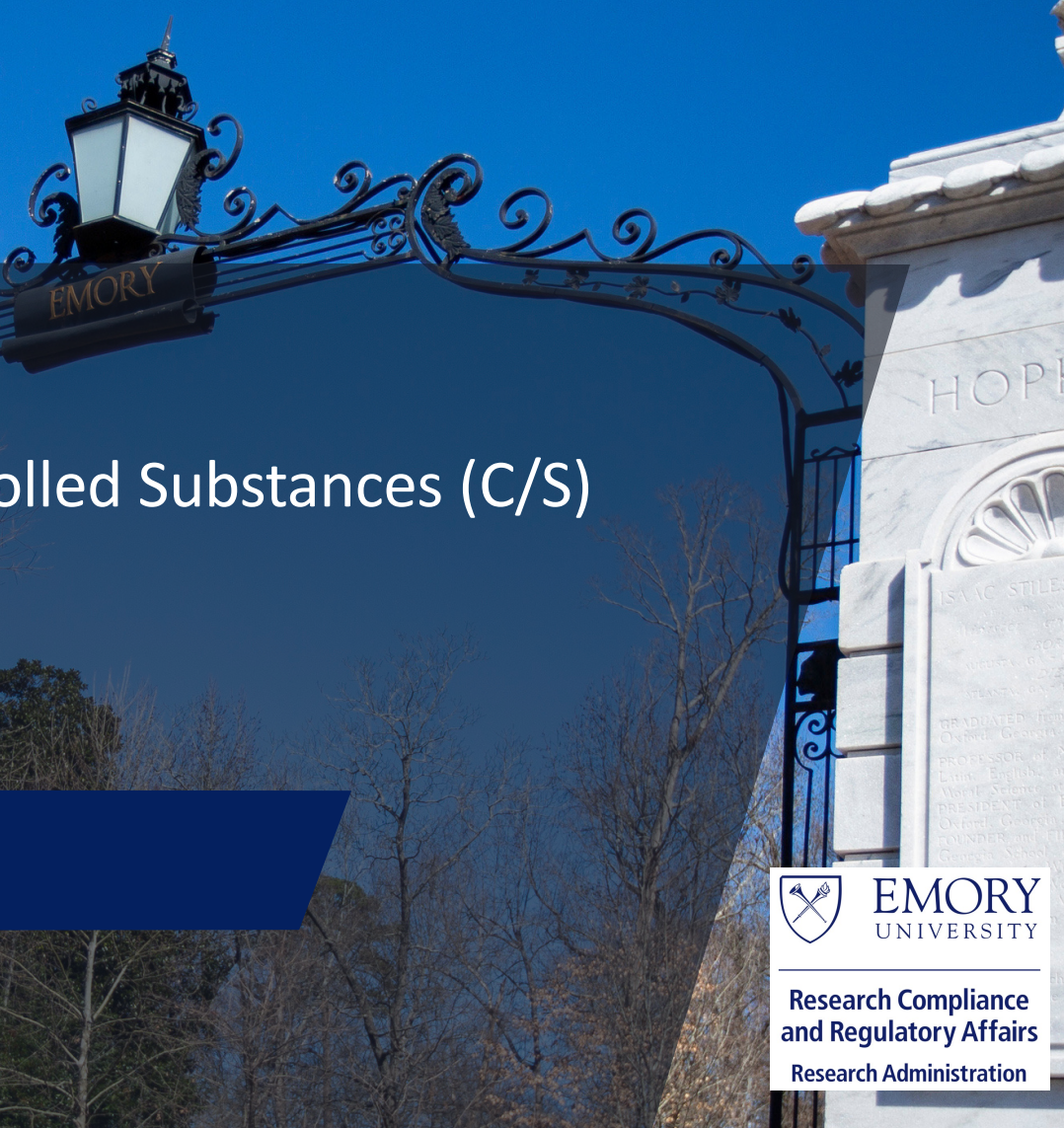




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Proper Destruction of Controlled Substances (C/S) and Dangerous Drugs (D/D)

August 14, 2024



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Research Compliance
and Regulatory Affairs
Research Administration

In this presentation

We will discuss :

- the regulations pertaining to destruction of CS/DD
- the proper disposal methods for C/S
- proper recordkeeping for C/S Destruction
- non-Recoverable Spills/Breakage of C/S
- requesting destruction of D/D
- proper recordkeeping for D/D

Then we will open the floor to Q & As



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Regulations



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State Regulations Pertaining to the Destruction of Dangerous Drugs

Ga. Comp. R. & Regs. 480-7-.04

(8) Record Keeping and Accountability:**(a)** Researchers shall establish and maintain records of all transactions regarding receipt, distribution or other disposition of dangerous drugs or controlled substances.

Federal Regulations Pertaining to the Destruction of Controlled Substances

All controlled substances to be destroyed by a registrant pursuant to 21 CFR 1317.95, must be destroyed in compliance with applicable federal, state, tribal, and local laws and regulations and must be rendered non-retrievable.

21 CFR 1317.90(a). A researcher may dispose of its controlled substances inventory in the following manner pursuant to 21 CFR 1317.05:

1. Promptly destroy that controlled substance in accordance with 21 CFR 1317.90 using an onsite method of destruction.
2. Send those controlled substances to an entity registered with DEA to handle returns/disposals (known as a reverse distributor).



At this time, the only way to destroy:

Controlled Substances are through a reverse distributor. Many labs use "The Rx Exchange"

Dangerous Drugs are picked up by EHSO, who then uses a licensed facility for incineration.

Disposal Methods



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Proper Documentation



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Controlled Substance Destruction Process

To properly reverse distribute C/S Registrants must:

1. Contact a DEA licensed reverse distributor such as www.therxe.com and set up an account.
2. Create an inventory of the C/S you wish to destroy. Separate Schedule I-II drugs from Schedule III-V drugs. You may use Form 4.
3. Schedule I-II C/S must be transferred to a reverse distributor using a DEA Form 222. The reverse distributor will send the Emory Registrant the DEA Form 222, as you are considered the Supplier and will maintain the original DEA Form 222. When you ship the C/S to the Supplier you note on the DEA Form 222 the day the drugs left your lab.
4. Schedule III-V C/S must be documented in the same manner. You may use Form 4 to document the transfer of C/S from the lab to the reverse distributor. It is important you have a record of when the C/S left your lab.
5. All records should be maintained in your DEA Ready Binder for 2 years.

PURCHASER INFORMATION The Rx Exchange 101 Prescription Drug Way ATLANTA, GA 30091			REGISTRATION INFORMATION REGISTRANT#: RX1235678 REGISTRATION TYPE: REVERSE DISTRIBUTOR SCHEDULES: 1N, 2N, 2, 3N, 3, 4, 5 ORDER FORM #: 12000022658 DATE ISSUED: 07/01/24 ORDER FORM 3 OF 3			SUPPLIER DEA # R S 1 2 3 4 5 6 7												
PART 1: TO BE FILLED IN BY PURCHASER AUTHORIZED PURCHASER NAME AND TITLE PRINT OR TYPE NAME AND TITLE AUTHORIZED PURCHASER SIGNATURE SIGNATURE OF REQUESTING OFFICIAL			PART 5: TO BE FILLED IN BY PURCHASER DATE SIGNED DATE			PART 2: TO BE FILLED IN BY PURCHASER John Smith BUSINESS NAME 101 Emory Way Room #456 STREET ADDRESS ATLANTA, GA 30033 CITY, STATE, ZIP CODE												
PART 3: ALTERNATE SUPPLIER IDENTIFICATION – TO BE FILLED IN BY FIRST SUPPLIER (name in Part 2): If order is endorsed to another supplier to fill ALTERNATE DEA 3			SIGNATURE - by first Supplier (OFFICIAL AUTHORIZED TO SIGN)			DATE												
PART 4: TO BE FILLED IN BY SUPPLIER NATIONAL DRUG CODE			NUMBER SHIPPED			DATE SHIPPED												
ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM NUMBER REC'D	NUMBER REC'D	DATE REC'D	4	5	9	6	3	0	7	0	0	*	*	NUMBER SHIPPED	DATE SHIPPED
1	1	100	OXYCODONE 5 MG														1	07/10/24
2	2	10ML	Fatal Plus			0	0	2	9	8	9	3	7	3	*	*	2	07/10/24
3	1	5G	Cocaine Base Raw Powder			1	0	1	9	1	6	2	4	2	*	*	1	07/10/24
4	1	1G	Psilocybin Raw Powder			2	6	4	3	6	8	0	0	1	*	*	1	07/10/24
5																		
6																		
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18																		
19																		
20																		



LAST LINE COMPLETED(MUST BE 20 OR LESS)

Sample Form 4: Schedule III-V Controlled Substance Destruction Log

Box 1: Registrant Information		
Registrant's Name: <i>John Smith</i>	DEA #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room 123, Atlanta, GA, 30325</i>

Box 2: Reverse Distributor DEA Registrant Information		
Registrant's Name: <i>Reverse Distribution LLC</i>	DEA #: <i>DR4758590</i>	Registered Address: <i>45738 Destruction Way, Atlanta, GA, 30325</i>

Box 3: Schedule III-V Destruction Log					
Date of Destruction	Name of Controlled Substance	Concentration/Strength	Total Volume/Quantity to be destroyed	Drug Form	Unique Bottle ID
<i>02/11/23</i>	<i>Buprenorphine HCL</i>	<i>0.3mg/ml</i>	<i>1ml</i>	<i>liquid</i>	<i>BUP0010</i>
<i>02/11/23</i>	<i>Ketamine HCL</i>	<i>100mg/ml</i>	<i>2ml</i>	<i>liquid</i>	<i>KET0003</i>
<i>02/11/23</i>	<i>Testosterone Cypionate USP</i>	<i>100</i>	<i>1 grams</i>	<i>powder</i>	<i>TEST001</i>
<i>02/11/23</i>	<i>Euthasol</i>	<i>390mg</i>	<i>5ml</i>	<i>liquid</i>	<i>EUTH005</i>
<i>02/11/23</i>	<i>Lorazepam</i>	<i>1mg</i>	<i>3m</i>	<i>tablets</i>	<i>LOR0009</i>
<i>02/11/23</i>	<i>Ketamine HCL</i>	<i>100mg/ml</i>	<i>5ml</i>	<i>liquid</i>	<i>KET0004</i>
<i>02/11/23</i>	<i>Buprenorphine HCL</i>	<i>0.3mg/ml</i>	<i>0.5ml</i>	<i>liquid</i>	<i>BUP0011</i>
<i>02/11/23</i>	<i>Ketamine HCL</i>	<i>100mg/ml</i>	<i>0.5ml</i>	<i>liquid</i>	<i>KET0005</i>
<i>02/11/23</i>	<i>Buprenorphine HCL</i>	<i>0.3mg/ml</i>	<i>2ml</i>	<i>liquid</i>	<i>BUP0012</i>
<i>02/11/23</i>	<i>Euthasol</i>	<i>390mg</i>	<i>3ml</i>	<i>liquid</i>	<i>EUTH006</i>

Breaks or Spills that are Non-Retrievable

If the breakage or spillage is clearly observed, but the controlled substances are *not* recoverable, you should document the incident on Form 5.

To maintain complete and accurate records in accordance with 21 CFR 1304.21(a), nonrecoverable breakage or spillage must be recorded on a DEA Form 41 and, as with any other form of disposal under 21 CFR part 1317, must be signed by two individuals who can testify that a breakage or spillage occurred.

[DEA Form 41 \(usdoj.gov\)](https://www.usdoj.gov)

Destruction of D/D through EHSO

All D/D and expired BUP SR/ER (obtained from a prescription only) must be destroyed by EHSO.

1. Create an inventory of the D/D you need to destroy using Form I
2. After EHSO picks up the D/D, document the day the D/D left your lab in Box 3
3. Maintain records for 2 years

Sample Form I: Dangerous Drug Destruction Log

Box 1: Registrant Information		
Registrant's Name: <i>John Smith</i>	GBP #: <i>RS1234567</i>	Registered Address: <i>123 Main Street, Room 5100C, Atlanta, GA, 30325</i>

Box 2: Destruction Information	
Method of Destruction: <i>EHSO</i>	Date of Destruction: <i>02/11/23</i>

Box 3: Dangerous Drug Destruction Log					
Date of Destruction	Name of Dangerous Drug	Concentration/Strength	Total Volume/Quantity to be destroyed	Drug Form	Unique Bottle ID
<i>02/11/23</i>	<i>Isoflurane</i>	<i>100</i>	<i>17ml</i>	<i>liquid</i>	<i>ISO001</i>
<i>02/11/23</i>	<i>Meloxicam</i>	<i>5mg/ml</i>	<i>20ml</i>	<i>liquid</i>	<i>MEL0010</i>
<i>02/11/23</i>	<i>Amoxicillin</i>	<i>200mg/5ml</i>	<i>10ml</i>	<i>powder</i>	<i>AMOX003</i>
<i>02/11/23</i>	<i>Tamoxifen Citrate</i>	<i>98%</i>	<i>2g</i>	<i>powder</i>	<i>TMX0013</i>
<i>02/11/23</i>	<i>Lidocaine 1%</i>	<i>500mg/50ml</i>	<i>7ml</i>	<i>liquid</i>	<i>LID0001</i>
<i>02/11/23</i>	<i>Isoflurane</i>	<i>100</i>	<i>125ml</i>	<i>liquid</i>	<i>ISO003</i>

Sample Form 13: Current Use and Disposition Form for Prescription Controlled Substances (BUP SR/ER)

Note: This form is only to be used when a Researcher obtains a controlled substance through a prescription for the clinical care of animals. One form needs to be used every new bottle received.

Box 1: Registrant/PI Information		
Registrant/PI Name: <i>Joe Smith</i>	DEA # (if applicable): <i>RS1234567</i>	Address: <i>123 Main Street, Atlanta, GA, 30325</i>

Box 2: Stock Bottle Information						
Name of Substance: <i>Buprenorphine SR</i>	Concentration/Strength: <i>0.05mg/ml</i>	Starting Volume/Quantity: <i>10ml</i>	Expiration Date: <i>08/30/2026</i>	Date added to inventory: <i>02/10/23</i>	Prescription #: <i>RX123546790</i>	Unique Bottle ID: <i>BPSR0023</i>

Box 3: Stock Bottle Disposition Information				
Name of Substance: <i>Buprenorphine SR</i>	Concentration/Strength: <i>0.05 mg/ml</i>	Total Volume/Quantity Disposed: <i>0.5 ml</i>	Method of Destruction: <i>ESD</i>	Disposition Date: <i>06/10/23</i>
Research Staff Printed Name: <i>Joe Smith</i>		Signature: <i>Joe Smith</i>		Date: <i>06/10/23</i>
Research Staff Printed Name: <i>JoAnn Taylor</i>		Signature: <i>JoAnn Taylor</i>		Date: <i>06/10/23</i>

Box 4: Current Prescription Controlled Substance Use Log						Unique Bottle ID: <i>BPSR0023</i>
Date	Starting Volume/Quantity	Amount Used	Balance Remaining	Printed Name of Person who Dispensed/Administered Drug	Reason for Use	
<i>02/11/23</i>	<i>10ml</i>	<i>0.5ml</i>	<i>9.5ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>	
<i>02/15/23</i>	<i>9.5ml</i>	<i>0.5ml</i>	<i>9.0ml</i>	<i>JoAnn Taylor</i>	<i>Pain Management</i>	
<i>02/19/23</i>	<i>9.0ml</i>	<i>1ml</i>	<i>8ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>	
<i>02/28/23</i>	<i>8ml</i>	<i>2ml</i>	<i>6ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>	
<i>03/05/23</i>	<i>6ml</i>	<i>0.5ml</i>	<i>5.5ml</i>	<i>Joe Smith</i>	<i>Pain Management</i>	
<i>03/10/23</i>	<i>5.5ml</i>	<i>5 ml</i>	<i>0.5ml</i>	<i>JoAnn Taylor</i>	<i>Pain Management</i>	



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Scheduling Destruction through EHSO



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EHSO Webpage

EHSO can only pick up Dangerous Drugs (D/D) and Buprenorphine ER/SR (BUP ER/SR) that was obtained by a prescription through DAR/EPC.

To request D/D or BUP ER/SR (RX only) waste pick up

1. Go to EHSO's website at [Home | Emory University | Atlanta GA](#)
2. Scroll down to Request Waste Collection

I'd like to...

- [Report An Incident, Illness, Injury or Near Miss](#)
- [Report a Spill](#)
- [Find a Safety Data Sheet \(SDS\)](#)
- [Get Fit Tested](#)
- [Request Waste Collection](#)

Learn More About:

- [Emory Laboratory Safety Binder](#)
- [Waste Management](#)

Profile in EHSA

If you do not already have a profile in EHSA, you will need to request one. We have a helpful [Video Link](#) on creating a profile.

PLEASE READ

NEW WASTE COLLECTION REQUEST PLATFORM

EHSO will transition its Waste Collection Request process to a new platform, EHS Assist (EHSA), on 08/01/23.

Please review the following training materials for the new process and contact us at chemwaste@emory.edu if you have any questions or need help.

[Requesting Waste Collection in EHSA \(PDF\)](#)

[EHSA Profile Template Descriptions \(PDF\)](#)

[How to Create a Waste Profile in EHSA \(Video\)](#)

[How to Create and Request Pickup of EHSO Provided Waste Containers in EHSA \(Video\)](#)

[How to Request Pickup for Expired/Unwanted Chemicals, Batteries, Cylinders and Aerosols \(Video\)](#)

[REQUEST WASTE COLLECTION](#)

Welcome to the EHSO Database

Quick Links

- Asbestos
- Chemical/Regulated Waste
- Inspections
- Radiation Safety
- SDS HUB
- TRAINING
- Z Files



PI Overview
Danisha Blossat



WELCOME TO EHS-assist

Contact us for help, guidance or training at 404-859-4613 or email us at chemwaste@emory.edu.

NEW HOW TO's:

- Campus Service - how to respond to an audit of inspection
- Research Safety - how to respond to an audit of inspection

NEW CHEMICAL WASTE PROCESS GUIDANCE:

- Video Review: Create & Edit Waste Profile
- Video Review: Bulk Waste
- Video Review: Labpack



Hazardous Waste Accumulation



Waste Supply Requests



Training Records



Safety Inspections



Inventory



Worker Registration



Permits



SDS



Satellite Accumulation



SOP Documents



Equipment

[+ Add a Waste Request](#)
[✎ Edit a Waste Request](#)
[🗑 Delete a Waste Request](#)
[📄 Supply Request](#)
[Waste Request Reports](#)
Status

Drag a column header and drop it here to group by that column

		Accumulate	Days Accumulated	Request Date	Request Number
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>
Hazardous Waste...	Request Received	No		08-10-2024	P240810001

Waste Profile Request Number: TBD

[Edit Profile](#)

Contact Edit Blossat, Danisha (P4379763)	Contact Phone (404)251-1216	Contact Email danisha.blossat@emory.edu
PI Name Edit Authorization, Dummy (pkey14738)	Department Environ Health & Safety Office (914500)	Location Edit WHITEHEAD BIOMEDICAL RESEARCH BUILDING : G44A

Comments for this request: ?

[📄 Order Replacement Containers & Labels](#)

Container 1 **Waste Type** Chemicals 📷

Accumulate No

*Physical Form	*# of Conts.	*Container Type	*Amount	*Unit of Measure	Quantity Disposed
<input type="text"/>	<input type="text" value="1"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Location of Waste (hood, bench, etc.):

Additional Hazardous Waste Label Information (100-character limit):

Container Contents

	Chemical Description	contains	% of Content	CAS #	Multiple Ingredients	Ingredients
	<input type="text" value="Search ...or click to enter Chemical Description"/>			<input type="text" value="Click to enter CAS #"/>		

Container 1 Waste Type Chemicals

Accumulate No

*Physical Form Liquid *# of Conts. 1 *Container Type Original manf. container *Amount 25 *Unit of Measure Milliliter Quantity Disposed 0

Location of Waste (hood, bench, etc.):

Additional Hazardous Waste Label Information (100-character limit):

Container Contents

	Chemical Description	contains	% of Content	CAS #	Multiple Ingredients	Ingredients
	<input type="text" value="Search ...or click to enter Chemical Description"/>			<input type="text" value="Click to enter CAS #"/>		

Select Chemical

Search By Chemical Description

Search By Chemical CAS # Show PI's Inventory

Drag a column header and drop it here to group by that column

	CAS #	Synonym	Vendor Name	Catalog
<input type="button" value="▼"/>	<input type="text"/>	<input type="text" value="pharm"/> <input type="button" value="x"/> <input type="button" value="▼"/> <input type="button" value="↕"/>	<input type="text"/>	<input type="text"/>
<input type="button" value="Select"/>	ALL-PHRM	Waste@: General Pharmaceutical		Template

Waste Profile [Edit Profile](#)

Request Number: TB

Contact [Edit](#) **Contact Phone** **Contact Email**
 Blossat, Danisha (P4379763) (404)251-1216 danisha.blossat@emory.edu

PI Name [Edit](#) **Department** **Location** [Edit](#)
 Authorization, Dummy (pkey14738) Environ Health & Safety Office (914500) WHITEHEAD BIOMEDICAL RESEARCH BUILDING : G44A

Comments for this request: ?

[Order Replacement Containers & Labels](#)

Container 1 **Waste Type** Chemicals **Accumulate** No

***Physical Form** Liquid ***# of Conts.** 1 ***Container Type** Original manf. container ***Amount** 25 ***Unit of Measure** Milliliter **Quantity Disposed** 25

Location of Waste (hood, bench, etc.):
 lock box see Danisha

Additional Hazardous Waste Label Information (100-character limit):

5 vials of meloxicam, ketamine, etc.

Container Contents

	Chemical Description	% of Content	CAS #	Multiple Ingredients	Ingredients
Remove	Search Waste@: General Pharmaceutical	100.00	ALL-PHRM	Yes	Mitomycin C - 0.00% () Cyclophosphamide - 0.00% () Warfarin - 0.00% () Lidocane - 0.00% ()

Would you like to Submit this request for pickup or Save this request?

[Save](#) [Save & Submit](#)

+ Add a Waste Request Edit a Waste Request Delete a Waste Request Supply Request Waste Request Reports Status: Not Completed

Drag a column header and drop it here to group by that column

		Accumulate	Days Accumulated	Request Date	Request Number ↓	Contents	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hazardous Wast...	Request Pickup	No	0		P240810001	Container 1 : 1 - 20.0 ML Original manf. container (Liquid) - [UN 3248, 3, 6.1, II] Waste@: General Pharmaceutical - 100.00%	

Report Parameters

what label # would you like to start printing on?

Cancel View Report

Hazardous Waste Label
Request Number: P240810001
Environmental Health and Safety Office 404-727-5922
CHEMWASTE@EMORY.EDU

PI, Program Owner : Authorization, Dummy
Department : Environ Health & Safety Office
Building - Rm : WHITEHEAD BIOMEDICAL RESEARCH BUILDING: G
Contact/Phone# : Blossat, Danisha / (404)251-1216

Waste Description: Waste@: General Pharmaceutical
Contents: Warfarin Cyclophosphamide
 Mitomycin C
 Lidocane

Additional contents: meloxicam, ketamine
Characteristics: Ignitable, Toxic

+ Add a Waste Request Edit a Waste Request Delete a Waste Request Supply Request Waste Request Reports Status: Not Completed

Drag a column header and drop it here to group by that column

		Accumulate	Days Accumulated	Request Date	Request Number ↓	Contents	W
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Hazardous Wast...	Request Pickup	No	0		P240810001	Container 1 : 1 - 20.0 ML Original manf. container (Liquid) - [UN 3248, 3, 6.1, I] Waste@: General Pharmaceutical - 100.00%	Cl

Confirm

Request pickup for this container?

P240810001
Waste@: General Pharmaceutical - 100.00%

No Yes

Thank you for participating today.

Our next webinar is September 18th, 2024, at 12pm.

Questions?



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