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Navigating Chemical and Waste Management Challenges in a Healthcare Setting

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Objectives

- Review the types of chemical classes usually encountered in hospitals, and the variety of wastes being generated
- Review common management practices and cover common mistakes that can lead to costly fines and create exposure risks
- Examples of best practices that hospital EHS staff can implement that can leverage risks posed by hazardous chemicals and generated waste

Types of Waste – Definitions

- **Hazardous Waste** – Waste with properties that make it dangerous or potentially harmful to human health or the environment based on ignitability, corrosiveness, reactivity, or toxicity
- **Pharmaceutical Waste** – Waste generated by the hospital containing pharmaceutical agents (excluding bodily waste from patients, visitors, and staff); pharmaceutical waste is primarily categorized as "regulated medical waste," but specific agents are categorized as "hazardous waste"
  - P-listed Chemicals – EPA category of discarded commercial chemical products that are considered acute hazardous wastes
  - U-listed Chemicals – EPA category of discarded commercial chemical products that are considered toxic wastes
- **Regulated Medical Waste** – health-care facility medical wastes targeted for handling and disposal precautions, which are regulated under a variety of state and federal laws and include microbiology laboratory waste, (e.g., microbiologic cultures and stocks of microorganisms); pathology and anatomy waste; blood specimens from clinics and laboratories; blood products; other body-fluid specimens; and certain sharp items (i.e., needles and scalpel blades), contaminated with blood

Hazardous Waste Generator Status

Regulatory Provision	Conditionally Exempt Small Quantity Generator (CESQG)	Small Quantity Generator (SQG)	Large Quantity Generator (LQG)
Hazardous Waste Generation Rate	≤ 220 lbs. of HW ≤ 2.2 lbs. acute HW	> 220 lbs. but < 2200 lbs. of HW ≤ 2.2 lbs. acute HW	> 2200 lbs. of HW > 2.2 lbs. acute HW
Pounds of hazardous waste generated in a calendar month			

Resource Conservation and Recovery Act (RCRA)

- Enacted in 1976, enforced by the EPA
- Federal regulation of the disposal of solid wastes
- Defines “hazardous waste”
- Encourages the minimization of waste generation

Hazardous Waste (40 CFR 261.31, 261.32, 261.33)

- P-Listed chemicals (acutely toxic chemicals)
- U-Listed chemicals (toxic chemicals)
- D-Listed (characteristic hazardous waste)
  - Ignitability
  - Corrosivity
  - Toxicity
  - Reactivity
- F-list (wastes from common manufacturing and industrial processes)
- K-list (wastes from specific industries)

Examples of P- and U-Listed Wastes in Oregon

Arsenic trioxide
Chlorambucil
Cyclophosphamide
Daunomycin
Epinephrine
Lindane
Melphalan
Mitomycin
Nicotine and Salts
Physostigmine
Reserpine
Streptozotocin
Warfarin and Salts

Containers that have held P-listed wastes are not RCRA empty unless they are triple rinsed and the rinsate discarded as hazardous waste

Additional Waste Streams

- Universal Waste
  - Batteries
    - Need to collect for disposal/recycling all batteries except alkaline
  - Bulbs
    - Fluorescent, compact fluorescent, metal halide, halogen, etc.
  - Mercury-Containing Equipment
    - Thermometers, blood-pressure cuffs, switches
- E-Waste
  - Computers, TVs, DVD, VHS, etc.

Additional Waste Streams

- Aerosol Cans
  - Maintenance operations, food and nutrition, environmental services, etc.
- Pathology
  - Alcohols, non-path vials, analyzer waste, specimens in formalin
- Used Oil

Characteristic – Ignitability

- Examples of ignitable wastes include:
  - Flammable liquids (flash point less than 140° F)
  - Aqueous solutions containing >24% alcohol
  - Certain compressed gases
- There are also a few strong oxidizers used in pharmaceuticals formulations; examples include silver nitrate and potassium permanganate
- The regulations covering the ignitability characteristic can be found in Title 40 of the Code of Federal Regulations, Part 261

Characteristic – Corrosivity

- This RCRA category refers to acids (pH less than 2) and bases (pH greater than 12.5) that are capable of corroding metal containers, such as storage tanks, drums, and barrels
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide
- The regulations covering the corrosivity characteristic can be found in Title 40 of the Code of Federal Regulations, Part 261, Section 22

Characteristic – Toxicity

- Toxic wastes are harmful or fatal when ingested or absorbed
- Approximately 40 chemicals which meet specific leaching concentrations
- The regulations covering the toxicity characteristic can be found in Title 40 of the Code of Federal Regulations, Part 261, Section 24

- Arsenic
- Barium
- Cadmium
- Chloroform
- Chromium
- Lindane
- m-Cresol
- Mercury (thimerosal)
- Phenylmercuric acetate
- Selenium
- Silver

Characteristic – Reactivity

- Reactive wastes are unstable under "normal" conditions
- They can cause explosions, toxic fumes, gases, or vapors when heated, compressed, or mixed with water
- Examples include:
  - Lithium batteries
  - explosives
- The regulations covering the reactivity characteristic can be found in Title 40 of the Code of Federal Regulations, Part 261, Section 23

What Is Pharmaceutical Waste?

- Any Partially-Used or Unused Medication Including:
  - Syringes
  - Vials, Bottles
  - IV Bags and Tubing With Medicine Additives
  - Loose Pills, Tablets, Capsules
  - Aerosol Inhalers
  - Creams, Ointments, Shampoos
  - Patient Prep-Alcohol and Iodine
- Empty Vials/Containers That Held P-Listed Drugs
  - Nicotine, Warfarin, etc.

Pharmaceutical waste which is not considered "hazardous waste" is considered "regulated medical waste," and will be disposed in red waste bags or sharps containers

Chemotherapy Waste

- Trace Chemo
  - Empty containers, flushed tubing, or gowns and gloves that were not spilled on
  - Must be incinerated but not as a hazardous waste
  - Yellow containers
- Bulk Chemo
  - Unused or partially used chemo, contaminated gowns or gloves, and spill cleanup material
  - Treat as hazardous waste
  - HW containers

Why Manage Pharmaceutical Waste?

- Federal Regulations
  - Resource Conservation and Recovery Act (RCRA)
  - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA – a.k.a. “Superfund”)
- State Regulations (WA and OR)
  - Mirror federal rules and regulations
  - Recent increased enforcement

Why Manage Pharmaceutical Waste?

- U.S. Geological Survey
  - Measured concentrations of 95 Organic Wastewater Contaminants in water samples from 139 streams in 30 states
    - Organic Wastewater Contaminants were found in 80% of the streams sampled
  - Pharmaceuticals and Other Chemicals Common in Landfill Waste
    - Study of 19 landfills across the United States found 129 of 202 pharmaceutical (prescription and nonprescription), household, and industrial chemicals in untreated leachate samples (prior to treatment and environmental release)

Regulatory Enforcement: The Joint Commission

- EC.01.01.01
  - EP 5 The hospital has a written plan for managing the following: hazardous materials and waste
- EC.02.02.01 The hospital manages risks related to hazardous materials and waste
  - EP 1 The organization creates and maintains an inventory that identifies hazardous materials and waste used, stored, or generated using criteria consistent with applicable law and regulation (for example, the Environmental Protection Agency [EPA] and the Occupational Safety and Health Administration [OSHA])

Waste Disposal Options

- Municipal Solid Waste Landfill
  - May be permitted to accept non-hazardous drug waste
- Regulated Medical Waste (RMW) Vendor
  - Infectious waste, sharps
  - Can accept TRACE chemotherapy waste
  - May be permitted to accept non-hazardous drug waste
- Hazardous Waste Incinerator
  - Permitted to handle RCRA hazardous waste
  - Most are NOT permitted to handle RMW
  - Can accept bulk chemotherapy waste

US Environmental Protection Agency Proposed Pharmaceutical Waste Rule

- Rule Summary
  - The EPA Administrator signed the proposed Management Standards for Hazardous Waste Pharmaceuticals Rule on August 31, 2015, and it was published in the Federal Register (FR) on September 25, 2015
  - EPA received a number of requests to extend the comment period and in response provided a 30-day extension; a notice announcing this extension was published in the Federal Register on November 5, 2015; comments closed 12/24/15
  - This rule proposes a tailored, sector-specific set of regulations for the management of hazardous waste pharmaceuticals by healthcare facilities (including pharmacies) and reverse distributors; it will provide standards to ensure the management of hazardous waste pharmaceuticals is safe and workable within the healthcare setting

Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

- Removes pharmaceutical waste totals from counting towards generator status
  - Including acute hazardous waste (P-Listed)
  - Still required to count other waste streams towards total
- Bans sewer disposal of hazardous waste pharmaceuticals
  - In line with most current requirements
  - Recommends to limit amount of non-hazardous pharmaceuticals that are placed in the sewer

Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

- Unit dose packaging, dispensing bottles, and vials no longer treated as hazardous waste if empty
- A healthcare facility will not have to comply with the satellite accumulation area regulations, which are a poor fit for healthcare facilities
- The facility will not need to specify hazardous waste codes on manifests
- The facility will be able to accumulate hazardous waste pharmaceuticals on site without a RCRA permit for 365 days
- The facility will have basic training requirements

Example of a Pharmaceutical Waste Management Action Plan

- Engage stakeholders to provide project feedback
- Identify department to provide program oversight
- Research vendors
- Meet with vendors to evaluate pharmaceutical waste project
- Conduct facility assessments with vendors to develop a budgetary estimate
- Begin review of staff training documents, presentations, and policies for revision or development
- Begin looking at supply sourcing
- Set target dates for staff training
- Establish central waste accumulation areas
- Finalize staff training documents, presentations, etc.
- Finalize contingency plans, waste minimization plans, other regulatory items
- Finalize date for hospital-wide program rollout
- Conduct pharmaceutical waste train-the-trainer sessions system-wide
- Hospital-wide program rollout

Pharmaceutical Waste Collection Options

Proposed Options:

- Option 1--Collect only EPA-regulated pharmaceutical waste
- Option 2--Collect all pharmaceutical waste, segregate regulated and non-regulated
- Option 3--Collect all pharmaceutical waste, no segregation
- For all options, some considerations include:
  - Who will manage program
  - Onsite labor support
  - Supplies

Option 1 Overview

Collect only EPA-regulated pharmaceutical waste

- Pros:
  - Lowest disposal cost (~10-15% of formulary is EPA regulated)
  - Potential for lower generator classification
  - One additional container
- Cons:
  - Complex training
  - Additional time burden for staff
  - Increased liability due to potential for mistakes

Option 1 Impacts

- Have pharmaceutical formulary characterized to determine what is EPA regulated
  - Must be kept up-to-date
  - New pharmaceuticals reviewed
  - Service cost
- Develop an identification system for regulated pharmaceuticals
  - Additional printers, custom labels, identify pharmaceuticals within the pharmacy system including at point of distribution
- Only HazWaste need to be collected
  - Increased opportunity for disposal error that could lead to a violation

Option 2 Overview

Collect all pharmaceutical waste, segregate regulated and non-regulated

- Pros:
  - Accurate record of regulated waste volume
  - Reduced waste costs
  - Potential for lower generator classification
- Cons:
  - Complex training
  - Additional time burden for staff
  - Increased liability due to potential for mistakes
  - Increased space requirements

Option 2 Impacts

- Have pharmaceutical formulary characterized to determine what is EPA regulated
  - Must be kept up-to-date
  - New pharmaceuticals reviewed
  - Service cost
- Develop an identification system for regulated pharmaceuticals
  - Additional printers, custom labels, identify pharmaceuticals within the pharmacy system including at point of distribution
- Waste need to be segregated
  - Increased opportunity for disposal error that could lead to a violation

Option 3 Overview

Collect all pharmaceutical waste, no segregation

- Pros:
  - Decreased opportunity for non-compliance
  - Simplified training
  - Minimal time commitment for staff
  - One additional container
- Cons:
  - Higher cost than Option 1 and 2
  - Increased hazardous waste volume
  - Potential for higher generator classification

Option 3 Impacts

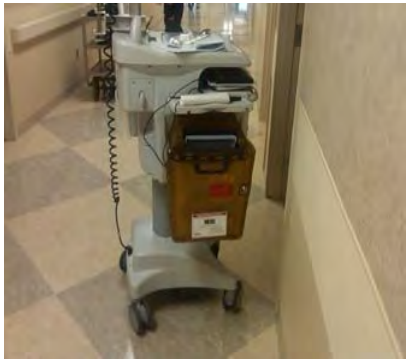
- Do not need a pharmaceutical formulary characterization
- Do not need to develop an identification system for regulated pharmaceuticals
- Only need to train staff on disposal procedure
- May require higher waste generator status

Container Decisions

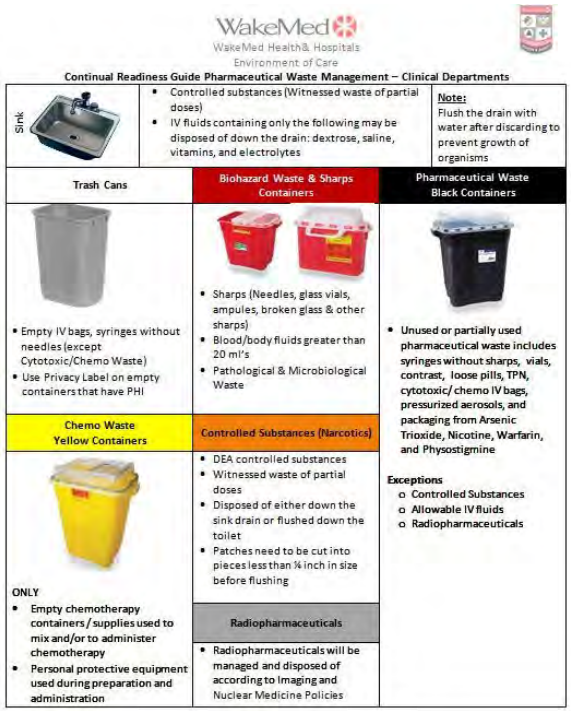
- Location of containers
  - Med Rooms
  - Soiled Utility Rooms
  - Procedure Rooms
  - Nursing Stations
- Size/type of containers
- Single-use or reusable
  - Consider purchasing heavy-duty liner
- Hazardous waste containers must be closed unless waste is being added or removed
- The accumulation containers must be located at or near the point of generation and under the control of the operator

Pharmaceutical Waste Container Examples

Source: WakeMed Health & Hospitals



Training



WakeMed
WakeMed Health & Hospitals
Environment of Care

Continual Readiness Guide Pharmaceutical Waste Management – Clinical Departments

Sink

- Controlled substances (Witnessed waste of partial doses)
- IV fluids containing only the following may be disposed of down the drain: dextrose, saline, vitamins, and electrolytes

Note: Flush the drain with water after discarding to prevent growth of organisms

Trash Cans	Biohazard Waste & Sharps Containers	Pharmaceutical Waste Black Containers
• Empty IV bags, syringes without needles (except Cytotoxic/Chemo Waste) • Use Privacy Label on empty containers that have PHI	• Sharps (Needles, glass vials, ampules, broken glass & other sharps) • Blood/body fluids greater than 20 ml's • Pathological & Microbiological Waste	• Unused or partially used pharmaceutical waste includes syringes without sharps, vials, contrast, loose pills, TPN, cytotoxic/ chemo IV bags, pressurized aerosols, and packaging from Arsenic Trioxide, Nicotine, Warfarin, and Physostigmine **Exceptions** o Controlled Substances o Allowable IV fluids o Radiopharmaceuticals
Chemo Waste Yellow Containers	**Controlled Substances (Narcotics)**	
ONLY • Empty chemotherapy containers / supplies used to mix and/or to administer chemotherapy • Personal protective equipment used during preparation and administration	• DEA controlled substances • Witnessed waste of partial doses • Disposed of either down the sink drain or flushed down the toilet • Patches need to be cut into pieces less than ¼ inch in size before flushing	
	Radiopharmaceuticals	
	• Radiopharmaceuticals will be managed and disposed of according to Imaging and Nuclear Medicine Policies	

What is USP 800?

- USP <800> sets standards for handling of hazardous drugs in healthcare settings
- In 2004, National Institute of Occupational Safety and Health (NIOSH) published an alert on hazardous drugs in healthcare settings – after USP 797 was released
- USP 797 revision in 2008 included a specific section for hazardous drugs (but only as it relates to sterile compounds)
- Based on published reports of adverse effects in healthcare personnel from exposure to hazardous drugs, USP 800 was developed

Source: http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

USP 800 Purpose

- The purpose of USP 800 is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection; the chapter defines processes intended to minimize the exposure to hazardous drugs in healthcare settings
- Receipt, storage, compounding, dispensing, administration, and disposal of sterile and non-sterile preparations

Scope of USP 800

- Protect personnel, preparations, and the environment
- Scope includes entire time a hazardous drug is in your facility: receiving through disposal
- Includes both nonsterile and sterile products and preparations
- Standards apply to all personnel who compound HDs preparations and all places where HDs are prepared, stored, transported, and administered

USP 800 Definitions

- Hazardous drugs
  - Any drug defined as hazardous by NIOSH on the basis of at least one of six criteria
    - Carcinogenicity
    - Teratogenicity or developmental toxicity
    - Reproductive toxicity in humans
    - Organ toxicity at low doses in humans or animals
    - Genotoxicity
    - New drugs that mimic existing hazardous drugs in structure or toxicity

USP 800 Timeline

- First published for public comment in March 2014
- Revised and presented for further public comment in December 2014
- Revised again and published in February 2016
- Will be harmonized with USP 797
  - Becomes official on **December 1, 2019**

Source: http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

USP 800 Timeline

- Applies to all healthcare personnel who handle hazardous drug preparations and all entities that store, prepare, transport, or administer hazardous drugs
- Including but not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians
- Ensuring compliance after standards become official on December 1, 2019 will be the responsibility of FDA, states, and other government authorities

http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

Potential Exposure Points

Designating a Point Person

- Designated individual
- Develops and implements appropriate procedures
- Oversees facility compliance with this chapter and other applicable laws, regulations, and standards
- Ensures competency of personnel
- Assures environmental control of the
- compounding areas

What Do You Need For Compliance?

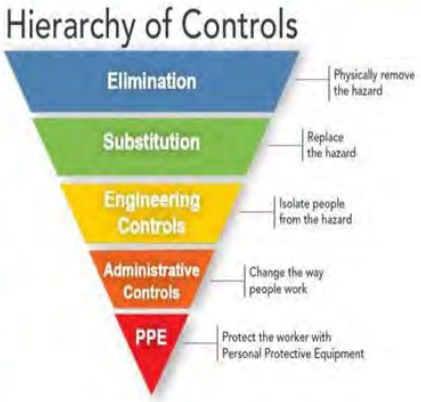
- Engineering controls (including primary, secondary, and supplemental)
- Robust work practices
- Comprehensive approach to prevent worker and environmental exposure
- Monitoring
- Competent personnel
- Availability of appropriate Personal Protective Equipment (PPE)

USP 800 – Managing Risk

What's the Assessment of Risk All About?

- USP <800> establishes the containment strategies and work practices best known to control hazardous drug contamination
  - Engineering controls
  - Protective equipment
  - Work practices

https://www.cdc.gov/niosh/topics/hierarchy/



USP 800 – PPE Requirements

- Personal Protective Equipment
  - Compounding: gloves, gowns, head, hair, and shoe covers
  - Administrating antineoplastic HDs: gloves
  - Administering injectable HDs: gloves, gowns
  - Double gloves and double shoe covers required for certain activities
  - Requirements for respirators
    - Must be used when unpacking HDs not contained in plastic
    - Cannot use surgical masks when respiratory protection is required

USP 800 – Policies/Procedures

- Entities must establish policies and procedures to ensure worker safety
- Competency assessed and documented every 12 months, when a new hazardous drug or equipment is introduced, or when a significant change in process occurs
- Medical surveillance program
  - Consider confidentiality of employees' medical information
  - Baseline assessment of health status and medical history
  - Records of HDs handled, including number handled and hours handling
  - Physical assessments, laboratory values, etc.

Safe Work Practices

- Standard Operating Procedures (SOPs)
- Documentation (pharmacy keeper software)
- Aseptic technique
- Containment technique
- Disposal
- Spill control

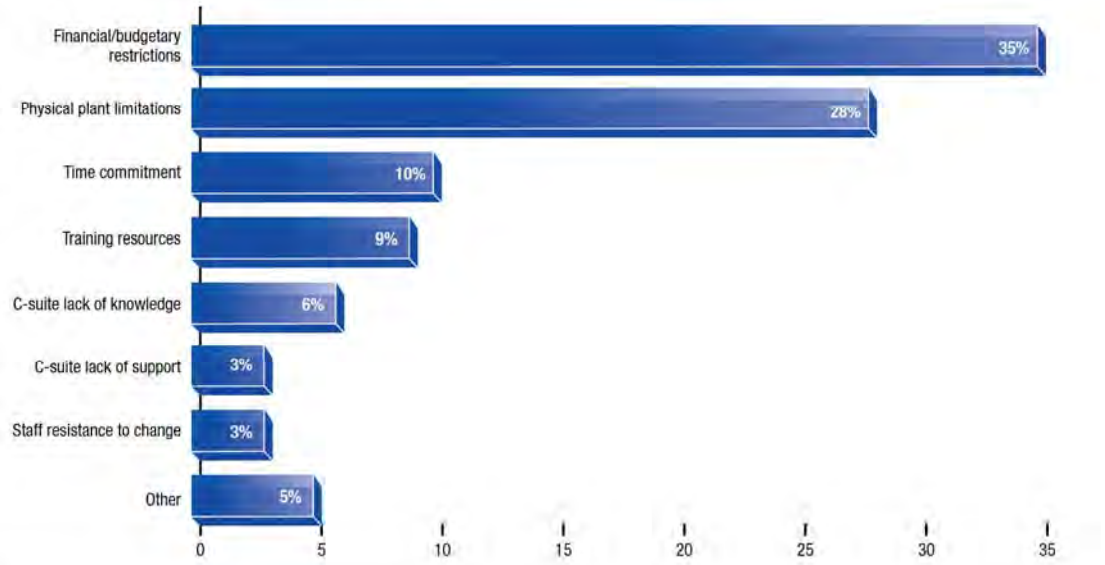
SOPs for Handling of HD Should Include:

- Hazard communication program
- Occupational safety program
- Labeling of HDs
- Procurement of HDs
- Use of proper engineering controls (e.g., C-PECs, C-SECs)
- Use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)
- Decontamination/deactivation, cleaning, and disinfection
- Transport
- Environmental monitoring
- Spill control
- Medical surveillance

FIGURE 7

Primary Challenge to Achieving USP Compliance

Once again, hospitals find financial restrictions and physical plant limitations to be the top challenges to achieving compliance with the USP compounding chapters.



Source: Cleanrooms & Compounding, October 2017, Volume 14, No 10., page 16

Summary

- There is no substitute for constant vigilance by an EHS professional in a healthcare setting
- Train, train, and train some more
- Have a strong communication strategy
- Stay ahead of regulations and best practices

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