



# **State and Federal Regulations: Pharmaceutical Rule**

**Northwest Hazardous  
Waste Conference  
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Dept. of  
Ecology

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# Developed by:



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**Local Hazardous Waste Management Program in King County**

LOCAL GOVERNMENTS FOR HEALTH AND THE ENVIRONMENT

**Interagency Regulatory Analysis Committee (IRAC)**

King County, Washington

# Acronyms

**CAFO:** Concentrated animal feeding operation

**CESQG:** Conditionally Exempt Small Quantity Generator

**CFR:** Code of Federal Regulations

**DEA:** Drug Enforcement Administration

**HHW:** Household hazardous waste

**HWTR:** Hazardous Waste & Toxics Reduction

**IRAC:** Interagency Regulatory Analysis Committee

**MRW:** Moderate Risk Waste

**OWC:** Organic wastewater contaminants

**RCRA:** Resource Conservation & Recovery Act

**RCW:** Revised Code of Washington

**TSD:** Treatment, storage, & disposal facility

**USGS:** United States Geological Survey

**UTC:** (Washington State) Utilities & Transportation Commission

**WTE:** (Spokane) Waste-to-Energy

# Pharmaceuticals – *What's the problem?*

- ❖ Washington State University asked:  
*“Are the controlled substances/pharmaceuticals going to Spokane WTE designated as dangerous waste?”*
- ❖ Pharmaceuticals and illegal street drugs are controlled by the Drug Enforcement Administration (DEA)
  - The DEA delegates to the Department of Health's Board of Pharmacy
  - Ecology's new regulation creates the concept of a controlled substance and controlled substances have to be disposed of in a way where they are not recoverable.

# Background – Dangerous Waste Regulation

- ❖ Ecology was granted authority to implement the federal law and add to it
- ❖ State regulations can be more stringent than federal regulations
- ❖ “Dangerous” waste is distinct from “solid” waste
  - Households and conditionally exempt generators are solid waste
  - Local ordinances can have more stringent requirements for disposal
- ❖ Regardless of the toxicity of the HHW, it is exempt from the Dangerous Waste Regulations.

# Background - Dangerous Waste Regulations

*The regulations are intended to protect human health and the environment.*

**Dangerous waste is:**



listed



ignitable



corrosive



toxic

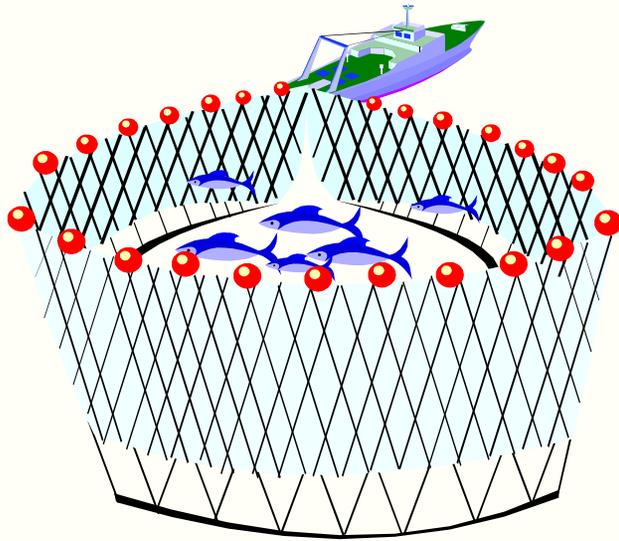


reactive

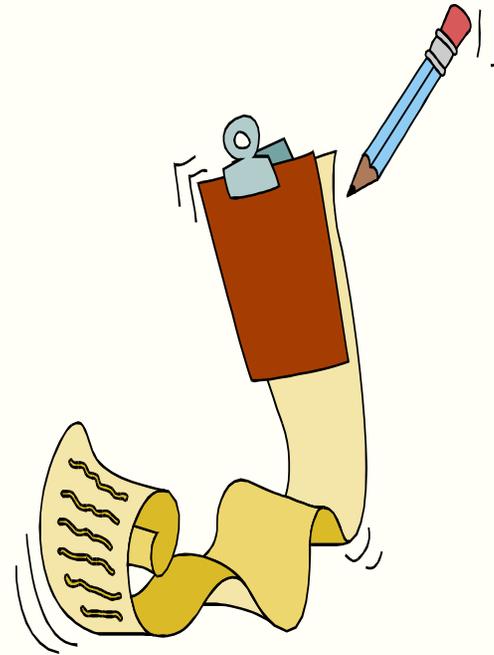
persistent  
(state-only)



# Comparing state & federal regulations



**State**



**Federal**

# *How do you know what's in it?*

- ❖ State approach requires complete information on ingredients.
- ❖ This complete information is rarely available to the disposer or consumer of the pharmaceutical.

# Discarded Chemical Products

- ❖ *Unused*, with a single active ingredient are listed with either a P or U code.
- ❖ *More* toxic products are P-listed
- ❖ *Less* toxic products are U-listed

# Examples of P-Listed Pharmaceutical Waste

Arsenic trioxide

P012

Epinephrine

P042

Nicotine

P075

Nitroglycerin

P081



Phentermine (CIV)

P046

Physostigmine Salicylate

P188

Warfarin >0.3%

P001

# Examples of U-Listed Pharmaceutical Waste

Saccharin  
U202

Melphalan  
U150

Lindane  
U129

Warfarin <0.3%  
U248



Uracil Mustard  
U237

Chloral Hydrate (CIV)  
U034

Selenium Sulfide  
U205

# *What is a Controlled Substance?*

- ❖ DEA classifies controlled substances into five categories (schedules I through V)
- ❖ Schedule I drugs have a high potential for abuse, other schedules have less potential

*For more information: DEA's website, CFR, Section 1308 – Schedules of Controlled Substances at*

[www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm](http://www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm)



# *Why do dangerous waste laws apply to pharmaceuticals?*

- ❖ Therapeutic “small doses” can accumulate in the environment.
- ❖ Presence of these chemicals in the environment can cause lower resistance to newly present toxins.
- ❖ Materials may not follow a normal dose-response curve (i.e. endocrine disruptors).
- ❖ 1999 USGS Water Quality Survey found one or more Organic Wastewater Contaminants (OWC) in 80% of stream samples.
- ❖ 13% of sites had more than 20 OWCs

# How Ecology resolved the problem

The new conditional exclusion was created to solve a very specific problem at hospitals and police organizations.

## **We needed to ask:**

- ✓ *What is the risk posed by disposal of pharmaceuticals?*
- ✓ *How can we meet the needs of multiple regulations?*
- ✓ *Where can the pharmaceuticals go for disposal so that the greatest number of needs are met?*

# Ecology's new regulation

## WAC 173-303-071 (3) (nn)

(i) Controlled substances, legend drugs, and over-the-counter drugs that are state-only dangerous wastes.

(A) Controlled substances as defined and regulated by chapter [69.50](#) RCW (Schedule I through V);

(B) Legend drugs as defined and regulated by chapter [69.41](#) RCW; and

(C) Over-the-counter drugs as defined and regulated by chapter [69.60](#) RCW.

(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.

...continued

(iii) For the purposes of this exclusion the term "drugs" means:

(A) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

(B) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) Substances (other than food) intended to affect the structure or any function of the body of man or other animals, as defined in RCW [18.64.011](#)(3). (Note: RCW [18.64.011](#) (3)(d) is intentionally not included in the definition of drugs for this exclusion.)

(iv) When possessed by any licensee the term drugs used in this exclusion means finished drug products.

# *What does this mean?*

- ❖ The conditional exclusion offers a disposal option that meets the need to destroy controlled substances.
- ❖ It is a disposal option that protects human health and environment.
- ❖ Our regulation of pharmaceutical waste is now more similar to other states.



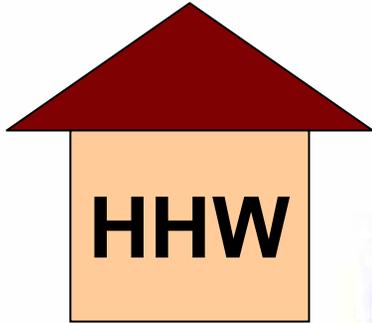
# Applicability



New rule applies to:

- **Police organizations:** This exclusion applies to the waste held in custody of law enforcement agencies.
- **Hospitals, pharmacies and people** (*called licensees*) who are authorized by the state Board of Pharmacy to possess controlled substances and legend/prescription drugs.

Note: This exclusion **does not** apply to manufacturers of pharmaceuticals.



**Household  
Hazardous Waste**

**&**

**Moderate Risk  
Waste**



**Facilities**



# MRW Considerations

- ❖ What percentage of environmental accumulation is due to **direct disposal** or excretion?
- ❖ Whether drugs end up in landfill **leachate**?
- ❖ Biosolids- Are excreted drugs a problem?
- ❖ CAFOs and veterinary drugs
- ❖ “Household” disposal (widespread disposal) versus hospital disposal (concentrated disposal).
- ❖ Poison control authorities may give different disposal directions to protect children.
- ❖ <http://www.epa.gov/esd/chemistry/pharma/images/drawing.pdf>

# Households

In 1996, a U.S. consumer survey showed:

- 1.4% returned medications to a pharmacy
- 54% disposed of medications in the garbage
- 35.4% flushed medications down the toilet or sink
- 7.2% did not dispose of medication
- 2% used all medication before disposal
- 5% of pharmacies had consistent disposal recommendations for their customers.

# *Why are drugs wasted?*

- ❖ Consumer does not use all medication  
*(they get well, change prescriptions, stop taking the medication, or pass away)*
- ❖ Medication expires after it is prescribed

# *Where are drugs wasted?*

## ❖ Households

“Households” are defined as:

## ❖ Consumers in households

## ❖ Long-term care facilities

– Medication prescribed to patient, is owned by patient

## ❖ Hotels

# How the new rule applies to HHW & MRW facilities

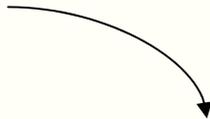
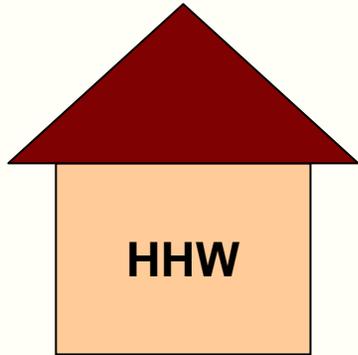
- ❖ Exclusion *does not* apply to household waste collected by an HHW facility (not licensee)
- ❖ HHW is “solid waste.” Spokane WTE most likely can accept this waste.
- ❖ DEA needs to be asked whether they care about controlled substances collected at HHW facilities
- ❖ Licensees can collect other state-only licensee waste and use new rule, e.g., Walgreens
  - Need to segregate waste
- ❖ If the pharmaceutical waste is “solid waste”, haulers need a solid waste handling permit from the UTC, unless you self-haul the waste.

# Disposal options for HHW & MRW facilities

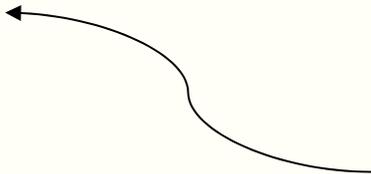
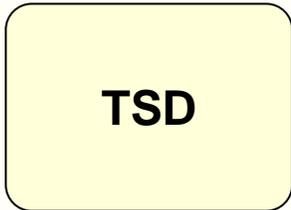
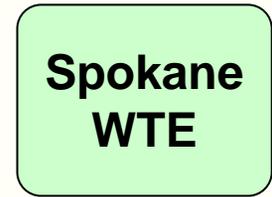
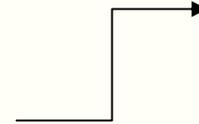
**IF** you wanted to do this:

- ❖ No specific guidelines from Ecology regarding how to separate medications for HHW collection
- ❖ Work with local permitter to include pharmaceuticals
- ❖ Your facility needs to work with your TSD facility or incinerator to determine best management. Incineration or hazardous waste landfill may be more ideal depending on substance.
- ❖ You may need to notify any or all of these agencies regarding your program: Ecology, DEA, local health departments

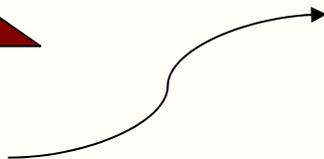
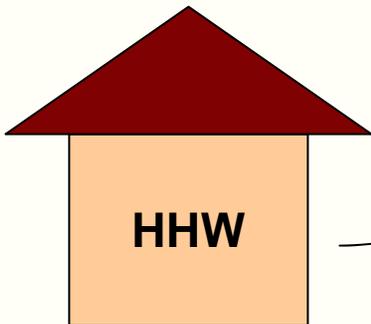
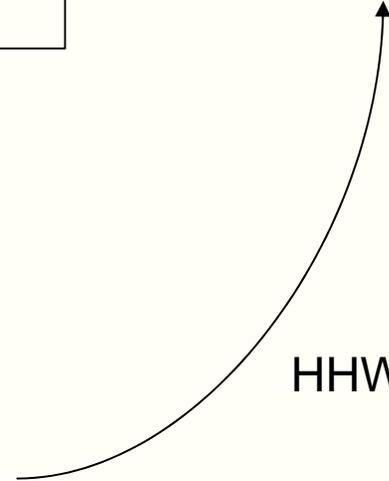
**HHW  
RCRA  
and  
State  
only**

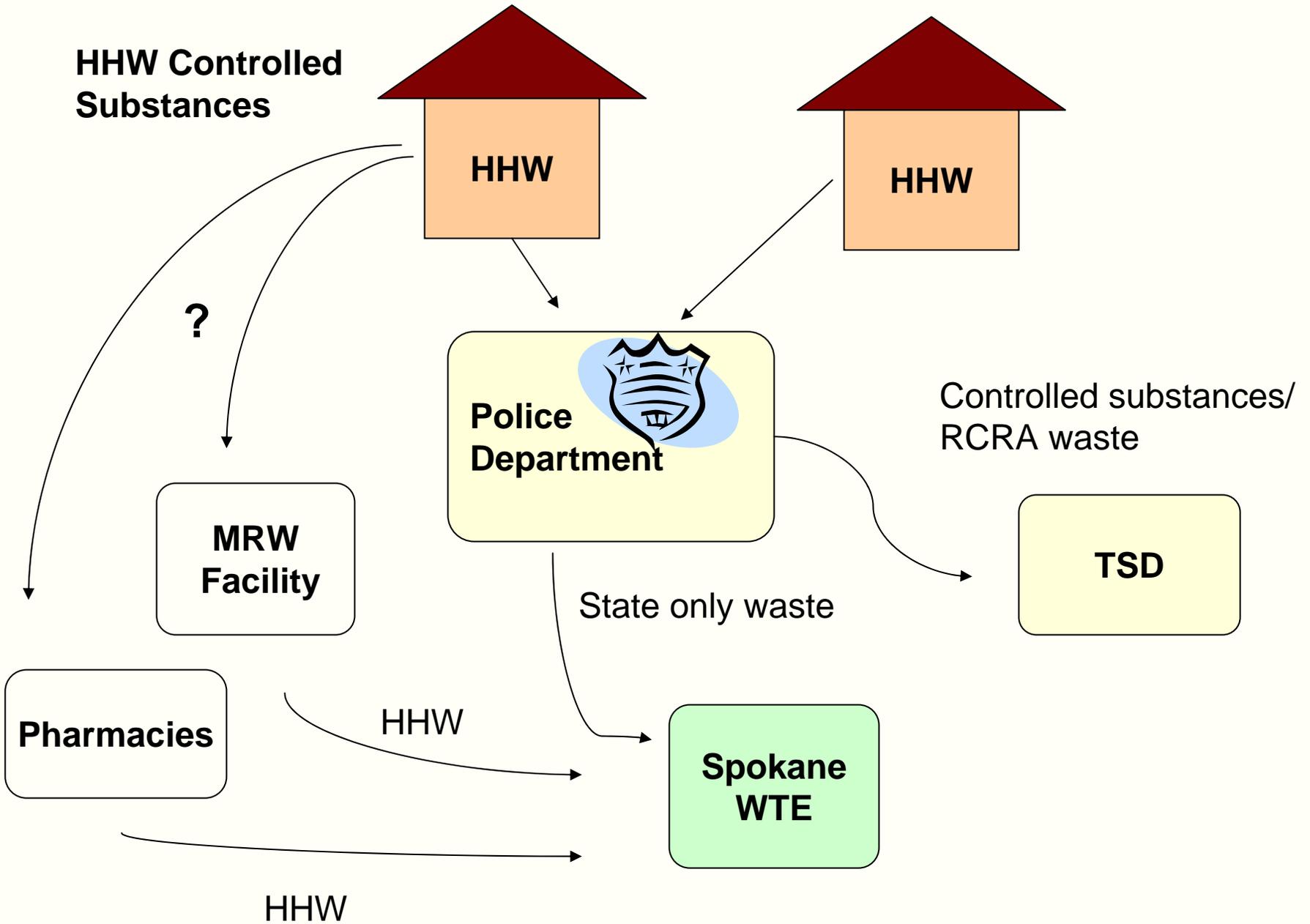


Licensee  
state only  
waste (and  
HHW)



HHW





# Resources (for Licensees)

- “Focus on Pharmaceutical Waste”
- “Pharmaceutical Waste Management Flowchart”
- “Managing Pharmaceutical Waste” website:  
[www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html](http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/index.html)



## Hazardous Waste & Toxics Reduction Program

[Hazardous Waste Management](#) | [Reporting Requirements](#) | [Hazardous Chemicals in Your Community](#)  
[Reducing Hazardous Waste & Hazardous Substances](#) | [HWTR Program Overview](#) | [Publications](#) | [Site Map](#)



### Managing Pharmaceutical Waste

- Home
- Focus Sheet
- Conditional Exclusion
- FAQs
- Best Management Practices
- What is Dangerous Waste?
- How do I decide to manage my waste? (flowchart)
- Resources and External Links
- Feedback Form

Welcome! Pharmaceuticals are an important part of maintaining human health. But compounds in pharmaceuticals with therapeutic benefits for humans at the right doses can be pollutants in the environment.

The information on this page is for medical facilities. In the future we may add pages for other groups that generate waste pharmaceuticals.

Medical facilities will find information on best management practices for pharmaceuticals and what disposal options are for this waste. Some pharmaceuticals are excluded from regulation if they meet certain criteria and if they are incinerated.

Please use the "Feedback" button to ask questions, suggest changes or additions to this web page, and to let us know what other topics you want to know about.

The purpose of this web page is to help you get information and resources to manage your pharmaceutical waste in a way that protects human health and the environment.

The Department of Ecology would like to thank the following groups for their assistance:

- [The Washington State Department of Health Board of Pharmacy](#)
- [The US Drug Enforcement Administration](#)
- [The Medical Industry Waste Prevention Roundtable](#)
- [King County Local Hazardous Waste Management Program staff](#)

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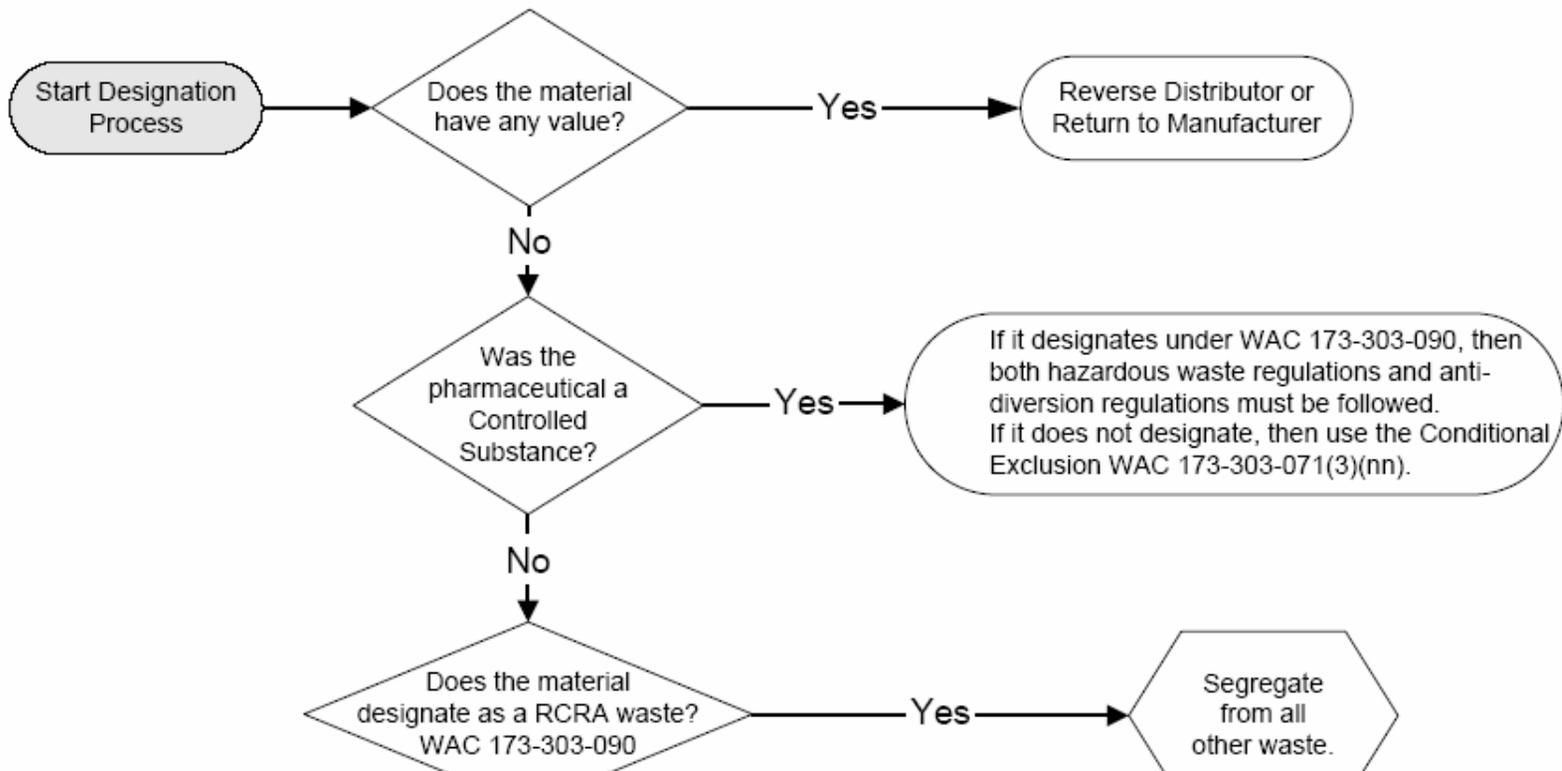
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Address <http://www.ecy.wa.gov/programs/hwtr/pharmaceuticals/pages/manage.pdf> Go Links

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# Pharmaceutical Waste Management Flowchart





Dept. of  
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*Thank you for attending this presentation.  
We hope you found it informative.  
Please call or e-mail us if you have any questions.*

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