Pharmaceutical Waste Guidance

(Updated March 2016)

1. Hazardous Waste Determinations

The Florida Department of Environmental Protection (FDEP) has recently received a number of request for help in determining whether hospital wastes are regulated hazardous waste under the federal Resource Conservation and Recovery Act (RCRA) and corresponding state law. Therefore, we are issuing the following regulatory determination with regard to medications formulated from chemicals that the Environmental Protection Agency (EPA) has listed as hazardous waste under 40 Code of Federal Regulations (CFR) 261.33 or that include ingredients that may cause the medications 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 regulatory interpretation memo October 15, 2007 concluding that the listing description of epinephrine does not include salts. Epinephrine HCL and epinephrine bitarterate, the medically active forms of epinephrine in common use are salts. Therefore, expired or damaged medications, including syringes such as Epi-Pens, that contain epinephrine or epinephrine residues as the sole active ingredients 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 No. P081

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

4. Warfarin/Coumadin – EPA No. 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 of 1mg. 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 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 that used. Phenol is the sole active ingredient, but is diluted with a carrier. Carries, 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 No. 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 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 waste (or Universal) waste when discarded.

8. Chromic Catgut Suture – 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 drain liquid as hazardous waste and manage the crushed glass as non-regulated material.

2. Best Management Practices for Medial 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 waste 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 this on file on site for 3 years.
4. Assuming that no other hazardous wastes are generated, a facility that generated 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 subject 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 cost 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
Physostigmine	P204
Physostigimine salicylate	P188
Wafarin >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	Trichloromonofluromethane	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 pharmaceuticals 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

For additional resources and guidance regarding pharmaceutical waste management, please visit: www.dep.state.fl.us/waste/pharm