



Florida Department of Environmental Protection

Bob Martinez Center
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

Rick Scott
Governor

Jennifer Carroll
Lt. Governor

Herschel T. Vinyard Jr.
Secretary

Pharmaceutical Waste Disposal Guidelines

Three most frequent violations:

1. The facility must decide if they are going to manage their waste pharmaceuticals under the HW rules or the UPW rules. If they have not met the UPW requirements, then all of the HW requirements apply.
2. No mixing HW and UPW rules i.e. no satellite accumulation containers under the UPW rule.
3. Samples cannot be sent to a reverse distributor because a reverse distributor will not give a facility credit for samples. By law: F.S. **499.028** Drug samples or complimentary drugs; starter packs; permits to distribute.- (9) All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

FACILITY IS IN COMPLIANCE:

- Facility has determined which pharmaceuticals are HW and managing them as HW
- Facility sending pharmaceuticals with a reasonable expectation of credit to a reverse distributor.
- Facility needs to meet all HW requirements for CESQG, SQG or LQG.
- HW pharmaceuticals are sent to a TSD, or to an authorized facility.

FACILITY IS IN COMPLIANCE:

- Facility is generating both HW (i.e. lab waste) and waste pharmaceuticals
- Facility has determined which pharmaceuticals are HW and manages the pharmaceuticals as UPW
- Facility must meet UPW requirements* and sends to a TSD or a State of FL notified UPW handler.
- Facility must meet all HW generator requirements for other HW (but does not include UPW when determining generator status)

FACILITY IS IN COMPLIANCE:

- Facility is generating only waste pharmaceuticals.
- Facility has determined which pharmaceuticals are HW and manages the pharmaceuticals as UPW
- Facility must meet UPW requirements* and sends to a TSD or a State of FL notified UPW handler.

FACILITY IS NOT IN COMPLIANCE:**

- Facility is generating both HW (i.e. lab waste) and waste pharmaceuticals
- Facility is managing their HW according to their generator status and meeting HW requirements.
- Facility sending all of their pharmaceuticals (hazardous and non-hazardous waste pharmaceuticals), including non-creditable items*** with creditable items via UPS (or other transportation company) to an out-of-state reverse distributor.

FACILITY IS NOT IN COMPLIANCE:**

- Facility is generating only waste pharmaceuticals.
- Facility sending all of their pharmaceuticals (hazardous and non-hazardous waste pharmaceuticals), including non-creditable items*** with creditable items via UPS (or other transportation company) to an out-of-state reverse distributor.

*UPW Handler requirements:

1. UPW rule requires all handlers to notify - there is no CESQG exemption. If the CESQG has not notified, is not in compliance with the UPW rule. Generators who have previously notified do NOT have to renotify.
2. Manage UPW in way to prevent releases, immediately respond to a release
3. Keep containers closed
4. Label the container “universal pharmaceutical waste” or “universal waste pharmaceuticals,” and with specific hazardous waste codes applicable to the UPW that is or may be placed in the container or tank
5. Small Quantity Handler can accumulate UPW no longer than a year after generated
6. Large Quantity Handler can accumulate UPW no longer than 6 months after generated
7. Must demonstrate an accumulation time, i.e. dating container, log, inventory, etc.
8. Document and conduct training of employees 3 months after hire date, annually.
9. Training records must be kept for 3 years.
10. Off-site shipments of UPW shall go to a handler or a reverse distributor who has notified the DEP pursuant to 62-730.186(6), F.A.C.; a destination facility as defined in 40 CFR 273.9; or a foreign destination.
11. DOT regulations still need to be followed for shipment of UPW. No comingling incompatible waste.
12. SQHs/LQHs can transport own UPW but must meet financial responsibility requirements of 62-730.170(2), F.A.C. if more than 5,000 kg or 1kg of p-listed transported at any one time.
13. Records of each UPW shipments must be kept for 3 years. The record shall consist of a written receipt, manifest, bill of lading or other written documentation. The records shall include the following:
 - (a) Name and address of the handler, reverse distributor, destination facility or foreign destination to which the UPW were sent
 - (b) Quantity of UPW sent
 - (c) Date the shipment

**A handler that transports a UPW to a reverse distributor or another handler must provide the reverse distributor or handler with written information sufficient to allow the reverse distributor or other handler to make knowledgeable decisions about the safe handling and proper disposal of the UPW.

***Only pharmaceuticals with a reasonable expectation of credit can be sent to reverse distributors. Dropped pills, non-creditable items, formulated mixtures, items with patient’s names, raw chemicals cannot be sent to reverse distributors for credit; therefore, a waste determination is required and the decision must be made to manage this waste as HW or UPW.

62-730.186(4)(e) “Hazardous waste pharmaceutical” means a “non-viable” “pharmaceutical” [as defined in paragraphs 62-730.186(4)(i) and 62-730.186(4)(h),

62-730.186(4)(i) “Non-viable” means a pharmaceutical that cannot be sold, returned to the manufacturer, wholesaler or reverse distributor with a reasonable expectation of credit, or donated to a charitable organization. Pharmaceuticals that are obviously “waste-like”, such as partial intravenous formulations; partial vials used in the preparation of intravenous (IV) formulations; outdated samples; other outdated items repackaged at the pharmacy; partial vials or vials used on the unit and not emptied (such as insulin and epinephrine dispensing devices); partial ointments, creams and lotions; partial inhalants; partial containers that are not empty as defined in 40 CFR 261.7 [as adopted in subsection 62-730.030(1), F.A.C.]; patient’s personal medications that have been left at the hospital; filled finished products that are rejected during the manufacturing process, so long as they are in their consumer package (such as bottle, jar, tube, or ampoule), do not support a reasonable expectation of credit and therefore are non-viable pharmaceuticals.

Pharmaceutical Waste Guidance

1. Hazardous Waste Determinations

The Florida Department of Environmental Protection (FDEP) has recently received a number of requests for help in determining whether hospital wastes are regulated as hazardous wastes under the federal Resource Conservation and Recovery Act (RCRA) and corresponding state law. Therefore, we are issuing the following regulatory determinations with regard to medications formulated from chemicals that the Environmental Protection Agency (EPA) has listed as hazardous under 40 Code of Federal Regulations (CFR) 261.33 or that include ingredients that may cause the medication to exhibit the toxicity characteristic under 40 CFR 261.24. [All sections of 40 CFR mentioned in this guidance have been adopted by reference as Florida law in Chapter 62-730, Florida Administrative Code (FAC).]

Pharmaceutical waste that meets the definition of hazardous waste may be managed as “universal waste” in Florida. This is a somewhat less stringent set of requirements which may be found in Rule 62-730.186, FAC. This guidance document is current as of **26 March, 2009**.

1. Epinephrine - EPA Waste No. P042

EPA published a regulatory interpretation memo October 15, 2007 concluding that the listing description for epinephrine does not include salts. Epinephrine HCL and epinephrine bitartrate, the medically active forms of epinephrine in common use, are salts. Therefore, expired or damaged medications, including used syringes such as Epi-Pens, that contain epinephrine or epinephrine residues as the sole active ingredient no longer have to be managed as hazardous waste (or universal waste in Florida) when discarded. This includes lidocaine preparations containing epinephrine.

2. Nicotine - EPA Waste No. P075

Nicotine is listed as an acutely hazardous waste in 40 CFR 261.33. FDEP agrees that used nicotine patches and gum are not hazardous waste because the listing description applies only to unused commercial chemical products and spill residues. Unused nicotine patches and gum are hazardous waste if discarded.

3. Nitroglycerine - EPA Waste No. P081

FDEP has adopted EPA's revisions to Part 261 that exempts waste nitroglycerine formulations that are not explosive from regulation as hazardous waste.

4. Warfarin/Coumadin - EPA Waste Nos. P001/U248 (if less than 0.3%)

In general, when unused and discarded, warfarin is P001, an acute listed hazardous waste. However, where the amount of warfarin in the waste is “present at concentrations of 0.3% or less,” the hazardous waste listing is U248. FDEP has laboratory data indicating that the amount of residue remaining in some containers which formerly held Coumadin (warfarin) pills ranges from 0.0033 to 0.0039%, compared with the initial amount of warfarin in the container. By extrapolation, the results

are applicable to bottles that formerly contained at least 50 coated tablets or capsules of Coumadin at a dosage of 10 milligram (mg), and bottles that formerly contained at least 110 coated tablets or capsules at a dosage of 1 mg. Therefore, FDEP has determined that containers which formerly held these two combinations of amounts and dosages are identified as U248 rather than P001. In that case, the containers would be “RCRA-empty” if all Coumadin pills have been removed. Triple rinsing is not required. “RCRA-empty” containers are not regulated as hazardous waste.

A generator of containers that formerly contained any other dosage/quantity combination of Coumadin pills, or that formerly contained liquid formulations or powders, may design and implement a laboratory study to demonstrate that the residues are <0.3% of the initial amount of warfarin in the container. Until such demonstration is made, containers that held other dosage/quantity combinations, or that held liquid or powder formulations, must be disposed of as P001 hazardous waste or triple rinsed in accordance with 40 CFR 261.7 to render them “RCRA-empty” and no longer hazardous waste.

EPA has been asked to review its national guidance on this matter, so FDEP’s interpretation is subject to revision based on the results of EPA’s evaluation.

5. Phenol - EPA Waste No. U188

Some over the counter medications such as Chloraseptic have phenol as the sole active ingredient. These are listed hazardous waste when unused packages are discarded in the trash rather than used. Phenol is the sole active ingredient, but is diluted with a carrier. Carriers, buffers, preservatives and fragrances or flavors in these products are not included for a functional property, and may be present in preparations without affecting their hazardous waste listing.

6. Hexachlorophene - EPA Waste No. U132

FDEP does not consider commercial cleaning preparations containing hexachlorophene such as pHisoderm or pHisoHex to meet the listing description for technical grade Hexachlorophene. Hexachlorophene is the main active ingredient, but is formulated with detergents and emulsifiers which are included for their functional cleaning properties, so hexachlorophene is not the sole active ingredient.

7. Chromium or Selenium supplements - EPA Waste Nos. D007 and D010

Waste liquids that have more than 5 milligrams per liter (mg/l) chromium or 1 mg/l selenium are hazardous wastes because they exhibit the toxicity characteristic under 40 CFR 261.24. Solids that contain these metals are also regulated if they leach these concentrations when tested by the toxicity characteristic leaching procedure (TCLP) specified in this rule. For soluble metals, 100 mg/kg chromium and 20 mg/kg selenium will fail the test. For vials and tablets of unused materials, most will fail the TCLP test based on dose per weight of tablet or unit. Health care facilities must monitor the concentration of the metals in diluted medications in order to determine if these are regulated as hazardous (or universal) waste when discarded.

8. Chromic Catgut Sutures - EPA Waste No. D007

Unused, discarded sutures should be presumed to be hazardous waste. FDEP is authorizing disposal of remnants and clippings generated during surgery as biomedical waste.

9. Insulin - potentially EPA Waste No. D024

Some insulin formulations contain m-cresol, and these are toxic hazardous wastes when m-cresol levels exceed 200 mg/l TCLP. It is permissible under hazardous waste regulations to crush the vials, handle the drained liquid as hazardous waste and manage the crushed glass as non-regulated material.

2. Best Management Practices for Medical Facilities Generating Acutely Hazardous Waste

Certain essential drugs used in medical practices are regulated under RCRA as acutely hazardous waste, or "P-listed" waste in 40 CFR 261.33. To be in compliance, the facility must dispose of **unused** preparations of these as hazardous waste or as "universal waste." Residues from a spill of **unused** preparations of P-listed waste must be managed as hazardous waste. A list of P-listed chemicals/drugs that may be on site can be found at the end of this BMP.

Following these simple guidelines will help your facility comply with RCRA.

1. Store all P-listed waste in a separate labeled container. It cannot be placed in the biohazard red box. Items for the separate container labeled "hazardous waste" or "acutely hazardous waste" include, but are not limited to, empty vials, bottles, and containers that contain or have contained epinephrine. Unused intravenous solutions or medications that contain a P-listed compound also must be disposed of as hazardous or universal waste. Only empty syringes used to administer the drug can go into the biohazard red box.
2. The container must be picked up and disposed of EITHER by a hazardous waste transporter that has registered with FDEP and has established financial assurance, OR by a transporter who has notified FDEP of its universal waste transporting activities.
3. The hazardous waste transporter will give you a copy of the manifest. You must keep it on file on site for 3 years.
4. Assuming that no other hazardous wastes are generated, a facility that generates less than 2.2 pounds (1 kilogram) of acutely hazardous waste in any calendar month is categorized as a Conditionally Exempt Small Quantity Generator (CESQG). Once this maximum amount is exceeded the facility would be considered a Large Quantity Generator and subjected to stricter regulations. The CESQG limit for non-acutely hazardous waste is 220 pounds (100 kilograms), which is approximately one-half of a 55 gallon drum.
5. Keep in mind once a product has expired it is considered a waste under RCRA (unless it can be returned to the manufacturer for credit), and must be disposed of in accordance with hazardous waste regulations. You can keep disposal costs down by monitoring the inventory and only keeping as much drug/chemical on site as needed.

3. RCRA “Listed Hazardous Waste” That May Be Found in Medical Practices

P-Listed hazardous wastes (acutely hazardous):

Chemical/drug	Waste Code
Arsenic trioxide	P012
Nicotine	P075
Phentermine (CIV)	P046
Physostigmine	P204
Physostigmine salicylate`	P188
Warfarin >0.3%	P001

U-Listed hazardous wastes:

Chemical/drug	Waste Code	Chemical/drug	Waste Code
Chloral hydrate	U034	Paraldehyde	U182
Chlorambucil	U035	Phenol	U188
Cyclophosphamide	U058	Reserpine	U200
Daunomycin	U059	Resorcinol	U201
Dichlorodifluoromethane	U075	Saccharin	U202
Diethylstilbestrol	U089	Selenium sulfide	U205
Hexachlorophene	U132	Streptozotocin	U206
Lindane	U129	Trichloromonofluoromethane	U121
Melphalan	U150	Uracil mustard	U237
Mitomycin C	U010	Warfarin <0.3%	U248

- *Not all the above chemicals/drugs are used in all practices*
- *This is not a complete list of all chemicals/drugs that may become hazardous waste*

For more information on hazardous pharmaceutical waste and universal pharmaceutical waste, please go to FDEP’s website and click on “Pharmacies” and “Pharmaceuticals Potentially Hazardous Waste When Discarded” under “General Hazardous Waste Publications” at

http://www.dep.state.fl.us/waste/quick_topics/publications/default.htm