Questions and Answers Regarding the Management of Waste Chemotherapy (Antineoplastic) Drugs

Currently, the Food and Drug Administration (FDA) has listed over 100 oncology drugs with approved indications. Less than half of these were approved prior to 1984, when federal hazardous waste regulations for generators became effective. Of these 100 drugs, EPA currently lists nine as potential hazardous wastes. Many of these drugs are known by trade names so in order to determine if a particular drug may be a listed waste, Region 2 recommends that you obtain the Chemical Abstracts Service (CAS) registry number and search for that chemical using the List of Lists -- Consolidated List of Chemicals Subject to the Emergency Planning and Community Right-to-Know Act (EPCRA) and Section 112(r) of the Clean Air Act (EPA 550-B-01-003) (http://www.epa.gov/ceppo/pubs/title3.pdf).

Please note that the following lists may not be complete and should be relied upon only as general guidance.

The nine oncology drugs that EPA currently lists as potential hazardous wastes are:

<table>
<thead>
<tr>
<th>EPA Waste Code</th>
<th>Chemical</th>
<th>Trade Names &amp; Synonyms</th>
<th>CAS Registry Number</th>
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<tr>
<td>P012</td>
<td>Arsenic Trioxide</td>
<td>Trisenox, Arsenic oxide (As2O3); Arsenic trioxide (As2O3); Arsenite; Arsenous oxide; Arsenic oxide; Arsenious oxide; Arsenious acid; Arsenious oxide; White arsenic; Arsenic(III) oxide; Arsenous acid; Arsenic sesquioxide (As2O3); Arsenic trioxide, solid; Arsenicum album; Arsenous acid anhydride; Arsenous anhydride; Diarsonic trioxide; Arsenic(III) trioxide; Arsenic(3) oxide</td>
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<tr>
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<td>Chlorambucil</td>
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<td>4-[Bis(2-chloroethyl)amino]-;</td>
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<td>chloroethyl)amino]benzene-;</td>
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<td>U058</td>
<td>Cyclophosphamide</td>
<td>Cytoxan; CTX; Neosar; Procytox; 2H-1,3,2-Oxazaphosphorin-2-amine, N,N-bis(2-chloroethyl) tetrahydro-, 2-oxide; 2H-1,3,2-Oxazaphosphorine, 2-[bis(2-chloroethyl)amino) tetrahydro-, 2-oxide; 2-Oxide-N,N-bis(2-chloroethyl) tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine; 2-(Bis(2-chloroethyl) aminotetrahydro-2H-1,3,2-oxazaphosphorine, 2-Oxide; N,N-Bis(2-chloroethyl) tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine 2-oxide</td>
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<td>U059</td>
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<td>Daunorubicin; Cerubidine; DaunoXome; Rubidomycin; Liposomal Daunorubicin; 5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy-.alpha.-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8S-cis)-; 5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy)-.alpha.-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8S-cis)-; 5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy-.alpha.-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8S-cis)-; 5,12-Naphthacenedione, 8-acetyl-10-[(3-amino-2,3,6-trideoxy-.alpha.-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-, (8S-cis)-; (8S-cis)-8-Acetyl-10-[(3-amino-2,3,6-trideoxy-.alpha.-L-lyxo-hexopyranosyl)oxy]-7,8,9,10-tetrahydro-6,8,11-trihydroxy-1-methoxy-5,12-</td>
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<td>Diethylstilbestrol</td>
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<td>Alkeran; L-PAM; L-Phenylalanine, 4-[bis(2-chloroethyl)amino]-; L-Phenylalanine, 4-[bis(2-chloroethyl)amino]; L-Phenylalanine, 4-[bis(2-chloroethyl) aminol]; Alanine, 3-[p-bis(2-chloroethyl)amino]phenyl-, L-; L-Phenylalanine, 4-[bis(2-chloroethyl)aminol]-</td>
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<td>U010</td>
<td>Mitomycin C</td>
<td>Mitomycin; Mutamycin; Mitocin-C; Azirino[2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[aminocarbonyl]oxy]methyl]-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-; (1aS,8S,8aR,8bS)-; Azirino[2,3:3,4]pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[aminocarbonyl]oxy]methyl]-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, (1aS-(1a.alpha., 8.beta., 8a.alpha.,8b.alpha.))-; Azirino[2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[aminocarbonyloxy]methyl]-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, (1aS-(1a.alpha.,8.beta.,8a.alpha.,8b.alpha.)))-; Ametycine; MMC; Azirino[2',3':3,4]pyrrolo[1,2-a]indole-4,7-dione, 6-amino-8-[[aminocarbonyl]oxy]methyl]-1,1a,2,8,8a,8b-hexahydro-8a-methoxy-5-methyl-, (1aS-(1a.alpha.,8.beta.,8a.alpha.,8b.alpha.))-;</td>
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<td>EPA Waste Code</td>
<td>Chemical</td>
<td>Trade Names &amp; Synonyms</td>
<td>CAS Registry Number</td>
</tr>
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<tr>
<td>U015 Azaserine</td>
<td>L-Azaserine; Diazoacetic acid ester with serine; 0-Diazoacetyl-L-serine</td>
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<td>U026 Chlornaphazin</td>
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</table>

There are also several other drugs used in cancer research or treatment; but not FDA approved as antineoplastics that may be hazardous wastes when disposed:
Other drugs used in cancer treatment may also be regulated as hazardous wastes because they exhibit one or more characteristics (ignitable, corrosive, reactive, or toxic (as determined by the toxicity characteristic leaching procedure (TCLP))). Generator knowledge or laboratory testing can be applied to determine whether any of these drugs are hazardous wastes when discarded (See 40 CFR 261 Subpart C).

In addition to the federal requirements, some states may regulate additional chemotherapy drugs as hazardous wastes or may regulate certain chemotherapy wastes as medical wastes.

During inspections, industry conferences, and EPA-sponsored training, EPA has found that there are frequently recurring questions regarding chemotherapy waste management. We have provided the questions and answers below. Please note that these answers are interpretations made by knowledgeable EPA Region 2 staff familiar with the federal RCRA regulations and the unique situations sometimes encountered in waste identification and management of healthcare wastes. For healthcare facilities located in other Regions and in states that are authorized to implement the RCRA program (i.e., New York and New Jersey in Region 2), we strongly suggest that you direct any questions to the proper regulatory authorities since reliance on Region 2 interpretations may not result in full compliance if the regulatory authority in those jurisdictions has arrived at a different interpretation.
**Question 1:** Some containers of chemotherapy drugs may expire or may no longer be of use at a hospital. These unopened containers are sent back to the manufacturer or distributor in a pharmacy take back. Is a container of chemotherapy drug sent back to the manufacturer or distributor for ultimate disposal considered a solid waste?

**Answer:** Yes. If the material is sent back for ultimate disposal, the material is a solid waste and if it is listed or exhibits a characteristic, it is a hazardous waste.

Reverse distribution is a process under which pharmaceutical (including chemotherapy drugs) or other products may be returned to the manufacturer for potential reuse. Pharmaceutical products may be returned for many reasons, including, among others: 1) an oversupply at the dispenser, 2) expiration of the recommended shelf life, 3) a recall has been initiated by the manufacturer, 4) the product was received as a result of a shipping error, and 5) the product has been damaged. In general the dispensers of the pharmaceutical products do not know whether the returned products will be reused, reclaimed, sold overseas, or disposed (i.e., they are not able to determine whether these materials are solid wastes). Because the dispensers receive credit for the returned products (either because the products actually have real value to manufacturer or because such credits are part of a competitive marketing approach), the products have a monetary value to the dispensers and they would not normally assume such materials to be wastes.

Under the federal regulations, such returned products are not considered solid wastes until a determination is made to discard these materials. The returned products themselves (being "commercial chemical products" under our classification system) are considered more product-like than waste-like (until a determination is made to dispose of them) because recycling by use/reuse is generally a viable option. If the underlying assumption is that the returned products will be recycled, until the manufacturer or wholesaler determines otherwise (assuming that this determination is beyond the ability of the dispenser), then those products managed within the reverse distribution system are not solid wastes until the manufacturer or wholesaler makes the determination to dispose of them. This view is based on our understanding that the system is established as a means to facilitate the recycling of reusable pharmaceutical products, rather than a waste management system.

However, if the dispenser has already determined that the materials cannot be reused (e.g., they are contaminated or severely damaged, they are a controlled substance that cannot be transferred to another party or the reissuance is otherwise prohibited by law, they are expired and the expiration date was determined through stability studies such that they are no longer useable, or the generator has determined (through investigation or based on past history) that the returned materials will be discarded by the manufacturer), then the materials are a solid waste and if they are listed or exhibit a characteristic, they are a hazardous waste.

There is a document that describes EPA’s position on reverse distribution of pharmaceuticals (see Returned Pharmaceutical Products 05/16/1991- available at www.epa.gov/rcraonline document number 11606). This letter made it clear that EPA did not intend for any person to use a reverse distribution system to relieve generators of the responsibility for making determinations.
about the discarding of materials as wastes. It remains the generator's responsibility to properly
identify secondary materials and that a reverse distribution system cannot be used as a waste
management service to customers/generators without the applicable regulatory controls on waste
management being in place.

Please also note that when shipping materials that qualify for reverse distribution, they must be
shipped in a manner appropriate to the material if it were new stock, including meeting relevant
OSHA and DOT requirements for hazardous materials management.

**Question 2:** A container of chemotherapy drug may be accessed in order to remove a portion
of the contents to prepare the correct dosage for administration to a patient. Some containers are
single dose containers and others are multiple dose containers. In either case, some unused
portion may remain in the container. Once the container has been accessed, it can no longer be
returned to the manufacturer/distributor and must be disposed. Is the unused portion of a
chemotherapy drug in an accessed non-returnable vial a hazardous waste?

**Answer:** Yes. If the material is listed or exhibits a characteristic, it is a hazardous waste,
unless the container meets the definition of an empty container (See 40 CFR 261.7). In an
April 25, 1988 letter from Devereaux Barnes, Director, Characterization and Assessment
Division, to Michael Geary of Bio-Ecological Services Inc. (RCRA Online Document #11343),
EPA stated that “the excess...undiluted amount to be discarded is unused commercial chemical
product. If the commercial chemical product is listed in 40 CFR 261.33, the material is a listed
hazardous waste...” In simpler terms, if the contents of the container are determined on-site to be
unusable, and the chemical is found on EPA’s list of hazardous wastes, then they would be
considered hazardous waste from the point at which they are determined to be no longer usable.

**Question 3:** A syringe or other measuring instrument may be used to access the container of
chemotherapy drug to prepare it for administration to a patient. After the chemotherapy drug
solution has been prepared and is no longer needed, is the syringe and/or its contents a hazardous
waste? If only a portion has been administered, is the amount remaining in the syringe a
hazardous waste? Are unused chemotherapy drugs in larger dispensing systems, such as IV bags
and lines, a hazardous waste? Does it matter if the IV bag is full, half full, or contains whatever
is left after the required dosage has been dispensed?

**Answer:** The April 25, 1988 memo cited above, stated that “the excess diluted or undiluted
amount to be discarded is unused commercial chemical product. If the commercial chemical
product is listed in 40 CFR 261.33, the material is a listed hazardous waste regardless of dilution
with water or saline...” if the antineoplastic agent is the sole active ingredient. Accordingly, a
chemotherapy agent diluted in water or saline in preparation for use, but not actually used for its
intended purpose, is a hazardous waste if found on the list at 40 CFR 261.33. As such, the
contents of unused syringes and IV bags could be hazardous waste. The unused syringe or IV
bag would also be considered hazardous waste unless all wastes have been removed that can be
removed using the practices commonly employed to remove materials from that

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type of container (e.g., pouring, pumping, and aspirating) and either no more than 1 inch of residue remains in the bottom of the dispenser or no more than three percent by weight of the total capacity of the dispenser remains (see 40 CFR 261.7). If the material in question was an acutely hazardous waste (e.g., P listed waste), then the container would also have to meet the additional requirement of triple rinsing with an appropriate solvent in order to meet the definition of an empty container. To minimize the exposure to these chemicals, EPA recommends that the entire volume of the unused waste and dispenser be managed as hazardous waste and that there be no attempt to remove any residue from the vial before disposal.

For syringes containing epinephrine that have been used, the regulatory status is quite different. The prevailing guidance comes from EPA’s December 1994 RCRA Hotline Monthly Summary (RCRA Online Document #9444.1994(10)) regarding excess epinephrine and epinephrine residue remaining in a syringe after the proper dose is injected. Like some antineoplastic agents, epinephrine is a listed commercial chemical product in 40 CFR 261.33 and is commonly used in the healthcare industry. The RCRA Hotline stated that “EPA 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.” EPA is still evaluating this issue and has not yet made a determination regarding expanding this interpretation to include materials other than epinephrine or dispensing devises other than syringes.

**Question 4:** EPA has listed only nine chemotherapy drugs as hazardous waste, but there are many other chemotherapy drugs that are not required to be managed as hazardous waste. Can EPA or states enforce the regulations against the non-listed chemotherapy drugs?

**Answer:** Only a small number of chemotherapy agents are listed as hazardous waste and are required to be managed as such. While other chemotherapy drugs may be neither characteristic nor listed hazardous wastes, and can be managed as non-hazardous solid waste (i.e., not subject to RCRA Subtitle C management or disposal requirements), this does not mean that RCRA has no authority over the disposal of the wastes. Chemotherapy agents, if managed improperly, meet the statutory definition of hazardous waste (42 U.S.C. 6903), which defines the term "hazardous waste" to mean a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may: (1) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (2) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

Chemotherapy drugs and other potentially harmful wastes, if disposed improperly, would be subject to the imminent and substantial endangerment provisions of RCRA 7003, 42 U.S.C. 6973. Bearing all of this in mind, EPA would strongly suggest managing this waste as hazardous and employing a permitted hazardous waste transporter and treatment or disposal facility to ensure proper disposal, even though it does not meet the regulatory definition of hazardous waste. Because the waste would pose a potential harm, management as hazardous waste would
minimize the potential liability of such waste shipped and disposed of under less stringent methods.

Question 5: It is difficult to train hospital staff on the proper segregation, handling, and storage of chemotherapy wastes because some must be handled as a hazardous waste, while others must be handled as a medical waste. Does EPA have any guidance on how to effectively ensure compliance of these materials?

Answer: EPA Region 2 recommends several practices and procedures as Best Management Practices, that healthcare facilities can use to ensure safe and proper handling of chemotherapy waste streams.

First, we recommend that healthcare facilities handle all chemotherapy waste streams as a hazardous waste. Only a small number of chemotherapy agents are listed as hazardous waste and are required to be managed as such. While other chemotherapy drugs may be neither characteristic nor listed hazardous wastes, and can be managed as non-hazardous solid waste), this does not mean that RCRA has no authority over the disposal of the wastes. Chemotherapy agents, if managed improperly, meet the statutory definition of hazardous waste, which is much broader than the regulatory definition. Chemotherapy drugs, if disposed improperly, would be subject to the imminent and substantial endangerment provisions of RCRA 7003. Bearing all of this in mind, R2 recommends managing this waste as hazardous and employing a permitted hazardous waste transporter and treatment or disposal facility to ensure proper disposal, even though it does not meet the regulatory definition of hazardous waste. Also, many facilities find it difficult to train hospital staff on the proper segregation, handling, and storage of chemotherapy wastes because some must be handled as a hazardous waste, while others must be handled as a medical waste. Although our recommendation may result in increased disposal costs since hazardous waste disposal often costs more per volume than medical waste disposal, some healthcare facilities have found this to be more efficient than trying to train all hospital staff potentially involved in handling chemotherapy wastes on the proper identification and management of these waste streams and ensuring that the proper procedures are followed. The increased costs for disposal may be offset by the reduced training and oversight needed under this approach and the potential liability for improper handling of chemotherapy waste streams is also greatly reduced.

Reverse distribution is an appropriate product management strategy that can be used to return unused chemotherapy agents to the manufacturer. See discussion under Question 1 above for a detailed discussion of this approach.

Another successful best management practice that we have seen is for the hospital to designate the pharmacy as an accumulation area for hazardous wastes. This allows the return of chemotherapy materials from any area of the hospital to the pharmacy and then the pharmacy determines whether it is one of the listed hazardous wastes. This requires that the pharmacy personnel be properly trained and the accumulation area must be designed and operated such that
it complies with the storage requirements. Please note that the pharmacy will usually not qualify as a satellite accumulation area since it is not located at or near the point of generation.

A simple procedure that can help staff to recognize which chemotherapy waste streams must be handled as a hazardous waste is to put a bright yellow dot or other marking on any container into which one of the regulated chemotherapy drugs is dispensed. This visual marking alerts any staff discarding that container that it must be handled differently than the other chemotherapy waste streams.

We also recommend that facilities establish a standard practice for management of used gloves and PPE. See discussion under Question 6 below for a detailed discussion of this approach.

**Question 6:** Personal protective equipment (PPE) is worn when preparing antineoplastic drugs. The PPE is then discarded as medical waste. Is the PPE a hazardous waste if it is contaminated with chemotherapy drugs? More generally, are gloves and PPE used with listed hazardous waste (i.e., F, K, U, or P-waste) considered to be hazardous waste? Could these materials be handled as trace chemotherapy wastes?

**Answer:** The purpose of wearing personal protective equipment, such as gloves, is to protect the user from unnecessary exposure to hazardous and toxic materials. The presumption is that releases, and subsequent exposure, to such materials will be minimized to the extent possible while working with these materials. In other words, systematic procedures should be in place that do not require a person to have direct contact with a hazardous or toxic material with gloves being the only barrier protecting the person. For example, if you need to mix something, you use a stirrer, not your hand. Similarly, if you need to transfer a powder to another container, you use a trowel or cup, not your hands. However accidental releases may occur and result in the contamination of the gloves.

In a laboratory or hospital setting in which listed hazardous waste is handled, gloves and PPE are typically worn to protect staff in the event of a spill in a relatively dry environment, rather than worn under an assumption that gloves and PPE will be contaminated under wet conditions. In this case, the gloves and PPE are only considered hazardous waste if they are known to be or are suspected of having been in contact with the waste. If the user suspects that a release may have occurred and the gloves or PPE may have been contaminated, a hazardous waste determination must be performed prior to disposal of the item(s) either through testing or the use of generator knowledge. Indications of contaminated gloves may include, but are not limited to, a shiny sheen, change in color, change in texture or feel of the gloves, or seeing the material on the glove. Gloves or PPE which are known to be or suspected of being contaminated with a listed hazardous waste must be managed as hazardous waste. If they do not come in contact with the waste, it is acceptable for gloves or PPE to be discarded in the trash as solid waste.
Facilities are likely to prefer to establish a standard practice for management of used gloves and PPE. In this case, the organization must observe and discuss the routine activities of staff. If it is determined that staff tend to get gloves and/or PPE contaminated with hazardous waste on a regular basis, it is recommended that all such equipment be either managed as hazardous waste or that a determination be made by the user for a piece of equipment when it is taken off. If it is determined that contamination of gloves or PPE is highly unlikely and occurs only on rare occasions, gloves or PPE can be treated as non-hazardous and discarded as trash, except when contamination is specifically known or suspected.

In a related matter, gloves or PPE that are contaminated with characteristic wastes or listed wastes that are listed solely for their characteristic are hazardous only if they display the characteristic of the waste itself.

Although some state regulatory programs provide a distinction between bulk chemotherapy wastes and trace chemotherapy wastes, the federal hazardous waste program does not recognize those distinctions when dealing with listed hazardous wastes. There is no lower concentration limit under which a listed hazardous waste can exit the regulatory system.

**Question 7:** What can I do with the container that chemotherapy waste came in? What can I do with dispensers used to handle chemotherapy waste? What should I do with rinseate used to rinse the containers?

**Answer:** For containers that held P-wastes, such as waste arsenic trioxide, any container which held the waste must be either managed as hazardous waste or triple-rinsed with an appropriate solvent, with the rinseate also managed as the corresponding P-listed hazardous waste (see 40 CFR 261.7). When the container is emptied after the third rinse, the container is now considered “RCRA empty.” Containers that held non-acute materials that meet the definition of an empty container are no longer subject to the federal regulations and can be reused for any other appropriate purpose (e.g., storing hazardous materials while accumulated on-site). Please note that even though a container meets the RCRA definition of empty, liability still exists under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for any contamination that results from such containers.