



Navigating Pharmaceutical Waste Management in Medical Facilities

Bay Area Pollution Prevention Group

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Goals for Today's Seminar

- To develop a better understanding of the regulatory and environmental reasons for managing pharmaceutical waste more stringently
- To understand how to comply with the federal Resource Conservation and Recovery Act (RCRA) as it applies to pharmaceutical waste
- To understand how to comply with California-hazardous pharmaceutical waste regulations under the Dept. of Health Services (DHS)
- To explore models for implementation of a pharmaceutical waste management program





Increasing Focus on Pharmaceutical Waste

- "Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health."
 - Dr. Christian Daughton, Chief, Environmental Chemistry Branch, USEPA National Exposure Research Laboratory
 - <http://www.h2e-online.org/tools/chem-pharm.htm>
- Warning: Side Effects Can Be Severe, Common drugs are seeping into our lakes, fish, and water supply. May 5, 2005 Milwaukee Journal/Sentinel
- Pharmaceuticals in Waterways Raise Concern: Effect on Wildlife, Humans Questioned. Washington Post, July 23, 2005



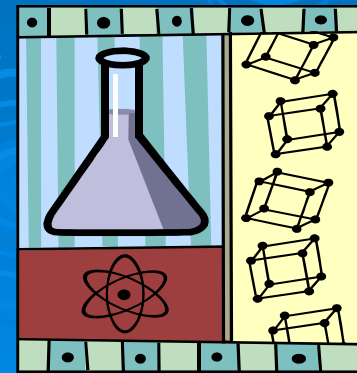
USGS Water Quality Study*

- First nationwide reconnaissance of occurrence of pharmaceuticals, hormones, other organic wastewater contaminants – March, 2002
- 139 streams in 30 states, analyzed for 95 different OWCs
- 82 of the 95 detected in at least one sample
- One or more OWCs found in 80% of stream samples
- 13% of sites had more than 20 OWCs
- Feature in Time Magazine, August 25, 2003 on continuing research
- Minnesota Study: Found 79 out of 92; 23 were pharmaceuticals

*<http://toxics.usgs.gov/pubs/OFR-02-94/index.html>

Below the Dose/Response Curve: Endocrine Disruptors

- Endocrine Disruptors: chemicals that interfere with the normal function of the endocrine system (glands including thyroid, adrenals, ovaries, testicles)
- Mimic hormone, trigger identical response, block a hormone
- Do not follow the normal dose/response curve
- Active at much lower doses, especially in the fetus and newborn
- Estradiols, progesterone, testosterone
- Lindane





Playing in an Ecosystem Near You

- Low sperm counts(50% reduction since 1939)
- Infertility
- Genital deformities
- Hormonally triggered human cancers
- Neurological disorders in children
 - Hyperactivity, attention deficit
 - Lowered IQ, rage reaction
- Developmental & reproductive problems in wildlife
- www.ourstolenfuture.org

Effects of Pharmaceuticals on Aquatic Organisms

- Drugs tested
 - Clofibric acid and naproxen sodium at 1000 nanograms/l (1 ppb) and 100 nanograms/l
- Test was to have been run for one week
- Had to terminate after 24 hours
- Clofibric acid induced milky, mucous response, difficulty with respiration, severe motility inhibition
- Naproxen effected behavior (slower), not as dramatic
- Also examined gene expression

Courtesy of Rebecca Klaper, Great Lakes WATER Institute



Impact on Exposure to Multiple Drugs on Daphnia

- Daphnia – the lab animal for water research
- Test involved clofibric acid, fluoxetine, erythromycin, triclosan, and trimethoprim
- Reproduction was disrupted to varying degrees indicating stress on organisms
- Most dramatic effect: significant increase in mortality in combo solutions

Colleen M. Flaherty, Stanley I Dodson. Effects of pharmaceuticals on Daphnia survival, growth, and reproduction. *Chemosphere*, In press, 2005.



Are We in Trouble.....Or Not???

- In the absence of definitive data, the argument has been made that the presence of EDCs, (including but not limited to drugs), and other drugs, many of which are not EDCs but include antibiotics, anti-cholesterol products, psychoactives, etc. is not an issue.
- In the absence of definitive data, others promote the Precautionary Principle





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

Hospitals for a Healthy Environment

2004 Champion for Change Award

- Enhanced focus on hazardous waste and pharmaceutical waste
 - <http://www.h2e-online.org/tools/chem-hwm.htm>
 - <http://www.h2e-online.org/tools/chem-pharm.htm>
- EPA grant to H2E to develop a pharmaceutical waste management blueprint
- EPA grant to H2E to train JCAHO inspectors on environmental issues
- www.h2e-online.org



Working Together
to Create
Healthy
Communities!



- Healthcare Environmental Resource Center
- Funded by EPA Office of Enforcement and Compliance Assistance and H2E
- Launched in April, 2005
- Environmental Compliance and Improvement Guide
 - “To improve compliance with JCAHO Environment of Care Standards”
 - <http://www.hercenter.org/regsandstandards/jcahointro.html>
- Hazardous waste determination
 - <http://www.hercenter.org/hazmat/hazdeterm.html>



Increasing USEPA Regulatory Activity

- EPA Region 2 (NY, NJ, Puerto Rico, VI) contacted 480 hospitals in 2003; Rx waste included.
- Region 2 Website: <http://www.epa.gov/region02/healthcare/>
 - North Shore University Hospital, Manhasset, NY fined \$40,000 (July 2003)
 - <http://www.epa.gov/Region2/news/2003/03066.htm>
 - Nassau University Medical Center, East Meadow, NY fined \$279,900 (Oct. 2003)
 - <http://www.epa.gov/region2/news/2003/03127.htm>
 - Mountainside Hospital, Montclair, NJ fined \$64,349 (Nov. 2003)
 - <http://www.epa.gov/Region2/news/2003/03139.htm>
 - Memorial Sloan Kettering Cancer Center, New York , NY, fined \$214,420
 - <http://www.epa.gov/region02/news/2004/04008.htm>
- EPA Region 1 New England contacted 250 hospitals in April, 2004
- Website: <http://www.epa.gov/NE/pr/2004/apr/040407.html>
 - Enforcement initiative in New England

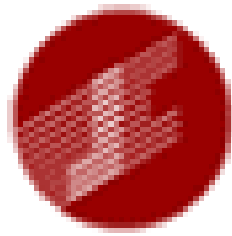
Region II Statement

“Hospitals and healthcare facilities must consider the proper handling of hazardous waste an integral part of their mandates to protect people's health,” said Jane M. Kenny, EPA Regional Administrator.

“Chemotherapy waste is an especially toxic waste produced by many medical facilities. Hazardous waste regulations are in place to help to ensure that facilities like Sloan-Kettering do not release these or other toxic chemicals into the environment.”

Increasing State Regulatory Activity

- **Florida**
- **Washington State**
- **California**
 - Resource Conservation & Recovery Act: Cal EPA Dept. of Toxic Substances
 - Medical Waste Management Act: Dept. of Health Services
 - <http://www.dhs.ca.gov/medicalwaste/>
 - Management of Pharmaceutical Medical Waste, October 15, 2002 DHS
 - Memo on sewer disposal of pharmaceutical waste, September 5, 2003 DHS
- **Minnesota**
 - Inspections began summer of 2004
 - Enforcement began July 1, 2005



Joint Commission

on Accreditation of Healthcare Organizations

New Initiatives at JCAHO

- Adding healthcare engineers to survey teams
- Beginning to ask questions about waste disposal
- H2E training JCAHO surveyors on environmental issues

Relationship to JCAHO Standards: Medication Management

➤ Standard MM.4.80

- *Medications returned to the pharmacy are appropriately managed.*

➤ Elements of Performance MM.4.80

- *3. The organization has a process in place that addresses how outside sources, if any, are used for destruction of medications.*

Relationship to JCAHO Standards: Environment of Care

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

[\[1\]](#) Hazardous materials (HAZMAT) and wastes. 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.)

Relationship to JCAHO Standards: Environment of Care

- **Rationale for EC.3.10**
- ***Organizations must identify materials they use that need special handling and implement processes to minimize the risks of their unsafe use and improper disposal.***

Relationship to JCAHO Standards: Environment of Care

- **Elements of Performance for EC.3.10**
- ***1. The organization develops and maintains a written management plan describing the processes it implements to effectively manage hazardous materials and wastes.***
- ***2. 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]).***

Relationship to JCAHO Standards: Environment of Care

- **Elements of Performance for EC.3.10**
- ***3. The organization establishes and implements processes for selecting, handling, storing, transporting, using, and disposing of hazardous materials and waste from receipt or generation through use and/or final disposal, including managing the following:***
 - ***Chemicals***
 - ***Chemotherapeutic materials***
 - **Radioactive materials**
 - **Infectious and regulated medical wastes, including sharps**
 - **See also 4. through 10**



NIOSH Hazardous Drug Alert

- National Institutes of Occupational Safety & Health
- Non-enforcement arm of OSHA, administered under Centers for Disease Control (CDC)
- Hazardous Drug Work Group met for 4 years
- Recently released comprehensive new guidelines for total life cycle management of OSHA “Hazardous Drug”
- Identifies “hazardous waste” and need for appropriate disposal
- <http://www.cdc.gov/niosh/topics/hazdrug/>

How is Pharmaceutical Waste Generated at the Healthcare Facility?

- IV Preparation
- General Compounding
- Spills/Breakage
- Partially Used Vials
- Partially Used Syringes/IVs
 - If Contaminated, Biohazardous
- Discontinued, Unused Preparations
- Unused Repacks (Unit Dose)
- Patients' Personal Medications
- Outdated Pharmaceuticals



Where is Pharmaceutical Waste Generated?

- Pharmacy/Satellites
- Patient Care Units
- ER/OR
- ICU/CCU/NICU
- Oncology/Hematology and other outpatient clinics
- Long Term Care Facilities
- Home Health Care Services



What Departments Get Involved in Generating and Managing Pharmaceutical Waste?

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



When is an Outdated Drug a Waste?

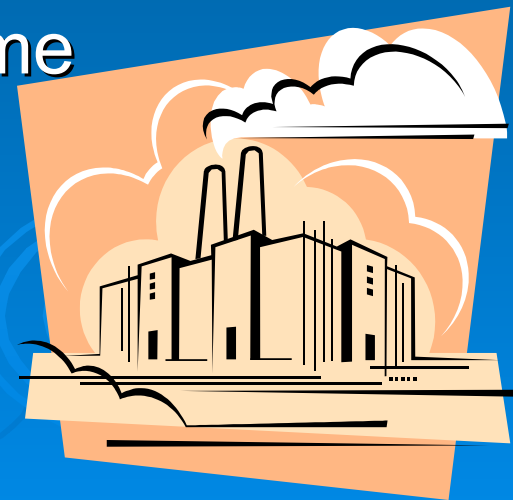
- At the time and place the decision is made to discard it
- Two EPA guidance letters to the industry:
 - Merck & Co., 1981
 - BFI Pharmaceutical, 1991
- Enables shipping of potentially creditable outdates to a reverse distributor as product
- PROHIBITS the shipping of waste-like items, such as unused IVs, partial vials, expired repacks, samples
- Hospital is liable for using due diligence in selecting a vendor



Everything You NEVER Wanted to Know About Incinerators.....

➤ Municipal Incinerator

- Permitted to burn municipal “garbage”
- Usually not permitted to handle infectious waste
- May be permitted to handle non-hazardous pharmaceuticals, with certain volume restrictions



Regulated Medical (Infectious) Waste Incinerators

- 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
- Regulated under the Clean Air Act
- Lower temperature, less controls than TSDF
- Ash disposed of in a municipal (non-hazardous) landfill; may or may not be lined

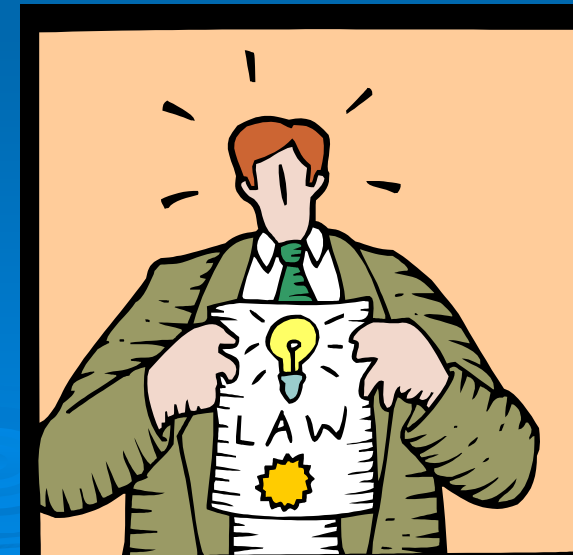
Hazardous Waste Incinerators

- Permitted by USEPA, known as a Treatment, Storage and Disposal Facility (TSDF)
- High temperature, molecular bonds broken
- Pollutants scrubbed, emits only water vapor, ash stored in a lined, hazardous waste landfill
- Authorized to accept the “worst of the worst” hazardous chemicals, shipped on a 5-part manifest
- Examples:
 - Clean Harbors/Safety Kleen
 - Heritage
 - Onyx
 - Teris



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
- Households are exempt



RCRA Risk Management & Liability

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



Which Discarded Drugs Become Hazardous Waste?

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



Chemotherapy Waste

- 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

Examples of P-Listed Pharmaceutical Waste

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

*Excluded from the P list federally and in California

Examples of P-Listed Pharmaceuticals

**CLEAR
NICODERM[®]
CQ[®]**
NICOTINE TRANSDERMAL SYSTEM
14 mg DELIVERED OVER 24 HOURS
STOP SMOKING AID

DO NOT OPEN POUCH UNTIL READY TO USE.
Apply every 24 hours on skin that is dry, clean
and free of lotions, oils, or creams. See
User's Guide for detailed instructions.
Keep out of reach of children and pets. Used patches have
adhesive residue. If swallowed, get
contact a Poison Control Center right away.
Fold patches by folding sticky ends together and
place in this box.
Do not use if pouch is open or torn.
Store at controlled room temperature
(20° - 25°C / 68° - 77°F)
Mylan Company
94043

5005826
5005826

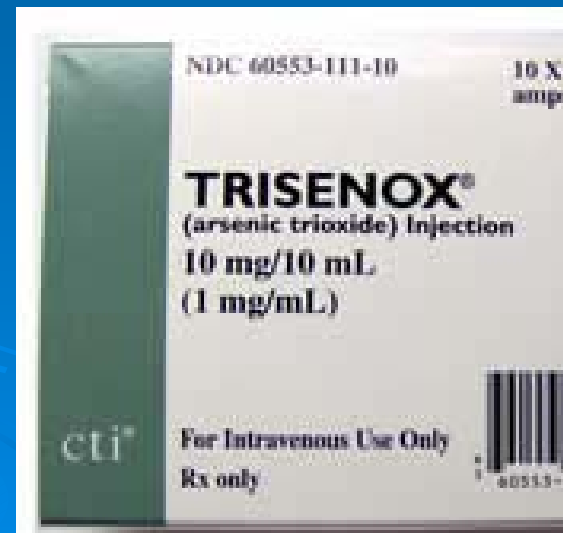


MYLAN[®]

NDC 0378-9112-16

**NITROGLYCERIN
TRANSDERMAL SYSTEM**

0.4 mg/hr (16 cm²)



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 | | |

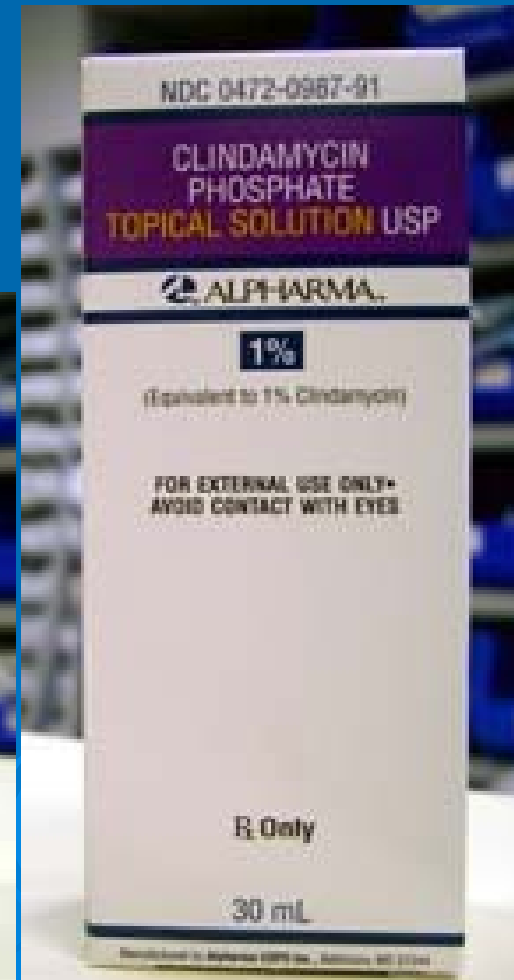
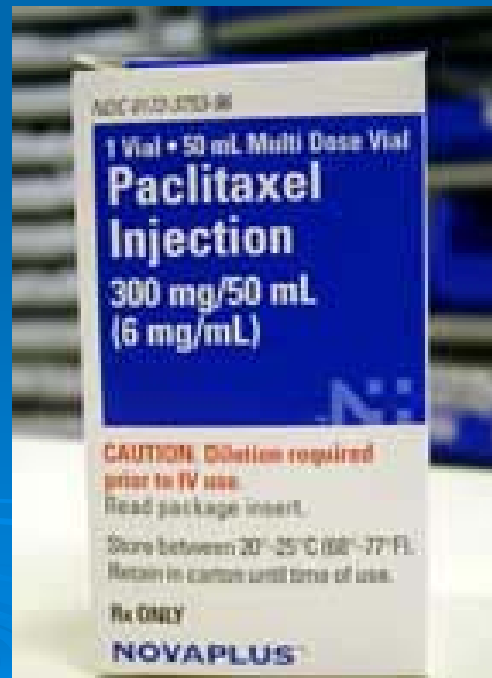
Examples of U-Listed Pharmaceuticals





Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point <math><140^{\circ}\text{F}</math>.
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparation
- Injections





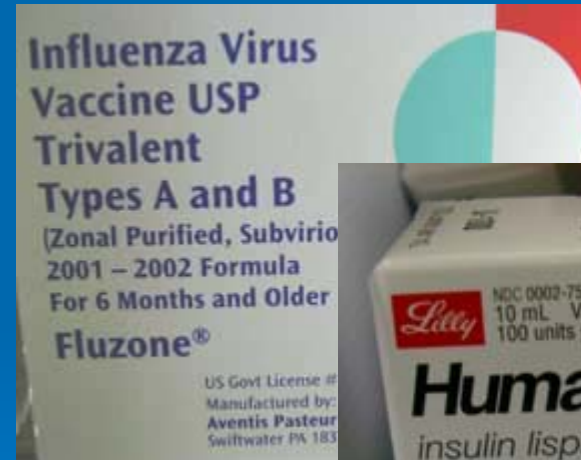
Characteristic of Corrosivity

- 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

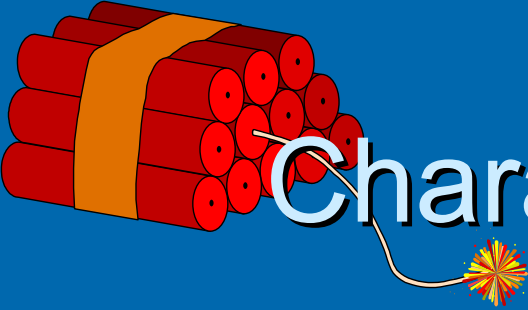
Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity



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 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.
- Cal EPA regulations contain similar language, so that medicinal nitroglycerin waste is not RCRA. Still must be evaluated for ignitability.
- Hazardous Waste Number for reactives: D003



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 $= 1$ kg P listed waste/month

Impact of P-listed Waste

- Only 1 kg or 2.2 pounds/month cause facility to become a large quantity generator
- Weights of P-listed drug waste must be combined with any other P-listed waste generated at the facility in a given month
- Technically, containers that have held P-listed wastes are not “RCRA empty” unless they are triple rinsed and the rinsate discarded as hazardous
 - Exception: EPA Hotline guidance and MPCA guidance exempts epinephrine syringe that has been injected into a patient and is therefore infectious waste; recently expanded to all P and U listed drugs in used syringes

Documenting Generator Status

- Large quantity generator: no need to record P waste separately.
- Small or very 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

California-Only Hazardous Waste: Catch 22

- 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



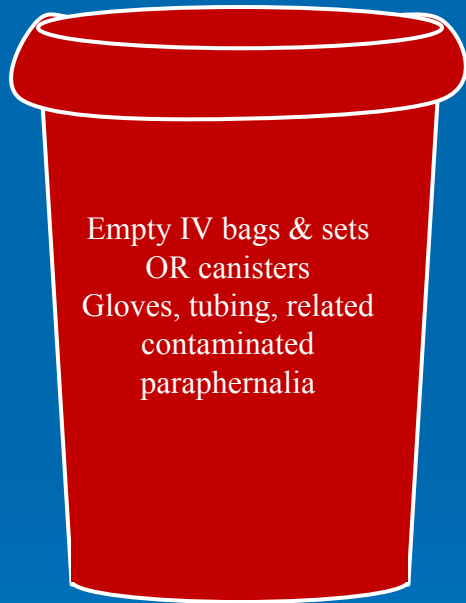


Hospital Waste Management: A World Unto Itself

- Red-bag, red sharps: infectious, blood borne
- Yellow or White sharps: trace chemotherapy vials
- Yellow or White bags: trace chemotherapy gowns, gloves, goggles, tubing, etc.
- Black or Dark Blue Sharps: RCRA Hazardous waste: chemicals (pharmaceuticals) defined as hazardous by USEPA
- White Sharps with Blue Top: Cal-Hazardous pharmaceutical waste
- Drain: D5W, Lactated Ringers, Sodium Chloride, electrolytes, vitamins (not necessarily minerals)



Red Bag Waste



Regulation: Blood Borne Pathogens Act,
Medical Waste Management Act

Acronym: RMW: Regulated Medical Waste

Contents: Pourable, squeezable, flakable,
drippable, blood, body fluids
(state specific)

Treatment: Primarily autoclave, microwave

Purpose: Render materials non-infectious,
non-recognizable (most states)

Final Disposition: Non-hazardous landfill

Red Sharps Waste



Regulation: Blood Borne Pathogens Act,
Medical Waste Management Act

Acronym: RMW: Regulated Medical Waste

Contents: Pourable, squeezable, flakable
blood; Sharps – used/unused
(state specific)

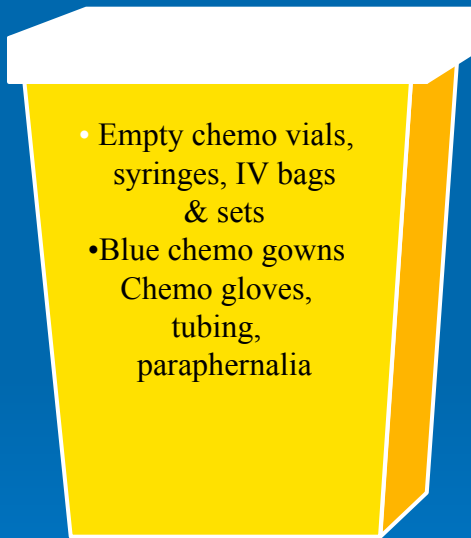
Treatment: Primarily autoclave, microwave

Purpose: Render materials non-infectious,
non-recognizable (most states)

Final Disposition: Non-hazardous landfill

Trace Chemotherapy Waste

Regulation: Medical Waste Management Act



Acronym: Trace Chemo

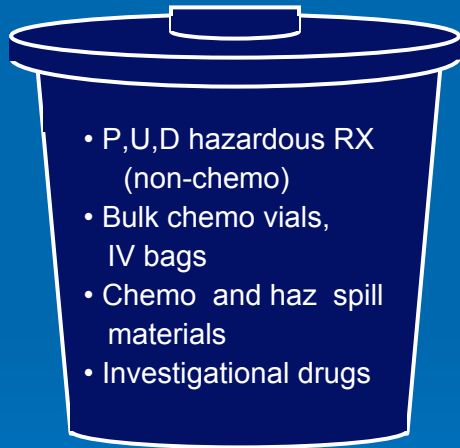
Contents: Trace contaminated chemo paraphernalia/RMW

Treatment: *Incineration at an RMW facility*

Purpose: Deactivation of chemo; disinfection

Final Disposition: *Non-hazardous landfill*

Hazardous Waste - Toxic



Regulation: Resource Conservation & Recovery Act

Acronym: RCRA

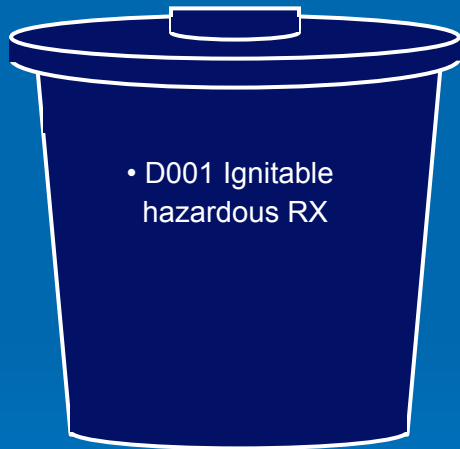
Contents: Toxic Hazardous Waste

Treatment: Incineration at a RCRA hazardous waste incinerator

Purpose: Destroy chemical compound entirely

Final Disposition: Lined hazardous waste landfill

Hazardous Waste - Ignitable



Regulation: Resource Conservation
& Recovery Act

Acronym: RCRA

Contents: Ignitable Hazardous Waste

Treatment: Incineration at a RCRA
hazardous waste incinerator

Purpose: Destroy chemical
compound entirely

Final
Disposition: Lined hazardous waste landfill

Traditional Chemo Waste Containers

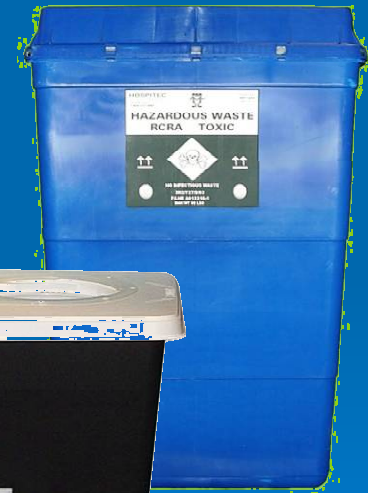


Empty vials,
syringes, IVs,
tubing, gowns,
gloves, etc.

New Hazardous Waste Containers

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

Hospitec



Kendall

Cal-Hazardous Rx Waste

Regulation: State specific

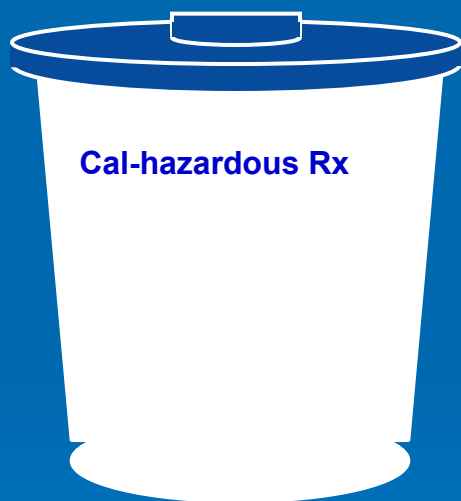
Acronym: Cal-hazardous Rx

Contents: All Rx not RCRA
except NaCl, D5W, vitamins, etc.

Treatment: Incineration at an RMW or
comparable facility

Purpose: Prevent drain disposal and
untreated landfilling

Final
Disposition: Non-hazardous landfill

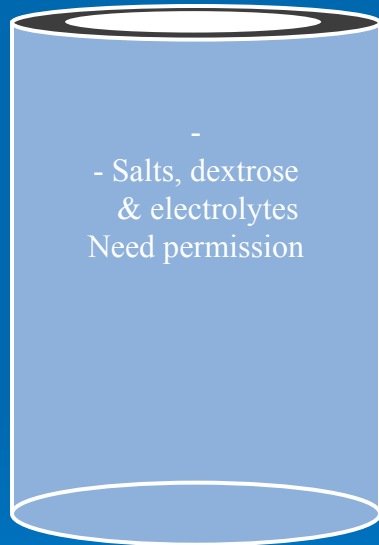


How should CAL-ONLY and non-hazardous drugs be stored and disposed?

- Segregate into a non-red, non-yellow container, such as beige or white with blue top (California Pharmaceutical Waste)
- Label “Incinerate Only”
- Dispose at a regulated medical waste incinerator that is permitted to accept non-hazardous pharmaceutical waste



Sewer System



Regulation: Local publicly owned treatment works

Acronym: POTW

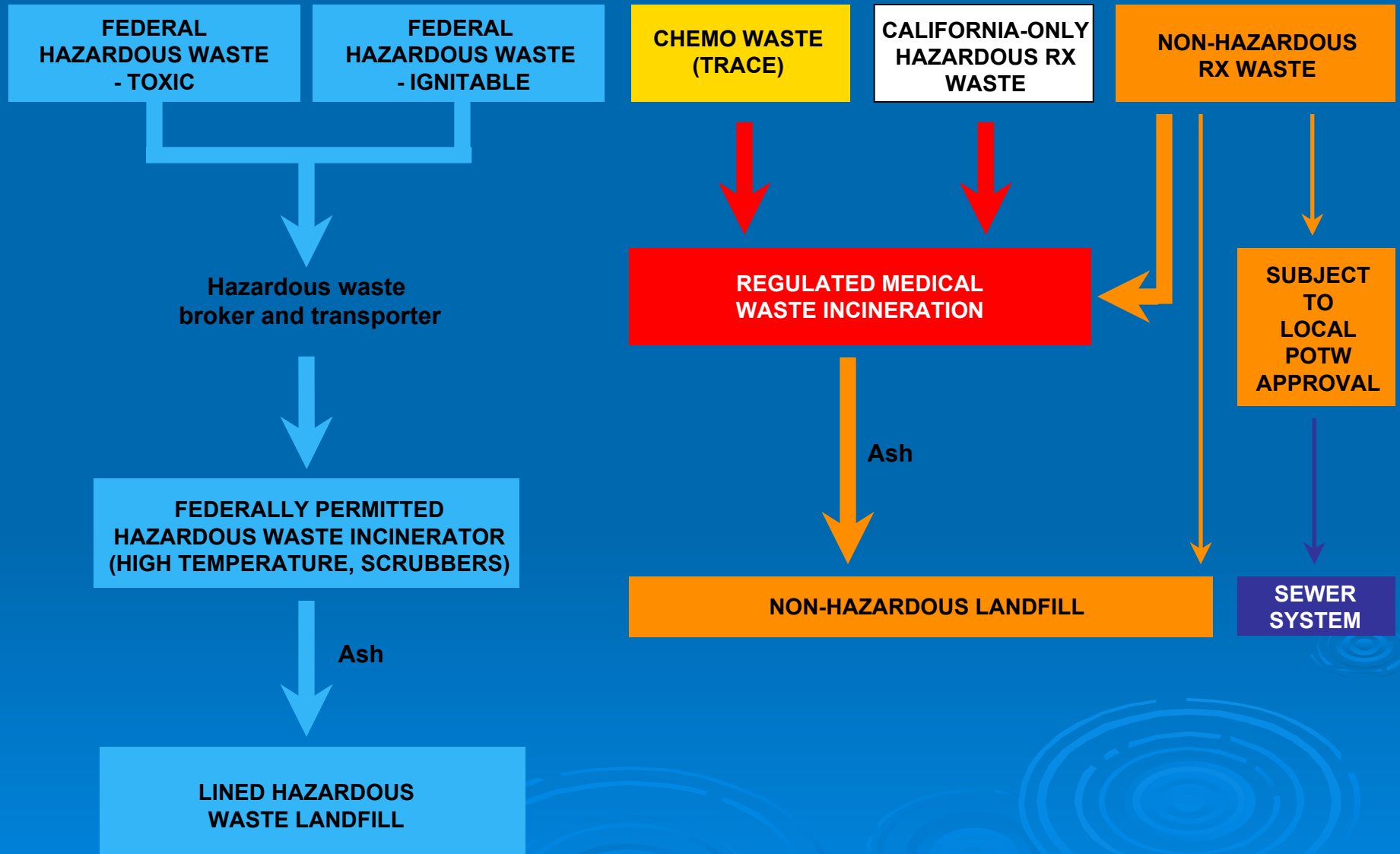
Contents: Unused innocuous IVs,
controlled substances???

Treatment: Various sewage treatment methods

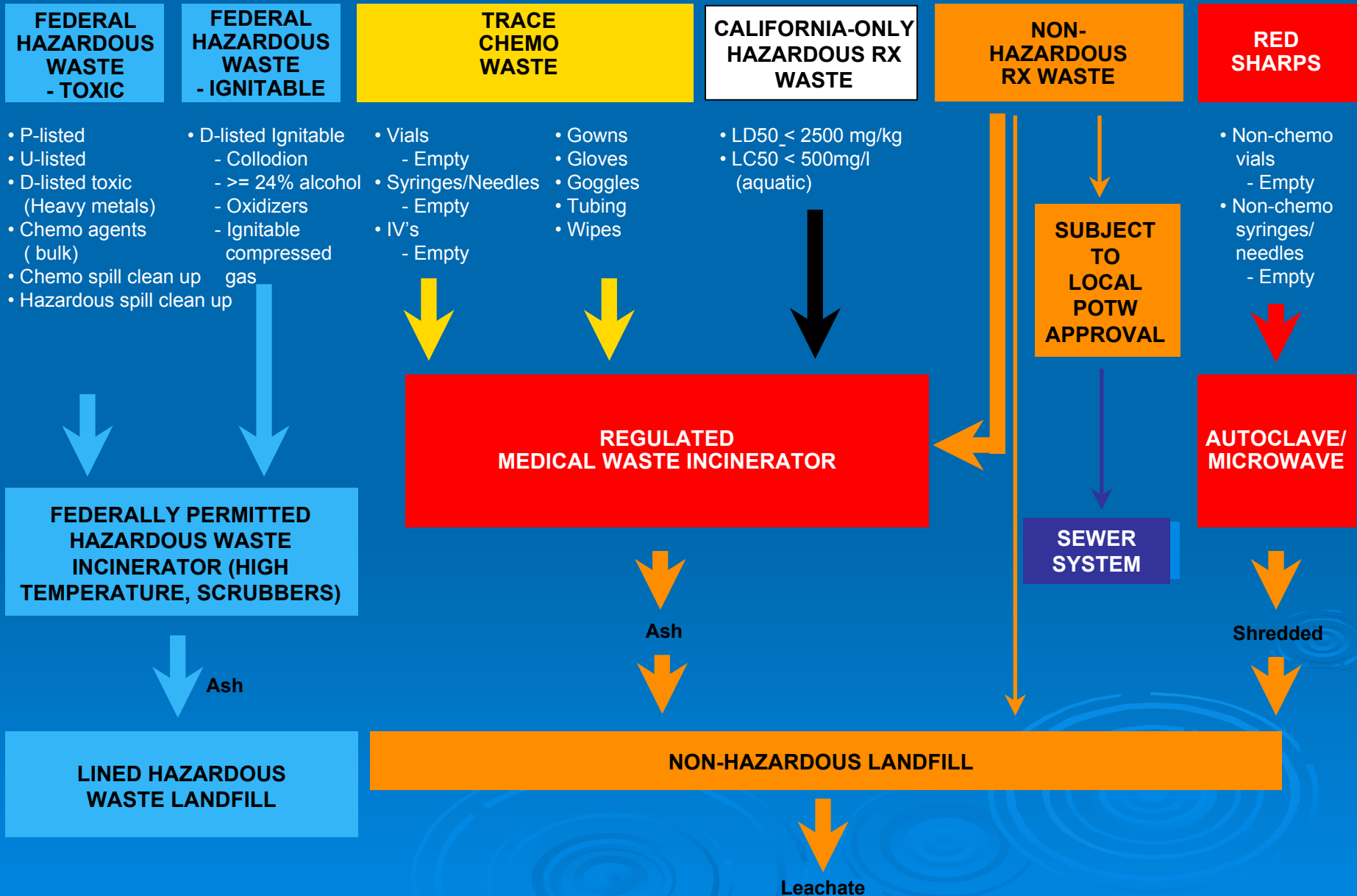
Purpose: Remove sediments, inactivate bacteria

Final Disposition: Surface water, ground water,
land disposal (sludge)

California Pharmaceutical Waste Categories



Recommended California Pharmaceutical Waste Streams



Managing Specialty Wastes

- **Controlled substances:**
 - Can be shipped to a reverse distributor as a transfer between registrants
 - May be able to sewer if permission received in writing from the local POTW
 - Small amounts often squirted into red sharps, etc.
- **Mixed wastes:**
 - Clean Harbors can accept mixed hazardous and infectious waste

How Should RCRA Hazardous Waste be Handled?

- Need a new waste stream in Pharmacy, certain Patient Care Areas, Oncology Clinics
- RCRA Hazardous Waste: Toxic
 - P, U, toxic Ds, MN01 (all Chemotherapy Residues, Chemo Spills)
- RCRA Hazardous Waste: Ignitable (D001)
- Can also use hazardous waste buckets available from brokers and disposal firms

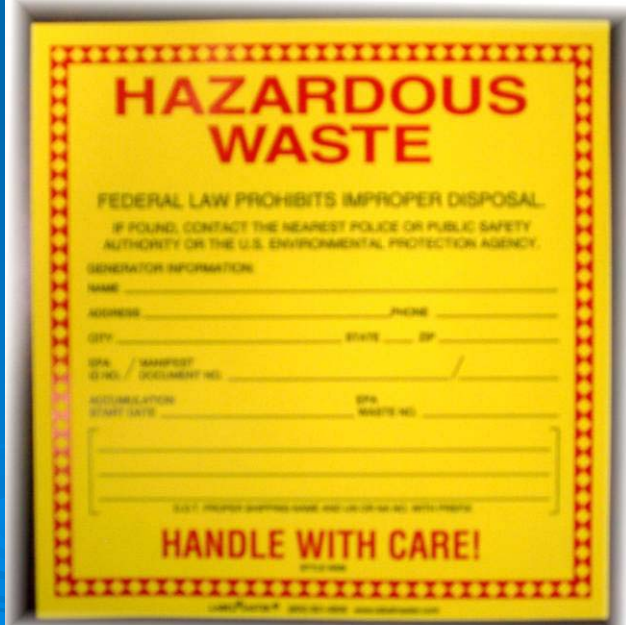
Satellite Accumulation

- Segregated, labeled and contained in areas where it is generated
- Available in all units in which hazardous waste is generated
- 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 three days after these quantities are reached

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 or 180 days based on generator status



HAZARDOUS WASTE

FEDERAL LAW PROHIBITS IMPROPER DISPOSAL.
IF FOUND, CONTACT THE NEAREST POLICE OR PUBLIC SAFETY
AUTHORITY OR THE U.S. ENVIRONMENTAL PROTECTION AGENCY.

GENERATOR INFORMATION

NAME _____ PHONE _____

ADDRESS _____

CITY _____ STATE _____ ZIP _____

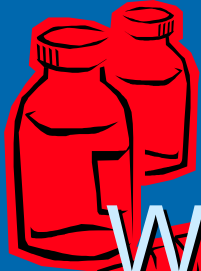
EPA ID NO. / MANIFEST DOCUMENT NO. _____

ACCUMULATION START DATE _____ EPA WASTE NO. _____

HANDLE WITH CARE!

How Should RCRA Hazardous Waste Be Disposed?

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



How Can Hazardous RX Waste Generation Be Minimized?

- Inherent limitations on substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect
- Tighter inventory control to reduce outdate generation, both original manufacturers' containers and repacks
- Pre-labeling of multi-dose items such as ointments, inhalers, as take-home meds
- Single dose vials vs. multiple dose vials
- Patient specific oral syringes vs. 10 cc. repacks (e.g. choral hydrate for pediatric use)



Solutions to Help Identify & Manage Pharmaceutical Hazardous Waste

➤ PharmE™ Formulary Analysis

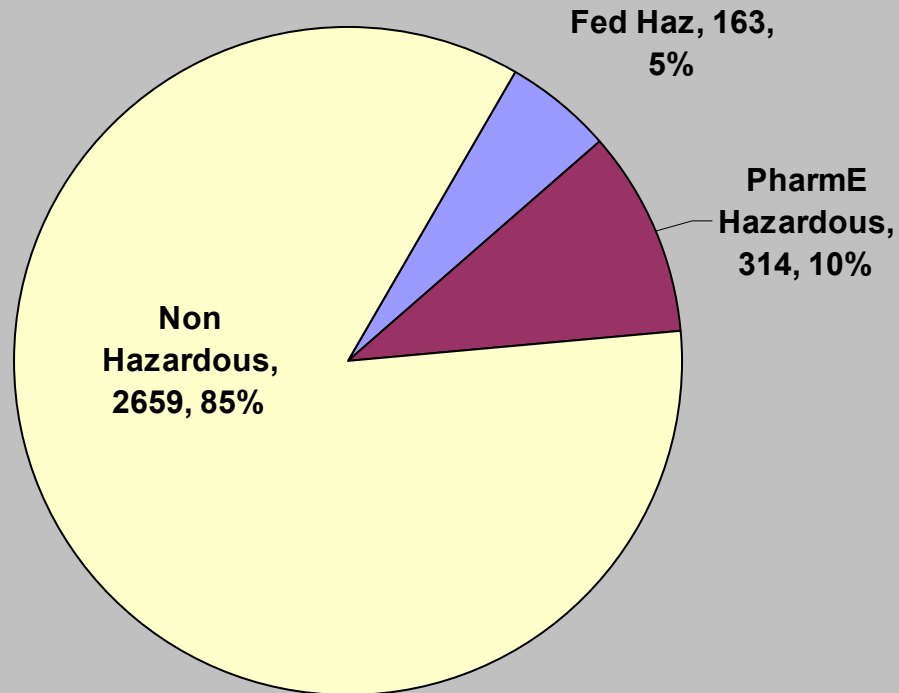
- A detailed analysis report of your formulary with complete pharmaceutical waste stream recommendations identifying all federally hazardous and PharmE Hazardous™ waste.

➤ PharmE™ Waste Wizard

- On-line subscription to over 130,000 items, updated with an average of 300 new items weekly; over 1,000 new hazardous items added in the past six months.

Memorial Hospital

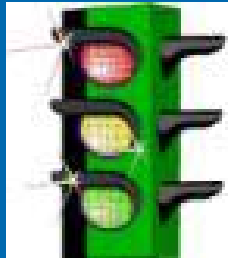
PharmE™ Formulary Analysis Summary of Results



Detailed Information by Therapeutic Category

		Fed Haz	PharmE Hazardous	Non Hazardous	Total
01	Anti_Infective Agents		30	274	304
17	Biologicals	4		29	33
21	Antineoplastic Agents	27	89	5	121
22	Endocrine and Metabolic Drugs	13	54	144	211
31	Cardiovascular Agents	29	2	340	371
41	Respiratory Agents	15	27	180	222
46	Gastrointestinal Agents	1		236	237
53	Genitourinary Products	1	12	29	42
57	Central Nervous System Drugs	10		239	249
64	Analgesics and Anesthetics	2	23	396	421
72	Neuromuscular Drugs		32	86	118
77	Nutritional Products	3	6	148	157
82	Hematological Agents	9	5	100	114
86	Topical Products	39	18	306	363
92	Miscellaneous Products	10	16	147	173
Total		163	314	2659	3136

Identifying Hazardous Pharmaceutical Waste Using the PharmE™ Waste Wizard



- **Federal Hazardous Waste**
- **PharmE Hazardous Waste**
- **California Hazardous Waste**

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A 2004 H2E "Champion for Change" Award Winner

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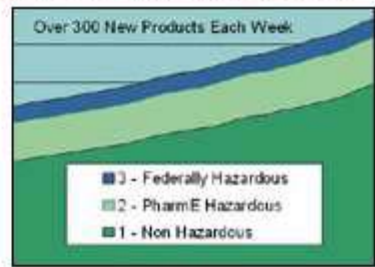
TOUR



*Establishing
**compliant and
cost-effective
procedures
to manage
pharmaceutical
waste.***

Pharm@™ Formulary Analysis
Get started by identifying your hazardous waste pharmaceuticals

Pharm@™ Waste Wizard
Keep up-to-date on-line with our weekly database updates



Pharm@™ On-Site Risk Assessment
Find out how your current pharmaceutical waste management practices can be improved

Pharm@™ Policies and Procedures
Use our EPA Resource Conservation and Recovery Act (RCRA) compliant templates to upgrade your policies and procedures.

[Forgot your Password?](#)

News Alert: PharmEcology[®] Announces a New Brand, a New Wizard, and New Waste Categories!



Welcome : James McCauley
PharmEcology Associates, LLC.
Brookfield,WI
Analysis for: WISCONSIN

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-  [How Does the Search Logic Work?](#)
-  [What Is "PharmE Hazardous™ Waste"?](#)
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Individual Product Search

Batch Product Search

PharmEcology Admin

Search By NDC Number

NEW SEARCH

NDC number:

(For example: 1234045610 or 1234-456-10 or 1234-456)

Search by Product Name

Product name:

Strength (optional):

Search by Generic Name or Active Ingredient

Generic name:

Manufacturer (optional):

Strength (optional):

*Hints

1. Enter a full or partial NDC number, with or without hyphens
2. Enter a full or partial product or generic name
3. Enter the beginning of the strength, ignoring the concentration or additional ingredients

SEARCH >>



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Individual Product Search Additional Information

Federal Hazardous Waste NEW SEARCH

Product:	00008-0263-01 EPINEPHRINE INJ 1MG/ML	1.00 ML Rx
Generic:	Epinephrine HCl	DEA: Non-Controlled
Manufacturer:	WYETH	

Recommended Waste Classification

**Regulated as federal hazardous waste:
 P042-Epinephrine**

Recommended Waste Stream

**Handle as hazardous waste:
 Toxic**

Highlights

- Federal Hazardous Waste
- PharmE Hazardous™ Waste
- Non-Hazardous Waste

- What Products are in the Database?
- How Does the Search Logic Work?
- What Is "PharmE Hazardous™ Waste"?
- Product Questions? Contact Us
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[Individual Product Search](#)
[Additional Information](#)
Federal Hazardous Waste
[NEW SEARCH](#)

Product:	00008-0263-01 EPINEPHRINE INJ 1MG/ML	1.00 ML Rx
Full name:	EPINEPHRINE HCL TUBEX	1.00 MG/ML
Reference:	eFACTS (Facts & Comparisons Online)	
Page:	Epinephrine	

EPINEPHRINE

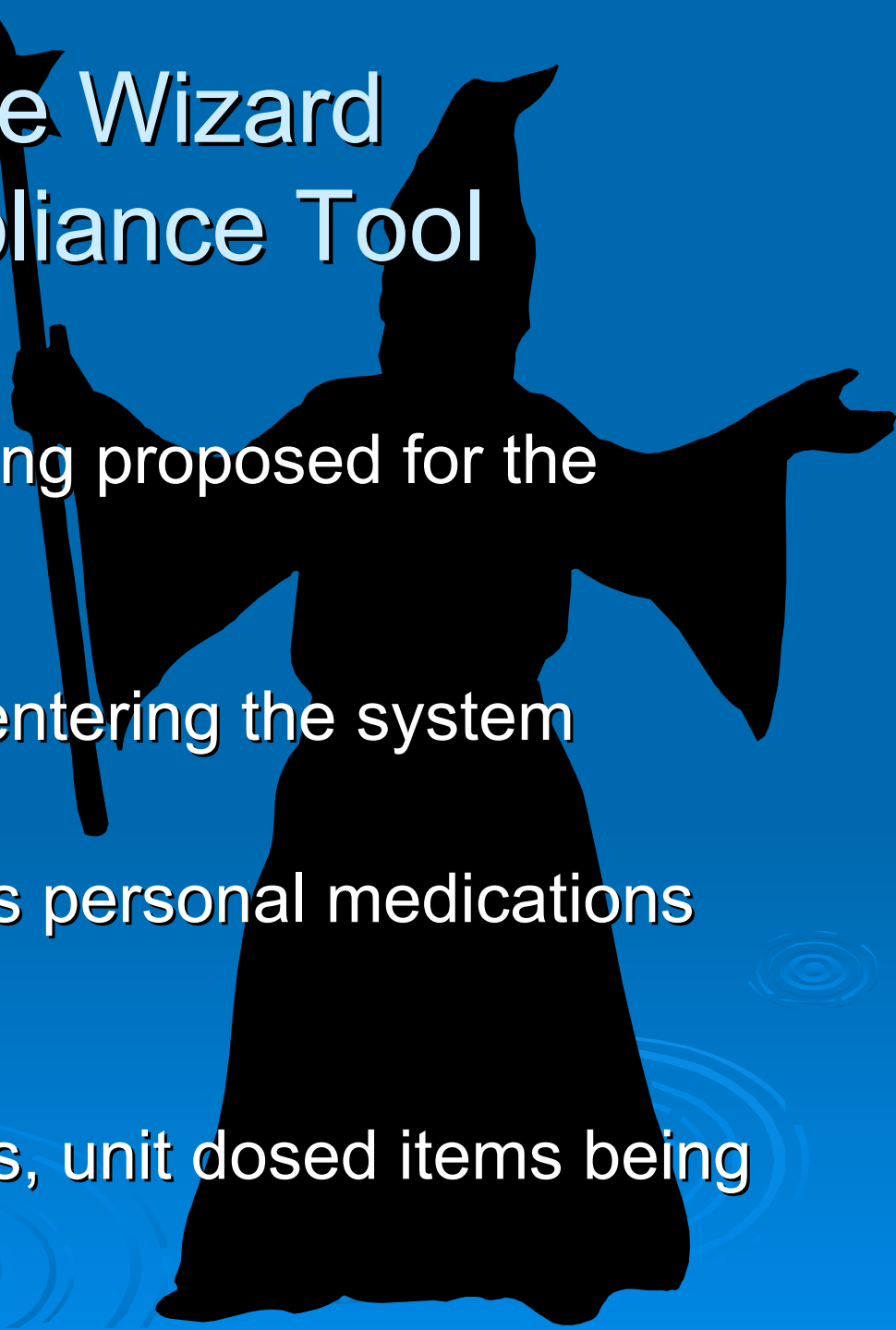
Epinephrine, is a P listed chemical, defined by USEPA as acutely hazardous waste when present as the sole active ingredient (P042).

Other than the exception noted below, all containers that have held P-listed waste must be managed as hazardous waste unless triple rinsed. If triple rinsed, all rinsate must also be treated as hazardous waste. The rinsed RCRA-empty container may then be disposed of as non-hazardous waste.

Based on a 1994 USEPA Hotline Report, epinephrine residue in a syringe used for administration is not regulated as a hazardous waste. The syringe is considered a "dispensing instrument", and, therefore, the contents were used for their intended purpose.

Using the Wizard as a Compliance Tool

- Evaluate new drugs being proposed for the formulary
- Categorize new drugs entering the system
- Categorize any patient's personal medications that need disposal
- Categorize any samples, unit dosed items being disposed



Goals of Rx Waste Management Review

- Assess the current situation
- Present Findings and Recommendations
- Develop an Action Plan
- Provide implementation assistance as needed
- Assist the organization to achieve cost-effective compliance with Cal EPA, DHS, and JCAHO/CMS



Benefits of a Comprehensive Hazardous Waste Disposal Plan

- JCAHO Environment of Care Performance Improvement Initiative
 - See both Medication Management and Environment of Care
- Reduces EPA, Cal EPA and DHS liability and risk exposure to a minimum
- Protects employees and patients
- Demonstrates responsible care in dealing with hazardous substances, hazardous wastes



Resources

- www.pharmacology.com
- Pharmaceutical Waste: <http://www.h2e-online.org/tools/chem-pharm.htm>
- Pharmaceuticals and Personal Care Products as Environmental Pollutants: <http://www.epa.gov/nerlesd1/chemistry/pharma/index.htm>
- Healthcare Environmental Resource Center: <http://www.hercenter.org/>
- A Guide on Hazardous Waste Management for Florida's Pharmacies, www.floridacenter.org.
- RCRA On-Line <http://www.epa.gov/rcraonline/>
- RCRA Hot Line 1-800-424-9346



Resources

- Pharmaceuticals and Personal Care Products as Environmental Pollutants:
<http://www.epa.gov/nerlesd1/chemistry/pharma/index.htm>
- Healthcare Environmental Resource Center:
<http://www.hercenter.org/>
- A Guide on Hazardous Waste Management for Florida's Pharmacies, www.floridacenter.org.



Specific Resources

- NIOSH Hazardous Drug Alert
 - <http://www.cdc.gov/niosh/topics/hazdrug/>
 - See Appendix A for a list of hazardous drugs
- PhaSeal™ closed transfer system
 - http://www.supergen.com/subpages/products/product_s.asp
- Hazardous Pharmaceutical Waste Containers
 - Hospitec: Christopher Hahn, (561) 833-2296, chris@hospitecinc.com
 - Kendall: Mike Liscio, (508) 261-8493, mike.liscio@tycohealthcare.com

General References

- www.pharmacology.com
- Pharmaceutical Waste: <http://www.h2e-online.org/tools/chem-pharm.htm>
- <http://www.pca.state.mn.us/industry/healthcare.html>
- RCRA On-Line <http://www.epa.gov/rcraonline/>
- RCRA Hot Line 1-800-424-9346
- Pharmaceuticals and Personal Care Products as Environmental Pollutants:
<http://www.epa.gov/nerlesd1/chemistry/pharma/index.htm>



