North Dakota's

Pharmaceutical Waste

Guidance

North Dakota Department of Health
Environmental Health Section
Division of Waste Management

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A. INTRODUCTION

North Dakota Hazardous Waste Management Rules require that "a person who generates a solid waste must determine if it is a hazardous waste." This guide will help you evaluate whether a waste being generated by your facility is hazardous or not.

Entities involved in health-care and/or pharmaceuticals are required to follow these regulations for any solid waste generated. This includes pharmacies, hospitals, physicians' offices, dentists' offices, school or plant nurse's office, other healthcare practitioners, outpatient care centers, ambulatory health-care services, assisted-care or long-term care facilities, veterinary clinics or animal hospitals and reverse distributors.

For the purposes of this guidance document, the definition of a pharmaceutical has been adapted from the definition of a drug under Chapter 43-15 NDCC. Therefore, "pharmaceutical" refers to any articles recognized as drugs in the official United States pharmacopeia, official national formulary, official homeopathic pharmacopeia, other drug compendium, or any supplement to any of them not containing a radioactive component that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; any articles other than food, not containing a radioactive component, intended to affect the structure or any function of the body of man or other animals; and any articles intended for use as a component of any articles specified in subdivision a, b, or c. This definition does not include sharps or other regulated infectious waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials. Information about the identification, segregation and management of sharps and regulated infectious wastes can be found in "A Guide to Understanding North Dakota's Infectious Waste Regulations" and is located at: www.ndhealth.gov/wm/SolidWasteProgram/InfectiousWaste.htm.

B. EXAMPLES OF SOURCES OF PHARMACEUTICAL HAZARDOUS WASTE

Health-Care Facilities

In the health-care facility's pharmacy, waste may be generated by IV prep, compounding, spills, discontinued or unused preparations, unused unit dose repacks and outdated pharmaceuticals. Waste may also be generated in other areas such as patients rooms, operating rooms, nursing stations and emergency rooms. Examples of waste include partially used vials, syringes and IVs, as well as patient's personal medications.

Pharmacies

Pharmacies may generate wastes via compounding or preparation, outdated pharmaceuticals, damaged packages, or consumer returns.

Long-Term Care Facilities

A long-term care facility generates waste as a result of its central management of

pharmaceuticals in its pharmacy or pharmacy-like area. These wastes would be subject to the regulations since the pharmaceuticals are under the control of the facility. However, pharmaceuticals that are under the control of the patient or resident would be excluded from regulation.

Ambulance Services

Ambulance services may generate waste due to expired, damaged or partially used or unused pharmaceuticals in their units.

C. TYPES OF HAZARDOUS WASTE

A waste is defined as hazardous if it is either a characteristic or listed waste.

Characteristic Hazardous Waste

A characteristic hazardous waste is defined as a waste that has been identified to exhibit one or more of the following attributes (D-list wastes):

1. Ignitable:
   A. Flash point is less than 140 degrees Fahrenheit. (Example: solutions containing more than 24% alcohol).
   B. An oxidizer defined by DOT.
   C. An ignitable compressed gas as defined by the U.S. Department of Transportation. (Example: some aerosol propellants).
2. Corrosive:
   A. The pH is less than or equal to 2.0 or greater than or equal to 12.5.
   B. It is a liquid and corrodes steel at a rate greater than six and thirty-five-hundredths millimeters per year.
   (Example: compounding chemicals, including strong acids, such as glacial acetic acid, and strong bases, such as sodium hydroxide).
3. Reactive:
   A. Reacts violently with water
   B. It is normally unstable and readily undergoes violent change without detonating.
   C. It forms potentially explosive mixtures with water.
   D. When mixed with water, it generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health.
4. Toxic: Fails the Toxicity Characteristic Leaching Procedure (TCLP). (Example: contains arsenic, barium, cadmium, chloroform, chromium, lindane, m-cresol, mercury, selenium or silver at a concentration equal to or greater than the regulatory level).

Listed Hazardous Waste

A listed hazardous waste is defined as a waste that appears on one of four lists of known hazardous wastes (F, P, K or U lists). Most pharmaceutical wastes will be listed under the P- and U-lists.

The P- and U-lists designate as hazardous waste, off-specification formulations and commercial grade formulations of certain unused chemicals that are being disposed. For a waste to qualify as P- or U-listed, the waste must meet the following three criteria:

1. The waste must contain one of the chemicals listed on the P- or U-list;
2. The chemical in the waste must be unused; and
3. The chemical in the waste must be in the form of a commercial chemical product (CCP).

For purposes of the P- and U-lists, a CCP is defined as a chemical that is one of the following:

- 100 percent pure;
- Technical (e.g., commercial) grade; or
- The sole active ingredient in a chemical formulation (saline and dextrose are not considered active ingredients).

While 100 percent pure means that the chemical is the only chemical constituent in the product, technical grade means that the formulation is not 100 percent pure, but is of a grade of purity that is either marketed or recognized in general usage by the chemical industry. Sole active ingredient means that the chemical is the only ingredient serving the function of the formulation.

D. EXCLUSIONS

Medicinal Nitroglycerin. Medicinal nitroglycerin formulations may be considered excluded from the P081 listing, unless they exhibit another characteristic, such as ignitability.

Epinephrine. Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. The Department considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a hazardous waste, however, if it exhibits a characteristic of hazardous waste.

This exemption extends to other P- and U-listed pharmaceuticals administered by syringe. Please note that if residue remaining within a needle and syringe exhibits a characteristic, the needle and syringe need to be managed as a hazardous waste (see Section F. Dual Waste). This applies only to syringes.

Epinephrine salts also are not included within the scope of the P042 listing. The epinephrine salts could be a hazardous waste, however, if they exhibit a characteristic of hazardous waste.

P- and U-list Exclusions. If a listed hazardous waste is listed solely because it exhibits the characteristics of ignitability, corrosivity, and/or reactivity, and the waste does not exhibit the characteristic for which it was listed, then it is not a hazardous waste.

E. NORTH DAKOTA SPECIFIC MANAGEMENT PROCEDURES

Chemotherapy Pharmaceuticals

The following chemotherapy pharmaceuticals are listed as hazardous waste in the North Dakota Hazardous Waste Management Rules:

- U035 Chlorambucil
- U058 Cyclophosphamide
- U059 Daunomycin
- U150 Melphalan
- U010 Mitomoycin C
- U206 Streptozotocin
- U237 Uracil mustard

Several new chemotherapy pharmaceuticals have been introduced since the rules were enacted that have not been characterized or listed. A current list of hazardous drugs prepared by the National Institute for Occupational Safety and Health (NIOSH) contains approximately 135 hazardous drugs, including new antineoplastics, antivirals, and endocrine disruptors. Endocrine disruptors have been of concern due to their possible effects on animal life, particularly aquatic life in the environment. The Department strongly recommends that health-care facilities include the drugs on the NIOSH list in their hazardous waste program. These agents, when disposed of, can potentially be considered hazardous waste.

Trace Chemotherapy Waste - Waste materials that have come into contact with or may contain a few drops of a chemotherapy drug. Empty vials, ampoules, IV's and tubing, personal protection equipment (PPE) such as gowns and gloves, and wipes are not considered hazardous waste. They should be put into a container and disposed of as listed below.

Bulk Chemotherapy Waste - Waste materials containing more than 3 percent of the material by weight or are saturated with chemotherapy drugs. Therefore non-empty vials, ampoules, IV's, and tubing are considered bulk chemotherapy waste and must be managed as hazardous waste. Contaminated PPE and materials used to clean up spilled chemotherapy drugs (rags, towels, pads, etc.) also must be managed as hazardous waste.

Syringes used to dispense chemotherapy drugs, that contain bulk chemotherapy waste, are considered dual waste. Please refer to Section F regarding the management of dual waste.

Filters from chemotherapy drug prep hoods also need to be evaluated to determine if they are a hazardous waste. In addition, each health-care facility must evaluate **all** prep hood filters to determine if they need to be managed as a hazardous waste.

Disposal

The Department recommends that all trace chemotherapy wastes be incinerated (at temperatures between 1,800 and 2,200 degrees Fahrenheit) for destruction. Autoclaving of these chemicals will not destroy them. Bulk chemotherapy waste must be managed as a hazardous waste and shipped to a treatment, storage or disposal facility.

Dispensing Instruments

Drug residues often remain in a dispensing instrument (i.e., pill bottles, wrappers, blisterpacks, foil that enclosed the pharmaceutical, or cups) after the instrument is used to administer medication. The Department considers such residues remaining in a dispensing instrument to have been used for their intended purpose and can be managed as nonhazardous waste. Any additional management practices listed in this guidance document should be followed.

Contaminated Personal Protective Equipment and Spill Materials

Personal protection equipment (PPE) that is worn to protect employees from exposure to hazardous chemicals may become contaminated and may need to be managed as a hazardous waste. Materials used to perform routine cleaning or decontamination of biological safety cabinets and glove boxes, and materials used to clean up spills also may become contaminated with hazardous waste and must be managed properly.

a. Listed Waste

PPE used during chem prep or use should be managed as trace chemotherapy waste.

PPE such as gloves and gowns that are known to be or suspected of having been contaminated with P- or U-listed hazardous waste must be managed as hazardous waste. PPE that is worn routinely but does not appear to have come into contact with listed waste, can be managed as a solid waste.

Any materials used to clean up spill of a material that would be a P- or U-listed waste when disposed must be managed as hazardous waste and cannot be discarded as a trace chemotherapy or solid waste.

b. Characteristic Waste

PPE and spill materials contaminated with characteristic wastes are hazardous only if the PPE and spill material exhibit a characteristic. If these materials exhibit a characteristic, they must be managed as a hazardous waste. If not, they can be managed as a solid waste.

Ambulance Services

Chapter 61-09-01.7 NDAC states, in part, that expired, damaged or unused prescription drugs from an ambulance service must be returned to a licensed pharmacy or pharmacist. All nonprescription drugs must be characterized and managed properly by the ambulance service.

In addition, Chapter 61-09-01.11 NDAC states, in part, that any unused portion of a prescription drug must be returned for disposal or destruction to the emergency room where the patient is being brought for care. The hospital must then manage the drug properly.

Nursing Supply Kits

Chapter 61-09-02-01.8 NDAC states, in part, that any unused portion of a prescription drug must be returned for disposal or destruction to the pharmacy supplying prescription drugs to the nurse or nursing agency.

Destruction of Controlled Substances

Chapter 61-04-03-01 NDAC states, in part, that Pharmacists and pharmacies are prohibited from destruction of controlled substances. Destruction of controlled substances is permitted and shall be limited to the executive secretary of the pharmacy board, or a compliance officer of the pharmacy board, or any one member of the pharmacy board. All U.S. Drug Enforcement Administration (DEA) regulations must be followed for the management and destruction of controlled substances.

Hospice Programs

Chapter 33-03-15-04.6.a NDAC states that the hospice program must have a policy for the disposal of controlled drugs maintained in the patients home when these drugs are no longer needed by the patient.

F. DUAL WASTE

Dual waste is health-care waste that meets the definition of both hazardous and infectious waste. These materials must be managed as both infectious waste and hazardous waste. Generally, pharmaceuticals are not considered infectious waste. However, pharmaceutical dispensing equipment, through use, could be. Sharps containing bulk chemotherapy drugs or pharmaceuticals that are considered characteristic hazardous waste would be considered dual waste. For example, a partially administered syringe containing flu vaccine that has thimerosal added as a preservative is a dual waste with a waste code of D009. Tubing and IV's with needles attached, containing blood or blood products, that contain bulk chemotherapy drugs or hazardous waste also fall into this category.

Sharps, tubing and IVs with attached needles containing bulk chemotherapy waste or hazardous waste must be placed in puncture-resistant containers and labeled as containing hazardous waste and infectious waste. Tubing and IVs (without an attached needle) containing blood and trace chemotherapy waste can still be managed as trace chemotherapy waste and must be incinerated, not autoclaved.

G. REVERSE DISTRIBUTION

An outdated pharmaceutical is generally considered waste at the time the decision is made to discard it. Most facilities use a reverse distributor to manage their outdated pharmaceuticals. Because these pharmaceuticals are being returned for possible manufacturer credit, they still have potential value and are not considered wastes. Keep records of what you have sent off-site to your reverse distributor. Should receipts show that your reverse distributor always disposes of

a pharmaceutical you send it, you need to find out why. If it can never be reused or given credit, then you need to manage it as a waste at your facility. The Department does not believe health-care facilities should use a reverse distribution system to relieve them of the responsibility for making determinations about the discarding of materials as wastes. It remains the generator's responsibility to properly identify materials as wastes. Second, a reverse distribution system cannot be used as a waste management service to generators without the applicable regulatory controls on waste management being in place.

Those pharmaceuticals that cannot be managed through reverse distribution - such as items outdated but not returnable for credit; product used in compounding or IV preparation; spilled or broken product no longer useable for its intended purpose; any items used in cleaning up a spill (vermiculite, paper towels, etc.); and manufacturers' samples - must be characterized as either hazardous or nonhazardous waste and managed properly. Controlled substances must be managed in accordance with the Controlled Substances Act or regulations issued under the U.S. Drug Enforcement Administration.

H. HOW TO DETERMINE IF YOUR WASTE IS HAZARDOUS

The generator may make this determination by using knowledge of the products and processes, testing the waste(s), or a combination of the two.

1. Material Safety Data Sheet (MSDS) - Each product should come with an MSDS. The MSDS may contain data to assist you in determining if your pharmaceutical would be a hazardous waste when disposed.

2. Testing - You can send your waste to a commercial laboratory to test the waste using the Toxicity Characteristic Leaching Procedure (TCLP).

3. Generator Knowledge - Talk to your supplier, manufacturer or other facilities to gather information about the status of your pharmaceutical.

The Department has prepared a list (Attachment 1) that contains products that may or may not be hazardous waste when discarded. It is meant to be a starting point to help businesses generating pharmaceutical waste. However, It is the responsibility of the generator of the waste to make a final waste determination.

I. GENERATOR STATUS

After you have determined which materials are hazardous waste you must determine how much hazardous waste you generate each month. This would include all hazardous waste generated at your facility, not just pharmaceutical hazardous waste. The set of rules you must follow depends on how much waste you generate, how much you store, and how long you store it.

1. **Large Quantity Generator (LQG)**: Generates, in any calendar month, 1,000 kg (2,200 lbs.) or more of hazardous waste; **or** generates, in any calendar month, or accumulates at any time, more than 1 kg (2.2 lbs.) of acute hazardous waste.

2. **Small Quantity Generator (SQG)**: Generates, in any calendar month, more than 100 kg (220 lbs.) but less than 1,000 kg (2,200 lbs.) of hazardous waste; **and** generates, in any calendar month, or accumulates at any time, no more than 1 kg (2.2lbs.) of acute hazardous waste.

3. **Conditionally Exempt Small Quantity Generator (CESQG)**: Generates no more than 100 kg (220 lbs.) of RCRA hazardous waste in any calendar month; **and** accumulates, at any time, no more than 1,000 kg (2,200 lbs.) of hazardous waste.

J. HAZARDOUS WASTE MANAGEMENT

The "North Dakota Hazardous Waste Compliance Guide" has much more information to assist you in the proper management of your hazardous pharmaceutical waste. The guide also provides information about generator status determinations, obtaining a State/EPA identification number, manifest, training, recordkeeping and reporting requirements and can be found on our web page at www.ndhealth.gov/wm/Publications. However, the following are some **general** guidelines you should follow in the proper handling of your hazardous pharmaceutical waste.

Separate and store outdated (unusable) pharmaceuticals from those that can be sent for reverse distribution. Do not mix hazardous pharmaceutical waste with regulated infectious waste for disposal.

Separate waste by hazardous waste classification: P- or U-listed, toxicity, ignitability, corrosivity or reactivity. (Do not place incompatible wastes in the same container.)

While containers of hazardous pharmaceutical waste are in storage:

- Each container must be labeled "hazardous waste".
- Each container must be clearly marked with an "accumulation start date". The accumulation start date is the date that waste is first placed (accumulated) in the container.
- Each container must be closed unless adding or removing waste.
- The storage area must maintain adequate aisle space for inspections and emergency response.
- The containers in storage must be inspected weekly, and an inspection log must be kept.

"Satellite accumulation" is defined as a location at or near the point of hazardous waste generation where waste initially is accumulated in containers before consolidating it at a designated accumulation area (i.e., centralized waste storage/accumulation area). These are used in areas where it takes a long time to collect waste, such as the chemotherapy drug prep room. Satellite accumulation containers must be managed in the following manner:

- The container is marked with the words "Hazardous Waste" or other words that identify the contents of the container;
- The container is in good condition and is compatible with the accumulated waste;
- The container is kept closed, except when it is necessary to add or remove waste;
- An accumulation start date must be clearly marked on the container when it is full and placed in storage.

Hazardous pharmaceutical waste must be shipped offsite to a hazardous waste treatment, storage or disposal facility (TSDF) for proper disposal. Make sure that the TSDF has a State/EPA identification number and is permitted to dispose of the waste you are shipping. Make sure that the transporter you use has a North Dakota Solid Waste Transporter permit and has a State/EPA identification number.

K. NONHAZARDOUS WASTE DISPOSAL OPTIONS

Nonhazardous pharmaceuticals should not be discharged to the sanitary sewer or septic tank. The waste water treatment plants are not equipped to remove the pharmaceuticals from the waste water prior to discharge back into North Dakota's rivers, streams and lakes. Some of the antibiotics in the medications can kill the bugs in the septic tank systems, rendering the systems inoperable.

However, there are some solutions from IV bags that can be safely discharged to the sewer such as saline solution, glucose solution, dextrose solution, lactate, vitamins, potassium, and other salts and electrolytes.

Nonhazardous pharmaceuticals should never be autoclaved. The Department encourages the incineration of nonhazardous pharmaceuticals. This would avoid diversion of the pharmaceuticals and management of contaminated leachate from the landfill. Nonhazardous pharmaceuticals can be disposed of at a permitted municipal solid waste landfill with approval from the landfill operators. Liquids must be solidified with some type of absorbent prior to disposal.

L. FOR MORE INFORMATION

Minnesota Pollution Control Agency, "Disposing of Unwanted Medications" at:
www.pca.state.mn.us/oea/hhw/pharmaceuticals.cfm

Washington State Department of Ecology information for medical facilities at:
www.ecy.wa.gov/programs/hwtr/pharmaceuticals/

Pharmaceutical waste "Frequently Asked Questions" at:
www.pharmecology.com/pedd/jsp/static/a2_waste_faqs.jsp

University of California - "Pharmaceutical Waste Guidelines" at:
www.ehs.uci.edu/programs/enviro/Pharmaceutical%20Waste.pdf

"Managing Pharmaceutical Waste, A 10-Step Blueprint for Healthcare Facilities In the United States", revised August 2008: www.hercenter.org/hazmat/tenstepblueprint.pdf

"Best Management Practices for Hospital Waste" Publication Number 05-04-013, October 2005, Washington State Department of Ecology: www.ecy.wa.gov/pubs/0504013.pdf

Pharmaceutical Wastes in Healthcare Facilities:
www.hercenter.org/hazmat/pharma.cfm

Florida publications about disposal of unwanted medications:
www.dep.state.fl.us/waste/categories/medications/pages/publications.htm

Questions or information requests concerning this document may be directed to Christine Roob, North Dakota Department of Health, Division of Waste Management, at 701.476.4121.

Attachment 1. Hazardous Waste Pharmaceuticals
(This list is not all inclusive)

Pharmaceutical or Constituent	D-List	P-List	U-List
Absolute alcohol & dehydrated, P.F.	D001		
Acetic acid	D002		
Acetone - nail polish remover and solvent	D001		U002
Acetophenetidin (veterinary analagesic)			U187
Actinomycin D solution in methanol	D001		
Adrenalin		P042	
Alcohol, pharmaceuticals containing >24% alcohol	D001		
Ammonia, aromatic Inhalant	D001		
Amyl nitrite	D001		
Arsenic trioxide		P012	
Barium	D005		
Carmustine	D001		
Castellani paint	D001		
Chloral (CIV) and chloral hydrate			U034
Chlorambucil (chemotherapy drug)			U035
Chlornaphazin (chemotherapy drug)			U026
Chloroform	D022		U044
Chromium	D007		
Coal tar solution	D001		
Collodion (or flexible collodion)	D001		
Compound W	D001		
Cresol	D026		
Cyclophosphamide (chemotherapy drug), Cytoxan (lyophilized), Neosar			U058
Daunomycin (chemotherapy drug), Rubomycin			U059
Dental antiseptic rinse	D001		

Pharmaceutical or Constituent	D-List	P-List	U-List
Dental amalgam (contains silver, mercury)	D009/ D011		
Dichlorobenzene (moth repellent and deodorizer blocks)			U071
Diechlorodifluoromethane			U075
Diethylstilbesterol (chemotherapy drug)			U089
Epinephrine (only if it is the sole active ingredient and is not a salt)		P042	
Ethyl chloride	D001		
Ethyl ether			U117
Ethylene oxide			U115
Etopside (chemotherapy drug)	D001		
Flexible collodion	D001		
Formaldehyde			U122
Formic acid	D002		
Glacial acetic acid	D002		
Hexachlorophene			U132
Hydrochloric acid	D002		
Lindane (some lice shampoos and sprays)			U129
Melphalan (chemotherapy drug)			U150
Mercury-containing pharmaceuticals (may be used as a preservative)	D009		
Mercury			U151
Mercury, (acetato-O)phenyl		P092	
Mercury fulminate		P065	
Methyl alcohol (Methanol)	D001		
Mitomycin C (chemotherapy drug)			U010
Naphthalene			U165
Nicotine & salts - antismoking gum, tablets/ capsules and patches		P075	
Oxalic acid crystals	D002		

Pharmaceutical or Constituent	D-List	P-List	U-List
Pacitaxel	D001		
Paraldehyde (DEA controlled)			U182
Phenol			U188
Phentermine (CIV)		P046	
Physostigmine		P204	
Physostigmine salicylate		P188	
Podophyllum resin topical	D001		
Potassium permanganate	D001		
Reserpine			U200
Resorcinol			U201
Saccharine (if not mixed with a second sweetener)			U202
Salycylic acid	D002		
Selenium	D010		
Selenium sulfide (Dandrex, Exsel, Selsun Blue)			U205
Silver	D011		
Silver nitrate	D011, D001		
Sporanox solution	D002		
Streptozotocin			U206
Strychnine		P108	
Thallium chloride			U216
o-Toluidine			U328
Trichloromonofluoromethane			U121
Uracil mustard			U237
Warfarin (when present at concentrations < 0.3%)			U248
Warfarin (when present at concentrations > 0.3%)		P001	
Vepesid	D001		