Interim Enforcement Policy
Pharmaceutical Waste Fact Sheet
Profiling and Notification

This fact sheet is a supplement to the *Interim Enforcement Policy for Pharmaceutical Waste in Healthcare* (Pub # 07-04-024). Within its enforcement discretion, the Washington State Department of Ecology (Ecology) will refrain from enforcing portions of the *Dangerous Waste Regulations* [Chapter 173-303 Washington Administrative Code (WAC)] at facilities meeting the conditions of the policy.

Most waste pharmaceuticals designate as either federal [Resource Conservation and Recovery Act (RCRA)] hazardous waste or Washington state-only dangerous waste [WAC 173-303-100]. In this document, "dangerous waste" includes both RCRA hazardous waste and state-only dangerous waste unless otherwise specified.

Any pharmaceutical waste not managed according to the policy is subject to full regulation under the *Dangerous Waste Regulations*.

Profiling Your Pharmaceutical Waste

The *Interim Enforcement Policy for Pharmaceutical Waste in Healthcare* requires facilities to conduct an initial pharmaceutical waste profile. The purpose of this document is to assist facilities with the profiling process. Always refer to the *Dangerous Waste Regulations* or the policy for more detail or call a hazardous waste specialist at your nearest Ecology regional office.

Pharmaceuticals, as defined by Revised Code of Washington (RCW) 69.04.009, are waste when they are non-viable. Non-viable pharmaceuticals are defined in the policy as pharmaceuticals that cannot be used, sold, or returned to a manufacturer, wholesaler, or reverse distributor for credit.

As the generator, you must designate your pharmaceutical waste and determine all applicable waste codes [see WAC 173-303-070 of the *Dangerous Waste Regulations*]. Under the policy, you can meet this requirement by compiling a profile.

It may be easier and more accurate to use separate profiles for individual departments or units within your facility. To decide if this is best for you, consider quantities of waste, frequency of pick-ups, and the needs of your dangerous waste transporter. If you have separate profiles for individual departments or units, include them all with your notification.

Step 1 – Identify Your RCRA Hazardous Pharmaceutical Waste

- Start with a copy of the attached **Example Waste Code List** of the most common RCRA hazardous waste codes for pharmaceutical waste.
- Cross off all pharmaceuticals on the list that are not on your formulary or inventory. Be sure to check with all departments that order their own pharmaceuticals such as Radiology.

- Next, cross off waste codes of pharmaceuticals you never dispose (i.e., they are always completely administered to a patient or always returned to the manufacturer or reverse distributor as a viable pharmaceutical). For example, if your facility determines unused barium-containing contrast agents are never disposed, cross it off the list.
- Add the waste codes for any containers that held P-listed pharmaceuticals.

You should now have:

- A comprehensive list of pharmaceuticals at your facility that must be managed as hazardous waste.
- The RCRA waste code and a brief description for each item on the list.

Example Profile after Step 1:

Waste Code	Description	Minimum % of Pharmaceutical Waste (by weight)	Maximum % of Pharmaceutical Waste (by weight)
P001	Warfarin (Concentration > 0.3%)		
P012	Arsenic Trioxide		
P042	Epinephrine, including containers		
P075	Nicotine, including containers		
U010	Mitomycin		
U058	Cyclophosphamide		
D001	Silver nitrate		
~~D005~~	~~Barium~~		
D009	Mercury		
D013	Lindane		

These resources may help you determine RCRA hazardous waste codes:

- Material Safety Data Sheets (MSDSs)
- Product inserts
- Internet searches
- Department of Ecology staff
- Consultants, service providers and vendors
- Practice Greenhealth (formerly Hospitals for a Healthy Environment - H2E) www.practicegreenhealth.org
- Healthcare Environmental Resource Center (HERC) www.hercenter.org

Step 2 – Estimate Quantity of Each RCRA Waste Pharmaceutical

Use knowledge of your facility's practices to estimate the relative amount of each pharmaceutical you dispose by weight. List this amount on the profile as a percentage range for each pharmaceutical. Some options for determining pharmaceutical waste quantities are below.

Option 1:

- Use or start a logging system to track the type and quantity of pharmaceuticals as they are placed in waste containers.
- Compile the log sheets to determine quantity of each RCRA waste code disposed.
- Convert the quantity for each waste code to percentage of total pharmaceutical waste disposed.

- Use this percentage and knowledge of fluctuations in pharmaceutical use and disposal to determine a representative disposal percentage range for each waste code.

Option 2:

- Collect all pharmaceutical waste.
- Sort and inventory contents by RCRA hazardous waste code.
- Convert the inventory quantity for each waste code to a percentage of the total pharmaceutical waste.
- Use this percentage and knowledge of fluctuations in pharmaceutical use and disposal practices to determine a representative disposal percentage range for each pharmaceutical.

Option 3:

- Use your dispensing software to determine quantities of pharmaceuticals dispensed in different departments.
- Talk to nursing staff in each department to estimate the types and quantities of pharmaceuticals disposed.
- Determine the quantity of each RCRA waste pharmaceutical disposed.
- Convert the quantity for each waste code to percentage of total pharmaceutical waste disposed.
- Use this percentage and knowledge of fluctuations in pharmaceutical use and disposal to determine a representative disposal percentage range for each waste code.

Example Profile after Step 2:

Waste Code	Waste Description	Minimum % of Pharmaceutical Waste (by weight)	Maximum % of Pharmaceutical Waste (by weight)
P001	Warfarin (Concentration > 0.3%)	2%	5%
P012	Arsenic Trioxide	1%	5%
P042	Epinephrine, including containers	5%	15%
P075	Nicotine, including containers	1%	5%
U010	Mitomycin	5%	10%
U058	Cyclophosphamide	5%	15%
D001	Silver nitrate	1%	3%
D009	Mercury	10%	25%
D013	Lindane	5%	10%

Step 3 – State-only Dangerous Waste

Unless you have designation documentation to prove otherwise, assume all remaining pharmaceutical waste designates as dangerous waste for Washington State Criteria for Toxicity or Persistence [WAC 173-303-100].

If these state-only pharmaceutical wastes are incinerated under the conditional exclusion, they are not considered dangerous waste [WAC 173-303-071(3)(nn)].

Your facility has the choice of:

1. Segregating state-only pharmaceutical wastes and sending them for incineration separately under the conditional exclusion. These wastes should not be included on the profile.
2. Mixing state-only pharmaceutical waste with the RCRA hazardous waste and managing it all under the policy. This meets the exclusion conditions so state dangerous waste codes are not necessary on the profile.

To include the state-only pharmaceutical waste on the profile under option 2 above:

- Add "Conditionally excluded state-only pharmaceutical waste" on the profile.

Follow the steps below to determine your percentage range for conditionally excluded state-only pharmaceutical waste:

Maximum Percentage Range

- Add up the minimum percentage range of RCRA codes.
- Subtract this number from 100.
- The difference is your maximum percentage range for conditionally excluded state-only pharmaceutical waste.

Minimum Percentage Range

- Add up the maximum percentage range of RCRA codes.
- Subtract this number from 100.
- The difference is your minimum percentage range for conditionally excluded state-only pharmaceutical waste.

Example Profile after Step 3:

Waste Code	Waste Description	Minimum % of Pharmaceutical Waste (by weight)	Maximum % of Pharmaceutical Waste (by weight)
P001	Warfarin (Concentration > 0.3%)	2%	5%
P012	Arsenic Trioxide	1%	5%
P042	Epinephrine, including all containers	5%	15%
P075	Nicotine, including all containers	1%	5%
U010	Mitomycin	5%	10%
U058	Cyclophosphamide	5%	15%
D001	Silver nitrate	1%	3%
D009	Mercury	10%	25%
D013	Lindane	5%	10%
---	Conditionally excluded state-only pharmaceutical waste	7%	65%

The waste codes on this profile can be transferred to the Uniform Hazardous Waste Manifest [EPA Form 8700-22]. Conditionally excluded state-only pharmaceutical waste does not need to be included on the manifest. Your shipping vendor may have additional requirements.

Step 4 – Send Your Profile to Ecology

You must notify the Department of Ecology of your intent to manage pharmaceutical waste under the policy. A notification form is included. If you do not notify, inspectors will expect you to comply with all the requirements of the *Dangerous Waste Regulations.*

Attach a copy of your initial profile(s) to the notification form. If you have separate profiles for individual departments or units, include them all with your notification.

The date of your notification form is the effective start date for managing waste under the *Interim Enforcement Policy for Management of Pharmaceutical Waste in Healthcare.*

Step 5 – Keep Your Profile Current

Update your profile every three years or whenever significant changes are made to your facility's operations or formulary. Changes may include, but are not limited to:

- Addition or loss of departments or services.
- Seasonal fluctuations in pharmaceuticals dispensed.
- Purchases of pharmaceuticals that result in either a new RCRA hazardous waste code or changes the frequency of the waste code.

Current and historical profiles are subject to inspection and must be kept on-site for five years. You do not need to send profile revisions to Ecology.

Note: Your waste vendors may require you to update your profile more frequently.

Step 6 – Reduce Your Volume of Pharmaceutical Waste

Pollution prevention (P2) opportunities may help you reduce the quantity of waste and save money on waste management costs. Examples of P2 options for pharmaceutical waste include:

- Just-in-time purchasing to reduce the amount of expired pharmaceuticals.
- Just-in-time delivery to patients to minimize waste.
- Frequent inventories to ensure pharmaceuticals are used prior to expiration and optimize reverse distribution of viable pharmaceuticals.
- Repackaging commonly used bulk pharmaceutical products into unit doses on-site.
- Purchasing pharmaceuticals that are wasted frequently in smaller than optimum unit of use.
- Dispensing oral liquids in unit-of-use oral syringes or doses.

Example RCRA P-Listed Waste Codes		
Note: must contain constituent as sole-active ingredient and be unused or discarded		
Waste Code	**Constituent of Concern**	**Product Name Examples:**
P001	Warfarin & Salts (concentration >0.3%)	Coumadin; Warfarin
P012	Arsenic Trioxide	Trisenox
P042	Epinephrine	Adrenalin; EpiPen; Eppy/N; Epifrin; Epinal; Anaphalaxis kit; Epinephrine (inhalants, injectibles, kits); Racepinephrine; Racord; Primatene Aerosol Inhaler
P046	Phentermine (CIV)	Phentermine (CIV)
P075	Nicotine	Nicotine Patches; Habitrol; Nicoderm; Nicorette; Nicotrol; Tetrahydronicotyrine
P188	Physostigmine salicylate	aka Eserine Salicylate
P204	Physostigmine	aka Eserine

Example RCRA U-Listed Waste Codes		
Note: must contain constituent as sole-active ingredient and be unused or discarded		
Waste Code	**Constituent of Concern**	**Product Name Examples:**
U010	Mitomycin C	Mitomycin; Mitomycin C; Mutamycin; Mutamycin VHA Plus
U015	Azaserine	Chemotherapy for Leukemia
U034	Chloral / Chloral Hydrate	Chloral hydrate (CIV)
U035	Chlorambucil	Leukeran
U044	*Chloroform*	*Not commonly seen*
U058	Cyclophosphamide	CTX; Cytoxan Injection, Lycophilized/VHA Plus; Neosar; Procytox
U059	Daunomycin	Daunorubicin, Cerubidin, DaunoXome, Rubidomycin; Liposomal; Idarubicin/Idamycin; Daunomycin
U075	Dichlorodifluoromethane	Dichlorodifluoromethane
U089	Diethylstilbesterol	Diethylstilbestrol, DES (synthetic estrogen), Stilphostrol
U121	Trichloromonofluromethane	Trichlorofluoromethane
U129	Lindane	G-Well Shampoo; Kwell; shampoo
U132	Hexachlorophene	Phisohex Disinfectant
U150	Melphalan	Alkeran; L-PAM; Melphalan
U151	Mercury	Mercurochrome; Mercury Iodide; Mercury Chloride; Mercury Sulfate
U182	Paraldehyde	Paral; Paraldehyde (CIV)
U187	Phenacetin	Acetophenetidin; typically Veterinary
U188	Phenol	Phenol; Liquified Phenol
U200	Reserpine	Resperine
U201	Resorcinol	Resorcinol
U205	Selenium sulfide	Exsel shampoo; selenium sulfide; Selsun
U206	Streptozotocin	Streptozotocin; Streptozocin; Zanosar
U237	*Uracil Mustard*	*Not commonly seen: Uracil Mustard; Uramustine*
U248	Warfarin & Salts (concentration <0.3%)	Warfarin

Example RCRA Characteristic Waste Codes			
Waste Code		**Characteristic Waste**	**Example Drug Formulations with these Characteristics:**
Ignitable	D001	Aqueous drug formulation containing 24% or more alcohol by volume and having a flashpoint of less than 140º F or 60º C (261.21(a)(1)).	Erythromycin Gel 2%
			Texacort Solution 1%
			Taxol Injection
		Liquid drug formulations, other than aqueous solutions containing less than 24% alcohol, with a flashpoint of less than 140º F or 60º C.	Flexible collodion - Flashpoint = 45º C
		Oxidizers or materials that readily supply oxygen to a reaction in the absence of air as defined by the DOT.	Amyl nitrite inhalers
			Silver nitrate applicators
		Flammable aerosol propellants meeting the DOT definition of compressed gas (261.21(a)(3)).	Primatene aerosol
Corrosive	D002	Corrosive[1]	Any solution with pH ≤ 2
			Any solution with pH ≥ 12.5
Reactive	D003	Reactive[2]	Any compound that is unstable and readily undergoes violent change; reacts violently, forms potentially explosive mixtures or generates toxic fumes when mixed with water; cyanide or sulfur waste that releases toxic fumes at pH between 2 and 12.5; or is explosive or capable of detonating at standard temperature and pressure.
Toxic	D004	Arsenic	Any P012 listed waste; Arsenic trioxide (also P012); Carbasone; Glycobiarosol; Thiacetarsamide
	D005	Barium	Barium sulfate (used in radiology); Barium Sulfidel Barium Hydroxide; Barium Chloride
	D007	Chromium	Multiple mineral preparations; Chromium; Chromium trioxide; Multiple Trace Element (also D010)
	D009	Mercury	Any U151 listed waste; Any drug w/ thimerosal or phenylmercuric acetate (vaccines, eye drops, nasal spray, etc)
	D010	Selenium	Any U205 listed waste; Dandruff shampoo, multiple mineral preparations
	D011	Silver	Silver sulfadiazine cream; Silver nitrate (also D001); Silvadene; Argyrol S.S.; Arzol Silver Nitrate (also D001)
	D013	Lindane	Treatment of lice, scabies
	D022	*Chloroform*	*Not commonly seen*
	D024	M-cresol	Insulin w/ Cresol

[1] Most corrosive waste will be compounding chemicals. Although compounded pharmaceuticals are eligible for management under the Interim Enforcement Policy, the compounding chemicals themselves must be managed under the Dangerous Waste Regulations.

[2] Nitroglycerin is the only pharmaceutical that we are aware of that may be considered reactive. Most medical formulations of nitroglycerin are not reactive. Medical formulations of Nitroglycerin that are not reactive are not considered P081 listed waste.

This form hereby notifies the Department of Ecology of our facility's intent to manage pharmaceutical waste under the *Interim Enforcement Policy for Pharmaceutical Waste in Healthcare*. We understand that we must follow the waste management as described under the policy in order to receive some enforcement discretion. We understand that not following all the management outlined under the policy subjects our pharmaceutical waste management to enforcement under the *Dangerous Waste Regulations* (Chapter 173-303 WAC). We understand that the policy only affects pharmaceutical waste management and that all other dangerous waste management is enforced under the *Dangerous Waste Regulations*.

Date of Submittal:	

Site Information	
Facility Name:	
Site Address:	
City / State / Zip:	

Mailing Address	
Name:	
Mailing Address:	
City / State / Zip:	

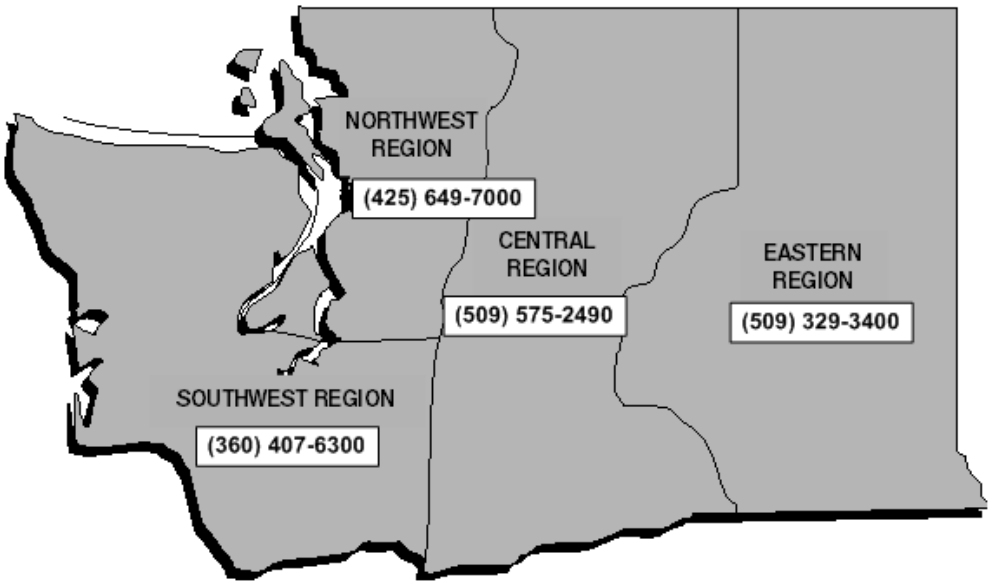
Primary Facility Contact:	
Name:	
Title:	
Phone:	
Email:	

Number of profiles attached:	

Certification – This form cannot be processed without both signatures.

Pharmacy Department Manager:	**Environmental Manager:**
_____ Signature	_____ Signature
_____ Printed Name	_____ Printed Name
_____ Title	_____ Title

Submit form to: Washington State Department of Ecology; Hazardous Waste and Toxics Reduction Program; P2 & Regulatory Assistance Section; PO Box 47600; Olympia, WA 98504-7600



If you need this information in an alternate format, please call the Hazardous Waste and Toxics Reduction Program at 360-407-6700. If you are a person with a speech or hearing impairment, call 711, or 800-833-6388 for TTY.