



RCRA Pharmaceutical Hazardous Wastes

Department of Environmental Protection
Division of Air Quality





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Disclaimer: While every effort to ensure the accuracy of the information in the pamphlet has been made, the information provided in this pamphlet is a summary of pharmaceutical wastes and is not a comprehensive list of RCRA requirements. The information is provided on an “as is” basis with no guarantee of completeness. The DAQ assumes no responsibility or liability for any errors or omissions in the content of this pamphlet. This pamphlet is not meant to replace the full RCRA rule citations.

For additional information, access CFR 40 Parts 239 through 282, as it will have the full extent of RCRA Requirements.

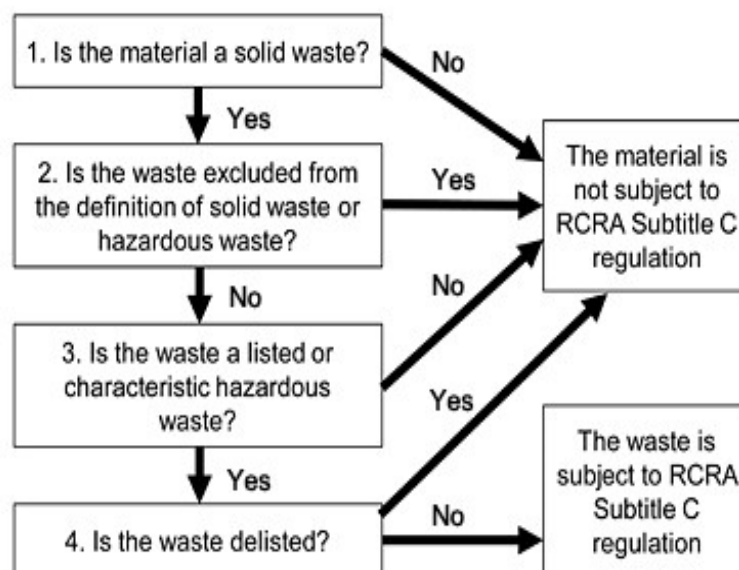
What are Pharmaceutical Hazardous Wastes?

Hazardous waste is defined as waste with properties that make it capable of having a harmful effect on either human health or the environment. The Resource Conservation and Recovery Act (RCRA) created the framework for a Cradle-to-Grave hazardous waste management program. Hazardous pharmaceutical waste is defined as a solid waste.

A solid hazardous waste can be characterized as being a solid, liquid, sludge, or compressed gas. A pharmaceutical (including over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs) is not classified as a hazardous waste if it is legitimately used/reused or reclaimed.

There are 4 lists that have defined certain wastes as hazardous, however, only P- and U-Listed hazardous wastes apply to hazardous pharmaceutical wastes. A complete list of P- and U-listed chemicals can be found using 40 CFR section 261.33.

The Hazardous Waste Identification Process





40 CFR Part 266, Subpart P



Under previous requirements, any facility that generates hazardous waste pharmaceuticals was subject to the RCRA hazardous waste generator regulations. These regulations vary depending on the total amount and type of hazardous waste generated at the site in a calendar month. Many healthcare facilities are considered large quantity generators (LQGs) because they generate more than 1 kilogram (kg) of acute hazardous waste per month. Under the final management standards, generators of hazardous pharmaceutical wastes will manage their hazardous waste pharmaceuticals under 40 CFR part 266, subpart P instead of the standard RCRA generator regulations found in 40 CFR part 262. Participation in subpart P is **mandatory for LQG and SQG**. Compared to the hazardous waste generator regulations, healthcare facilities operating under the new standards will have the following benefits:

- ❖ A healthcare facility will not be a LQG, with all the associated requirements, when it generates more than 1 kg of acute hazardous waste pharmaceuticals in a month;
- ❖ A healthcare facility will not have to comply with the satellite accumulation area regulations, which are a poor fit for healthcare facilities;
- ❖ A healthcare facility will not need to specify hazardous waste codes on manifests;
- ❖ A healthcare facility will be able to accumulate hazardous waste pharmaceuticals on-site without a RCRA permit for 365 days, an increase of 275 days over the current generator regulations; and
- ❖ A healthcare facility will have basic training requirements.

U-Listed Pharmaceutical Wastes

U- listed wastes are designated hazardous waste if they meet the following 3 criteria:

- ❖ The waste must contain one of the chemicals listed on the U list;
- ❖ The chemical in the waste must be unused; and
- ❖ The chemical in the waste must be in the form of a commercial chemical product.

Both P- and U-listed chemicals are defined by the EPA as hazardous when the chemical is either 100 percent pure, technical (e.g., commercial) grade or the sole active ingredient in a chemical formulation. **U-listed wastes differ from P-listed, as P-listed wastes are acute wastes.**

Material	Code	Use
Acetone	U002	Solvent in pharmaceutical formulations
Acetyl Chloride	U006	Cholesterol testing
Mitomycin C	U010	Chemotherapy, antineoplastic
Azaserine	U015	Antifungal, antineoplastic
Chlornaphazin	U026	Antineoplastic
BN-butyl alcohol	U031	Bactericide, pharmaceutical manufacturing, pain control, anti-hemorrhagic
Chloral Hydrate	U034	Cough syrups, sleeping pills, sedative
Chlorambucil	U035	Chemotherapy
P-Chloro-m-Cresol	U039	Antiseptic
2-Chloroethyl Vinyl Ether	U042	Anesthetics and sedatives manufacture

U-Listed Pharmaceutical Wastes Cont.

Material	Code	Use
Cresylic acid	U052	Antiseptics, disinfectants
Cyclophosphamide	U058	Chemotherapy, antineoplastic
Daunomycin	U059	Chemotherapy, antineoplastic
Dichlorodifluoromethane	U075	Propellant in oral, nasal & inhalation aerosols treating asthma & COPD
Diethylstilbestrol	U089	Chronic myelogenous leukemia (CML), and Kaposi's sarcoma.
Ethyl Acetate	U112	Drug flavoring agent, topical anesthetic, in the pharmaceutical industry as an extraction solvent in the production of pharmaceuticals
Ethylene Oxide	U115	Surgical instrument sterilant
Ethyl Ether	U117	Disinfectant, anesthetic
Thiourea	U219	An antithyroid compound & lab research
Trichloromonofluoromethane	U121	Aerosol propellant in topical sprays
Formaldehyde	U122	Antiseptic, disinfectant, preservative
Formic Acid	U123	Diuretic, heart and muscle treatment
Lindane	U129	Scabicide, lice
Hexachlorophene	U132	Topical anti-infective anti-bacterial; surgical scrub.
Cacodylic Acid	U136	Dermatologic
Methanol	U154	Solvent in pharmaceutical manufacture, etc.
Melphalan	U150	Chemotherapy, antineoplastic
Mercury	U151	Dental amalgam, devices (thermometers)

U-Listed Pharmaceutical Wastes (Cont.)

Material	Code	Use
3- Methylchloranthrene	U157	Cancer research
Methylthiouracil	U164	Thyroid inhibitor
Naphthalene	U165	Antiseptic, anthelmintic
Paraldehyde	U182	Sedative, hypnotic
Phenol	U188	Antiseptic, anesthetic, antipruritic
Reserpine	U200	Treatment of high blood pressure
Resorcinol	U201	Treatment of acne, eczema, psoriasis, seborrhea, corns, callouses, warts & more.
Saccharin	U202	Sugar substitute, food preparation
Selenium dioxide	U204	Treatment of Selenium dioxide deficiency; alternative medicine use for
Selenium sulfide	U205	Hashimoto's thyroiditis & high cholesterol.
Streptozotocin	U206	Chemotherapy Streptozotocin, antineoplastic
Bromoform	U225	Sedative, hypnotic, antitussive
Uracil mustard	U237	Chemotherapy
Warfarin < 0.3%	U248	Anticoagulant
3- Methylchloranthrene	U157	Cancer research
Methylthiouracil	U164	Thyroid inhibitor
Naphthalene	U165	Antiseptic, anthelmintic
Paraldehyde	U182	Sedative, hypnotic
Phenol	U188	Antiseptic, anesthetic, antipruritic
Reserpine	U200	Treatment of high blood pressure
Resorcinol	U201	Treatment of acne, eczema, psoriasis, seborrhea, corns, callouses, warts & more.
Saccharin	U202	Sugar substitute, food preparation
Selenium dioxide	U204	Treatment of Selenium dioxide deficiency; alternative medicine use for

P-Listed Pharmaceutical Wastes

P-listed wastes have the same criteria as U-listed wastes. However, P-listed wastes are acute hazardous wastes from discarded commercial chemical products.

Material	Code	Use
Warfarin >0.3%	P001	Blood thinner
Dalfampridine (4-aminopyridine)	P008	Multiple sclerosis
Arsenic Acid	P010	Chemotherapy
Arsenic Trioxide	P012	Chemotherapy
Arsenic	P012	veterinary medicine, severe parasitic diseases
Epinephrine	P042	Emergency allergy kits, certain types of glaucoma, eye surgery, cardiac arrest
Diisopropylfluorophosphate	P043	Treatment of chronic glaucoma; also veterinary use & experimental neuroscience
Phentermine	P046	Appetite suppressant
Benzeneethanamine, alpha,	P046	Methamphetamine. Appetite suppressant to manage obesity.
alpha-dimethyl-Nitroglycerin	P075	Smoking cessation, nicotine patches, etc.
	P081	Coronary vasodilator in angina treatment
Octamethylpyrophosphoramidate	P085	Treatment of myasthenia gravis
Phenylmercury acetate	P092	Bactericide, pharmaceutical aid in contact lens solutions and nasal sprays
Potassium Silver Cyanide	P099	Bactericide
Strychnine	P108	Veterinary tonic and stimulant
Physostigmine Salicylate	P188	Acholinergics (liberates/acts like acetylcholine)
Physostigmine	P204	Acholinergics (liberates/acts like acetylcholine)



Drug Sequestration Unit



A sequestration unit is an alternative unused pharmaceutical disposal method. Drug sequestration units are often marketed to hospitals for the collection of leftovers, partially administered pharmaceuticals EPA recommends that healthcare facilities take a conservative approach by when disposing of pharmaceutical wastes. Sequestration units may not be put in the trash. The unit must be disposed of using hazardous waste combustors for treatment, then sent to a hazardous waste landfill for disposal.

Additional Links

Information drug sequestration units:

<https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#h4>

Information on pill neutralizer tablets: <https://www.webmd.com/drugs/2/drug-21733/neutralize-oral/details>

Information on reverse distribution: <https://www.fдли.org/2022/03/reverse-distribution-serving-public-health-under-range-of-state-rules/>

EPA pharmaceutical hazardous wastes final rule:

<https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>

EPA Blueprint Guide

https://www.epa.gov/system/files/documents/2022-10/10_step_blueprint_guide_final_9-22.pdf

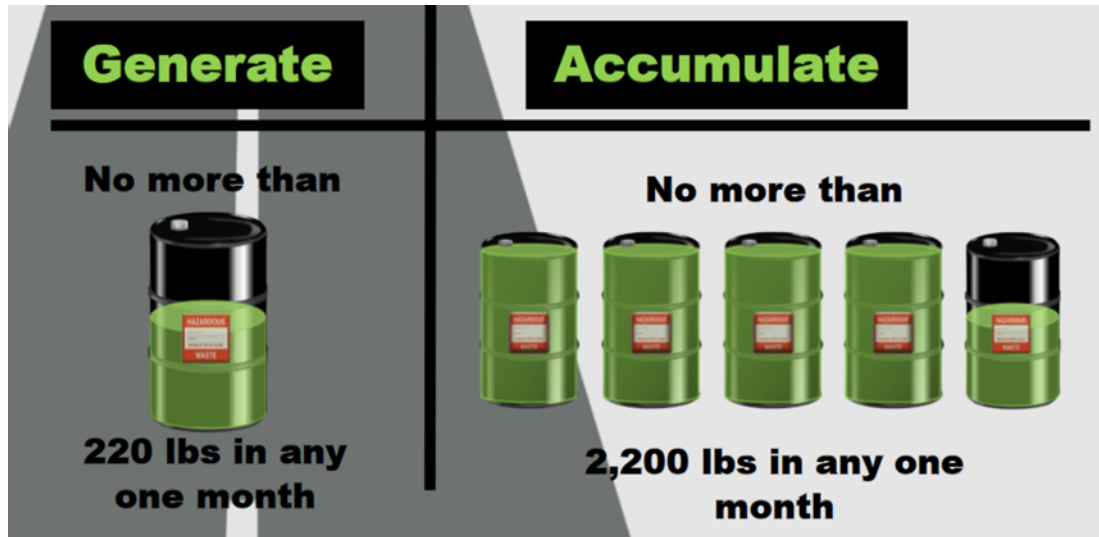
McCoy's White Paper

<https://www.mccoysseminars.com/library/rcra/wp/HWPharma.pdf>

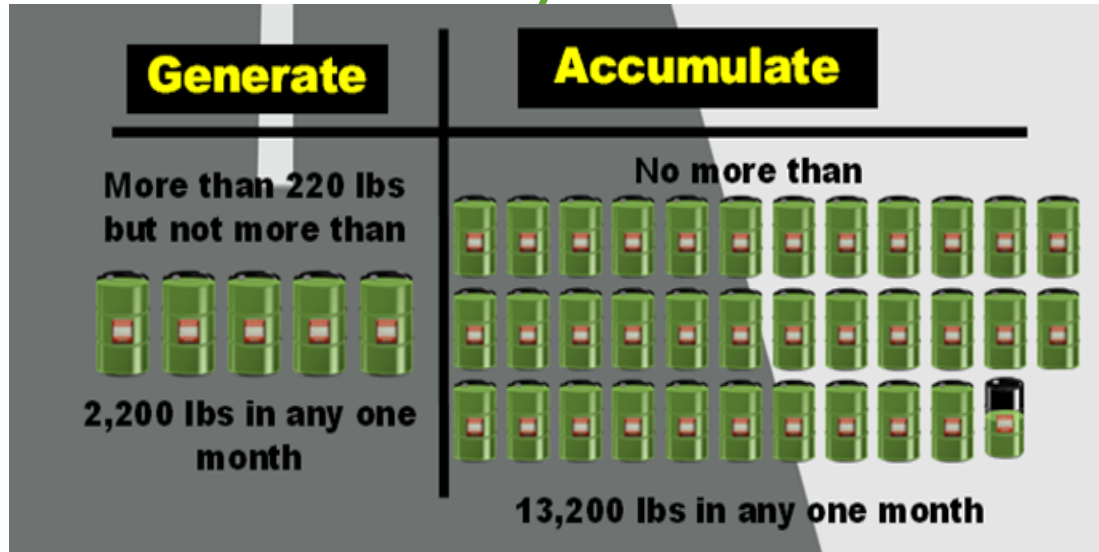
Hazardous Waste Classifications

Classification	Can Generate...	Can Accumulate...	Amount of Time Stored
Very Small Quantity Generator	≤ 220 lbs. of hazardous waste in any one month	$\leq 2,200$ lbs. of hazardous waste at any time	No limit
	And ≤ 2.2 lbs. of acute hazardous waste in any one month	Or ≤ 2.2 lbs. of acute hazardous waste at any time	
Small Quantity Generator	> 220 lbs. or $< 2,200$ in any one month	$\leq 13,200$ lbs. of hazardous waste at any time	No more than 180 days (or 270 days if applicable)
	And less < 2.2 lbs. of acute waste in any one month	Or ≤ 2.2 lbs. of acute hazardous waste at any time	
Large Quantity Generator	$\geq 2,200$ lbs. in any one month	No limit	No more than 90 days unless exempt
	Or ≥ 2.2 lbs. of acute waste in any one month		

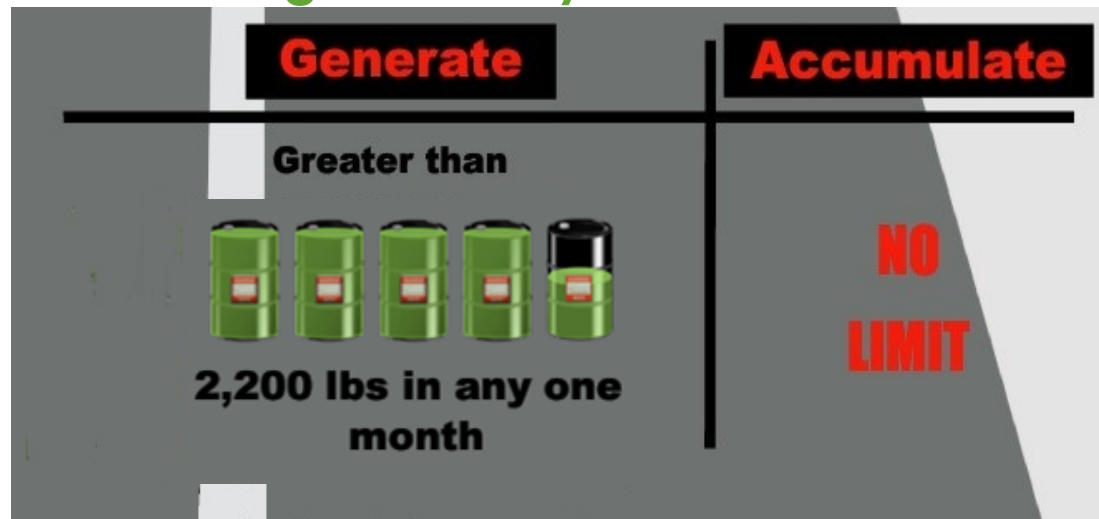
Very Small Quantity Generator



Small Quantity Generator



Large Quantity Generator





Contact Information

For more information, please contact the
WVDEP Division of Air Quality at:

**West Virginia Department of Environmental
Protection**

Division of Air Quality

601 57th Street, SE

Charleston, WV 25304

Phone: (304) 926-0475

**Or contact the DAQ's Small Business
Assistance Program at: (304) 926-0499 ext. 41251**

