

RCRA and Pharmaceutical Waste Management: A Brief Federal Overview



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What is RCRA?

- RCRA = Resource Conservation and Recovery Act
- Goals:
 - To protect HH&E from the potential hazards of waste disposal
 - To conserve energy and natural resources
 - To reduce the amount of waste generated
 - To ensure that wastes are managed in an environmentally sound manner

RCRA: Regulations, Guidance and Policy

- EPA translates the RCRA “the Act” passed by congress into regulations
- Guidance documents are issued by EPA to provide instructions on how to implement RCRA requirements. Guidance documents can also be EPA’s interpretations of RCRA.
- Policy statements outline EPA’s position on a topic or give instructions on how a procedure should be conducted

Guidance and policy documents are posted at:
www.epa.gov/rcraonline

Solid Wastes (Subtitle D)

- Solid waste (non-hazardous)
 - Garbage, refuse, sludges, industrial wastes and other discarded materials
 - Solid wastes can be solid, semi-solid, liquid or gaseous
 - A solid waste is a material that is discarded by being either abandoned, inherently waste-like, a certain military munitions or recycled
- Solid waste management is predominantly regulated at the state/local level
- EPA recommends a hierarchical approach to SW management: source reduction, recycling/reuse, treatment

Hazardous Wastes (Subtitle C)

- Federal regulations for generators, transporters and treatment, storage and disposal facilities (TSDFs)
 - 40 CFR 260-266, 268, 270-272
 - A state can be authorized by EPA to run the subtitle C program
 - EPA reviews each state's program, and if it is at least as stringent as the federal program, the state is granted the authority to run its own program in lieu of the federal program
- There are no RCRA regulations that are specifically directed toward hospitals or other health care facilities
 - Health care facilities must comply with the same RCRA generator requirements as any other industry

What Is a HW Under RCRA?

- To be a RCRA hazardous waste, the waste:
 - Must first be considered a solid waste
 - Then it must either be
 - Specifically listed (F, K, P or U-list – see slides #16-19); or
 - exhibit a hazardous waste characteristic (ignitable, corrosive, reactive or toxic – see slides #20-21)
- Note:
 - It has been estimated that only 5-10% of the pharmaceuticals on the market are **federal** RCRA hazardous wastes
 - hazardous waste \neq biohazardous waste
 - hazardous waste \neq hazardous drug

HW Generators

- Generators (40 CFR 262) are divided into 3 categories depending on the amount of HW produced per month
 - Large Quantity Generator (LQG)
 - Small Quantity Generator (SQG)
 - Conditionally-Exempt Small Quantity Generator (CESQG) (40 CFR 261.5)
- It is the responsibility of the generator to identify, and appropriately manage, HW
- Link to a “user friendly” document which organizes all of the requirements by generator status

<http://www.epa.gov/epawaste/hazard/downloads/tool.pdf>

Generator Requirements

| | CESQG | SQG | LQG |
|--|--|-----------------------------|---|
| Quantity Handled by Category | ≤ 100 kg/Month ≤ 1 kg acute/month (P-listed) | < 1,000 kg/month | $\geq 1,000$ kg/month >1 kg acute/month (P-listed) |
| EPA ID # | Not required | Required | Required |
| On-Site Accumulation Limit | $\leq 1,000$ kg ≤ 1 kg acute ≤ 100 kg spill residue from acute | < 6,000 kg | No quantity limit |
| Accumulation Time Limit (without a storage permit) | None | < 180 days or < 270 days | < 90 days |
| Manifest | Not required | Required | Required |
| Personnel Training | Not required | Basic training | Full training |

Generator Requirements (cont.)

| | CESQG | SQG | LQG |
|--|---|--|--|
| Storage Requirements | None | Basic requirements | Full compliance |
| Send to: | State approved solid waste facility or RCRA permitted/interim status facility | RCRA permitted/interim status facility | RCRA permitted/interim status facility |
| Biennial Reporting | Not required | Not required | Required |
| Contingency Plan | Not required | Basic plan | Full plan |
| Emergency Procedures | Not required | Required | Full plan required |
| DOT Hazmat Transport Requirements | Yes (if required by DOT) | Yes | Yes |

Where Do Household Pharmaceutical Wastes Fall Under RCRA?

- Non-hazardous household wastes are regulated under subtitle D of RCRA (local level)
- Household hazardous wastes (HHWs) are exempt from federal subtitle C regulations (40 CFR 261.4(b)(1))
 - HHWs remain exempt even if collected but the collected HHW must be managed in accordance with all state and local requirements for the management of solid waste
 - Furthermore, HHWs remain exempt when transported, stored, treated or disposed (see 45 FR 33099, May 19, 1980)
 - The exemption is lost if HHW is mixed with HW, unless it is HW from a CESQG (see RCRAOnline #11681)

Note: Some states do have more stringent requirements for HHW

More on HHW

- Why does federal EPA exempt HHW from subtitle C regulation?
 - When enacting RCRA, congress indicated that the federal HW program should not regulate household wastes (see 45 FR 33099, May 19, 1980)
- Nevertheless, EPA recommends that collected HHWs be managed as HW
 - Also recommend that sponsors contract with HW management professionals (see RCRAOnline # 11377)
 - Remember: states may be more stringent and may require that collected HHWs be managed as HW

HW Transporters

- Move HW from the generator's site to a facility that recycles, treats and/or disposes the waste
- Requirements (40 CFR 263)
 - Obtain an EPA identification number
 - Comply with the manifest system
 - Set of forms, reports and procedures that track HW
 - Respond to HW discharges
 - Comply with DOT regulations

<http://www.epa.gov/osw/hazard/transportation/transporters.htm>

Treatment, Storage and Disposal Facilities

- TSDF Requirements (40 CFR 264 and 265)
 - Air Emissions – TSDFs are required to control the emission of VOCs
 - Unit Specific Technical Requirements (e.g., tank standards)
 - Closure
 - Corrective Action/HW Cleanup
 - Financial Assurance
 - Ground Water Monitoring
 - Land Disposal Restrictions
 - Permits

<http://www.epa.gov/osw/hazard/tsd/index.htm>

Land Disposal Restrictions (LDRs)

- Complements the unit-specific technical standards
 - Physical barriers to protect ground water
- Requires that HW undergo a physical or chemical change before land disposal (40 CFR 268)
 - Disposal Prohibition – Prior to land disposal, the HW must meet concentration-based standards or technology-based standards (e.g. combustion, stabilization, biodegradation, etc.)
 - Dilution Prohibition – cannot dilute HW to circumvent proper treatment
 - Storage Prohibition – cannot indefinitely store HW

<http://www.epa.gov/osw/hazard/tsd/ldr/index.htm>

Finally, What is EPA Doing?

- In the process of finalizing the addition of hazardous pharmaceutical wastes to the federal universal waste program
- Drafting BMPs for pharmaceutical waste disposal for health care facilities
- Awarded grants for pilot take-back programs
- Fish tissue study and POTW Wastewater study

For more information on EPA activities, see:
<http://www.epa.gov/waterscience/ppcp/>

Appendix

The RCRA Hazardous Waste Listings

- Specifically listed by RCRA
 - **F list** (40 CFR 261.31) – common manufacturing and industrial process wastes from non-specific sources
 - **K list** (40 CFR 261.32) – wastes from specific industries
 - **P list** (40 CFR 261.33(e)) – commercial chemical products (acutely hazardous)
 - **U list** (40 CFR 261.33(f)) – commercial chemical products

* Note: P- and U- listings use chemical names with CAS#,s, not trade names

<http://www.epa.gov/epawaste/hazard/wastetypes/pdfs/listing-ref.pdf>

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P- and U- Listings

- Commercial chemical product (CCP)
 - A chemical substance which is the commercially pure grade, a technical grade, OR a formulation in which the chemical is the **sole active ingredient**
 - sole active ingredient = the listed chemical is the only ingredient performing the intended function. If there is another chemical that is also an active ingredient (even if listed), then that particular drug waste is not a **listed HW**
- Also, to meet the listing, the CCP must not have been used for its intended purpose
 - Has not been used includes:
 - Leftover pharmaceuticals not given to patient
 - Container or dispensing instrument containing the leftover pharmaceutical (except for syringes that have been used to administer a drug)

Appendix

Examples of P-Listed CCPs Having Pharmaceutical Uses

- Warfarin >0.3% (P001)
- Arsenic trioxide (P012)
- Epinephrine base (P042)
 - EPA has clarified that epinephrine salts are not included in the P042 listing (RO# 14778)
- Phentermine (P046)
- Nicotine (P075)
- Nitroglycerine (P081)
 - if medicinal nitroglycerine does not exhibit the characteristic of reactivity (for which it was listed), then it is not considered a listed hazardous waste (RO# 14654)
- Physostigmine salicylate (P188)
- Physostigmine (P204)

Appendix

Examples of U-Listed CCPs Having Pharmaceutical Uses

- Mitomycin C (U010)
- Chloral hydrate (U034)
- Chlorambucil (U035)
- Cyclophosphamide (U058)
- Daunomycin (U059)
- Dichlorodifluoromethane (U075)
- Diethylstilbestrol (U089)
- Trichloromonofluoromethane (U121)
- Lindane (U129)
- Hexachlorophene (U132)
- Melphalan (U150)
- Mercury (U151)
- Paraldehyde (U182)
- Phenol (U188)
- Reserpine (U200)
- Resorcinol (U201)
- Selenium sulfide (U205)
- Streptozotocin (U206)
- Uracil mustard (U237)
- Warfarin $\leq 0.3\%$ (U248)

Appendix

The RCRA Hazardous Waste Characteristics

- If the pharmaceutical waste is not specifically listed, then it may be a HW because it exhibits a **characteristic** of hazardous waste (ignitability, corrosivity, reactivity or toxicity)
- A generator can either use a standardized test method or apply general knowledge of the waste's properties in making this determination

Appendix

The RCRA HW Characteristics (cont.)

There are 4 characteristics of HW

1. **Ignitability (D001)** – can create fire under certain conditions, spontaneously combustible, or have flashpoint less than 60°C (40 CFR 261.21)
2. **Corrosivity (D002)** – acid or bases capable of corroding metal (40 CFR 261.22)
3. **Reactivity (D003)** – unstable during normal conditions (40 CFR 261.23)
4. **Toxicity (D004-D043)** – identified via the Toxicity Characteristic Leaching Procedure (TCLP). The TCLP identifies wastes likely to leach concentrations of contaminants that may be harmful (40 CFR 261.24)
 - Examples of TC chemicals/heavy metals that have pharmaceutical uses: As, Ba, Cd, Cr, Hg, Se, Ag, Chloroform, Lindane, and M-cresol

Appendix

Management of Containers

- A container that held a P-listed CCP must be managed as a HW, unless the container is rendered “RCRA empty” (see 40 CFR 261.7(b)(3))
 - RCRA empty for a P-listing = the container has been triple-rinsed
 - Rinsate must be managed as HW
- A container that held a U-listed CCP or a characteristic HW is RCRA empty and is not a HW when (40 CFR 261.7(b)(1)):
 - All of the pharmaceutical has been removed that can be removed by normal means; AND
 - No more than 3% by weight of the total capacity of the container remains