

RCRA Pharmaceutical Waste - An Inspector's Viewpoint

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Generator Classifications

- **Conditionally Exempt Small Quantity Generator**

- Each month generates less than 220 pounds of hazardous waste and less than 2.2 pounds of acute hazardous waste
- Never stores more than 2,200 pounds of hazardous waste or 2.2 pounds of acute hazardous waste

- **Small Quantity Generator**

- In any month generates between 220 and 2,200 pounds of hazardous waste and less than 2.2 pounds of acute hazardous waste
- Stores up to 13,200 pounds of hazardous waste and less than 2.2 pounds of acute hazardous waste

- **Large Quantity Generator**

- In any month generates more than 2,200 pounds of hazardous waste or more than 2.2 pounds acute hazardous waste
- Stores more than 13,200 pounds of hazardous waste or more than 2.2 pounds of acute hazardous waste



What Counts toward your Generator Status:

- Hazardous waste pharmaceuticals (Characteristic or U & P Listed)
- Wastes generated in on-site outpatient clinics or histology labs
- "P" Listed inner packaging
- Other Hazardous Wastes generated within the hospital


What Doesn't Count toward your Generator Status:

- Non-hazardous waste pharmaceuticals (all others)
- RCRA Empty containers other than "P" listed drugs
- Pharmaceuticals returned for credit through "reverse distribution"
- Non-Hazardous Chemo drugs (if segregated)
- Universal Waste

HW Chemo vs Trace Chemo

Black box or yellow bag






HW Chemo vs Trace Chemo

Black box or yellow bag

- The term “**bulk chemotherapy**” is not a regulatory term but is used to differentiate chemotherapy containers that are not “RCRA empty.”
 - Partial bottles of chemo agents which are not needed to complete a dosage.
 - IV bags that go unused or are only partially emptied.
 - Empty bottles of P-Listed chemo pharmaceuticals
 - Non-RCRA “bulk Chemo that the facility chooses to dispose of as Hazardous Waste



HW Chemo vs Trace Chemo

Black box or yellow bag

- All chemotherapy paraphernalia should be managed as **trace** chemotherapy waste if there has been the potential for exposure to chemotherapy contamination. Items that are appropriate for management as trace chemotherapy waste include:
 - “RCRA empty” vials, syringes, IV bags, and tubing;
 - Gowns, gloves, wipes and other paraphernalia associated with routine handling, preparation, and administration of chemotherapy; and,
 - Wipes and other materials used during routine cleaning and decontamination of a Biological Safety Cabinet or glove box (unless alcohols, phenols or other hazardous materials are used).

HW Chemo vs Trace Chemo

Black box or yellow bag





Storage Time Limits

- CESQG can store waste indefinitely.
 - If onsite HW reaches 2,200 pounds facility becomes an SQG.
 - If onsite HW of P-waste reaches 2.2 lbs facility becomes a LQG
- SQG's can store waste for up to 180 days.
- LQG's can store waste for up to 90 days.



Container Management

Satellite Accumulation Areas

- “At or Near” the point of Generation and under the control of the operator.
- Containers must be kept closed except when filling or emptying.
- Must be marked with the words “Hazardous Waste” or other words that describe the waste.



Where Might Satellite Accumulation Areas be Located?

Pharmacy/Satellites

Patient Care Units

Emergency Room/Operating Room

Intensive Care Unit (ICU)

Oncology/Hematology

Other Outpatient Clinics

Long Term Care Facilities

Satellite Accumulation Containers

- Sept 2008 Position Paper in CAV packet





Container Management

<90 or <180 Day Storage Areas

- Must be marked with the words “Hazardous Waste” and Accumulation Start Date.
- Containers must be kept closed except when filling or emptying.
- Adequate Aisle Space.
- Managed to prevent a rupture or leak.
- Access to emergency equipment and communications or an alarm system.

HW Accumulation Areas





Inspections

■ SQG's

- Weekly for hazardous waste storage containers
- Daily/weekly for hazardous waste storage tanks
- Log recommended but not required

■ LQG's

- Weekly for hazardous waste storage containers
- Daily/bimonthly/yearly for hazardous waste storage tanks
- Log required



Hazardous Waste Training

- SQG's

- Basic waste handling familiarization & emergency procedures
- Documentation not required but recommended

- LQG's

- Full training
- Initial & Annual refresher
- Documentation required

Hazardous Waste Manifest

- SQG's & LQG's required to ship waste using hazardous waste manifest form.
- Must keep copies for 3 years.

Form 304 (Rev. 1-2002) Hazardous Waste Manifest

SHIPPER INFORMATION

Name of Shipper: _____

Address: _____

City: _____ State: _____ Zip: _____

U.S. EPA ID No. (if applicable): _____

RECEIVER INFORMATION

Name of Receiver: _____

Address: _____

City: _____ State: _____ Zip: _____

U.S. EPA ID No. (if applicable): _____

WASTE DESCRIPTION

U.S. EPA Hazardous Waste Code (see 40 CFR 261.24)	Quantity (kg or lb)	Weight (kg or lb)	U.S. EPA ID No. (if applicable)	U.S. EPA ID No. (if applicable)

ADDITIONAL INFORMATION

1. Special Handling Instructions and Additional Information: _____

2. Declaration of Shipper's Responsibility: I hereby declare that the contents of this manifest are true and accurate, and that I am a generator of hazardous waste as defined in 40 CFR 261.24. I am not a transporter or a person who is not a generator of hazardous waste as defined in 40 CFR 261.24. I am not a transporter or a person who is not a generator of hazardous waste as defined in 40 CFR 261.24.

3. Declaration of Receiver's Responsibility: I hereby declare that I am a person who is not a generator of hazardous waste as defined in 40 CFR 261.24. I am not a generator of hazardous waste as defined in 40 CFR 261.24.

4. Declaration of Transporter's Responsibility: I hereby declare that I am a transporter of hazardous waste as defined in 40 CFR 261.24. I am not a generator of hazardous waste as defined in 40 CFR 261.24.

5. Declaration of Treatment, Storage, and Disposal Facility's Responsibility: I hereby declare that I am a treatment, storage, and disposal facility as defined in 40 CFR 261.24. I am not a generator of hazardous waste as defined in 40 CFR 261.24.

6. Declaration of Manifest Completion: I hereby declare that this manifest is complete and accurate, and that I am a generator of hazardous waste as defined in 40 CFR 261.24. I am not a transporter or a person who is not a generator of hazardous waste as defined in 40 CFR 261.24.



Hazardous Waste Manifest

Different from RMW Tracking Sheet

- 5 part form, hold on to initial copy and wait for copy to be mailed to you.
- Should get copy mailed back from TSDF (Treatment Storage or Disposal Facility) within 35 days. - “Cradle to Grave”
- Person signing the manifest is certifying that the materials shipped match the manifest. - Discrepancy Report



Biennial Report

- LQG's required to submit a report every two years summarizing waste shipments such as waste types, quantities, transporter and TSD facilities utilized.



Contingency Plan

- SQG's - Basic plan

- By the phone: Emergency Coordinator name & telephone #, fire department telephone #,
- Post location of fire extinguishers & alarm & spill equipment.



Contingency Plan

■ LQG's - Full Plan

- Actions & Roles of Staff and Emergency Personnel in case of Emergency
- Agreements with Local Authorities (Fire, Police)
- Names and phone #s of Emergency Coordinators
- Location & Capabilities of Spill & Emergency Equipment.
- Evacuation Procedures Signals & Routes




Preparedness & Prevention

- Familiarize fire, police, hospital with wastes generated and potential hazards
- Have emergency response contractor agreement.




Picking a TSDF – **You are in Control**

- You are Ultimately Responsible for Any Waste You Generate (Joint & Several Liability)
- Ask about disposal methods (Incineration, Treatment, Bulking...)
- Certificate of Destruction - Not worth much, but maybe better than nothing.



What other hazardous wastes are generated in your hospital?

- Solvents generated in histology labs (F003, D001).
- Formaldehyde used in morgues (U122).
- Crushed florescent bulbs from maintenance (D011).



What other regulated wastes are generated in your hospital?

- Used oils - container must be marked “Used Oil”, not regulated as haz-waste if destined for recycling.
- Universal Wastes - Batteries, Light Bulbs, Mercury Containing Equipment (& in NJ Electronics), must be marked UW, packaged to prevent breakage & shipped at least once a year.
- RMW -Red Bag Waste

Universal Waste

Batteries - Containers everywhere

Bulbs – Where do I put them all?





Top 5 RCRA Tips for Hospitals:

1) Visit your <90/<180 day storage area the day before your next pickup.

- Check for aisle space, access to com. or alarm system, spill equip.
- Make sure all containers are labeled & dated (<90 or 180 days?)
- Make sure all containers are closed.
- Weekly inspections?

2) Make sure Universal Waste is being properly managed.

- Bulbs - labeled? Safe from breaking? bulb crusher = HW & Air permit
- Batteries - buckets, buckets, everywhere – labeled? closed?
- Computers/Electronics/TVs - labeled? protected from breakage?
- All - Shipped at least once a year? Paperwork?, Training?



Top 5 RCRA Tips for Hospitals:

- 3) Make sure true HW chemo waste isn't being disposed of as RMW
 - Mixture rule (any mixture of a listed hw & a solid waste is HW)
 - Bulk vs Trace really equals Contaminated vs Not Contaminated
 - RCRA Empty = <3% by weight & emptied by all normal means

- 4) Make sure your Satellite Accumulation Containers are;
 - Closed
 - Labeled
 - At or Near the "point of generation"
 - How many do you have & where?

- 5) Visit the "other places" that generate HW in the hospital
 - The Lab - Xylenes used as tissue fixatives
 - The Morgue - Formaldehyde & Formalin
 - The Chemo outpatient areas (See #3 above)



Additional Resources

NIOSH Hazardous Drug Alert

www.cdc.gov/niosh/docs/2004-165/#sum

OSHA Technical Manual

http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#app_vi:2_1

Pharmaceutical waste webpage:

www.h2e-online.org/hazmat/pharma.html

Healthcare Education Resource Center (HERC)

Blueprint on Pharmaceutical Waste Management (Revised)

www.hercenter.org/hazmat/tenstepblueprint.pdf

NJDEP Hazardous Waste Enforcement's Compliance Assistance Page

<http://www.nj.gov/dep/enforcement/ca-intro.html>