

# Pharmaceutical Waste Management

## *A Guide for Medical Care Facilities in South Dakota*

Pharmacies, hospitals, health care and veterinary clinics generate not only infectious medical waste, but pharmaceutical wastes. While infectious medical wastes must be rendered noninfectious prior to disposal as a solid waste, pharmaceutical wastes are different in that some may need to be managed and disposed as a hazardous waste. Medical and veterinary care personnel can use this fact sheet to help determine whether a pharmaceutical waste is hazardous waste. *Note:* This waste determination begins with the assumption that the drugs cannot be returned to the supplier or manufacturer for reformulation or redistribution.

### **Background**

The State's Hazardous Waste rules are found under the Administrative Rules of South Dakota (ARSD) Chapter 74:28. These rules are enforced by the South Dakota Department of Environment and Natural Resources' (DENR) Hazardous Waste Program. Although the program is not conducted by the federal Environmental Protection Agency (EPA), the EPA does ensure the state maintains an adequate program by performing annual oversight evaluations. You will note that under ARSD Chapter 74:28, the state has adopted the federal hazardous waste regulations by reference. A link to both sets of rules is found at: <http://denr.sd.gov/des/wm/hw/hwmainpage.aspx>

Whether you represent a medical facility or industrial manufacturing operation, you must ensure that the wastes generated are properly managed and disposed. Determining whether a waste is a hazardous waste serves as the starting point and establishes the base upon which all other potential hazardous waste generator requirements are built.

1. **Identification.** Determine whether the drugs are a hazardous waste.

As with any type of waste destined for disposal, it is the generator's responsibility to determine whether that waste is a hazardous waste. To make that determination, refer to the state's hazardous waste rules under ARSD Chapter 74:28:22:01, adopting by reference 40 CFR 261. Unused, outdated pharmaceuticals may be specifically listed in the P- or U-series lists under 40 CFR 261.33. When not specifically listed, if the pharmaceutical exhibits one or more hazardous waste characteristics assigned under 40 CFR 261.21 to 264.24 (ignitable; corrosive; reactive; or toxic using the Toxicity Characteristic Leaching Procedure test), it will also be a hazardous waste.

Product Material Safety Data Sheets can help with many waste determinations. Additional help can be obtained through the DENR's website at: <http://denr.sd.gov/des/wm/hw/hwpharma.aspx> or by contacting the Waste Management Program's hazardous waste staff at 605-773-3153.

2. **Amount.** Once you've determined which pharmaceuticals are considered hazardous wastes and which are nonhazardous solid wastes, calculate the weight you have of each category. The amount of hazardous waste generated on-site within a calendar month determines the *generator category* for your facility, and the respective requirements you'll need to follow.

a. Hazardous Waste Generator Categories

- i. Large Quantity Generator (LQG): generates more than 2,200 pounds of hazardous waste; or more than 2.2 pounds of acute (P-series) hazardous waste per calendar month.
- ii. Small Quantity Generator (SQG): generates more than 220 pounds but less than 2,200 pounds of hazardous waste within one calendar month; and less than 2.2 pounds of acute hazardous waste within one calendar month.
- iii. Conditionally Exempt Small Quantity Generator (CESQG): generates less than 220 pounds of hazardous waste and less than 2.2 pounds of acute hazardous waste within one calendar month.

(Note: some facilities may wish to go above and beyond the regulations by managing some drugs as hazardous waste even though they are not considered such under the hazardous waste rules. Potent drugs, such as some chemotherapy drugs, that are not on the P- or U-series waste lists and do not exhibit any of the four hazardous waste characteristics would not be a regulated hazardous waste. Managing them along with regulated hazardous wastes is the prerogative of the facility, and is considered a Best Management Practice (BMP). In these cases, the state would still not consider such wastes hazardous waste, and would not require the facility to include the weight of these materials as part of the facility's monthly hazardous waste generation rate. Records indicating the type and amount of drugs handled under BMP policies should be maintained on file.)

3. **Storage.**

Containers: Hazardous waste pharmaceuticals must be placed:

- a. In containers that are compatible with the wastes they contain;
- b. In containers that are in good condition, not leaking;
- c. In containers that are securely closed unless and until wastes are being added or removed;
- d. In containers that are properly labeled.

Time Limits: On-site storage limits are dependent upon the facility's generator category:

- a. LQGs: 90 days from the date the waste was first placed into the container.\*
- b. SQGs: 180 days from the date the waste was first placed into the container\*, unless the waste is transported over 200 miles to the destination disposal facility. If the waste must be transported over 200 miles to the destination disposal facility, the facility is allowed 270 days to safely store the waste on-site.
- c. CESQGs: Although no time limit is established for CESQGs to store their hazardous waste on-site, should an amount of 6000 kilograms (13,200 pounds) accumulate at any one time, the facility becomes subject to all of the SQG requirements.

\* - On-site storage times: The storage clock starts ticking the day a waste is first placed into a container, unless the container is a satellite accumulation container. See ARSD 74:28:23:01 adopting by reference 40 CFR 262.34(b).

4. **Disposal.** Waste pharmaceuticals that are hazardous waste need to be transported to a permitted hazardous waste treatment, storage or disposal facility (TSDF). Hazardous waste contractors and transporters available to service pharmaceutical wastes generated in South Dakota can be found on DENR's website at: <http://denr.sd.gov/des/wm/hw/hwcontractors.aspx>

Waste pharmaceuticals that are not hazardous waste must still be disposed at a permitted municipal solid waste (MSW) facility.

Records of waste shipments should be maintained on file at your facility.

Additional resources and assistance available to medical facilities specific to identifying and managing pharmaceutical wastes can be obtained through the following links. Please note that inclusion of service companies does not represent an endorsement by DENR.

<http://www.pharmecology.com/pedd/jsp/index.jsp>

<http://pwaste.com/default.asp>

<http://www.productstewardship.us/displaycommon.cfm?an=1&subarticlenbr=181>

<http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/health.pdf>

<http://www.whitehouse.gov/ondcp>