

# Understanding Changes to Virginia's Regulated Medical Waste Management Regulations (9VAC20-121, Amendment 3)

### Webinar Series Part 4 of 5

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### **Acronyms/Terms to Know Today:**

RMW – Regulated Medical Waste

Cat. A – Category A Waste

PBR – Permit-By-Rule

P.E. – Professional Engineer

SWIA - Solid Waste Information and Assessment

WTE – Waste to Energy Facility



### **Five Part Webinar Series Objectives**

Part 1 – Define the problem! What's Broken?

- How are Virginia hospitals and other healthcare facilities doing in general in complying with the hazardous waste regulations?
- Discuss common non-compliance problems with the Hazardous Waste Regulations
- Identify the typical waste streams generated in Virginia hospitals and other healthcare facilities (July 22<sup>nd</sup>)

Part 2 – Understand the baseline regulations for accurately identifying and managing the hazardous wastes that hospitals and other healthcare facilities generate (July 29<sup>th</sup>)

**Part 3** – Understand the regulations for complying with the Hazardous Waste Pharmaceuticals rule (August 5<sup>th</sup>)

Part 4 – Understand and make you aware of changes to the regulated medical waste (RMW) regulations (Today, August 12<sup>th</sup>)

Part 5 – To the Future and Back! Discuss best management practices and the do's and don'ts for managing hazardous waste in hospitals and other healthcare facilities (August 19<sup>th</sup>)



### **Overview**

- Purpose of Regulations
- Regulatory Outline
- Types of Regulated Medical Waste (RMW) & Exemptions
- Standards for Management of All RMW
- Permitting of RMW Facilities & Permit Exemptions
- Standards for RMW Transfer Stations & Treatment Facilities
- Helpful Resources



## **Purpose of Regulated Medical Waste Regulations**

Regulations effective March 15, 2023

- Identify solid wastes considered to be regulated medical waste
- Require more stringent management to prevent the spread of disease
- Applies to anyone who generates, stores, transfers, transports, treats, disposes, or otherwise handles regulated medical waste



HOSPITALS & DOCTOR'S OFFICES



**NURSING HOMES** 



**PHARMACIES** 



**DENTAL OFFICES** 



### **Regulatory Outline**

- Chapter 120 repealed & replaced with new Chapter 121
- Specifies standards for:
  - o Generators
  - Transporters
  - Transfer Stations
  - o Treatment Facilities

#### **Definitions**

Part I (9VAC20-121-10)

#### **General Information**

Part II (9VAC20-121-20 thru 90)

#### Standards for Management of All RMW

Part III (9VAC20-121-100 thru 160)

## Standards for RMW Transfer Stations and Treatment Facilities

Part IV (9VAC20-121-200 thru 290)

#### **Permitting of RMW Facilities**

Part V (9VAC20-121-300 thru 340)

#### **Variance Application Procedures**

Part VI (9VAC20-121-400 thru 420)

**FORMS** 

Docs Incorporated By Reference





#### Regulated Medical Waste Management Regulations, Amendment 3

#### Crosswalk of Regulations (Current v. Previous Chapter)

This document provides a crosswalk of Amendment 3 to the <u>Virginia Regulated Medical Waste Management</u> <u>Regulations (9VAC20-121)</u>, to clarify the new location of each part and section in the current chapter (Chapter 121) compared to the previous chapter (Chapter 120). The new regulations are effective March 15, 2023, and background information on Amendment 3 to the regulations is available on the <u>Virginia Regulatory Town Hall webpage</u>.

Part I. Definitions	New Section 9VAC20-121-	Previous Sections 9VAC20-120-
Definitions	10	10

Part II. General Information	New Section 9VAC20-121-	Previous Sections 9VAC20-120-
Purpose	20	30
Administration	30	40
Applicability	40	50; 830
Prohibitions	50	100; 160; 180; 300; 690
Enforcement and appeal	60	N/A
Public participation and information	70	N/A
Relationship to other bodies of regulation	80	70; 120; 190; 230; 320
Identification of regulated medical waste	90	80; 90; 100; 110; 120; 130; 140; 150



**Types of Regulated Medical Waste** (9VAC20-121-90)









animalcare.umich.edu



And ANY solid waste suspected by the health care professional in charge of being capable of producing infectious disease in humans



## Types of Regulated Medical Waste (9VAC20-121-90)



Health Department in Tazewell County, Illinois



Medcycle





Cardinal Health



### **Poll Question**

Which of these should NOT be disposed of as regulated medical waste? (check all that apply)

- ☐ Urine cup
- ☐ Expired unused needles
- Pathology sample
- Leftover medication
- ☐ Suction tubing containing blood





Bed linen,
instruments, and
medical care
equipment
cleaned & reused
for their original
purpose



Reusable medical devices & used health care products returned for reprocessing per FDA & transported per DOT









When emptied and not capable of releasing blood or infectious materials



urine collection bags and tubing



suction canisters



suction tubing



IV solution bags and tubing



colostomy bags and ileostomy bags



urostomy bags



hemovac



urine specimen cup

#### Also includes:

- plastic fluid containers
- enteral feeding containers and tubing
- urine bottles

An item may be subject to the Bloodborne Pathogen Standard (and considered regulated medical waste) if it could potentially release liquid or semi-liquid blood or potentially infectious materials, or if it could potentially release caked dried blood or potentially infectious materials.

unless a health care professional has determined the item to be capable of producing infectious disease













Discovery Life Sciences

Tissue blocks fixed in paraffin wax or similar embedding materials (except prions)

Human remains provided to educational programs as anatomical gifts

Southern Crescent Technical College









\*Not specifically exempt by regulation, but must characterize as hazardous or non-hazardous; some drugs could be radioactive



Household Sharps

#### MANAGEMENT OF HOUSEHOLD SHARPS

#### What are household sharps?

Household sharps are needles, syringes with attached needles, lancets, auto injectors (insulin pens), and other items with a sharp edge that are generated at home through self-care, rather than under the care of a home healthcare professional or at a healthcare facility.

Household sharps may be disposed in the regular trash following the STEPS TO SAFE DISPOSAL below

Mail-back programs are also available, though a disposal fee or vendor requirements may apply. Check with your local healthcare provider, pharmacy, or locality for more information as there may be other options for safe disposal in your community.

Packaging requirements for solid waste disposal



#### STEPS TO SAFE DISPOSAL

#### RIGID/HEAVY-DUTY PLASTIC CONTAINER

Place sharps in an FDA-cleared sharps container specifically designed for HOME USE OR

Use an empty, rigid or heavy-duty, opaque, plastic container such as detergent or bleach bottles.

**DO NOT** place household sharps in glass containers, plastic soda bottles, milk jugs, or aluminum cans.

#### SEAL TO PREVENT LEAKAGE

Seal with a tight-fitting lid or screw cap. Wrap heavy-duty tape around the lid of homemade sharps containers.



Use permanent ink to print in large, legible text: "HOUSEHOLD SHARPS—DO NOT RECYCLE" OR "HOME GENERATED SHARPS"

#### DISPOSE WITH THE REGULAR TRASH

Place sealed, labeled sharps containers in the regular trash.

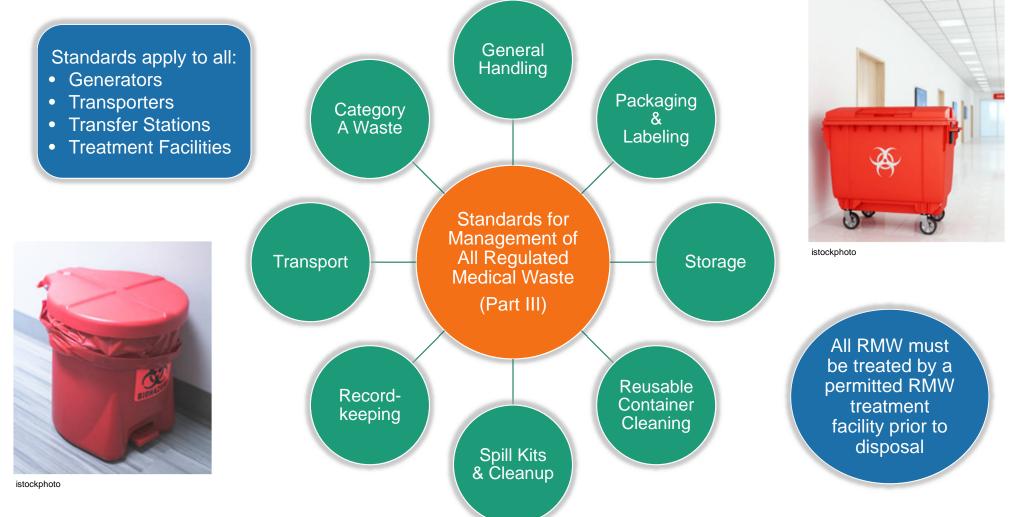
#### DO NOT

- Recycle sharps or sharps containers
- · Place loose sharps directly into trash bags
- · Flush sharps down the toilet









DEQ

## General Handling (9VAC20-121-100)

- Identify and segregate RMW
- Use PPE when handling and packaging
- Maintain packaging integrity





RMW bag damaged (torn) during handling



Damaged and leaking RMW containers from improper handling and storage



## **General Handling (9VAC20-121-100)**

- Cart tippers, slides, conveyors and similar equipment must control movement & impact
- No damage to packaging, leaks or spills
- Cannot compact, compress, or subject RMW to violent mechanical stress



Cart tipping of RMW into autoclave bin



Waste crushed/compressed by stacking of steel cages

## Packaging and Labeling (9VAC20-121-110)

- Clearly legible label with biohazard symbol and:
  - o Generator name, address, phone number
  - o For hospitals, department or lab of origin
  - "Regulated Medical Waste," "Biohazard,"
     or "Infectious Waste" in large print



- Wheeled carts red and/or biohazard symbol, secured or sealed when not filling to prevent leaks
- Wheeled carts & roll-off containers liquids, anatomical waste, animal carcasses, etc. can't be placed directly inside; need to be in separate rigid, leak-proof containers with sufficient absorbent material



Liner/lid not properly secured



Single overhand knot





## **Storage (9VAC20-121-120)**



Staging area for RMW; boxes are stacked too high (higher than 6 ft); note wet area on the floor

- Maintain packaging integrity
- Protect from elements, vectors & trespassers
- Upright/stable configuration & less than 6 feet above floor level to minimize spill potential
- Clean, orderly, free of standing liquid & debris
- Prevent unauthorized access
- Additional requirements for large quantity generators, transfer and treatment facilities:
  - o Impermeable surfaces, floor drains, signage



## Storage Time Limits for RMW Generators (9VAC20-121-120.D)

### **Small Quantity Generators (less than 250 gal per month)**

- Arrange for removal of stored RMW at least once per MONTH
- No RMW shall be stored onsite for more than 45 days
- No more than 250 gal RMW shall be stored onsite at any time

### Large Quantity Generators (250 gal or more per month)

- Arrange for removal of <u>stored</u> RMW at least once per WEEK
- No RMW shall be stored onsite for more than 10 days

Clearly demonstrate length of time in storage



Bag/box not in storage yet when still filling it up

Time limits start when container is full and moved to storage



## Storage Time Limits for Permitted RMW Facilities (9VAC20-121-120.D)

- Transfer Stations store up to 7 days unrefrigerated (15-day max)
- Treatment Facilities treat or remove at least weekly (10-day max)
- Clearly demonstrate time in storage
- Employ methods to track specific waste throughout duration of management



Veolia



## Reusable Containers (9VAC20-121-130)

- Clean and disinfect after each use
- 3 new options for disinfection
- Discharge wash water to sanitary sewer
- Cannot reuse if damaged or contaminated

## Spill Kits and Cleanup (9VAC20-121-140)

- Spill kits in RMW management areas
- Repackage spilled waste, clean and disinfect, and replenish spill kit



200-gal reusable containers, broken handles & lid locks









## Recordkeeping (9VAC20-121-100.I)

Waste treated onsite
(if permitted to treat)

Waste shipped offsite

Waste received from offsite

- Keep at least 3 years
- Make available for DEQ review as requested
- 25% rule for generators (9VAC20-121-120.E)
- RMW transfer & treatment facilities have additional requirements



## **Transportation (9VAC20-121-150)**

- Follow USDOT Hazardous Materials Regulations (49 CFR Parts 171-180) for shipping papers, packaging, labeling, marking and vehicle placarding
- Upright/stable configuration
- Limit access to vehicles and equipment used for RMW
- Ensure surfaces are clean and impermeable to liquids
- Spill kits

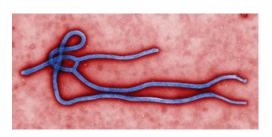


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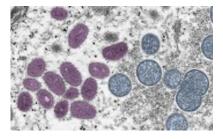


## **Category A Waste (9VAC20-121-160)**

- Category A Waste waste contaminated with a Category A infectious substance
- Category A infectious substance capable of causing permanent disability or life-threatening or fatal disease



Ebola Virus, CDC Cultures + patient waste



Mpox Virus, CDC (Clade I cultures only)

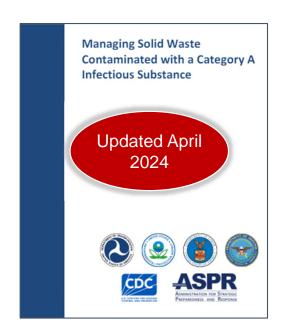


 Package & transport per US DOT HMR or special permit



## **Category A Waste (9VAC20-121-160)**

- Segregate from other types of RMW
- Manage only on cleanable & impermeable surfaces
- No stacking of Cat A Waste containers
- Equipment/handling cannot cause bioaerosols
- Notify DEQ within 24 hours of exceeding 250 gal
- 10-day storage limit unless extension approved
- Special requirements for treatment
- DOT special permit required for transport







### **Poll Question**

Which of these regulated medical waste handlers require a permit from the Virginia Dept. of Environmental Quality? (check all that apply)

- Generators
- □ Transporters
- □ Transfer Stations
- □ Treatment Facilities



### Who needs a RMW permit?

- RMW Transfer Station (includes vehicle parked for more than 24 hours or more during transport)
- RMW Treatment Facilities (autoclaves, alkaline hydrolysis, chemical treatment, dry heat treatment, incineration, microwave, or alternate treatment technology)





RMW Permit-by-Rule (PBR) Exemptions

(9VAC20-121-300.E.1-5)

**Generators** 

**Cleanups** (72 hrs)

**Emergency** 

CRIME SCENE - WATER

**Sharps** Drop **Boxes** 



americansecuritycabinets.com

**Effluent** Decontamination **Systems** 

Incinerators/ **WTE** 

10% RMW

Addfield.com

**MEDICAL WASTE** 

**Transporters** 

Astell Scientific Effluent Decontamination System

DEQ

### **RMW Market Products**



https://www.cardinalhealth.com/content/dam/corp/web/documents/catalog/cardinal-health-medivac-medi-solid-plus-solidifiers.pdf







## RMW Permit-By-Rule (PBR) Application Requirements (9VAC20-121-310)

- DEQ RMW PBR Form and permit fee (\$390)
- Notice of Intent
- Certification of Siting (9VAC20-121-210)
- Design Plans P.E. Certified (9VAC20-121-310.A.2.d)
- Authorization to discharge to sanitary sewer/POTW
- P.E. Certification of Design/Construction (9VAC20-121-220)



https://www.deq.virginia.gov/permits/waste/ medical-waste



## RMW PBR Application Requirements (cont.) (9VAC20-121-310)

- Certification Facility meets standards for management of RMW (Part III) and Transfer and/or Treatment (Part IV), as applicable
  - Regulated Medical Waste Management Plan (9VAC20-121-330)
  - Emergency Contingency Plan (shared with local responders)
- Treatment Plan (9VAC20-121-330.E.)
- Alternate Treatment Technology, if applicable
- Treated Waste Disposal Plan (9VAC20-121-280.D)

**Treatment Facilities** 

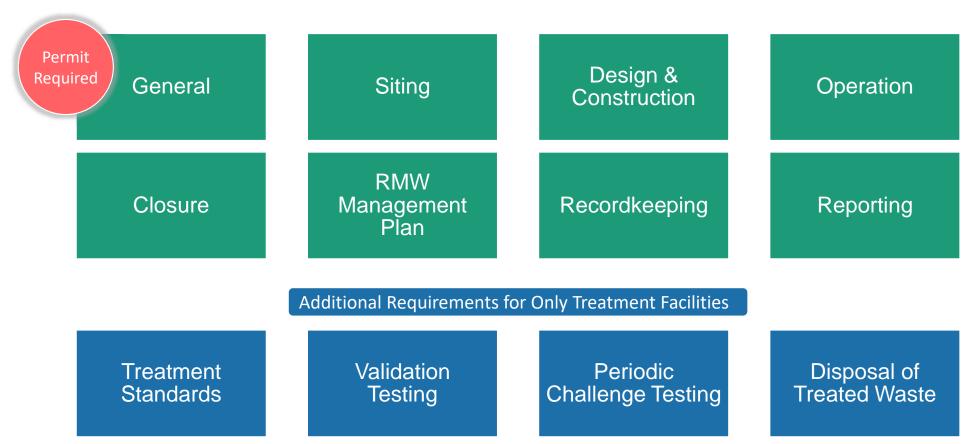


## RMW PBR Application Requirements (cont.) (9VAC20-121-310)

- Demonstration of legal control over the site
- State Corporation Commission Certification
- Closure Plan (9VAC20-121-330.G)
- Financial Assurance
- Other DEQ Media Permits
- Variance Petition, if applicable (9VAC20-121-400)



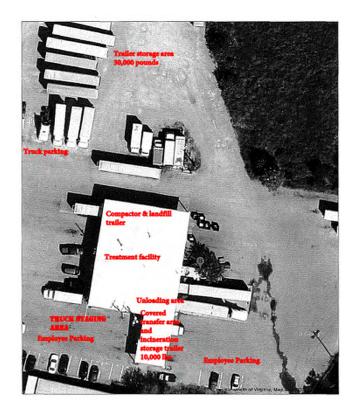
### Standards for RMW Transfer Stations & Treatment Facilities



DEQ

## Siting Standards (9VAC20-121-210)

- Access to paved or surfaced roads
- Not in areas subject to base floods
- No closer than:
  - 50 ft from property boundary
  - 50 ft from perennial stream/river
  - 200 ft from residence or recreational park
  - 200 ft from health care facility, school or similar (unless located at one of those institutions)
- Provide room to minimize traffic, allow safe management of RMW and safe operation of facility.





## **Design and Construction (9VAC20-121-220)**

- Suitable access road and on-site queuing capacity
- Adequate size loading and unloading areas designed for efficient transfer of RMW
- Access controls (fencing, gates, locks, badge system or similar, to limit access to RMW storage, transfer or treatment areas.
- Adequate lighting for site control
- Covered areas for RMW management and all on cleanable surfaces (no floor coverings such as carpet, if tile needs to be sealed)
- Fire alarm and protection system







## Design and Construction (9VAC20-121-220) (cont.)

- Bermed pavement or equivalent controls at loading docks or bay doors to contain leaks and spills
- Floors sloped or graded to drain effluent and wash water. All wastewater discharged directly to approved sanitary sewer system.
- Ventilation that discharges to minimize human exposure to the waste.
- Water supply for cleaning purposes
- Effluent and/or wash water shall not drain or discharge to surface water unless under VPDES permit.





## Design and Construction (9VAC20-121-220) (cont.)

- Fixed radiation detectors to monitor all waste (captive RMW facilities may provide certification that there is no radioactive materials or waste onsite.)
- Slides, cart tippers, conveyors designed and constructed to maintain integrity of packaging
- RMW storage areas designed per 9VAC20-121-120
- If managing reusable containers/carts for RMW, need designated area for manual or mechanical cleaning/disinfection per 9VAC20-121-130







# Regulated Medical Waste Management Plan (9VAC20-121-230.B & 330)

- Permitted facilities must operate per their RMW plan
- Annual recertifications due within 1 year from date of last certification
- Treatment Plan (not applicable to transfer stations)

#### **Certification Page**

Waste Acceptance Plan

**Unauthorized Waste Control Plan** 

**Operations Plan** 

**Treatment Plan** 

**Emergency Contingency Plan** 

Closure Plan



## **Operational Standards (9VAC20-121-230)**

- Manage waste in accordance with PBR, RMW Management Plan, and per regulations for packaging, labeling, handling, transportation, and storage.
- Implement unauthorized waste program
- Housekeeping
- Monthly inspections of all major aspects of facility operation
- Staff training



Spilled RMW in autoclave cart lift pit



### Treatment Plan (9VAC20-121-330.E)

- Equipment Information
- Process description, controls and fail-safe mechanisms,
- Ventilation requirements, HEPA filter (99.97% efficiency for 0.3 microns) for negative pressure in vessels
- Maintenance requirements for equipment and electronic controls
- Discharges
- Validation and periodic challenge protocols
- Treatment achieve 6 Log<sub>10</sub> reduction in viable spore concentration



Autoclave at UVA Health System



## **Treated Waste Disposal Plan (9VAC20-121-280.D)**

- Copy of the plan should be provided to solid waste management facility
- Describe how treated waste will be packaged and transported to each solid waste management facility
- Discuss type of RMW treated and method used to treat
- Name and contact information for any transfer station or other intermediate facilities where treated waste transferred or temporarily stored prior to transport to a disposal facility
- Plan shall be distributed to disposal facilities and updated and redistributed when there are changes to facility operation that impact the plan.





## Recordkeeping (9VAC20-121-340)

- Monitoring (if required)
- SWIA Reports (except captive facilities)
- Disclosure Statements & Quarterly Updates
- Operator Certification (at least 1 key personnel with Class III WMFO license)
- Waste received from offsite
- Waste shipped/transferred offsite
- Unauthorized waste records
- Monthly self-inspection log
- Employee training records
- PBR application records



#### Additional Treatment Facility Records

- Onsite Treatment Log
- Validation and Periodic Challenge Testing Results
- Distributions of Treated Waste Disposal Plan



## 24-Hour Verbal / 5-day Written Reporting (9VAC20-121-340)

- Interruptions requiring emergency contingency plan or diversion of waste
- RMW releases from fire, explosion, storm, etc.
- Unauthorized discharges to surface water
- Spills of RMW in unprotected areas (outside)
- Storage beyond capacity or timeframe
- Failing periodic challenge testing
- Unauthorized waste or Cat A waste receipt
- Shipment in inappropriate packaging



2017 Explosion at RMW Treatment Facility



## **RMW Emergency Permits (9VAC20-121-310.B)**

#### **Emergency Permits may be issued to address:**

- Management of RMW at a site not already permitted
- Management of waste types not already covered by permit



- A new/temporary emergency treatment unit or method
- Other activities not already covered by a permit

Emergency permit term = 90 days (can be renewed 3 times)



## RMW PBR Update Requirements for Existing Facilities (9VAC20-121-40)

Existing permitted facilities required to submit updated permit application documents by **September 15**, **2024**, including:

- DEQ Form RMW PBR
- Disclosure Statement (if key personnel changes)
- Design and Construction Certification
- Design Plans
- Facility Standards Certification

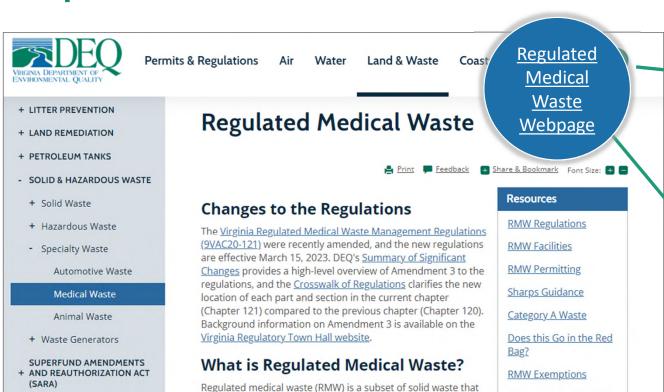
- RMW Management Plan (including Treatment and Validation Plans for each treatment unit)
- Closure Plan and Closure Cost Estimate
- SCC Certification (if not previously provided)
- Permit Fee (\$390)







## **Helpful Resources**



https://www.deg.virginia.gov/land-waste/solid-hazardous-waste/specialty-waste/medical-waste

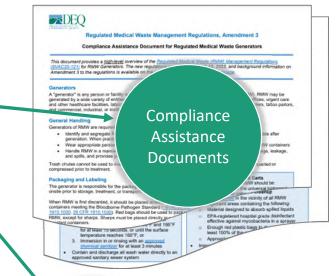
an infectious disease.

is subject to more stringent management standards in order to

prevent potential exposure to pathogens that could transmit

Sign up to receive DEQ

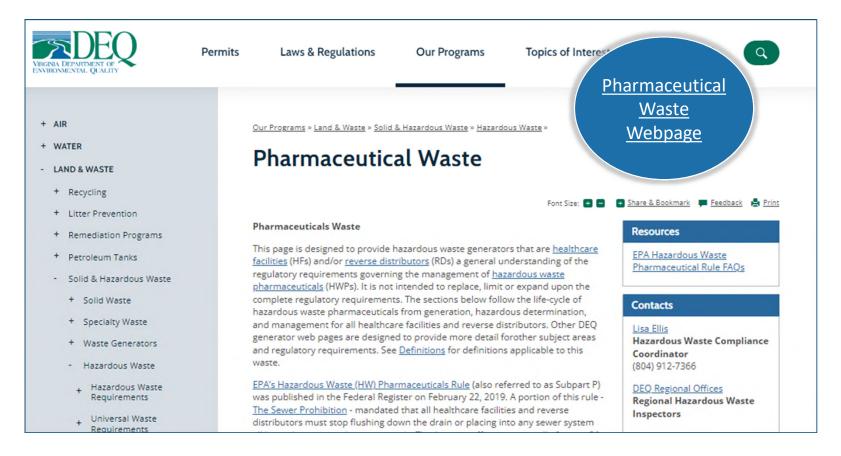
News







#### **Pharmaceutical Waste Resources**



https://www.deq.virginia.gov/our-programs/land-waste/solid-hazardous-waste/hazardous-waste/pharmaceutical-waste



#### **Questions**

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