees with the comment, and the text has been clarified.

	broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.	
Sharon L. Baumann, DoD	**3. 9VAC20-121-160.C, Management of Category A Waste** **Comment:** The DoD is concerned that the regulation does not provide definitive guidance that clarifies the packaging and labeling standard. **Discussion:** The packaging and labeling standard should meet the current United Nations standards/provisions for UN3549, Category A waste, and not the older standards used during the Ebola crisis. **Recommendation:** The following revision to 9VAC20-121-160.C is provided for consideration to provide additional clarity. **Recommended Language:** Waste Transporter Information and Responsibilities for Category A waste are specified in Section 6 of Managing Solid Waste Contaminated with a Category A Infectious Substance. Packaging and labeling of Category A waste for transport must comply with the "packaging and labeling provisions applicable to United Nations requirements noted under UN3549, "Medical waste, category A, affecting animals only, solid" or "Medical waste, category A, affecting humans, solid".	The Board appreciates the suggestion, but determines that the requirement as written in the proposed regulations are sufficient to protect the health, safety and welfare of the public. No change has been made in response to this comment.
Sharon L. Baumann, DoD	**4. 9VAC20-121-240. B.1.a, Treatment standards** **Comment:** The word "noncombustible" should replace "noncombustion" for correctness.	The text has been revised to clarify that human pathological and anatomical waste shall be treated by incineration or other method as approved by the Department.
Sharon L. Baumann, DoD	**5. 9VAC20-121-240.B.8, Treatment standards** **Comment:** The DoD is concerned that the regulation does not provide clarity for operation of any treatment unit. **Discussion:** The regulation is too generic and may not include specific information for operation of any treatment unit. **Recommendation:** The following revision to 9VAC20-121-240.B.8 is provided for your consideration: **Recommended Language:** Prior to operation of any treatment unit, the facility must conduct validation testing in accordance with 9VAC20-121-260 and an approved treatment plan to establish the appropriate operating parameters for effective treatment of regulated medical waste. The results of the testing must be submitted to the department for review and approval in accordance with 9VAC20-121-320. The facility shall not receive or treat regulated medical waste until the department has approved the validation results, operating parameters, and protocols to be used for the treatment unit. Revalidation shall be conducted as required by 9VAC20-121-260. Use of bioassays to	9VAC20-121-240 B 1 d of the regulation already includes text similar to the suggested revision requiring toxin inactivation procedures to include the use of bioassays during validation testing. No changes have been made in response to this comment.

	validate the effectiveness of toxin inactivation is necessary to meet required protocols and should not be assumed.	
Jason Folker	**RMW /Testing Concerns** My concern is indirectly related to the new proposed regulations and as required by § 10.1-1408.2 of the Code of Virginia, a regulated medical waste management facility must have at least one operator licensed by the Board for Waste Management Facility Operators. To obtain the license, it requires passing a test which covers several hundred pages of regulations. I have not received one justifiable reason for changing the test from open book, to closed book testing, after inquiring several times. The ability to memorize several hundred pages of regulations and recall for a test does not seem to be a good demonstration of comprehension. Regulations were made to be referenced, and the test should be an indicator of one's ability to locate and make applicable to a specific situation or question. The closed book test seems to intentionally eliminate candidates or potential operators, which in turn eliminates more jobs, greater impacting the small businesses within the proposed medical waste arena.	State law does not provide DEQ or the Virginia Waste Management Board with the authority to revise licensing criteria or examination procedures for waste management facility operators. Under §54.1-2211 of the Code of Virginia, the Board for Waste Management Facility Operators promulgates regulations and standards for the training and licensing of operators. No change has been made to the regulation in response to this comment.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
9VAC20-121-10		Defines autoclave as a sterilization process.	Defines autoclave as a treatment process.	The word "sterilization" has been replaced with the word "treatment." The word "sterilization" implies inactivation of 100% of applicable microbes whereas effective treatment of regulated medical waste must achieve a 6 Log 10 (99.9999%) or greater reduction of applicable microbes. The revised term is more precise and improves clarity.
9VAC20-121-10		Defines body fluids and clarifies that the term "body	Defines body fluids and clarifies that the term "body fluids" does	Replaced "toenail" with "nail." Nail clippings includes both fingernail clippings and toenail clippings. Neither are considered body

		fluids" does not include toenail clippings.	not include nail clippings.	fluids, and are therefore not considered regulated medical waste. This replacement makes this exclusion to the definition more correct.
9VAC20-121-10		Defines the term sharps.	Revises the definition of sharps to be similar to 49 CFR 173.134(a)(6) of the US DOT Hazardous Materials Regulations and excludes unused (uncontaminated) sharps in the original packaging from the definition.	This clarification ensures that these regulations are more consistent with federal transportation regulations, which will reduce confusion and make it easier for the regulated community to identify regulated medical waste.
9VAC20-121-10		Defines unauthorized waste and provides examples.	Defines unauthorized waste, provides examples, and clarifies that the types of wastes that are considered unauthorized waste are site-specific.	The definition of unauthorized waste has been revised to provide more flexibility in what is considered authorized or unauthorized waste considering the facility's site-specific conditions and permit allowances.
9VAC20-121-40 B	9VAC20-121-40 B 1-9	Provides 6 months for existing permitted facilities to submit a new permit application to come into compliance with the new regulations.	Provides 18 months for existing permitted facilities to submit an updated permit application and outlines what documents need to be submitted to come into compliance with the new regulations. Public participation will not be required for existing facilities unless the updated application includes changes that result in a different type of facility.	The proposed regulations eliminate the requirement for 10-year permit renewal; therefore, a set time frame for submittal of updated permit applications has been outlined in the regulation. The time frame for existing facilities to submit updated permit applications to come into compliance with the new regulations has been extended from 6 months to 18 months. The regulatory text has also been revised to clarify that permit applications for existing facilities will not need to include public participation unless the facility type is changing. The Board has determined that a six month time frame may be impractical or difficult for facilities and the extended time will also allow DEQ time to provided training and compliance assistance.

9VAC20-121-70 D 3		Requires public notice of certain documents to be provided on the department's internet website.	Requires public notice of certain documents to be provided on the department's website.	The word "internet" was removed as it is not necessary for the interpretation of the requirement. Necessary to correct a typographical error.
9VAC20-121-90 B 2 d		Identifies the types of sharps that are considered regulated medical waste.	Identifies the types of sharps that are considered regulated medical waste, using terminology that is similar to 49 CFR 173.134(a)(6) of the US DOT Hazardous Materials Regulations.	The text has been clarified for consistency with the revised definition of "sharps" and for consistency with the federal transportation regulations. Necessary to interpret this requirement correctly.
9VAC20-121-90 C 4		Identifies that human remains are not solid waste or regulated medical waste under conditions meeting all of 4 criteria.	Identifies that human remains that meet any one of 4 conditions are not solid waste or regulated medical waste.	The text has been revised to clarify that each of the items under subdivision 4 represent separate exempt scenarios and are not dependent upon each other. Necessary to correct a typographical error that had inadvertently changed the meaning of this requirement.
9VAC20-121-90 C 8		Exempts used health care products and contaminated medical devices or equipment when reprocessed in accordance with FDA requirements	Two criteria specify conditions under which used health care products and contaminated medical devices or equipment being sent offsite for recycling or disposal are regulated medical waste.	The text has been revised to clarify that not all used health care products and contaminated medical devices or equipment being sent offsite for recycling or disposal are regulated medical wastes, but rather only those that meet the specific criteria for the identification of regulated medical waste under 9VAC20-121-90 B. Necessary to make the requirement properly specific.
9VAC20-121-90 C 10		Exempts certain tissue blocks fixed in paraffin or similar embedding materials for examinations and requires subsequent management	Certain fixed tissue blocks that are no longer needed may be managed and disposed of as solid waste, but may be managed more stringently.	The text has been revised to allow generators the flexibility to manage certain fixed tissue blocks as either solid waste or regulated medical waste to provide more options for disposal (e.g. incineration, when appropriate). Necessary to correct a typographical error that had inadvertently changed the meaning of this requirement.

		and disposal as solid waste.		
9VAC20-121-90 D 1 a		Prohibits treated waste from being packaged as regulated medical waste.	Prohibits treated waste from being repackaged as regulated medical waste.	The word “packaged” has been replaced with the word “repackaged.” The text has been revised to recognize that the packaging of some regulated medical waste may remain intact even after proper treatment, and because it has been treated, it may be disposed of as solid waste. If the waste is repackaged as regulated medical waste, it shall be managed as regulated medical waste. Necessary to clarify requirement.
9VAC20-121-90 D 3		Identifies solid wastes which are not considered regulated medical waste, including toenail clippings.	Identifies solid wastes which are not considered regulated medical waste, including nail clippings.	Replaced “toenail” with “nail.” Nail clippings, including both fingernail clippings and toenail clippings, are not considered regulated medical waste. Necessary to correct and clarify the list of solid wastes not considered regulated medical waste.
9VAC20-121-90 D 6		Identifies solid wastes that are not considered regulated medical waste, excluding unused or expired sharps.	Identifies solid wastes that are not considered regulated medical waste, including unused or expired (and uncontaminated) sharps in the original packaging.	Inserted “unused sharps in the original packaging” and deleted “This does not apply to unused or expired sharps, which are a regulated medical waste in accordance with 9VAC20-121-90 B 2 d.” This clarification ensures that these regulations are more consistent with federal transportation regulations. Necessary to clarify which sharps are not regulated medical wastes.
9VAC20-121-90 D 12		Exempts waste generated from the care of an animal by its owner and specifies that some veterinary wastes, such as sharps, are still regulated medical waste.	Exempts waste generated from the care of an animal by its owner and clarifies that waste generated through veterinary practice is only regulated medical waste if it meets either of the two criteria of regulated medical waste under 9VAC20-121-90 B.	The text has been revised to clarify that the exemption for animal care waste is not limited to only household and farm locations, and that not all waste generated by veterinary practice is regulated medical waste but rather only those that meet the specific criteria for the identification of regulated medical waste. Necessary to ensure that the requirements are interpreted properly.

9VAC20-121-100 B		Requires regulated medical waste to be identified and segregated from other waste.	Requires the generator to identify and segregate regulated medical waste from other waste.	The text has been revised to clarify that the generator is the entity responsible for identifying and segregating regulated medical waste from other waste. Necessary to ensure that the entity responsible is clearly specified.
9VAC20-121-120 D 3		Outlines regulated medical waste storage requirements for treatment facilities and requires recordkeeping.	Treatment facilities are required to keep records listed under 9VAC20-121-340 only insofar that they are applicable.	The referenced section of the regulations, 9VAC20-121-340 outlines recordkeeping requirements for all types of facilities. "As applicable" was added to clarify that treatment facilities would only be required to maintain records associated with the type of activities associated with receiving, treating, and shipping waste material as outlined in 9VAC20-121-340. Necessary to clarify requirement and avoid confusion in recordkeeping.
9VAC20-121-120 D 4		Outlines regulated medical waste storage requirements for transfer stations and requires recordkeeping.	Transfer stations are required to keep records listed under 9VAC 20-121-340 only insofar that they are applicable.	The referenced section of the regulations, 9VAC20-121-340 outlines recordkeeping requirements for all types of facilities. "As applicable" was added to clarify that transfer stations would only be required to maintain records associated with the type of activities associated with receiving and shipping waste material as outlined in 9VAC20-121-340. Necessary to clarify requirement and avoid confusion in recordkeeping.
9VAC20-121-120 D 5		Requires transfer stations and treatment facilities to track the length of time regulated medical waste is stored onsite.	A "log" is another allowable method for tracking the length of time regulated medical waste is stored onsite.	The text has been revised to clearly specify that a "log" may be used by transfer stations and treatment facilities to track the length of time regulated medical waste is stored onsite. This is a standard, accepted industry practice and is necessary to retain flexibility in demonstrating compliance.
9VAC20-121-230 K 4		Requires removal of unauthorized waste within 10 days of discovery.	Requires removal of unauthorized waste within 10 days of discovery, but allows a department-approved	Provides the owner/operator additional time to make arrangements for the management of wastes when the department determines that national treatment capacity is constrained or where pre-existing plans are not in place and

			alternate timeframe of up to 30 days for removal of unauthorized waste.	approves an alternative timeframe. Necessary to provide alternatives when the 10-day timeframe is not feasible.
9VAC-20-121-230 V 5 & 6	9VAC20-121-230 V 5, 6 & 7	Outlines annual training requirements for operators of transfer stations and treatment facilities.	Outlines annual training requirements for operators of transfer stations and treatment facilities, and clarifies which training requirements are applicable to treatment facility operators only.	Training requirements for permitted facilities were modified to limit training on treatment equipment and challenge testing to treatment facility operators. Necessary to clarify that since not all permitted facilities operate treatment units and do challenge testing, training requirements should be limited to those that do.
9VAC20-121-240 B 1 a		Prohibits treatment of human pathological and anatomical waste and animal carcasses by a noncombustion process unless approved by the department.	Requires human pathological and anatomical waste and animal carcasses to be treated by incineration unless an alternative treatment process is approved by the department.	The text has been reworded to clarify that human pathological and anatomical waste and animal carcasses shall be treated by incineration or other method as approved by the Department. Necessary to more clearly specify allowed treatment methods and ensure the requirements are interpreted properly.
9VAC20-121-240 B 16		Requires reusable treatment carts and containers (such as autoclave carts) to be clean and free of treated waste residuals before reuse.	Requires reusable treatment carts and containers to be cleaned on a periodic basis to remove the buildup of more than de minimis amounts of treated waste residual on cart and container surfaces.	Reworded to specify how reusable treatment carts and containers shall be kept clean and free of treated waste residuals. Necessary because the original requirement was impractical and difficult to achieve.
9VAC20-121-240 C 1		Requires autoclaves to be operated at minimum operating temperatures, pressures, and cycle times, and alternate	Requires autoclaves to be operated at temperatures, pressures, and residence times that are demonstrated through validation	Reworded to require autoclave operation at conditions that are demonstrated through site-specific validation testing to achieve reliable and effective treatment of the waste stream, instead of requiring a standard set of autoclave operating conditions. Minimum temperature

		parameters may be demonstrated through validation testing to achieve effective treatment of regulated medical waste.	testing to achieve effective treatment of regulated medical waste. The minimum autoclave operating temperature and pressure allowed by the regulation is 250^{o}F at 15 psi.	and pressure are specified based on accepted industry practice. The possibility of needing longer treatment cycles to treat wet loads is also emphasized. This is necessary to ensure that facilities have the flexibility to adapt the treatment method to operating conditions that are demonstrated to be effective.
9VAC20-121-240 C 3		Requires pulling three vacuums prior to the residence phase of an autoclave treatment cycle.	Requires pulling two vacuums prior to the residence phase of an autoclave treatment cycle, unless additional vacuum is required as determined through validation testing to ensure adequate steam exposure to a particular waste or packaging type.	The text has been revised to require a minimum of two (instead of three) pre-vacuums, unless based on the results of validation testing, additional vacuum is needed to ensure adequate steam exposure for certain waste or packaging types. Pulling multiple vacuums prior to the residence phase of the treatment cycle conditions the waste and its packaging to ensure that all portions of the waste in the treatment unit receive adequate steam exposure. Adequate steam exposure ensures that minimum temperatures necessary for effective treatment are achieved in all portions of the waste in the treatment unit.
9VAC20-121-250 G 1 a		Requires applicant to provide a description of the wasteload composition as part of an alternate treatment technology application.	Requires applicant to provide a description of the waste load composition as part of an alternate treatment technology application.	“Wasteload” (1 word) was revised to “waste load” (2 words). Necessary to correct a typographical error.
9VAC20-121-260 C 2		Requires surrogate wasteload configuration used in validation testing to be consistent with the configuration	Requires surrogate waste load configuration used in validation testing to be consistent with the configuration anticipated to be used during routine operation.	“Wasteload” (1 word) was revised to “waste load” (2 words). Necessary to correct a typographical error.

		anticipated to be used during routine operation.		
9VAC20-121-260 E 2		Requires thermochemical recording devices (e.g. data loggers or thermocouples) to be used during validation testing.	Clarifies the minimum number of thermochemical recording devices required during validation testing.	The text has been revised to clarify how many thermochemical recording devices shall be used during validation testing in accordance with standard, accepted industry practice. The number of devices used during validation testing is critical to gather enough data to determine appropriate operating parameters that will result in effective treatment of all waste and waste types in the treatment unit. Necessary to make the requirement properly specific and ensure effective treatment of regulated medical waste.
9VAC20-121-280 D 1-3	9VAC20-121-280 D 1-5	Treatment facilities are required to have written agreements with permitted solid waste management facilities receiving the treated waste.	A treated waste disposal plan containing the elements formerly required in the written agreement must be provided to facilities receiving treated waste. The plan must be updated and redistributed when necessary and records kept of distribution of the plan.	The text has been revised to require a treated waste disposal plan with the desired information be provided to facilities receiving treated waste, rather than requiring a written or contractual agreement between the treatment facility and receiving facility. The treatment facility shall document distribution of the plan and update and redistribute it when there are changes that impact the plan. Necessary to provide more flexibility to facilities to make transportation arrangements as necessary and to avoid regulatory interference with contractual agreements.
9VAC20-121-300 C 2		Requires a new permit-by-rule for any change in design or process of a facility that will, in the opinion of the department, result in a substantially different type of facility.	Requires a new permit-by-rule for any change in design or process of a facility that will result in a different type of facility, and provides specific examples of those changes.	Additional text has been added to clarify what would constitute a new or different type of facility requiring a new permit-by-rule as opposed to changes requiring only a permit modification as addressed by 9VAC20-121-310 A 6. The revised language is more precise and improves clarity for both the agency and the regulated community.

9VAC20-121-310 A 2 f		Requires a certification that the facility meets certain operational standards, which are documented in a regulated medical waste management plan.	Requires a certification that the facility meets certain operational standards, and that a copy of the regulated medical waste management plan (which describes how the facility meets those standards) is provided to the department.	The text was revised to clarify that a copy of the regulated medical waste management plan shall be provided along with the certification that the facility meets certain operational standards. A copy of the plan is required in order for the facility to demonstrate how certain operational standards have been met at the particular facility. Necessary to clarify the original intent.
9VAC20-121-310 A 2 i		Requires, as part of the permit application submittal, a written agreement with solid waste management facilities receiving treated waste.	Requires, as part of the permit application submittal, a treated waste disposal plan addressing facilities receiving treated waste.	This text was updated for consistency with changes to 9VAC20-121-280 D, which was revised to require a treated waste disposal plan instead of a written agreement with solid waste management facilities receiving treated waste. Necessary to make the permit application requirements correct.
9VAC20-121-330 E 11		Requires, as part of the treatment plan, a written agreement with solid waste management facilities receiving treated waste.	Requires, as part of the treatment plan, a treated waste disposal plan addressing facilities receiving treated waste.	This text was updated for consistency with changes to 9VAC20-121-280 D, which was revised to require a treated waste disposal plan instead of a written agreement with solid waste management facilities receiving treated waste. Necessary to make the treatment plan requirements correct.
9VAC20-121-340 C		Requires facility to maintain accurate written records.	Regulation allows written or digital records to be maintained.	This revision allows the facility maintain written or digital records and acknowledges that some facilities may have digital recordkeeping or tracking systems which can provide requested information. Necessary to conform to more modern recordkeeping standards.
Documents Incorporated by Reference		Reference to Pipeline and Hazardous Materials Safety Administration's 2019 document for management of waste	Reference to Pipeline and Hazardous Materials Safety Administration's 2022 document for management of waste	Reference was updated to the most current version of the federal policy for management of Category A waste, as found on the PHMSA website (https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Cat%20A%20Waste%20

		contaminated with a Category A infectious substance.	contaminated with a Category A infectious substance.	Planning%20Guidance_Final_ 2022_06.pdf).

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

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	Several terms were added or clarified to more clearly identify facility types (including Captive Regulated Medical Waste Management Facility, Regulated Medical Waste Transfer Station, and Regulated Medical Waste Treatment Facility). Definitions were added to address Category A waste (e.g. Category A infectious substance and Category A waste) as a type of regulated medical waste. Several definitions were added to address enhanced procedures for validation and challenge testing (e.g. biological indicator, challenge testing, exposure time, operating parameters, parametric controls, and validation testing).
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.

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
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, such as operating without a permit or discharging RMW into surface waters, groundwaters, or storm drains. 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).
80, 90, 100, 110, 130, 140, 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 one section. Additional RMW examples and exemptions added based on frequent questions from the public and regulated community. Identified Category A waste

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
			as a type of RMW. Clarified the exemption for household waste, including household sharps. Clarified when human blood and body fluids solidified by absorbent gel, powder, or similar means are RMW. Clarified that acupuncture needles are RMW (sharps).
120	Deleted	Exemptions to the regulations	Section focuses on items that are not solid waste and exemptions are already addressed in VSWMR, 9VAC20-81-95.
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, 300 A, 300 C, 310, 390, 470, 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 and added requirement to maintain records of receipt, shipment or treatment of RMW for at least three years. Added requirement for cart tippers, conveyors, and similar equipment to control movement and impact to maintain the integrity of the RMW packaging.
200, 210, 220, 240, 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. Added requirement for waste packages not to be overfilled and conditions for conveying RMW in wheeled carts.

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
230	Deleted	Etiological agents	Section 230 is deleted here as the section of the federal regulations that used to define "etiologic agent" no longer exists (42 CFR 72 has been repealed). Reference to management of select agents or toxins (new term for etiological agents) added in 121-80.
170, 330 - 380	120*	Storage of Regulated Medical Waste Storage requirements currently based on volume of RMW generated weekly (either less than 100 gallons or more than 100 gallons per week) and if amount of RMW stored onsite exceeds 200 gallon threshold. RMW stored more than seven days must be refrigerated with 15 day max onsite storage time.	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: • Generators of less than 250 gal/month shall be on a monthly pick-up schedule, maximum 45 day hold • Generators of 250 gal/month or more shall be on a weekly pick-up schedule, maximum 10 day hold • Transfer Stations may store up to 7 days unrefrigerated, maximum of 15 day hold • Treatment Facilities shall treat or remove RMW on a weekly basis, maximum 10 day hold
260 380	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. Added requirement for disinfectants to be EPA-registered with options to use heated rinse water with minimum temperature requirements or certain chemical sanitizers, as consistent with national industry guidance on cleaning of reusable containers.
270 280	140	Management of Spills of Regulated Medical Waste	Section was recodified and consolidated 120-270 & 280. Minor clarifications to existing disinfection requirements added, including requirement for disinfectants to be EPA-registered hospital grade disinfectants effective against mycobacteria unless an alternate EPA-registered disinfectant is demonstrated to be as protective of human health and appropriate for the type of RMW and surface being disinfected.
320	Deleted	Management of radioactive materials	Section 320 is deleted here. Reference to management of radioactive materials 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
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 (a subset of RMW), referencing the federal guidance "Managing Solid Waste Contaminated with a Category A Infectious Substance" (see Documents incorporated by reference). Added storage, notification, and treatment requirements for Category A waste. Clarified that Category A waste treated in accordance with the special requirements of this section is no longer Category A waste or RMW and can be disposed of at a permitted solid waste disposal facility in accordance with the VSWMR.
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. Added requirements for suitable access road, queuing capacity, access controls, lighting, covered areas with cleanable and impermeable surfaces, drainage,

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
			water supply, fixed radiation detectors, sizing for sufficient storage capacity and designated areas for cleaning of reusable containers as applicable.
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 with VSWMR criteria applicable to all solid waste management (non-disposal) facilities for consistency.
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. Removed requirement for shredding of RMW. Minimum 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. Updated spore inactivation requirement to 6 Log 10 reduction for consistency with industry standards. Additional requirements around use of biological indicators for equipment validation and challenge testing added including number, type and placement of biological indicators. Added requirements for handling RMW in treatment unit during power failure, interruption, or incomplete treatment cycle.

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
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, location, type, and placement of biological indicators, number of test runs, process monitoring, reporting, and specifying when validation must be repeated (e.g. at least once every five years).
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 decrease over time with facility operation and passing test results (twice a day for the first 30 days of operation, weekly for the first six months of operation, and monthly after six months of operation). Added procedures for response following challenge test failure including how to handle the RMW in the failed load. The current requirement for periodic challenge testing is only one (1) challenge test (spore test) per month with only one (1) biological indicator in the waste load, regardless of the volume of waste treated per load. This doesn’t allow for representative testing and was updated in the proposed regulation (as described 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
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 for RMW treatment facilities to provide treated waste disposal plans to the solid waste transfer and disposal facilities to receive treated RMW that will specify how treated waste will be packaged, with additional options for packaging including clear bags and bags with sterilization indicators.
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 for public participation and submission of certifications and documents to make the RMW PBR application consistent with the VSWMR PBR submission requirements. Per new

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
			121-40.B., all existing on-site or off-site/full PBR holders will have to submit new PBR applications. 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: • Waste Acceptance Plan; • Unauthorized Waste Control Plan; • Operations Plan; • Treatment Plan (if applicable); • Emergency Contingency Plan; and • Closure Plan 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.
810	deleted	Amendment of permits	Section 810 is deleted here. Revised wording from amendment to modification

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
			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
980	Deleted	Small medical waste treatment devices	Section 980 is deleted. Per RAP consensus, separate requirements for

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
			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 the most recent federal policy titled "Managing Solid Waste Contaminated with a Category A Infectious Substance." Document is referenced in new section 121-160.

Table 1: Changes to Existing VAC Chapter(s)

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.

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 as a result of this regulatory action.

Attachment A- Permitted RMW Treatment Facilities

Permit ID	Facility Name	Unit Type	Captive (Y/N)	Owner Type
PBR157	Old Dominion University - Norfolk	Autoclave	Yes	Public University
PBR159	University of Mary Washington - Fredricksburg	Autoclave	Yes	Public University
PBR167	University of Virginia Medical Center	Autoclave	Yes	Hospital
PBR168	George Mason University - Prince William Campus	Autoclave	Yes	Public University
PBR176	VDACS Lab -Warrenton	Autoclave	Yes	State Agency
PBR505	Microbac Laboratories Incorporated - Sterling	Autoclave	Yes	Private Lab
PBR552	Virginia Commonwealth University Medical Center	Autoclave	Yes	Hospital
PBR566	Virginia Hospital Center - Arlington	Chem-Clav	Yes	Hospital
PBR576	George Mason University - Fairfax Campus	Autoclave	Yes	Public University
PBR617	Curtis Bay Medical Waste Services - Petersburg	Autoclave	No	Private Treatment

Attachment B- Permitted RMW Transfer Stations

Permit ID	Facility Name	Unit Type	Captive (Y/N)	Owner Type
PBR143	Curtis Bay Medical Waste Services VA LLC - Roanoke	Transfer Station	No	Private
PBR517	Stericycle Chesterfield RMW Transfer Station	Transfer Station	No	Private
PBR606	Daniels Sharpsmart RMW Transfer Station	Transfer Station	No	Private
PBR624	Agape Pet Services of Virginia LLC	Transfer Station	No	Private
PBR634	Curtis Bay Medical Waste Services - Norfolk	Transfer Station	No	Private
PBR637	Sharps Compliance Inc	Transfer Station	No	Private