



Resource Conservation and Recovery Act (RCRA)

Pharmacy Waste Management: An Emerging Issue

***Presented by U.S. EPA, Region 7
Waste Enforcement and
Materials Management Branch***

***to the Missouri Recycling Association
(MORA) Conference
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Pharmacy Waste Management: An Emerging Issue

Presenter:

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Goals of Presentation

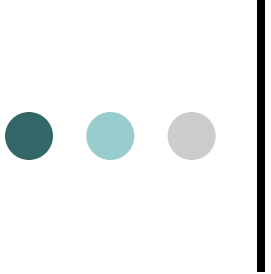
- Assist MORA members gain a better understanding of the Resource Conservation and Recovery Act (RCRA).
- Provide an overview of the RCRA Program, specifically on waste determinations, waste handling, and waste disposal of pharmaceutical wastes.





Purpose of Presentation

- Overview of pharmaceutical waste management from the regulatory perspective
 - Why these wastes need to be managed properly.
 - What needs to be done to meet the regulations.
- Briefly discuss the proposed pharmaceutical amendment to the Universal Waste Rule (UWR)
 - Impact on how to manage pharmaceutical wastes
 - The proposed pharmaceutical amendment to the UWR is tentatively scheduled to be finalized in 2011.



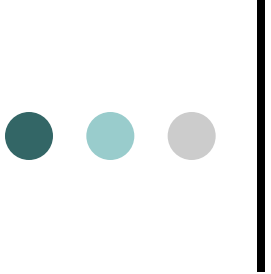
Why do Pharmaceutical Wastes need to be managed?

- Pharmaceutical wastes are regulated by RCRA Subtitle C
- RCRA Subtitle C - hazardous waste regulations (40 CFR 260 - 279)
 - Generators – LQG, SQG, and CESQG
 - Transporters
 - Treatment, storage, and disposal facilities (TSDF)



RCRA Subtitle C: Hazardous Waste Management

Generator Status	Monthly Hazardous Waste Generation Rate (kilograms)	Monthly Acute Hazardous Waste Generation Rate (kilograms)	Maximum storage amount of hazardous waste (kilograms)
LQG	> 1,000	> 1	N/A
SQG	Between 100 and 1,000	<1	6,000
CESQG	<100	<1	1,000



How does RCRA Subtitle C affect how Pharmaceutical Wastes are managed?

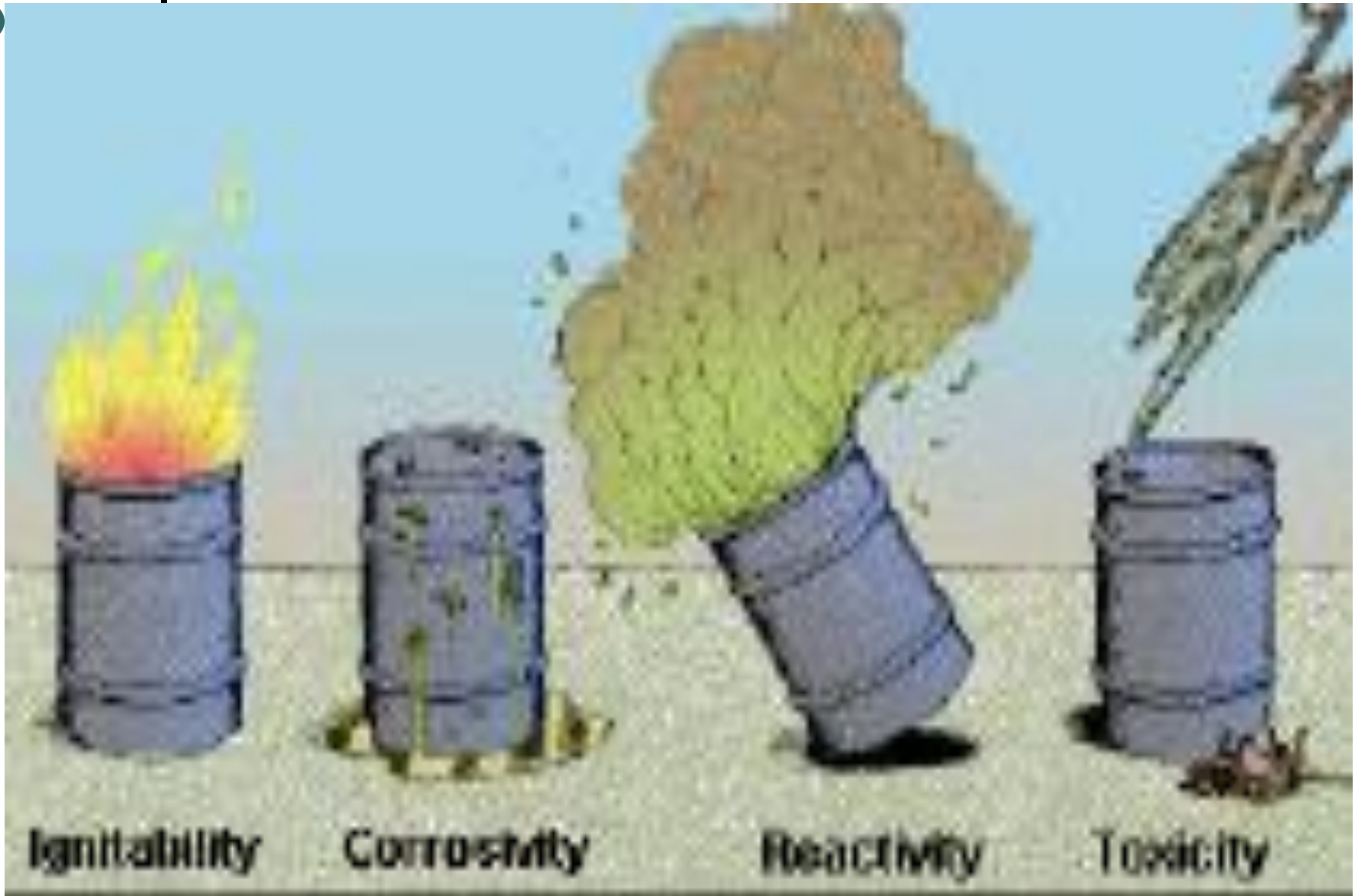
- RCRA Subtitle C is managed by authorized states and EPA
- Iowa is the only state that is not currently authorized to manage any portion of the RCRA Subtitle C program
- The state program must be fully equivalent to, no less stringent than, and consistent with the federal program
 - Contact the EPA or your state with questions about compliance
 - Always check with your state for additional compliance requirements

What is a “Hazardous Waste?”

- **Hazardous waste is a waste with properties that make it dangerous or capable of having a harmful effect on human health or the environment**
- **All wastes must be solid wastes before they are considered hazardous wastes**



RCRA Characteristic Hazardous Wastes





RCRA Listed Hazardous Wastes

- Non-Specific Sources (F)
- Specific Sources (K)
- Discarded Commercial Chemical Products, Off-Specification Species, Container Residues, and Spill Residues Thereof (P and U)



How are Pharmaceutical Wastes classified as Hazardous Wastes?

- P-listed hazardous wastes
 - Manufactured chemical listed by its generic name
 - Epinephrine: P042
 - Nicotine, & salts: P075
- U-listed hazardous wastes
 - Specific chemicals identified as toxic
 - Mercury: U151
 - Benzene: U019
- Commercial Chemical Product (CCP)
- Sole active ingredient



Key EPA Resources for Managing Pharmaceutical Wastes

- **EPA websites:**

- <http://www.epa.gov/compliance/civil/rcra/index.html>
- <http://www.epa.gov/compliance/civil/rcra/rcraenfreq.html>
- <http://cfpub.epa.gov/compliance/resources/publications/assistance/sectors/pharmaceuticals/index.cfm>

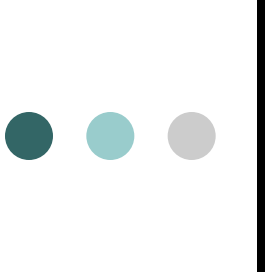
- **RCRA Online database:**

- <http://www.epa.gov/wastes/inforesources/online/>
- RO # 14788 – clarification of the epinephrine syringe interpretation, extended to other P- and U-listed drugs
- RO # 13718 – epinephrine syringe interpretation
- RO # 14778 – scope of HW listing for epinephrine (P042), references older RCRA Online documents
- RO # 13530 – commercial chemical product (CCP) definition in 40 CFR 261.33
- RO # 14012 – definition of CCPs for solid waste vs. HW determination
- RO # 14654 – nitroglycerine under mixed-rule and derived-from rule
- RO # 13622 – nitroglycerin pills as CCPs



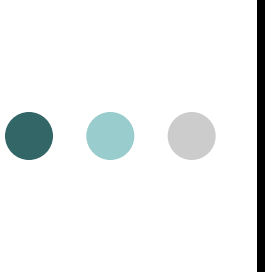
What are Pharmaceutical Wastes?

- Commercial Chemical Product (CCP), 40 CFR 261.33(d)
 1. Pure, unused chemical having the generic name in the P- or U-list
 2. Manufacturing chemical intermediates that have those names
 3. Off-spec variations of the pure chemical or chemical intermediates
 4. Residues of these chemicals in containers that do not meet the definition of “RCRA empty”
 5. Clean-up residue and debris resulting from spills of these chemicals
 6. Sole active ingredient
 7. Technical grade of the chemical
 8. Manufacturing process wastes



What needs to be done to meet the Pharmaceutical Waste management regulations?

- Waste Identification
- Recordkeeping and reporting requirements
- Disposal requirements



Compliance Issues with Pharmaceutical Wastes

- Waste Identification

- **Failure to make a hazardous waste determination on a waste stream is RCRA's No. 1 violation!**

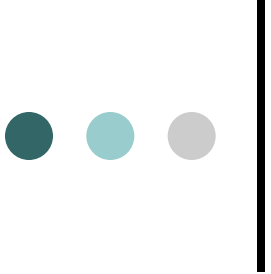
- 40 CFR 262.11

Disposal Requirements

- Storage and Disposal Requirements for:

Generator Size	Storage Time Limits	Disposal Paperwork
LQG	90 days	Manifest
SQG	180/270 days	Manifest or Tolling Agreement (for reclaimed wastes)
CESQG	---	40 CFR 261.5(f)(3) and 40 CFR 261.5(g)(3)

- LDRs (40 CFR 268)



Proposed changes to Pharmaceutical Waste Management

- Brief discussion of the proposed pharmaceutical amendment to the Universal Waste Rule (UWR)



Background:

What Is the Universal Waste Rule?

- The universal waste program is an alternate set of regulations which streamlines hazardous waste management standards for certain hazardous wastes that have been federally designated as universal wastes (UW)
 - Generators have the option of managing these wastes as HW under RCRC subtitle C or as UWs
- So, what does this mean?
 - A universal waste **is still a hazardous waste**, but the generator requirements are simplified in order to:
 - Promote the collection of these wastes
 - Promote the proper recycling, treatment or disposal of these wastes
 - UWs still need to be disposed of at permitted hazardous waste treatment, storage and disposal facilities



What Are the Current Federal Universal Wastes?

- Batteries, pesticides, Mercury-containing equipment (MCEs), and lamps
 - States can have additional hazardous wastes in their UW programs
- Why are these wastes special?
 - Compared to other hazardous wastes, these wastes are relatively low-risk during accumulation and transport
 - They are frequently generated in a wide variety of settings
 - They are generated by a vast community
 - Present in significant volumes in non-hazardous waste management systems (e.g., households)

See: preamble to the Universal Waste Rule 60 FR 25493 (1995)



Proposal to Add Hazardous Pharmaceutical Wastes to UWR

- In December 2008, FR notice was published
 - Comment period extension was published January 30, 2009
 - Commenting period ended March 4, 2009
- Applies to RCRA hazardous pharmaceutical wastes
 - P and U listed wastes (see 40 CFR 261.33(e) and (f))
 - Characteristic wastes
 - Ignitability, corrosivity, reactivity and toxicity (see 40 CFR 261.21-24)
- Proposed rule applies to pharmacies, hospitals, doctors' and dentists' offices, ambulatory care centers, outpatient care centers, residential care facilities, vet clinics and other facilities that generate this type of waste



Proposed Requirements

(As compared to current generator requirements)

- Increased accumulation threshold
 - SQHUW = <5,000 kg total of UW at any time
 - LQHUW = ≥5,000 kg total of UW at any time
- No EPA ID number for SQHUW
- No manifesting requirements for handlers
 - LQHUW have basic recordkeeping requirements; no tracking required for SQHUW
- Increased storage time
 - 1-year storage
- Basic training requirements
- Transporters
 - No manifest requirement and consequently no EPA ID number.



Comments Received

- Over 100 comments received (9 requesting extension)
 - Trade associations
 - States
 - RDs/waste management
 - Hospitals
 - POTWs
 - Municipalities
 - NGOs
 - Federal Agencies
 - Miscellaneous



Comments

- General support for the rule
- 3 states oppose (CO, MN and WI)
 - Rule is unnecessary
 - education and enforcement is key
 - Need healthcare facility (HCF)-specific regulations
 - Rule will not encourage better waste management
 - Rule removes the paper trail regulators depend on
 - Pharmaceuticals do not meet the criteria of a UW

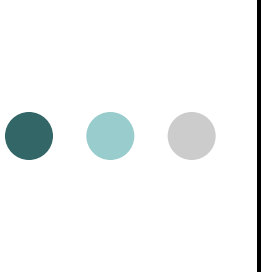


Major Issues/Concerns of Supporters

- Security
 - no manifests and/or EPA IDs
 - Closed containers
 - Labels
 - Handler thresholds/accumulation times
- Non-compliance
 - Need education/enforcement
 - Still cheaper to mismanage
- Outdated listings
 - Rule covers only a small percentage of approved drugs
- Reverse distributors
- DEA

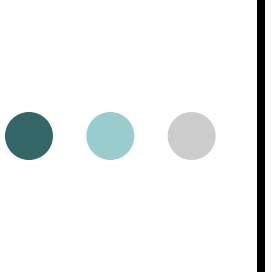
Appendix: UW vs. Subtitle C (handlers)

	Universal Waste Requirements		Generator Requirements		
	Small Quantity Handler of Universal Waste (SQHUW)	Large Quantity Handler of Universal Waste (LQHUW)	Conditionally Exempt Small Quantity Generator (CESQG)	Small Quantity Generator (SQG)	Large Quantity Generator (LQG)
Quantity Handled by Category	accumulate < 5,000 kg (11,000 lb) on site at any one time	accumulate 5,000 kg (11,000) or more on site at any one time	generate ≤ 100 kg (220 lb) per month ≤ 1 kg acute per month	generate < 1,000 kg (2,200 lb) per month	generate ≥ 1,000 kg per month > 1 kg acute per month
EPA ID #	Not required	Required	Not required	Required	Required
On-Site Accumulation Limit	< 5,000 kg	No quantity limit	≤ 1,000 kg ≤ 1 kg acute ≤ 100 kg spill residue from acute	< 6,000 kg	No quantity limit



Appendix: UW vs. Subtitle C (handlers)

	Universal Waste Requirements		Generator Requirements		
	Small Quantity Handler of Universal Waste (SQHUW)	Large Quantity Handler of Universal Waste (LQHUW)	Conditionally Exempt Small Quantity Generator (CESQG)	Small Quantity Generator (SQG)	Large Quantity Generator (LQG)
Storage Time Limit (without a storage permit)	1 year, unless for proper recovery, treatment, or disposal	1 year, unless for proper recovery, treatment, or disposal	None	≤ 180 days or ≤ 270 days	≤ 90 days
Manifest	Not required	Not required, but must keep basic shipping records	Not required	Required	Required
Personnel Training	Basic training	Basic training geared toward employee responsibilities	Not required	Basic training	Full training



Appendix: UW vs. Subtitle C (transporters)

	Universal Waste Transporters	Hazardous Waste Transporters
Compliance with Department of Transportation (DOT)	yes	yes
EPA ID Number	none	yes
Allowance to Store up to 10 days at a Transfer Facility	yes	yes
Manifest Requirements	none	yes
Response to Releases	yes	yes, with more complex requirements

● ● ● | Any overview questions?



Who do I contact at EPA?

- National Superfund/EPCRA/RCRA Hotline
1-800-424-9346
- EPA Region 7 Oil and Chemical Spill Hotline
913-281-0991
- Iowa EPA Region 7 Environmental Action Line
1-800-223-0425
- Lisa Lauer, EPA, Headquarters
Office of Resource Conservation and Recovery
(ORCR)
703-308-7418



Additional questions, specific concerns, or comments?

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