Pursuant to ch. 227, Wis. Stats., the Wisconsin Department of Natural Resources has finalized and hereby certifies the following guidance document.

<table>
<thead>
<tr>
<th>DOCUMENT ID</th>
<th>WA-19-1258-C</th>
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<tbody>
<tr>
<td>DOCUMENT TITLE</td>
<td>Managing Chemotherapy Waste</td>
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<tr>
<td>PROGRAM/BUREAU</td>
<td>Waste and Materials Management</td>
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<tr>
<td>STATUTORY AUTHORITY OR LEGAL CITATION</td>
<td>Ch. 291, Wis. Stats.</td>
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**DATE SENT TO LEGISLATIVE REFERENCE BUREAU (FOR PUBLIC COMMENTS)**

October 14, 2019

**DATE FINALIZED**

November 6, 2019

**DNR CERTIFICATION**

I have reviewed this guidance document or proposed guidance document and I certify that it complies with sections 227.10 and 227.11 of the Wisconsin Statutes. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is not explicitly required or explicitly permitted by a statute or a rule that has been lawfully promulgated. I further certify that the guidance document or proposed guidance document contains no standard, requirement, or threshold that is more restrictive than a standard, requirement, or threshold contained in the Wisconsin Statutes.

Signature: [Signature]  
Date: November 6, 2019
Introduction
Chemotherapy waste includes chemotherapy drugs, their containers (vials, bottles, other packaging) and items contaminated with chemotherapy drugs, such as IV bags and tubing, syringes, gowns, gloves, sheets and pads. This fact sheet will help you determine if your waste is trace chemotherapy waste, bulk chemotherapy waste, listed hazardous waste or characteristic hazardous waste and provides information on how to manage these different waste types. In this document, chemotherapy waste includes both antineoplastic and cytotoxic wastes.

What chemotherapy wastes are hazardous wastes?
Wastes can be hazardous waste because of their characteristics (ignitability, corrosivity, reactivity and toxicity) or because they are specifically listed as hazardous waste. Listed hazardous wastes include spent materials (F- and K-listed wastes) and commercial chemical products (U- and P-listed wastes. See “Evaluating and Managing Pharmaceutical Waste” at dnr.wi.gov/files/pdf/pubs/wa/wa1257.pdf.

Nine chemotherapy drugs are listed or characteristic hazardous waste. The following table lists the generic name, brand name and U.S. Environmental Protection Agency (EPA) waste codes for these drugs.

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Waste Code</th>
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<tbody>
<tr>
<td>Arsenic Trioxide</td>
<td>Trisenox</td>
<td>P012, D004</td>
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<tr>
<td>Chlorambucil</td>
<td>Leukeran</td>
<td>U035</td>
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<tr>
<td>Cyclophosphamide</td>
<td>Cytoxan, Neosar</td>
<td>U058</td>
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<tr>
<td>Daunomycin</td>
<td>Daunorubicin, Cerubidin, DaunoXome, Rubidomycin</td>
<td>U059</td>
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<tr>
<td>Diethystilbestrol</td>
<td>DES, Stilphostrol</td>
<td>U089</td>
</tr>
<tr>
<td>Melphalan</td>
<td>Alkeran, L-PAM</td>
<td>U150</td>
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<tr>
<td>Mitomycin C</td>
<td>Mitomycin, Mutamycin</td>
<td>U010</td>
</tr>
<tr>
<td>Streptozotocin</td>
<td>Streptozocin, Zanosar</td>
<td>U206</td>
</tr>
<tr>
<td>Uracil Mustard</td>
<td>Uramustine</td>
<td>U237</td>
</tr>
</tbody>
</table>

Note: This list may not be all-inclusive since new products may be introduced at any time.

Learn more about hazardous waste at dnr.wi.gov search ”hazardous waste.”

Chemotherapy waste contaminated with listed hazardous waste chemotherapy drugs is listed hazardous waste and must be managed as hazardous waste. Chemotherapy waste contaminated with characteristic hazardous waste chemotherapy drugs should be tested to determine if the mixture is a characteristic hazardous waste; if you do not test chemotherapy waste, you should manage it as characteristic hazardous waste. Containers that held hazardous waste chemotherapy drugs, and do not meet the definition of “empty,” are hazardous waste when discarded. See “ Managing Empty Containers” at dnr.wi.gov/files/pdf/pubs/wa/wa1256.pdf.

How should my facility manage chemotherapy wastes?
Unused, expired or discontinued chemotherapy drugs
You may donate unused or discontinued chemotherapy drugs as product to pharmacies or medical facilities participating in the cancer drug repository program. The drugs must be more than six months from their expiration date and in their original, unopened tamper-evident unit dose packaging. Find additional information on the Wisconsin Department of Health website at: dhs.wisconsin.gov/bqaconsumer/cancerdrugreposy.htm.

You may return chemotherapy drugs to the manufacturer or a reverse distributor for credit or as a product. Chemotherapy drugs are only eligible for reverse distribution if they are not leaking or partially used liquids or pastes and do not display any other characteristics that would likely make them ineligible for return. Do not mix drugs eligible for return with other non-returnable pharmaceuticals.

Chemotherapy drugs that can no longer be used and cannot be donated to the cancer drug repository or returned to the manufacturer or reverse distributor are considered waste. Manage chemotherapy waste that is a listed or characteristic hazardous waste as hazardous waste. Use the attached Flow Chart Evaluation Tool to determine whether chemotherapy waste you generate is hazardous waste.
What is the difference between trace and bulk chemotherapy waste?

Trace chemotherapy wastes fall into two categories:
• Items contaminated with residual amounts of chemotherapy drugs, such as empty drug bottles, drug dispensing devices or IV bags and tubing.
• Gloves, gowns, masks, goggles and other disposable items used when administering chemotherapy drugs if chemotherapy drugs have not spilled, leaked or dripped on them.

Bulk chemotherapy waste is any waste contaminated with more than residual amounts of chemotherapy drugs. Examples include:
• drug dispensing devices or IV bags that are not completely empty;
• gloves, gowns or other materials that have chemotherapy drugs spilled on them; and
• spill cleanup materials.

Trace chemotherapy waste
Segregate the different wastes; if you mix nonhazardous trace chemotherapy waste with infectious waste or solid waste, the mixture must be managed as trace chemotherapy waste (i.e., incinerated). Manage nonhazardous trace chemotherapy waste as follows:
• Place all trace chemotherapy waste in rigid, puncture-resistant plastic containers labeled “trace chemotherapy” and “incinerate only” and send it to a medical waste, solid waste or municipal waste incinerator approved to take the waste.
• Place soft trace chemotherapy waste, including items like gloves, disposable gowns, 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 resistance and send it to a medical waste incinerator.

Bulk chemotherapy waste
Chemotherapy waste that is not trace chemotherapy waste or hazardous waste is bulk chemotherapy waste. The DNR strongly recommends you manage nonhazardous bulk chemotherapy waste, including nonhazardous chemotherapy drugs, as trace chemotherapy waste and send it to a medical waste or hazardous waste incinerator.

Can I place all chemotherapy waste in one container for incineration?
Yes. If all chemotherapy waste is placed in one container, it must be managed as hazardous waste unless you have made a determination that only nonhazardous chemotherapy waste is in the container. You may set up two waste chemotherapy containers; one for hazardous chemotherapy waste and one for nonhazardous chemotherapy waste. Send containers of hazardous chemotherapy waste to a licensed or permitted hazardous waste incinerator. Label containers of nonhazardous chemotherapy waste as containing nonhazardous bulk and trace chemotherapy waste and “incinerate only” and send the containers to a hazardous waste incinerator or medical waste incinerator.

Where can I get more information?
Visit dnr.wi.gov search “healthcare waste.”

Disclaimer: This document is intended solely as guidance and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. Any regulatory decisions made by the Department of Natural Resources in any matter addressed by this guidance will be made by applying the governing statutes and administrative rules to the relevant facts.

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Flow Chart Evaluation Tool: Chemotherapy Waste

This flow chart will help you determine how to manage chemotherapy waste. In addition to this evaluation, you will need to determine whether the waste is also regulated under other rules (e.g., as infectious waste, a controlled substance, radioactive waste, etc.). The flow chart notes contain important information that will help ensure correct evaluation and proper management of chemotherapy waste. Remember, you must evaluate all chemotherapy waste generated at your facility.

Is the waste a chemotherapy drug eligible for the cancer drug repository program, a reverse distribution program, or return to the manufacturer?  
- **Yes**: Manage the drug as product.  
- **No**: Manage as hazardous waste.

Is the waste an empty container that held chemotherapy drugs?  
- **Yes**: Did the container hold a chemotherapy drug that is a listed or characteristic hazardous waste?  
  - **Yes**: Manage as hazardous waste.  
  - **No**: Manage as trace chemotherapy waste.
  
  *Does the container meet the definition of “empty”?!*

  *Manage as hazardous waste.*  

  *Manage as trace chemotherapy waste.*

Is the waste contaminated with only nonhazardous chemotherapy drugs?  
- **Yes**: Manage as trace chemotherapy waste.  
- **No**: Manage as hazardous waste.

Is the waste a U- or P-listed hazardous waste chemotherapy drug?  
- **Yes**: Manage as hazardous waste.  
- **No**: Manage as hazard.

Is the waste contaminated with a P- or U-listed hazardous waste?  
- **Yes**: Manage as hazardous waste.  
- **No**: Manage as hazardous waste.

Is the waste a chemotherapy drug that is a characteristic hazardous waste?  
- **Yes**: Manage as hazardous waste.  
- **No**: Manage as hazardous waste.

Is the waste a mixture of solid waste and characteristic hazardous waste that exhibits a hazardous waste characteristic?  
- **Yes**: Manage as hazardous waste.  
- **No**: Manage as trace chemotherapy waste.

Managing waste as trace chemotherapy waste: Manage nonhazardous trace chemotherapy waste according to the requirements in s. NR 526.055, Wis. Adm. Code. Send trace chemotherapy waste to a solid waste, medical waste or hazardous waste incinerator approved to accept trace chemotherapy waste. Trace chemotherapy waste that is mixed with infectious waste must be managed and incinerated as a trace chemotherapy waste. Alternate methods of treating infectious waste (e.g. mechanical grinding or gas, steam or chemical disinfection) will not destroy the toxic properties of the chemotherapy drugs.

Flow Chart Notes

1 Drugs that can be donated to the cancer drug repository program, sent back to the manufacturer or sent to a reverse distribution program are products since they can still be used for their intended purposes or are eligible for credit. As products, these drugs are not subject to the hazardous waste or solid waste (trace chemotherapy, infectious, medical waste) requirements, but other regulations may apply.

2 Containers (vials, IV bags, bottles and other packaging) are empty when all material has been removed by normal means, such as by pouring or aspirating. An empty container should only contain a few drops or a residue clinging to the sides.

2A Determine whether the container held a characteristic or P- or U-listed hazardous waste. See flow chart note 4 to determine if the drug is a P- or U-listed hazardous waste. See flow chart note 6 to determine if the drug is a characteristic hazardous waste. Manage empty nonhazardous containers as trace chemotherapy waste.

2B Since the container held a characteristic or P- or U- listed hazardous waste, you must determine if the container meets the definition of “empty”. A container that held a P-listed hazardous waste must be triple rinsed to meet the definition of “empty.” A container that held a U-listed or characteristic waste must have less than 3 percent total capacity remaining in the container to be empty. For more information about empty containers, see the DNR fact sheet, Managing Empty Containers at https://dnr.wi.gov/files/pdf/pubs/wa/wa1256.pdf. Manage empty containers as trace chemotherapy waste. Manage non-empty containers as characteristic or listed hazardous waste.

3 Trace chemotherapy waste contains no more than a residue of nonhazardous chemotherapy drugs. Trace chemotherapy waste includes containers that are empty or gloves, masks, gowns or other disposable items used when administering chemotherapy drugs if no spills occurred. If chemotherapy drugs have spilled, dripped or leaked, the item is bulk chemotherapy waste. Best management practice is to manage all nonhazardous bulk chemotherapy waste as trace chemotherapy waste (send to a licensed or approved incinerator).

4 To be a P- or U-listed waste, the discarded drug must be an unused product and the chemical listed as the P- or U-waste must be the sole active ingredient. The active ingredient is the substance that is pharmaceutically active. A mixture of 2 or more chemotherapy drugs containing more than one active ingredient is not P- or U-listed waste. Manage discarded, unused P- or U- listed chemotherapy drugs (e.g. expired drugs) as hazardous waste. Waste residue remaining in a syringe or needle after administration is considered a used chemotherapy drug and is not a P- or U- listed hazardous waste. Containers, such as IV bags or vials, are P- or U- listed hazardous waste unless they meet the definition of empty.

5 Materials contaminated with P- or U-listed hazardous wastes are themselves P- or U-listed hazardous waste by the mixture rule. See the DNR publication “Is Your Waste Hazardous?” (link above) for more information. Manage equipment, garments, absorbents and spill clean-up material contaminated with P- or U-listed waste as hazardous waste.

6 Characteristic hazardous wastes include:
   - D001 ignitable wastes—liquids having a flash point less than 140°F, spontaneously combustible nonliquids or flammable gases and oxidizers;
   - D002 corrosive wastes—aqueous liquids with a pH ≤ 2.0 or ≥ 12.5 or liquids that corrode plain steel at a rate greater than 0.250 inches per year;
   - D003 reactive wastes—normally unstable materials, materials that react violently with water or detonate, explode or generate toxic gases when mixed with water; and,
   - D004 to D043 toxic wastes—wastes containing certain metals, organics or pesticides that leach out of the waste under certain conditions at or above maximum allowable concentrations. A mixture of arsenic trioxide and other chemotherapy drugs may be a characteristic hazardous waste for arsenic toxicity (D004). Manage characteristic hazardous waste as hazardous waste.

7 Mixtures of characteristic hazardous waste and solid waste are hazardous waste if the mixture exhibits a hazardous waste characteristic. For example, absorbent materials used to clean up a spill of an arsenic trioxide chemotherapy drug mixture may be a characteristic hazardous waste for arsenic toxicity (D004). Manage mixtures exhibiting a hazardous waste characteristic as hazardous waste.

8 The DNR strongly recommends that all nonhazardous chemotherapy waste be sent to a medical waste incinerator or a solid waste, municipal waste or hazardous waste incinerator approved to accept chemotherapy waste. Sending bulk chemotherapy waste to a solid waste landfill may cause chemotherapy drugs to be released into the liquids seeping through the landfill (leachate). The leachate may be sweered without adequate treatment to destroy the toxic effects of the chemotherapy drugs. Do not dispose of bulk chemotherapy waste with infectious waste since some infectious waste treatment methods will not destroy the toxic properties of the chemotherapy drugs and may lead to chemical exposure of waste handlers.