



Guide for Dangerous Pharmaceutical Waste Generators in Washington State

Options for Managing Pharmaceutical Waste

07-04-025

April 2008

The *Interim Enforcement Policy for Pharmaceutical Waste* was developed to address questions and needs identified by the healthcare industry. Within its enforcement discretion, 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.

This guide provides a summary of requirements for managing pharmaceutical waste under:

- The *Dangerous Waste Regulations* (regulations).
- The *Interim Enforcement Policy for Pharmaceutical Waste* (policy).
- The Conditional Exclusion for State-Only Pharmaceutical Waste (exclusion).

A generator may choose to manage pharmaceutical waste under the *Dangerous Waste Regulations* or the policy. A generator may also use the conditional exclusion for state-only pharmaceutical waste [WAC 173-303-071(3)(nn)] with either the *Dangerous Waste Regulations* or the policy. Pharmaceutical waste management can be a combination of all three columns in this guide.

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 (DW) includes both RCRA hazardous waste and state-only dangerous waste unless otherwise specified.

This guide does not include all applicable dangerous waste requirements. Always refer to the *Dangerous Waste Regulations* or the policy for more detail. A generator can also call a hazardous waste specialist at their nearest Ecology Regional Office (phone numbers below). Additional requirements from other agencies may also apply.

If you need more information contact your nearest Ecology regional office:

Central Regional Office (509) 575-2490

Eastern Regional Office (509) 329-3400

Northwest Regional Office (425) 649-7000

Southwest Regional Office (360) 407-6300

Dangerous Waste Regulations – Chapter 173-303 WAC

	Requirements that Apply to All Waste Generators Chapter 173-303 WAC	Conditional Exclusion for Pharmaceutical Waste WAC 173-303-071(3)(nn)	Interim Enforcement Policy for Pharmaceutical Waste Ecology publication #07-04-024
	<p><i>This column highlights some of the requirements that apply to all dangerous waste generators in the state, including businesses that generate pharmaceutical waste.</i></p> <p><i>The Dangerous Waste Regulations can be used in combination with the conditional exclusion and the Interim Enforcement Policy for Pharmaceutical Waste in Healthcare.</i></p>	<p><i>This column highlights how waste pharmaceuticals that are state-only dangerous waste can be managed under the conditional exclusion.</i></p> <p><i>The conditional exclusion in the Dangerous Waste Regulations excludes state-only pharmaceutical waste from the regulations provided all the conditions are met.</i></p> <p><i>The conditional exclusion can be used with the Dangerous Waste Regulations or the Interim Enforcement Policy for Pharmaceutical Waste in Healthcare.</i></p>	<p><i>This column highlights the conditions necessary to receive inspector enforcement discretion from the Dangerous Waste Regulations for pharmaceutical waste.</i></p> <p><i>The policy can be used in combination with the conditional exclusion and the Dangerous Waste Regulations.</i></p>
Applicability	<ul style="list-style-type: none"> • For purposes of this publication, this column applies to any pharmaceutical waste from patient or animal care facilities and retail pharmacies. • Requirements differ by generator status: <ul style="list-style-type: none"> ○ LQG – Large Quantity Generator. ○ MQG – Medium Quantity Generator. ○ SQG¹ – Small Quantity Generator. 	<ul style="list-style-type: none"> • Pharmaceutical waste that designates as a state-only dangerous waste (WAC 173-303-100) and not a federal RCRA waste. RCRA waste must be managed as hazardous waste. • Waste that does not meet the criteria of the conditional exclusion is subject to the full requirements of the <i>Dangerous Waste Regulations</i>. • Exclusion requirements apply to all, regardless of generator status. 	<ul style="list-style-type: none"> • The Interim Enforcement Policy applies to pharmaceutical waste from patient care facilities and retail pharmacies except radioactive pharmaceutical waste, anesthesia gases, or compounding chemicals. It does not apply to non-pharmaceutical waste. • Facilities must follow the management requirements of the policy to receive enforcement discretion. Not following the policy requirements subjects the waste to the full requirements of the <i>Dangerous Waste Regulations</i>. • Policy requirements apply to all, regardless of generator status.
Waste Designation	<ul style="list-style-type: none"> • All pharmaceutical waste must be designated (WAC 173-303-070). 	<ul style="list-style-type: none"> • All pharmaceutical waste must be designated (WAC 173-303-070). 	<ul style="list-style-type: none"> • Establish a profile of all applicable waste codes and approximate quantities for pharmaceutical waste.
Notification and Identification Number	<ul style="list-style-type: none"> • RCRA ID # required for MQG and LQG facilities. 	<ul style="list-style-type: none"> • RCRA ID # required for MQG and LQG facilities. 	<ul style="list-style-type: none"> • RCRA ID # required for MQG and LQG facilities. • Send Ecology notification of use of the policy and a copy of your profile.

Dangerous Waste Regulations – Chapter 173-303 WAC

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Monthly Waste Generation Amount	<p>Monthly generation of dangerous waste affects generator status. (WAC 173-303-070(7 & 8), and -201).</p> <ul style="list-style-type: none"> • SQG – less than 2.2 lbs of acutely hazardous waste (AHW) or extremely hazardous waste (EHW, specifically WT01 waste code) and less than 220 lbs of dangerous waste (DW). • MQG –220 lbs to 2200 lbs DW. • LQG – more than 2200 lbs DW or more than 2.2 lbs of AHW or WT01. 	<ul style="list-style-type: none"> • Monthly generation of dangerous waste affects generator status. • State-only pharmaceutical waste managed under the exclusion does not count toward generator status. 	<ul style="list-style-type: none"> • Monthly generation of dangerous waste affects generator status. • Pharmaceutical waste managed under the policy does not count toward generator status.
Waste Accumulation Amount	<ul style="list-style-type: none"> • LQG – no limits. • MQG/SQG – no more than 2,200 lbs at any one time. • Refer to WAC 173-303-070(8), and -200(1),(2). 	<ul style="list-style-type: none"> • No limits for applicable pharmaceutical waste. 	<ul style="list-style-type: none"> • No limits for pharmaceutical waste.
Accumulation Time Limit	<ul style="list-style-type: none"> • LQG – 90 days. • MQG – 180 days. • SQG – no time limit. 	<ul style="list-style-type: none"> • No limits for applicable pharmaceutical waste. • Accumulation limits still apply to all other dangerous wastes. 	<ul style="list-style-type: none"> • 180 days for all pharmaceutical waste. • Accumulation limits still apply to other waste.
Accumulation Container Standards	<ul style="list-style-type: none"> • MQG/LQG – good condition, non-leaking, compatible with waste, closed/protected, 30" aisle space, response to spills, leaks and emergencies, weekly inspections, separate incompatible waste, containment system. • SQG –manage pharmaceutical waste in a way that does not pose a threat to human health and the environment. Local regulations may apply. 	<ul style="list-style-type: none"> • Manage applicable pharmaceutical waste in a way that does not pose a threat to human health and the environment. 	<ul style="list-style-type: none"> • Manage waste in a way that does not pose a threat to human health or environment. • Place absorbent material in the bottom of containers storing liquid waste. • Use containers compatible with their contents. • Do not mix incompatible wastes. • Keep accumulation containers closed unless adding or removing waste. • Have spill cleanup materials and personal protective equipment on-site. • Collect dual waste in separate containers.

Dangerous Waste Regulations – Chapter 173-303 WAC

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Container Labeling	<p>LQG / MQG:</p> <ul style="list-style-type: none"> • “Dangerous Waste.” • Major risk label (e.g., “Ignitable”, “Corrosive”, “Toxic”). • Accumulation start date. • Refer to WAC 173-303-200(1)(c),(1)(d). <p>SQGs:</p> <ul style="list-style-type: none"> • Major risk labels • Refer to WAC 173-303-070(8). 	<ul style="list-style-type: none"> • No requirements for applicable pharmaceutical waste. • Regulation requirements still apply to all other dangerous wastes. 	<ul style="list-style-type: none"> • “Non-Viable Hazardous Pharmaceutical Waste.” • “Dual waste” is a combination of pharmaceutical and infectious waste. • Major risk label (e.g., “Ignitable”, “Corrosive”, “Toxic”). • Accumulation start date. • Regulation requirements still apply to all non-pharmaceutical dangerous wastes.
Accumulation Area Inspections	<ul style="list-style-type: none"> • Must be scheduled, documented, and deficiencies corrected. • SQGs are not required to inspect. • Refer to WAC 173-303-200(1)(e),320(1),(2) (a), (b),(d),(3). 	<ul style="list-style-type: none"> • No requirements for applicable waste but highly recommended. • Regulation requirements still apply to all other dangerous wastes. 	<ul style="list-style-type: none"> • No requirements for pharmaceutical waste, but highly recommended. • Regulation requirements still apply to all other dangerous wastes.
Personnel Training	<p>Specific requirements vary by generator status.</p> <ul style="list-style-type: none"> • LQG – WAC 173-303-200(1)(e),-330. • MQG – WAC 173-303-201(2)(b). • SQG – not required WAC 173-303-070(8). 	<ul style="list-style-type: none"> • No requirements for applicable waste. • Regulation requirements still apply to all other dangerous wastes. 	<ul style="list-style-type: none"> • Appropriate training for handling of hazardous waste pharmaceuticals. • Regulation requirements still apply to all other dangerous wastes.
Disposal	<p>LQG / MQG:</p> <ul style="list-style-type: none"> • Ship to a RCRA permitted treatment, storage, disposal (TSD) facility. • Refer to WAC 173-303-200(1)(a). <p>SQG:</p> <ul style="list-style-type: none"> • Must meet disposal requirements as outlined in WAC 173-303-070(8)(b). 	<ul style="list-style-type: none"> • Incinerate state-only pharmaceuticals at either: <ul style="list-style-type: none"> ○ A permitted municipal solid waste incinerator, or ○ An incinerator meeting the following criteria: <ul style="list-style-type: none"> ▪ Heat input of more than 250 million Btu/hr. ▪ Combustion zone of more than 1500° F. • Regulation requirements still apply to all other dangerous wastes. 	<ul style="list-style-type: none"> • Ship to a RCRA permitted incinerator. • State-only pharmaceutical waste may be shipped to an incinerator that meets the exclusion criteria. • Regulation requirements still apply to all other dangerous wastes.

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<p>Empty Containers</p>	<ul style="list-style-type: none"> ● Containers are “empty” and solid waste when: <ul style="list-style-type: none"> ○ Emptied using all normal means, and ○ Contain less than 3% of container capacity, and either ○ Did not contain a pharmaceutical designating as P-listed (AHW) or WT01 (EHW), or ○ Contained a P-listed or WT01 EHW pharmaceutical and have been triple-rinsed (WAC 173-303-160). ● Since rinsing pharmaceutical containers is not practical, containers from P-listed or WT01 pharmaceuticals are usually managed as dangerous waste. ● All chemo containers should be managed as dangerous waste unless designation information shows they are not dangerous waste. ● <i>Refer to WAC 173-303-160.</i> ● Some examples of P-listed containers include used epinephrine syringes, physostigmine ampoules, and IV bags from arsenic trioxide. <p><i>Note: Normal means of emptying pharmaceutical containers include fully depressing a syringe, fully administering an IV bag, and withdrawing all the contents of a vial with a syringe.</i></p>	<ul style="list-style-type: none"> ● Containers are “empty” and solid waste when: <ul style="list-style-type: none"> ○ Emptied using all normal means, and ○ Contain less than 3% of container capacity, and either ○ Did not contain a pharmaceutical designating as P-listed (AHW) or WT01 (EHW), or ○ Contained a P-listed or WT01 pharmaceutical and have been triple-rinsed (WAC 173-303-160). ● Manage containers from pharmaceuticals designating as WT01 EHW under WAC 173-303-100 as dangerous waste or under the conditional exclusion (see Disposal). ● Ecology recommends handling all empty chemo containers as pharmaceutical waste. As a best management practice (BMP), empty chemo containers not from a P-listed compound should be sent to an incinerator under the conditional exclusion. <p><i>Note: Normal means of emptying pharmaceutical containers include fully depressing a syringe, fully administering an IV bag, and withdrawing all the contents of a vial with a syringe.</i></p>	<ul style="list-style-type: none"> ● Containers are “empty” and solid waste when: <ul style="list-style-type: none"> ○ Emptied using all normal means, and ○ Contain less than 3% of container capacity, and either ○ Did not contain a pharmaceutical designating as P-listed (AHW) or WT01 (EHW), or ○ Contained a P-listed or WT01 pharmaceutical and have been triple-rinsed (WAC 173-303-160). ● Manage all empty chemo containers as dangerous waste under the policy <u>unless</u> they are designated and segregated. <ul style="list-style-type: none"> ○ Manage P-listed containers as dangerous waste. ○ Empty chemo containers that did not carry a P-listed chemo may be sent to an incinerator under the conditional exclusion. ○ Manage containers not meeting the “empty” criteria as dangerous waste and sent to a RCRA permitted incinerator. <p><i>Note: Normal means of emptying pharmaceutical containers include fully depressing a syringe, fully administering an IV bag, and withdrawing all the contents of a vial with a syringe.</i></p>

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Waste Controlled Substances	<ul style="list-style-type: none"> ● Manifest waste controlled substances that are also hazardous waste to a RCRA permitted incinerator with Drug Enforcement Administration (DEA) registration. ● Transporter must have a RCRA transporter ID # and DEA registration. ● Disposal of dangerous waste by any other means, including sewer, sharps containers and linens, is not allowed. ● Send only viable controlled substances to reverse distributors. 	<ul style="list-style-type: none"> ● Controlled substances that designate as state-only pharmaceutical waste may be incinerated at a facility that meets the requirements of the exclusion (see Disposal) and has DEA registration. ● Transporter must be a DEA registrant. 	<ul style="list-style-type: none"> ● Waste controlled substances may be sent to either a: <ul style="list-style-type: none"> ○ DEA-registered and RCRA permitted incinerator, or ○ Reverse distributor if final disposal is at an appropriately permitted incinerator: <ul style="list-style-type: none"> ▪ Hazardous waste sent to a RCRA permitted incinerator. ▪ State-only pharmaceutical waste sent to an incinerator that meets the conditional exclusion criteria. ● Partially administered controlled substances from patient-care areas that cannot be returned to the pharmacy are only eligible for disposal to sewer with authorization from the sewer authority.
Dual Waste	<ul style="list-style-type: none"> ● Send to an incinerator permitted to accept both RCRA hazardous waste and infectious or potentially-infectious materials. ● Transporter must have a RCRA transporter ID # and meet infectious waste requirements. 	<ul style="list-style-type: none"> ● State-only dual waste may be disposed at an incinerator meeting the criteria of the exclusion and permitted to accept infectious or potentially-infectious materials (see Disposal). ● Transporter must meet infectious waste requirements. 	<ul style="list-style-type: none"> ● Send to an incinerator permitted to accept both RCRA hazardous waste and infectious or potentially-infectious materials. ● Transporter must have a RCRA transporter ID # and meet infectious waste requirements. ● State-only dual waste can be segregated and managed under the conditional exclusion.

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<p>Chemotherapy Waste</p>	<ul style="list-style-type: none"> • Send chemotherapy waste that is also dangerous waste to a RCRA permitted facility. • Manage any materials contaminated with RCRA listed chemotherapy agents (P- or U-) as RCRA hazardous waste. • Manage any materials contaminated with other chemotherapy agents as dangerous waste unless designation documentation shows they are not dangerous waste. Materials contaminated with state-only dangerous waste are eligible for the conditional exclusion. • Containers that held chemotherapy agents might be dangerous waste (see Empty Containers). • Ecology recommends following the NIOSHⁱ Alert: <i>Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings</i> (2004), www.cdc.gov/niosh/docs/2004-165/. • Label chemotherapy waste containers according to the OSHAⁱⁱ <i>Hazard Communication Standard</i> 29 CFR 1910.1200 in addition to Ecology requirements. 	<ul style="list-style-type: none"> • Waste containing chemotherapy agents designating as state-only dangerous waste can be disposed at an incinerator meeting the disposal criteria above (see Disposal). • As a BMP consider managing all bulk chemotherapy at a hazardous waste incinerator. • Containers which held chemotherapy agents that designated as WT01 must either be managed as dangerous waste or under the conditional exclusion (see Empty Containers). • Ecology recommends following the NIOSH Alert: <i>Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings</i> (2004), www.cdc.gov/niosh/docs/2004-165/. • Label chemotherapy waste containers according to the OSHA <i>Hazard Communication Standard</i> 29 CFR 1910.1200 in addition to Ecology requirements. 	<ul style="list-style-type: none"> • Dispose of all chemotherapy waste (bulk, trace and contaminated materials) at a RCRA permitted incinerator, unless the RCRA hazardous waste is designated and segregated: <ul style="list-style-type: none"> ○ Send RCRA hazardous chemotherapy waste to a RCRA permitted incinerator under the policy. ○ State-only chemotherapy waste may be sent to either a RCRA permitted incinerator under the policy or to an incinerator meeting the conditions of the exclusion [WAC 173-303-071(3)(nn)]. • As a BMP, consider managing all bulk chemotherapy waste at a RCRA permitted incinerator. • Containers that held chemotherapy agents might be dangerous waste (see Empty Containers). • Ecology recommends following the NIOSH Alert: <i>Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings</i> (2004), www.cdc.gov/niosh/docs/2004-165/. • Label chemotherapy waste containers according to the OSHA <i>Hazard Communication Standard</i> 29 CFR 1910.1200 in addition to Ecology requirements.

ⁱ National Institute of Occupational Safety and Health

ⁱⁱ Occupational Safety and Health Administration

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Contaminated Materials	<ul style="list-style-type: none"> Manage any materials contaminated with P-listed or U-listed pharmaceuticals as a listed RCRA hazardous waste. Any materials contaminated with other dangerous waste pharmaceuticals must be managed as dangerous waste unless the contaminated material designation information shows it does not designate. 	<ul style="list-style-type: none"> Materials contaminated with pharmaceuticals that do not designate as RCRA hazardous waste (<i>WAC 173-303-090</i>), are eligible to be managed under the conditional exclusion. A generator may manage contaminated materials as solid waste only when designation information shows they are not a state-only dangerous waste. 	<ul style="list-style-type: none"> Any materials contaminated with pharmaceutical waste may be managed as pharmaceutical waste under the Interim Enforcement Policy.
Reverse Distribution	<ul style="list-style-type: none"> Send only viable² pharmaceuticals to a reverse distributor. 	<ul style="list-style-type: none"> Send only viable pharmaceuticals to a reverse distributor. 	<ul style="list-style-type: none"> Send only viable pharmaceuticals to a reverse distributor. Non-viable waste controlled substances may be sent to a DEA-licensed reverse distributor if final disposal is at an appropriately permitted incinerator (see Waste Controlled Substances).
Manifest	<p>LQG / MQG:</p> <ul style="list-style-type: none"> Must use a Uniform Hazardous Waste Manifest [EPA Form 8700-22]. Refer to <i>WAC 173-303-180</i>. <p>SQG:</p> <ul style="list-style-type: none"> Bill of lading may be substituted. Refer to <i>WAC 173-303-070(8)</i>. 	<ul style="list-style-type: none"> No manifest requirements for state-only pharmaceutical waste managed under the conditional exclusion. Documentation of shipment and disposal is highly recommended. State-only pharmaceutical waste managed under the conditional exclusion does not have any waste codes. 	<ul style="list-style-type: none"> Must use a Uniform Hazardous Waste Manifest [EPA Form 8700-22] for all pharmaceutical waste managed under the policy.
Exception Reporting	<ul style="list-style-type: none"> 45 days if signed manifest is not received back from TSD. Refer to <i>WAC 173-303-220(2)</i>. 	<ul style="list-style-type: none"> No requirements for state-only pharmaceutical waste managed under the exclusion. 	<ul style="list-style-type: none"> 45 days if signed manifest is not received back from the permitted incinerator. Refer to <i>WAC 173-303-220(2)</i>.
Recordkeeping	<p>Keep the following records on-site for 5 years:</p> <ul style="list-style-type: none"> Manifests. Annual reports. Exception reports. Designation documentation. SQG – not required, but encouraged. Refer to <i>WAC 173-303-210(2),(3)(a)</i>. 	<ul style="list-style-type: none"> Not required for state-only pharmaceutical waste, but highly recommended. Records of shipment and disposal may be required to show proof of proper management under the conditional exclusion. 	<p>Keep the following records on-site for 5 years:</p> <ul style="list-style-type: none"> Manifests. Annual reports. Exception reports. Pharmaceutical waste profile. Reverse distributor receipts/invoices/credits.

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Annual Reporting	<ul style="list-style-type: none"> • Dangerous waste pharmaceutical included and counted toward generator status. • Required for all generators with a RCRA ID #. • <i>Refer to WAC 173-303-070(8)(b)(iv), -220(1).</i> 	<ul style="list-style-type: none"> • State-only pharmaceutical waste excluded from reporting and not counted toward generator status. 	<ul style="list-style-type: none"> • Exclude pharmaceutical waste managed under the policy from reporting and do not count it toward generator status.
Transportation Requirements	<ul style="list-style-type: none"> • Hazardous waste transporter required. • Transporters must have all other appropriate licenses such as: <ul style="list-style-type: none"> ○ Utilities and Transportation (UTC) ○ Department of Transportation (DOT) ○ Drug Enforcement Administration (DEA) ○ WA State Board of Pharmacy (BOP) • SQGs may ship off-site to a permitted TSD, a moderate risk waste facility, or to a permitted solid waste facility [WAC 173-303-070(8)]. 	<ul style="list-style-type: none"> • None by Ecology. • Transporters must have all other appropriate licenses such as: <ul style="list-style-type: none"> ○ UTC, DOT, DEA, and BOP 	<ul style="list-style-type: none"> • Hazardous waste transporter required. • Transporters must have all other appropriate licenses such as: <ul style="list-style-type: none"> ○ UTC, DOT, DEA, and BOP
Export Requirements	<ul style="list-style-type: none"> • Comply with EPA export requirements as required by WAC 173-303-230(1). • Recommend following World Health Organization's <i>Guidelines for Drug Donations</i>. 	<ul style="list-style-type: none"> • If incinerated out of the US, EPA export requirements as required by WAC 173-303-230(1) must be met in addition to the conditional exclusion. 	<ul style="list-style-type: none"> • Comply with EPA export requirements as required by WAC 173-303-230(1). • Recommend following World Health Organization's <i>Guidelines for Drug Donations</i>.

End Notes:

¹ SQG standards for management under WAC 173-303 can be found at <http://www.ecy.wa.gov/pubs/96404.pdf>. SQGs must designate their waste, manage it in a manner that prevents harm to human health and the environment, and dispose of pharmaceutical waste properly. SQGs choosing to manage pharmaceutical waste under the Interim Enforcement Policy must follow the management outlined in the policy to receive the enforcement discretion. Not following the management outlined in the policy subjects a facility to enforcement of the *Dangerous Waste Regulations*.

² A **non-viable pharmaceutical** is a pharmaceutical that cannot be used, sold, or returned to the manufacturer, wholesaler or reverse distributor for credit. A **viable pharmaceutical** is a pharmaceutical that can be returned to a manufacturer, wholesaler, or reverse distributor for credit. Any pharmaceutical disposed without credit is non-viable.

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.