Stericycle®

WHITE PAPER

Pharmaceutical Waste Management

www.Stericycle.com • 888-563-2369

TABLE OF CONTENTS

PHARMACEUTICAL WASTE MANAGEMENT

The Issues and Regulation of Pharmaceutical Waste Management – overview

The EPA's recent focus on pharmaceutical waste management has been influenced by increasing evidence of pharmaceuticals in drinking water. An Associated Press series on pharmaceutical waste in May 2009, reported that EPA has found traces of pharmaceuticals in the drinking water of over 41 million Americans. There is cause for concern regarding the unknown human and ecological impacts of trace amounts of pharmaceuticals in the water we drink and the water that is crucial habitat for our flora and fauna.

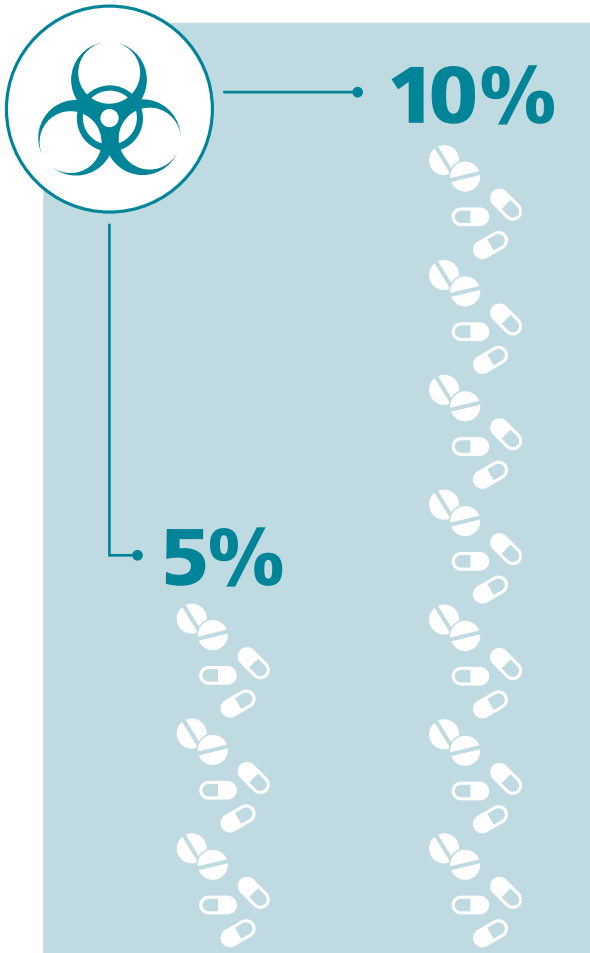
The regulation of pharmaceutical waste is nothing new. Under the Resource Conservation and Recovery Act of 1976 (RCRA), many pharmaceuticals have been classified as hazardous waste for more than thirty years. This section paper report reviews the current pharmaceutical waste management requirements under RCRA and provides guidance for the classification and management of pharmaceuticals that must be managed as hazardous waste in accordance with the Federal EPA's regulations. This paper does not address state regulatory requirements nor requirements under other statutes that impact the pharmaceuticals, such as the Clean Water Act, Food Drug and Cosmetic Act, Controlled Substances Act, etc.

WHICH PHARMACEUTICALS ARE HAZARDOUS WASTE?

About 5% to 10% of the pharmaceutical products can be classified as hazardous waste.
To identify which of your pharmaceutical products are hazardous, you must understand how the EPA classifies hazardous waste because the hazardous waste classification process is no different for you than it is for a factory or chemical manufacturer. Surprising? But just as you would not expect the service provider that changes your car oil or antifreeze to toss it down the drain, the EPA does not condone disposing of hazardous pharmaceuticals via the water system.

There are four questions that must be answered to determine if a pharmaceutical product is regulated by the EPA as a hazardous waste:

1) Is it a **solid waste**?
2) Does it qualify for an **exemption**?
3) Is it a **characteristic waste**?
4) Is it a **listed waste**?



About **5% to 10%** of the pharmaceutical products can be classified as hazadous waste.

1 IS IT A SOLID WASTE?

All wastes must be evaluated to determine if they are solid wastes. If they are solid wastes, they must be immediately evaluated to determine if they are hazardous waste. However, you will find that many of the solid wastes that you generate are not regulated as hazardous waste.

The term "solid waste" has little to do with whether or not the material is a solid. Although the term solid waste is the term of art used in the regulations, the focus of this question is an assessment of how the material is currently or will ultimately be managed. **A solid waste is defined as any discarded material that is either abandoned, recycled, or is inherently waste-like. Therefore, when you first accumulate a waste for its eventual disposal (such as drop a pill into a waste container), you have abandoned it and it is a solid waste**.

How does this apply to shelf-life expired pharmaceuticals? In most cases, the expiration date is the date the product is abandoned and therefore it's the date the material becomes a solid waste. Of course, a pharmaceutical product could become a solid waste before its expiration date, if it is accumulated for disposal before it expires.

PHARMACEUTICALS AS HAZARDOUS WASTE?

Universal waste is a category of hazardous waste that has somewhat streamlined requirements established by the EPA. Currently, universal wastes include batteries, lamps, pesticides, and mercury containing equipment. **The EPA has proposed to add pharmaceuticals to the list and two states, Florida and Michigan, have already done so. What does this mean to you?**

States will remain subject to DOT hazardous materials transportation regulations. Those pharmaceuticals that are subject to DOT requirements will have to be packaged, marked, labeled, placarded, and identified on DOT shipping papers.

The streamlined benefits of the universal waste rule apply primarily in how they are stored on-site and counted toward your generator status. Universal waste need not be stored in a satellite accumulation point or a 90-day storage area. Instead, universal waste can be stored in any safe location for up to one year on-site. Containers used to store universal waste must be structurally sound, kept closed and managed in a way that prevents releases to the environment. Universal wastes do not count toward your large/small quantity generator status; however, if you ever store over 5,000 kg of universal waste on-site, you will be classified as a large quantity universal waste handler and you will be required to notify your state of this status.

There are several options on how universal waste containers must be marked, including either the words "Universal waste" or "Waste" or "Used" followed by the name of the waste, such as lamps, batteries, mercury-containing equipment, pesticides, or pharmaceuticals.

2 DOES IT QUALIFY FOR AN EXEMPTION?

There are several dozen exemptions that have been established either to encourage recycling or to avoid regulating wastes with low risks. Pharmaceuticals are rarely recycled and they do not qualify for most of the exclusions, which apply to very specific waste types.

3 IS IT A CHARACTERISTIC WASTE?

If a solid waste displays any of the following properties, known as characteristics, the waste must be managed as a hazardous waste: ignitable, corrosive, reactive, or toxic. These characteristics have very precise definitions, which are briefly summarized below. This summary does not take into account every exception or exclusion, therefore, we encourage you to review the full text of the regulations at 40 CFR 261 for additional details.

Ignitable (D001):

If a solid waste displays any of the following properties, it is an ignitable hazardous waste and is assigned the waste code D001:

- It is a liquid with a flash point less than 140° F. However, if an alcohol is the only constituent of the product that contributes to its ignitability, and if it is an aqueous alcohol solution containing less than 24% alcohol by volume, it is not ignitable. Bear in mind that a waste with more than 24% alcohol cannot be diluted to this concentration to reclassify it as non-hazardous without a hazardous waste treatment permit or similar authorization. (40 CFR 261.21)
- It is a non-liquid that causes fire through friction, absorption of moisture, or spontaneous chemical change. (40 CFR 261.21)
- It is a flammable gas or an oxidizer. (40 CFR 261.21)

Examples of ignitable wastes include alcohol-based cough syrups, ethylene oxide, methanol, bromine tablets, zinc powder, xylene, aerosol cans with flammable propellants, and petroleum naphtha.

Corrosive (D002):

Strong acids, bases, and materials that are corrosive to steel are classified as corrosive, with the waste code D002. This definition includes aqueous wastes with a pH of < 2 or > 12.5 as well as liquids that can corrode steel at a rate greater than ¼ inch per year. Examples include glutaraldehyde, formic acid, hydrochloric acid, and sodium hydroxide solution.

Reactive (D003):

If a waste displays any of the following properties, it is classified as reactive hazardous waste. Unlike the other characteristics, there are no EPA-defined testing procedures, therefore you should **refer to the product insert, MSDS, or other available data to determine if it could display any of these properties:**

- It is normally unstable and readily undergoes violent change without detonating.
- It reacts violently with water.
- It forms potentially explosive mixtures with water.
- When mixed with water, it generates toxic gases, vapors, or fumes in a quantity sufficient to present a danger to health or the environment.
- It is a cyanide or sulfide-bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors, or fumes that pose a danger to health or the environment.
- It is readily capable of detonation, explosive decomposition, or reaction at standard temperature or pressure.
- It is an explosive that is classified by the Department of Transportation (DOT) as being forbidden in transportation or it is classified as DOT divisions 1.1 through 1.3.

Examples of reactive wastes include acetyl chloride, chromic acid, organic peroxides, hypochlorites, perchlorates, permanganates, sulfides, and non-empty aerosol cans containing flammable gases.

Toxic (D004 – D043):

Although there might be hundreds of thousands of products that could be toxic, the EPA only designates chemicals (see Table 1), which if present in a waste, render the waste toxic. **To determine the concentration of these chemicals, a test known as the Toxicity Characteristic Leaching Procedure (TCLP) is used.**

Some of the chemicals to look for include selenium, silver, chromium, mercury, and cresol. Mercury and m-cresol are commonly used as vaccine preservatives.

TOXIC HAZARDOUS WASTE AND TCLP THRESHOLDS

(TABLE 1)

EPA HW #	Contaminant	Regulatory Level (mg/l)	EPA HW #	Contaminant	Regulatory Level (mg/l)
D004	Arsenic	5.0	D032	Hexachlorobenzene	0.13
D005	Barium	100.0	D033	Hexachlorobutadiene	0.5
D018	Benzene	0.5	D034	Hexachloroethane	3.0
D006	Cadmium	1.0	D008	Lead	5.0
D019	Carbon Tetrachloride	0.5	D013	Lindane	0.4
D020	Chlordane	0.03	D009	Mercury	0.2
D021	Chlorobenzene	100.0	D014	Methoxychlor	0.10
D022	Chloroform	6.0	D035	Methyl Ethyl Ketone	200.0
D007	Chromium	5.0	D036	Nitobenzene	2.0
D023	o-Cresol	200.0	D037	Pentachlorophenol	100.0
D024	m-Cresol	200.0	D038	Pyridine	5.0
D025	n-Cresol	200.0	D010	Selenium	1.0
D026	Cresol	200.0	D011	Silver	5.0
D016	2,4-D	10.0	D039	Tetrachlorethylene	0.7
D027	1,4-Dichlorobenzene	7.5	D015	Toxaphene	0.5
D028	1,2-Dichloroethane	0.5	D040	Trichloroethylene	0.5
D029	1,1-Dichloroethylene	0.7	D041	2,4,5-Trichlorophenol	400.0
D030	2,4-Dinitrotolene	0.13	D042	2,4,6-Trichlorophenol	2.0
D012	Endrin	0.02	D017	2,4,5-TP (Silvex)	1.0
D013	Heptachlor (& its hydroxide)	0.008	D043	Vinyl Chloride	0.2

Source: 40 CFR 261.24

4 IS IT A LISTED WASTE?

There are four lists of hazardous waste, known as the F-list, K-list, P-list, and U-list. Each of these lists is summarized below together with examples that could be found in hospital settings.

F-list

These are called non-specific source wastes because they could potentially be generated by a variety of facilities. Only the first few are found in hospital settings, but rarely in the pharmacy. These include spent solvents and degreasers containing, to name just a few, acetone, toluene, benzene, methyl ethyl ketone, and several others. An important distinction regarding the solvents on the F-list is that they **only become hazardous waste after they become spent following use as a solvent.** If they are not used for their solvent properties, they are not F-list wastes, but could of course display one of the characteristics noted above. The complete F-list can be found at 40 CFR 261.31 and is summarized in (see Table 2).

F-LIST HAZARDOUS WASTES (TABLE 2)

Waste Code	Waste Stream
F001 – F005	Spent solvents
F006 – F009	Electroplating waste
F010 – F012, F019	Metal heat treating waste
F020 – F023, F026 – F028	Dioxin-bearing waste
F024, F025	Chlorinated aliphatic hydrocarbons
F032, F034, F035	Wood preserving waste
F037, F038	Petroleum refinery waste
F039	Multisource leachate

Source: 40 CFR 261.31

K-list

This list contains wastes from specific industrial sources, such as from the manufacture of organic and inorganic chemicals. These wastes are not generated in hospital or university settings.

P- and U-Lists

Both of these lists apply to **unused chemicals** such as those that are no longer needed, have exceeded their shelf life, spill residue, or residue remaining in the product container. What distinguishes the P-list from the U-list is their degree of danger. **Products on the P-list are acutely hazardous, while most of those on the U-list are toxic.**

The P and U- lists apply to the specifically listed unused chemicals. For mixtures and formulations, the listings only apply when a single chemical on one of these lists is the only active ingredient. Examples of P- and U-list waste are shown in Tables 3 and 4. The complete lists are at 40 CFR 261.33.

Drug packages are considered hazardous waste if they formerly held any P- or U- list chemicals and if they are not empty. Empty is defined differently for each of these lists. Packages that formerly held P-list commercial chemical products are empty if they have been triple rinsed with a suitable solvent. Although it might be feasible to rinse bottles and similar containers, it might not be feasible to rinse foil or plastic packages. Therefore, it is usually more convenient to manage the container itself as P-list waste.

The rinsate must be managed as P-list hazardous waste unless it can be used on-site for its intended purpose or discharged as wastewater in accordance with the facility's wastewater discharge permit.

Packages that formerly held U-list commercial chemical products are empty after they have been emptied to the best of your ability, using your conventional methods, and they contain less than one inch of residue or less than three percent by weight.

P-LIST PHARMACEUTICAL (TABLE 3)

Waste Code	Waste Stream
P001	Warfarin > 0.3%
P012	Arsenic trioxide
P042	Epinephrine*
P046	Phentermine
P081	Nitroglycerin (R)**
P188	Physostigmine salicylate
P204	Physostigmine

* This listing refers to epinephrine, with the CAS number 51-43-4. The EPA issued an interpretation on salts in October 2007 indicating that the salts are not P042 waste. However, you should check with your state environmental agency to determine if it follows EPA's interpretation.

**When listed wastes are annotated with an I, C, or R in parentheses, this indicates that the waste is subject to the hazardous waste regulations when the waste displays the ignitability, corrosivity, or reactivity characteristics. Nitroglycerin patches, for example, typically do not display the characteristic of reactivity.

Source: 40 CFR 261.33

U-LIST PHARMACEUTICAL (TABLE 4)

Waste Code	Waste Stream
U010	Mitomycin C
U034	Chloral hydrate
U035	Chlorambucil
U058	Cyclophosphamide
U059	Daunomycin
U129	Lindane
U150	Melphalan
U202	Saccharin
P204	Physostigmine
U205	Selenium sulfide
U206	Streptozotocin
U237	Uracil mustard
U248	Warfarin & salts > 0.2%

Source: 40 CFR 261.33

Generator Status

Depending on the amount of **hazardous waste generated** at your facility, you could be a conditionally exempt, small, or large quantity generator. The scope of the regulations increases along with the amount of hazardous waste you generate. Use Table 5 to determine your site's generator status.

GENERATOR STATUS (TABLE 5)

Large Quantity Generator	> 1000 kg (2,205 lb.) non-acute hazardous waste	>1 kg acute hazardous waste
Small Quantity Generator	> 100 kg but < 1000 kg (220 – 2,205 lb.)	<1 kg acute hazardous waste
Conditionally Exempt Generator	< 100 kg (220 lb.) hazardous waste	<1 kg acute hazardous waste

Temporary Accumulation of Hazardous Waste

The locations in which **large and small quantity generators accumulate hazardous waste are known as satellite accumulation points and central accumulation points.** Although conditionally exempt facilities need not establish these areas, these facilities find that it is an efficient way to accumulate their wastes.

Off-site Transportation

Before hazardous waste can be shipped off-site, it must be placed in containers that meet U.S. Department of Transportation requirements, a hazardous waste manifest must be prepared, and you must specify the appropriate placard for the waste transporter. This can be an arduous procedure for a novice, but is not difficult for anyone who has received DOT hazardous material training. Personnel who perform any of the following job functions must be trained and tested at least every three years so that they know how to: safely prepare hazardous waste (or other hazardous materials) for shipment, select containers, place hazardous waste into containers, mark or label containers, fill out or sign hazardous waste manifests, load hazardous waste onto vehicles, or specify the placard required on the transport vehicle.

Containers Used for Waste Transportation

To identify an appropriate container for hazardous waste transportation, follow these steps:

1. Locate the proper shipping name of the waste in column 2 of the hazardous materials table at 49 CFR 172.101
2. Find the regulatory reference specified for non-bulk packages in column 8(b) of the table. This will be a three digit number that will replace the Xs in 49 CFR 173.XXX.
3. Review the 49 CFR 173.XXX citation for a list of authorized containers
4. You can use any of the listed containers, provided that they are compatible with the waste you place in the container and the container is filled and sealed in accordance with its manufacturer's instructions

Hazardous Waste Manifest

The hazardous waste manifest is a document that accompanies your waste from your facility to the hazardous waste treatment, storage, or disposal facility that you have selected for your waste. It identifies your site as the waste generator; the transporter that carries your waste off-site; and the destination hazardous waste treatment, storage, disposal, or recycling facility. The manifest is required for off-site shipments from facilities classified as large or small quantity generators. The manifest is not required for, but is commonly used by conditionally exempt small quantity generators.

As the generator of the waste, you are responsible for the completeness and accuracy of the information entered on the manifest. Some of the key information on the manifest includes:

- The DOT basic description of the waste, which includes the following information obtained from the hazardous material table at 49 CFR 172.101: proper shipping name, hazard class, identification number, and packing group.
- The notation "RQ" added to each basic description for wastes shipped in an amount of at -least its reportable quantity. Reportable quantities are listed in 49 CFR 172.101 Appendix A.
- The total quantity of each waste type, together with the type of container, and the EPA hazardous waste code.
- A certification indicating that the waste is identified, packed, marked, and labeled in accordance with applicable regulations.
- A certification indicating that your facility is implementing a waste minimization program
- The signature of a designated person at your facility indicating that the above information is accurate. The person who signs the certification must have completed DOT hazardous materials training.

Land Disposal Notice

Most hazardous wastes have been banned from land disposal. Instead, the waste must be treated to meet treatment standards established by the EPA. Hazardous waste generators must notify the facilities to which they ship their waste that the waste is subject to the land disposal restrictions and that the waste cannot be land disposed unless it meets the treatment standard designated by EPA for the waste. Most companies that transport hazardous waste provide waste generators with a land disposal notice form to prepare or, the transporter provides a land disposal notice form that is pre-prepared for the generator's waste streams. The treatment standards can vary depending on the waste, its subcategory, and reatability group. Some of the treatment standards are technology based – requiring a specific method of treatment such as incineration, while others are concentration based – allowing any form of treatment except dilution.

Vehicle Loading

After you've taken great strides to safely manage your hazardous waste while it is stored on-site, you must also ensure that it is safely handled when it is shipped off-site. Critical questions to answer include:

- Are the waste containers sealed in accordance with the manufacturer's instructions?
- Are the waste containers secured on the transporter's vehicle?
- Have we confirmed that there are no incompatible materials loaded on the transporter's vehicle? (see the compatibility chart at 49 CFR 177.848)

CONSEQUENCES OF NONCOMPLIANCE

T**he primary objective of the hazardous waste regulations is to protect the environment and human health from the dangers of hazardous waste.** The primary consequence of non-compliance is environmental deterioration which ultimately impacts our health and well being.

Noncompliance can also result in monetary fines and imprisonment. The EPA has the authority to assess civil penalties of up to $27,500 per day per violation, or criminal penalties of $50,000 per day and up to 5 years in jail. http://www.epa.gov/waste/inforesources/pubs/training/enforced.pdf Moreover, violators can be assessed jail terms of ten years or more, depending on the severity of the violation. Each state environmental agency has similar enforcement authority.

IN CONCLUSION

While the management of hazardous pharmaceuticals is required by the regulations, the appropriate disposal of non-hazardous pharmaceuticals is a Best Demonstrated Practice—managing all of your pharmaceutical waste to assure that pharmaceuticals will not enter the water.

WHAT HAPPENS TO PHARMACEUTICAL INVENTORY IN A HEALTHCARE FACILITY?

Stericycle provides you with Comprehensive Solutions to assure that your facility is compliant. When you need an answer for your Pharmaceutical Waste, we can provide the solution.

To find out more Information please call (866) 783-7422

www.Stericycle.com

888-563-2369

Stericycle®

28161 N. Keith Drive
Lake Forest, IL 60045