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Fast-Track Regulation
Agency Background Document

Agency name	Virginia Waste Management Board
Virginia Administrative Code (VAC) Chapter citation(s)	9VAC20-121
VAC Chapter title(s)	Regulated Medical Waste Management Regulations
Action title	Document Incorporated by Reference Update
Date this document prepared	September 30, 2024

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, 9VAC20-121, incorporate by reference the federal interagency guidance document titled “Managing Solid Waste Contaminated with a Category A Infectious Substance (June 2022)”. The federal Category A waste guidance document was updated in April 2024 by the National Security Council-led Countering Biological Threats Interagency Policy Committee, in collaboration with numerous federal agencies, including but not limited to the Centers for Disease Control and Prevention, Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Environmental Protection Agency, and Occupational Safety and Health Administration. This regulatory action will amend the Regulated Medical Waste Management Regulations to incorporate by reference the latest (2024) version of the document in order to remain consistent with federal guidance and keep the regulated community apprised of the latest guidelines on the management of Category A waste.

Category A waste is a subset of regulated medical waste that is contaminated with a Category A infectious substance, a substance which can cause permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Both federal and state regulations have more stringent management standards for Category A waste than for other types of regulated medical waste to prevent the spread of highly infectious disease (such as Ebola Virus). The federal Category A waste guidance document provides critical information about the management of Category A waste, including key procedures and applicable regulations, considerations for waste management planning and decision making, and treatment and inactivation information for specific pathogens classified as Category A infectious substances.

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.

DEQ – Department of Environmental Quality
VAC – Virginia Administrative Code

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.

On October 23, 2024, the Virginia Waste Management Board:

1. Authorized DEQ to promulgate the proposal for public comment using the fast-track process established in § 2.2-4012.1 of the Code of Virginia for regulations expected to be non-controversial. The board's authorization constituted its adoption of the regulation at the end of the public comment period provided that (i) no objection to use of the fast-track process is received from 10 or more persons, or any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, and (ii) DEQ does not find it necessary, based on public comments or for any other reason, to make any changes to the proposal.

2. Authorized DEQ to set an effective date 15 days after close of the 30-day public comment period provided (i) the proposal completes the fast-track rulemaking process as provided in § 2.2-4012.1 of the Code of Virginia and (ii) DEQ does not find it necessary to make any changes to the proposal.

Mandate and Impetus

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

Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.

The Regulated Medical Waste Management Regulations, 9VAC20-121, incorporate by reference the federal interagency guidance document titled “Managing Solid Waste Contaminated with a Category A Infectious Substance (June 2022)”. The federal guidance document was updated in April 2024. This regulatory action will amend the Regulated Medical Waste Management Regulations to incorporate by reference the latest (2024) version of the document to remain consistent with federal guidance and keep the regulated community apprised of the latest guidelines on management of Category A waste.

This regulatory action is expected to be noncontroversial because the document incorporated by reference is a federal guidance document and does not create new regulatory requirements, nor does it remove the obligation to comply with existing applicable federal, state, and local laws and regulations. The guidance document aims to provide essential information and decision-making considerations to prepare hospitals and healthcare facilities, emergency responders, waste management facilities, and other entities to effectively manage Category A waste associated with infectious disease incidents.

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 regulatory action is to amend the Regulated Medical Waste Management Regulations, 9VAC20-121, to incorporate by reference the latest (2024) version of the federal guidance document on the management of Category A waste. The regulations currently incorporate by reference the 2022 version of the document. The document will be updated to the 2024 version, in order to incorporate the most recent federal guidelines into the regulations. No other regulatory text requires revision.

This regulatory change is essential to protect the health, safety, and welfare of citizens as it will provide the most accurate and up-to-date information to the regulated community (i.e., hospitals and healthcare facilities, emergency responders, waste management facilities, and other entities) on all aspects of the safe and proper management of Category A waste to prevent the spread of highly infectious disease. The federal guidance document provides critical information about the management of Category A waste, including key procedures and applicable regulations, considerations for waste management planning and decision making, and treatment and inactivation information for specific pathogens classified as Category A infectious substances.

The goal of this regulatory change is to ensure that the regulated community has access to the latest information on Category A infectious substances and pathogens to ensure proper management of Category A waste. Incorporating by reference the most recent version of the Category A waste guidance document will make the Commonwealth's regulations consistent with the latest federal guidelines, decrease confusion by the public and regulated community on matters related to Category A waste, and increase the ease of use of the regulations. This regulatory action will help generators of regulated medical waste and facilities more easily and more quickly locate applicable regulatory requirements and best management practices, as well as increase understanding of the safest and most effective ways to manage more highly infectious regulated medical waste. This regulatory change will prevent the regulated community from potentially considering or utilizing out-of-date information on treatment and inactivation of specific Category A infectious substances, which could result in the mismanagement of Category A waste.

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.

This regulatory action updates an existing document incorporated by reference to the most recent version. No other regulatory text requires revision. The regulations currently incorporate by reference the federal interagency guidance document on management of Category A waste published in June 2022. The guidance document was updated and republished in April 2024. This regulatory action will amend the regulations to incorporate by reference the latest (2024) version of the document, which includes several technical changes as well as editorial changes summarized below.

Technical changes were made to Appendices F-1 and F-2 of the guidance document. Appendix F-1 now provides classification, packaging, shipping, inactivation, and disinfection information for waste contaminated with Marburg virus. Protocols for managing Marburg contaminated waste have been consolidated with existing protocols for managing Ebola contaminated waste due to their similarities. Both viruses are considered Select Agents and cause clinically similar and severe diseases in humans. Waste contaminated with either virus is Category A waste, requires a Department of Transportation special permit for transport, and is inactivated through autoclaving or incineration to ensure the waste is no longer infectious.

Appendix F-2 was updated to reflect modern terminology for Mpox virus (or MPXV, formerly known as the Monkeypox virus), and the two types of this virus. Clade I and Clade II (formerly known as the Congo Basin and West African clades, respectively) of MPXV cause clinically different diseases with Clade I responsible for more severe illness and death. Appendix F-2 was updated to clarify that not all types of MPXV contaminated waste are Category A waste. Only MPXV Clade I viral cultures (i.e., intentionally propagated viruses) and other waste materials contaminated with MPXV Clade I viral cultures are Category A waste, require a Department of Transportation special permit for transport, and are inactivated through autoclaving or incineration to ensure the waste is no longer infectious. Other MPXV contaminated waste (including patient waste from either MPXV clade as well as MPXV Clade II cultures) can be managed as (regular) regulated medical waste rather than Category A waste. Regulated medical waste that does not meet the criteria for Category A waste still requires treatment to ensure the waste is no longer infectious prior to disposal but is subject to less stringent standards for general handling, packaging/labeling, storage, and transport than Category A waste.

The main body of the guidance document also includes minor editorial changes (i.e. updating hyperlinks, updating the full name and logo of the Administration for Strategic Preparedness and Response, correcting typographical errors, etc.).

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 incorporating by reference the most recent version of the federal guidance document will ensure the clarity and certainty of information related to management standards for Category A waste. This regulatory action will make the Commonwealth's regulations consistent with the latest federal guidelines and ensure that both regulatory requirements and federal guidelines for Category A waste are accessible to the public and regulated community in one central location. This will decrease confusion by the public and regulated community, increase ease of use of the regulations, and ultimately result in safer management of highly infectious regulated medical waste to prevent the spread of infectious disease. There are no disadvantages to the public or the Commonwealth associated with this regulatory change.

Requirements More Restrictive than Federal

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

There are no analogous federal regulations for the management of regulated medical waste. The document incorporated by reference is a federal guidance document and does not create new regulatory requirements, nor does it remove the obligation to comply with existing applicable laws and regulations. Therefore, there are no new requirements more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no other State Agencies particularly affected.

Localities Particularly Affected

The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no localities particularly affected.

Other Entities Particularly Affected

The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no other entities particularly affected.

Economic Impact

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

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no projected costs, savings, fees, or revenues resulting from the regulatory change.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no projected costs, savings, fees, or revenues resulting from the regulatory change.
For all agencies: Benefits the regulatory change is designed to produce.	This regulatory change will make the Commonwealth's regulations consistent with the latest federal guidelines on Category A waste, decrease confusion by the public and regulated community, and increase ease of use of the regulations.

Impact on Localities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.

Projected costs, savings, fees or revenues resulting from the regulatory change.	The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no projected costs, savings, fees, or revenues resulting from the regulatory change.
Benefits the regulatory change is designed to produce.	This regulatory change will make the Commonwealth's regulations consistent with the latest federal guidelines on Category A waste, decrease confusion by the public and regulated community, and increase ease of use of the regulations.

Impact on Other Entities

If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, no individuals, businesses, or other entities are likely to be affected by the regulatory change.
Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, no individuals, businesses, or other entities are likely to be affected by the regulatory change.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	The document incorporated by reference is a federal guidance document and does not create new regulatory requirements. Therefore, there are no projected costs for affected individuals, businesses, or other entities resulting from this regulatory change.
Benefits the regulatory change is designed to produce.	This regulatory change will make the Commonwealth's regulations consistent with the latest federal guidelines on Category A waste, decrease confusion by the public and regulated community, and increase ease of use of the regulations.

Alternatives to Regulation

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

One alternative to this regulatory change is to maintain the regulations as is, which incorporates by reference an outdated (2022) version of the federal Category A waste guidance. In that case, the regulations are inconsistent with the latest federal guidelines on Category A waste. This creates confusion for the public and the regulated community, and decreases the ease of use of the regulations, as generators of regulated medical waste and facilities are not able to quickly locate all applicable requirements and best management practices for Category A waste in one central location. It could also cause generators and management facilities to potentially consider or utilize out-of-date information on

treatment and inactivation of specific Category A infectious substances, which could result in the mismanagement of Category A waste. Therefore, the agency is proposing this regulatory action to incorporate by reference the latest (2024) version of the federal guidance document on the management of Category A waste.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Regulatory Flexibility Analysis

Consistent with § 2.2-4007.1 B of the Code of Virginia, 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 document incorporated by reference is a federal guidance document and does not create new regulatory requirements, nor does it remove the obligation to comply with existing applicable federal, state, and local laws and regulations. Therefore, alternative regulatory methods are not applicable. The only alternative is to maintain the regulations as is, which incorporates by reference an outdated (2022) version of the document. In that case, the regulations are inconsistent with the latest federal guidelines on Category A waste. This creates confusion for the public and the regulated community, and decreases the ease of use of the regulations, as generators and facilities are not able to quickly locate all applicable requirements and best management practices for Category A waste in one central location.

If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below.

Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The Virginia Waste Management Board is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any

alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: https://townhall.virginia.gov. Comments may also be submitted by mail or email to Rebecca Rathe at P.O. Box 3000, Harrisonburg, VA 22801, phone: (540) 830-7241, or email: Rebecca.Rathe@deq.virginia.gov. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. 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. Use all tables that apply, but delete inapplicable tables.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
9VAC20-121, Documents Incorporated by Reference		Managing Solid Waste Contaminated with a Category A Infectious Substance (June 2022), approved for publication by the National Security Council (NSC)-led Homeland and Critical Infrastructure Resilience (HCIR) and Countering Biological Threats (CBT) Interagency Policy Committees on June 3, 2022	The document incorporated by reference will be updated to the 2024 version, to incorporate the most recent federal guidance on Category A waste management. The benefit of this update is to provide the most accurate and up-to-date information to the public and regulated community. Incorporating the most recent version of the document incorporated by reference will make the Commonwealth's regulations consistent with the latest federal guidelines, decrease confusion by the public and regulated community, increase ease of use of the regulations, and ultimately result in safer management of highly infectious regulated medical waste to prevent the spread of infectious disease.