



# Subpart P: An Inspector's Point of View At Healthcare Facilities

Nick Baier

Stephan Szardenings

# Note:

- This presentation is focusing primarily on requirements an inspector will review for Subpart P only.
- Depending on your facility, this point of view may not cover all requirements an inspector may be reviewing.
- It is likely an inspector will also be reviewing requirements for:
  - Hazardous waste (non-pharmaceutical)
  - Universal waste
  - Regulated medical waste

# An Inspection from NJDEP's Perspective



Pre-Inspection



Site Walkthrough



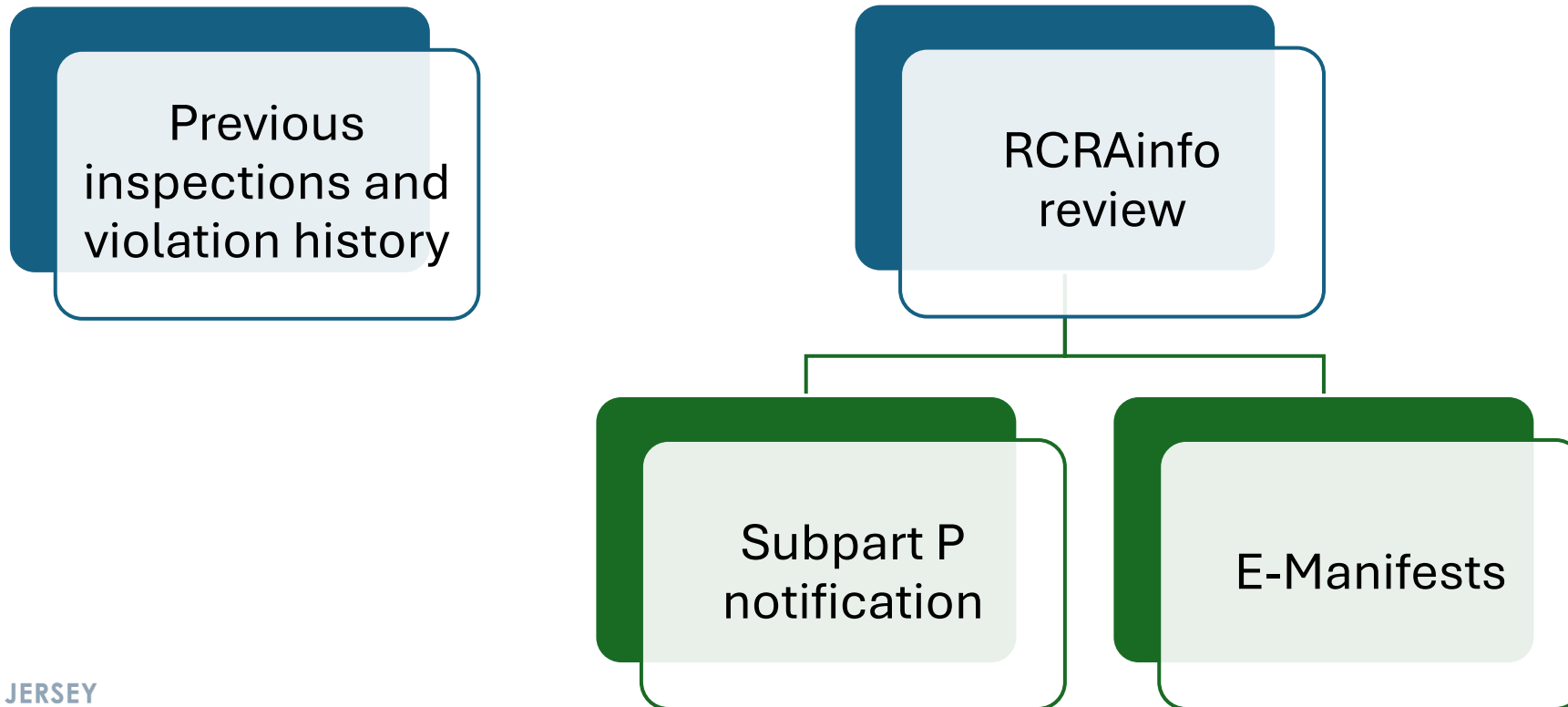
Documentation  
Review



Violations

# Pre-Inspection

# Pre-Inspection



Example of DEP  
pre-inspection report.

Program	PI Name	PI Number	Activity Number	Activity Type	Lead Investigator	Inspection Date	Compliance Outcome	Inspection Report	Locked
Water Quality			SCI 210001	*Standard Compliance Inspection	Lockward, Daniel	5/26/2021	In Compliance	<a href="#">Click for Inspection Summary...</a>	Y
Water Quality			SCI 210001	*Standard Compliance Inspection	Lockward, Daniel	5/26/2021	Out of Compliance, Non-referred	<a href="#">Click for Inspection Summary...</a>	Y
Hazardous Waste			SCI 210001	*Standard Compliance Inspection	Chiles, Tiffany	2/17/2021	In Compliance	<a href="#">Click for Inspection Summary...</a>	Y
Hazardous Waste			SCI 210001	*Standard Compliance Inspection	Chiles, Tiffany	2/17/2021	Out of Compliance	<a href="#">Click for Inspection Summary...</a>	Y

## Enforcement Actions


All Enforcement Actions that exist at the site regardless of status and date range.

Program	PI Name	PI Number	Activity Number	Effective Date	Activity Type	Doc Status	Penalty Assessed	Outstanding Balance	Enforcement Action
Air			NEA 010001	5/1/02	XSA	Closed	\$1,500.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Air			NEA 040001	4/6/05	XSA	Closed	\$6,000.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Air			PEA 000001	7/27/00	AON	Closed	\$0.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Air			PEA 010001	8/13/01	AON	Superseded	\$3,000.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Air			PEA 020001	5/23/02	AON	Superseded	\$6,000.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Air			PEA 030001	5/2/03	NOV	Closed	\$0.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Air			PEA 130001	10/23/13	NOV	Closed	\$0.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Hazardous Waste			BEA 240001		HBR	Pending	\$0.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>
Hazardous Waste			NEA 210001	6/14/21	XSA	Closed	\$7,200.00	\$0.00	<a href="#">Click for Enforcement Action Info</a>

# Previous Inspections



# RCRAinfo: Subpart P Notification



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Nicholas

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## View Source Record

General Information

Revision History Details

<b>Received Date</b> 10/18/2019	<b>Non-notifier</b>	<b>Extract to Public?</b> Yes
<b>Accessibility</b>		<b>Acknowledgement Flag</b>

1. Reason for Submittal

Obtaining or updating an EPA ID number for an on-going regulated activity that will continue for a period of time. (Includes HSM activity) [Source N]

2. Site ID

<b>EPA ID</b> 	<b>Activity Location</b> NJ
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3. Site Name

**Name**

4. Site Location

Location Address

<b>Street Number</b>	<b>Street 1</b>	<b>Street 2</b>
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# RCRAinfo: Subpart P Notification

*Example of correct notification.*

C. Waste Codes for State Regulated (non-Federal) Hazardous Wastes

**B. Hazardous Waste Codes (State)**

None Selected

**11. Additional Regulated Waste Activities**

**A. Other Waste Activities**

**1. Transporter of Hazardous Waste**

None Selected

**3. United States Importer of Hazardous Waste**

None Selected

**5. Importer/Exporter of SLABs**

None Selected

**2. Underground Injection Control**

None Selected

**4. Recognized Trader**

None Selected

**B. Universal Waste Activities**

**1. Large Quantity Handler of Univ Waste**

None Selected

**2. Destination Facility for Universal Waste**

None Selected

**C. Used Oil Activities**

**1. Used Oil Transporter**

None Selected

**2. Used Oil Processor and / or Re-refiner**

None Selected

**3. Off-Specification Used Oil Burner**

None Selected

**4. Used Oil Fuel Marketer**

None Selected

**D. Pharmaceutical Activities**

**Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.**

Healthcare Facility

**Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.**

No

**E. State Activities**

# RCRAinfo: Subpart P Notification

A healthcare facility who is an LQG or SQG after counting all hazardous waste must notify they are operating under subpart P.

[40 CFR 266.502(a)(1)]

## D. Pharmaceutical Activities

**Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.**

Healthcare Facility

**Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.**

No



# Improper Subpart P Notification Examples

- Improper notification: “None selected”

D. Pharmaceutical Activities
<p><b>Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.</b></p> <p>None Selected</p>
<p><b>Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.</b></p> <p>No</p>

- Improper notification: marked as withdrawing


D. Pharmaceutical Activities
<p><b>Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.</b></p> <p>None Selected</p>
<p><b>Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals.</b></p> <p>Yes</p>

# RCRAInfo: E-Manifest Review

Confirming that manifest entries for waste pharmaceuticals include the PHRM or PHARMS code.

## 9-13. Waste Information

### Waste Characteristics (Total lines: 1)

Line Number	HM	U.S. DOT Description	Containers	Type	Total Quantity	Units	Waste Codes	Management Method Code	Action
1	X	UN3248 <u>WASTE MEDICINE</u> , LIQUID, FLAMMABLE, TOXIC, N.O.S. (ALCOHOLS, MITOMYCIN) II 3 6.1 D001=100#	2	DF	45	P	D001, D024, U010, U058, U035, <u>PHRM</u>	H141	

# Site Inspection

# Commonly Inspected Areas

## Patient Care Floors/Wings

- Soiled Utility Rooms
- Medication Rooms
- Select Patient Rooms

## Laboratories (Histology, Cytology, etc.)

## Pharmacy(s)

## Central Accumulation Area(s)

- Hazardous Waste
- Pharmaceutical Waste
- Regulated Medical Waste

# Container Inspection

Inspectors will be walking through the previously mentioned areas looking for the following container requirements:

## Labels

*[40 CFR 266.502(e)]*

## Accumulation time limits

*[40 CFR 266.502(f)(1)] & [40 CFR 266.502(f)(2)]*

## Closed containers

*[40 CFR 266.502(d)(3)]*

## No leaks

*[40 CFR 266.502(d)(1)]*

# Container Inspection

Inspectors will be walking through the previously mentioned areas looking for the following container requirements:

## Labels

[40 CFR 266.502(e)]

Must be labeled “*Hazardous Waste Pharmaceuticals*”

## Accumulation time limits

[40 CFR 266.502(f)(1)] & [40 CFR 266.502(f)(2)]

## Closed containers

[40 CFR 266.502(d)(3)]

## No leaks

[40 CFR 266.502(d)(1)]

# Container Inspection

Inspectors will be walking through the previously mentioned areas looking for the following container requirements:

## Labels

[40 CFR 266.502(e)]

## Accumulation time limits

[40 CFR 266.502(f)(1)] & [40 CFR 266.502(f)(2)]

Must demonstrate that the length of time non-creditable hazardous waste pharmaceuticals have been accumulating is less than one year using one of the following methods:

- Dates on individual containers
- Inventory logs
- Area marked with date the earliest container started accumulation

## Closed containers

[40 CFR 266.502(d)(3)]

## No leaks

[40 CFR 266.502(d)(1)]

# Container Inspection

Inspectors will be walking through the previously mentioned areas looking for the following container requirements:

## Labels

*[40 CFR 266.502(e)]*

## Accumulation time limits

*[40 CFR 266.502(f)(1)] & [40 CFR 266.502(f)(2)]*

## Closed containers

*[40 CFR 266.502(d)(3)]*

Lids must be closed when not actively filling containers

## No leaks

*[40 CFR 266.502(d)(1)]*

# Container Inspection

Inspectors will be walking through the previously mentioned areas looking for the following container requirements:

## Labels

*[40 CFR 266.502(e)]*

## Accumulation time limits

*[40 CFR 266.502(f)(1)] & [40 CFR 266.502(f)(2)]*

## Closed containers

*[40 CFR 266.502(d)(3)]*

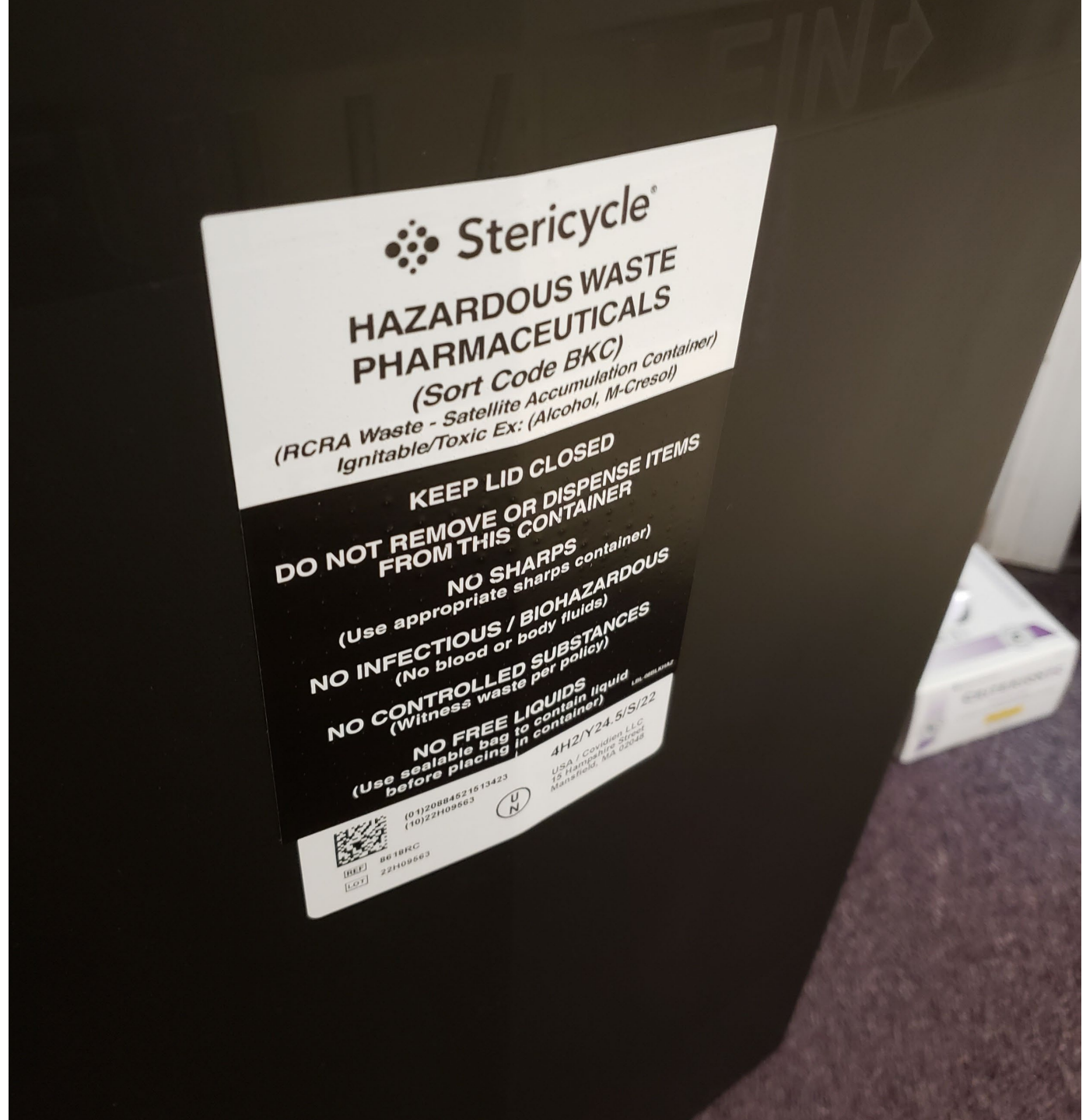
## No leaks

*[40 CFR 266.502(d)(1)]*

Containers correctly labeled  
“Hazardous Waste  
Pharmaceuticals”.

*Potential violation: can  
facility demonstrate  
containers are accumulating  
for less than one year?*

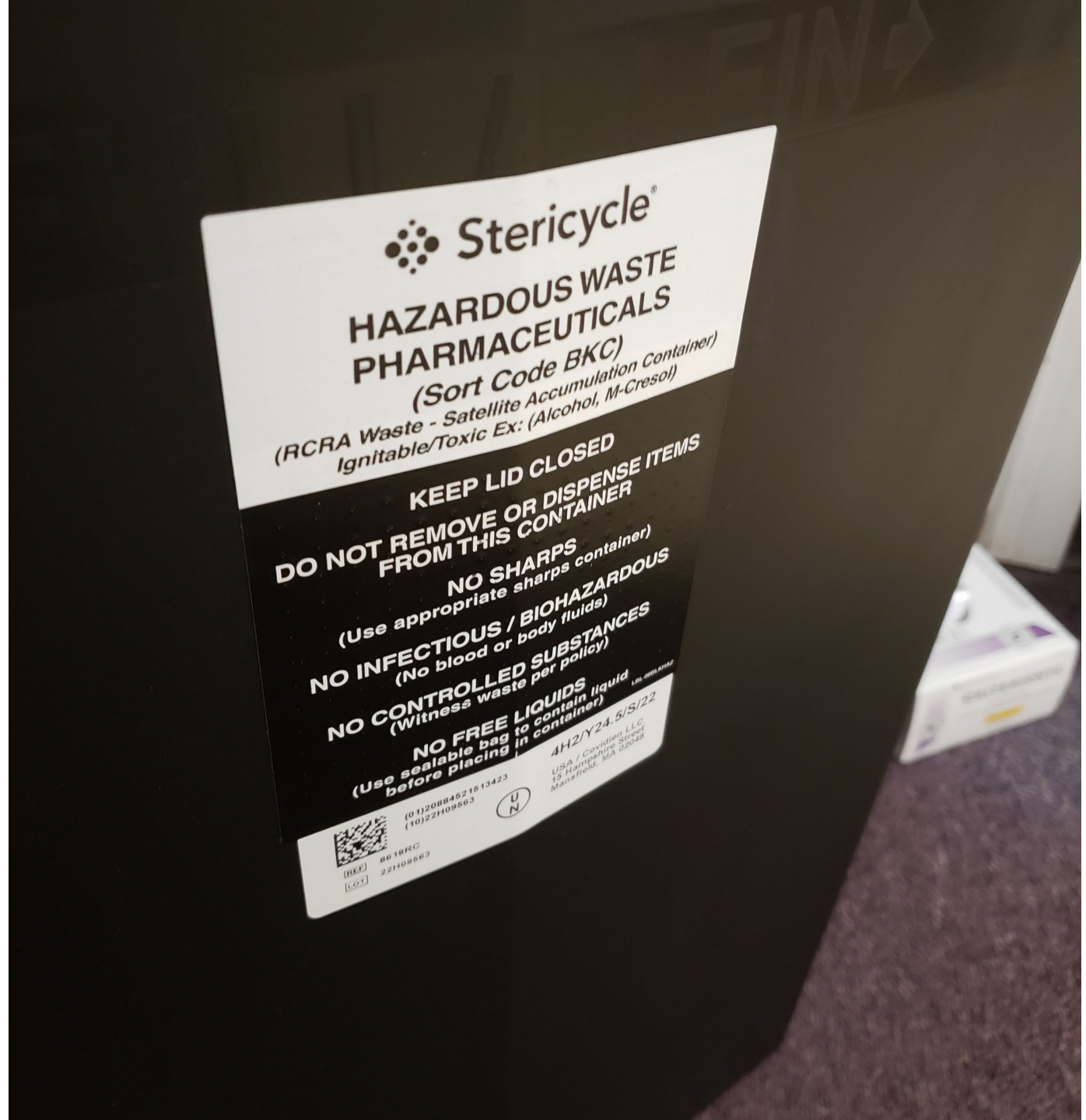
# Container Examples



# But is this a Satellite Accumulation Area?

*No, under Subpart P there are no satellite accumulation areas for hazardous waste pharmaceuticals.*

*All containers holding hazardous waste pharmaceuticals must have accumulation start date demonstrated using one of the three methods at 40 CFR 266.502(f)(2).*



*Potential violation:  
container is not closed.*

# Container Examples



*Potential violation: containers are not labeled “Hazardous Waste Pharmaceuticals”.*

*Potential violation: can facility demonstrate containers are accumulating for less than one year?*

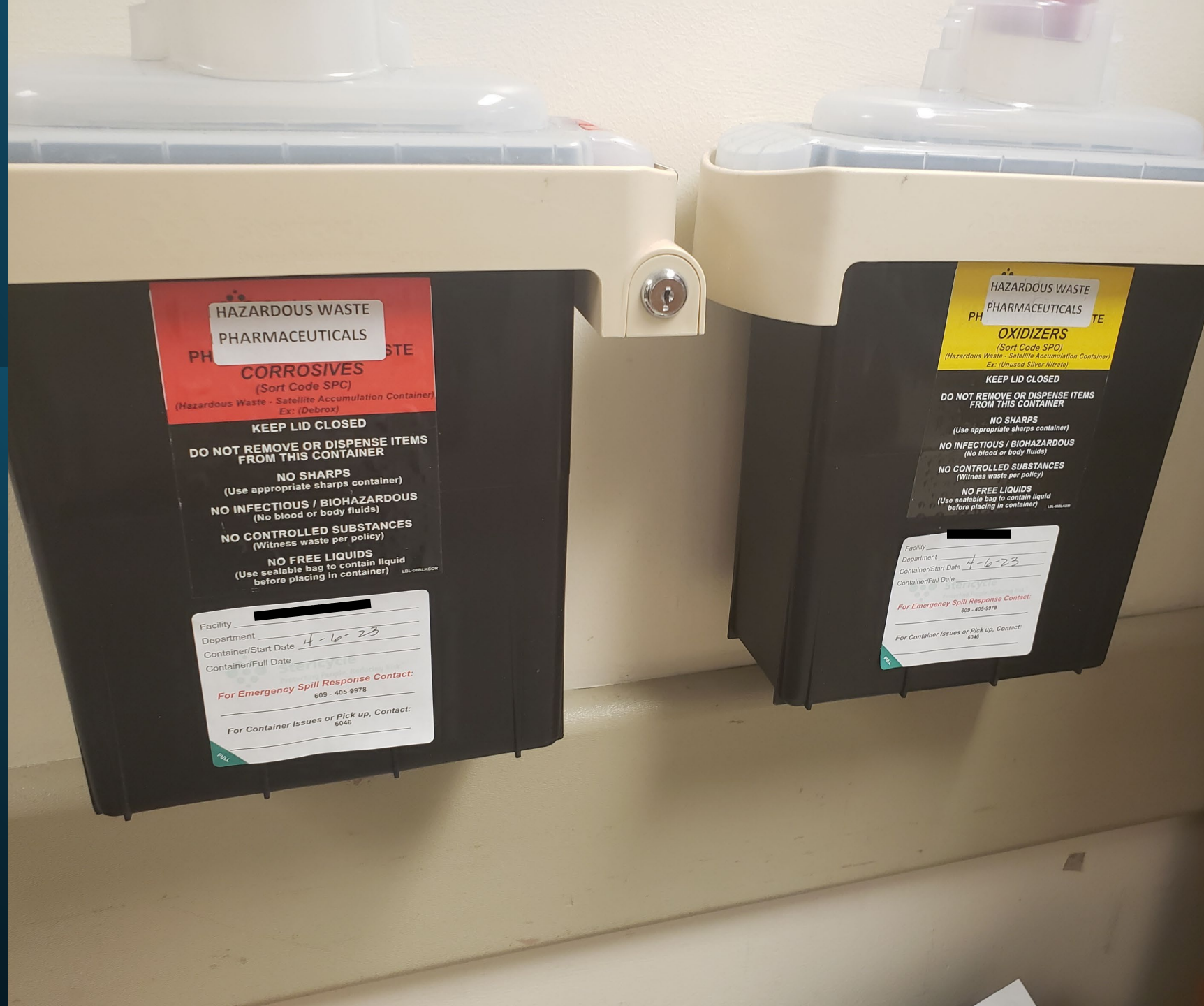
# Container Examples



# Container Examples

Containers correctly labeled “Hazardous Waste Pharmaceuticals”.

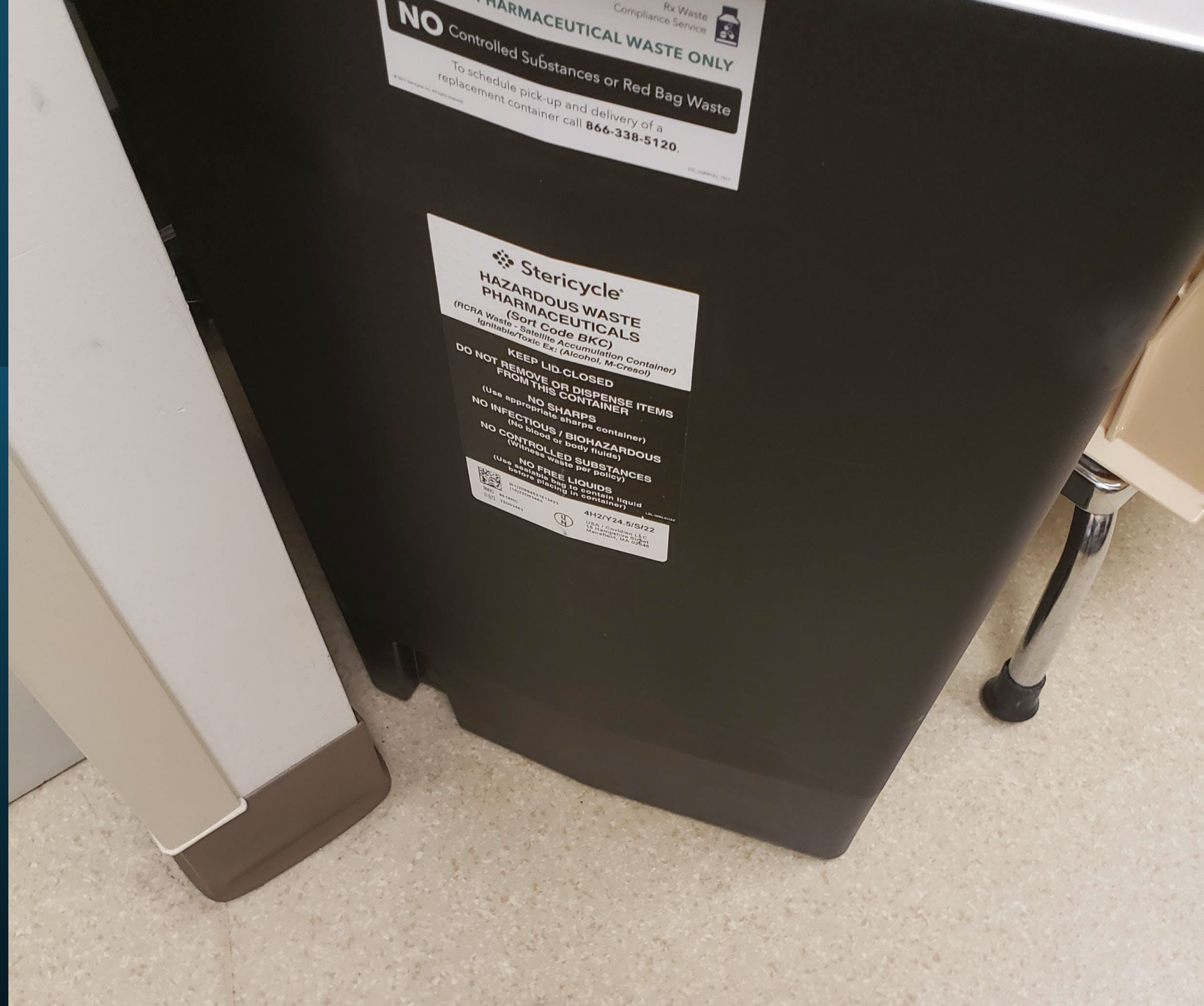
Containers are marked with an accumulation start date.



# Container Examples

*Container labeled with the words “Hazardous Waste Pharmaceuticals”.*

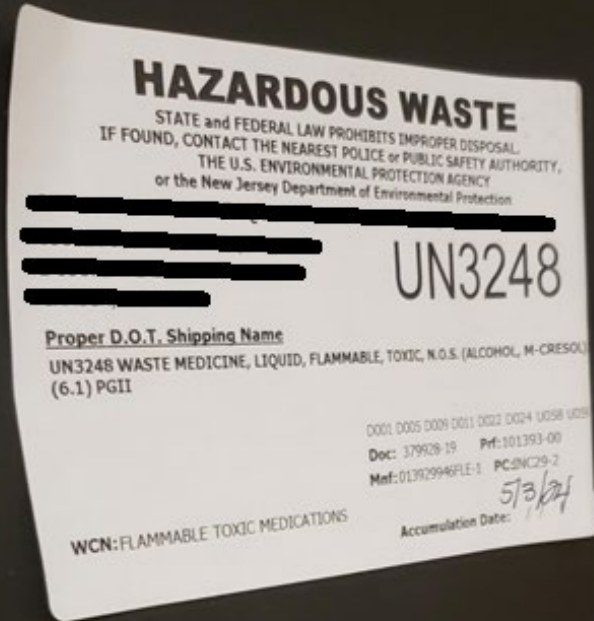
*Potential violation: can the facility demonstrate the length of time the container has been accumulating?*



# Container Examples

*Containers marked with an accumulation start date.*

*Potential violation: container labeled “Hazardous Waste” instead of “Hazardous Waste Pharmaceuticals”.*



# Container Examples

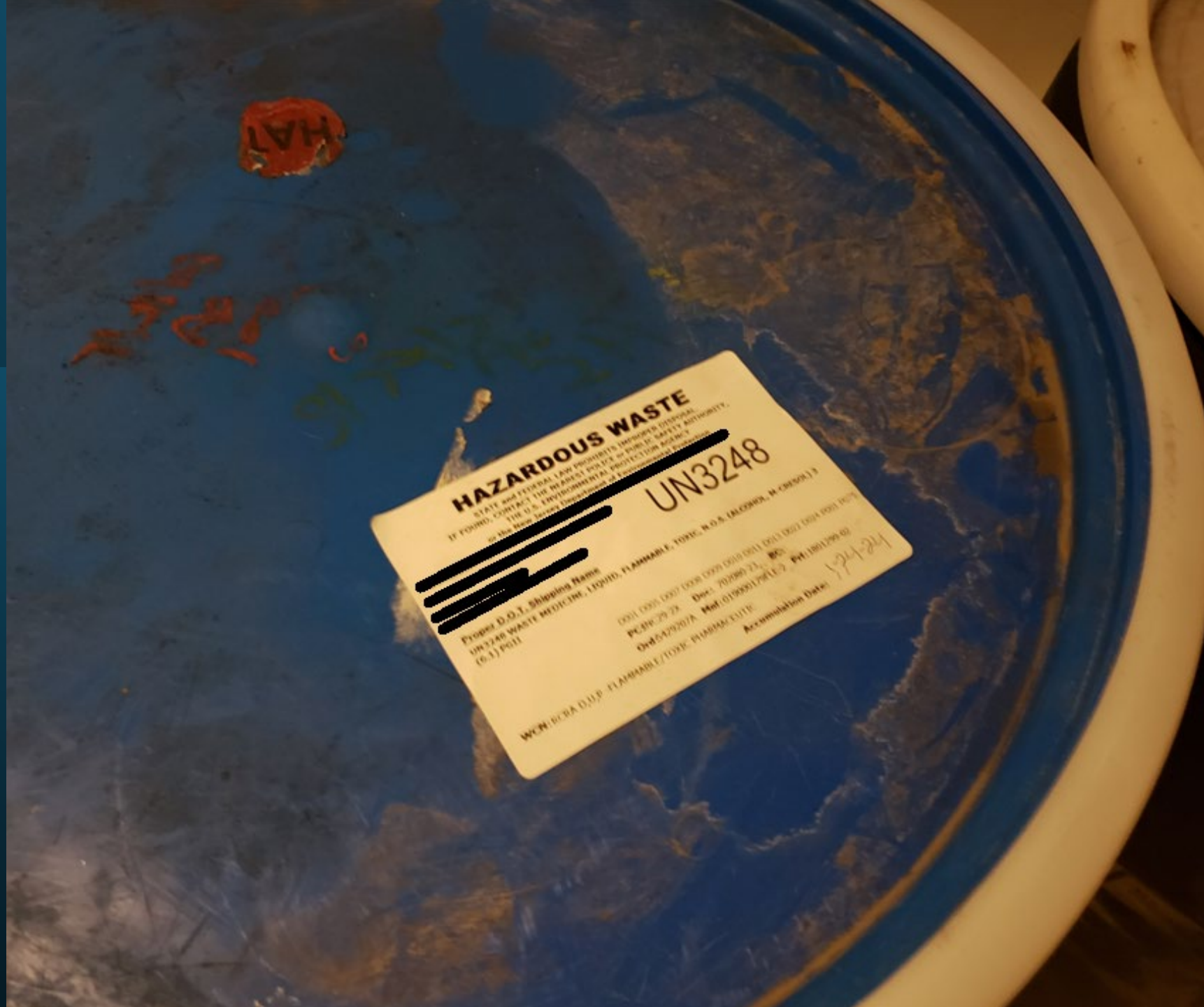
*Potential violation: containers are open and are overflowing.*



# Container Examples

*Containers marked with an accumulation start date.*

*Potential violation: container is labeled “Hazardous Waste” instead of “Hazardous Waste Pharmaceuticals”.*



# Container Examples

*Container correctly labeled  
“Hazardous Waste  
Pharmaceuticals”.*

*Container has  
accumulation start date  
written on right side.*



# Containers with Potentially Creditable Hazardous Waste Pharmaceuticals

No container requirements for potentially creditable hazardous waste pharmaceuticals.

# DEA Containers

- A pharmaceutical that is both a DEA controlled substance and a hazardous waste pharmaceutical is exempt from RCRA if:
  - It is not sewerred
  - It is managed correctly under DEA
  - It is destroyed by a method that meets DEA non-retrievable standard

# DEA Containers

- A DEA container where DEA controlled substances are co-mingled with non-DEA hazardous waste pharmaceuticals
  - Container must be managed under Subpart P

# Documentation Review

# Documentation Required Under Subpart P

HAZARDOUS  
WASTE  
MANIFESTS

TRAINING  
RECORDS

WASTE  
DETERMINATIONS

# Manifest Requirements

Inspectors are typically checking the following major areas when reviewing manifests:

Manifests maintained on site for at least 3 years.  
*[40 CFR 266.502(j)(1)]*

- Facility can utilize manifests currently uploaded on RCRAinfo's e-manifest system to maintain records. Facility must be able to access RCRAinfo.

TSDf signed copies of manifests received.

Exception reports filed if signed copy was not received within 60 days of the transport date.  
*[40 CFR 266.502(i)(2)(i)(A)]*

Information is accurately filled out:

- EPA ID numbers match
- Generator/Transporter/TSDf information is correct
- Waste descriptions, codes, and quantities appear accurate

Manifests for Hazardous Waste Pharmaceuticals use PHRM or PHARMS code in section 13.  
*[40 CFR 266.508(a)(2)(ii)]*

# Manifest Examples

Potential violation:  
PHARMS/PHRM code is  
not used on manifest for  
hazardous waste  
pharmaceutical  
shipment.

Please print or type. Work Order ID 000046666 Form Approved: OMB No. 2050-0039

UNIFORM HAZARDOUS WASTE MANIFEST		1. Generator ID Number	2. Page 1 of 1	3. Emergency Response Phone 800-424-9300	4. Manifest Tracking Number
Generator's Site Address (if different than mailing address)					
6. Transporter 1 Company Name Approved Storage & Waste Hauling Inc.				U.S. EPA ID Number NYR000076513	
7. Transporter 2 Company Name				U.S. EPA ID Number	
8. Designated Facility Name and Site Address Cycle Chem Inc. 217 S First St Elizabeth, NJ 07206				U.S. EPA ID Number NJ000220046	
Facility's Phone: (908) 355-5800					
9a. HW and Packing Group (if any)	9b. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number)	10. Containers No. Type	11. Total Quantity	12. Unit	13. Waste Codes
1. UN1950, AEROSOLS, FLAMMABLE, 2.1		1 DF	G		D001
2. UN3248, WASTE MEDICINE LIQ FLAMMABLE TOXIC NOS(ETHANOL, DAUNOMYCIN)(3.1)PGII		1 DF	G		D001
14. Special Handling Instructions and Additional Information ERG 131-D					
15. GENERATOR'S/OFFEROR'S CERTIFICATION: I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. If export shipment and I am the Primary Exporter, I certify that the contents of this consignment conform to the terms of the attached EPA Acknowledgment of Consent. I certify that the waste minimization statement identified in 40 CFR 262.27(a) (if I am a large quantity generator) or (b) (if I am a small quantity generator) is true.					
16. International Shipments <input type="checkbox"/> Import to U.S. <input type="checkbox"/> Export from U.S. <input type="checkbox"/> Port of entry/exit: <input type="checkbox"/> Date leaving U.S.: Month Day Year 10 26 20					
17. Transporter Acknowledgment of Receipt of Materials Transporter 1 Printed/Typed Name Signature Month Day Year 10 26 20 Transporter 2 Printed/Typed Name Signature Month Day Year					
18. Discrepancy					

GENERATOR	NO.	Type							
	1.	UN1950, AEROSOLS, FLAMMABLE, 2.1	1	DF	G	D001			
	2.	UN3248, WASTE MEDICINE LIQ FLAMMABLE TOXIC NOS(ETHANOL, DAUNOMYCIN)(3.1)PGII	1	DF	G	D001			

*Potential violation:  
PHARMS/PHRM code is  
not used on manifest for  
hazardous waste  
pharmaceutical  
shipment.*

9a. HM	9b. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number, and Packing Group (if any))	10. Containers		11. Total Quantity	12. Unit Wt./Vol.	13. Waste Codes		
		No.	Type					
(X)	1. RQ UN3248 <u>WASTE MEDICINE, LIQUID,</u> <u>FLAMMABLE, TOXIC, N.O.S., 3 (6.1), PGII, (PHENOL,</u> <u>METHANOL), (D004-D009), ERG#131</u>	5	DF	200	P	U002	U010	U03
						U044	U052	U05

# Manifest Examples

Mitomycin/Cisplatin are chemotherapy drugs that, when discarded unused, are a U010 hazardous waste and thus a hazardous waste pharmaceutical.

Potential violation:  
PHARMS/PHRM code is not used on manifest for hazardous waste pharmaceutical shipment.

Please print or type.

Form Approved. OMB No. 2050-0039

UNIFORM HAZARDOUS WASTE MANIFEST

2. Page 1 of 2

3. Emergency Response Phone Number: 877-460-1038

6. Transporter 1 Company Name: Environmental Waste Minimization, Inc. U.S. EPA ID Number: PAR000501577

7. Transporter 2 Company Name: Horvath Truck Inc. U.S. EPA ID Number: PAD14674828

8. Designated Facility Name and Site Address: Veolia ES Technical Solution, LLC, 1 Eden Lane, Flanders, NJ 07834 U.S. EPA ID Number: NJD980536593

MAIL

9a. HM: X

9b. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number, and Packing Group (if any)): UN2811, Waste Toxic solids, organic, n.o.s. (Mitomycin, Cisplatin), 6.1, III, (U010) TM

10. Containers: No. 001, Type DF

11. Total Quantity: 30

12. Unit Wt./Vol.: P

13. Waste Codes: U010

14. Special Handling Instructions and Additional Information: Document # D349043, 111952, 1.) Approval #: 333058; ERG # 154 CHEMO WASTE/NON INFECTIOUS (X) DF, T-139

15. GENERATOR'S/OFFEROR'S CERTIFICATION: I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. If export shipment and I am the Primary Exporter, I certify that the contents of this consignment conform to the terms of the attached EPA Acknowledgment of Consent. I certify that the waste minimization statement identified in 40 CFR 262.27(a) (if I am a large quantity generator) or (b) (if I am a small quantity generator) is true.

16. International Shipments: ☐ Import to U.S., ☐ Export from U.S., Port of entry/exit: Date leaving U.S.:

17. Transporter Acknowledgment of Receipt of Materials: Month 12, Day 13, Year 12

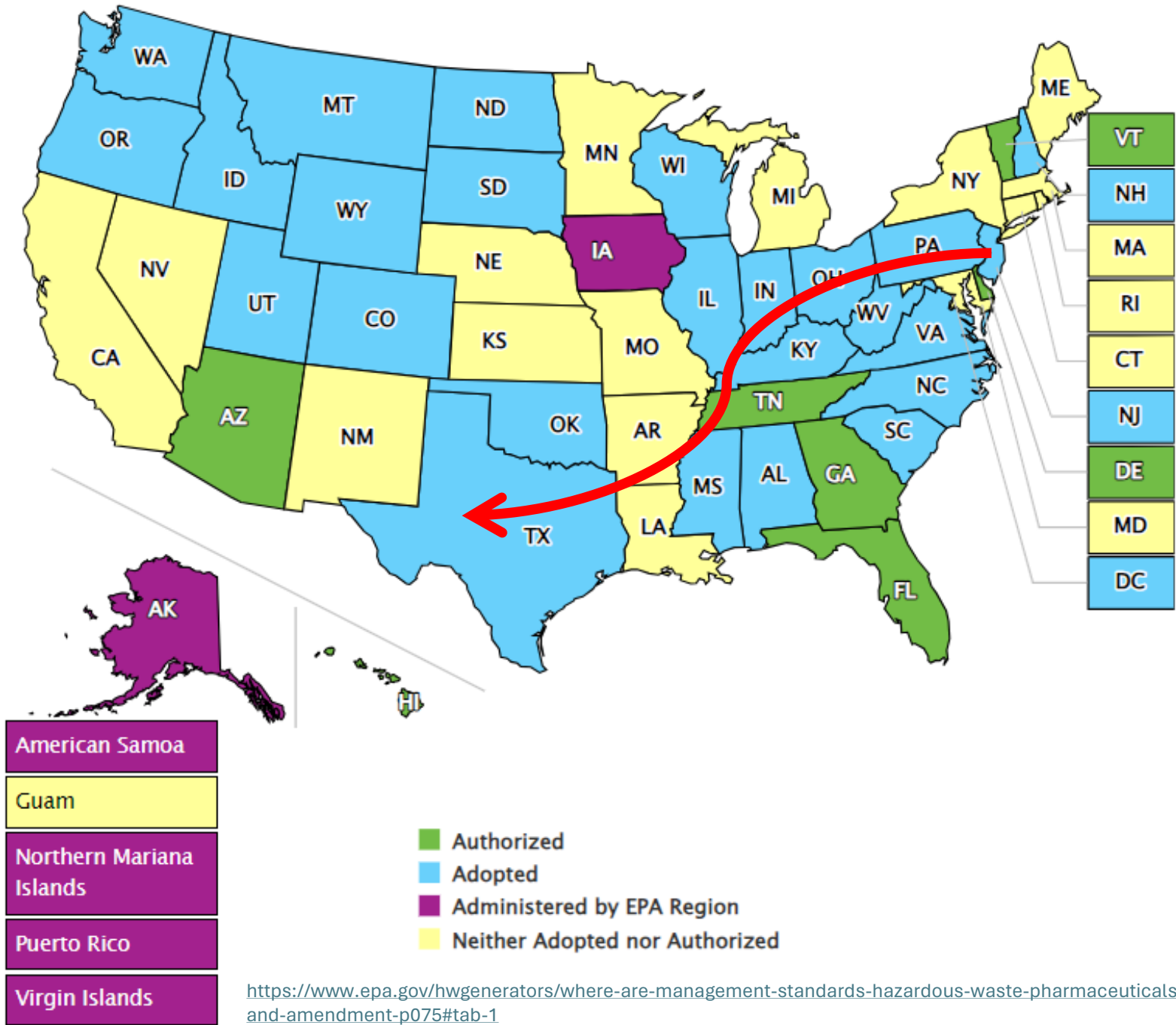
18. Discrepancy: 18a. Discrepancy Indication Space: ☐ Quantity, ☐ Type, ☐ Residue, ☐ Partial Retention, ☐ Full Retention

973-691-3922

9a. HM	9b. U.S. DOT Description (including Proper Shipping Name, Hazard Class, ID Number, and Packing Group (if any))	10. Containers		11. Total Quantity	12. Unit Wt./Vol.	13. Waste Codes		
		No.	Type					
X	1. UN2811, Waste Toxic solids, organic, n.o.s. (Mitomycin, Cisplatin), 6.1, III, (U010) TM	001	DF	30	P	U010		

Manifest for hazardous waste pharmaceuticals going from NJ to another state that has adopted Subpart P: only need PHARMS/PHRM code.

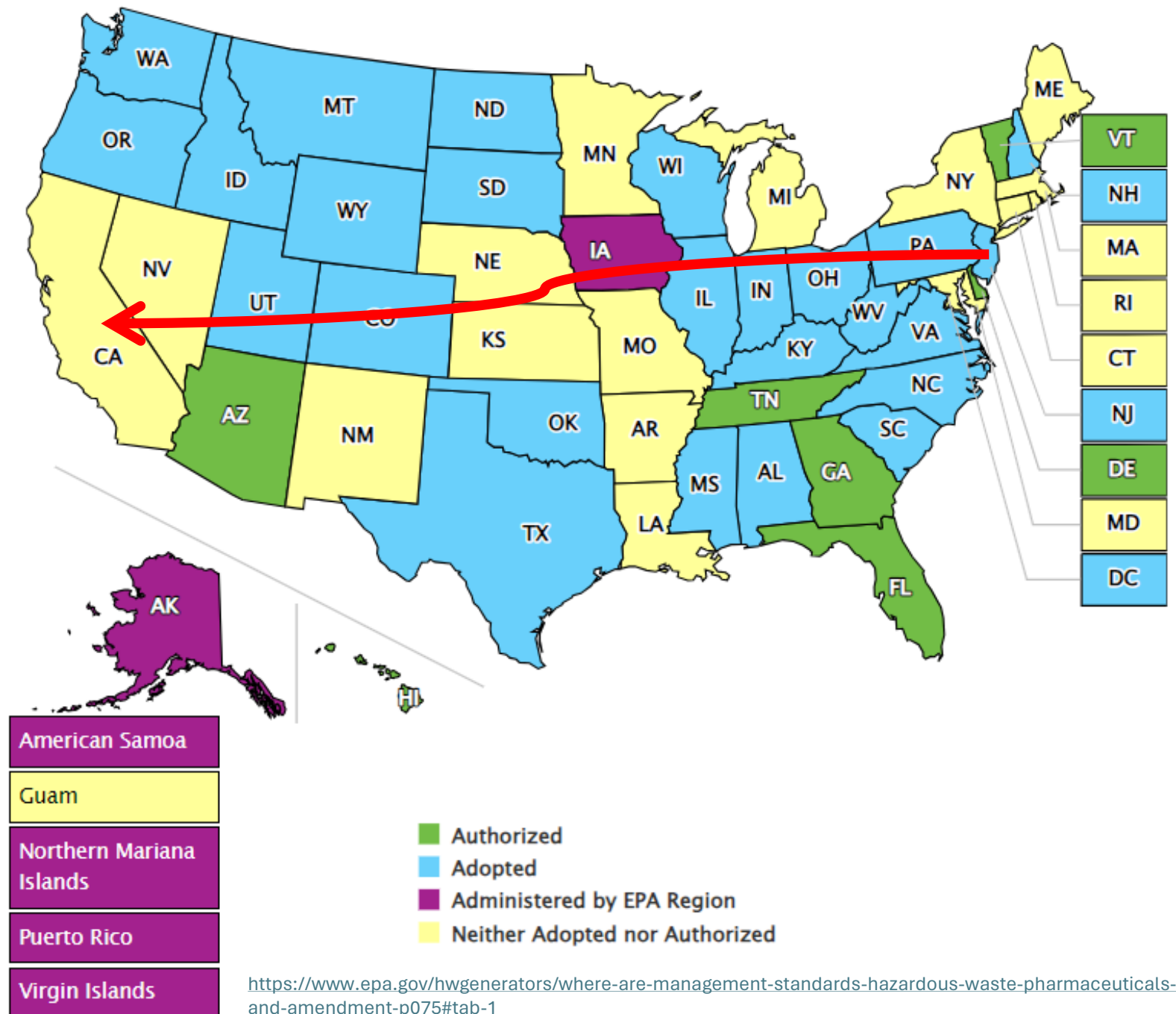
# Subpart P Adoption and the PHARMS code



<https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075#tab-1>

If going to a state that has not adopted Subpart P: manifest must also include hazardous waste codes in addition to PHARMS/PHRM code.

## Subpart P Adoption and the PHARMS code



# Training Records

- Facility must ensure all personnel who manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies. *[40 CFR 266.502(b)]*
- Facility must maintain records of personnel training.

# Waste Determinations

- Facility must determine whether a pharmaceutical is a hazardous waste pharmaceutical. *[40 CFR 266.502(c)]*
- A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with [§ 262.11\(f\)](#), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. *[40 CFR 266.502(j)(3)]*

# Violations

# Most Common Violations

New Jersey Department of Environmental Protection  
Bureau of Hazardous Waste Compliance and Enforcement  
NOTICE OF VIOLATION Attachment

EXPLANATION OF THIS NOTICE (additional pages \_\_\_\_ of \_\_\_\_ )

Site Name \_\_\_\_\_ Date \_\_\_\_\_

In accordance with the Grace Period Law, the Department will not assess a penalty against you for the violations marked with an asterisk \* below, if you take voluntarily action to address and correct these violations within the time periods indicated on CORRECTIVE ACTION PAGE(S).

ADDITIONAL VIOLATION(S):

Subject: Subpart P Notification Citation: 40 CFR 266.502(a)(1)

Description of Noncompliance: Failure of a healthcare facility to notify NJDEP it is operating under Subpart P using RCRAinfo (non-minor).

☐ violation immediately above corrected at time of issuance

Subject: PHARMS Codes Citation: 40 CFR 266.508(a)(2)

Description of Noncompliance: Failure of a healthcare facility to use the PHARMS/PHRM code in box 13 of the hazardous waste manifest for shipments of hazardous waste pharmaceuticals (minor).

☐ violation immediately above corrected at time of issuance

# Most Common Violations

☐ violation immediately above corrected at time of issuance

Subject: Open Containers Citation: 40 CFR 266.502(d)(3)  
Description of Noncompliance: Failure of a healthcare facility to ensure that all containers holding hazardous waste pharmaceuticals are closed except when adding waste into the container (minor).

☐ violation immediately above corrected at time of issuance

Subject: Container Labels Citation: 40 CFR 266.502(e)  
Description of Noncompliance: Failure of a healthcare facility to ensure all containers holding hazardous waste pharmaceuticals are labeled with the words "Hazardous Waste Pharmaceuticals" (non-minor).

☐ violation immediately above corrected at time of issuance

issuer's initials \_\_\_\_\_ rec'd by initials \_\_\_\_\_

## NJDEP COMPLIANCE ASSISTANCE PACKET

<https://www.nj.gov/dep/enforcement/docs/compliance-assistance-packet-2020-v20-3.pdf>

### 8/1/19 SUBPART P SEMINAR

<https://www.state.nj.us/dep/enforcement/docs/HW%20Pharms%20Final%20Rule%20-%20NJ%20Training.pdf>

### 8/1/19 COMPLIANCE ADVISORY

<https://www.nj.gov/dep/enforcement/advisories/2019-04.pdf>

# COMPLIANCE ASSISTANCE PACKET

FOR

## HAZARDOUS WASTE GENERATORS



# Contacts

## Stephan Szardenings, Environmental Specialist III

- Bureau of Hazardous Waste Compliance and Enforcement, Northern Field Office
- C: 609-439-9650
- [Stephan.Szardenings@dep.nj.gov](mailto:Stephan.Szardenings@dep.nj.gov)

## Nick Baier, Environmental Specialist II

- Bureau of Hazardous Waste Compliance and Enforcement, Central Field Office
- C: 609-358-2067
- [Nicholas.Baier@dep.nj.gov](mailto:Nicholas.Baier@dep.nj.gov)