



PHARMACEUTICAL WASTE MANAGEMENT GUIDELINES



Enclosure (1)

GUIDELINES

TABLE OF CONTENTS

EXECUTIVE SUMMARY	
References.....	1
Background.....	1
Purpose.....	1
Scope.....	2
Action.....	2
Resources.....	4
1. PHARMACEUTICAL CATEGORIES	
a. RCRA Hazardous Pharmaceuticals.....	5
b. BMP Non-Hazardous Pharmaceuticals.....	6
c. Non-RCRA Antineoplastics.....	7
d. Investigational Pharmaceuticals.....	7
2. DEVELOPING A PHARMACEUTICAL WASTE PROGRAM	
a. Guidelines for Managing RCRA Hazardous Pharmaceuticals and Antineoplastics.....	7
b. Guidelines for Managing Trace Chemotherapy Waste.....	14
c. Guidelines for Managing BMP Non-Hazardous Pharmaceuticals.....	15
d. Guidelines for Handling of Controlled Substances.....	17
e. Guidelines for Managing Dual RCRA Hazardous Waste and Regulated Medical Waste (RMW).....	18
f. Guidelines for Usage of Pharmaceutical Reverse Distribution (RD).....	19
g. Guidelines for Integrating New Pharmaceutical Procedures Into an EMS.....	21
h. Guidelines for Re-Evaluating the Hazardous Waste Generation Status of the Military Treatment Facility.....	21
Appendix A - TOOLS AND RESOURCES.....	23
a. Getting Started	
b. Understanding and Applying the Regulations	
c. Considering Best Management Practices for Non-Regulated Wastes	
d. Considering the Management Options	
e. Getting Ready for Implementation	
f. Launching the Program	
Appendix B – OSHA Technical Manual Appendix VI: 2-1. Some Common Drugs that are Considered Hazardous.....	26

Appendix C – NIOSH Publication No. 2004-165: Preventing Occupational Exposure to
Antineoplastic and Other Hazardous Drugs in Health Care Settings – Appendix
A - Drugs Considered Hazardous.....29

PHARMACEUTICAL WASTE MANAGEMENT GUIDELINES

EXECUTIVE SUMMARY

REFERENCES

- (a) 40 CFR 260-279, EPA Hazardous Waste Management Regulations
- (b) National Institute of Occupational Safety and Health (NIOSH) Hazardous Drug Alert Appendix A
- (c) Occupational Safety and Health Administration (OSHA), Technical Manual Section 6, Chapter 2, Appendix VI: 2-1 OPNAVINST 5090.1B or most current version
- (d) US Department of Health and Human Services National Toxicology Programs Report on Carcinogens (11th Edition)

BACKGROUND

The Resource Conservation and Recovery Act (RCRA) was enacted in 1976 and governs the management of solid and hazardous waste generated within the United States. In the past several years, the Environmental Protection Agency (EPA) and state environmental protection inspectors have determined that healthcare facilities have not been managing hazardous waste in compliance with RCRA. A number of pharmaceuticals and formulations of pharmaceuticals meet the definition of hazardous waste under RCRA. EPA and some state environmental agencies are now requiring healthcare facilities to identify, segregate, contain, and appropriately label, store, transport, and dispose of these hazardous wastes in compliance with RCRA regulations. As a result of this focus on the part of regulators, surveyors for the Joint Commission (JC) are also including pharmaceutical waste management in their survey questions.

PURPOSE

These guidelines discuss categorizing pharmaceutical waste, maintaining and updating an inventory of pharmaceutical waste streams, managing waste storage sites throughout the military treatment facility (MTF), and disposing of waste material. The guidelines provide suggestions on how to manage your program. MTFs can make the final decisions on the best way to develop and maintain the requirements set forth. Pharmaceutical waste that meet the requirements delineated in 40 CFR 261.33(e) (P list) or 40 CFR 261.33(f) (U list), or exhibits a characteristic of hazardous as defined in the 40 CFR 261 must be managed and disposed of in accordance to Federal, State, and local regulations. Therefore, the purpose of these guidelines is:

- a. To provide policy and guidelines for MTFs generating pharmaceutical waste and to

ensure the implementation of Reference (a), 40 CFR 260-279, EPA Hazardous Waste Management Regulations.

- b. To provide Best Management Practice (BMP) guidelines for the management of other non-RCRA Pharmaceutical waste included in these guidelines.

SCOPE

There are four (4) categories of pharmaceutical waste that need to be managed and they are defined as follows:

RCRA Hazardous Waste: Waste pharmaceuticals that meet the definition of a hazardous waste and must be segregated and managed as hazardous waste. These include nine antineoplastic agents.

Non-RCRA Antineoplastic Hazardous Waste: The Navy Bureau of Medicine and Surgery (BUMED) Environmental Programs (EP) Directorate has made the decision to manage all antineoplastic agents as hazardous waste regardless of whether or not they are technically listed as RCRA antineoplastic hazardous waste due to their inherent toxicity. Non-RCRA antineoplastic hazardous waste includes all antineoplastic agents used for the treatment of cancer that are not regulated by RCRA.

BMP Hazardous Waste: Pharmaceuticals which meet the criteria in these guidelines should be evaluated for possible management as RCRA hazardous waste as a best management practice. The decision will be made at the facility level. Additional guidance is provided in these guidelines.

BMP Non-Hazardous Pharmaceutical Waste: All other pharmaceutical waste not included in one of the above three definitions. As a best management practice, consider managing all pharmaceuticals not managed as hazardous waste through incineration at a regulated medical waste or municipal incinerator permitted to accept non-hazardous pharmaceutical waste. This decision can be made at the facility level.

ACTION

All medical treatment facilities use pharmaceuticals in the normal course of their treatment of patients. Pharmaceutical waste will be routinely generated during the course of compounding of specialty items, IV admixture preparation and administration, accidental spills and breakage, and other routine functions. All activities are responsible for implementing the guidelines established in these guidelines. Implementation of this guidance requires multidisciplinary participation from Environmental Programs, Pharmacy, and Nursing. It is recommended that MTFs use their Environment of Care Committee (EOCC) as the action team for implementing this guidance.

- a. Commanding officers or officers in charge should: Appoint a Pharmaceutical

Waste Officer (**PWO**) to establish, manage, and monitor the pharmaceutical waste management program at the command.

- b. The PWO should document the implementation of references (a) and (b) and this guidance to include:
 - (1) Identification and classification of all pharmaceuticals purchased by the activity, including any purchased by departments other than pharmacy which meet the criteria of a hazardous waste (federally and in the state in which the activity is located) if discarded. This list shall include the following information:
 - (a) National Drug Code, generic name, brand name, strength, dosage form, and package size; and
 - (b) Appropriate waste code: Federal P, U, or D plus specific number; state waste code if applicable.
 - (2) Identification of all pharmaceuticals purchased by the activity, including any purchased by departments other than pharmacy, that meet the criteria of an antineoplastic, as defined within these guidelines. This list shall include the following information: National Drug Code, generic name, brand name, strength, dosage form, and package size.
 - (3) A method for identifying and/or labeling all drugs received into the facility which become hazardous waste when discarded.
 - (4) A method for identifying and/or labeling all drugs dispensed to nursing units and other patient care units, including the Emergency Department, Surgical Suites, outpatient clinics, and any tenants residing within the activity, which become hazardous waste when discarded.
 - (5) A method for collecting and containerizing any drugs which become hazardous waste at or near the point of waste generation, including within the pharmacy and all patient care areas (Satellite Accumulation).
 - (6) Policies and procedures for transferring the collected hazardous pharmaceutical waste to the activity's hazardous waste storage area (Storage Accumulation).
 - (7) Policies and procedures for profiling, labeling, manifesting, transporting, and disposing of all hazardous pharmaceutical waste in compliance with federal and state hazardous waste regulations.
- c. The Hazardous Waste Program Manager and/or Environmental Program Manager shall:

- (1) Develop a training program for all relevant personnel within the Environmental Programs Division, Pharmacy Department, and Nursing Department on handling and disposing of hazardous waste;
- (2) Develop an inspection program to ensure compliance with state and federal hazardous waste regulations;
- (3) Assure appropriate Occupational Safety and Health Administration Hazardous Waste Operations and Emergency Response (OSHA HAZWOPER) or comparable Awareness Level training is provided for any staff engaged in transporting hazardous waste from Satellite Accumulation Areas to Storage Accumulation Areas;
- (4) Conduct a re-evaluation of the hazardous waste generator status of the activity based on the addition of hazardous pharmaceutical waste to the generated waste stream;
- (5) Develop new Standard Operating Procedures (SOPs) to ensure implementation of the enclosed guidelines;
- (6) Integrate the new SOPs into the Environmental Management System (EMS);
and
- (7) Modify other existing SOPs as necessary to implement this guidance and the enclosed guidelines.

RESOURCES

The following forms need to be reviewed and completed for pharmaceutical waste that may be managed as hazardous waste.

- a. Hazardous Waste Manifests. Information on these forms is available at <http://www.epa.gov/epaoswer/hazwaste/gener/manifest/>)
- b. Notification of Regulated Waste Activity (EPA Form 8700-12) is available at <http://www.epa.gov/epaoswer/hazwaste/data/form8700/forms.htm>

1. PHARMACEUTICAL CATEGORIES

INTRODUCTION

The following pharmaceutical categories are included in these guidelines: Resource Conservation and Recovery Act (RCRA) Hazardous Pharmaceuticals, Best Management Practice (BMP) Non-Hazardous Pharmaceuticals, and Non-RCRA Antineoplastics. This section gives a brief summary of the requirements and/or best management practices for each of these materials. Appendix A of this guideline includes tools and resources for further information.

a. RCRA Hazardous Pharmaceuticals

Determine if any stocked pharmaceuticals meet the definitions of hazardous waste by applying the criteria noted below:

- 1) The generic or chemical name is listed in 40 CFR 261.33 (e) (P list) or (f) (U list) or comparable state regulations
 - i. Empty containers which have held pharmaceuticals listed in 40 CFR 261.33 (e), or P-listed wastes, must be managed as hazardous waste except for used epinephrine syringes.
 - ii. Common P-listed pharmaceuticals used in the military treatment facility setting are:
 1. P042 – Epinephrine
 2. P075 – Nicotine, & salts
 3. P081 – Nitroglycerine (R)
 4. P204 – Physostigmine
 5. P188 – Physostigmine salicylate
 6. P001 – Warfarin & salts, when present at concentrations greater than 0.3%
 7. P012 – Arsenic Trioxide
 - iii. Common U-listed wastes used in the military treatment facility setting are:
 1. U034 – Chloral (as the hydrate)
 2. U035 – Chlorambucil
 3. U058 – Cyclophosphamide
 4. U059 – Daunomycin
 5. U075 – Dichlorodifluoromethane
 6. U089 – Diethylstilbestrol
 7. U129 – Lindane
 8. U150 – Melphalan
 9. U010 – Mitomycin C
 10. U200 – Reserpine
 11. U201 – Resorcinol

12. U205 – Selenium sulfide
 13. U206 – Streptozotocin
 14. U121 – Trichloromonofluoromethane
 15. U248 – Warfarin & salts, when present at concentrations of 0.3% or less
- 2) The formulation exhibits a characteristic of hazardous waste as defined by the following:
 - i. 40 CFR 261.21 Characteristic of ignitability
 - ii. 40 CFR 261.22 Characteristic of corrosivity
 - iii. 40 CFR 261.23 Characteristic of reactivity
 - iv. 40 CFR 261.24 Toxicity characteristic
 - 3) The formulation exhibits a characteristic of hazardous waste as defined by state hazardous waste regulations (note specifically California, Minnesota, Washington State, Rhode Island, and Michigan).

NOTE

EMPTY CONTAINERS WHICH HAVE HELD PHARMACEUTICALS LISTED IN 40 CFR 261.33 (E), OR P-LISTED WASTES MUST BE MANAGED AS HAZARDOUS WASTE EXCEPT FOR USED EPINEPHRINE SYRINGES.

b. BMP Non-Hazardous Pharmaceuticals

All drugs that do not meet the criteria stated above are categorized as BMP Non-Hazardous Pharmaceuticals. BMP Non-Hazardous Pharmaceuticals that meet any of the criteria listed below must be incinerated. If a regulated medical waste incinerator is not available, they should be disposed of as hazardous waste.

- 1) **Combo P-,U-**: Formulations containing more than one P or U-listed drug or combinations of P or U-listed drugs with other active ingredients.
- 2) **OSHA**: Drugs listed in the Occupational Safety and Health Administration (OSHA) [Technical Manual Section 6, Chapter 2, Appendix VI: 2 -1](#). This list is included as Appendix B of this guideline.
- 3) **CARCIN**: Drugs listed in the US Department of Health and Human Services National Toxicology Program's [Report on Carcinogens \(11th Edition\)](#).
- 4) **OSHA** or **NIOSH**: Additional drugs meeting OSHA or NIOSH criteria.
- 5) **LD50**: Drugs with LD50s at or below 50mg/kg.
- 6) **EDC**: Endocrine disrupting compounds not listed in any of the above references.
- 7) **VITMIN**: Vitamin/mineral preparations that may fail the toxicity characteristic due to chromium, selenium, or cadmium for which there is inadequate data to make a hazardous waste determination.

c. Non-RCRA Antineoplastics

BUMED has decided to treat all non-RCRA antineoplastic agents as RCRA Hazardous Pharmaceuticals because of their inherent toxicity. Identify which pharmaceuticals are Non-RCRA Antineoplastics by applying the criteria noted below:

- 1) Agents are listed on the National Institute of Occupational Safety and Health (NIOSH) Hazardous Drug Alert Appendix A at <http://www.cdc.gov/niosh/docs/2004-165/2004-165d.html#o>. This list is also found in Appendix C of this guideline.
- 2) Any drug that is used in chemotherapy treatments.

d. Investigational Pharmaceuticals

For investigational pharmaceuticals not approved for use in the USA, review literature provided by the manufacturer for proper handling.

2. DEVELOPING A PHARMACEUTICAL WASTE PROGRAM

INTRODUCTION

This section is divided into Guidelines for Managing: a) RCRA Pharmaceuticals and Antineoplastics, b) Trace Chemotherapy Waste; and c) BMP Non-Hazardous Pharmaceuticals. These types of materials are to be managed differently; therefore, separate guidance is given for each.

a. Guidelines for Managing RCRA Pharmaceuticals and Antineoplastics

1) Current Pharmaceutical Inventory

- i. Obtain a complete inventory of all pharmaceuticals currently stocked within the activity. This inventory may be most easily obtained by requesting a one-year purchase history from the prime vendor. Request the data be formatted on a spreadsheet or in a database with the following data fields:

- | | |
|----------------------|----------------|
| ▪ National Drug Code | ▪ Brand Name |
| ▪ Generic Name | ▪ Manufacturer |
| ▪ Strength | ▪ Dosage Form |
| ▪ Package Size | |

See Table 1 for an example format.

Table 1

Report Label Name	Waste Classification	Waste Stream	EPA Code 1	Reason	Addtnl Reason
EPIPEN-JR INJ 0.15MG	Regulated as federal HW	Toxic	P042-Epinephrine	Epinephrine	
ERYTHROMYCIN PAD 2%	Regulated as federal HW	Ignitable	D001-Ignitable	Alcohol >= 24%	
ERYTHROMYCIN SOL 2%	Regulated as federal HW	Ignitable	D001-Ignitable	Alcohol >= 24%	
ETHYL CHLOR AER	Regulated as federal HW	Ignitable	D001-Ignitable	Ignitable aerosol	
ETOPOSIDE INJ 20 MG/ML	Regulated as federal HW	Ignitable	D001-Ignitable	Alcohol >= 24%	
FLUOCINONIDE SOL 0.05%	Regulated as federal HW	Ignitable	D001-Ignitable	Alcohol >= 24%	
FLURBIPROFEN SOL 0.03% OP	Regulated as federal HW	Toxic	D009-Mercury	Mercury preservative	Thimerosal Preservative
FML S.O.P. OIN 0.1% OP	Regulated as federal HW	Toxic	D009-Mercury	Mercury preservative	
FORTEO SOL 750/3ML	Regulated as federal HW	Toxic	D024-m-Cresol	M-cresol	
GENASAL SPR 0.05%	Regulated as federal HW	Toxic	D009-Mercury	Mercury preservative	
HIBTITER INJ	Regulated as federal HW	Toxic	D009-Mercury	Mercury preservative	Thimerosal 1:10,000
HUMALOG INJ 100/ML	Regulated as federal HW	Toxic	D026-Cresol	Cresol	
HUMALOG PEN INJ 100/ML	Regulated as federal HW	Toxic	D026-Cresol	Cresol	
HUMATROPE INJ 5 MG	Regulated as federal HW	Toxic	D024-m-Cresol	M-cresol	
HUMULIN INJ 70/30	Regulated as federal HW	Toxic	D024-m-Cresol	M-cresol	
HUMULIN N INJ U-100	Regulated as federal HW	Toxic	D024-m-Cresol	M-cresol	

If pharmaceuticals have been purchased from other sources, these must be added to the spreadsheet. Add two columns to the spreadsheet for the following two data fields: “Antineoplastic (Y/N)” and “RCRA Waste Code” For each pharmaceutical that meets the criteria for a hazardous waste, list the appropriate federal and state waste code.

- ii. Insert a column entitled “Non-RCRA Antineoplastic Pharmaceutical Waste” in the spreadsheet and document the criteria used to make the determination from the list in Section 1.b. Use the abbreviations given in the above list of criteria.
 - iii. Insert a column in the spreadsheet or a field in the database entitled “BMP Hazardous Pharmaceutical Waste” and document the criteria used to make the determination from the above list. Use the abbreviations given in the above list of criteria, Section 1.c.
- 2) Maintenance of Inventory Spreadsheet

- i. Assignment of Personnel. Assign one representative from the Pharmacy and one representative from the Environmental Programs Department (EPD) to be responsible for monitoring all new unique national drug codes entering the facility.
- ii. Maintenance of Inventory Spreadsheet. Assigned personnel must continuously update the Inventory of Pharmaceutical Wastes with all new drugs that are purchased. All RCRA regulated pharmaceutical waste, antineoplastic pharmaceutical waste, and BMP pharmaceutical wastes that will managed as Hazardous Waste shall be identified in the inventory.
- iii. Assignment of Waste Code. Assigned personnel must make a hazardous waste determination based on 40 CFR 261. The appropriate RCRA hazardous waste code must be assigned for all RCRA regulated pharmaceutical wastes.
- iv. Assignment of Hazardous Drug Reason Code. Assigned personnel must evaluate non-RCRA pharmaceuticals against the Antineoplastic Pharmaceutical Waste criteria listed in Section 1.c. and the Best Management Practice (BMP) criteria listed in Section 1.b. The appropriate criteria should then be documented in the “Hazardous Pharmaceutical Waste Spreadsheet.” Criteria can be found in bold print in Section 1.b.
- v. Maintenance of Labeling Guidance. All labeling guidance must be updated in accordance with Section 2.a.3.

3) Labeling

- i. Labeling Pharmacy Shelf Stickers. Place hazardous waste identification labels on the shelf stickers of all pharmaceuticals that have been identified as RCRA Hazardous Waste in Section 1.a. or Non-RCRA Antineoplastic Pharmaceutical

Waste in Section 1.c. If your installation chooses to follow the Section 1.b. proposed guidelines for Best Management Practices then place identification labels on the respective shelf stickers for these pharmaceuticals as well.

- ii. Training of Pharmacy Personnel. Train pharmacy personnel to label all hazardous waste pharmaceuticals with the appropriate hazardous waste notification sticker when dispensing the pharmaceutical directly to the nursing units.
- iii. Labeling Compounded Items and IV Admixtures. Develop a system for labeling all compounded preparations and IV admixtures that meet the criteria of a hazardous waste when discarded.
- iv. Establishing Messages In Automated Dispensing Cabinets. For those pharmaceuticals that meet the criteria of a hazardous waste, enter an appropriate message into all automated dispensing cabinets such as “Dispose of any waste drug in hazardous waste container. Do not remove from original packaging.”

4) Manifesting

The EPA mandated Uniform Hazardous Waste Manifest must be used for the transportation of all RCRA hazardous wastes after 5 September 2006 as described in Section 1.a.7. The Uniform Manifest allows a maximum of six waste codes. If state-specific codes are in use (e.g., currently Michigan and Minnesota), these must be listed first, followed by the EPA hazardous waste codes most representative of the waste. Non-RCRA antineoplastic pharmaceutical waste need not be listed on the manifest; however, all other guidance in Section 1.a.7 must be followed.

5) Satellite Accumulation of Hazardous Pharmaceutical Waste

- i. Assignment of Personnel. Train EPD, Pharmacy, and Nursing personnel on the concept of satellite accumulation as defined in 40 CFR 262.34 (1) and (2). Satellite accumulation sites, which are under the control of the operator of the process generating the waste, are intended for the storage of hazardous waste generated at or near any point of generation where wastes initially accumulate. No more than 55 gallons of a U-listed or characteristic waste (as defined/ listed in 40 CFR 261) may be accumulated at one time. No more than one quart of P-listed waste (also as defined in 40 CFR 261) may be accumulated at one time. Upon reaching those limits, the containers must be transferred to a less than 90-day storage area within three days. (Some states, such as Maryland, require immediate transfer.) As indicated by the name, waste from less than 90-day storage areas must be manifested and properly transported off-site in less than 90 days.

- ii. Selection of Sites. Choose satellite accumulation sites based on convenience for pharmacy and nursing personnel. Satellite accumulation sites should be secure such that patients and visitors do not have access. The control of the operator can refer to a locked dirty utility room with restricted entry.
 - iii. Marking of Containers. Satellite accumulation containers should bear the words “Hazardous Waste.” If toxic and ignitable hazardous waste pharmaceuticals are being segregated, the additional words “Toxic” and “Ignitable” should appear on the appropriate containers. The Hazardous Waste label is affixed at the time of purchase but the additional Toxic or Ignitable labels or both will need to be affixed when the container is set up for use. In some states, the initial start date of satellite accumulation is required. There is no federal time limit; however, some states, such as California, have a one year limit for total time in residence, including satellite accumulation areas and less than 90-day storage areas. Check with your state’s requirement.
 - iv. Choice of Containers. Black containers can be ordered using the GSA Schedule.
- 6) Guidelines for Less than 90 Day Storage Areas for Hazardous Pharmaceutical Waste
- i. Assignment of Personnel. Proper maintenance of a less than 90-day storage area (small quantity generators as defined in 40 CFR 261 are actually allowed to have less than 180 day storage areas; however, MTFs routinely generate enough P-listed waste to be considered large quantity generators) is a highly technical function. The person assigned to this responsibility should be the Hazardous Waste Manager for the facility.
 - ii. Transfer of Hazardous Pharmaceutical Waste. When the pharmacy or a patient care area fills a container in a satellite accumulation area $\frac{3}{4}$ full, personnel in that area must contact the Hazardous Waste Manager or designated assistant and request a transfer to the less than 90-day storage area.
 - iii. Assuring Containment During Transport to Less Than 90-Day Storage Area. Precautions must be made to ensure that the lid fits tightly, is closed, and is transported in such a manner as to remain upright with no chance of tipping or spillage.
 - iv. Training of Transport Personnel. MTFs that are large quantity hazardous waste generators as defined in 40 CFR 261 have specific training requirements. Personnel transporting hazardous waste from satellite accumulation areas to less than 90-day storage areas must have appropriate OSHA Hazardous Waste Operations and Emergency Response (HAZWOPER) or equivalent training as required by 29 CFR 1910.120.

- 7) Guidelines for Profiling, Labeling, Manifesting, Transporting, and Disposing of Hazardous Pharmaceutical Waste
- i. Assignment of Personnel. The Hazardous Waste Manager or Environmental Program Manager is the appropriate person to oversee this function. Defense Reutilization and Maintenance Organization (DRMO) and the contracted hazardous waste vendor must also be closely involved.
 - ii. Development of Profile. The “Hazardous Pharmaceutical Waste Spreadsheet” generated by following the guidance in Section 2 a.1 should be used to develop the profile. All waste codes should be submitted to DRMO and the hazardous waste vendor. Upon acceptance, six waste codes most representative of the actual waste generated will be used to complete the Uniform Hazardous Waste Manifest. The most frequently generated pharmaceutical waste codes (e.g., epinephrine P042) can be applied to all pharmaceutical waste containers, regardless of actual contents.
 - iii. Segregation of Ignitable and Toxic Wastes. It will be the decision of the vendor and final disposer if ignitable and toxic wastes can be combined. This option would greatly simplify the segregation and collection of waste pharmaceuticals throughout the MTF. These waste streams can only be combined if a waste profile is generated.¹ They CANNOT be combined if the waste pharmaceuticals are lab-packed.² Lab-packing is a time consuming process and not appropriate for pharmaceutical hazardous waste in finished dosage forms (e.g. tablets, capsules, IVs, ointments, etc.). Lab-packing is appropriate and should be used for bulk chemicals, including bulk pharmaceuticals (e.g. resorcinol, phenol, glacial acetic acid, potassium permanganate).
 - iv. Re-certification. The Hazardous Waste (HW) profile will need to be re-certified annually. The hazardous waste vendor should initiate this process, but the MTF should also take responsibility for ensuring this is accomplished.
 - v. New Waste Codes. If new pharmaceuticals are brought into the facility that are designated as hazardous waste with new waste codes, these must be submitted to the hazardous waste vendor and added to the profile at the time they are brought into the inventory.
 - vi. State-Specific Waste Codes. Several states have additional codes for chemicals including pharmaceuticals that must be segregated and disposed of as hazardous

¹ See 49 CFR 173.24 General requirements for packaging and packages and 49 CFR 173.24(a) Additional requirements for non-bulk packaging and packages.

² See 49 CFR 173.12 Exceptions for shipments of waste materials (b)(2)(iii).

waste. These waste codes should also be submitted to the hazardous waste vendor for review. These codes take priority on the Uniform Hazardous Waste Manifest and must be listed before federal EPA waste codes.

- vii. Labeling. If the satellite accumulation containers are to be shipped for disposal they must be re-labeled with the required EPA/DOT hazardous waste shipping label. The Hazardous Waste Manager, DOT-trained designated employee, or hazardous waste vendor should complete this function. If the contents are removed and consolidated, the final shipping container must be labeled with the EPA/DOT hazardous waste shipping label.
- viii. Manifesting. The hazardous waste vendor should prepare the manifests based on the accepted waste profiles. The Hazardous Waste Manager or appropriately-trained employee should sign the manifests prior to shipment. A tickler file should be maintained to assure the signed copy of the manifest from the receiving hazardous waste facility is received by the MTF within the required timeframe. If not, the vendor must be contacted and the contact documented. For large quantity generator facilities (such as MTFs) if the signed manifest is not received within 35 days, contact the hazardous waste vendor. For Large Quantity Generators, if the signed manifest is not received within 45 days, an exception report must be filed with the EPA Regional Office or state environmental protection agency. State regulations may be more stringent and should be consulted. Information regarding the new Uniform Hazardous Waste Manifest may be accessed at <http://www.epa.gov/epaoswer/hazwaste/gener/manifest/>. Check for state-specific manifesting requirements at <http://www.epa.gov/epaoswer/hazwaste/gener/manifest/registry/states.htm>.
- ix. Transporting and Disposing. A permitted hazardous waste hauler/transporter or a permitted Transfer, Storage, and Disposal (TSD) facility must take custody of the hazardous waste at the time of shipment. This vendor may be the final disposer or may be a broker that transfers the waste to a final disposer. Copies of permits, notices of violation, and other due diligence documents should be on file for all vendors within the chain of custody.

8) Guidelines for Segregating and Containerizing Hazardous Pharmaceutical Waste

- i. Determination of Placement of Hazardous Waste Containers. Determine size, placement, and number of hazardous waste containers that will be needed.
 - 1. Pharmacy – in the central pharmacy and satellites; ensure that each assigned area has an appropriate number of hazardous waste containers.
 - 2. Nursing – in each nursing area, the Emergency Department, Surgical Suites, and outpatient clinics; ensure that each dirty utility room has an appropriate number of hazardous waste containers.

- ii. Training of Personnel. Train personnel in the proper use and management of the hazardous waste containers. Training shall include the following components:
 1. All nursing personnel must be trained on the meaning of the hazardous waste notification labels.
 2. Any discarded pharmaceutical that has a hazardous waste notification label must be placed into the appropriate hazardous waste container.
 3. The hazardous waste container must remain closed when not in active use.
 4. If P-listed waste is routinely added to the container, a log must be maintained if one quart of P-listed waste may accumulate before the container is filled. This is most likely during orthopedic and ophthalmic surgery and in the cardiac intensive care units.
 5. If one quart of P-listed waste accumulates, Environmental Program Department (EPD) must be notified immediately to come and remove the container as soon as possible and replace it with an empty container. In any event, replacement should occur within 24 hours.
 6. When the container is $\frac{3}{4}$ full, nursing unit and other patient care area personnel should notify EPD for timely removal.
 7. Empty stock containers should be available in or near the soiled utility rooms at all times to ensure proper containment when a current container is full.
 8. Nursing personnel should not retrieve items that have been placed into the hazardous waste container for any reason.
 9. Nursing and housekeeping personnel should not transfer filled containers to EPD or other storage locations.

b. Guidelines for Managing Trace Chemotherapy Waste

- 1) Assignment of Personnel. The Regulated Medical Waste Manager is the appropriate person to oversee this function.
- 2) Definition of Trace Chemotherapy Waste. Trace chemotherapy waste is not a federally defined term but is referenced in California and Wisconsin state regulated medical waste regulations. These definitions include but are not limited to the following items when they have come into contact with, or had the potential to come into contact with, chemotherapy agents: syringes, drug dispensing devices and broken or empty chemotherapy drug vials, gloves, disposable gowns, towels, empty intravenous solution bags and empty tubing. For the nine listed chemotherapy agents, the containers must be “RCRA Empty.”

- 3) “RCRA Empty.” For the eight U-listed chemotherapy drugs, the containers are considered “RCRA empty” if all the contents have been removed that can be removed by normal means, including aspiration with a needle and syringe, AND there is no more than 3 percent left in the container. These are then considered trace chemotherapy waste. For arsenic trioxide, which is a P-listed hazardous waste, all containers shall be managed as hazardous waste, not trace chemotherapy waste, since “RCRA empty” would require triple rinsing with the rinsate disposed as hazardous waste.
- 4) Trace Chemotherapy Containers. Containers labeled as Chemotherapy Waste can be purchased in both yellow and white, and as floor units and needleboxes. These should be used for all trace chemotherapy items to clearly differentiate them from red bag and red sharps containers. Yellow trace chemotherapy bags may be used in trolleys for soft trace chemotherapy items such as gloves, gowns, and wipes as a cost savings measure.
- 5) Trace Chemotherapy Is Also Regulated Medical Waste. Trace chemotherapy containers are also labeled as regulated medical waste, enabling bloody tubing, used syringes, and other contaminated materials used in chemotherapy preparation and administration to be placed in these containers.
- 6) Disposal of Trace Chemotherapy Containers. Trace chemotherapy bags and sharps containers must be incinerated at a regulated medical waste incinerator. They should not, under any circumstances, be autoclaved (per NIOSH Hazardous Drug Alert³).
- 7) Rationale for Yellow/White Color Coding. There is a misperception in healthcare facilities that all red-bagged waste is still being incinerated. Due to the closure of most medical waste incinerators under the Clean Air Act, the majority of red-bagged waste, with the exception of pathology waste, is autoclaved or microwaved and then landfilled. Autoclaving of chemotherapy causes aerosolization which can expose waste management employees (see NIOSH Hazardous Drug Alert). Disposal in the landfill is also not appropriate. Color-coding is an effective method for assisting employees in proper labeling of containers for incineration and provides one more quality assurance check.

c. Guidelines for Managing BMP Non-Hazardous Pharmaceuticals

- 1) Assignment of Personnel. The Hazardous Waste Manager or Regulated Medical Waste Manager is appropriate to manage this function, based on the Best Management Practices followed by the installation.
- 2) Definition of Non-Hazardous Pharmaceutical Waste. Non-hazardous pharmaceutical waste represents about 85 percent of the inventory of most hospital pharmacies. For

³ The NIOSH Hazardous Drug Alert can be accessed at <http://www.cdc.gov/niosh/docs/2004-165/>.

the purposes of these guidelines, non-hazardous pharmaceutical wastes are those waste pharmaceuticals that do not meet the definition of RCRA hazardous pharmaceuticals, or the definition of non-RCRA antineoplastics or the definition of BMP Hazardous Pharmaceutical wastes (see Section 1. a-c). Non-hazardous pharmaceutical waste does include antibiotics, antidepressants, controlled substances, and a number of other potent pharmaceuticals that have the potential or have been shown to cause endocrine disruption in aquatic species and antibiotic resistance in bacterial populations.

- 3) Background Information. Additional negative effects on human health and the environment are being intensively researched. Some state environmental protection agencies, such as California and Washington, prohibit the disposal of waste drugs through sewerage, with some exceptions for controlled substances. Some municipalities, such as Little Rock, AR, also prohibit sewerage of most pharmaceuticals. With the continuing documentation of the prevalence of pharmaceuticals in surface, ground, and drinking water, it is reasonable to assume that wastewater treatment facilities will become more aggressive in prohibiting the entry of waste pharmaceuticals into their system.
- 4) Options available for Non-Hazardous Pharmaceutical Waste Management. The most effective alternative to sewerage and landfilling of non-hazardous waste pharmaceuticals is incineration at either a municipal solid waste incinerator or a regulated medical waste incinerator. These facilities must be permitted to handle non-hazardous pharmaceuticals. The facility will request a list of drugs that may be sent for treatment. The list generated in Section 1 should provide those pharmaceuticals that do not meet the criteria of RCRA and related items. The regulated medical waste vendor that currently incinerates pathology waste and trace chemotherapy waste is a logical choice for this function.
- 5) Containerization of Non-Hazardous Pharmaceutical Waste. There are currently two companies manufacturing containers dedicated to this waste stream. The Tyco Kendall Sharp Safety Division manufactures a white container with a blue top in various sizes. It is labeled PharmaSafety and includes needleboxes with restricted entry. The Daniels Company Pharmasmart containers are reusable and can save considerable money. They are white with a purple top and also include needleboxes with restricted entry.
- 6) Placement of Non-Hazardous Pharmaceutical Waste Containers. These containers should be placed in close proximity to the hazardous waste containers discussed in Section 2.a.1. of these guidelines.
- 7) Landfilling as an Option. Landfilling is not an optimum option for several reasons. The landfill should require a Material Safety Data Sheet (MSDS) for all pharmaceuticals that may be sent to it. Usually landfills will not accept liquids, which would preclude unused IVs from being managed through this option. As containers are crushed, the contents will eventually leach and the leachate of most

landfills is added to the sewer system. The goal of keeping the waste pharmaceuticals out of the aquatic ecosystem is therefore not met, and potentially exposes the hospital to environmental risks and liabilities.

- 8) Training. All pharmacy and nursing personnel must be trained to dispose of all pharmaceuticals that are NOT labeled for special disposal as non-hazardous pharmaceutical waste in the appropriate containers.
- 9) Manifesting. There are no official manifests for non-hazardous pharmaceutical waste. The selected vendor should provide their usual and customary manifest or shipping document, specifying the contents as non-hazardous pharmaceutical waste or a related term.
- 10) Security. It is imperative that whatever option is chosen, security be maintained throughout the transport and disposal process. Pharmaceutical waste should always be incinerated through a witnessed conveyor system, never through a pit feed process, due to the opportunity for diversion.

d. Guidelines for the Handling of Controlled Substances

- 1) The Drug Enforcement Administration (DEA) requires that controlled substances that are to be wasted at a healthcare facility must be destroyed “beyond reclamation” and that process must be witnessed and documented by two healthcare professionals (licensed doctor, nurse, mid-level practitioner or pharmacist). (Pharmacist’s Manual available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm>.)
- 2) The least expensive and most convenient method of disposing of controlled substances in liquid, tablet, or capsule form has traditionally been through drain disposal. In some cases, items such as used fentanyl patches have also been disposed through flushing into the sewer system. While this approach satisfies DEA requirements, it is not the most environmentally-sound method of disposal. To ensure that no state or municipal regulations are being violated by this practice, the facility that wishes to continue this practice should contact the appropriate local and state wastewater treatment authorities in writing and request permission to continue this practice. Since all quantities are documented, estimated quantities can be provided per month to assist regulatory agencies in making an informed decision.
- 3) A second option for the disposal of significant quantities of unwanted waste controlled substances, such as unused or partial IV morphine drips, is to transfer these items to a reverse distributor that is registered with the Drug Enforcement Administration to accept DEA schedules II through V. This is considered a transfer between DEA registrants and all relevant paperwork and inventory requirements must be met. These are defined in the DEA regulations (see 21 CFR 1300 to 1316). Expired controlled substances in the original manufacturers’ containers should routinely be sent through reverse distribution to obtain credit whenever possible.

- 4) A third option is the transfer of waste controlled substances to a hazardous waste vendor that is registered as a reverse distributor with the Drug Enforcement Administration to accept DEA schedules II through V. This is also considered a transfer between DEA registrants and all relevant paperwork and inventory requirements must be met. These are defined in the DEA regulations (see 21 CFR 1300 to 1316). This option is also appropriate for the disposal of chloral hydrate, U034, a schedule IV controlled substance that is also a RCRA hazardous waste.
 - 5) If sewerage is not an option due to state or municipal regulations, such as in the State of California, and the other options are not viable due to location or cost constraints, contact the local or regional DEA office for additional guidance.
 - 6) Regardless of the option selected, ensure that all reporting procedures meet DEA reporting requirements for that option.
- e. **Guidelines for Managing Dual RCRA Hazardous Waste and Regulated Medical Waste (RMW)**
- 1) **Definition of Dual RCRA Hazardous Waste and Regulated Medical Waste (RMW)** - A waste which meets the definition of both a RCRA hazardous waste (40 CFR 261) and a regulated medical waste as defined by state medical waste regulations. An example would be a syringe and needle that were used for the transfer of arsenic trioxide, a P-listed hazardous waste. The needle, being a sharp, meets the definition of regulated medical waste in most states. Because the syringe held a P-listed waste, it is not considered "RCRA empty" unless it has been triple rinsed, which is not a good management option. Therefore the used syringe is a dual waste as defined in these guidelines.
 - 2) **Containment and Labeling of Dual Waste.** Specially-marked containers should be set up in appropriate areas where dual wastes are most likely to be generated. Where sharps are expected, a needlebox (white/blue top) is ideal since access is restricted in the same manner as a red needlebox. The original labeling should be augmented with two additional labels. One label should say "Hazardous Waste." The second label should contain the traditional designation of a biohazardous or regulated medical waste. Each must be in plain view. Note that the needlebox is not adequate packaging for shipment and must be overpacked within a spill-proof, leak-proof container meeting Packing Group II standards. An alternative is a black Kendall hazardous waste container (no black needlebox was available on the market at the time of issuance of these guidelines). In this case, a biohazardous or regulated medical waste label must be added to the hazardous waste label. This container is designed for shipping of hazardous waste.
 - 3) **Storage of Dual Waste.** The hazardous waste classification of the dual waste takes precedence for storage requirements. Therefore, dual waste must be stored in the Satellite Accumulation Area. At that time the more detailed hazardous waste

shipping label should be affixed and completed. The biohazardous label must remain prominently displayed also.

- 4) Shipping of Dual Waste. The vendor must be permitted to transport and dispose of both RCRA hazardous waste and regulated medical waste and should demonstrate that capability by providing permit information. Two hazardous waste vendors which have this capability are Veolia (formerly Onyx) and Clean Harbors. The dual waste must be manifested as hazardous waste. Check with the vendor for additional manifesting requirements for your state.
- 5) Minimization of Dual Waste Generation. The management of this waste stream is more costly than either RCRA hazardous waste alone or regulated medical waste alone and generation of dual waste should be minimized whenever possible. The 1994 EPA Hotline exemption of used syringes containing epinephrine residue should be considered to enable these sharps to be managed as regulated medical waste. This is the only exemption for a P-listed drug and applies only to used syringes.

f. Guidelines for the Usage of Pharmaceutical Reverse Distribution (RD)

- 1) Definition of Pharmaceutical Reverse Distribution. Pharmaceutical reverse distribution is the process of returning outdated, expired pharmaceuticals in the original manufacturer's packaging to a third-party company (reverse distributor) for the purpose of obtaining credit for the expired pharmaceuticals from the manufacturer.
- 2) Functions of a Pharmaceutical Reverse Distributor. The pharmaceutical reverse distributor maintains current return policies for all pharmaceutical manufacturers and compares each returned outdated product to these policies. If the conditions of the product meet the return policies of the manufacturer, the item is returned to the manufacturer or its designated agent (which may be the same or another reverse distributor) and a credit is issued to the pharmacy, most often through the prime vendor (drug distributor).
- 3) Use of Pharmaceutical Reverse Distribution by the DoD. The DoD routinely uses pharmaceutical reverse distribution for the management of outdated, expired products in their original manufacturer's packaging to maximize credits back to the government. The Pharmacy Department manages this process.
- 4) Limits of Pharmaceutical Reverse Distribution. Based on two interpretive letters from the USEPA to Merck & Co. (a pharmaceutical manufacturer) in 1981 and to Browning-Ferris Industries (BFI) Pharmaceutical (a pharmaceutical reverse distributor) in 1991, the EPA regards outdated, expired products in their "original manufacturer's container" as "products" as they move back through the supply chain, and until a final decision has been made as to their disposition. The decision to declare the product as "waste" may occur at the reverse distributor or at the manufacturer or its designated agent. The interpretive letters are clear that reverse

distribution is NOT to be used in lieu of a waste management system for waste-like items. “EPA does not intend for hazardous waste brokers 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 what becomes waste. Second, 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.”⁴ The reverse distributor must distinguish waste from creditable products, and hence must properly notify the original waste generator regarding the amount and characteristics of the wastes to be disposed of at a third-party permitted waste management facility.

- 5) Applicability to MTF PHARMACEUTICAL WASTE MANAGEMENT GUIDELINES. Regardless of the claims of some reverse distributors that they can accept pharmaceutical waste from facilities in addition to legitimate outdated, expired products, this is not the official position of the USEPA. Opened vials, unused IVs solutions, repackaged tablets and capsules, and other obviously “waste-like” items must be managed as waste and not sent through reverse distribution.
- 6) Exception for Controlled Substances. Due to the difficulty in disposing of controlled substances regulated by the Drug Enforcement Administration (DEA), reverse distributors are registered with DEA to accept controlled substances. In Schedules II through V, reverse distributors provide a disposal option for non-hazardous controlled substances as a transfer between registrants. Some hazardous waste transporters and Treatment, Storage, or Disposal Facilities (TSDFs) have also obtained DEA registration as reverse distributors and provide appropriate disposal options for hazardous controlled substances, such as chloral hydrate, a listed hazardous waste (U034) and a controlled substance in Schedule IV. These firms do not provide the traditional reverse distribution function of evaluating the returned item for credit; however, and are focused exclusively on waste management. Expired products in the original manufacturer’s packaging which are controlled substances should routinely be returned for possible credit through traditional reverse distributors, again as a transfer between registrants. Refer to Section 2.d. for additional information on managing expired and waste controlled substances.
- 7) Regional and State Regulatory Considerations. In the original EPA interpretive letters noted above, USEPA made the ruling that some returned products being accepted by reverse distributors might be reused or recycled. For expired products, this has not been the case. Therefore, some USEPA Regions, such as Region 2, and some states, have tightened the interpretation to the effect that if credit is never given for a particular drug product, and that product would become a hazardous waste if discarded, the healthcare facility must no longer send that product through reverse distribution but must manage it as a hazardous waste at the facility. The itemized waste records of the reverse distributor are used to make this determination. Some states have completely prohibited the shipment of any outdated drugs through reverse

⁴ Excerpt from a letter from Sylvia K. Lowrance, Director, Office of Solid Waste, to Mark J. Schulz, President, Pharmaceuticals Division, Inc., Browning-Ferris Industries on May 16, 1991.

distribution if they would become hazardous waste when discarded, citing that the lack of the real potential for recycling and reuse removes them from eligibility. Federally, only 5% of pharmacy inventories fall into this category; however, the management burden is increasing significantly. Since this is a relatively fluid situation, it is important that all facilities contact their USEPA Region and state environmental regulatory authority to determine the current requirements for the use of reverse distribution.

- 8) Florida Universal Waste Rule. There is a pending regulation in the State of Florida that would include pharmaceutical hazardous waste in the definition of Universal Waste within that state. It appears that the regulation would permit Florida-licensed reverse distributors to become Universal Waste Handlers. Since there are no permitted RCRA incinerators in the State of Florida, any universal waste pharmaceuticals would need to be properly identified, labeled, and manifested prior to leaving the State of Florida for final disposal. The US Navy sees no advantage to introducing a third party into what is essentially a waste management process. Facilities in Florida are not encouraged to utilize this option at the present time. BUMED will continue to monitor the implications of this pending regulation after it becomes law.

g. Guidelines for Integrating New Pharmaceutical Procedures Into an EMS

- 1) Assignment of Personnel. The Hazardous Waste Manager and the Hazardous Materials Manager are the appropriate persons to oversee this function in close communication with the contractor or other personnel responsible for developing and maintaining the EMS.
- 2) Areas Impacted. Virtually every section of the EMS must be revisited for possible revisions, especially those dealing with hazardous waste generation.
- 3) Impact on Hazardous Materials Management. The list of hazardous pharmaceutical wastes should be closely reviewed with the Pharmacy and Nursing Departments to determine how they are routinely handled and if employee exposure is an issue. The hazardous materials list should be updated to include those pharmaceuticals listed in Appendix A of the NIOSH Hazardous Drug Alert.⁵

h. Guidelines for Re-Evaluating the Hazardous Waste Generation Status of the Military Treatment Facility

- 1) Assignment of Personnel. The Hazardous Waste Manager or Environmental Program Manager is the appropriate person to oversee this function.
- 2) Current Hazardous Waste Generator Status. If the current hazardous waste generator status of the activity is that of a Large Quantity Generator (LQG), no further action is necessary. If the current hazardous waste generator status of the activity is that of a

⁵ The NIOSH Hazardous Drug Alert can be accessed at <http://www.cdc.gov/niosh/docs/2004-165/>.

Small Quantity Generator (SQG) or a Conditionally Exempt Small Quantity Generator (CESQG), the recommendations of this guidance should be followed and any changes in generator status made accordingly. State designations of generator status may vary slightly and must be complied with accordingly.

- 3) Documentation of P-listed Waste Generation. All P-listed pharmaceutical wastes must be documented per calendar month if the activity is a SQG or CESQG. If the total quantity of P-listed wastes, including from areas other than pharmaceutical waste, exceeds 1 kg (2.2 lbs) for any calendar month, the activity must meet the requirements of a LQG for that month, which essentially requires re-notification to EPA of LQG status and compliance with LQG regulation requirements. Additional storage limits also apply but are not usually the determining factor with respect to hazardous pharmaceutical waste. Check with state and federal regulations to ensure that all requirements have been considered.
- 4) P-listed Waste Epinephrine. The most common areas in a MTF that generate P-listed pharmaceutical waste are the operating room suites (IV epinephrine for orthopedic and ophthalmic surgery), and the cardiac intensive care units (IV epinephrine for cardiac management). It is very difficult for a full service hospital to remain either a SQG or a CESQG due to the volumes of waste epinephrine generated. Since the containers are not “RCRA empty” unless they are triple rinsed,⁶ all containers that have held epinephrine, except in a used syringe, must also be managed as P-listed hazardous waste.
- 5) P-listed Waste Nitroglycerin. Medicinal nitroglycerin has been excluded federally from hazardous waste status under revisions to the Mixture and Derived-From Rules.⁷ Each state must adopt this revision before medicinal nitroglycerin is excluded as a P-listed waste in that state. Check with your state environmental protection agency for the status of this exclusion.
- 6) Updating Generator Status. If the MTF must update its generator status, a re-notification must be made to EPA using the forms available at <http://www.epa.gov/epaoswer/hazwaste/data/form8700/forms.htm> or to the state environmental protection agency. Check with the state environmental protection agency to determine the required procedure.
- 7) Modifying the Hazardous Waste Management Plan and EMS. If the activity is moving from a SQG or a CESQG to a LQG, extensive changes in the Hazardous Waste Management Plan and Environmental Management System must be made to ensure compliance.

⁶ RCRA Online # 13718

<http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f1c1deb3648a62a868525670f006bccd2!OpenDocument>

⁷ Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived-From Rules.

<http://www.epa.gov/fedrgstr/EPA-WASTE/2001/May/Day-16/fl1411.htm>

TOOLS AND RESOURCES (APPENDIX A)

a. Getting Started

- EPA Pharmaceutical Industry Sector Notebook:
<http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/pharmaceutical.html>
- Cradle-to-Cradle Stewardship of Drugs for Minimizing Their Environmental Disposition While Promoting Human Health Parts 1 and 2:
<http://www.epa.gov/nerlesd1/chemistry/ppcp/images/green1.pdf> and
<http://epa.gov/nerlesd1/chemistry/ppcp/images/green2.pdf>
- USEPA Region 2 Guidance on Healthcare Hazardous Wastes, including pharmaceuticals: <http://www.epa.gov/region2/healthcare>

b. Understanding and Applying the Regulations

General

- The RCRA Orientation Manual: <http://www.epa.gov/epaoswer/general/orientat/>
- RCRA hazardous waste regulations on e-CFR: <http://ecfr.gpoaccess.gov>

Hazardous Waste Identification

- RCRA Online # 13718: Epinephrine Residue In A Syringe Is Not P042 (December 1994):
<http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1c1deb3648a62a868525670f006bccd2!OpenDocument>
- Nitroglycerin Exclusion 66 FR 27286 Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived -From Rules can be accessed at:
<http://www.epa.gov/EPA-WASTE/2001/May/Day-16/f11411.htm>

Chemotherapy Waste

- Recommendations for Chemotherapy Spill Response detailed in the OSHA Technical Manual C.5: http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#5
- Recommendations for Respirator Protection detailed in the OSHA Technical Manual B.6.c: http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#5
- Chemotherapy spills on carpet:
http://www.des.nh.gov/nhppp/Healthcare_P2/default.asp?link=faq6
- The NIOSH Hazardous Drug Alert: <http://www.cdc.gov/niosh/docs/2004-165/>

Controlled Substances

- Controlled substance schedules:
<http://www.deadiversion.usdoj.gov/schedules/index.html>
- The DEA Diversion website: <http://www.deadiversion.usdoj.gov/new.htm>
- The regulations applying to controlled substances, 21 CFR 1300 to 1399:
<http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html>

- The Pharmacist's Manual, a summary of the DEA disposal requirements:
<http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.htm/>

Generator Status

- Small and large quantity generators must register with EPA for an Identification Number. Registration forms and instructions for small and large quantity generator identification numbers:
<http://www.epa.gov/epaoswer/hazwaste/data/form8700/forms.htm#waste>

Drain Disposal

- Tri-TAC Memo to POTW Pretreatment Coordinators and Managers, September 23, 2003: <http://www.ciwmb.ca.gov/WPIE/HealthCare/TriTACMemAtt.pdf>

Aerosol Cans

- RCRA Online #11782: Regulatory Status Of Used Residential And Commercial/Industrial Aerosol Cans (October 1993):
<http://yosemite.epa.gov/osw/rcra.nsf/ea6e50dc6214725285256bf00063269d/0c95b3d30e33cdb68525670f006bece7!OpenDocument>

c. Considering Best Management Practices for Non-Regulated Wastes

- The NIOSH Hazardous Drug Alert: <http://www.cdc.gov/niosh/docs/2004-165/>
- The Occupational Safety and Health Administration (OSHA) Technical Manual Section 6, Chapter 2, Appendix VI: 2: http://www.osha-slc.gov/dts/osta/otm/otm_vi/otm_vi_2.html
- The Toxicology Program's Report on Carcinogens (11th Edition):
<http://ntp.niehs.nih.gov/ntp/roc/toc11.html>
- The full Precautionary Principle statement: <http://www.gdrc.org/u-gov/precaution-3.html>

d. Considering the Management Options

- The OSHA Hazardous Waste Operations and Emergency Response Standard:
<http://www.osha.gov/html/faq-hazwoper.html>

e. Getting Ready for Implementation

Locating Your Satellite Accumulation Areas

- USEPA's Frequently Asked Questions about Satellite Accumulation Areas, March 17, 2004: <http://www.epa.gov/osw/specials/labwaste/memo-saa.htm>

Selecting the Right Vendor(s)

- Licensed hazardous waste transport, storage, and disposal facilities nationwide:
http://www.epa.gov/enviro/html/rcris/rcris_query_java.html

Reverse Distribution

- RCRA Online # 11012 Applicability of 261.33 to Discarded Products:
<http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/b630cd51dc85edc58525670f006bce84!OpenDocument>

- RCRA Online # 11606 Returned Pharmaceutical Products:
<http://yosemite.epa.gov/osw/rcra.nsf/ea6e50dc6214725285256bf00063269d/a3a7a7a8f297438b8525670f006be5d8!OpenDocument>

Pharmaceutical Waste Management Policies and Procedures

- Healthcare Guidance to Pollution Prevention Implementation through Environmental Management Systems can be accessed at: <http://www.epa.gov/region2/ems>

f. Launching the Program

Filling out the Forms

- Information about hazardous waste manifests:
<http://www.epa.gov/epaoswer/hazwaste/gener/manifest/>.
- 40 CFR 173.24 contains general requirements for packaging and packages
- 40 CFR 173.24(a) for additional requirements for non-bulk packaging and packages.
- 49 CFR 173.12 (b)(2)(iii) has exceptions for shipments of waste materials
- Information on the 40 CFR Part 268 Land Disposal Restrictions:
<http://www.epa.gov/epaoswer/general/orientat/rom36.pdf>.

OSHA TECHNICAL MANUAL APPENDIX VI: 2-1 SOME COMMON DRUGS THAT ARE CONSIDERED HAZARDOUS (APPENDIX B)

APPENDIX VI: 2-1. SOME COMMON DRUGS THAT ARE CONSIDERED HAZARDOUS.

Appendix VI:2-1 is not all-inclusive, should not be construed as complete, and represents an assessment of some, but not all, marketed drugs at a fixed point in time. Appendix VI:2-1 was developed through consultation with institutions that have assembled teams of pharmacists and other health care personnel to determine which drugs should be handled with caution. These teams reviewed product literature and drug information when considering each product.

Sources for this appendix are the "Physicians Desk Reference," Section 10:00 in the *American Hospital Formulary Service Drug Information*,⁶⁸ IARC publications (particularly Volume 50),⁴³ the Johns Hopkins Hospital, and the National Institutes of Health, Clinical Center Nursing Department. No attempt to include investigational drugs was made, but they should be prudently handled as hazardous drugs until adequate information becomes available to exclude them.

Any determination of the hazard status of a drug should be periodically reviewed and updated as new information becomes available. Importantly, new drugs should routinely undergo a hazard assessment.

CHEMICAL/GENERIC NAME	SOURCE*
ALTRETAMINE	C
AMINOGLUTETHIMIDE	A
AZATHIOPRINE	ACE
L-ASPARAGINASE	ABC
BLEOMYCIN	ABC
BUSULFAN	ABC
CARBOPLATIN	ABC
CARMUSTINE	ABC
CHLORAMBUCIL	ABCE
CHLORAMPHENICOL	E
CHLOROTIANISENE	B
CHLOROZOTOCIN	E
CYCLOSPORIN	E
CISPLATIN	ABCE
CYCLOPHOSPHAMIDE	ABCE
CYTARRABINE	ABC

DACARBAZINE	ABC
DACTINOMYCIN	ABC
DAUNORUBICIN	ABC
DIETHYLSTILBESTROL	BE
DOXORUBICIN	ABCE
ESTRADIOL	B
ESTRAMUSTINE	AB
ETHINYL ESTRADIOL	B
ETOPOSIDE	ABC
FLOXURIDINE	AC
FLUOROURACIL	ABC
FLUTAMIDE	BC
GANCICLOVIR	AD
HYDROXYUREA	ABC
IDARUBICIN	AC
IFOSFAMIDE	ABC
INTERFERON-A	BC
ISOTRETINOIN	D
LEUPROLIDE	BC
LEVAMISOLE	C
LOMUSTINE	ABCD
MECHLORETHAMINE	BC
MEDROXYPROGESTERONE	B
MEGESTROL	BC
MELPHALAN	ABCE
MERCAPTOPURINE	ABC
METHOTREXATE	ABC
MITOMYCIN	ABC
MITOTANE	ABC
MITOXANTRONE	ABC
NAFARELIN	C
PIPOBROMAN	C
PLICAMYCIN	BC
PROCARBAZINE	ABCE
RIBAVIRIN	D
STREPTOZOCIN	AC
TAMOXIFEN	BC
TESTOLACTONE	BC

THIOGUANINE	ABC
THIOTEPA	ABC
URACIL MUSTARD	ACE
VIDARABINE	D
VINBLASTINE	ABC
VINCRISTINE	ABC
ZIDOVUDINE	D

*** Sources**

- A - The National Institutes of Health, Clinical Center Nursing Department
- B - Antineoplastic drugs in the [*italicize the following text name*] Physicians' Desk Reference
- C - American Hospital Formulary, Antineoplastics
- D - Johns Hopkins Hospital
- E - International Agency for Research on Cancer

**NIOSH PUBLICATION NO. 2004-165: PREVENTING
OCCUPATIONAL EXPOSURE TO ANTINEOPLASTIC AND
OTHER HAZARDOUS DRUGS IN HEALTH CARE SETTINGS /
APPENDIX A – DRUGS CONSIDERED HAZARDOUS**

(APPENDIX C)

The listing below will be updated annually on this website.

Sample list of drugs that should be handled as hazardous*		
Drug	Source	AHFS Pharmacologic-Therapeutic Classification
Aldesleukin	4,5	10:00 Antineoplastic agents
Alemtuzumab	1,3,4,5	10:00 Antineoplastic agents
Alitretinoin	3,4,5	84:36 Miscellaneous skin and mucous membrane agents (Retinoid)
Altretamine	1,2,3,4,5	Not in AHFS (Antineoplastic agent)
Amsacrine	3,5	Not in AHFS (Antineoplastic agent)
Anastrozole	1,5	10:00 Antineoplastic agents
Arsenic trioxide	1,2,3,4,5	10:00 Antineoplastic agents
Asparaginase	1,2,3,4,5	10:00 Antineoplastic agents
Azacitidine	3,5	Not in AHFS (antineoplastic agent)
Azathioprine	2,3,5	92:00 Unclassified therapeutic agents (immunosuppressant)
Bacillus Calmette-Guerin	1,2,4	80:12 Vaccines
Bexarotene	2,3,4,5	10:00 Antineoplastic agents
Bicalutamide	1,5	10:00 Antineoplastic agents
Bleomycin	1,2,3,4,5	10:00 Antineoplastic agents
Busulfan	1,2,3,4,5	10:00 Antineoplastic agents
Capecitabine	1,2,3,4,5	10:00 Antineoplastic agents
Carboplatin	1,2,3,4,5	10:00 Antineoplastic agents
Carmustine	1,2,3,4,5	10:00 Antineoplastic agents
Cetrorelix acetate	5	92:00 Unclassified therapeutic agents (GnRH antagonist)
Chlorambucil	1,2,3,4,5	10:00 Antineoplastic agents
Chloramphenicol	1,5	8:12 Antibiotics
Choriogonadotropin alfa	5	68:18 Gonadotropins
Cidofovir	3,5	8:18 Antivirals
Cisplatin	1,2,3,4,5	10:00 Antineoplastic agents
Cladribine	1,2,3,4,5	10:00 Antineoplastic agents
Colchicine	5	92:00 Unclassified therapeutic agents (mitotic inhibitor)
Cyclophosphamide	1,2,3,4,5	10:00 Antineoplastic agents

Cytarabine	1,2,3,4,5	10:00 Antineoplastic agents
Cyclosporin	1	92:00 Immunosuppressive agents
Dacarbazine	1,2,3,4,5	10:00 Antineoplastic agents
Dactinomycin	1,2,3,4,5	10:00 Antineoplastic agents
Daunorubicin HCl	1,2,3,4,5	10:00 Antineoplastic agents
Denileukin	3,4,5	10:00 Antineoplastic agents
Dienestrol	5	68:16.04 Estrogens
Diethylstilbestrol	5	Not in AHFS (nonsteroidal synthetic estrogen)
Dinoprostone	5	76:00 Oxytocics
Docetaxel	1,2,3,4,5	10:00 Antineoplastic agents
Doxorubicin	1,2,3,4,5	10:00 Antineoplastic agents
Dutasteride	5	92:00 Unclassified therapeutic agents (5-alpha reductase inhibitor)
Epirubicin	1,2,3,4,5	10:00 Antineoplastic agents
Ergonovine/methyletergonovine	5	76:00 Oxytocics
Estradiol	1,5	68:16.04 Estrogens
Estramustine phosphate sodium	1,2,3,4,5	10:00 Antineoplastic agents
Estrogen-progestin combinations	5	68:12 Contraceptives
Estrogens, conjugated	5	68:16.04 Estrogens
Estrogens, esterified	5	68:16.04 Estrogens
Estrone	5	68:16.04 Estrogens
Estropipate	5	68:16.04 Estrogens
Etoposide	1,2,3,4,5	10:00 Antineoplastic agents
Exemestane	1,5	10:00 Antineoplastic agents
Finasteride	1,3,5	92:00 Unclassified therapeutic Agents (5-alpha reductase inhibitor)
Floxuridine	1,2,3,4,5	10:00 Antineoplastic agents
Fludarabine	1,2,3,4,5	10:00 Antineoplastic agents
Fluorouracil	1,2,3,4,5	10:00 Antineoplastic agents
Fluoxymesterone	5	68:08 Androgens
Flutamide	1,2,5	10:00 Antineoplastic agents
Fulvestrant	5	10:00 Antineoplastic agents
Ganciclovir	1,2,3,4,5	8:18 Antiviral
Ganirelix acetate	5	92:00 Unclassified therapeutic agents (GnRH antagonist)
Gemcitabine	1,2,3,4,5	10:00 Antineoplastic agents
Gemtuzumab ozogamicin	1,3,4,5	10:00 Antineoplastic agents
Gonadotropin, chorionic	5	68:18 Gonadotropins
Goserelin	1,2,5	10:00 Antineoplastic agents
Hydroxyurea	1,2,3,4,5	10:00 Antineoplastic agents
Ibritumomab tiuxetan	3	10:00 Antineoplastic agents
Idarubicin	1,2,3,4,5	Not in AHFS (antineoplastic agent)
Ifosfamide	1,2,3,4,5	10:00 Antineoplastic agents

Imatinib mesylate	1,3,4,5	10:00 Antineoplastic agents
Interferon alfa-2a	1,2,4,5	10:00 Antineoplastic agents
Interferon alfa-2b	1,2,4,5	10:00 Antineoplastic agents
Interferon alfa-n1	1,5	10:00 Antineoplastic agents
Interferon alfa-n3	1,5	10:00 Antineoplastic agents
Irinotecan HCl	1,2,3,4,5	10:00 Antineoplastic agents
Leflunomide	3,5	92:00 Unclassified therapeutic agents (antineoplastic agent)
Letrozole	1,5	10:00 Antineoplastic agents
Leuprolide acetate	1,2,5	10:00 Antineoplastic agents
Lomustine	1,2,3,4,5	10:00 Antineoplastic agents
Mechlorethamine	1,2,3,4,5	10:00 Antineoplastic agents
Megestrol	1,5	10:00 Antineoplastic agents
Melphalan	1,2,3,4,5	10:00 Antineoplastic agents
Menotropins	5	68:18 Gonadotropins
Mercaptopurine	1,2,3,4,5	10:00 Antineoplastic agents
Methotrexate	1,2,3,4,5	10:00 Antineoplastic agents
Methyltestosterone	5	68:08 Androgens
Mifepristone	5	76:00 Oxytocics
Mitomycin	1,2,3,4,5	10:00 Antineoplastic agents
Mitotane	1,4,5	10:00 Antineoplastic agents
Mitoxantrone HCl	1,2,3,4,5	10:00 Antineoplastic agents
Mycophenolate mofetil	1,3,5	92:00 Immunosuppressive agents
Nafarelin	5	68:18 Gonadotropins
Nilutamide	1,5	10:00 Antineoplastic agents
Oxaliplatin	1,3,4,5	10:00 Antineoplastic agents
Oxytocin	5	76:00 Oxytocics
Paclitaxel	1,2,3,4,5	10:00 Antineoplastic agents
Pegaspargase	1,2,3,4,5	10:00 Antineoplastic agents
Pentamidine isethionate	1,2,3,5	8:40 Miscellaneous anti-infectives
Pentostatin	1,2,3,4,5	10:00 Antineoplastic agents
Perphosphamide	3,5	Not in AHFS (antineoplastic agent)
Pipobroman	3,5	Not in AHFS (antineoplastic agent)
Piritrexim isethionate	3,5	Not in AHFS (antineoplastic agent)
Plicamycin	1,2,3,5	Not in AHFS (antineoplastic agent)
Podofilox	5	84:36 Miscellaneous skin and mucous membrane agents (mitotic inhibitor)
Podophyllum resin	5	84:36 Miscellaneous skin and mucous membrane agents (mitotic inhibitor)
Prednimustine	3,5	Not in AHFS (antineoplastic agent)
Procarbazine	1,2,3,4,5	10:00 Antineoplastic agents
Progesterone	5	68:32 Progestins
Progestins	5	68:12 Contraceptives
Raloxifene	5	68:16.12 Estrogen agonists-antagonists

Raltitrexed	5	Not in AHFS (antineoplastic agent)
Ribavirin	1,2,5	8:18 Antiviral
Streptozocin	1,2,3,4,5	10:00 Antineoplastic agents
Tacrolimus	1,5	92:00 Unclassified therapeutic agents (immunosuppressant)
Tamoxifen	1,2,5	10:00 Antineoplastic agents
Temozolomide	3,4,5	10:00 Antineoplastic agents
Teniposide	1,2,3,4,5	10:00 Antineoplastic agents
Testolactone	1,2,3,4,5	10:00 Antineoplastic agents
Testosterone	5	68:08 Androgens
Thalidomide	1,3,5	92:00 Unclassified therapeutic agents (immunomodulator)
Thioguanine	1,2,3,4,5	10:00 Antineoplastic agents
Thiotepa	1,2,3,4,5	10:00 Antineoplastic agents
Topotecan	1,2,3,4,5	10:00 Antineoplastic agents
Toremifene citrate	1,5	10:00 Antineoplastic agents
Tositumomab	3,5	Not in AHFS (antineoplastic agent)
Tretinoin	1,2,3,5	84:16 Cell stimulants and proliferants (retinoid)
Trifluridine	1,2,5	52:04.06 antivirals
Trimetrexate glucuronate	5	8:40 Miscellaneous anti-infectives (folate antagonist)
Triptorelin	5	10:00 Antineoplastic agents
Uracil mustard	3,5	Not in AHFS (antineoplastic agent)
Valganciclovir	1,3,5	8:18 Antiviral
Valrubicin	1,2,3,5	10:00 Antineoplastic agents
Vidarabine	1,2,5	52:04.06 Antivirals
Vinblastine sulfate	1,2,3,4,5	10:00 Antineoplastic agents
Vincristine sulfate	1,2,3,4,5	10:00 Antineoplastic agents
Vindesine	1,5	Not in AHFS (antineoplastic agent)
Vinorelbine tartrate	1,2,3,4,5	10:00 Antineoplastic agents
Zidovudine	1,2,5	8:18:08 Antiretroviral agents