

Regulated Medical Waste Management Regulations, Amendment 3

Compliance Assistance Document for Prospective Regulated Medical Waste Treatment Facilities

This document provides a high-level overview of the [Regulated Medical Waste \(RMW\) Management Regulations \(9VAC20-121\)](#) for potential new RMW Treatment Facilities. The new regulations are effective March 15, 2023, and background information on Amendment 3 to the regulations is available on the [Virginia Regulatory Town Hall webpage](#).

Permit Requirements

RMW Treatment Facilities are required to obtain a [permit-by-rule](#) prior to operation. The following must be submitted to the [DEQ Regional Office](#) as part of the [permit application](#):

- DEQ Form RMW PBR
- Notice of Intent
- Disclosure Statement
- [Operator Certification](#)
- Local Government Certification
- Public Participation Results
- Siting Certification
- Design and Construction Certification
- Design Plans
- Authorization to Discharge
- Facility Standards Certification
- RMW Management Plan, including Treatment (and Validation) Plan for each treatment unit
- [Treatment Technology Approval](#) (if applicable)*
- Treated Waste Disposal Plan
- Closure Plan and Closure Cost Estimates
- Demonstration of Site Legal Control
- State Corporation Commission Certification
- [Proof of Financial Responsibility](#)
- Permit Fee (\$390)

If the permit application submission is deemed complete, the applicant will be granted authorization to initiate validation testing. Validation results and operating parameters must be approved prior to acceptance of RMW for treatment.

*Note that alternate treatment technologies require [additional review](#) and approval by DEQ prior to the permitting process.

Siting of New Facilities

A new RMW Treatment Facility should:

- Be adjacent to or have direct access to paved/surfaced roads capable of withstanding anticipated load limits
- Not be sited or constructed in areas subject to base floods
- Not be closer than:
 - 50 feet to any property boundary
 - 50 feet to any perennial stream or river
 - 200 feet to any residence or recreational park area
 - 200 feet to any health care facility, school, or similar type public institution, unless the facility is located at the health care facility, school, or similar type public institution
- Provide room to minimize traffic congestion and allow for safe management of RMW and safe operation

Design and Construction Standards

The facility should be [designed and constructed](#) to include the following features:

- All-weather access road
- Onsite queuing capacity
- Adequately sized unloading/loading areas
- Access controls (fencing, gates, locks, etc.)
- Adequate lighting (fixed or portable)
- Covered areas with impermeable surfaces
- Bermed pavement, liquid retaining lip, or equivalent at loading docks and near rolling or bay doors to contain potential leaks and spills
- Floors sloped to drain and discharge directly to an approved sanitary sewer system
- Ventilation discharged to minimize exposure
- Water supply for cleaning purposes
- Fire alarm and protection system
- Fixed radiation detector for waste screening*
- Effluent, wash water and runoff shall not discharge to surface waters (unless thru a VPDES permit)
- Any slides, tippers, conveyors, etc. must control movement/impact to maintain packaging integrity
- Adequate storage areas with sufficient capacity
- Designated areas for cleaning and disinfection if reusable containers are managed

*Not required at captive facilities that demonstrate that there is no potential for management of radioactive materials

Operational Requirements

General Requirements

- Comply with the standards for [general handling](#), [packaging and labeling](#), and [transport](#) of RMW
- Adhere to the permitted process rate and maximum designed storage capacity
- Maintain infrastructure and equipment as designed and permitted
- Implement emergency plan within 24 hours of equipment becoming inoperable

Storage of Regulated Medical Waste

- [Store](#) RMW in a way that maintains the integrity of the packaging, and prevents damage and spills
- Maintain packaging in upright stable configuration
- Stacked containers must be <6 ft above floor level
- Store on surfaces that are impermeable to liquids
- Provide treatment or removal of all RMW stored onsite on at least a weekly basis
- No RMW may be stored more than 10 days (total)
- Clearly demonstrate how many days RMW is stored onsite (e.g., date outer packaging, maintain an inventory, log, barcode system, etc.)

Reusable Carts and Containers

- Clean and disinfect immediately after each use
- Clean with detergent and water
- Disinfect using one of the following options:
 1. An EPA-registered general or broad-spectrum disinfectant following instructions on label
 2. Heated rinse water between 180°F and 195°F for at least 15 seconds, or until the surface temperature reaches 160°F, or
 3. Immersion in or rinsing with an [approved chemical sanitizer](#) for at least 3 minutes

Unauthorized Waste Control

- Detect and segregate unauthorized wastes and remove/manage within 10 days of discovery
- Maintain fixed radiation detection equipment to screen incoming waste

Signage and Access Control

- Post signs or markings on access points for RMW management and storage areas
- Secure those areas to prevent unauthorized access and limit to only those designated

Housekeeping and Self-Inspections

- Maintain [spill kits](#) in the vicinity of RMW management areas & address spills immediately
- Keep floors and operational areas clean, orderly, and free of standing liquid and debris
- Contain and direct-discharge effluent, wash water, and runoff to an approved sanitary sewer system
- Ensure floor drains are free-draining at all times
- Conduct monthly self-inspections of all major aspects of facility operations necessary to ensure compliance with the regulations and remedy or repair any issues as soon as feasible

Training

Operators should be trained annually on the following:

- Unauthorized waste control program
- General handling of RMW and use of personal protective equipment
- Packaging, labeling, and storage of RMW
- Cleaning and disinfection of reusable containers
- Facility housekeeping and management of spills
- Overall process and equipment operation
- Treatment units and periodic challenge testing
- Emergency contingency plan procedures

+ *Class III operator's license required by [18VAC155-20-110](#)*

Treatment Standards

All RMW and its packaging should be treated by an approved process that meets the following [treatment standards](#):

- The treatment method and operating parameters should be appropriate and effective for the waste type treated.
- Built-in automatic controls and fail-safe mechanisms should ensure waste cannot bypass the treatment process.
- Size reduction, grinding, shredding, or puncturing of containers is only permissible if integral to the treatment unit and the facility demonstrates that the device prevents employee exposure to the waste, contains aerosols, and treats or filters air evacuated from the chamber during processing.
- Treatment should be in closed vessels under negative pressure that filters all vents, discharges, and fugitive emissions of air through a high efficiency particulate air filter with efficiency of 99.97% for 0.3 microns. Air and gases sterilized by the process are not required to pass through a filter.
- Treatment units should operate in accordance with specific operating parameters (e.g., pressure, temperature, residence time, etc.) and protocols established through validation testing and approved by the department.
- Real time monitoring instrumentation integral to the unit should be used to record operating parameters.
- Effective treatment must achieve a **6 log₁₀** or greater reduction of viable spore concentrations of the most appropriate bacterial species for the treatment method, which is demonstrated by no growth in all treated biological indicators and growth in all untreated biological indicators during validation and challenge testing.

Treatment Standards (continued)

- Door alignment, gaskets, locking mechanisms, and other components of a treatment unit that utilizes a pressure vessel (such as an autoclave) should achieve a complete seal during operation to prevent leaking of steam, liquid, or waste and avoid decreases in pressure or temperature that could cause isolated cold spots inside the unit.
- Reusable treatment carts and containers should 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.
- Specific department approval is required to treat Category A Waste.

The regulations require [additional standards](#) for each specific treatment method (autoclaves, microwaves, etc.).

Validation Testing

Prior to operation, and at least once every five years, [validation testing](#) in accordance with an approved treatment plan is required to establish appropriate operating parameters for effective treatment. Validation testing should employ the use of:

- **Process controls** – At least three separate treatment runs performed on three separate days, using three distinct surrogate waste loads, during which DEQ is present to witness at least one complete validation test run.
- **Biological indicators** – The number of biological indicators is based upon the amount of waste to be processed. Each biological indicator must have a minimum concentration of 6 log₁₀ spores.
- **Process monitoring** – Thermochemical indicators, thermochemical recording devices, and parametric controls must be used to demonstrate the treatment unit achieves minimum operating parameters.

Validation test results and operating parameters must be submitted to the department for review and approval.

Periodic Challenge Testing

[Challenge testing](#) requires the use of biological indicators to demonstrate continued, effective operation and should be performed under full loading of RMW in accordance with the facility's approved treatment plan.

Challenge testing is required at least once a month under normal operation. An increased testing frequency is required during the first six months of operation and after a challenge test failure.

RMW treated during and after a challenge test should not be shipped offsite until the test is complete with passing results (i.e., treatment process achieves operational parameters, no growth in all treated biological indicators, and growth in all untreated biological indicators).

Disposal of Treated Waste

Properly treated waste should be disposed of at a permitted solid waste disposal facility (or hazardous waste disposal facility if treated residuals are determined to be hazardous waste). Treated waste should be packaged as follows:

- Where non-bulk treatment is used, place treated waste in sealed bags or containers allowing visible assessment of treatment (e.g., clear bags or treatment cart liners, bags with sterilization indicators). Opaque bags and special labels are permissible if agreed to by the receiving facility.
- Where bulk treatment is used and waste is immediately placed or compacted in closed containers that are more than 64 gallons in volume, repackaging in bags is not required.

A [Treated Waste Disposal Plan](#) describing how treated waste will be packaged, labeled, and transported should be provided to each permitted solid waste management facility receiving the waste for transfer or disposal.

Regulated Medical Waste Management Plan

The facility should maintain and operate in accordance with an [RMW Management Plan](#) including the following elements:

- Certification Page (must recertify plan annually)
- Waste Acceptance Plan
- Unauthorized Waste Control Plan
- Operations Plan
- Treatment Plan (including a copy of the Treated Waste Disposal Plan)
- Emergency Contingency Plan**
- Closure Plan

**Must be provided to local police & fire departments, local emergency manager and local emergency health coordinator

Recordkeeping

The following [records](#) must be maintained in hard copy or digital form for at least 3 years from the date of the record:

- Monitoring, calibration, & maintenance
- Regulated Medical Waste Management Plan
- Disclosure Statements (and quarterly updates)
- Waste received from offsite, along with generator records affirming loads do not contain hazardous or radioactive waste (unless facility is permitted to accept those waste types)
- Waste shipped/transferred offsite
- Onsite treatment log
- Results of periodic challenge testing
- Distributions of the Treated Waste Disposal Plan
- Unauthorized waste records
- Monthly self-inspection log
- Employee training records

Reporting

[Solid Waste Information & Assessment \(SWIA\) Reports](#) must be submitted annually by March 31st (unless the facility is captive).

The following conditions require 24-hr (oral) and 5-day (written) reporting to the [DEQ Regional Office](#):

- Noncompliance, emergency, or unusual condition that may endanger health, environment, or facility operation
- Interruptions requiring use of emergency contingency plan or diversion of RMW to another facility
- RMW releases from a fire, explosion, storm, etc. that could endanger health or environment outside the facility
- Unauthorized discharges to surface water
- Spills of RMW in any areas not protected from the elements, such as outside of a building
- Storage of RMW beyond capacity or storage timeframes
- Failing results of periodic challenge testing
- Receipt or discovery of unauthorized waste, or Category A Waste
- Shipment of RMW offsite in inappropriate packaging