



Drug Waste Management The Straight Dope

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Interagency Regulatory Analysis Committee

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Washington State's Issue:

- “The DEA requires us to destroy controlled substances in DEA-permitted incinerators, none of which are RCRA or state-permitted (for state-only dangerous waste). How do we comply when a waste drug is both a controlled substance AND a dangerous waste?”
- Some wastes must be destroyed, but since we cannot designate them, we can't destroy them!

Manifestation of a Problem

- Waste pharmaceuticals not destroyed in a timely fashion risk DEA enforcement
- Law enforcement evidence rooms could store no more and police risked losing court cases if evidence was not properly managed
- Hospitals and universities found designation too complex, so incurred the added expense of RCRA management for everything
- Industry requested information and guidance for compliance

Why Involve IRAC?

- Forum

- discuss regulatory gaps and conflicts
- share varied perspectives
- safe, neutral environment
- facilitated process

- Process

- IRAC is neither the regulator nor the regulated
- IRAC's only goal is a quality solution

Stakeholders in the Process

- Regulated Community
 - Hospitals & Pharmacies
 - Universities (UW&WSU)
 - Reverse Distributors & Consultants
 - Police Depts
 - Spokane WTE Facility
 - Associations (MIRT, WSPA)
- Regulating Community
 - WA Ecology: The Change Agent
 - WA Board of Pharmacy
 - US Drug Enforcement

Pharmaceuticals are Regulated by Other Agencies for Other Reasons

- Federal Drug Enforcement Administration
- Federal Food and Drug Administration
- State Boards of Pharmacy

- JCAHO Accredits and Inspects Hospitals
Joint Commission on Accreditation of Healthcare Organizations

Pharmaceuticals - Designed for Persistence, to Pack a Punch

- Drugs, some personal care products (dandruff & lice shampoos, cosmetics)
- hormones, steroids, antibiotics, analgesics, anti-depressants, chemotherapeutics, impotence drugs, etc.
- USGS study (Koplin, et al., 2002) found wide range of PPCPs in 80% of US waters

Some Pharmaceutical Wastes Designate as Hazardous Under RCRA or State Laws

- P-listed wastes (epinephrine, warfarin, nitroglycerine)
- U-listed wastes (lindane, chemotherapy)
- Ignitable (isopropyl alcohol for compounding)
- Corrosive (glacial acetic acid, NaOH, wart remover!)
- Toxic (w/As, Ba, Cd, Cr, Hg, Se, Au)
- http://www.floridacenter.org/brochures_bulletins/rcra_pharmacies.pdf

Pharmaceuticals Generally Fall into Three Categories

- Controlled Substances (DEA)
 - RCRA and state-designated hazardous wastes are found in all three categories
 - *Destruction* is required (DEA) for controlled substances and illegal drugs
- Legend Drugs (Prescription)
- Over-the-Counter Medicines

Most Pharmaceutical Wastes Improperly Disposed

- Few in Health Care Industry pay close attention to waste management
- Few know anything about RCRA (survey)
- RCRA-designated pharmaceutical wastes estimated to be 5% of the total
 - 4 Million Pounds / Year in the US
 - Most not handled according to RCRA regs

Result

- Washington State Dept of Ecology amended rules to exclude pharmaceutical wastes from dangerous (hazardous) waste designation IF they are destroyed in incinerators meeting specific conditions

Result

- Washington Administrative Code
173-303-071 (3) (nn) (ii)

Controlled substances, legend drugs, and over-the-counter drugs that are held in the custody of law enforcement agencies or possessed by any licensee as defined and regulated by chapter 69.50 RCW or Title 18 RCW and authorized to possess drugs within the state of Washington are excluded, provided the drugs are disposed of by incineration in a controlled combustion unit with a heat input rate greater than 250 million British thermal units/hour, a combustion zone temperature greater than 1500 degrees Fahrenheit, or a facility permitted to incinerate municipal solid waste.

Who This Affects and How

- Rule applies to
 - Ambulatory Care Centers, Clinics, Dental Offices, Dialysis Centers, Doctors' Offices, Hospitals, Long-term Care Facilities, Pharmacies, Police, Prisons, Veterinarians
- What it means for them
 - Waste isn't counted if managed this way
 - They can meet DEA and Board of Pharmacy regulations

Helping Them Comply

- Best Management Practices for Waste Pharmaceutical Management
 - developed by IRAC Workgroup
 - published by Ecology on their website:
- **<http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html>**

Jargon & Concepts

Hazardous =/ Biohazardous	Degree of Hazard	Wasting Narcotics
3 ml rule	Disposal Versus Destruction	Credits
Reverse Distributor	<ul style="list-style-type: none">· Controlled Substance· Legend Drug· OTC	Aborted and Partial Doses

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Pharmaceutical Waste Survey Objectives

- Filling data gaps helped Ecology with the rule
 - Quantity
 - Characterization, physical state and waste categories
 - Current management practices and awareness of rules
- Surveyed King County businesses and extrapolated to State-wide generators
- Completed in one month

Pharmaceutical Waste Survey Highlights

- 60 surveys completed
- 121 individual wastestreams
- Chemotherapy wastes: to HW or biohazardous waste disposal
- Most drug wastes go to sewer, garbage and biohazardous waste containers
- 94% were not aware of RCRA

Pharmaceutical Waste Quantities

- Statewide extrapolation, annual generation
 - All pharmaceutical wastes: 1 million pounds
 - Excluding IV fluids: 250,000 pounds
- Lowest generation rate: vet, 1 lb/year
- Highest generation: hospital, 7000 lb/year
- Conclusion: quantities are relatively small

What would be an ideal system?

- Preferred Management Options
 - Drop off at pharmacy: 27%
 - Vendor pick up: 25%
 - Reverse distributor handle it: 25%
 - Use associated hospital service: 20%
- Other comments
 - better inventory control systems needed
 - already over-regulated, collection/disposal is too much
 - must be convenient, cheap & easy

Reverse Distributors

- Reverse Distributor: a controlled substance registration category to return or dispose
- Returns Industry: manage returns for the drug manufacturer, facilitate transfer of funds to drug dispensers for unused product
- Manufacturer Credits: drug marketing strategy and diversion risk reduction

Regulatory Guidance on Returns

- Receive returned drugs as “product”
- Returns company decides what is waste, becomes the generator
- No HW transportation or TSDF permit needed from distributor to returns co.
- Basis for interpretation: drug recycling potential

Reverse Distributor Survey Objectives

- Identified companies providing service in King County
- Determined scope of service
- Not a “compliance audit”
- Produced *Resource Directory for the Management of Pharmaceuticals in King County* (on presentation CD)

Reverse Distributor Highlights

- Of 27 reverse distributors nationwide, 23 service the King County area
- Most are located in Eastern United States, 1 in Washington
- Reverse distributors incinerate most drugs at municipal waste-to-energy plants; most RCRA drugs go to RCRA permitted incinerators

Who's the Generator?

- Destruction only service: 15
- No credit processing: 4
- EPA generator ID#: 5 - No, 2 - don't know
- Pre-shipment segregation: 1
- Pre-shipment screening: 6

27 reverse distributors nationwide were surveyed

Continuing Initiatives

- FDA bar-code labels for drugs: include RCRA (yes/no) tag?
- EPA Innovation Pilot grant: Expanding Pharmaceutical Waste Management in Hospitals
- Creative high-tech inventions
- Product stewardship solutions for household wastes?