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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Virginia Waste Management Board
Virginia Administrative Code (VAC) citation(s)	9VAC20-120
Regulation title(s)	Virginia Regulated Medical Waste Management Regulations
Action title	Amendment 3
Date this document prepared	May 29, 2018

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended 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 modernize the standards for general handling and treatment of RMW based on current industry best management practices. 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 natural resources and human health.

In addition, a periodic/small business impact review of this regulation will be conducted as part of this regulatory action. Please see the periodic review/small business impact review announcement section for the specific details on the conduct of the review.

Acronyms and Definitions

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

"Category A Waste" means regulated medical wastes that are categorized as Category A infectious substances as defined by 49 CFR 173.134 of the United States Department of Transportation (USDOT) Hazardous Materials Regulations (HMR). Category A waste poses a higher degree of risk than Category B waste.

"Challenge Testing" means periodic monitoring or testing of a regulated medical waste treatment device or system that employs the use of biological indicators to demonstrate continued, effective operation of the device or system.

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

"RMW" means Regulated Medical Waste

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

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

"Validation Testing" means procedures conducted at the site of a regulated medical waste treatment facility prior to initial operation of a treatment system or device, the purpose of which is to demonstrate, under pre-established operating parameters, the effective treatment of regulated medical waste.

Legal basis

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

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

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

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 will be evaluated during the regulatory development phase.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

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 provisions that are being considered 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.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

One alternative is to keep the current regulations as they are; in which case, the existing regulation will continue to be cumbersome, disjointed, and outdated regarding technologies and best management practices for the treatment and management of RMW. However, if other alternatives are identified during the participatory process, they will be considered and developed as appropriate. The process for this regulatory action will involve the use of a regulatory advisory panel that will include members of the regulated community and the public in an effort to elicit cost effective ideas for developing the necessary provisions.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Please include one of the following choices: (1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is ; (2) a panel will not be used; or (3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: (1) consideration of additional exemptions (2) appropriate storage and refrigeration requirements for generators and permitted facilities; (3) minimum requirements for disinfection following spills; (4) design considerations and operational requirements for RMW transfer stations and treatment facilities; (5) disposal standards for treated wastes; (6) operating parameters, validation, and periodic challenge testing for treatment technologies; (7) ideas to be considered in the development of this proposal; (8) the costs and benefits of the alternatives stated in this background document or other alternatives; (9) potential impacts of the regulation; and, (10) impacts of the regulation on farm and forest land preservation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation. Please see the periodic review/small business impact review announcement section below for details on specific comments requested for the periodic/small business impact review of this regulation being conducted as part of this regulatory action.

The Board is using a regulatory advisory panel to develop a proposal. Please see the Regulatory Panel section for further information.

Anyone wishing to submit written comments may do so by mail, email or fax to Debra Harris, Office of Regulatory Affairs, P.O. Box 1105, Richmond, VA 23218; Telephone: (804) 698-4209; Fax: (804) 698-4019; Email Address: Debra.Harris@deq.virginia.gov. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site (http://www.townhall.virginia.gov/L/Forums.cfm**).**

Please note written comments must include the name and address of the commenter. In order to be considered, comments must be received before midnight on the last day of the public comment period.

Public hearing at proposed stage

Also, indicate whether a public hearing is to be held to receive comments.

A public hearing will not be held following the publication of the proposed stage of this regulatory action unless requests for a public hearing are received during the NOIRA public comment period from at least 25 persons.

Periodic review/small business impact review announcement

If you wish to use this NOIRA to announce a periodic review (§ 2.2-4017 & EO-17 (2014)) and a small business impact review (§ 2.2-4007.1) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete this section.

In addition, pursuant to Executive Order 17 (2014) and § 2.2-4007.1 of the Code of Virginia, the agency is conducting a periodic review and small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical 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.

Regulatory panel

Please indicate, to the extent known, if advisers (e.g., regulatory advisory panel or negotiated rulemaking panel) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using a panel in the development of the proposal; 2) the agency is using a panel in the development of the proposal; or 3) the agency is inviting comment on whether to use a panel to assist the agency in the development of a proposal.

The Board is using a panel to develop a proposal. Persons interested in assisting in the development of a proposal should notify the department contact person (see the Public Participation section) by the end of the comment period and provide their name, address, phone number, email address and the organization you represent (if any). The primary function of the panel is to advise the Department regarding development of recommended regulatory amendments for Department consideration through a collaborative approach of negotiation and consensus. Please note, multi-applications from a single company, organization, group or other entity count as one for purposes of making the decision specified in the preceding sentence. Notification of the composition of the panel will be sent to all applicants.

Family Impact

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

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