Regulations & References

The information provided in this presentation is based on the referenced Code of Federal Regulations and State regulations. This data is presented only as a reference. For complete requirements or legal counsel on hazardous waste regulations and interpretations, generators should consult their legal department, the applicable Code of Federal Regulations and applicable State regulatory agencies.
Pharmaceutical Waste Management

- Issues & Concerns surrounding RX waste
- Federal and State Regulations
- Regulatory & Industry Issues
- Defining Pharmaceutical Waste
- Implementing a Pharmaceutical Waste Program
Laboratory

- Solvents: Xylene, Alcohol,
- Clear Rite
- PAP Smear Kits
- Formalin
- Reagents
- Test Kits
- Cleaning Supplies
- Hand Sanitizers
- pH Adjusters
- Picric Acid
- Ictotest/Clinitest/
- Acetest Tablets
- Equipment Discharge
- Stains/Staining Lines
- Thermometers
**Maintenance**

*Paint Shop*
- Solvent-Based Paint
- Aerosol/Spray Paint
- Paint Thinners
- Rags

*Maintenance Shop*
- Oil Related Materials
- Aerosols
- Solvents
- Grease/Degreaser
- Boiler Chemicals
- Batteries/Light Bulbs

*Woodworking Shop*
- Varnishes
- Wood Stains
- Solvents

*Groundskeeping*
- Pesticides
Housekeeping

- Hand Sanitizers
- Cleaning Supplies
- Aerosols
- Fluorescent Light Bulbs
- Batteries
- Electronics & Electronic Equipment
• Organic Wastewater Contaminants (OWCs) in 80% of streams tested
• 33% of OWCs detected were pharmaceuticals in Minn. alone

Media Coverage
• 3/9/08 USA Today - “AP Probe finds drugs in drinking water”
• 9/15/08 USA Today/AP - “Hospitals dumping drugs into water”
• 5/24/10 Modern Healthcare - “Drugged”

EPA Regulatory Activity
• Notice of Violations and warnings
• Increasing regulatory scrutiny nationwide
• Fines in excess of $450,000 ($37,500 per day per occurrence)
The Viagra in the water makes me want to swim upstream, but the Prozac is making me too tired.
Understanding the Issues

• Do you know what is considered “pharmaceutical waste?"
• Is your facility properly identifying, segregating and disposing of pharmaceutical waste?
• Does your facility manage the disposal process internally or use outside resources?
• What laws, regulations and Joint Commission Standards apply to pharmaceutical waste?
Hospitals

• **Without Any Program**
  - Mix of waste disposal from solid waste, collection and segregation, all hazardous waste, red bag, and flushing
  - Capturing trace chemo; sometimes have a bulk chemo program

• **With a Rudimentary Program – Internally Managed**
  - Capturing trace and bulk chemo
  - Capturing P-listed waste in the pharmacy (disposable containers)
  - No program outside of pharmacy

While most hospitals that believe they’re in compliance by capturing listed wastes, they typically are not familiar with nor collecting characteristically hazardous waste, not segregating incompatible hazardous wastes nor is the program facility-wide
Rx Waste Disposal: Who is Involved?

- US Environmental Protection Agency
  Resource Conservation and Recovery Act of 1976 (RCRA)
  Clean Water Act of 1972 (CWA)
- US Department of Transportation (DOT)
- Drug Enforcement Agency (DEA)
- Occupational Safety & Health (OSHA)
- The Joint Commission (TJC)
- State Regulatory Agencies (EPA & DOT)
- Publicly Owned Treatment Works (POTW)
• Hazardous waste determinations not done or incorrect
• Labeling of hazardous waste not done or incorrect
• Throwing hazardous waste down the drain
• Improper disposal of chemotherapy drugs
• Inadequate training for employees in HW management
• Not conducting proper weekly inspections of HW storage
• No or inadequate HW manifests
• Lack of emergency contingency plan
• Improper management of expired pharmaceuticals

“Identification and Management of Regulated Hazardous Waste” – EPA Region 2
**EPA Waste Generator Status**

**Large Quantity Generator Hazardous Waste Generator**
- $\geq 1000$ kg/mo of non-acute hazardous waste
- $\geq 1$ kg/mo of acute hazardous waste (P-Listed)

**Small Quantity Generator Hazardous Waste Generator** *
- Between 100 kg and 1000 kg/mo of non-acute hazardous waste
- $< 1$ kg/mo of acute hazardous waste (P-Listed)

**CESQG Conditionally Exempt Small Quantity Generator**
- $< or = 100$ kg/mo of non-acute hazardous waste
- $< 1$ kg/mo of acute hazardous waste (P-Listed)

* **SQG status must be verified & documented monthly**
• SQG status requires measurement and documentation that monthly acute hazardous (P-Listed) waste volume does not exceed 1 kg (2.2 lbs)

<table>
<thead>
<tr>
<th>REQUIREMENT</th>
<th>SQG</th>
<th>LQG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazardous waste identification</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>EPA ID number</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>RCRA training</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Exception reporting</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Hazardous waste storage</td>
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<td>Yes</td>
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<td>Weekly inspections</td>
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<td>Yes</td>
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<tr>
<td>Manifest use</td>
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<td>Yes</td>
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<tr>
<td>Emergency coordinator</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Emergency response planning</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Contingency plan</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Biennial reporting</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
– Proper management of all pharmaceuticals which are considered controlled substances

– These pharmaceuticals are *never* considered a waste by the DEA and must be managed appropriately to avoid diversion and for final destruction

– Hospital/entity which is a DEA registrant must be responsible for proper inventory tracking
Clean Water Act (40 CFR Parts 122 and 403)

- A sewer connected to a publicly owned treatment works (POTW) is regulated by Federal, State, and POTW issued permits

- Pollutants include sewage, chemical wastes (i.e. pharmaceuticals) and biological materials

- EPA notification requirement for sewer discharge of RCRA hazardous waste
– Management of materials being flushed or poured down the drain
– Restrictions on types of chemicals (including pharmaceuticals), blood and other materials
– Mostly managed locally
– Bound by Federal EPA standards under Water Division and often further regulated by State regulatory agencies
DOT regulations (49 CFR):
1. Classification, description, and packaging
2. Proper marking and labeling
3. Segregation into proper streams
4. Training
5. Security

Hazmat Implementation Act:
- Fine section rewritten to raise fines
- Average fine is $30,000 per violation and range up to $100,000

U.S. DOT HM229
- If a generator ships hazmat without proper documentation the **carrier must report it** or the carrier can be prosecuted with the shipper.
MM.01.01.03 - Medication Management
- The hospital safely manages high-alert and hazardous medications
- The hospital identifies, in writing, high-alert and hazardous medications
- The hospital has a process in place that addresses how outside resources, if any, are used for the destruction of pharmaceuticals.

EC.02.02.01 - Environment of Care
- The hospital manages its hazardous materials wastes risks.
- The hospital minimizes risk associated with disposing of hazardous medications.

LD.04.01.01 - Leadership
- The hospital complies with law and regulation.
• Do you know what is considered “pharmaceutical waste”?

• Is all pharmaceutical waste either P- or U-listed?
Pharmaceutical Waste consists of any pharmaceutical that is:

- No longer used for its intended purpose
- Not returnable for credit
- Designated for discard

**Examples**

- Partial vials (safety caps removed)
- Un-dispensed
- Pre-instilled IVs
- Hospital repacks
- Pre-filled syringes

- Partial syringes
- Discontinued meds
- Un-administered meds
- Patient prescriptions
- Physician RX samples
• **What is Waste Characterization?**
   > Identification of hazardous waste per EPA/RCRA regulations

• **What is characterized?**
   > Active AND inactive ingredients, including preservatives

• **What about DOT regulations?**
   > Determine DOT hazardous material class at NDC/item level

• **Other concerns?**
   > NIOSH and OSHA best practices re: non-EPA evaluated dangerous drugs (TJC monitored)

• **NOTE:** Material Safety Data Sheets do not always provide data on inactive or preservative ingredients
Listed Waste (Commercial Chemical)

- **P – Listed** (Acutely Hazardous) Coumadin/warfarin, Nicotine, Physostigmine, Arsenic Trioxide, epinephrine*, nitroglycerin*
- **U – Listed** (Toxic) - Chemotherapy drugs

*Federal exemptions requires state adoption of US EPA interpretations (e.g. epinephrine salts and medicinal nitroglycerin)*

**Characteristic Waste** – Ignitable, Corrosive, Reactive, Toxic

**Incompatible Waste**

In addition to the two RCRA defined hazardous waste categories (Listed & Characteristic), RCRA & US DOT address incompatible waste. Incompatible drugs are those that CANNOT be placed in the same container without danger of a chemical reaction.
Examples of Listed RX Waste

**P – Listed**
- Arsenic trioxide
- Epinephrine (Base)
- Nicotine
- Physostigmine
- Warfarin

**U – Listed**
- Chemotherapy drugs
- Cytoxan
- Chloroform
- Mercury
- Mitomycin
- Phenol
- Saccharin
- Selenium Sulfide
Examples

• Lantus
• Humalog
• Humulin N
• Humulin R
• Centrum Silver
• Flovent
• Taxol
• Atrovent
Characterization Results

- Non-Haz: 89%
- Chemo: 5%
- Haz: 6%
RCRA Training
- Employees involved with or occupationally exposed to hazardous waste
- Completed within 6 months of hiring
- Annual retraining
- Record retention requirement

Hazard Communication Training
- Employees involved with or occupationally exposed to hazardous chemicals must be trained in accordance with 29 CFR 1910.200
- Completed at time of initial assignment to job

DOT Training
- Employees involved with or occupationally exposed to hazardous materials must be trained in accordance with 49 CFR Subpart H 265 (172.702 & 172.704)
- Completed within 90 days of hiring
- Retraining every three years
- Record retention requirement
Satellite Accumulation: EPA
40 CFR 262.34(c)(1)

- Accumulate up to 55 gallons of hazardous waste or one quart of acutely hazardous (P-Listed) waste
- At or near the point of generation where wastes initially accumulate
- Under the control of the operator of the process generating the waste
- Container requirements
  - Marked “Hazardous Waste” or words identifying contents
  - Compatible with waste
  - Closed except when adding or removing waste
  - Not be handled, opened, or stored in a manner that causes it to leak
• Identify satellite accumulation areas
• Locations
  - Pharmacy
  - Patient-care areas
    - Med rooms
    - Soiled utility rooms
    - Nurses stations
    - Under the Generator’s Control
**BLACK**
Compatible Hazardous

Non-Hazardous

**BLACK**
Incompatible Hazardous

Sharps/Biohazard Containers

Trace Chemo Containers

Bulk Chemo Containers
Incinerate all Rx Waste – industry best practice (ASHP, Practice Greenhealth, EPA Office of Water)

*NOTE: Non-RCRA hazardous RX waste can be over-classified and incinerated at a regulated medical waste incineration facility*

- RCRA hazardous waste **MUST** be transported by a licensed hazardous waste hauler
- RCRA hazardous must be managed at an EPA-permitted hazardous waste facility
- Check permit limitations of RCRA hazardous waste incinerators & transporters
The Disposal Process

- **Trace Chemo**
  Disposal as regulated medical waste/incineration

- **RCRA Hazardous/Bulk Chemo**
  Manifested transport & disposal as RCRA hazardous waste (EPA/DOT regulations)

- **Non-RCRA Hazardous**
  Disposal via incineration per industry best practices
Developing and Implementing a Pharmaceutical Waste Management Program
1. Understanding the need for a pharmaceutical waste program based on regulatory involvement and environmental concerns.

2. Evaluate how pharmaceutical waste is currently being handled in comparison to federal and state regulations.

3. Identify a group of leaders in your facility that have a passion for the environment, will champion multi-departmental cooperation and administration support.
Reusable versus Disposable Rx Waste Containers

- **CONTAINER REUSE RATES** - 95% (8 gal) and 100% (17 gal) *

- **MATERIALS COST SAVINGS** - $21,019 to $26,083 savings *

- **ENVIRONMENTAL STEWARDSHIP** - 3.4 to 4.7 tons of plastic *

* Based on a 24 month case study of RX waste container usage in a 150 licensed bed, acute-care hospital, with 30 satellite accumulation locations.
Departments with champions that help advocate for compliant and environmentally responsible pharmaceutical waste disposal:

- Pharmacy
- Nursing
- Nursing Education
- Quality/Accreditation
- Safety
- Environmental Services
- Risk Management
- Infection Control
- Facilities/Materials Management
- Public Relations
1. **Identification and Information Systems**
   - Formulary characterization
   - Waste codes on pharmacy labels and in dispensing cabinets (Pyxis, Omnicell, etc.) to simplify waste segregation & disposal
   - Select locations for pharmaceutical waste containers in pharmacies and patient care areas

2. **Staff education**
   - Pharmacy
   - Nursing
   - Environmental Services
Involve the Key Stakeholders

Gives them the chance to understand their involvement

Gives you the chance to hear their concerns and issues

Allows you to identify and address road blocks ahead of time

Allows you to understand their “cultural” issues that will affect the program development
COMMUNICATE, COMMUNICATE, COMMUNICATE!

Internal communication
- Intranet
- Website
- Newsletter

Communicate to staff BEFORE implementation
- Program announcement – *Who, What & Why*
- Training dates
- Program start date

External communication UPON implementation
- Press releases - "Green Initiative"*
- Assuring regulatory compliance
- Environmental stewardship – “The right thing to do”
- Employee & community safety
Things to consider when determining a program for your hospital...

• What medications are being disposed and where, in what quantities, at what cost
• BMP to reduce generation of unused Rx
• Regulatory & accreditation guidelines
• Options for disposal & BMP for non-hazardous Rx
• Resources available including but not limited to containers, characterization, training, internal container exchange, packaging of waste
• Space for a Central Accumulation Area (CAA) that meets all EPA & state requirements
Typical post-implementation issues

- Continuing education for current and new staff
- Container audits
- Container inventory management
- Impact on EPA generator status
- Taking ownership for the success of the program
- Focus on “Knowing only what you need to know” for clinical staff
- Improper waste segregation (e.g. RMW in Rx containers, sharps in Rx containers, empties in Rx containers, nothing in Rx containers)
Pharmaceutical Waste Management Summary

1. Understanding what pharmaceutical waste is and how to handle it
2. Regulatory and TJC compliance issue
3. Environmental Stewardship
4. Implementing an environmentally sustainable Rx waste program
5. Looking beyond the Pharmacy
6. What’s in the future?
   • EPA Universal Waste Rule for pharmaceutical waste
   • EPA Office of Water BMP’s
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