Pharmaceutical Management Technical Brief

Green Guide for Health Care **Chemical Management Credit 3**

Overview

In 2002, Americans filled 3,340,000,000 outpatient prescriptions. That's 12 prescriptions for every man, woman, and child in America.[1] While most of these pharmaceuticals provide a health benefit, frequently the waste associated with their use is poorly managed. Too often, pharmaceuticals and controlled substances, personal care products, and antimicrobials are disposed directly to the sewer. Conventional wastewater treatment is inadequate to render these compounds harmless; as a result, they are often discharged virtually unchanged to lakes, rivers, streams and oceans, where they can impact wildlife and humans.

Waste pharmaceutical agents that are incinerated produce air emissions such as dioxins, acid gases, carbon monoxide, heavy metals and carbon dioxide. These emissions contribute to air pollution, global warming, and are harmful to humans and the environment. Some, such as dioxins, are carcinogens. Moreover, the ash from incineration often must be disposed of as hazardous waste. Despite these concerns, disposal of waste pharmaceuticals via well-managed incineration is the preferred method of disposal at this time.

The current best management scenario for waste pharmaceuticals is pollution prevention (P2), a waste management strategy that aims to eliminate and/or reduce the toxicity of the waste. Pollution prevention in the pharmaceutical industry also entails manufacturers' minimizing waste during production as well as minimizing the level of metabolites excreted from the body. Pharmaceuticals and personal care products can also be procured and distributed in a manner that minimizes waste.

GGHC v2.2 Chemical Management Credit 3 encourages health care facilities to develop and implement an integrated pharmaceutical waste management system and a pharmaceutical waste minimization plan.

The Challenges

Challenges for the pharmacist to enact pollution prevention include: incomplete knowledge regarding the impact and requirements for proper management of pharmaceutical waste, incomplete knowledge regarding the financial liabilities associated with pharmaceutical waste, and lack of time. Waste from the pharmacy can be generated due to overstocking and early expiration or dispensation to a patient who does not use the medication. Often, pharmacists do not have time to fully assess inventory management or dispensing practices that would minimize waste at the source. Furthermore, many health care institutions and pharmaceutical companies have not developed the internal infrastructure necessary to effectively eliminate pharmaceutical waste through purchasing practices and take-back programs.

Pharmaceutical disposal is challenged by the absence of a disposal method that adequately addresses public health and environmental concerns. With incineration the present best method of disposal, the importance of reducing total pharmaceutical waste production becomes paramount.

By developing and implementing pollution prevention (P2) strategies and working closely with pharmaceutical providers, health care organizations have the opportunity to make tremendous progress

[1] "Prescription Drug Use in America: The Startling Numbers And Their Implications," Medication Sense.Com, http://www.medicationsense.com/articles/july_sept_03/prescript_drug_use.html, 2003.

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towards responsible pharmaceutical management. The pollution prevention tips provided in this Technical Brief are first steps toward that goal.

Best Practices

Pollution Prevention

1. Improve Inventory Control

- Enact clinical processes that minimize outdated pharmaceuticals. A MnTAP (Minnesota Technical Assistance Program) study found that the top 20 outdated pharmaceuticals are: Epinephrine, crash cart epinephrine, Combivent, Humalog, Glucagen, Lantus, Glutose gel, morphine sulfate, Nitrostat, Novolog, Hydralazine, Pneumovax, Lidocaine, Synthroid, Amiodarone, Cetacaine, adenosine, Ketamine, Naloxone and Nubain.[2]
- Determine whether it is necessary to offer the product. Can another, less toxic product be substituted in an emergency? For example Glutose gel 45 gram can be substituted with Glutose gel 15 gram.
- Can multiples of dosage types be used rather than stocking all doses, especially for esoteric medications?
- Determine minimum/maximum order points for each item stocked in the Pharmacy to ensure that inventory is purchased in appropriate quantities and used prior to expiration.
- Review reverse distribution practices to ensure your facility's returns do not exceed the national average of 2%.
- Purchase vials and similar items in the smallest available package size needed based on usage. If pharmaceuticals routinely expire due to the size of the carton available, notify the facility's group purchasing organization (GPO) and request that they negotiate for more appropriate manufacturer packaging.
- Rotate potentially hazardous waste such as epinephrine syringes out of emergency carts and into more active areas such as the Emergency Room or Operating Suites prior to outdating (three months or more dating is recommended for emergency carts).
- Some epinephrine products have a longer shelf life than others. Use of longer shelf-life epinephrine products will minimize waste from crash carts and other areas that store the pharmaceutical for emergencies.
- Encourage manufacturers to provide accurate expiration dates. In most instances, a pharmaceutical's expiration date is little more than an arbitrary date rather than the true active life.

2. Pharmaceutical dispensing – Reduce the number of pharmaceuticals dispensed and returned that cannot be re-prescribed.

- Use of automated dispensing systems such as Pixis can reduce pharmaceutical waste and allow for re-distribution.
- Some automated dispensing systems and computerized inventory systems can run par usage reports to determine stock quantities.
- Blister packaging and other single dose formulations allow for re-dispensing.

[2] "Reducing Pharmaceutical Waste from Patient Care Settings," MN Technical Assistance Program (MnTAP), University of MN, 2007, http://www.mntap.umn.edu/health/94-PharmWaste.htm.

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- Advocate for reuse of properly stored pharmaceuticals in facilities such as long-term care centers.
- Label pharmaceuticals for outpatient use to allow patients to take home medications after discharge.

3. **Substitute less toxic pharmaceuticals or mechanical methods for products containing toxic substances such as persistent bioaccumulative toxic chemicals (PBTs).**
   - Mercury-free products (e.g., thimerosal, phenylmercuric acetate) should be procured whenever possible.
   - M-cresol should be eliminated as a preservative whenever possible.
   - Di-ethyl hexyl phthalate (DEHP) is a plasticizer used in poly vinyl chloride (PVC) plastic, intravenous bags (IV), tubing and other medical devices. DEHP is known to leach out of PVC IV bags into the patient. DEHP is thought to be an endocrine-disrupting chemical. Use of PVC/DEHP-free products minimizes patient exposure to DEHP. For more information on DEHP avoidance, see the *Green Guide for Health Care* Toxic Reduction through Environmentally Preferable Purchasing Technical Brief.
4. **Minimize packaging or dispensing mechanisms**
   - Purchase products with minimal packaging to reduce hazardous waste packaging. Packaging in contact with hazardous waste and P-listed pharmaceuticals (e.g., warfarin >0.3%, epinephrine, arsenic trioxide, nicotine) must be managed as hazardous waste.
   - Use non-PVC dispensing systems such as Duplex. These products weigh one third less than alternatives that contain PVC.
5. **Limit samples –** Establish mechanisms and policies to limit sales samples in order to avoid the necessity of disposing of outdated supplies. For example, only permit samples with one-year minimum expiration.
6. **Minimize personal protective equipment waste –** Mix chemicals in batches, minimize spills, and institute regular staff training.
7. **Education –** Educate consumers/patients regarding therapeutic doses and overmedicating, especially the danger of using multiple over-the-counter medications simultaneously (e.g. cold medications). This practice not only improves patient safety but also minimizes pharmaceutical waste.
8. **Manage unused medication –** Offer return and proper disposal of unused medications to patients and customers. Work with physicians to offer “mini” or “trial” prescriptions to minimize unused medication due to adverse reactions or unwanted side effects.
9. **Provide information on proper disposal channels for patients and customers –** Advocate for proper disposal information to be included on medication packaging.
10. **Encourage your health care facility to purchase pharmaceutical-free meat –** Use of antibiotics and steroids in the animal feed industry also contributes to pharmaceutical pollution. For more information on healthy food in hospitals, see the *Green Guide for Health Care* Food Technical Brief.

Waste Management

Pharmaceutical waste that cannot be prevented should be managed in compliance with regulations and in a manner that minimizes public exposure and release to the environment. In addition to developing and implementing pollution prevention practices, develop a waste management and disposal plan.

1. **Waste Management and Disposal Plan**
   - Specify which pharmaceuticals are regulated. See Appendices A and B.

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- Outline procedures for safe and proper disposal of regulated waste. See Appendix D.
- Outline procedures for safe and proper disposal of non-regulated waste. See Appendices C and D.
- Cover the following categories of waste pharmaceuticals: hazardous waste, waste chemotherapy items (that are not hazardous waste), controlled substances, waste IV solutions containing only electrolytes, vitamins, parenteral nutrition, dextrose or saline and all other pharmaceuticals including antibiotics/antivirals, hormones, coagulation therapy, cardiac, gastrointestinal, ointments, etc.
- Develop tracking and disposal strategies.
- Train employees on safe and appropriate disposal.

2. Hazardous Waste Pharmaceuticals

- All waste pharmaceuticals must be evaluated for hazardous waste characteristics and listings under the U.S. EPA's Resource Conservation and Recovery Act (RCRA).[3] The wastes also must be evaluated in accordance with state, local and OSHA regulations (Appendices A through C). Review the Minnesota Pollution Control Agency waste pharmaceuticals fact sheet for more information.[4]
- The U.S. EPA defines pharmaceutical waste as "discarded medicinal pharmaceuticals and related products from pharmacies, hospitals, clinics, pharmaceutical manufacturers, etc."[5] They cannot be reused for their intended purpose and must be remanufactured for use. Examples include: partial vials; opened containers; dispensed IV; opened tubes; loose pills; expired pharmaceuticals; patients' personal medications; waste materials containing excess pharmaceuticals (syringes, IV bags, tubing, vials, etc.); open pharmaceuticals that cannot be used; containers that held pharmaceuticals; pharmaceuticals that are intended to be discarded; and, contaminated garments, absorbents and spill cleanup material, except for materials with only trace contamination.
- Often, expired and unused pharmaceuticals are returned through reverse distribution for reuse and/or remanufacture. This practice is satisfactory if the items are not "waste-like" as per EPA's definition. If a reverse distribution service is used, it is important to ensure that they are qualified and licensed to properly manage pharmaceuticals that are ultimately deemed to be hazardous waste. They should also certify all other waste pharmaceuticals will be incinerated.

3. Controlled Substances

Dispose of waste-controlled substances (e.g., substances regulated by the U.S. Drug Enforcement Agency (DEA)) using a reverse distributor or hazardous waste hauler who is registered with the DEA.

4. Investigational Pharmaceutical Waste

Ensure policies and procedures are in place to identify and properly dispose of investigational pharmaceutical waste.

5. Non-Hazardous Pharmaceutical Waste

Set up a policy and practices to manage all pharmaceutical waste in an environmentally responsible manner. Some pharmaceutical agents such as saline, dextrose, parenteral nutrition and other relatively benign, simple compounds may be sewered. However, permission must be obtained from

[3] http://www.epa.gov/rcraonline/
[4] www.pca.state.mn.us/publications/w-hw4-45a.pdf
[5] http://iaspub.epa.gov/trs/trs_proc_qry.navigate_term?p_term_id=27723&p_term_cd=TERMDIS

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the wastewater treatment plant. The remaining pharmaceutical waste, even if it is not hazardous waste, should be incinerated at a well-managed incinerator and not disposed via the sewer.

Use a "well-managed incinerator":

- Permitted by the state or EPA.
- Performs testing of its emissions and has strict operating and emission controls.
- Some municipalities incinerate rather than landfill their waste. It may be possible for a health care facility to incinerate their non-hazardous waste pharmaceuticals as industrial waste at municipal incinerators if permission is given. As with sewering, waste pharmaceuticals should not be disposed untreated to a landfill.
- To locate well-managed, permitted incinerators in your state, contact your local environmental agency.
- *Minimizing Risk to Community Health with Incineration* – Poly vinyl chloride (PVC) plastic contributes to dioxin formation when incinerated. Because some dioxins are carcinogens and endocrine disrupting chemicals, minimizing their production and release to the environment is protective of public health. Many pharmaceutical products are prepared and dispensed in PVC-containing IV bags and tubing. To the extent possible, ensure that all pharmaceutical waste being incinerated is PVC-free.
- "Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States" is available on-line at www.h2e-online.org/docs/h2epharmablueprint41506.pdf

Benefits

Health

Reduction of pharmaceutical waste and proper disposal through well-managed incineration reduces the public health impact of untreated waste being reintroduced to humans through drinking water obtained from lakes and streams. Many pharmaceuticals contain toxic chemicals, including known carcinogens and endocrine disruptors that can contribute to deleterious health effects, particularly in sensitive populations, such as the very young.

Ecologic

Disposal of pharmaceutical waste directly to sewer can impact the health of aquatic ecologies in a similar manner to humans. Because pharmaceuticals are so challenging to contain after they have entered the biosphere, eliminating them at their source is the most effective way to reduce further ecologic contamination.

Economic

Health care organizations can realize significant economic savings by implementing a comprehensive pollution prevention (P2) plan. Minimizing purchases for inventory can virtually eliminate the necessity to dispose of expired, unused pharmaceuticals. Furthermore, pharmaceuticals can represent a large percentage of annual regulated and hazardous waste disposal. Reducing waste at its source pays back through lowering the facility's hazardous waste designation, and all of the expensive operational measures associated with large quantity generators. Minimizing the quantity and toxicity of pharmaceutical waste reduces labor and management costs, as well as occupational liability.

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Case Study

Tri-County Hospital, Wadena, MN

Tri-County Hospital in Wadena, Minnesota reviewed its reverse distribution waste to discover 9 percent of its pharmaceutical inventory was sent back. Benchmarking themselves against the national average of 2%, Tri-County reorganized its pharmaceuticals management program. Identifying ambulances and crash carts as the locations most likely to allow medications to expire, the facility implemented a policy to reduce the ambulance stock of two pharmaceuticals on MnTAP's list of top 20 most outdated pharmaceuticals. An inventory analysis discovered that epinephrine (a P-listed pharmaceutical, according to RCRA regulations) could be reduced by 6 vials; and, lidocaine, by 15 vials per ambulance. A pharmacy staff member also began to regularly conduct an inventory analysis of all crash carts and stations to relocate medications within three months of expiration to areas of high use. Additionally, Tri-County began to generate par usage reports with its computerized inventory system to consolidate redundant dosages of pharmaceuticals. These activities led to improved pharmaceutical inventory management and saved $25,000 in purchase and disposal costs.

For more information, visit www.mntap.umn.edu/health/94-PharmWaste.htm.

Resources

In addition to the resources noted in the Green Guide for Health Care, the following may offer additional guidance:

Daughton, C. "Cradle to Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health," Part I & II, *Environmental Health Perspective*, 111:5, 757-785, May 2003.

Health Care without Harm, www.noharm.org

MN Pollution Control Agency, http://www.pca.state.mn.us/health, http://www.pca.state.mn.us/publications/w-hw4-45a.pdf.

Pharmaceutical Waste: Disposing of Unwanted Medication, www.moea.state.mn.us/hhw/pharmaceuticals.cfm

Resource Conservation and Recovery Act requirements, Large Quantity Generator requirements, www.hercenter.org

A Remedy for Prescription Drug Disposal, www.deq.state.mi.us/documents/deq-ess-tas-cau-Rxbrochure.pdf

Sustainable Hospitals Project, www.sustainablehospitals.org

Tech Brief authored by Catherine Zimmer, MS, EHS, BSMT, Minnesota Technical Assistance Program. Reviewed by Julie Johnson, R Ph, MN Pharmacist's Association.

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Appendix A
Pharmaceutical Hazardous Wastes – Definitions

"Characteristic" Pharmaceuticals

Many waste pharmaceuticals may not appear on a regulatory list of hazardous waste but still exhibit "characteristics" of hazardous waste. The "characteristics" defined in RCRA are listed below. Other characteristics may be included in state and local regulations. For example, Minnesota regulations include a "Lethal" characteristic.

- *Ignitable (EPA Waste Code D001)* – A waste chemical with a flashpoint of less than 140° F is an ignitable hazardous waste. *Examples:* Mineral Spirits, Ethanol, D-Limonene, Formalin, Xylene.
- *Aqueous Solutions* – For aqueous solutions containing alcohol, any chemical or preparation with 24% or more alcohol is ignitable. *Examples:* Rubbing alcohol (denatured ethyl and isopropyl), Benzoin Tincture, Retin A® Gel, Listerine® Mouthwash (Original Formulation).
- *Non-aqueous Solutions* – Preparations that use acetone, ether, flexible collodion or other solvents as a base may have a flash point less than 140° F and should be managed as a hazardous waste when discarded.
- *Ignitable Compressed Gas* – Aerosols that use a flammable propellant (the label has the word "Flammable") should be managed as a hazardous waste when discarded. A simplified approach is to consider all discarded aerosols as hazardous waste. *Examples:* Solarcaine® Spray, Right Guard®, Primatene® Mist, Ethyl Chloride (chloroethane), Fluro-Ethyl (25% ethyl chloride, 75% dichlorotetrafluorethane).

  Note – Although a propellant is not ignitable, it might contain chlorofluorocarbons, which may be an F or U listed hazardous waste or may cause problems in certain incinerators. It is important to discuss this waste stream with disposal facilities to ensure that the facilities are properly permitted to dispose of chlorofluorocarbon waste. Also, large quantities of aerosols (such as case quantities) present a hazard in case of fire and should be stored in a secure, confined space.

Oxidizer (EPA Waste Code D001) – Oxidizers readily supply oxygen to a reaction in the absence of air. *Examples of oxidizers include, but are not limited to:* oxides, organic and inorganic peroxides, permanganates, perrhenates (contain Rhenium), chlorates, perchlorates, persulfates, nitric acid, organic and inorganic nitrates, iodates, periodates, bromates, perselenates, perbromates, chromates, dichromates, ozone, and perborates. Bromine, chlorine, fluorine, and iodine react similarly to oxygen under some conditions and are therefore also oxidative materials.

Corrosive (EPA Waste Code D002) – Corrosive hazardous wastes are defined as an aqueous solution[6] having a pH less than or equal to 2 or greater than or equal to 12.5 or other chemicals that corrode steel or damage skin. *Examples include:* phenol, glacial acetic acid, sodium hydroxide, hydrochloric acid, and mediplast® (40% Salicylic Acid). See Appendix A for the complete definition.

Reactive (EPA Waste Code D003) – Chemical wastes that are unstable, explosive or will generate toxic gases or fumes are classified as reactive. Specifically, a reactive chemical will do one or more of the following:

- React violently with water
- Form potentially explosive mixtures with water
- When mixed with water, generate toxic gases, vapors, or fumes in a quantity sufficient to present a danger to human health or the environment

[6] For the corrosive characteristic, "aqueous solution" is defined as 20% or more water.

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- Be a cyanide or sulfide bearing waste which, when exposed to pH conditions between 2.0 and 12.5 can generate toxic gases, vapors, or fumes in a quantity sufficient to present a danger to human health or the environment
- Be capable of detonation or explosive reaction if it is subjected to a strong initiating source or if heated under confinement
- Be readily capable of detonation or explosive decomposition or reaction at standard temperature and pressure
- Be normally unstable and readily undergo violent change without detonating
- Be a forbidden explosive as defined in the Code of Federal Regulations, Title 49.

Toxic

A toxic waste is one which, when using the Toxicity Characteristic Leaching Procedure (TCLP), leaches any number of metallic, organic, or pesticide contaminants in concentrations greater than or equal to concentrations specified by regulation. These contaminants cover approximately forty chemicals, including: arsenic, barium, cadmium, chloroform, chromium, Lindane, cresol, mercury, selenium, and silver at specific concentrations of mg/L. (For the complete list of the toxicity constituents, visit www.epa.gov/osw/hazwaste.htm.)

Pharmaceuticals that are compounded with ignitable solvents or contain heavy metals, such as mercury, must be treated as hazardous waste when they are disposed.

The *Toxicity Characteristic Leaching Procedure* is a laboratory test designed to mimic landfill conditions. The waste is pH adjusted, mixed and analyzed for the toxicity contaminants. For complete details of the procedure, refer to Code of Federal Regulations 40 Part 260.11. If the resulting analyses exceed any of the regulatory levels, then the waste is hazardous due to the "toxicity" characteristic.

For example, a hospital laboratory test requires that chloroform be used as one of the reagents. The resulting mixture of chloroform, patient specimen and other reagents may be defined by U.S. EPA as "toxic" due to the presence of chloroform. To determine whether or not this specimen must be managed as hazardous chemical waste, the TCLP test is used. If the chloroform concentration in the waste specimen is greater than or equal to 6.0 mg/L (ppm) then it must be managed as hazardous chemical waste.

Note, the regulatory limit is measured in parts per million, which is extremely low. In the example above if the chloroform is present at percent (parts per hundred) concentrations, e.g. 10 mls in 100 mls total; it is likely that the resultant waste will be hazardous chemical waste. Parts per hundred (percent) is ten thousand times larger than parts per million.

It is important to remember this relationship when using a chemical that has a toxicity constituent listed on the Material Safety Data Sheet (MSDS). When using a MSDS as a guide, remember that the concentrations of constituents are listed as *percentages.* Toxicity characteristic regulatory limits are listed as *parts per million*. To be sure that a hazardous waste toxicity constituent is *not* present, especially when it is expected in a chemical, ask the manufacturer for a Certificate of Analysis.

Examples of common toxic wastes:

- Chromic Chloride 20mcg/ml
- Thimerosal®-containing products. (e.g. pharmaceuticals and lab reagents)
- Pesticides
- Selenium shampoos
- Vitamins

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"Listed" Pharmaceuticals

RCRA lists over 350 commercial chemical products which are hazardous waste when discarded. The "U-List" is comprised of "toxic" chemicals; the "P-List" is comprised of "acutely toxic" chemicals under RCRA.

U-Listed Pharmaceuticals/Chemicals

Pharmaceutical/Chemical	EPA Code
Acetone	U002
Azaserine	U015
Bromoform	U225
Cacodylic Acid	U136
Carbon Tetrachloride	U211
Chloral Hydrate	U034
Chlorambucil	U035
Chlornaphazin	U026
2-Chloroethyl Vinyl Ether	U042
Chloroform	U044
Creosote	U051
Cresols	U052
Cyclophosphamide	U058
Cyclophosphamide	U058
Daunomycin	U059
Dichlorobenzenes	U0700, U071, U072
Diethylstilbestero	U089
Ethyl Acetate	U112
Formaldehyde	U122
Formic acid	U123
Hexachlorophene	U132
Lindane	U129
Melphalan	U150
Mercury	U151
Mitomycin C	U010
N-butyl alcohol	U031
Paraldehyde	U182
p-Chloro-m-Cresol	U039
Phenacetin	U187
Reserpine	U200
Resorcinol	U201
Saccharin	U202
Selenium sulfide	U205
Streptozotocin	U206
Tetrachloroethylene	U210
Thiram	U244
Trichloroethylene	U228
Uracil mustard	U237
Warfarin < 0.3%	U248

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P-Listed Pharmaceuticals/Chemicals*

Pharmaceutical/Chemical	EPA Code
Arsenic	P012
Arsenic Trioxide	P012
3-Benzyl Chloride	P028
Chloropropionitrile	P027
Cyanide Salts	P030
Epinephrine	P042
Nicotine	P075
Nitroglycerin	P081
Osmium Tetroxide	P087
Phentermine	P046
Phenylmercuric Acetate	P092
Physotigmine	P204
Physotigmine salicylate	P188)
Potassium Silver Cyanide	P099
Sodium Azide	P105
Strychnine	P108
Warfarin > 0.3%	P001

*Pharmaceutical and chemicals that are "P-Listed" under RCRA have special management concerns. Because these wastes are "acutely toxic," generation of small quantities (one kilogram or 2.2 lbs per month) imposes stricter hazardous waste requirements. If a health care facility or pharmacy generates 2.2 lbs or greater per month (on average) of P-listed hazardous waste, it must operate as a RCRA "Large Quantity Generator" of hazardous waste. Large quantity generator (LQG) requirements include limits on the quantity of waste that can be stored on site, 90 day time limits for storing hazardous waste on site, annual training for all personnel handling hazardous waste and specific emergency plan requirements to manage adverse hazardous waste events.

Chemotherapeutics

Nine chemotherapeutic agents are P or U listed (i.e., discarded unused chemicals) under RCRA. They are listed in the table below. Due to their toxicity and risk, it is recommended that all chemotherapeutic agent waste be managed as hazardous.

Chemotherapeutic Pharmaceuticals/Chemicals

Chemotherapeutic	EPA Code
Chlorambucil (Leukeran)	U035
Cyclophosphamide (Cytoxan, CTX, Neosar)	U058
Daunomycin (Daunorubicin, Cerubidine, DaunoXome, Rubidomycin	U059
Diethystilbestrol (Diethylstilbesterol, DES, Stilbestrol, Honvol, Stilbesterol)	U089
Melphalan (Alkeran, L-PAM)	U150
Mitomycin C (Mitomycin, Mutamycin)	U010

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Chemotherapeutic	EPA Code
Chlorambucil (Leukeran)	U035
Streptozotocin (Streptozocin, Zanosar)	U206
Uracil Mustard	U237
Arsenic Trioxide (Trisenox)	P012

- Waste associated with the preparation of chemotherapeutics or other RCRA listed drugs, e.g. gowns, gloves, pads, and visibly soiled chux, must also be managed as hazardous waste. Non-visibly soiled waste may be managed as non-hazardous. A facility may choose to also incinerate this waste as "trace chemo."
- Hazardous waste has specific container, labeling, tracking, storage, transporting and disposal requirements. Refer to state and local requirements to ensure full compliance.

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Appendix B

Pharmaceutical Hazardous Wastes

(*Note*: this is list is provided as a guide and is not meant to be all-inclusive)

CAS #	HAZARDOUS CHEMICAL; GENERIC NAME	RCRA CODE	P LIST
645-05-6	ALTRETAMINE		
125-84-8	AMINOGLUTETHIMIDE		
446-86-6	AZATHIOPRINE		
7440-39-3	BARIUM	D005	
9041-93-4	BLEOMYCIN		
55-98-1	BUSULFAN		
7440-43-9	CADMIUM	D006	
41575-94-4	CARBOPLATIN		
154-93-8	CARMUSTINE		
305-03-3	CHLORAMBUCIL	U035	
56-75-7	CHLORAMPHENICOL		
67-66-3	CHLOROFORM	UO44/DO22	
569-57-3	CHLOROTRIANISENE		
54749-90-5	CHLOROZOTOCIN		
7440-47-3	CHROMIUM	D007	
15663-27-1	CISPLATIN		
8001-58-9	CREOSOTE	U051	
1319-77-3	CRESOL (CRESYLIC ACID)	U052/D026	
50-18-0	CYCLOPHOSPHAMIDE	U058	
59865-13-3	CYCLOSPORIN		
147-94-4	CYTARABINE		
4342 03-4	DACARBAZINE		
50-76-0	DACTINOMYCIN		
20830-81-3	DAUNORUBICIN	U059	
75-71-8	DICHLORODIFLUOROMETHANE	U075	
117-81-7	DI (ETHYLHEXYL) PHTHALATE	U028	
56-53-1	DIETHYLSTILBESTROL	U089	
23214-92-8	DOXORUBICIN		
51-43-4	EPINEPHRINE	P042	x
50-28-2	ESTRADIOL		
2998-57-4	ESTRAMUSTINE		
57-63-6	ETHINYL ESTRADIOL		
33419-42-0	ETOPOSIDE		
50-91-9	FLOXURIDINE		
51-21-8	FLUOROURACIL		
13311-84-7	FLUTAMIDE		
82410-32-0	GANCICLOVIR		

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CAS #	HAZARDOUS CHEMICAL; GENERIC NAME	RCRA CODE	P LIST
70-30-4	HEXACHLOROPHENE	U132	
127-07-1	HYDROXYUREA		
58957-92-9	IDARUBICIN		
3778-73-2	IFOSFAMIDE		
76543-88-9	INTERFERON ALFA-2A		
99210-65-8	INTERFERON ALFA-2B		
4759-48-2	ISOTRETINOIN		
9015-68-3	L-ASPARAGINASE		
53714-56-0	LEUPROLIDE		
14764-73-4	LEVAMISOLE		
58-89-9	LINDANE	U129/D013	
13010-47-4	LOMUSTINE		
108-39-4	m-CRESOL	D024	
51-75-2	MECHLORETHAMINE		
520-85-4	MEDROXYPROGESTERONE		
595-33-5	MEGESTROL ACETATE		
148-82-3	MELPHALAN	U150	
50-44-2	MERCAPTOPURINE		
7439-97-6	MERCURY	U151/D009	
59-05-2	METHOTREXATE		
50-07-7	MITOMYCIN C	U010	
53-19-0	MITOTANE		
65271-80-9	MITOXANTRONE		
76932-56-4	NAFARELIN		
54-11-5	NICOTINE	P075	X
55-63-0	NITROGLYCERIN	P081	X
95-48-7	o-CRESOL	D023	
123-63-7	PARALDEHYDE	U182	
106-44-5	p-CRESOL	D025	
62-44-2	PHENACETIN	U187	
108-95-2	PHENOL	U188	
62-38-4	PHENYLMERCURIC ACETATE	P092/D009	X
57-64-7	PHYSOSTIGMINE SALICYLATE	P188	X
57-47-6	PHYSOSTIGMINE	P204	X
54-91-1	PIPOBROMAN		
18378-89-7	PLICAMYCIN		
671-16-9	PROCARBAZINE		
50-55-5	RESERPINE	U200	
108-46-3	RESORCINOL	U201	
36791-04-5	RIBAVIRIN		
81-07-2	SACCHARIN	U202	
128-44-9	SACCHARIN SODIUM	U202	
7782-49-2	SELENIUM	D010	

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CAS #	HAZARDOUS CHEMICAL; GENERIC NAME	RCRA CODE	P LIST
7488-56-4	SELENIUM SULFIDE	U205	
7440-22-4	SILVER	D011	
7632-00-0	SODIUM NITRITE	D002	
18883-66-4	STREPTOZOCIN	U206	
57-24-9	STRYCHNINE	P108	X
10540-29-1	TAMOXIFEN		
968-93-4	TESTOLACTONE		
54-64-8	THIMEROSAL (CONTAINS MERCURY)	D009	
154-42-7	THIOGUANINE		
52-24-4	THIOTEPA		
79-01-6	TRICHLOROETHYLENE	U228	
75-69-4	TRICHLOROMONOFLUOROMETHANE	U121	
66-75-1	URACIL MUSTARD	U237	
5536-17-4	VIDARABINE		
865-21-4	VINBLASTINE		
57-22-7	VINCRISTINE		
81-81-2	WARFARIN POTASSIUM (>.3%)	P001	X
81-81-2	WARFARIN POTASSIUM (<0.3%)	U248	
129-06-6	WARFARIN SODIUM (<0.3%)	U248	
129-06-6	WARFARIN SODIUM (>0.3%)	P001	X
30516-87-1	ZIDOVUDINE		
7440-66-6	ZINC		
557-34-6	ZINC ACETATE		
04468-02-4	ZINC GLUCONATE		
1314-13-2	ZINC OXIDE		
7733-02-0	ZINC SULFATE		
557-08-4	ZINC UNDECYLENATE		

CAS #	COMPOUNDING CHEMICALS	RCRA CODE	P LIST
64-19-7	ACETIC ACID	D001/D002	
67-64-1	ACETONE	U002/D001	
64-17-5	ALCOHOL (ETHYL)	D001	
10-982-7	ALCOHOL (ISOPROPYL)	D001	
39-939-6	BENZOIN (TINCTURE)	D001	
56-23-5	CARBON TETRACHLORIDE	U211	
8007-45-2	COAL TAR	D001	
60-29-7	ETHER	D001	
50-00-0	FORMALDEHYDE	U122/D001	
64-18-6	FORMIC ACID	U123/D002	
	GREEN SOAP TINCTURE	D001	
1647-01-0	HYDROCHLORIC ACID	D002	
7553-56-2	IODINE	D001/D002	
21908-53-2	MERCURIC OXIDE	D009	

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CAS #	COMPOUNDING CHEMICALS	RCRA CODE	P LIST
129-16-8	MERCUROCHROME (MERBROMIN)	D009	
67-56-1	METHANOL	U154/D001	
7697-37-2	NITRIC ACID	D002	
144-62-7	OXALIC ACID	D002	
7664-38-2	PHOSPHORIC ACID	D002	
518-28-5	PODOPHYLLUM RESIN	D002	
1310-58-3	POTASSIUM HYDROXIDE	D002	
7722-64-7	POTASSIUM PERMANGANATE	D001	
7761-88-3	SILVER NITRATE	D011/D001	
22199-03-2	SILVER SULFADIAZINE	D011	
1310-73-2	SODIUM HYDROXIDE	D002	
7681-52-9	SODIUM HYPOCHLORITE	D002	
7664-93-9	SULFURIC ACID	D002	
127-18-4	TETRACHLOROETHYLENE	U210/D039	
76-03-9	TRICHLOROACETIC ACID	D002	
79-01-6	TRICHLOROETHYLENE	U228/D040	

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Appendix C

Environmental Risks

Some states have identified categories of drugs that present risks to the environment and water. Preferred management of these waste pharmaceuticals is via incineration. The Minnesota Pollution Control Agency has identified the following categories as those that should be incinerated, even though technically they are not hazardous waste per Federal RCRA.

- *Carcinogen* - Drug listed as known to be a human carcinogen in Part A of Section II of the 11th Report on Carcinogens, 2004, published by the U.S. National Toxicology Program (NTP), or as reasonably anticipated to be a human carcinogen in Part B of Section II of the 11th Report. The 11th Report is available on the NTP's Web site at: http://ntp.niehs.nih.gov/ntp/roc/toc11.html
- *Chemotherapy agent* - Drug approved by the U.S. Food and Drug Administration (FDA) for drug treatment of cancer, or used by the healthcare facility for off-label treatment of cancer, and which acts by causing cell death or by significantly decreasing cell growth or reproduction. A list of drugs approved for treatment of cancer by the FDA is available on the FDA's Web site at: http://www.fda.gov/cder/cancer/druglistframe.htm
- *Combination U/P-Listed drug* - Drug with more than one active ingredient containing at least one ingredient included on the P-List, or containing at least one ingredient included on the U-List. Drugs that have been used for their intended purpose are not subject to this definition.
- *Controlled Substance* - Drug defined as a Schedule I-V Controlled Substance by the U.S. Drug Enforcement Agency (DEA). A list of Controlled Substances is available on the DEA's website at: http://www.deadiversion.usdoj.gov/schedules/schedules.htm
- *Endocrine Disruptor* - Drug that meets the general description of an endocrine disruptor as contained in Chapter 3, Section II of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) Final Report, 1998, published by the U.S. Environmental Protection Agency (EPA). The general description of an endocrine disruptor is available on the EPA's Web site at: http://www.epa.gov/scipoly/oscpendo/docs/edstac/chap3v14.pdf
- *NIOSH Hazardous Drug* – A drug listed in Appendix A of the NIOSH Alert: *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings*, NIOSH Publication 2004-165, published by the U.S. National Institute for Occupational Safety and Health (NIOSH), or that meets one or more of the hazardous drug criteria contained in Appendix A of the NIOSH Alert. The Alert is available on the NIOSH Web site at: http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html
- *OSHA Hazardous Drug* – A drug listed in Appendix VI: 2-1 of the OSHA Technical Manual, *OSHA Directive TED 01-00-015*, as amended, published by the U.S. Occupational Safety & Health Administration (OSHA), or that meets one or more of the hazardous drug criteria contained in Section VI, Chapter 2, Section II, of the Manual. The Manual is available on OSHA's Web site at: http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

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Appendix D

Sample Disposal Flow Chart[7]

Type of Waste	Description of Waste	Description of Container	Type of Treatment
Hazardous Toxic and Best Management Practices (BMP) Toxic	▪ P, U and toxic D wastes ▪ All bulk, non-listed chemotherapy drugs ▪ Non-listed toxic drugs ▪ PPE with visible contamination	Black or dark blue	Incineration at RCRA hazardous waste facility
Hazardous Ignitable	▪ D001 wastes	Black or dark blue	Incineration at RCRA hazardous waste facility
Hazardous and Infectious	▪ Hazardous toxic wastes and BMP toxic wastes combined with infectious/regulated medical waste ▪ Entire contents of sharps containers if P-listed hazardous waste was properly or improperly discarded in container	Sharps container (e.g., white/blue) with a Hazardous Waste and infectious label applied	Incineration at a facility permitted to handle RCRA hazardous and infectious waste
Trace Chemotherapy	▪ "RCRA empty" vials of chemotherapy agents, syringes/needles, IVs ▪ PPE used to prepare or administer chemotherapy without visible contamination	Yellow or white	Incineration at infectious waste facility
Drain Disposal	▪ NaCl, dextrose, vitamins, electrolytes	Sewer	Local wastewater treatment plant (permission required)
BMP Non-Regulated	▪ All other drugs	White with blue top (most common)	Incineration at infectious or municipal solid waste facility
Controlled Substances	▪ DEA regulated wastes rendered unusable	Sharps or other locking container	Reverse distributor or hazardous waste hauler with DEA license.

[7] Modified from "Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States", Hospitals for a Healthy Environment, http://www.h2e-online.org/docs/h2epharmablueprint41506.pdf, 2006.

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