pharmecology Associates, LLC

Providing Environmental Consultation to the Healthcare Industry™

Managing Pharmaceutical Waste in Healthcare

NEWMOA Webcast

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Charlotte A. Smith, R. Ph., M.S.
President
csmith@ pharmecology.com
www.pharmecology.com
262-814-2635

Pharmaceutical Waste: A Waste Stream Whose Time has Come

- Research into water contamination
- Focus on hospitals
  - Hospitals for a Healthy Environment
  - CleanMed Conference
- Increasing USEPA Focus
  - Hazardous waste regulations
- Increasing State Regulatory Focus
- 2004 JCAHO Standards

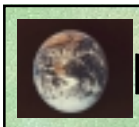
USGS Water Quality Study*

- 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
- Recent feature in Time Magazine, August 25, 2003 on continuing research

*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
- www.ourstolenfuture.org



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
  - Rage reaction
  - Lowered IQ
- Developmental & reproductive problems in wildlife

Hospitals for a Healthy Environment (H2E)

- 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
- Hazardous Chemical Minimization Document
- http://www.h2e-online.org/pubs/chemmin/pharmacy.pdf
- Tools for prioritizing hazardous pharmaceuticals
- http://www.h2e-online.org/pubs/chemmin/chappf.pdf

Hospitals for a Healthy Environment

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
- Intersecting regulatory agencies
  - EPA, DEA, OSHA, State Boards of Pharmacy

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."

Joint Commission on Accreditation of Healthcare Organizations

- Authorized by the Centers for Medicare and Medicaid Services (CMS)
- Conduct team surveys of hospitals
  - Previously every 3 years
  - Going to unannounced
- Type I violations very serious
- Loss of accreditation means loss of federal funding
- http://www.jcaho.org/

Relationship to 2004 JCAHO Standards: Environment of Care

- **Standard EC.3.10**
- ***The organization manages it 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 2004 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.***

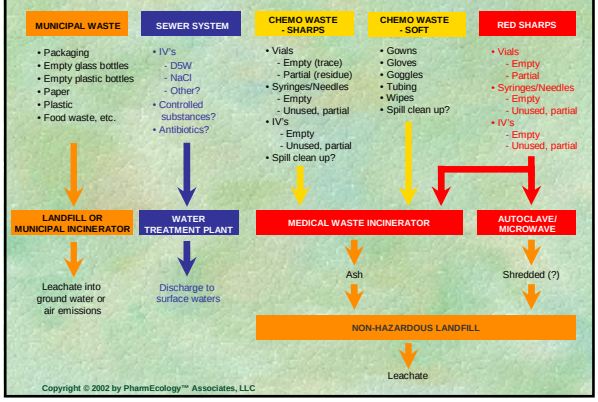
Relationship to 2004 JCAHO Standards: Environment of Care

- **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 2004 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

Contents of Current Pharmaceutical Waste Streams



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

Which Discarded Drugs Become Hazardous Waste under RCRA?

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

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

Examples of P-Listed Pharmaceuticals

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

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
Melphalan	U150	*Uracil Mustard*	U237
Mitomycin C	U010	Warfarin<0.3%	U248

Examples of U-Listed Pharmaceuticals

Chemotherapy Waste

- Seven 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
- "Empty" for U-listed waste means all contents removed that can be removed through normal means
  - 3 ml allowance in common practice is a misunderstanding of the definition of "RCRA empty"

Chemo Waste

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

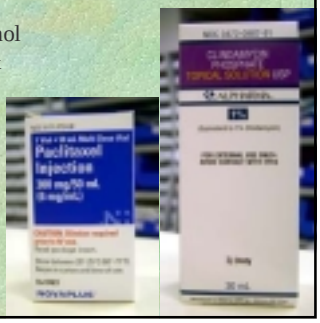
Hazardous Waste

Residue or bulk chemo in vials, unused IV's, P, U. toxic D

Christopher Hahn, Hospitec, (561) 833-2296, chris@hospitecinc.com

Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point<140° F.
- 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

Characteristic of Toxicity

- Approximately 40 chemicals which meet specific leaching concentrations
- Examples of potential toxic pharmaceuticals:
- Arsenic
- Barium
- Cadmium
- Chloroform
- Chromium
- Lindane
- m-Cresol
- Mercury (thimerosal)
- phenylmercuric acetate)
- Selenium
- Silver

Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- Nitroglycerin formulations are excluded federally from the P081 listing as non-reactive as of August 14, 2001 under FR: May 16, 2001.
- Some states have adopted the exclusion.
- Hazardous Waste Number: D003

How Can RCRA Hazardous Waste be Identified?

- The PharmEcology Wizard enables a search by product for waste management recommendations
- Over 113.000 items, updated with an average of 175 new items weekly; over 500 new hazardous items added in the past six months
- Search by NDC, product or generic name, active ingredient
  - Recommendations citing federal regulations and recommended waste streams
  - State regulation alerts if more stringent than federal
  - Risk Management alerts based on professional knowledge (e.g. chemotherapy agents not regulated at the state or federal level)

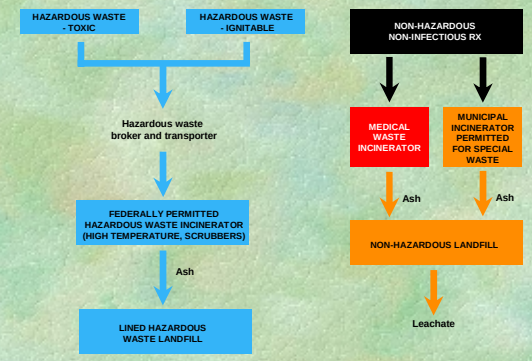

Regulated as federal hazardous waste:
P042 - Epinephrine
Handle as hazardous waste:
Toxic


Regulated as federal hazardous waste:
D005 - Barium
Handle as hazardous waste:
Toxic

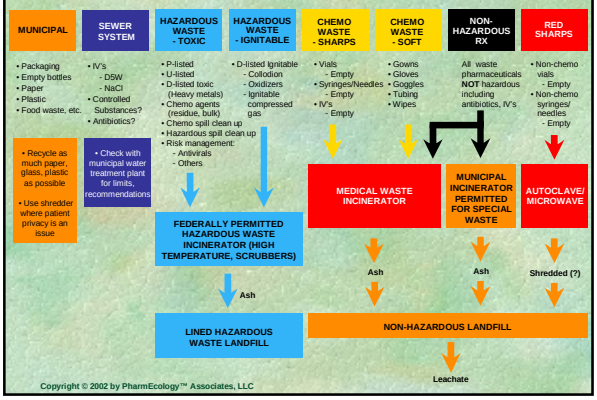
How Should RCRA Hazardous Waste be Handled in Healthcare Organizations?

- **Need a new waste stream 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)**
- **Hospitec has developed a dedicated hazardous waste containment system**
- **Can also use hazardous waste buckets available from brokers and disposal firms**

Recommended Additional Pharmaceutical Waste Streams



Recommended Revised Pharmaceutical Waste Streams

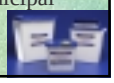


How Should RCRA Hazardous Waste Be Disposed?

- 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)

What About Non-Hazardous Drugs?

- Check with local Publicly Owned Treatment Works (POTW) for disposal options for unused IVs
- Segregate into a non-red, non-yellow container, such as beige or white with blue top (California Pharmaceutical Waste)
- Label "Non-hazardous Pharmaceutical Waste – Incinerate Only"
- Dispose at a regulated medical waste or municipal incinerator that is permitted to accept non-hazardous pharmaceutical waste



Tools for Healthcare Organizations

- Electronic formulary review service
  - Jump-starts the pharmacy by providing immediate feedback
- PharmEcology Wizard
  - Ability to respond to spills, compare equivalents, keep up with marketplace
- On-site review
  - A one or two day visit to the facility followed by an Action Plan and Findings and Recommendations

Resources

- www.pharmecology.com
- Pharmaceutical Waste: http://www.h2e-online.org/tools/chem-pharm.htm
- USEPA Region 2 Website: http://www.epa.gov/region02/healthcare/
- "Safely Managing Hazardous Materials and Hazardous Waste," ASHP Clinical Midyear, 2001, Handouts on CD-Rom
- RCRA On-Line www.epa.gov/rcraonline
- RCRA Hot Line 1-800-424-9346

Resources

- Improper Discard of Toxic Drugs Hurts Environment, Leads to Fines, AJHP, Vol 58, #17 September 1, 2001 pp 1576-1578.
- Pharmaceutical Waste Survey, King County, Washington State, April 29, 2003, http://www.metrokc.gov/hazwaste/pubs/studies.html#pharmwastesurvey
- Your Risks in Handling Outdated and Unusable Drugs: A Guide to JCAHO and Regulatory Standards. Capital Returns, Inc., 1998 Call 1-800-950-5479
- A Guide on Hazardous Waste Management for Florida's Pharmacies, www. floridacenter.org.
- Guidelines for Reverse Distributors: Minimum Federal Regulatory Standards, www.returnsindustry.com