South Dakota Department of Agriculture and Natural Resources (SDDANR)

Pharmaceutical Waste Management
E-Cigarettes, Vaping Liquids and Other Nicotine Wastes

A Guide for South Dakota Businesses, Schools and Governmental Agencies

Background

On February 22, 2019, the Environmental Protection Agency (EPA) published a final rule titled 'Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine' (https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075). This rule, also referred to as the Subpart P Rule, became effective in South Dakota on September 3, 2019 (https://sdlegislature.gov/Rules/DisplayRule.aspx?Rule=74:28). Under the Subpart P requirements, the term "pharmaceutical" is defined as:

> Any drug or dietary supplement; any electronic nicotine delivery system [ENDS] (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials).

Liquid nicotine products requiring disposal are considered an acute (P075) listed hazardous waste. As a result, unused, partially used, or empty (but not triple-rinsed) ENDS, nicotine containers, or e-liquids generated by businesses and schools need to be disposed of in compliance with the state's hazardous waste requirements. Guidance for managing those items is provided below.

Nicotine-Containing Wastes

The hazardous waste regulations consider discarded commercial chemical products, off-specification species, container residues, and spill residues containing nicotine and salts (chemical name 3-(1-methyl-2-pyrrolidinyl)-Pyridine and salts; CAS # 54-11-5) as a P075 acute hazardous waste. **Importantly, this listing does <u>not</u> include patches, gums and lozenges that are approved by the Food and Drug Administration (FDA) as over-the-counter nicotine replacement therapies.** Those items may be disposed in the regular trash.

Products that are considered P075 hazardous wastes include:

- Vaping liquid containing nicotine.
- Vaping liquid spill clean-up residue.
- Rinse water or solvents from rinsing nicotine and vaping liquid containers.
- E-cigarettes (used or unused) whose liquid reservoirs have not been removed.
- Storage containers and e-cigarette cartridges that held nicotine or nicotine-containing vaping liquid that have not been triple-rinsed.

Storage and Disposal of Nicotine-Containing Wastes

Sites accumulating more than 2.2 pounds (1 kilogram) of nicotine-containing wastes within a calendar month are considered Large Quantity Generators (LQGs) of hazardous waste and need to follow the Subpart P requirements for storing nicotine wastes on-site. LQGs of nicotine-containing waste must also make arrangements to ship those wastes off-site to a permitted hazardous waste disposal facility for proper disposal. When calculating the amount of waste, the site need only consider the weight of the nicotine-containing liquid, not the device, container, housing or packaging that goes with it. Sites that generate less than 2.2 pounds of the nicotine-containing waste are considered Very Small Quantity Generators (VSQGs) and have other options for disposal. See provisions for VSQGs that are outlined at the end of this guidance. **Note: Neither VSQG nor LQG hazardous waste generators can dispose of unwanted pharmaceuticals into or through the drain/sewer system.**

Sites considered LQGs of nicotine-containing waste need to meet the following requirements:

- Obtain a Hazardous Waste ID number: As an LQG of hazardous waste subject to the pharmaceutical waste requirements, your site needs to notify the state of that activity and obtain a Hazardous Waste ID number (HW ID). Sites that may already have a HW ID will still need to notify as a Subpart P operation. The form can be obtained through the following link: https://www.epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-and-treatment-storage-and
  There are no fees associated with obtaining an ID number in South Dakota. After completing Sections 1 through 10, mark 'Yes' in Section 11.D.; sign and date the form. Keep a copy of the form and mail the original to:
  SDDANR – Waste Management Program/HW Section
  523 E. Capitol Avenue
  Pierre, SD 57501
- Personnel Training: Sites must ensure that all personnel managing the waste are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal operations as well as in emergency situations.
- Waste Storage:
  - Storage containers must be structurally sound, compatible with its contents and lack evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.
  - Storage containers need to be kept closed and secured in a way that prevents unauthorized access.
  - Storage containers need to be labeled or clearly marked with the phrase "Hazardous Waste Pharmaceuticals."
  - Wastes may be stored on-site for one year or less.
- Recordkeeping: Nicotine-containing wastes must be shipped off-site for disposal at a permitted hazardous waste disposal facility. Waste shipments must be accompanied by a hazardous waste manifest. Copies of the manifest must be maintained on file for at least three years from the date the shipment was received by the disposal facility. Sites subject to Subpart P are *not* required to complete a hazardous waste biennial report, unless it is considered an LQG for its non-pharmaceutical hazardous wastes.

Other Considerations

Recalls: Materials being managed in accordance with a recall strategy approved by the FDA are not subject to these requirements until the FDA approves the destruction of the recalled items.

Potentially Creditable Material: Retail operations may have the option of sending unused products to a Reverse Distributor where a decision is made to provide credit for returns. Retail operations managing nicotine-containing waste as a potentially creditable pharmaceutical must meet the following requirements:

- Using product knowledge or testing, determine whether the product, should it become a waste, would be considered a P075 hazardous waste.
- Maintain the following records for at least three years: copies of shipping papers prepared in accordance with U.S. Department of Transportation requirements (if applicable), and delivery confirmation documentation.
- Should a spill or release occur, immediately contain and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals.

VSQG Requirements: As noted earlier, if less than 2.2 pounds of nicotine-containing waste is accumulated or generated within a calendar month, your site is a Very Small Quantity Generator. Options for managing wastes as a VSQG are as follows:

- Manage the material in accordance with the Subpart P requirements, outlined above for LQGs; or,
- Transport the material to a site that is affiliated with, or under the control of, the same ownership as the current site, and that operates in compliance with the Subpart P requirements outlined above. The waste received by the affiliated entity must manage the received materials with their own waste, in compliance with Subpart P; or,
- Ensure the waste is transported to a proper disposal facility, in accordance with the state's VSQG hazardous waste provisions. **Note: disposal of hazardous waste pharmaceuticals down the drain into the sewer is prohibited.**

Batteries: Because electronic devices contain batteries, the department suggests removing batteries before disposing of the device. LQGs may recycle batteries as a Universal Waste, in accordance with the following provisions:

- Store batteries in a way that prevents releases to the environment, within a container that is in good condition, kept closed except when batteries are added or removed from the container, compatible with the batteries it contains, and labeled as "Universal Waste", or "Universal Waste Batteries", or "Waste Batteries".
- Universal waste batteries may be stored on-site for up to one year.
- Universal waste batteries need to be shipped off-site to a battery recycler.

Additional Resources

Additional resources are offered through the following links. Please note that the inclusion of service companies does not represent an endorsement by DANR.

- South Dakota's Hazardous Waste Regulations (ARSD 74:28): https://danr.sd.gov/Environment/WasteManagement/HazardousWaste/default.aspx
- Federal (EPA) Hazardous Waste Regulations (40 CFR Parts 260 – 279):
  - Parts 260-265: https://www.ecfr.gov/cgi-bin/text-idx?SID=941ed272f177590131de87ab4b36ae02&pitd=20180701&tpl=/ecfrbrowse/Title40/40cfrv28_02.tpl#0
  - Parts 266-279: https://www.ecfr.gov/cgi-bin/text-idx?SID=941ed272f177590131de87ab4b36ae02&pitd=20180701&tpl=/ecfrbrowse/Title40/40cfrv29_02.tpl#0
- SDDANR Pharmaceutical Waste Management website: https://danr.sd.gov/Environment/WasteManagement/HazardousWaste/PharmaceuticalWaste.aspx
- SDDANR Pharmaceutical Waste Management – Guidance for Healthcare Facilities: https://danr.sd.gov/Environment/WasteManagement/HazardousWaste/docs/Pharmaceutical%20Waste%20Management_2019.pdf
- Federal Environmental Protection Agency (EPA) Pharmaceutical Waste Rule website and rule (84 FR No. 36): https://www.epa.gov/hwgenerators/management-hazardous-waste-pharmaceuticals
- EPA Compliance Assistance website: http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/health.pdf
- Healthcare Environmental Resource Center (HER) website: https://www.hercenter.org/
- PharmEcology website: http://www.pharmecology.com/pedd/jsp/index.jsp
- Practice Greenhealth website: https://www.practicegreenhealth.org/
- Universal Wastes: https://www.epa.gov/hw/universal-waste
- DANR Waste Management Program/Hazardous Waste Section: 605-773-3153