Implementing a Pharmaceutical Waste Management System

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Frequently asked questions…

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- There will be a Q&A session at the end of the presentation.
  - Chat window
  - Q&A panel
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Goals

- To develop a better understanding of the regulatory and environmental reasons for managing pharmaceutical waste more stringently
- To review the definitions of a hazardous waste as they apply to waste pharmaceuticals
- To explore implementation models for the management of hazardous pharmaceutical waste

Who Are the Regulators?

- USEPA & 10 Regions
  - Office of Solid Waste, Hazardous Waste Division
  - Office of Water
- Authorized State Hazardous Waste Programs
  - Every state except Iowa and Alaska
- Local Publicly Owned Treatment Works (POTWs)
  - Must meet federal effluent guidelines
- The Joint Commission
  - Primary accrediting body for many hospitals
  - Federal funding dependent on accreditation

The Faroes Statement

- 200 environmental scientists from five continents met at the Faroes Islands in the North Atlantic –May 24, 2007
- Warned of fetal exposure to toxic substances resulting in "fetal programming" to the 2nd and 3rd generation
- Lifelong effects: obesity, diabetes, cancers, ADHD, Parkinson's, Alzheimer's, reduced immune system
- "The dose makes the poison" replaced by "The timing makes the poison"
- New approach to testing of chemicals strongly advocated; 80% of major chemicals never tested for damage to early development
- http://www.precaution.org/lib/rpr-html.htm

Precautionary Principle

- "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Wingspread Conference, Racine, WI 1998

Preliminary 2008 Effluent Guidelines Program Plan (Pre-publication version)

- Published in Federal Register Oct. 18th, 2007
- Major pollutants of concern in discharges include pharmaceuticals and endocrine-disrupting compounds (EDCs)
- Focus area: Unused pharmaceuticals
  - Physician offices, long-term care facilities, veterinary care servcies, hospitals and clinics
- Soliciting data, information, and comments on a variety of questions relating to disposal of unused pharmaceuticals

EPA's Clean Water Act Review of the Management of Unused Pharmaceuticals for the Health Services Industrial Sector

- **What is the Scope of the Study?**
  - Highlight good voluntary practices on an industry that may have significant discharges of consequence to the environment
  - Focus include **u**nused or expired pharmaceutical discharges to municipal wastewater treatment plants from hospitals, long-term care facilities, and veterinarians
- **What are They Studying?**
  - Current industry practices, guidance and regulatory requirements
  - Source, and pass through or inhibition, associated with these discharges at municipal wastewater treatment plants
- **Schedule:**
  - CY2007: Complete data collection for identifying current industry practices, existing guidance/requirements, and possible BMPs
  - FY2008: Estimate pollutant loadings, identify possible best practices for controlling pollutant discharges and associated costs, and final report.

Relationship to The Joint Commission Standards: Environment of Care

- **Standard EC.3.10**
- ***The organization manages its hazardous materials and waste[1] risks.***

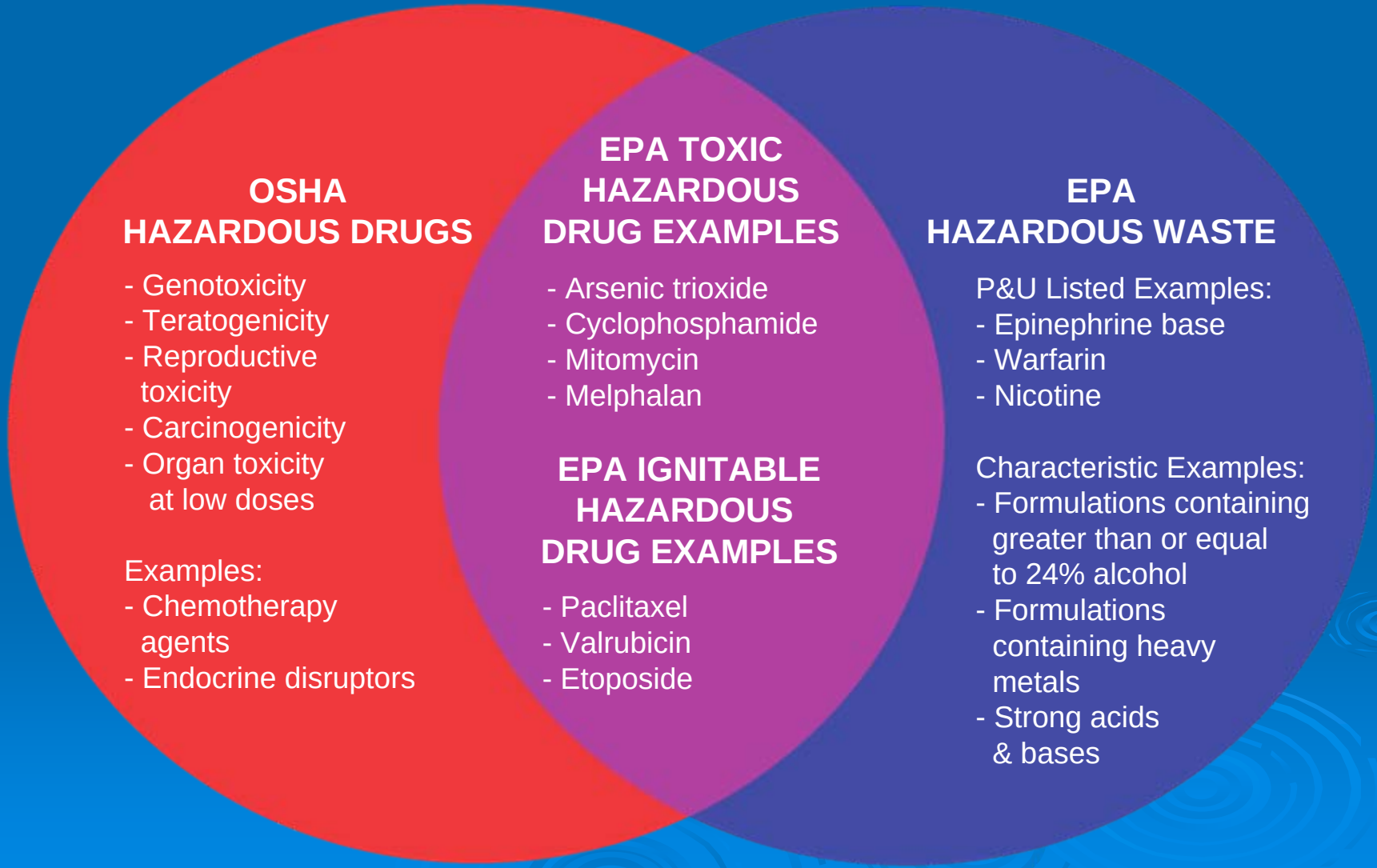
[1] Hazardous materials (HAZMAT) and waste:
Materials whose handling, use, and storage are guided or regulated by local, state, or federal regulation. Examples include OSHA's Regulations for Bloodborne Pathogens (regarding the blood, other infectious materials, contaminated items which would release blood or other infectious materials, or contaminated sharps), the Nuclear Regulatory Commission's regulations for handling and disposal of radioactive waste, management of hazardous vapors (such as glutaraldehyde, ethylene oxide, and nitrous oxide), ***chemicals regulated by the EPA, Department of Transportation requirements***, and hazardous energy sources (for example, ionizing or non-ionizing radiation, lasers, microwaves, and ultrasound.)

OSHA Hazardous Drugs

- NIOSH Hazardous Drug Alert
  - Hazardous drugs as defined by OSHA/NIOSH intersect but are not the same as EPA hazardous wastes
- ASHP Guidelines on Handling Hazardous Drugs
  - Deal primarily with OSHA employee exposure issues but also refer to required or recommended hazardous pharmaceutical waste management practices

Hazardous Drugs vs. Hazardous Waste

Where OSHA & EPA Meet

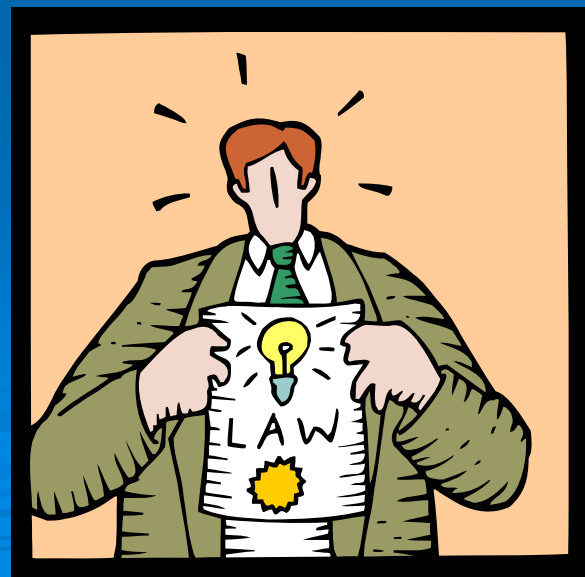


What Departments Get Involved in Generating and Managing Pharmaceutical Waste?

- Pharmacy
- Nursing
- Infection Control
- Environmental Services
- Safety
- Facility Management
- Risk Management
- Materials Management

RCRA: The Defining Regulation

- Resource Conservation & Recovery Act
  - Enacted in 1976, enforced by the EPA
  - Federal regulation of the disposal of solid wastes
  - Encourages the minimization of waste generation
- Defines “hazardous waste”
- “Cradle to Grave” tracking of hazardous waste

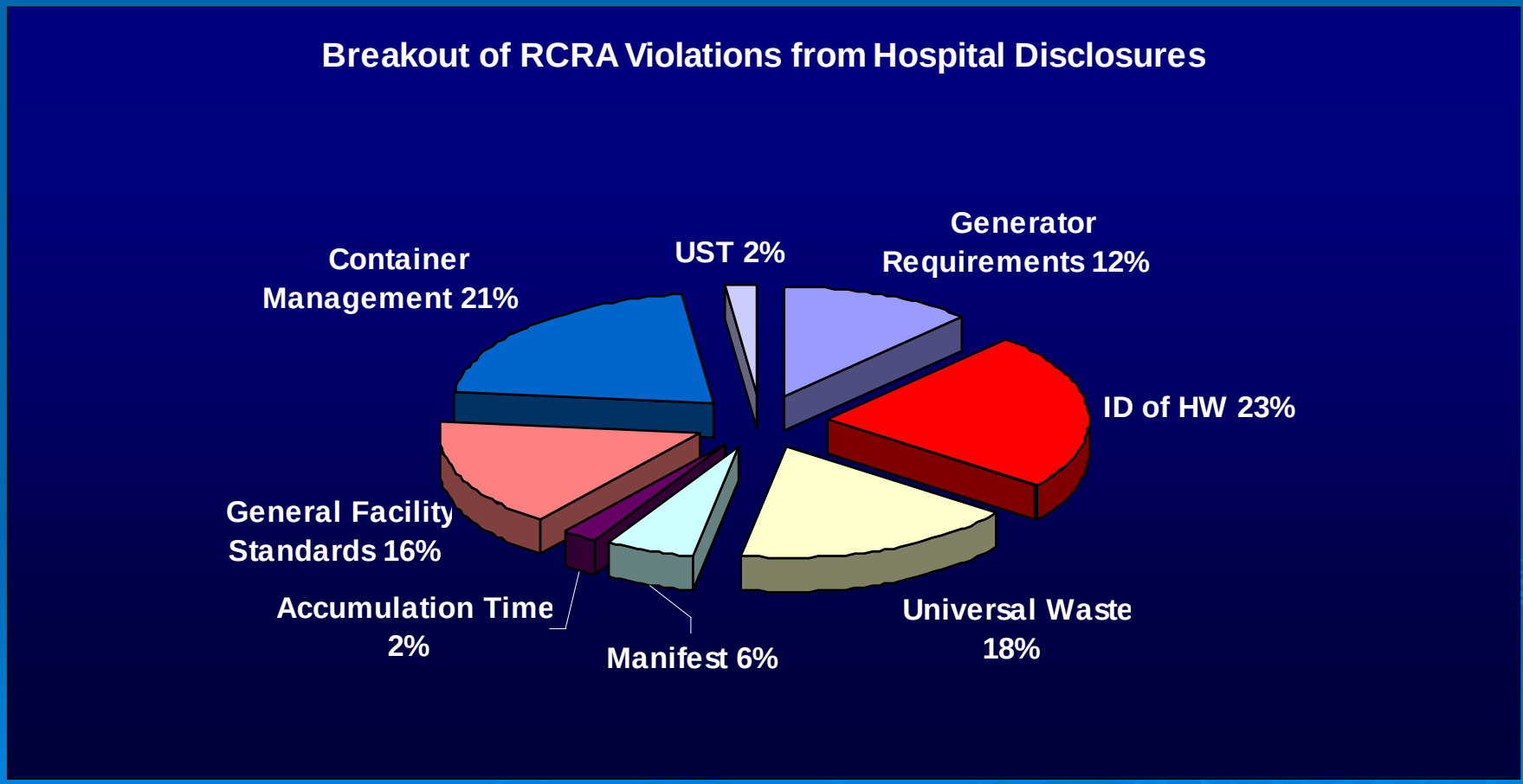


RCRA Risk Management & Liability

- Civil and criminal liability
  - Civil: State/USEPA enforcement
  - Criminal: FBI, Attorney General, Grand Jury
- Corporate fines: $32,500/violation/day
- Personal liability: fines and/or imprisonment
- No statute of limitations
- Managers up through CEO liable

http://www.epa.gov/compliance/resources/policies/criminal/exercise.pdf

Healthcare RCRA Violations



Slide courtesy of John Gorman, USEPA Region 2

Which Discarded Drugs Become RCRA Hazardous Waste?

- P-listed chemicals
  - Sole active ingredient; unused
- U-listed chemicals
  - Sole active ingredient; unused
- Characteristic of hazardous waste
  - Ignitability
  - Toxicity
  - Corrosivity
  - Reactivity

Examples of P-Listed Pharmaceutical Waste

Arsenic trioxide	P012
Epinephrine base*	P042
Nicotine	P075
Nitroglycerin** (weak)	P081
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine Salicylate	P188
Warfarin >0.3%	P001

*Salts excluded federally as of Oct. 16th, 2007; States may or may not accept this position

** Excluded from the P list federally and in a number of states

Examples of P-Listed Pharmaceuticals

Examples of U-listed Pharmaceutical Waste

- Chloral Hydrate(CIV) U034
- *Chlorambucil* U035
- *Cyclophosphamide* U058
- *Daunomycin* U059
- *Diethylstilbestrol* U089
- *Melphalan* U150
- *Mitomycin C* U010
- *Streptozotocin* U206
- Lindane U129
- Saccharin U202
- Selenium Sulfide U205
- *Uracil Mustard* U237
- Warfarin<0.3% U248

Examples of U-Listed Pharmaceuticals

Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point<140° F
- Non-aqueous solutions with flash points <140 ° F
- Oxidizers
- Flammable aerosols
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparations
- Injections

Characteristic of Corrosivity

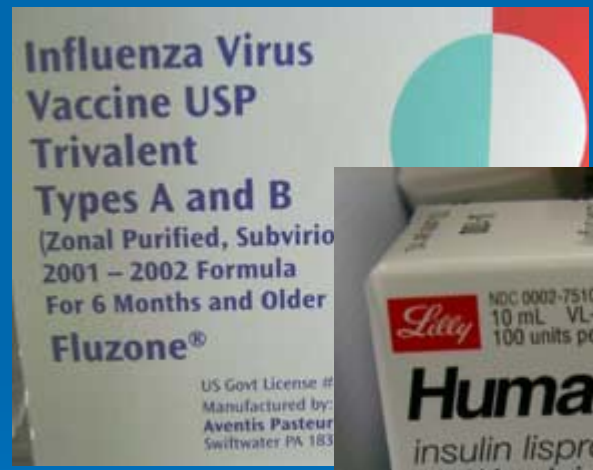
- An aqueous solution having a pH < or = 2 or > or = to 12.5
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide
- Hazardous waste number: D002

Characteristic of Toxicity

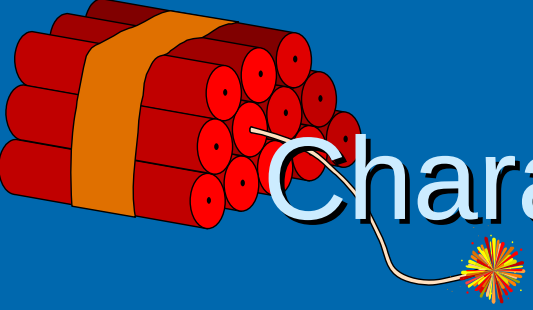
- 40 chemicals which must be below specific leaching concentrations
- Must pass the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN (total parenteral nutrition)– may come out of regulation due to dilution
- Examples of potential toxic pharmaceuticals:
- Arsenic
- Barium
- Cadmium
- Chromium
- Lindane
- m-Cresol
- Mercury (thimerosal, phenylmercuric acetate)
- Selenium
- Silver

Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Heavy Metals: Selenium, Chromium and Silver



Preservatives: thimerosal & m-cresol



Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- Nitroglycerin formulations may be considered excluded federally from the P081 listing as non-reactive as of August 14, 2001 under FR: May 16, 2001, unless they exhibit another characteristics, such as ignitability.
- Many, but not all state, have adopted the federal exclusion for nitroglycerin. Waste must still be evaluated for ignitability.
- Hazardous Waste Number for reactives: D003

States Having Stricter Definitions of Hazardous Waste

- Washington State
- Minnesota
- California
- Michigan
- Rhode Island
- Oregon

Chemotherapy Agents: Many Are Not Regulated by RCRA

- About 100 chemotherapy agents not regulated by EPA
- Examples:
  - Alkylating agents: Cisplatin, Thiotepa
  - Antimetabolites: Fluorouracil, Methotrexate
  - Hormonal (antiandrogen): Lupron® (leuprolide)
  - Hormonal (antiestrogen): Tamoxifen
  - Mitotic Inhibitor: Taxol® (paclitaxol)

Chemotherapy Waste Summary

- Eight chemotherapy agents are U-listed; one is P-listed
- Medical waste hauler protocols for “Chemo Waste”
  - Empty vials, syringes, IV’s
  - Treated as infectious medical waste preferably through regulated medical waste incineration
- If not empty, should be placed into Hazardous Waste container

Definition of “Empty”

- “P” List

  Containers of “P” listed chemicals are considered hazardous waste, unless they have been rinsed three times and the rinsate discarded as hazardous waste.

- “U” List

  Containers of “U” listed chemicals are empty only when

  - All contents removed that can be removed through normal means
  - And no more than 3% by weight remains
  - Example: “Empty” Cytoxan vial would be “trace” chemotherapy

What Is PharmE Hazardous® Waste?

- **Drugs which may cause harm to human health or the environment and need to be managed according to BMPs**
  - **NIOSH Hazardous Drug Alert Appendix A**
  - **The US Department of Health and Human Services National Toxicology Program's Report on Carcinogens (11th Edition)**
  - **Drugs with LD50s at or below 50mg/kg**
  - **Endocrine disruptors**
- **Identified as PharmE Hazardous® in Inventory Analysis**
- **BMP recommendation is to segregate at least chemo agents into RCRA toxic hazardous waste containers and to dispose of other agents through incineration**

Federal Waste Generation Status

- Large Quantity Generator (LQG): generates more than 1000 kg/month of hazardous waste or >1 kg/month “P” listed waste.
- Small Quantity Generator (SQG):Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month “P” listed waste.
- Conditionally Exempt Small Quantity Generator (CESQG) : Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month

Documenting Generator Status

- Large quantity generator: no need to record P waste separately.
- Small quantity generator or CESQG: need to segregate all P-listed including empty containers and document weights per calendar month
- Cannot exceed 1 kg or 2.2 lbs/month for any given month

How Should RCRA Hazardous Waste be Handled?

- Need one or two new waste streams in Pharmacy, certain Patient Care Areas, Oncology Clinics
- RCRA Hazardous Waste: Toxic
  - P, U, toxic Ds, (all Chemotherapy Residues, Chemo Spills)
- RCRA Hazardous Waste: Ignitable (D001)
- May be able to combine these into one waste stream based on state and waste vendor requirements

Traditional Chemo Waste Containers

Empty vials, syringes, IVs, tubing, gowns, gloves,etc.

New Hazardous Waste Containers

Bulk chemo in vials, unused IV's, P, U. toxic D

Covidien/Kendall

How Should RCRA Hazardous Waste Be Disposed?

- Either contract with a hazardous waste broker or develop internal expertise for:
  - Labeling
  - Waste profiling
  - Manifest preparation
  - Land ban preparation
- Contract with a federally permitted RCRA hazardous waste incineration facility (TSDF: Treatment, Storage & Disposal Facility)

How Should Non-hazardous Drugs be Handled, Stored and Disposed?

- BMPs strongly discourage sewering and landfilling of non-hazardous drugs
- Organization can minimize risks by adopting BMPs
- Possible exception: controlled substances due to difficulty in rendering non-recoverable under Drug Enforcement Administration (DEA) regulations
- Consider segregating into white Covidien container with blue top Label “Incinerate Only”
- Dispose at a regulated medical waste incinerator or municipal incinerator that is permitted to accept non-hazardous pharmaceutical waste

A Quick Primer on Incinerators

- Municipal
  - Permitted to burn municipal “garbage”
  - Usually not permitted to handle infectious waste
  - May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions
- Medical Waste
  - Permitted by USEPA and the state to accept pathology waste, red bag and red sharps waste, trace chemo waste
  - May be permitted to accept non-hazardous pharmaceutical waste
- Hazardous Waste
  - Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
  - High temperature, molecular bonds broken
  - Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 6-part Uniform Manifest

Common Pharmaceutical Waste Stream Management

Type of Waste Container	Color code	Contents	Treatment Method
Red bag (non-pathology)	Red	Biohazardous (RMW) + Rx	Autoclave/ Landfill
Red sharps/ needlebox	Red	Biohazardous; needles, etc. + Rx	Autoclave/ Landfill
Trace chemo Rx	Yellow or White	Bulk & Trace Chemo, needles, tubing	RMW Incineration
Sewer		Unused IVs, tablets, etc.	Wastewater Treatment Plant
Municipal Trash		Unused ointments, etc.	Landfill

Pharmaceutical Waste Management Recommendations

Type of Waste Container	Color code	Contents	Treatment Method
Red bag (non-pathology)	Red	Biohazardous (RMW) No Rx	Autoclave/ Landfill
Red sharps/ needlebox	Red	Biohazardous; needles, No Rx	Autoclave/ Landfill
Trace chemo Rx	Yellow or White	Biohazardous & Trace Chemo	RMW Incineration
RCRA Toxic Hazardous Rx	Black	RCRA & BMP Hazardous Rx	RCRA TSDF
RCRA Ignitable Hazardous Rx	Black	RCRA Hazardous Rx	RCRA TSDF
Non-hazardous Rx	White/Blue	Non-hazardous Rx	RMW Incineration

Satellite Accumulation

- Segregated, labeled and contained in areas where it is generated
- Available in all units in which hazardous waste is generated & must be under the control of the operator
- Label each container as “Hazardous Waste” with the appropriate waste stream noted
- No time limit to fill the container
- No more than 55 gallons of U listed and characteristic waste or 1 quart of P listed waste may be accumulated
- Must be moved to storage accumulation within 3 days after these quantities are reached (federal regulations)
  - Some states are stricter

Storage Accumulation

Hazardous Waste Storage Accumulation Site:

- Provides a safe and secure storage area for hazardous waste while it awaits shipping.
- Same locked area as mercury, xylene, formaldehyde, lab chemicals
- Maximum storage time:
  - 90 days if LQG; 180 days if SQG
- Must maintain an inspection log

Considering the Optimal Management Options

- Need to label items that need segregation in a manner that makes it easy for pharmacy and nursing personnel
- Shelf stickers in pharmacy
- Data Applied to Dispensing Software and/or
- Message inserted into Pyxis, etc. and MAR (Medication Administration Record) and/or
- Stickers Applied Manually

Getting Implementation Done: Choosing a Model

- Model 1: Automated sorting device
  - In development
- Model 2: Labeling electronically
- Model 3: Labeling manually
- Model 4: Central collection and sorting
- Model 5: Manage all as hazardous waste

Model 2: Electronic Labeling

- Entire inventory is analyzed
- Shelf stickers in pharmacy
- Data is entered into the dispensing software at the NDC or “pneumonic” level
- Label prints with pre-determined code
  - HW1, RCRA1, Black Bin, etc.
- Nursing staff are trained on waste segregation based on codes
- Black “satellite accumulation” containers in soiled utility rooms
- Hybrid Model: North Memorial Health Care
  - Programmed automated dispensing machines (e.g., Pyxis)

Model 3: Manual Labeling of Hazardous Waste

- Entire inventory is analyzed
- Items are stickered either on shelf label
- Items are stickered upon dispensing
- Nursing staff are trained on waste segregation based on stickers
- Black “satellite accumulation” containers in soiled utility rooms
- Model program: North Memorial Health Care
  - http://www.hospitalconnect.com/hfmmagazine/jsp/articledisplay.jsp?dcrpath=HFMMAGAZINE/PubsNewsArticleGen/data/2006March/0603HFM_DEPT_EnvirSer&domain=HFMMAGAZINE

North Memorial Health Care

Robbinsdale, MN

SPECIAL DISPOSAL REQUIRED

Photos courtesy of
North Memorial Health Care

Model 4: Centralizing Segregation

- All pharmaceutical waste is collected in hazardous waste containers in the pharmacy and in the nursing units
- The mixed waste is removed to the central hazardous waste storage accumulation area
- Sorting is done by hazardous waste vendor or trained hospital staff based on an analysis of the inventory
- Hazardous waste and related items are manifested and disposed as such
- Model: Abbott Northwestern Hospital

Abbott Northwestern Hospital

Minneapolis, MN

Model 5: Managing All Pharmaceutical Waste as Hazardous

- Easiest, most expensive
- May still need to sort out ignitables
- Still need to do analysis of inventory to determine waste codes for manifesting
- Hybrid Model: UW Health, Madison, WI
  - All tablets/capsules/solids hazardous
  - IVs hazardous if RCRA, PharmE Hazardous™ (BMP)

UW Health
Madison, WI

pharmEcology® Associates, LLC

Providing Environmental Consultation to the Healthcare Industry™

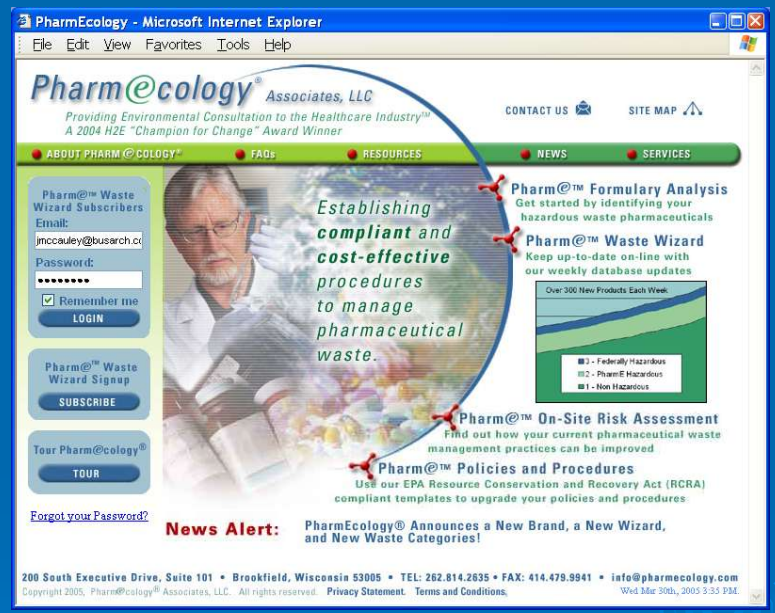
PharmEcology® offers solutions through Premier Purchasing Partners to identify and manage pharmaceutical waste in a cost effective and EPA compliant manner

PharmE® Pharmaceutical Waste Management System™

- Inventory Analysis
- PharmE® Waste Wizard
- On-Site Risk Assessment
- PharmE® Policies & Procedures
- Implementation Support & Certification

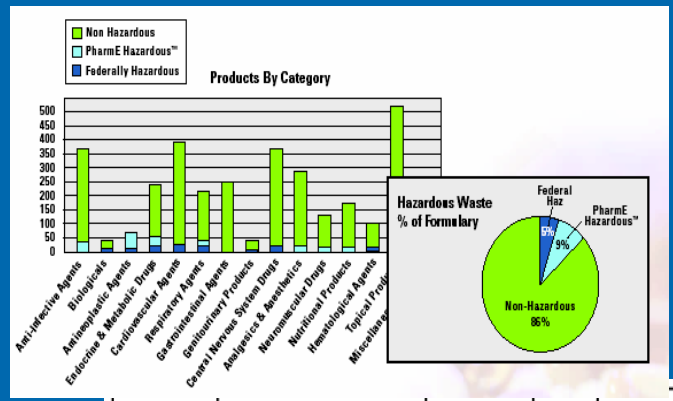
PharmEcology® Services

- Determine which pharmaceuticals become hazardous waste
  - PharmE Inventory Analysis
  - PharmE Waste Wizard
- Develop a Gap Analysis, Action Plan, and Implementation Strategy
  - PharmE On-Site Risk Assessment
  - PharmE Implementation Support and Certification
- Customize Policy and Procedure Templates
  - PharmE Policies and Procedures



PharmE Inventory Analysis

- Most cost-effective method of identifying hazardous Rx waste
- Identifies P, U, and D listed drugs
- Identifies PharmE Hazardous drugs
  - NIOSH Hazardous Drug Alert
  - Endocrine disruptors
  - Other non-listed hazardous drugs
- 12 month purchase history summary provided by wholesaler
- 10 working day turnaround



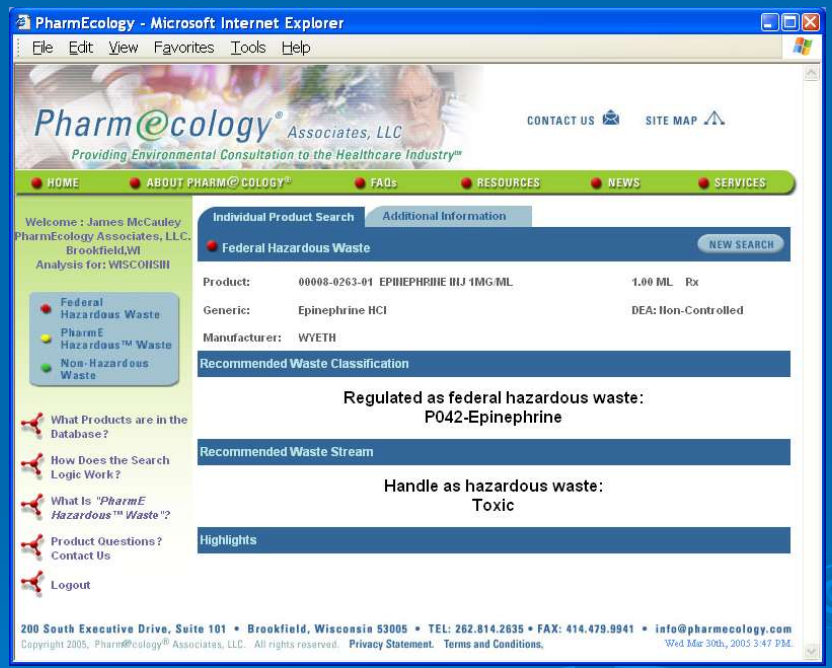
NDC	Product	Waste Class	Waste Stream	Waste Code
00074492134	ADRENALINE 0.1MG/ML ABBJCT	Fed Hazardous	Toxic	P042 - Epinephrine
00904777035	MEDIHALER-EPI INHALER	Fed Hazardous	Ignitable	D001 - Ignitable
49502050001	EPIPEN 0.3MG AUTO-INJECTOR	Fed Hazardous	Toxic	P042 - Epinephrine
11980011915	EPIFRIN 0.5% EYE DROPS	Fed Hazardous	Toxic	P042 - Epinephrine
11980012215	EPIFRIN 1%EYE DROPS	Fed Hazardous	Toxic	P042 - Epinephrine
615/				

NDC	Product	Waste Class	Waste Stream	Waste Code
66479013929	METHOTREX SOD 1 GM P/F VL	PharmE hazardous	Toxic	NIOSH - Antineoplastic
65483059010	IMURAN 50 MG 100	PharmE hazardous	Toxic	NIOSH-Immunosuppressive
00015301238	BICNU 100 MG VL	Federal hazardous	Ignitable	Alcohol > 24%

*Sample Data. Results truncated for presentation purposes

PharmE® Waste Wizard

- Patented 24/7 web-based search engine
- Access to over 160,000 drug products and their waste categorizations
- Search on NDC, brand name, generic name
- Annual subscription location based; unlimited use, unlimited users
- Review new drugs entering the formulary; patients' personal meds; samples; non-pharmacy purchases (eg. Radiology)



PharmE® On-site Risk Assessment, Policies and Procedures, Implementation Support & Certification

- One-day on-site risk assessment
- 90 minute seminar for all relevant managers
- 2 hours each with pharmacy, nursing, safety/environmental services
- Gap Analysis and Action Plan
- Remote implementation support for 12 to 18 months
- Policy and Procedure Templates for 5 implementation models
- PharmE Certification upon completion


PharmE® Certification

PharmEcology® Associates, LLC hereby certifies and confirms that on

NAME OF ORGANIZATION

has developed pharmaceutical waste management systems designed to meet the requirements of the USEPA Resource Conservation & Recovery Act, state and local environmental regulations, and The Joint Commission Medication Management and Environment of Care Standards with respect to the management of pharmaceutical waste.

Charlotte A. Smith, R. Ph., M.S.
President, Pharmecology® Associates, LLC

Summary

- Managing hazardous pharmaceutical waste is an emerging and rapidly evolving management area
- Several implementation models are available and more may evolve
- Successful implementation will require an interdisciplinary team committed to moving forward
- The rewards include cost-effective compliance and evidence of a commitment to environmental excellence

Resources

- NIOSH Hazardous Drug Alert
  - http://www.cdc.gov/niosh/docs/2004-165/#sum
- ASHP Guidance on Handling Hazardous Drugs
  - http://www.ashp.org/s_ashp/bin.asp?CID=6&DID=5420&DOC=FILE.PDF
- OSHA Technical Manual
  - http://www.osha-slc.gov/dts/osta/otm/otm_vi/otm_vi_2.html
- Hospitals for a Healthy Environment
  - http://www.h2e-online.org/
  - Pharmaceutical waste webpage: http://www.h2e-online.org/hazmat/pharma.html
  - Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities In the United States: http://www.h2e-online.org/docs/h2epharmablueprint41506.pdf
- PharmEcology Associates, LLC
  - www.pharmecology.com
  - FAQs, state and federal waste regulations, subscription search engine
  - PharmE™ Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria
- Pharmaceuticals and Personal Care Products as Environmental Pollutants:
  - http://www.epa.gov/nerlesd1/chemistry/pharma/index.htm

Questions?

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