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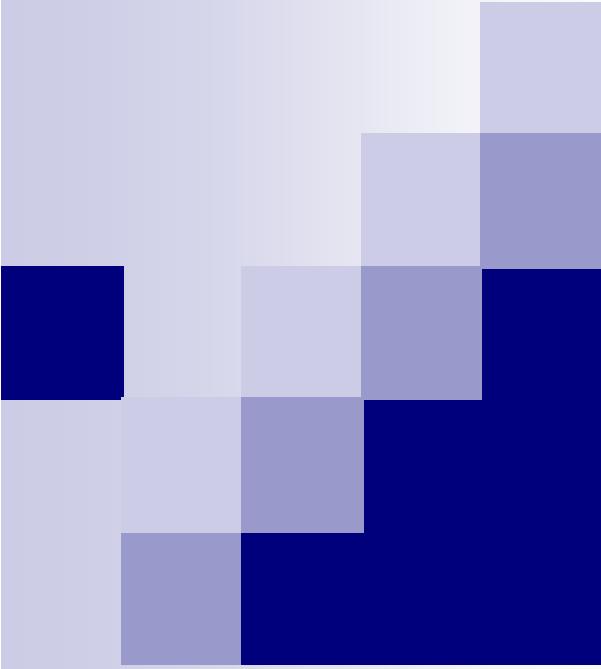
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RCRA Pharmaceutical Waste - An Inspector's Viewpoint

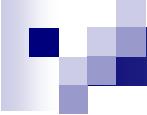
Paul King

Principal Environmental Specialist

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Phone (609) 439-9728 Fax (609) 292-3970



Generator Classifications

- Conditionally Exempt Small Quantity Generator

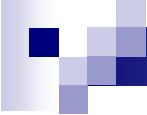
- Each month generates less than 220 pounds of hazardous waste and less than 2.2 pounds of acute hazardous waste
 - Never stores more than 2,200 pounds of hazardous waste or 2.2 pounds of acute hazardous waste

- 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

Is it a Hazardous Waste?



Does the Waste Exhibit A Hazardous Waste Characteristic?

As per 261.20A solid waste, not excluded from regulation under 261.4(b), is a hazardous waste if it exhibits one of the following characteristics:



Ignitability



Corrosivity



Reactivity



Toxicity



Characteristic of Ignitability

Hazardous Waste Number: D001

Aqueous Solution containing 24% alcohol or more by volume & flash point<140° F

Non-aqueous solutions with flash points <140 ° F

Flammable aerosols

Oxidizers

Examples:

Rubbing Alcohol

Topical Preparations such as Erythromycin Gel 2%

Injections such as Taxol

Inhalents such as Primatene aerosol

Oxidizers could include potassium permanganate



Characteristic of Corrosivity

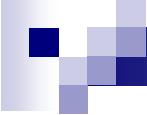
Hazardous Waste number: D002

Having a pH ≤ 2 or \geq to 12.5

Examples: Primarily compounding chemicals:

Sodium Hydroxide

Glacial Acetic Acid



Characteristic of Reactivity

Hazardous Waste Number: D003

Must meet one of eight separate criteria identifying certain explosive and water reactive wastes

Nitroglycerin formulations are considered excluded Federally from the P081 listing, unless they exhibit another characteristics, such as ignitability.

Does the Waste Exhibit the Characteristic of Toxicity?

EPA HW No. ¹	Contaminant	CAS No. ²	Regulatory Level (mg/L)
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0
D023	o-Cresol	95-48-7	200.0
D024	m-Cresol	108-39-4	200.0
D025	p-Cresol	106-44-5	200.0
D026	Cresol		200.0
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7
D030	2,4-Dinitrotoluene	121-14-2	0.13
D012	Endrin	72-20-8	0.02

Does the Waste Exhibit the Characteristic of Toxicity?

EPA HW No. ¹	Contaminant	CAS No. ²	Regulatory Level (mg/L)
D031	Heptachlor (and its epoxide)	76-44-8	0.008
D032	Hexachlorobenzene	118-74-1	0.13
D033	Hexachlorobutadiene	87-68-3	0.5
D034	Hexachloroethane	67-72-1	3.0
D008	Lead	7439-92-1	5.0
D013	Lindane	58-89-9	0.4
D009	Mercury	7439-97-6	0.2
D014	Methoxychlor	72-43-5	10.0
D035	Methyl ethyl ketone	78-93-3	200.0
D036	Nitrobenzene	98-95-3	2.0
D037	Pentachlorophenol	87-86-5	100.0
D038	Pyridine	110-86-1	5.0
D010	Selenium	7782-49-2	1.0
D011	Silver	7440-22-4	5.0
D039	Tetrachloroethylene	127-18-4	0.7
D015	Toxaphene	8001-35-2	0.5
D040	Trichloroethylene	79-01-6	0.5
D041	2,4,5-Trichlorophenol	95-95-4	400.0
D042	2,4,6-Trichlorophenol	88-06-2	2.0
D017	2,4,5-TP (Silvex)	93-72-1	1.0
D043	Vinyl chloride	75-01-4	0.2



Characteristic of Toxicity

Hazardous waste numbers: D004 – D043

40 chemicals which must be below specific leaching concentrations
Must pass the Toxicity Characteristic Leaching Procedure (TCLP)

Examples of potential toxic ingredients of pharmaceuticals:

Arsenic (D004)

Barium (D005)

Cadmium (D006)

Chromium (D007)

Mercury (D009) (thimerosal, phenylmercuric acetate)

Selenium(D010)

Silver (D011)

Lindane (D013)

m-Cresol (D024) (insulin preservative)

Is the Solid Waste A Listed Hazardous Waste?



As per 261.30 A *solid waste* is a *hazardous waste* if it is listed in this part, unless it has been excluded from this list under per 260.20 and 260.22:

“F” Hazardous Wastes From Non-specific Sources (261.31)

Waste Xylene Mixtures – F003

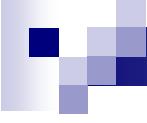
“K” Hazardous Wastes From Sources (261.32)

Is the Solid Waste A Listed Hazardous Waste?



As per 261.30 A *solid waste* is a *hazardous waste* if it is listed in this part, unless it has been excluded from this list under per 260.20 and 260.22:

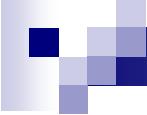
“P” & “U” Discarded Commercial Chemical Products, Off-specification Species, Container Residues, And Spill Residues (261.33)



Commercial Chemical Product Definition

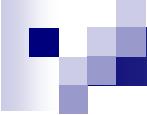
As per 261.33(d) - Comment

Commercial Chemical Products - A chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient.



Examples of U-listed Pharmaceutical Wastes

■ Chloral Hydrate (CIV)2	U034	■ Mitomycin C (chemo)	U010
■ Chlorambucil (chemo)	U035	■ Paraldehyde (CIV)	U182
■ Chloroform	U044	■ Phenacetin	U187
■ Cyclophosphamide (chemo)	U058	■ Phenol	U188
■ Daunomycin (chemo)	U059	■ Reserpine	U200
■ Dichlorodifluoromethane	U075	■ Resorcinol	U201
■ Diethylstilbestrol	U089	■ Saccharin	U202
■ Formaldehyde	U122	■ Selenium sulfide	U205
■ Hexachlorophene	U132	■ Streptozotocin (chemo)	U206
■ Lindane	U129	■ Trichloromonofluoromethane	U121
■ Melphalan (chemo)	U150	■ Uracil mustard (chemo)	U237
■ Mercury	U151	■ Warfarin <0.3%	U248



Acutely Hazardous Waste

“P” Listed Wastes

An Acute Hazardous Waste is normally designated by a "P" number as its waste code. Acute hazardous waste is a category of hazardous waste that can exerts its toxicity with exposure to smaller quantities and in a shorter period of time than non-acute hazardous waste. This category of hazardous waste for the reasons mentioned has different reporting requirements. Sites that generate in any single calendar month, or accumulated at any time, 1 kg (2.2 lbs.) of acute hazardous waste are a RCRA LQG and must submit a Biennial Hazardous Waste Report to the Department for that reporting year.



Examples of P-Listed Pharmaceutical Wastes

Arsenic trioxide	P012
Epinephrine base*	P042
Nicotine	P075
Nitroglycerin** (weak)	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

*Salts excluded federally as of Oct. 15th, 2007; Many states have adopted this position.

** Excluded from the P list federally and in many states.

Empty P-Listed Packaging



Ray R R



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EPA Memo- November 4, 2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 4 2011

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: Containers that Once Held P-listed Pharmaceuticals

FROM: Suzanne Rudzinski, Director *Suzanne Rudzinski*
Office of Resource Conservation and Recovery

TO: RCRA Division Directors, EPA Regions 1-10

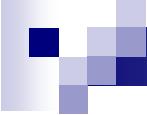
[http://yosemite.epa.gov/osw/rcra.nsf/0/57B21F2FE33735128525795F00610F0F/\\$file/14827.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0/57B21F2FE33735128525795F00610F0F/$file/14827.pdf)

As the regulatory language makes clear, it is only the residue in the non-RCRA-empty container that is considered a P-listed hazardous waste; the container itself is not a hazardous waste. Accordingly, it is only the weight of the residue in the container that needs to be counted toward generator status; the weight of the container does not need to be counted toward generator status (see November 1983 Q&A; November 25, 1980, 45 FR 78527; and December 23, 1993 memo from Shapiro to Peter Joseph).

HW Chemo vs Trace Chemo

Black box or yellow bag

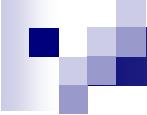




HW Chemo vs Trace Chemo

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

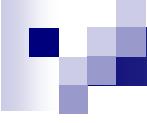
Black box or yellow bag





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)

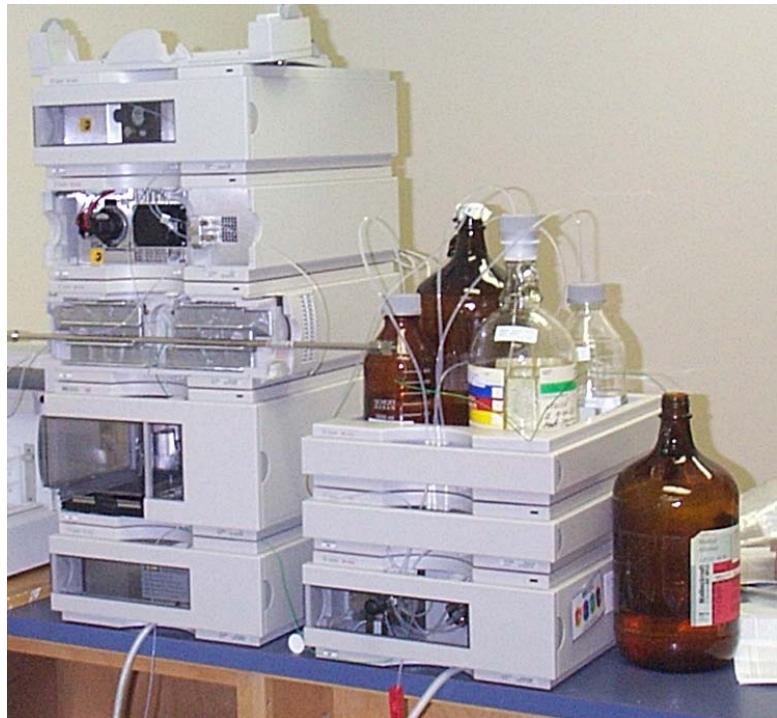
Oncology/Hematology

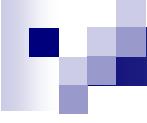
Other Outpatient Clinics

Long Term Care Facilities

Satellite Accumulation Containers

- Sept 2008 Position Paper in CAV packet

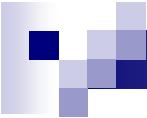




Container Management

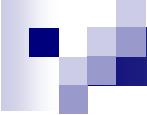
<90 or <180 Day Storage Areas

- 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

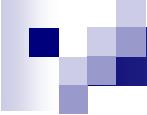


Hazardous Waste Training

- 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.



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 TSDF facilities utilized.



Contingency Plan

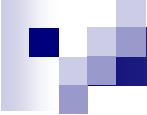
- SQG's - Basic plan
 - By the phone: Emergency Coordinator name & telephone #, fire department telephone #,
 - Post location of fire extinguishers & alarm & spill equipment.



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



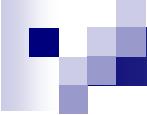
Preparedness & Prevention

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



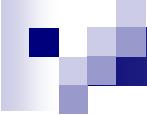
Picking a TSDF – You are in Control

- 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?

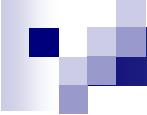
- Used oils - container must be marked “Used Oil”, not regulated as haz-waste if destined for recycling.
- Universal Wastes - Batteries, Light Bulbs, Mercury Containing Equipment (& in NJ Electronics), must be marked UW, packaged to prevent breakage & shipped at least once a year.
- RMW -Red Bag Waste

Universal Waste

Batteries - Containers everywhere

Bulbs – Where do I put them all?





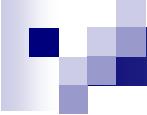
Top 5 RCRA Tips for Hospitals:

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?

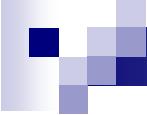
2) Make sure Universal Waste is being properly managed.

- 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>

EPA P-Listed Residue Memo 11/4/11

[http://yosemite.epa.gov/osw/rcra.nsf/0/57B21F2FE33735128525795F00610F0F/\\$file/14827.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0/57B21F2FE33735128525795F00610F0F/$file/14827.pdf)