Managing Chemotherapy Waste

Guidance on Solid and Hazardous Waste Requirements

Introduction

Healthcare facilities generate a variety of waste streams including pharmaceutical waste that may also be hazardous waste. Chemotherapy waste, which is a pharmaceutical waste, presents regulatory challenges because the chemotherapy wastes may fall into one or more of the following three regulatory categories:

- Trace chemotherapy waste regulated under s. NR 526.055, Wis. Adm. Code.
- Infectious waste regulated under s. NR 526.05, Wis. Adm. Code.
- Hazardous waste pharmaceutical regulated under subchapter P of ch. NR 666, Wis. Adm. Code.

Hazardous waste regulations are found in chapters <u>NR 600-679</u> of the Wisconsin Administrative Code

This guidance document provides information on how to identify and manage trace chemotherapy waste (TCW) and chemotherapy waste that is pharmaceutical hazardous waste.

Definitions and Terms

Antineoplastic drugs are cytotoxic chemicals, acting to prevent, inhibit or halt the development of a tumor. Their toxicity to cell growth stops tumor growth but is also what makes these drugs dangerous.

Biological cancer drugs (biologics) Many newer generation cancer drugs are biologics and are no longer antineoplastic chemicals. Examples of biologics are monoclonal antibodies, cancer vaccines, chimeric antigen receptor (CAR) T-cell therapy, cytokine therapy, and oncolytic virus therapy. <u>If the waste is determined to not be hazardous</u>, these biologics are more appropriately disposed as infectious or solid waste.

Managing chemotherapy waste as hazardous waste: Hazardous waste has specific management requirements for marking, labeling, time limits for storing, transportation, disposal methods and record-keeping. Hazardous waste generators must comply with the applicable requirements in s. NR 660 to 679, Wis. Adm. Code. More information is on the DNR's Hazardous Waste Resources webpage: https://dnr.wi.gov/topic/Waste/HWResources.html.

- Small Quantity Generator Responsibilities (WA-294): <u>https://apps.dnr.wi.gov/doclink/waext/wa294.pdf</u>
- Very Small Quantity Generator Responsibilities (WA-295): <u>https://dnr.wi.gov/files/pdf/pubs/wa/wa295.pdf</u>
- Waste Determination and Recordkeeping (WA-1152): <u>https://dnr.wi.gov/files/pdf/pubs/wa/wa1152.pdf</u>





Chemotherapy drugs are antineoplastic, cytotoxic chemicals used to inhibit cancer growth. Chemotherapy wastes include chemotherapy drugs, their containers (vials, bottles, other packaging) and items contaminated with chemotherapy drugs, such as IV bags and tubing, syringes, gloves, and spill clean-up materials.

Hazardous waste (HW) has a specific regulatory meaning in under the Resource Conservation and Recovery Act (RCRA) and wastes may be hazardous due to a characteristic or because it is listed. [s. NR 661.0021 to 661.0024, Wis. Adm. Code]

Hazardous Waste Pharmaceuticals (HW Pharma) are pharmaceuticals that fit the above HW criteria. [s. NR 666.500(2), Wis. Adm. Code]

 Subchapter P regulations were developed to streamline the management of hazardous waste pharmaceuticals for facilities operating under the regulation. [NR 666.500 through NR 666.510, Wis. Adm. Code]

For more information, review the following guidance document and webpage:

- Healthcare Facilities: Pharmaceutical Wastes and Subchapter P (WA-1902): <u>https://apps.dnr.wi.gov/doclink/waext/wa1902.pdf</u>
- Healthcare Facilities: Definitions (WA-1214): <u>https://apps.dnr.wi.gov/doclink/waext/wa1214.pdf</u>
- Healthcare Facility Waste Overview: <u>https://dnr.wisconsin.gov/topic/HealthWaste/Business.html</u>

Hazardous drug according to The National Institute for Occupational Safety and Health (NIOSH) is a drug that poses a carcinogenic, reproductive or developmental hazard. A drug that is classified as hazardous by NIOSH is not necessarily a hazardous waste.

Potentially creditable HW pharma [s. NR 666.500(10)(d), Wis. Adm. Code] may be returned to the manufacturer or a reverse distributor for credit. HW pharma are only eligible for reverse distribution if they are:

- o not leaking
- o unexpired or not more than one year past their expiration date
- o do not display any other characteristics that would likely make them ineligible for return
- Manage potentially creditable HW pharmaceuticals according to the standards in s. NR 666.503, Wis. Adm. Code. Do not mix drugs eligible for return with other non-returnable pharmaceuticals.

Unused, unexpired or discontinued chemotherapy drugs may be donated as product to pharmacies or medical facilities participating in the cancer drug repository program. The drugs must be more than three months from their expiration date (will not expire until at least 90 days after the donation is made) and in their original, unopened tamper-evident unit dose packaging.

Find additional information on the Wisconsin Department of Health's Drug Repository Program at: <u>https://www.dhs.wisconsin.gov/guide/cancer-drugrepo.htm</u>

Non-creditable HW pharma [s. NR 666.500(6), Wis. Adm. Code] are drugs that can no longer be used, cannot be donated to the cancer drug repository, or returned to the manufacturer or reverse distributor, and are destined for disposal. This includes:

- o investigational drugs and free samples of pharmaceuticals
- o residues of pharmaceuticals remaining in empty containers
- contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Trace chemotherapy waste (sometimes called bulk chemotherapy waste) [s. NR 500.03(237m), Wis. Adm. Code] are items contaminated with antineoplastic chemotherapy drugs and includes items that have come into contact with chemotherapy drugs such as:

- o drug dispensing devices, containers or IV bags
- o gloves or other materials that have come into contact with chemotherapy drugs
- spill cleanup materials

For an updated list of antineoplastic drugs that would be considered TCW, consult the "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings" at <u>https://www.cdc.gov/niosh/docs/2016-161/default.html</u>.

Chemotherapy Drugs that are HW Pharmaceuticals

The DNR is aware of 10 chemotherapy drugs that are HW pharmaceuticals when discarded. The following table lists the generic name, brand name, and the U.S. Environmental Protection Agency (EPA) waste codes for these drugs.

Generic name	Brand Name	Waste Code
Arsenic trioxide	Trisenox	P012, D004
Chlorambucil	Leukeran	U035
Cyclophosphamide	Cytoxan, Neosar	U058
Daunomycin	Daunorubicin, Cerubidin, DaunoXome, Rubidomycin	U059
Diethystilbestrol	DES, Stilphostrol	U089
Melphalan	Alkeran, L-PAM	U150
Mitomycin C	Mitomycin, Mutamycin	U010
Streptozotocin	Streptozocin, Zanosar	U206
Uracil Mustard	Uramustine	U237

Excess, unadministered, HW chemotherapy drugs must be managed as HW pharmaceuticals when discarded. [s. NR 661.0033(1), Wis. Adm. Code]

Containers that held HW chemotherapy drugs, and do not meet the definition of RCRA empty, are hazardous waste pharmaceuticals when discarded. [s. NR 666.507, Wis. Adm. Code]

See <u>Managing Empty Containers (WA-1256)</u>.

Management and Disposal

Chemotherapy waste can be combined or be managed separately as HW Pharma and non-HW TCW chemotherapy wastes. If combining chemotherapy wastes, the waste must be managed as HW pharmaceuticals unless you have made the determination that only non-HW chemotherapy waste is in the container. Note that metal bearing pharmaceutical waste cannot be incinerated as a disposal method. See the DNR publication, <u>Healthcare Facilities: Pharmaceutical Wastes and Subchapter P (WA-1902)</u>, for more details.

Management of HW Pharma

- Manage as HW pharmaceuticals under the standards in s. NR 666.502, Wis. Adm. Code.
- Label containers of HW pharmaceutical chemotherapy waste as "Hazardous Waste Pharmaceuticals"
- Send to a licensed or permitted hazardous waste incinerator.

Management of non-HW TCW

Tamoxifen is an example of an antineoplastic chemotherapy drug that is not a hazardous waste pharmaceutical but is dangerous because of its properties of anti-angiogenetic activity and as a selective estrogen receptor modulator. To reduce potential harm to human health and the environment these non-HW TCW chemicals should be disposed of by incineration. The recommended management practice for handling non-HW TCW is as follows [s. NR 526.055(3), Wis. Adm. Code]:

- Place all breakable TCW in rigid, puncture-resistant plastic containers labeled "trace chemotherapy waste" and "incinerate only" and send it to a medical waste, or hazardous waste incinerator approved to take the waste.
- Place soft TCW, including items like gloves, towels, empty IV bags and tubing, in either a rigid plastic container or a tear-resistant plastic bag or double plastic bag that meets or exceeds 165 grams labeled "**trace chemotherapy waste**" and "**incinerate only**" and send it to a medical waste or hazardous waste incinerator approved to take the waste.
- Place sharps contaminated with chemotherapy drugs in a sharps container marked "**trace chemotherapy waste**" and "**incinerate only**" and send the sharps to a medical waste incinerator approved to take the waste.

If non-HW TCW is mixed with infectious waste or solid waste, the mixture must be managed as TCW (i.e., incinerated).

Resources and Contact Information

For more information including <u>publications</u>, inspection forms, and administrative codes and statutes, go to <u>dnr.wi.gov</u> and search "hazardous waste resources." Use the *Additional Resources* menu to navigate to specific topics. For staff contact information, go to the <u>staff directory</u> and enter "hazardous waste requirements" in the subject field and choose the appropriate county contact.

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Mailing address: DNR Waste and Materials Management Program, PO Box 7921 Madison, WI 53707 Email: <u>DNRWasteMaterials@Wisconsin.gov</u>

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