Pharmaceutical Waste Update and RCRA Review

Bay Area Pollution Prevention Group

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Agenda

- What's looming on the pharmaceutical waste horizon?
- What defines a hazardous pharmaceutical waste federally and in California?
- What new waste streams are needed?

AP Investigative Reports:
Drugs in Drinking Water & Healthcare Pharm Waste

- **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 AP inquiry into disposal practices by hospitals, long term care facilities, other healthcare organizations
  - Majority of 5,700 hospitals and 45,000 long-term care 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

Senate & House Hearings on Drugs in Water

- Senate Hearing
  - April 15th, 2008
  - Senators Barbara Boxer, Frank Lautenberg
  - Witnesses included:
    - Benjamin Grumbles, Assistant Administrator for Water, USEPA
    - Robert Hirsch, Ph. D. Associate Director for Water, USGS

- House Committee on Transportation and Infrastructure
  - Subcommittee on Water Resources and Environment
  - September 19th, 2008
  - Witnesses included:
    - Benjamin Grumbles, Assistant Administrator for Water, USEPA
    - Dr. Matthew Larsen, Associate Director for Water, USGS

Pending Legislation

- Drug Free Water Act of 2009
  - Introduced into the House by Michigan Rep. Candice Miller on January 7, 2009
  - Requires EPA to convene a Task Force regarding proper disposal of unused pharmaceuticals
- Safe Drug Disposal Act of 2009
  - Introduced into the House by Washington State Rep. Jay Inslee on February 25, 2009
  - 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

EPA's Clean Water Act Review Mandatory Survey

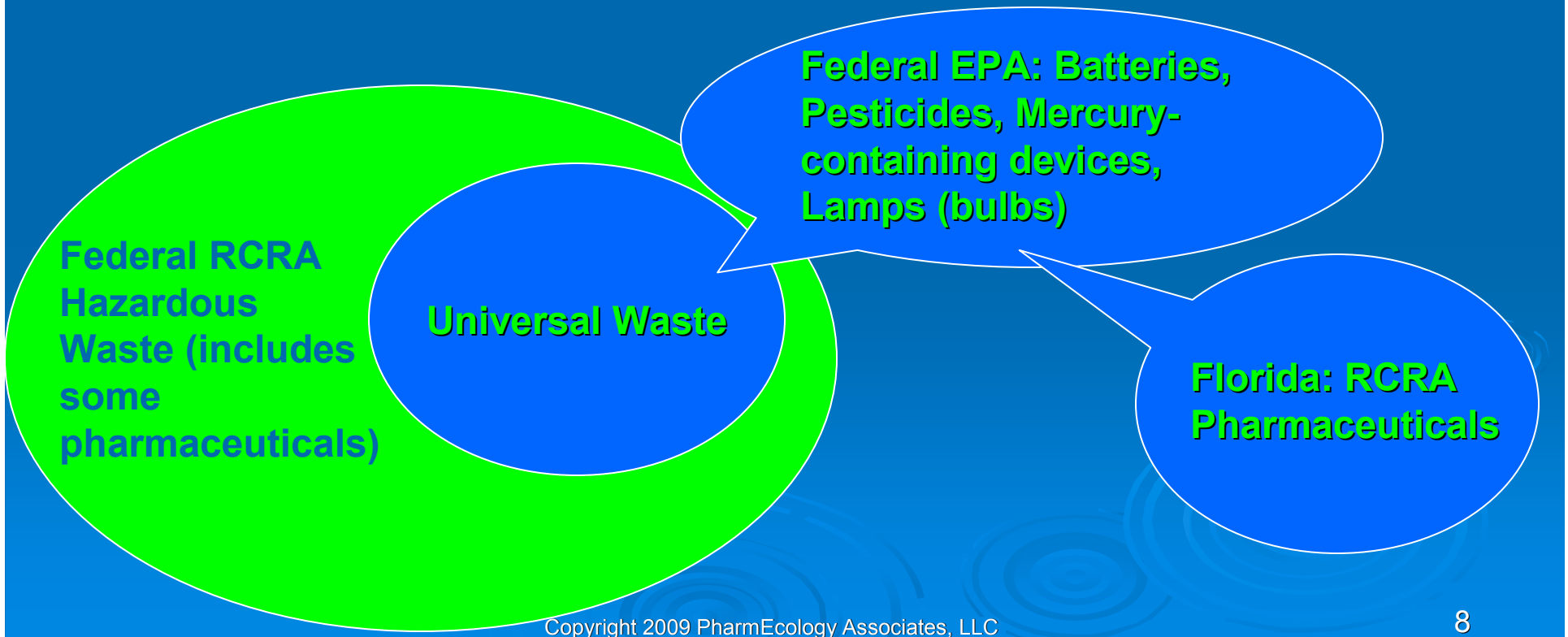
- **Mandatory survey for Unused Pharmaceuticals** Disposal in the Health Services Industry
  - All companies that receive questionnaire must respond within 60 days
  - Failure to respond may result in criminal fines, civil penalties, and other sanctions, as provided by law
  - May require documentation of disposed drugs for a 30 day period
- Potentially 3500 facilities will be sampled
  - Includes a sample of hospitals, long term care facilities, hospices, and veterinary practices
  - To be administered Sept-Nov of 2009
- http://www.epa.gov/fedrgstr/EPA-WATER/2008/August/Day-12/w18606.pdf
- http://www.epa.gov/guide/304m/
- www.epa.gov/ost/ppcp

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 18 months minimum for federal enactment; states may or may not adopt

RCRA and Universal Waste

"Universal Waste" is a subset of RCRA hazardous waste.



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.

General Goals of UWR

- To encourage resource conservation
- To improve implementation of current RCRA subtitle C hazardous waste regulatory program
- To separate UW from the municipal waste stream

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

What Makes Drug Waste Unique? Security Issues

- Legend Pharmaceuticals (Rx only) are deliberately restricted in their availability to the consumer AND within the supply chain due to their inherently “ dangerous” status regarding human use
- The street value of non-controlled substances continues to climb due to increased drug costs and shrinking personal resources
- Waste pharmaceuticals continue to have value, including empty vials of IV admixtures that can be used for introducing counterfeit drugs back into the supply chain

Unintended Consequences: No Chain of Custody

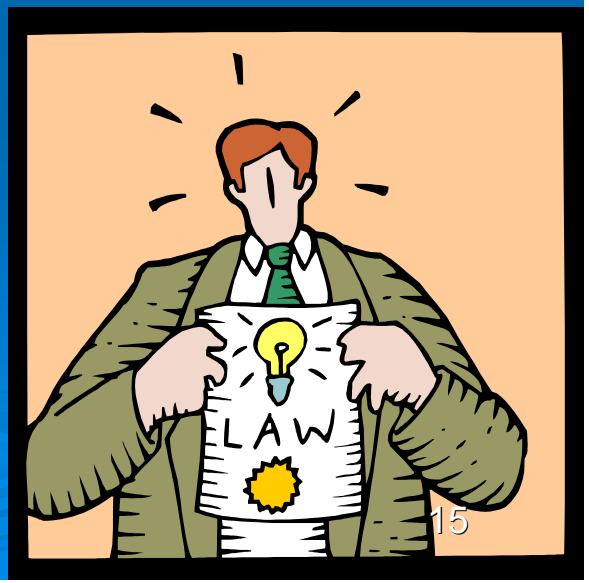
- Small Quantity Handlers would be completely unreported and unregulated by EPA or any other interested party
- Waste pharmaceuticals, and their packaging, could be re-introduced into the supply chain through secondary wholesalers or sold directly onto the black market or inappropriate disposal
- No chain of custody would assure appropriate destruction due to loss of the 6-part manifest

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

- NO:
  - It will take a MINIMUM of 18 months for a new rule to 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

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



Enforcement in California

- RCRA is enforced by USEPA Region 9 and by the California EPA Dept. of Toxic Substances Control (DTSC)
- California State Hazardous Waste is enforced by Dept. of Public Health (DPH) under the Medical Waste Management Act (MWMA)

EPA Just Took A Cost-of-Living Raise

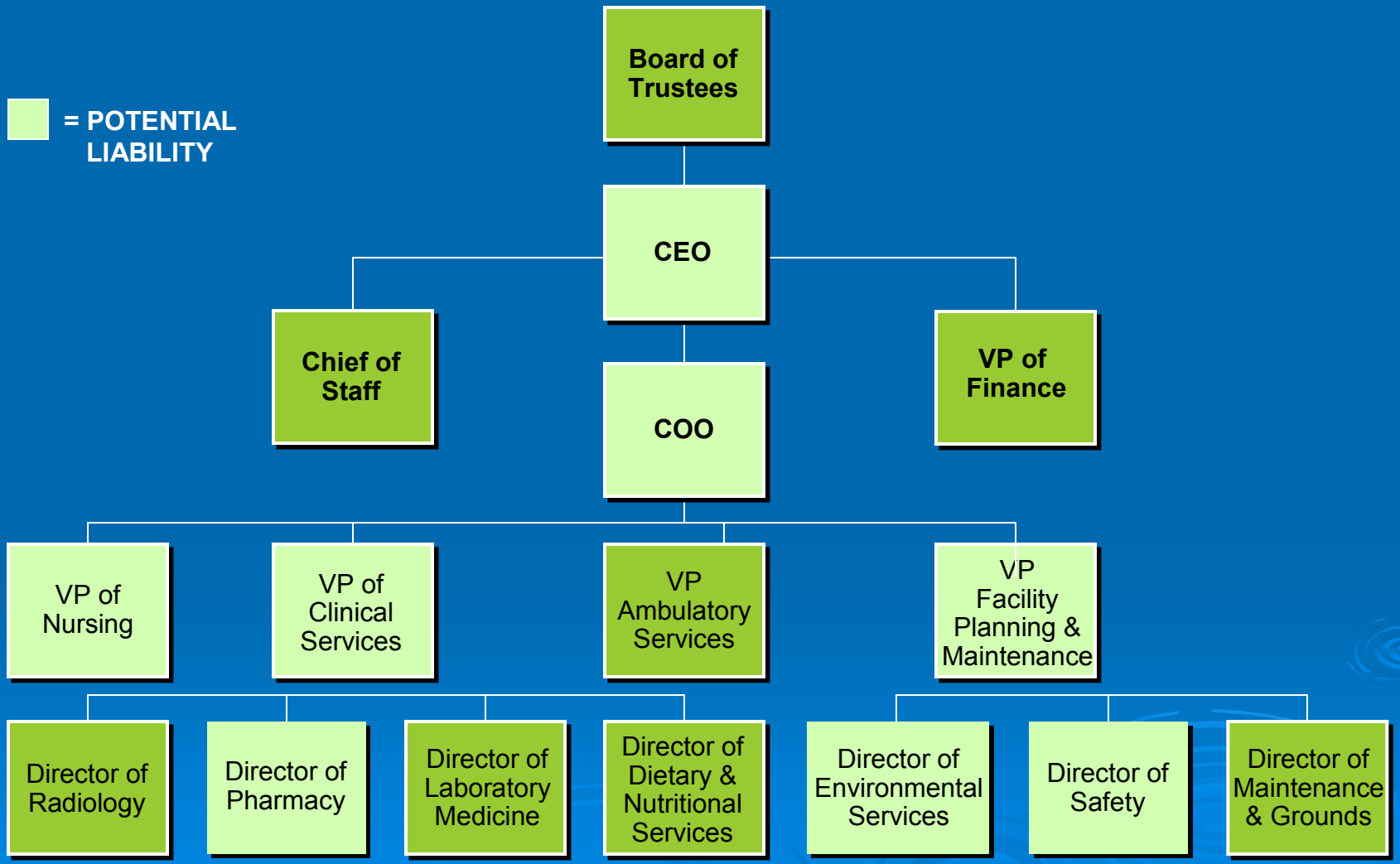
- Civil Monetary Penalty Inflation Adjustment Rule
  - Mandatory periodic increase in fines
- Authority to issue civil fines raised from $32,500 to $37,500 as of January 12, 2009
- Avoids “cost of doing business” violations
- http://www.epa.gov/fedrgstr/EPA-GENERAL/2009/January/Day-07/g31452.htm

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

Potential Liability for Rx Hazardous Waste Management



Applying Your Knowledge!

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

Which Discarded Drugs Become RCRA Hazardous Waste?

- P-listed chemicals
  - Sole active ingredient; unused, and empty containers
- 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. 15th, 2007; California agrees with this position.

** Excluded from the P list federally and in California.

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

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

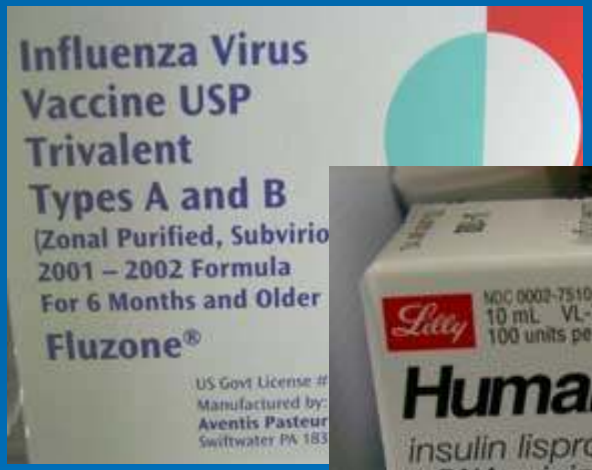
- An aqueous solution having a pH < or = 2 or > or = to 12.5
- Examples: Primarily compounding chemicals
  - Glacial Acetic Acid
  - Sodium Hydroxide
- Hazardous waste number: D002

Characteristic of Toxicity

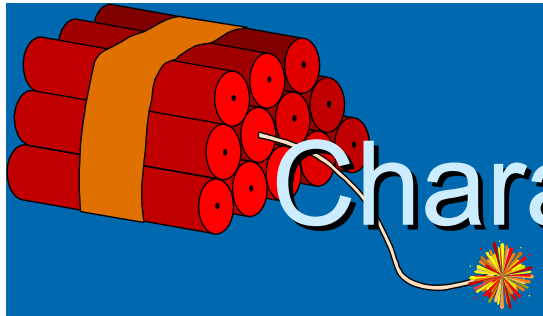
- 40 chemicals which must be below specific leaching concentrations
- Must pass the Toxicity Characteristic Leaching Procedure (TCLP)
- Must evaluate IVs, such as TPN – may come out of regulation due to dilution
- Examples of potential toxic pharmaceuticals:
  - Arsenic
  - Barium
  - Cadmium
  - Chromium
  - 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

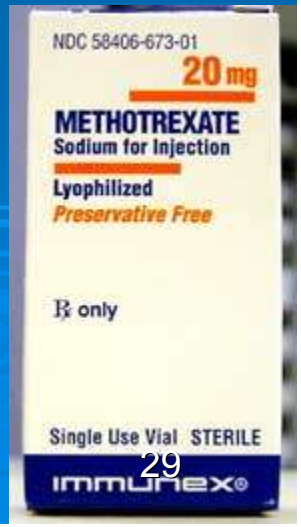


Characteristic of Reactivity

- 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.
- California had already excluded weak nitroglycerin. Waste must still be evaluated for ignitability.
- Hazardous Waste Number for reactives: D003

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)



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

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

- Epinephrine syringe exclusion expanded to other P and U-listed drugs federally by USEPA. California has accepted this exclusion.

PharmE Hazardous® Waste: Keeping Up with Drug Development

- **Drugs that are potentially hazardous to human health and the environment**
  - NIOSH Hazardous Drug Alert Appendix A
  - OSHA Technical Manual Section 6, Chapter 2, Appendix VI: 2 -1
  - The US Department of Health and Human Services National Toxicology Program's Report on Carcinogens (11th Edition)
  - Other chemotherapy agents not already listed as RCRA hazardous
  - Additional drugs meeting OSHA or NIOSH criteria
  - Drugs with LD50s at or below 50mg/kg
  - Endocrine disruptors

- **Identified as PharmE Hazardous in Inventory Analysis**
- **BMP recommendation is to segregate into RCRA toxic hazardous waste containers**

Trace 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

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

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

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

- DPH prohibits sewering 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

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
- Practice GreenHealth (fka Hospitals for a Healthy Environment)
  - http://www.practicegreenhealth.org/
  - Pharmaceutical waste webpage: http://www.h2e-online.org/hazmat/pharma.html
- Bay Area Pollution Prevention Group
  - Cal Blueprint on Pharmaceutical Waste Management
  - http://www.bacwa.org/LinkClick.aspx?fileticket=dLjPqQLP5nI%3d&tabid=71&mid=415
- 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
- Covidien
  - http://www.kendallsharpsafety.com/SharpSafety/pageBuilder.aspx?topicID=81045

QUESTIONS?

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