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What Hospitals Need To Know About Pharmaceutical Waste Compliance

Waste2Green4Healthcare

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.

Presentation Objectives

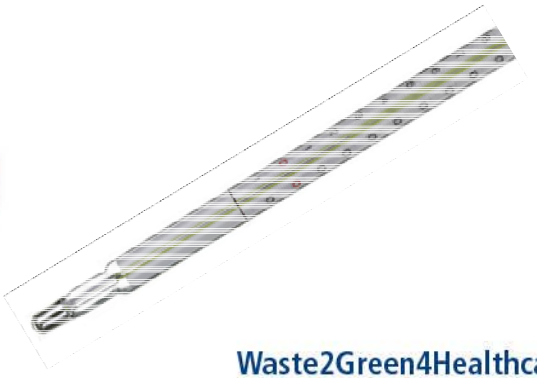
Pharmaceutical Waste Management

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

Hospital Regulated Waste Streams

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



Hospital Regulated Waste Streams

Maintenance / Environmental Services

Paint Shop

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

Maintenance Shop

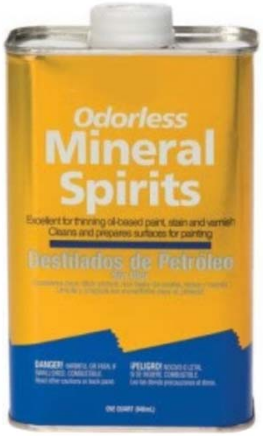
- Oil Related Materials
- Aerosols
- Solvents
- Grease/Degreaser
- Boiler Chemicals
- Batteries/Light Bulbs

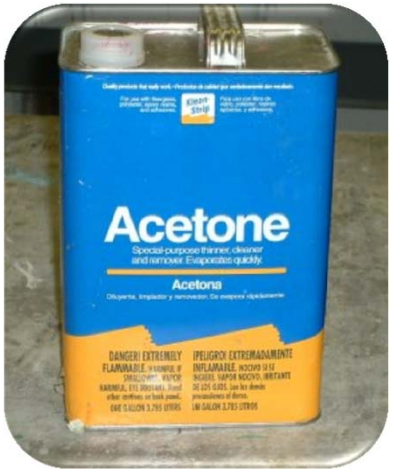
Woodworking Shop

- Varnishes
- Wood Stains
- Solvents

Groundskeeping

- Pesticides

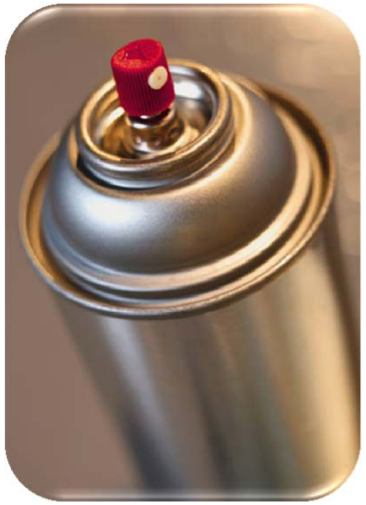




Hospital Regulated Waste Streams

Housekeeping

- Hand Sanitizers
- Cleaning Supplies
- Aerosols
- Fluorescent Light Bulbs
- Batteries
- Electronics & Electronic Equipment



A Growing Focus on Rx Waste

USGS (US Geological Survey) Water Survey (1999-2000)

- 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 country wide
- Fines in excess of $450,000

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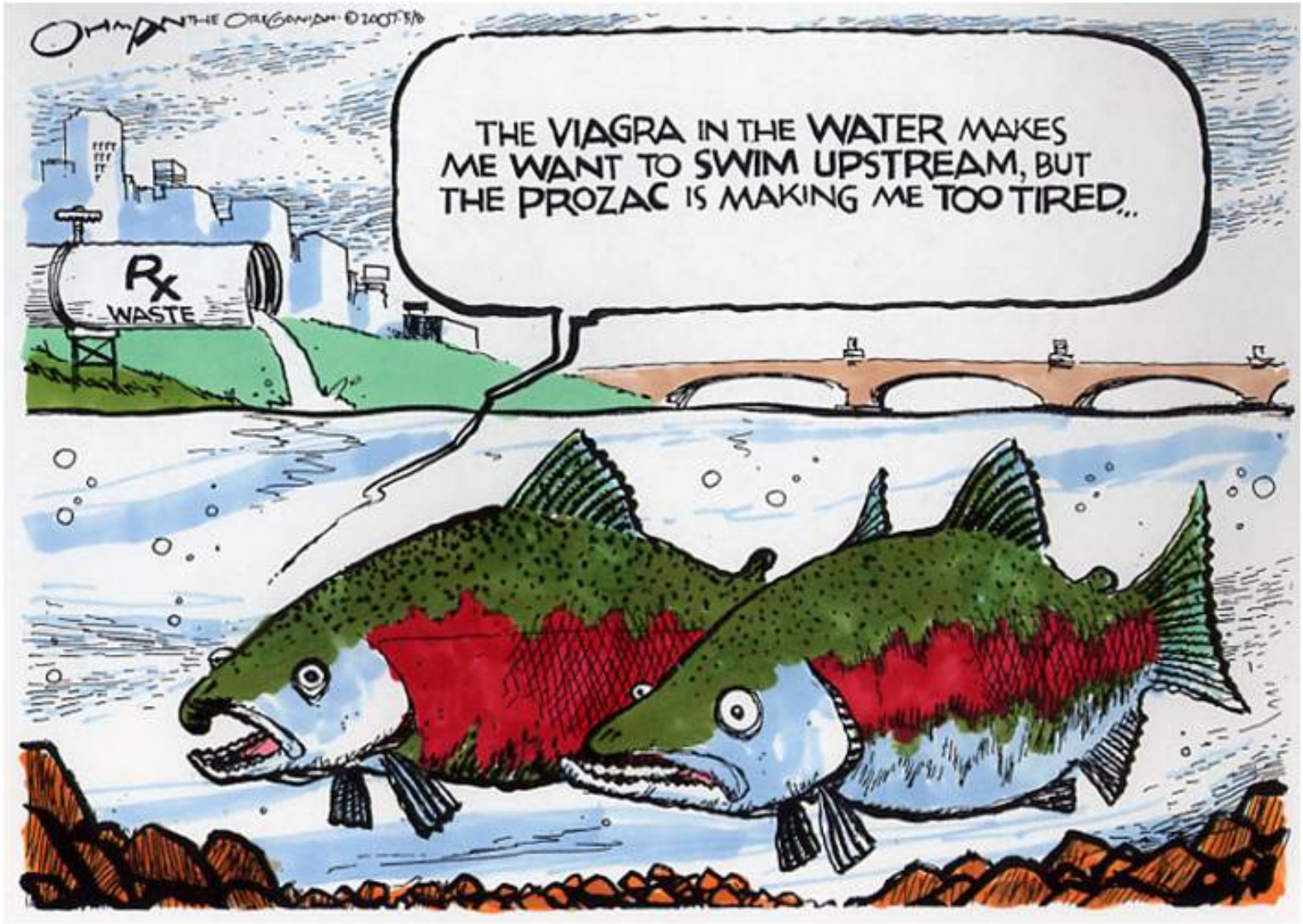
THE VIAGRA IN THE WATER MAKES ME WANT TO SWIM UPSTREAM, BUT THE PROZAC IS MAKING ME TOO TIRED...
Rx
WASTE

Stericycle

Understanding the Issues

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

Current State of Rx Programs

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 have a full program capturing listed wastes, they typically are not familiar with characteristically hazardous waste or incompatible hazardous waste streams nor is the program house wide

Rx Waste Disposal: Who is Involved?

- US Environmental Protection Agency

  Resource Conservation and Recovery Act (RCRA)
  Clean Water Act (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)

Common EPA Inspection Issues

- Hazardous waste determinations not done or incorrect
- Labeling of hazardous waste not done or incorrect
- Throwing HW 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

Determining Generator Status

EPA Waste Generator Status

Large Quantity Generator Hazardous Waste Generator

> = 1000 kg/mo of non-acute hazardous waste

>= 1 kg/mo 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*

EPA Waste Generator Requirements

- SQG status requires measurement and documentation that monthly acute hazardous (P-Listed) waste volume does not exceed 1 kg (2.2 lbs)

REQUIREMENT	SQG	LQG
Hazardous waste identification	Yes	Yes
EPA ID number	Yes	Yes
RCRA training	Yes	Yes
Exception reporting	Yes	Yes
Hazardous waste storage	Yes	Yes
Weekly inspections	Yes	Yes
Manifest use	Yes	Yes
Emergency coordinator	Yes	Yes
Emergency response planning	Yes	Yes
Contingency plan	No	Yes
Biennial reporting	No	Yes

Controlled Substances & the DEA

- Proper management of all pharmaceuticals which are considered controlled substances
- These pharmaceuticals are not considered a waste but must be managed appropriately for final destruction
- Hospital/entity which is a registrant must be responsible for proper inventory tracking

Rx Waste – Sewer Disposal

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

POTW:
Publicly Owned Treatment Works

- Management of materials being flushed or poured down the drain
- Restrictions on types of chemicals, blood or other fluids and/or pharmaceuticals
- Mostly managed locally
- Bound by Federal EPA standards under Water Division and often further regulated by State regulatory agencies

U.S. DOT Regulations

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.

TJC Accreditation

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.

Rx Waste & Waste Segregation

BLACK
Hazardous
Compatible

BLACK
Hazardous
Incompatible

Non-Hazardous

Sharps/Biohazard
Containers

Trace Chemo
Containers

Bulk Chemo
Containers

What is Pharmaceutical Waste?

- *Do you know what is considered "pharmaceutical waste"?*

- *Is pharmaceutical waste all either P- or U-listed?*

The Basics of Pharmaceutical Waste

Pharmaceutical Waste consists of any pharmaceutical that is:

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

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

Waste Characterization

- **What is Waste Characterization?**

  Identification of hazardous waste per EPA/RCRA regulations

- **What is characterized?**

  Active AND inactive or preservative ingredients

- **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 Sheets do not always provide data on inactive or preservative ingredients*

EPA – RCRA Hazardous Drug Categories

Listed Waste (Commercial Chemical)

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

Requires State adoption of US EPA interpretations re: 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 addresses ***incompatible*** waste. Incompatible drugs are those that **CANNOT** be placed in the same container without danger of a chemical reaction

Training is Required

RCRA Training

- Employees involved with or occupationally exposed to hazardous waste
- Completed within 6 months
- 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
- Retraining every three years
- Record retention requirement

Satellite Accumulation: EPA

40 CFR 262.34(c)(1)

- Accumulate 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

Satellite Accumulation Areas

- Identify satellite accumulation areas
- Locations

Pharmacy

Patient-care areas

- Med rooms
- Soiled utility rooms
- Nurses stations
- Under the Generator's Control

Transportation and Destruction

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 appropriately EPA permitted hazardous waste facility
- Check permit limitations of RCRA hazardous waste incinerators & transporters

Getting Started

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.

Materials Management: Materials Efficiency

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.*

A Team Effort!

Departments with champions that help advocate for compliant and environmentally responsible pharmaceutical waste disposal:

Pharmacy	***Environmental Services***
Nursing	***Risk Management***
Nursing Education	***Infection Control***
Quality/Accreditation	***Facilities/Materials Management***
Safety	***Public Relations***

Program Implementation

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

Achieving Organizational “Buy In”

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

Achieving Organizational Buy In

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

Achieving Organizational Buy In

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

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Protecting People. Reducing Risk.™

THANK YOU!!!!

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