



Managing Pharmaceutical Waste

County of San Diego, Dept. of Environmental Health, Hazardous Materials Division

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Agenda

What's new: legislative and regulatory update

RCRA 101: Which drugs become hazardous waste

Practical steps to get started

Making it happen: practical examples



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Drugs in Drinking Water & Healthcare Pharmaceutical Waste

AP Associated Press

March 9, 2008

5-month inquiry discovered that drugs were detected in the drinking water supplies of 24 major metropolitan areas

Reported that there are no sewage treatment systems engineered to remove pharmaceuticals

Acknowledged continuous low-level exposure to chemo drugs, hormones, anti-depressants, antibiotics, and seizure meds found in our water could be impacting human health.

September 14, 2008

Continuing inquiry into disposal practices by hospitals, long term care facilities, other healthcare organizations

Majority of medical facilities flush unwanted drugs down the drain and do not document amounts according to EPA survey

Extrapolation of data from 14 representative facilities in Minnesota yielded an estimated total volume of 250 million pounds of drug waste annually, including packaging



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Pending Legislation

Drug Free Water Act of 2009

Introduced into the House on January 7, 2009: HR 276

Requires EPA to convene a Task Force regarding proper disposal of unused pharmaceuticals

Safe Drug Disposal Act of 2009

Introduced into the House on February 25, 2009: HR 1191

Introduced into the Senate on June 24, 2009: S 1336

To amend the Controlled Substances Act to provide for the disposal of controlled substances by ultimate users and care takers through State take-back disposal programs

To amend the Federal Food, Drug and Cosmetic Act to prohibit recommendations on drug labels for the disposal by flushing

Secure & Responsible Drug Disposal Act of 2009

Introduced into the House on March 5, 2009: HR 1359

Introduced into the Senate on June 18, 2009: S. 1292

To amend the Controlled Substances Act to enable consumer take-back programs



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EPA May Regulate Pharms in Drinking Water

104 chemicals being considered for possible regulation under the Safe Drinking Water Act

Pharmaceuticals considered for the first time

Several estrogens included:

estradiol, estrone, ethinyl estradiol, mestranol

Also erythromycin (antibiotic) & nitroglycerin (cardiac)

Collection and evaluation will take years (2013)

but could result in drinking water standards for drugs

http://www.pharmacology.com/pedd/jsp/static/a6_news_alert.jsp



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EPA Proposal to Add Pharmaceuticals to Universal Waste Rule

Federal Register publication Dec 2, 2008 – Comments were due March 4, 2009

<http://www.epa.gov/fedrgstr/EPA-WASTE/2008/December/Day-02/f28161.htm>

Information:

<http://www.epa.gov/epawaste/hazard/wastetypes/universal/pharm.htm>

Proposed UWR only applies to drug waste that meets the definition of RCRA hazardous waste

Only intended for healthcare-type generators, not manufacturers

Intent to streamline pharmaceutical waste management and encourage consumer take-back programs

Estimated April, 2011 for federal enactment; states may or may not adopt

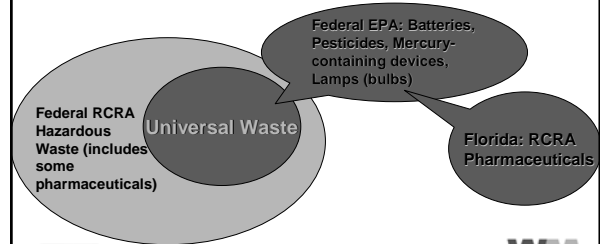


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RCRA and Universal Waste

“Universal Waste” is a subset of RCRA hazardous waste.



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Impact of Universal Waste Regulations

Applies ONLY to 4% of drugs in the marketplace that are RCRA hazardous waste... does not address other 96% of drugs.

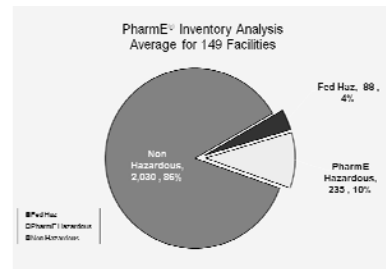
Brings attention to the industry regarding the proper disposal of pharmaceutical waste.



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Percentage of RCRA & PharmE Haz[®] in 149 Hospitals, 2008



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Specific Benefits of Adding Pharmaceuticals to UWR

Hazardous pharmaceutical waste would no longer contribute to the generator size

Storage time limits would increase to one year total (currently in California), allowing more time in storage accumulation area



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Economic Impact

Suggested practice of managing all Rx waste as universal waste

Fee differential as large as 5x to 10x between medical incineration and RCRA hazardous waste incinerator

RMW: \$.19/lb - \$.50/lb

RCRA: \$.95/lb - \$4.95/lb



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Burning Question: Should I Wait for the UWR to Develop My System?

NO:

It will take over 12 months for a new rule to be adopted federally

It will take YEARS for each state to adopt either the federal version or their own version of the UWR

Hazardous waste will still need to be identified and manifested when traveling through states that have not adopted the UWR

Your organization will still need to segregate hazardous waste to avoid premier disposal charges



2009 MM Standards Standard MM.01.01.03

The organization safely manages high-alert and hazardous medications.

4. Minimizes risks associated with managing hazardous medications.



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2009 EOC Standards Standard EC.02.02.01

The organization manages risks related to hazardous materials and waste.

1. Maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. Only those addressed by law and regulation need to be included.
3. Has written procedures, including use of precautions and PPE, to follow in response to hazardous material and waste spills or exposures.
4. Implements its procedures in response to hazardous material and waste spills or exposures.



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2009 EOC Standards Standard EC.02.02.01

5. Minimizes risks associated with selecting, handling, storing, transporting, using, and disposing hazardous chemicals.

8. Minimizes risks associated with disposing hazardous medications.

11. For managing hazardous materials and wastes, the hospital has the permits, licenses, manifests, and MSDSs required by law and regulation.

12. Labels hazardous materials and waste. Labels identify the contents and hazard warnings.



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2009 EOC Standards Standard EC.04.01.01

The organization collects information to monitor conditions in the environment.

8. Based on its process(es), the hospital reports and investigates the following: Hazardous materials and waste spills and exposures.



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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

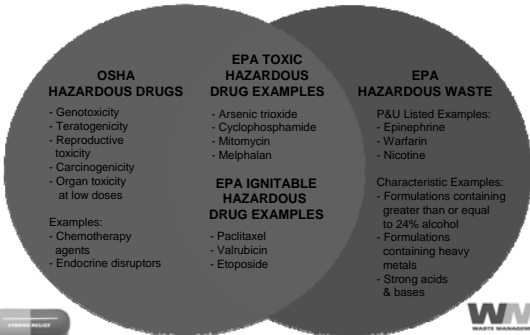
Deal primarily with OSHA employee exposure issues but also refer to required or recommended hazardous pharmaceutical waste management practices



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Hazardous Drugs vs. Hazardous Waste Where OSHA & EPA Meet



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Where is Pharmaceutical Waste Generated?

- Pharmacy/Satellites
- Patient Care Units
- ER/OR
- ICU/CCU/NICU
- Oncology/Hematology, Ambulatory OR, and other outpatient clinics
- Radiology
- Satellite Medical Clinics
- Long Term Care Facilities



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When is an Outdated Drug a Waste?

At the time and place the decision is made to discard it

Two EPA guidance letters to the industry:

- Merck & Co., 1981
- BFI Pharmaceutical, 1991

Enables shipping of potentially creditable outdates to a reverse distributor as product

PROHIBITS the shipping of waste-like items, such as unused IVs, partial vials, expired repacks, samples

Hospital is liable for using due diligence in selecting a vendor

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Non-returnable Waste

20060516 04:13 pm



Returnable Expired Product

20060516 04:26 pm

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Enforcement in California and San Diego County

RCRA is enforced by USEPA Region 9 and by the California EPA Dept. of Toxic Substances Control (DTSC)

San Diego County is certified by Cal EPA to enforce RCRA within the County as a CUPA (Certified Unified Program Agency)

California State Hazardous Waste is enforced by Dept. of Public Health (DPH) under the Medical Waste Management Act (MWMA)

San Diego County is the local implementing and enforcement agency for the MWMA in the County

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RCRA: Risk Management & Liability

Civil and criminal liability

Civil: State/USEPA enforcement

Criminal: FBI, Attorney General, Grand Jury

Corporate fines: \$37,500/violation/day

Personal liability: Fines and/or imprisonment

No statute of limitations

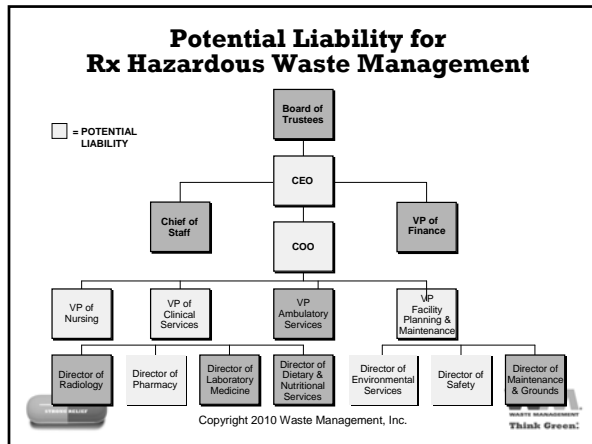
Managers up through CEO liable

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



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Applying Your Knowledge!

Mix & Match Exercise
The "All-Seeing Eye"
holds the clues!

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Which Discarded Drugs Become Hazardous Waste?

P-listed chemicals (acutely hazardous)
Sole active ingredient; unused; empty containers

U-listed chemicals (toxic)
Sole active ingredient; unused

Characteristic of hazardous waste

- Ignitability
- Toxicity
- Corrosivity
- Reactivity

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Examples of P-Listed Pharmaceutical Waste

Arsenic trioxide (chemo)	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. 15th, 2007; California has adopted this position.
**Excluded from the P list federally and in California.

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Examples of U-Listed Pharmaceutical Waste

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

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Examples of U-Listed Pharmaceuticals

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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



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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



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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 – may come out of regulation due to dilution

Examples of potential toxic pharmaceuticals:

Arsenic	m-Cresol
Barium	Mercury (thimerosal, phenylmercuric acetate)
Cadmium	Selenium
Chromium	Silver
Lindane	



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Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity



Heavy metals: selenium, chromium and silver

Preservatives: thimerosal & m-cresol

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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, unless they exhibit another characteristics, such as ignitability.

CalEPA DTSC has adopted the federal exclusion for nitroglycerin.

Hazardous Waste Number for reactives: D003



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Three Types of Chemotherapy Waste



Trace Chemotherapy Waste (yellow)

Medical waste hauler protocols for "Chemo Waste"

Empty vials, syringes, IV's, gowns, gloves, ziplock bags

Treated as infectious medical waste through regulated medical waste incineration

"Bulk" Chemotherapy Waste (black)

If not empty, should be placed into RCRA Hazardous Waste container

Spill Clean-up (black)

Manage as RCRA Hazardous Waste



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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 and D codes

Containers of "U" listed chemicals or D codes 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

Residue of "P" or "U" listed drugs in a used syringe is exempted and should be discarded as biohazardous waste or trace chemo. California has adopted.



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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



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The Medical Waste Management Act and California-Only Hazardous Waste

Causes pharmaceutical waste to be defined as "biohazardous" – out of sync with usual and customary definition as infectious waste

Defines "empty" chemo container

Defines pharmaceuticals as all drugs that are not RCRA and not radioactive

Intent is to regulate CAL-ONLY haz waste

Requires incineration at a regulated medical waste facility or approved alternative



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California Hazardous Waste

Primary applicable criteria is an LD50 of 2500 mg/kg or less

Changed from original criteria of LD50 of 5000 mg/kg or less

New criteria is half as stringent

Acute aquatic 96-hour LC50 < 500mg/liter

Carcinogenicity, acute toxicity, chronic toxicity, bioaccumulative, persistence in the environment

No complete list

Practical solution: manage all non-RCRA pharmaceuticals as Cal-Hazardous



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How Should California Hazardous Pharmaceutical Waste be Handled, Stored and Disposed?

DPH prohibits sewerage and landfilling of California Hazardous drugs

Segregate into appropriate non-RCRA Pharmaceutical Waste container

Label "Incinerate Only"

Dispose at a regulated medical waste incinerator in accordance with the Medical Waste Management Act



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Managing Controlled Substance Waste

Conflicting messages from DPH, DEA

San Diego County working with agencies to determine best compromise

Possible scenario:

Small amounts of CS e.g. 2 ccs in a syringe: sewer with written permission from local POTW

Larger amounts of CS e.g. 100 cc morphine drip: return to Pharmacy Dept. for reverse distribution

Need consensus from both DPH and DEA



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Management Recommendations For Pharmaceutical Waste

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	Biohazardous & Trace Chemo	RMW Incineration
RCRA Toxic/ Ignitable Hazardous Rx	Black	RCRA & BMP Hazardous Rx	RCRA TSDF
Cal-hazardous Rx	White/Blue	Cal-hazardous Rx	RMW Incineration



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Containment

Traditional Chemo Waste Containers

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



Hazardous Waste Containers

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



Cal-Hazardous Waste Containers

Cal-Hazardous pharmaceuticals



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How Do I Begin?

- Identify which drugs will become hazardous waste
- Determine which implementation model to use
- Pilot your labeling/segregation program in the pharmacy and oncology units
- Develop & implement full house roll-out
- Get PharmE Certified!



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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



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How Should RCRA Hazardous Waste be Handled?

Need a new waste stream in Pharmacy, Patient Care Areas, Oncology Clinics

RCRA Hazardous Waste: Toxic
P, U, toxic Ds, (all Chemotherapy Residues, Chemo Spills)

RCRA Hazardous Waste: Ignitable (D001)

Hazardous waste vendor develops a waste profile that includes all possible waste codes



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How Should RCRA Hazardous Waste Be Disposed?

Either contract with a hazardous waste broker or develop internal expertise for:

- Waste profiling
- Manifest preparation
- Land ban preparation

Contract with a federally permitted RCRA hazardous waste incineration facility (TSDF: Treatment, Storage & Disposal Facility)



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Approaches to Pharmaceutical Waste Management

- Model 1: Automatic Sorting Device
EcoRex™ by Vestara Medical
- Model 2: Data Applied to Dispensing Software
- Model 3: Stickers Applied Manually
- Model 4: Centralizing Segregation
- Model 5: Managing All Drug Waste As Hazardous



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Labeling the Pharmacy Shelves

Avery Standard Shipping labels



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Label Alert: PYXIS

Medications dispensed by the PYXIS medication station

P, U, D, or HD a pop-up alert to properly dispose of the medication

Pyxis alert:

THIS DRUG IS A FEDERAL HAZARDOUS WASTE TYPE (specifies P, U, D)

DISPOSE >TRACE IN "BLACK" CONTAINER OR RETURN TO PHARMACY



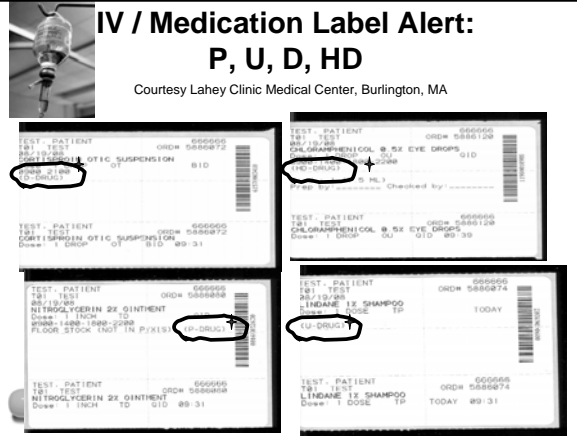
Courtesy Lahey Clinic Medical Center, Burlington, MA

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IV / Medication Label Alert: P, U, D, HD

Courtesy Lahey Clinic Medical Center, Burlington, MA



Labeling & Containers

Items identified by PharmE Inventory Analysis

- Marked with black labels
- "Special Disposal Required"
- Coded in Pyxis dispensing machine also

Black hazardous waste containers purchased from Covidien

SPECIAL DISPOSAL REQUIRED

Courtesy North Memorial Health Care



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NEW Hazardous Waste Containers

YELLOW "Soft" Hamper
Trace/Soft Chemo/Bio

- > Gowns, Gloves, Cloak and soiled linens, (ONLY)



YELLOW HARD CONTAINER
Trace / Sharps

- > EMPTY Syringes or Sharps
- > TRACE amounts of Chemo / Biotherapy ONLY Empty syringes, IV bags, tubing



P, U, D, HD, BLACK CONTAINER
> BULK (Larger than TRACE) amounts of Chemo / Bio





- > Chemo-Spill products



Courtesy Lahey Clinic Medical Center, Burlington, MA



Example: "D" Type Hazard Insulin Containing M-Cresol

- A used syringe of this type of insulin → 
- An empty insulin vial → 
- A half empty insulin vial → 
- An outdated insulin vial → 



Courtesy Lahey Clinic Medical Center, Burlington, MA



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



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Documenting Generator Status

Large quantity generator: no need to record P waste separately.

Small or conditionally exempt small quantity generator: 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



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Creating a Hazardous Waste Profile

Work with hazardous vendors to create a certified hazardous waste profile of all toxic & ignitable drug waste, including ignitable aerosols

Ship commingled as UN3248, Waste Medicine, Liquid, Flammable, Toxic, n.o.s., 3 (6.1), PG II

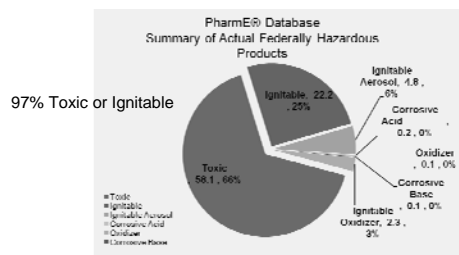
Ship any corrosive acids/bases or oxidizers separately



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Percentage of Hazard Categories in 149 Hospitals (2008)



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Hazardous Pharmaceutical Waste Storage Accumulation



Cal-Hazardous Pharmaceutical Waste

Managed through
medical waste
incineration under the
Medical Waste
Management Act



Courtesy North Memorial Health Care



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Examples of Cal-Hazardous Pharmaceutical Waste Collection & Storage



Final Steps

Staff cooperation and participation will be required
for successful program implementation

Remaining steps include:

- Pilot your labeling/segregation program in the pharmacy and selected nursing units
- Modify the program as necessary
- Finalize policies and initiate system-wide implementation



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PharmE[®] Certification Process*

Review of customized policies and procedures for
compliance

Site visit to ascertain that policies and
procedures have been implemented

Upon completion, notification sent to EPA Region
and respective state environmental protection
agency

Press release assistance for local coverage

*Prerequisite: PharmE Inventory Analysis



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First PharmE Certification: Northern Michigan Regional Hospital



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Resources

Bay Area Pollution Prevention Group

Cal Blueprint on Pharmaceutical Waste Management

<http://www.bacwa.org/LinkClick.aspx?fileticket=dLJpQLP5n%3d&tabid=71&mid=415>

NIOSH Hazardous Drug Alert

<http://www.cdc.gov/niosh/docs/2004-165/#sum>

ASHP Guidance on Handling Hazardous Drugs

<http://www.ashp.org/Import/PRACTICEANDPOLICY/PolicyPositionsGuidelinesBestPractices/BrowsebyDocumentType/GuidelinesMain.aspx>

OSHA Technical Manual

http://www.osha.gov/dts/osta/otm/vi/otm_vi_2.html

Practice GreenHealth (formerly Hospitals for a Healthy Environment)

<http://www.practicegreenhealth.org/>

Pharmaceutical waste webpage: <http://www.h2e-online.org/hazmat/pharma.html>

Healthcare Education Resource Center (HERC)

Blueprint on Pharmaceutical Waste Management (Revised)

<http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

WMHS PharmEcology Services

www.pharmacology.com

FAQs, state and federal waste regulations, PharmE[®] Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria



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QUESTIONS?

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