

Dangerous Waste Pharmaceuticals Guide

A Guide for Washington Health Care Facilities



Hazardous Waste and Toxics Reduction Program Washington State Department of Ecology Olympia, Washington

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Related Information

Form ECY 070-133: <u>Notification of Dangerous Waste Site Identification (ID) Form</u>¹ Publication 20-04-010: <u>Counting Dangerous Waste Under the Dangerous Waste Regulations</u>² Publication 20-04-016: <u>Focus on: Large Quantity Generator Consolidation of Small Quantity</u> <u>Generator Dangerous Waste</u>³ Publication 21-04-022: <u>How Do I Manage My Dangerous Waste Pharmaceuticals</u>⁴ Publication 23-04-035 Focus on: Dangerous Waste Pharmaceutical Containers⁵

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¹ https://apps.ecology.wa.gov/publications/SummaryPages/ECY070133.html

² https://apps.ecology.wa.gov/publications/SummaryPages/2004010.html

³ https://apps.ecology.wa.gov/publications/SummaryPages/2004016.html

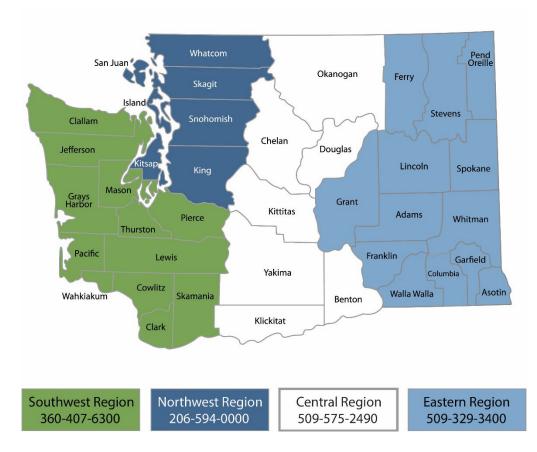
⁴ https://apps.ecology.wa.gov/publications/SummaryPages/2104022.html

⁵ https://apps.ecology.wa.gov/publications/SummaryPages/2304035.html

⁶ www.ecology.wa.gov/contact

⁷ www.ecology.wa.gov/accessibility

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Region	Counties served	Mailing Address	Phone
Southwest	Clallam, Clark, Cowlitz, Grays Harbor, Jefferson, Mason, Lewis, Pacific, Pierce, Skamania, Thurston, Wahkiakum	PO Box 47775 Olympia, WA 98504	360-407-6300
Northwest	Island, King, Kitsap, San Juan, Skagit, Snohomish, Whatcom	PO Box 330316 Shoreline, WA 98133	206-594-0000
Central	Benton, Chelan, Douglas, Kittitas, Klickitat, Okanogan, Yakima	1250 W Alder St Union Gap, WA 98903	509-575-2490
Eastern	Adams, Asotin, Columbia, Ferry, Franklin, Garfield, Grant, Lincoln, Pend Oreille, Spokane, Stevens, Walla Walla, Whitman	4601 N Monroe Spokane, WA 99205	509-329-3400
Headquarters	Across Washington	PO Box 47600 Olympia, WA 98504	360-407-6000

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Acronyms and Definitions

Acronyms and Abbreviations

Acronym	Meaning	
DEA	United States Drug Enforcement Agency	
DW	Dangerous waste	
Ecology	Washington State Department of Ecology	
EPA	United States Environmental Protection Agency	
MQG	Medium quantity generator	
QEL	Quantity exclusion limit	
RCRA	Resource Conservation and Recovery Act	
SQG	Small quantity generator	
USDOT	United States Department of Transportation	

Definitions

Term	Meaning	
Acute hazardous waste	Dangerous waste sources ⁸ F020, F021, F022, F023, F026, or F027, and discarded chemical products ⁹ that are identified with a dangerous waste number beginning with a "P," including those wastes mixed with source, special nuclear, or by-product material subject to the Atomic Energy Act of 1954.	
Control	The power to direct the policies of the generator, whether by the ownership of stock or voting rights. Contractors, consultants, and transporters who operate generator facilities on behalf of a different person, as defined in this section, shall not be deemed to control such generators.	
Extremely	Those dangerous and mixed wastes designated in WAC 173-303-100 as	
hazardous waste	extremely hazardous.	
Health care	Any person that is lawfully authorized to:	
facility	• Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or	
	• Distribute, sell, or dispense pharmaceuticals, including over-the- counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.	
	This definition includes, but is not limited to, wholesale distributors, third- party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services,	

⁸ Listed in WAC 173-303-9904.

⁹ Listed in WAC 173-303-9903.

Term	Meaning	
	pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals.	
	This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistic centers.	
Long-term care facility	A licensed entity that provides assistance with activities of daily living, medication administration to one or more individuals at the facility. The definition includes, but is not limited to hospice facilities, nursing facilities skilled nursing facilities, and the skilled nursing care portions of continuing care retirement communities.	
	Not included are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.	
Noncreditable dangerous waste pharmaceutical	A prescription dangerous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit, or a nonprescription dangerous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.	
	This includes, but is not limited to, drugs pertaining to an investigation, free samples of pharmaceuticals received by health care facilities, residue of pharmaceuticals remaining in empty containers, pharmaceutical-contaminated personal protection equipment, floor sweepings, and clean-up materials from the spills of pharmaceuticals.	
Person	An individual, trust, firm, joint stock company, federal agency, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, or any interstate body.	
Potentially creditable dangerous waste pharmaceutical	A prescription dangerous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is in original manufacturer packaging, ¹⁰ undispensed, and unexpired or less than one year past expiration date.	
	This term does not include evaluated dangerous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over the- counter drugs, homeopathic drugs, and dietary supplements.	
Quantity Exclusion Limit	The quantity of dangerous waste generated in a calendar month used to distinguish when a dangerous waste is only subject to the small quantity generator provisions, the medium quantity generator provisions, or when a dangerous waste is subject to the large quantity generator provisions.	
State-only dangerous waste pharmaceutical	Dangerous waste pharmaceutical that only exhibits a state criteria under WAC 173-303-100.	

¹⁰ This does not include pharmaceuticals that were subject to a recall.

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Introduction

This guide outlines the basic requirements for health care facilities managing dangerous waste pharmaceuticals in Washington state.

Health care facilities must comply with the state's <u>Dangerous Waste Regulations</u>.¹¹ Ecology's rule, **WAC 173-303-555: Special requirements for the management of dangerous waste pharmaceuticals** (special requirements), went into effect in October 2020.



These special requirements for health care facilities are based on federal management standards for hazardous waste pharmaceuticals.¹² However, there are two significant differences:

- We include state-only dangerous waste pharmaceuticals in addition to U.S. Environmental Protection Agency (EPA) hazardous waste pharmaceuticals.
- We require long-term care facilities¹³ to determine if the special requirements apply to them based on the amount of dangerous waste they generate.

See additional guidance on our managing pharmaceutical waste webpage.¹⁴

The special requirements do not apply to:

- Nonpharmaceutical dangerous waste generated by the health care facility.
- Pharmaceuticals that are legitimately used, reused, donated, or reclaimed—including over-the-counter pharmaceuticals.
- Pharmaceutical waste from households.

WAC 173-303-555¹⁵ lists the special requirements for managing dangerous waste pharmaceuticals.

¹¹ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303

¹² 40 Code of Federal Regulations Part 266 Subpart P, also known as RCRA Subpart P.

¹³ EPA defines long-term care facilities with fewer than 20 beds as small quantity generators.

¹⁴ https://ecology.wa.gov/PharmaWaste

¹⁵ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

Facilities Affected by the Special Requirements

The special requirements only apply to health care facilities that provide preventative, diagnostic, therapeutic, rehabilitative, or palliative care to improve the physical or mental condition of humans and animals, or who sell or distribute pharmaceuticals. Health care facilities include:

- Hospitals and clinics
- Doctor's offices
- Dental clinics
- Veterinary clinics
- Pharmacies

- Retal stores and warehouses who sell pharmaceuticals
- Long-term care facilities
- Ambulance services
- Outpatient surgery centers
- Vape retailers
- Medical clinics within larger facilitie
- K-12 schools and universities

WAC 173-303-555(1)¹⁶ defines the term health care facility.

Do the special requirements apply?

The special requirements relating to the sewer prohibition and empty containers apply to **all health care facilities**, regardless of the amount of waste generated. Read more about them in the <u>requirements for all health care facilities</u> section.

You must count both your dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste **each month** to determine if these special requirements apply to your facility.

If you are below the following thresholds, the requirements are optional:

- Less than or equal to 2.2 pounds of dangerous waste with a quantity exclusion limit (see <u>definitions section</u>) (QEL) of 2.2 pounds, and
- Less than or equal to 220 pounds of dangerous waste with a QEL of 220 pounds, and
- Less than or equal to 220 pounds of residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any dangerous waste with a QEL of 2.2 pounds.

Then you can choose either:

- **Option 1:** Manage your dangerous waste pharmaceuticals under these special requirements.
- **Option 2:** Manage all dangerous waste under the requirements applicable to small quantity generators.¹⁷

¹⁶ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

¹⁷ See small quantity generators requirements in WAC 173-303-170(2)(a)(i) and WAC 173-303-171 (https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-170 and https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-171).

Dangerous wastes with a 2.2-pound QEL include P-listed acute hazardous waste and WT01 extremely hazardous waste. Wastes with a 220-pound QEL include U-listed wastes as well as characteristic and state-only dangerous wastes.

Learn more on our <u>Washington state-only criteria webpage</u>.¹⁸ For a visual representation, see our <u>How Do I Manage My Dangerous Waste Pharmaceuticals</u>? flowchart.¹⁹ See examples of dangerous waste pharmaceuticals on the <u>common pharmaceutical wastes webpage</u>.²⁰

WAC 173-303-070²¹ provides designation requirements for all generators of dangerous waste.

What is your generator category under the special requirements?

If the special requirements for pharmaceutical waste apply to your facility, only count nonpharmaceutical dangerous waste to determine your generator category. The management requirements for nonpharmaceutical dangerous waste are based on your generator category.²²

Quantity of nonpharmaceutical dangerous waste with a monthly QEL* of 2.2 pounds	Quantity of nonpharmaceutical dangerous waste with a monthly QEL of 220 pounds	Quantity of residue from a cleanup of nonpharmaceutical dangerous waste with a monthly QEL of 2.2 pounds	Generator Category
Greater than 2.2 pounds	Any amount	Any amount	Large quantity generator
Any amount	Greater than or equal to 2,200 pounds	Any amount	Large quantity generator
Any amount	Any amount	Greater than 220 pounds	Large quantity generator
Less than or equal to 2.2 pounds	Greater than 220 pounds and less than 2,200 pounds	Less than or equal to 220 pounds	Medium quantity generator
Less than or equal to 2.2 pounds	Less than or equal to 220 pounds	Less than or equal to 220 pounds	Small quantity generator

Table 1: Generator category under the special requirements.

*Quantity exclusion limit (QEL)²³ is the quantity of dangerous waste generated in a calendar month.

WAC 173-303-170(10) and (11)²⁴ define applicability requirements for health care facilities.

¹⁸ https://ecology.wa.gov/StateOnlyDW

¹⁹ https://apps.ecology.wa.gov/publications/SummaryPages/2104022.html

²⁰ https://ecology.wa.gov/RCRA-waste-codes

²¹ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-070

²² http://ecology.wa.gov/GeneratorCategory

²³ Quantity exclusion limits are defined in WAC 173-303-169.

²⁴ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-170

Examples of health care facilities with special requirements

Alpha Hospital

Alpha Hospital generated the following dangerous waste this month:

- 40 pounds of dangerous waste pharmaceuticals (including 3 pounds of P042 – epinephrine waste with a QEL of 2.2 pounds).
- 70 pounds of spent solvent from laboratories.
- 15 pounds of glutaraldehyde from sterilizing equipment.
- 10 pounds of paint waste from building maintenance.



This hospital **must** manage all dangerous waste pharmaceuticals under the special requirements because it generated more than 2.2 pounds of dangerous waste with a QEL of 2.2 pounds.

When Alpha Hospital counts nonpharmaceutical waste (70 pounds + 15 pounds + 10 pounds), its final generator category is small quantity generator (SQG). It must manage nonpharmaceutical dangerous waste from the laboratories, sterilizing, and maintenance under the SQG standards in the Dangerous Waste Regulations.

Alpha Hospital is deactivating their waste glutaraldehyde on site under the <u>treatment by</u> <u>generator</u>²⁵ guidelines. They must maintain a treatment log and report this activity on their Site ID form.

Beta Hospital

Beta Hospital generated the following dangerous waste this month:

- 40 pounds of dangerous waste pharmaceuticals (including 1 pound of dangerous waste pharmaceuticals with a QEL of 2.2 pounds).
- 200 pounds of spent solvent from laboratories.
- 15 pounds of glutaraldehyde from sterilizing equipment.
- 10 pounds of paint waste from building maintenance.

This hospital **must** manage all dangerous waste pharmaceuticals under the special requirements because it generated more than 220 pounds when it counted all its dangerous waste with a QEL of 220 pounds.

When Beta Hospital counts just nonpharmaceutical waste (200 pounds + 15 pounds + 10 pounds), its final generator category is medium quantity generator (MQG). It must manage

²⁵ https://ecology.wa.gov/DW-treatment-by-generator

nonpharmaceutical dangerous waste from the laboratories, sterilizing, and maintenance under the MQG standards in the Dangerous Waste Regulations.

Gamma Clinic

Gamma Clinic generated the following dangerous waste this month:

- 40 pounds of dangerous waste pharmaceuticals (including 1 pound of dangerous waste pharmaceuticals with a QEL of 2.2 pounds).
- 5 pounds of aerosol cans.
- 10 pounds of expired cleaning solutions.
- 20 pounds of glutaraldehyde from sterilizing equipment.



When Gamma Clinic counts all its dangerous waste (40 pounds + 5 pounds + 10 pounds + 20 pounds), its generator category is small quantity generator (SQG). Gamma Clinic has the **option** to manage dangerous waste pharmaceuticals under the special requirements or under the SQG standards in the Dangerous Waste Regulations.

Small quantity generator health care facilities

Health care facilities that are small quantity generator (SQG) after counting both dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste have two options.

Option 1

Manage dangerous waste pharmaceuticals under all the special requirements found in <u>WAC 173-303-555</u>.²⁶

Manage **nonpharmaceutical dangerous waste** under the SQG regulations in WAC 173-303-170(2)(a)(i)²⁷ and -171.²⁸

Long-term care facilities that are SQGs have the option to manage their dangerous waste pharmaceuticals in an onsite collection receptacle as authorized by the U.S. Drug Enforcement Administration (DEA) in WAC 173-303-555(5)(c).²⁶

Option 2

Manage dangerous waste pharmaceuticals and nonpharmaceutical dangerous waste under the SQG regulations.²⁹

²⁶ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

²⁷ https://app.leg.wa.gov/wac/default.aspx?cite=173-303-170

²⁸ https://app.leg.wa.gov/WAC/default.aspx?cite=173-303-171

²⁹ Found in WAC 173-303-170(2)(a)(i) and WAC 173-303-171. See them online at

https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-170 and

https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-171, respectively.

SQGs can still take advantage of:

- Options for SQGs found in <u>WAC 173-303-555(5)</u>.³⁰
- The conditional exemption for controlled substances found in WAC 173-303-555(7).³⁰

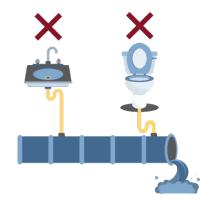
WAC 173-303-170(2)(a)(i)³¹ and -171³² list requirements for small quantity generators. WAC 173-303-555(5)³⁰ lists options available for SQGs.

Special requirements for all health care facilities

No sewer disposal for dangerous waste pharmaceuticals

Dangerous waste pharmaceuticals cannot be discharged into any sewer system that passes through a publicly owned treatment works.

Health care facilities cannot dispose of any dangerous waste into septic tanks.



WAC 173-303-555(6)³⁰ prohibits sewer disposal of dangerous waste pharmaceuticals by any health care facility.

Empty containers



You must determine if dangerous waste pharmaceutical containers are empty to ensure proper disposal. Once empty, they can be disposed as solid waste. If they are not empty, they may be designated a dangerous waste pharmaceutical.

Table 2 explains how to determine if each type of container is empty or not empty. For additional guidance review our Focus on: Dangerous Waste Pharmaceutical Containers publication.³³

³⁰ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

³¹ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-170

³² https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-171

³³ https://apps.ecology.wa.gov/publications/SummaryPages/2304035.html

Table 2: How types of containers are determined as empty or not empty.			
Container type	Examples	Container is empty and solid waste when:	Container is not empty. May be dangerous waste pharmaceuticals when:
Syringe	 Epinephrine syringe 	 Contents are fully administered Plunger is fully depressed 	 Contents are only partially administered Note: the remaining contents may be squirted into a dangerous waste container so the syringe is solid waste.
Vials and ampules—less than 1 liter	 Single-dose lidocaine 	 Contents are completely removed 	 Contents are only partially removed
Bottles—less than 1 liter or 10,000 pills	 Warfarin pill bottle Barium contrast agent 	 All pills are removed (dispensed or collected as waste) All liquids are poured out of the bottle (for use or collected as waste) 	Medication remains inside bottle
Unit-dose containers	 Blister packs Paper cups Prepackaged medications 	 Contents are dispensed 	Medication remains inside of container
Unit-dose delivery devices	 Patches Epinephrine auto-injectors 	 Patches are applied to the patient 	 Open, but doses not administered Expired devices Used epinephrine auto- injectors are never fully empty
Intravenous (IV) bags	ChemotherapyAntibiotics	 Contents are fully administered 	Bag is partially administered
Inhalers	Aerosol inhalers	 It meets the definition of empty in WAC 173- <u>303-160(2)</u>³⁴ 	 It does not meet the definition of empty in <u>WAC 173-303-</u> <u>160(2)³⁴</u>
Tubes of gels, creams, and ointments	Hydrocortisone cream	 It meets the definition of empty in WAC 173- <u>303-160(2)</u>³⁴ 	 It does not meet the definition of empty in <u>WAC 173-303-</u> <u>160(2)</u>³⁴
Nebulizers	 Asthma nebulizer 	 It meets the definition of empty in <u>WAC 173-</u> <u>303-160(2)³⁴</u> 	 It does not meet the definition of empty in WAC 173-303- <u>160(2)</u>³⁴
Aerosol cans	 Foot fungal spray 	 It meets the definition of empty in WAC 173- <u>303-160(2)</u>³⁴ 	 It does not meet the definition of empty in WAC 173-303- <u>160(2)</u>³⁴

Table 2: How types of containers are determined as empty or not empty.

WAC 173-303-555(8)³⁵ includes additional descriptions about pharmaceutical containers' status as empty or not empty.

³⁴ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-160

How to manage noncreditable dangerous waste pharmaceuticals under the special requirements

This section outlines the basic requirements for health care facilities managing noncreditable dangerous waste pharmaceuticals under the special requirements in <u>WAC</u> <u>173-303-555</u>.³⁶ It does not include all of the requirements or different management options that may be available under the <u>dangerous waste regulations</u>.³⁷ You can always check the regulations or call a hazardous waste specialist at your <u>regional office</u>³⁸ for more information.

If you are a small quantity generator opting into the special requirements, you must follow all the requirements in WAC 173-303-555.

Notification

If your facility is following these special requirements, you must <u>notify Ecology</u>³⁹ within 60 days of being subject to the special requirements. If you do not already have an EPA/State Identification (ID) number, you must apply for one.

Small quantity generator notification requirements

If you are a small quantity generator managing all of your dangerous waste under the SQG requirements, your facility's generator category may change from one month to the next. If your category increases—even just for one month—you become subject to the special requirements. This means you must notify us within 60 days and obtain an EPA/State ID number if you do not already have one.

Annual reporting

All facilities with an active EPA/State ID number are required to file a <u>dangerous waste annual</u> <u>report</u>⁴⁰ by March 1 for the previous year. Dangerous waste pharmaceuticals managed under the special requirements do not need to be included on your annual report. You can withdraw from the special requirements once your facility is no longer subject to WAC 173-303-555.

Training

Your facility must train personnel managing dangerous waste pharmaceuticals. Training must be relevant to the responsibilities for each position.

WAC 173-303-555(3)(b)⁴¹ details training requirements for positions managing dangerous waste pharmaceuticals.

³⁶ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

³⁷ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303

³⁸ https://ecology.wa.gov/Contact

³⁹ https://ecology.wa.gov/DWNotification

⁴⁰ https://ecology.wa.gov/DWReport

⁴¹ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

Container management

Noncreditable dangerous waste pharmaceuticals must be:

- Secured to prevent unauthorized access.
- Stored in containers that are:
 - Closed when not in use.
 - Structurally sound and non-leaking.
 - Compatible with the contents.
 - Labeled or marked "Hazardous Waste Pharmaceuticals" or "Dangerous Waste Pharmaceuticals."
 - Labeled or marked with the date the contents first became waste. Records can also be used to document waste has been on site less than one year.



Health care facilities must immediately respond to <u>dangerous waste</u> <u>pharmaceutical spills</u>.⁴²

WAC 173-303-555(3)(d)⁴³ details the container standards for health care facilities managing dangerous waste pharmaceuticals.

Shipments

Your facility may accumulate noncreditable dangerous waste pharmaceuticals on site for one year or less.

When it is time to ship the waste, noncreditable dangerous waste pharmaceuticals must go to a RCRA permitted treatment, storage, or disposal facility unless you are using the alternate disposal options under -555(7) or (10). The special requirements outline specific packaging requirements following U.S. Department of Transportation (USDOT) regulations.

When using a Uniform Hazardous Waste Manifest to document shipments of noncreditable dangerous waste pharmaceuticals, you must put the letters "PHRM" on the manifest instead of waste codes.

WAC 173-303-555(9)⁴³ details the requirements for shipping noncreditable dangerous waste pharmaceuticals.

Recordkeeping

The recordkeeping requirements for noncreditable dangerous waste pharmaceuticals are the same as other dangerous waste. Keep all records for at least five years after the waste is disposed. Your records must be available if an Ecology inspector requests them.

⁴² https://ecology.wa.gov/Report-a-spill

⁴³ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

Records include:

- Notifications and withdrawals. See the <u>notification</u> section for guidance about this.
- Waste determination results.
- Manifest records for disposal of noncreditable dangerous waste pharmaceuticals.
- Manifests or other shipping records for disposal of:
 - Potentially creditable dangerous waste pharmaceuticals.
 - State-only dangerous waste pharmaceuticals managed under -555(10) and the authorization letter for alternate incinerator disposal.

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- Waste controlled substance.
- Dangerous waste pharmaceuticals and potentially creditable dangerous waste pharmaceuticals received from off-site small quantity generators. See the <u>consolidating</u> waste pharmaceuticals from small quantity generators section for guidance about this.
- Potentially creditable dangerous waste pharmaceuticals sent to a reverse distributor. See the <u>potentially creditable dangerous waste pharmaceuticals</u> section for guidance.

WAC 173-303-210⁴⁴ and WAC 173-303-555(3), (4), (9), (10), and (11)⁴⁵ detail generator recordkeeping requirements for dangerous waste pharmaceuticals.

Consolidating waste pharmaceuticals from small quantity generators

A health care facility may consolidate waste pharmaceuticals from off-site small quantity generator health care facilities that manage their pharmaceuticals under <u>Option 2</u> when:

- All facilities involved:
 - Are under the control of the same person (see definition section), or
 - Have a contractual or business relationship where the receiving facility supplies pharmaceuticals to the small quantity generator.
- The receiving health care facility follows the special requirements for management of dangerous waste pharmaceuticals.
- The receiving health care facility keeps records of shipments received for 5 years after disposal of the waste.

<u>WAC 173-303-555(3)(o) and (4)(b)</u>⁴⁵ details the rules for consolidating dangerous waste pharmaceuticals from small quantity generators under the special requirements.

⁴⁴ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-210

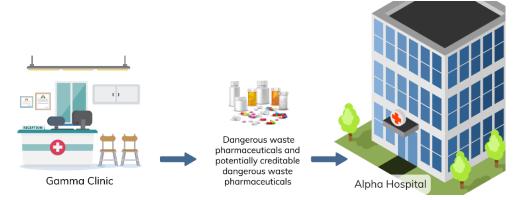
⁴⁵ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

Examples of consolidating dangerous waste pharmaceuticals under the special requirements

Clinics and associated hospitals

Gamma Clinic operates the outpatient clinics for Alpha Hospital and they are both part of the same system. Because Gamma Clinic is a small quantity generator after counting all its dangerous waste (including pharmaceuticals) and has chosen to manage under Option 2:

- Alpha Hospital can consolidate Gamma Clinic's noncreditable dangerous waste pharmaceuticals.
- Alpha Hospital must manage all the small quantity generator dangerous waste pharmaceuticals under the special requirements.
- Gamma Clinic can also send its potentially creditable dangerous waste pharmaceuticals to Alpha Hospital to consolidate and send to a reverse distributor.



Long-term care facilities and supplying pharmacies

Many long-term care facilities have a contractual relationship with a pharmacy in which the pharmacy supplies many of the pharmaceuticals for the facility's residents.

If a long-term care facility is a small quantity generator, it can send its noncreditable and potentially creditable dangerous waste pharmaceuticals to its contracted pharmacy for management under Washington's special requirements or RCRA subpart P, if the pharmacy is located outside of Washington state.

Controlled Substances

Controlled substances that are collected, stored, transported, and disposed in compliance with all applicable DEA regulations are conditionally exempt from most of the special requirements.

Containers used to manage controlled substances **must** be incinerated at an allowed facility⁴⁶ unless DEA provides you with written approval that the treatment system meets the destruction standards in the Controlled Substances Act.



Ecology recommends segregating controlled substances from other dangerous waste pharmaceuticals. Controlled substances accumulated in the same container with other dangerous waste pharmaceuticals are not exempt and must be managed as dangerous waste pharmaceuticals under the special requirements.

<u>WAC 173-303-555(7)</u>⁴⁷ defines the conditional exemption for dangerous waste controlled substances, including a list of the type of facilities where controlled substances may be managed.

Washington state-only dangerous waste pharmaceuticals

State-only dangerous waste pharmaceuticals may be sent to alternate combustion facilities as listed in WAC 173-303-555(7)(b)(iii). This option is available to health care facilities following the special requirements.

Health care facilities must:

e counted toward the applicability of the special requirements.

State-only dangerous waste

pharmaceuticals must be

- Segregate RCRA hazardous waste pharmaceuticals for disposal at a permitted treatment, storage and disposal facility.
- Maintain shipping records for at least 5 years.
- Have a letter from the local regulatory or permitting authority that confirms the final facility may accept the waste. This letter must be available for review upon request.

WAC 173-303-555(10)⁴⁷ details the disposal options for state-only dangerous waste pharmaceuticals.

⁴⁷ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

⁴⁶ Refer to WAC 173-303-555(7)(b) to see criteria for facilities that can incinerate your controlled substance treatment residue.

Potentially creditable dangerous waste pharmaceuticals

You may send potentially creditable dangerous waste pharmaceuticals to reverse distributors. You must have a reasonable expectation of credit. Do not send noncreditable dangerous waste pharmaceuticals to a reverse distributor.

It is your responsibility to verify that your reverse distributor:

- Has an active EPA/State ID Number, and
- Is regulated under:
 - o <u>WAC 173-303-555</u>,⁴⁸
 - RCRA subpart P, or

Small quantity generator health care facilities may send potentially creditable dangerous waste pharmaceuticals for consolidation at an affiliated health care facility (see <u>consolidating waste</u> pharmaceuticals section).

• Equivalent out-of-state dangerous waste pharmaceuticals regulations.

WAC 173-303-555(4) and (5)⁴⁸ defines standards for health care facilities managing potentially creditable dangerous waste pharmaceuticals.

Shipping potentially creditable dangerous waste pharmaceuticals

If your facility uses a reverse distributor for potentially creditable dangerous waste pharmaceuticals, you must keep paper or electronic records for each shipment for at least five years from the date of shipment. The records must:

- Confirm delivery.
- Be prepared according to USDOT regulation 49 C.F.R. Part 172, Subpart P, when applicable.
- Be readily available upon request by a compliance inspector.

Reverse distributors must confirm receipt of delivery of the potentially creditable dangerous waste pharmaceuticals shipment. If you do not receive confirmation within 35 calendar days, you must contact the carrier and the receiving facility to determine the status.

<u>WAC 173-303-555(11)</u>⁴⁸ defines the standards for health care facilities shipping potentially creditable dangerous waste pharmaceuticals to a reverse distributor.



⁴⁸ https://apps.leg.wa.gov/WAC/default.aspx?cite=173-303-555

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