

Washington State Department of Ecology's Interim Enforcement Policy

Managing Healthcare Pharmaceutical Waste

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Observed Common Practices

Pharmacy:

- Reverse Distributor
 - Most unused pharmaceutical waste going to reverse distributor
- *Only viable pharmaceuticals allowed for returns*

Observed Common Practices

Patient Care Areas:

- Sharps containers
- Sewer / Linens
 - Witnessed destruction of controlled substances
- Red bag
- Bulk chemotherapy in trace containers

- *These are not appropriate waste management options for dangerous waste pharmaceuticals*

Pharmaceutical Management Difficulties in Hospitals

- Fast pace
- Patient care is main priority
- Many waste generation points
- Limited space
- Lots of staff handle pharmaceuticals
- Public access
- Many different pharmaceutical wastes
- Multiple agencies with requirements
- Different rules apply out of state

Policy Goals

- Keep pharmaceuticals out of the environment
- Simplify pharmaceutical waste management
- Clarify Dangerous Waste Requirements

Ecology's Role

1. Protect human health and the environment
2. Ecology cannot be less stringent than EPA

Cost does not change two items above

Policy Benefits

- Do not report pharmaceutical waste on Dangerous Waste Annual Report
- Does not count towards generator status
- Generic profile vs. continuous designation
- Fewer accumulation & training requirements
- Accumulate up to 180 days

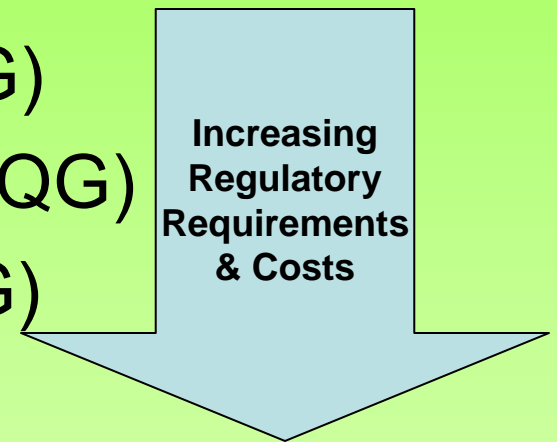
Policy Benefits: Counting

Reduce Generator Status:

- *Is your facility really a Small Quantity Generator?*
 - 2.2 lbs of Epinephrine = Large Quantity Generator (LQG)
 - Weight includes containers of P-listed or WT01 pharmaceuticals
 - e.g. syringes, vials, IV bags

Policy Benefits: Generator Status

- ↓ Generator status = ↓ HW regulatory requirements
 - Small Quantity Generator (SQG)
 - Medium Quantity Generator (MQG)
 - Large Quantity Generator (LQG)



Policy Benefits: Generic Profile

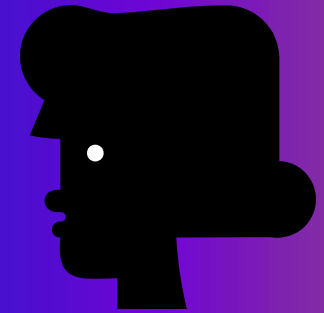
Designation under *DW* regulations:

- Must be done for each waste shipment
- Requires detailed knowledge or testing of each pharmaceutical
- For every pharmaceutical you dispose:
 - Determine all possible waste codes
 - Track exact quantities

Designation under *Policy*:

- May use profile for up to 3 years
 - Must update with major changes to formulary or services provided
- Use your formulary and operations knowledge to:
 - Determine all possible waste codes
 - Determine quantity estimates of each waste code

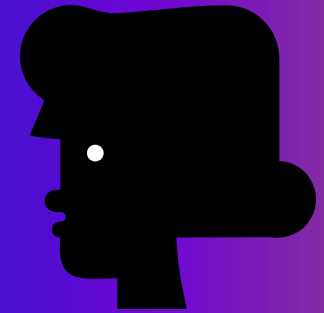
Profiling: Step 1



- Check the Example RCRA waste code list
 - Determine matches with your formulary
 - Cross off any you don't dispose
 - Add waste codes for DW containers

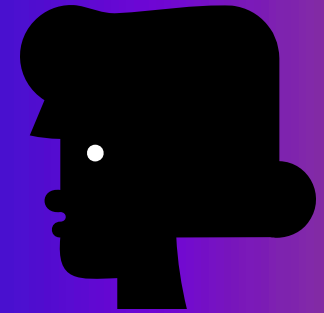
- End with a list of potential RCRA waste codes

Example Profile: Step 1



Waste Code	Waste Description	Minimum % of Pharmaceutical Waste (by weight)	Maximum % of Pharmaceutical Waste (by weight)
P042	Epinephrine		
P075	Nicotine		
U010	Mitomycin		
U188	Phenol		
D001	Silver nitrate		
D008	Barium		
D009	Mercury		
D013	Lindane		

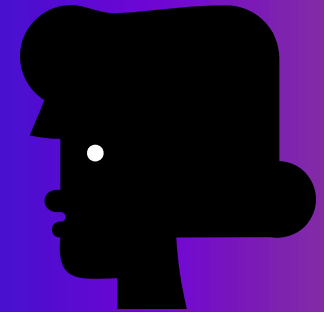
Profiling: Step 2



- Estimate waste quantity for each RCRA waste code

- Option 1:
 - Determine department formulary
 - Identify type and amount of waste
 - Use staff knowledge
 - Determine the amount of each RCRA waste code disposed

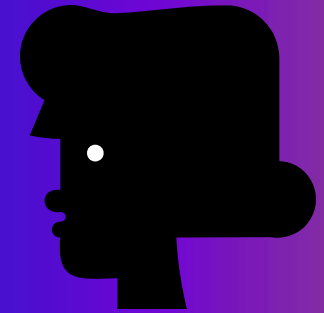
Profiling: Step 2



- Estimate waste quantity for each RCRA waste code

- Option 2:
 - Log type and amount when put in waste container
 - Compile records to determine total amount by RCRA waste code

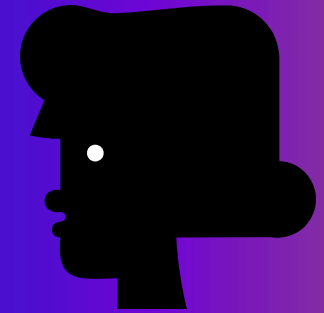
Profiling: Step 2



- Estimate waste quantity for each RCRA waste code

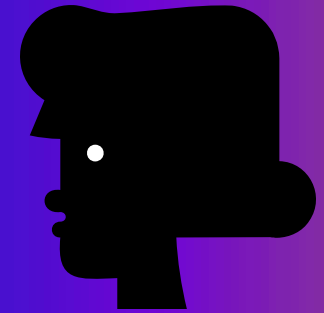
- Option 3:
 - Collect all pharmaceutical waste containers
 - Sort contents by RCRA waste code
 - Inventory

Example Profile: Step 2



Waste Code	Waste Description	Minimum % of Pharmaceutical Waste (by weight)	Maximum % of Pharmaceutical Waste (by weight)
P042	Epinephrine	5%	15%
P075	Nicotine	5%	10%
U010	Mitomycin	5%	10%
U188	Phenol	2%	4%
D001	Silver nitrate	1%	3%
D009	Mercury	10%	25%
D013	Lindane	5%	10%

Profiling: Step 3

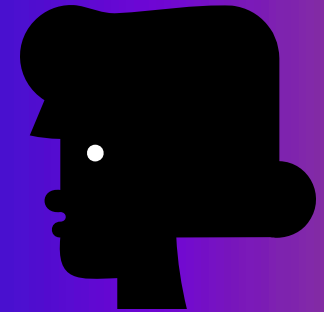


Determine the amount of State-only pharmaceutical waste

Conditionally Excluded
State-only Pharmaceutical
Maximum % = 100% - Sum of
RCRA
Minimum %

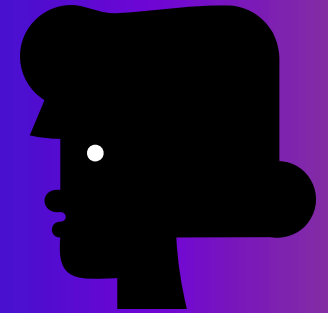
Conditionally Excluded
State-only Pharmaceutical
Minimum % = 100% - Sum of
RCRA
maximum %

Example Complete Profile



Waste Code	Waste Description	Minimum % of Pharmaceutical Waste (by weight)	Maximum % of Pharmaceutical Waste (by weight)
P042	Epinephrine	5%	15%
P075	Nicotine	5%	10%
U010	Mitomycin	5%	10%
U188	Phenol	2%	4%
D001	Silver nitrate	1%	3%
D009	Mercury	10%	25%
D013	Lindane	5%	10%
---	Conditionally excluded state-only pharmaceutical waste	23%	67%

Complete Profile



- Use as documentation of waste designation
- Provides waste codes and quantities for the Hazardous Waste Uniform Manifest

Notification



- Send Ecology a form including:
 - Notice of intent to use *Policy*
 - Copy of profile
 - Brief description of your profiling process
 - Signatures:
 - Pharmacy representative
 - Environmental manager

- If a notification is not submitted, Ecology will assume you are managing pharmaceuticals under the *Dangerous Waste Regulations*

Accumulation

- Containers
 - Compatible with waste
 - Contents compatible with each other
 - Absorbent material if holding liquids
 - Keep closed unless adding or removing
 - In good condition

Accumulation

- Labeling
 - “Non-Viable Pharmaceuticals”
 - Major Risk Label
 - e.g. “Toxic” or “Flammable”
 - Accumulation Start Date

- Maximum of 180 days
- Spill clean-up equipment available

Segregation

- Minimum Required Containers:
 - Solid and solids containing liquid pharmaceutical waste
 - Includes chemotherapy waste
 - Reverse Distributor
 - Viable & controlled substances
 - Dual Waste
 - Biomedical & Hazardous
- Additional segregation is optional for each container above:
 - RCRA
 - State-Only

Transportation



- Uniform HW Manifest
- HW Transporter with RCRA ID #
- Board of Pharmacy License
- DEA Registration
- Department of Transportation Registration
- Utilities and Transportation Commission Permit

Proper Disposal



All pharmaceutical waste
managed under the *Policy*

must go to a

RCRA

permitted
incinerator



Conditional Exclusion

State-only pharmaceutical waste:

- Excluded from *Dangerous Waste Regulations* if sent for incineration at a facility:
 - Permitted for municipal solid waste, or
 - With a heat input of 250 million BTU/hour, and
 - Combustion temperature > 1500 °F

- Must have proper documentation

Disposal Exceptions



- Witnessed Destruction of Controlled Substances
 - Patient care areas only
 - Return to pharmacy whenever possible for reverse distribution
 - Sewer only with POTW permission

Reverse Distribution



- Viable pharmaceuticals that receive credit
- Facilities must ensure that waste controlled substances sent to a reverse distributor are disposed of properly
 - RCRA controlled substances must be sent to a RCRA incinerator
 - State-only controlled substances may go to a permitted municipal incinerator
- Must have proper documentation

Training



- All staff involved in pharmaceutical waste management must be trained
 - Safety
 - Emergency procedures
 - Proper waste management
 - Recordkeeping

Recordkeeping



Retain the following onsite for 5 years:

- Hazardous waste uniform manifests
- Annual reports
- Exception reports
- Updated pharmaceutical waste profile
- Reverse distributor receipts or invoices
- DEA Certificates of destruction

What's Best for You?

It depends:

- Actual generator status
- RCRA vs. non-RCRA disposal costs
- Quantity and type of pharmaceutical waste
- Ability and cost to designate on-site
- Time and space for on-site management
- Education and oversight capability
- Benefits received by a decrease in generator status

Comparing the Options

Interim Enforcement Policy

- Easiest on-site management for pharmaceutical waste
- Least time intensive designation
- Pharmaceutical waste does not affect generator status
- Increases the amount of waste going to TSD

Dangerous Waste Regulations

- Most demanding on-site management for all pharmaceutical waste
- Most time intensive designation
- Pharmaceutical waste affects generator status
- All dangerous waste must go to a TSD

Comparing the Options

Interim Enforcement Policy

- Easiest on-site management for pharmaceutical waste
- Least time intensive designation
- Pharmaceutical waste does not affect generator status
- Increases the amount of waste going to TSD

Conditional Exclusion WAC 173-303-071(3)(nn)

- Cheapest off-site management for state-only pharmaceutical waste
- Moderate time required for designation
- RCRA pharmaceutical waste still affects generator status
- Excluded pharmaceutical waste does not affect generator status
- Reduces the amount of waste going to a TSD

Questions?

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