DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH VA 22042

IN REPLY REFER TO
BUMEDINST 6570.3A CH-1
BUMED-M37
30 Nov 2018

BUMED INSTRUCTION 6570.3A CHANGE TRANSMITTAL 1

From: Chief, Bureau of Medicine and Surgery

Subj: SAFE HANDLING AND DISPOSAL OF OCCUPATIONALLY HAZARDOUS DRUGS AND ENVIRONMENTALLY HAZARDOUS DRUGS

Encl: (1) Revised page 3 and new page 3a

1. Purpose. This change transmittal revises the status of the instruction, indicating it is cleared for public release.

2. Action. Remove page 3 of the basic instruction and replace with enclosure (1) of this change transmittal.

3. Records Management

a. Records created as a result of this change transmittal, regardless of format or media, must be maintained and dispositioned for the standard subject identification codes (SSIC) 1000, 2000, and 4000 through 13000 series per the records disposition schedules located on the Department of the Navy/Assistant for Administration (DON/AA), Directives and Records Management Division (DRMD) portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx.

b. For questions concerning the management of records related to this change transmittal or the records disposition schedules, please contact your local records manager or the DON/AA DRMD program office.

C. FORREST FAISON III

Releasability and distribution:
This change transmittal is cleared for public release and is available electronically only via the Navy Medicine Web site, http://www.med.navy.mil/directives/Pages/BUMEDInstructions.aspx

7. Responsibilities. Commanding officers or officers in charge of any activity handling OHDs or generating waste containing EHDs must:

a. Appoint a pharmacist as the Hazardous Drugs Officer and establish a multi-disciplinary or joint hazardous drugs committee. The Committee will be chaired by the Hazardous Drugs Officer, and will consist of representatives from safety, industrial hygiene, occupational medicine, pharmacy, nursing, environmental management, and others, as appropriate. The committee will, in partnership with supervisors and appropriate specialists, develop an OHD safety and health plan as described in reference (a), section VI, chapter 2, paragraph V.A.2. This plan must be reviewed and its effectiveness evaluated at least annually and updated as necessary. A key element of this plan will be to perform and document multi-disciplinary risk assessments to determine who is enrolled in the OHD medical surveillance program, as noted in enclosure (5).

b. Identify a department, clinic, or location as the emergency treatment facility that will provide evaluation and care of workers with skin or eye exposures to OHDs immediately after initial flushing of the affected area(s).

c. Appoint a member of the pharmacy staff as the primary point of contact (POC) for the management of pharmaceutical waste. The pharmaceutical waste POC will have oversight for each area in which pharmaceutical waste is generated (e.g., pharmacies, treatment areas, etc.) and the responsibility to ensure written procedures are developed, implemented, and maintained. The pharmaceutical waste POC must receive the appropriate training, as delineated in enclosure (5), paragraph 11. The pharmaceutical waste POC must work with the facility EPM and host installation Hazardous Waste Manager (HWM) to ensure proper pharmaceutical waste management and disposal per enclosures (4) and (5).

8. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned for the standard subject identification codes (SSIC) 1000, 2000, and 4000 through 13000 series per the records disposition schedules located on the Department of the Navy/Assistant for Administration (DON/AA), Directives and Records Management Division (DRMD) portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx.

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact your local records manager or the DON/AA DRMD program office.

9. Review and Effective Date. Per OPNAVINST 5215.17A, Public Health Emergency Preparedness & Response (BUMED-M37) will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, Department of Defense, Secretary of the Navy, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim, and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.

/s/
C. FORREST FAISON III

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7700 ARLINGTON BOULEVARD
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IN REPLY REFER TO
BUMEDINST 6570.3A
BUMED-M3B7
22 Dec 2016

BUMED INSTRUCTION 6570.3A

From: Chief, Bureau of Medicine and Surgery

Subj: SAFE HANDLING AND DISPOSAL OF OCCUPATIONALLY HAZARDOUS DRUGS AND ENVIRONMENTALLY HAZARDOUS DRUGS

Ref: (a) through (t) see enclosure (1)

Encl: (1) References
(2) Acronyms
(3) Common Drugs Considered Occupationally Hazardous by the Occupational Safety and Health Administration
(4) Pharmaceutical Waste Management
(5) Procedures for Safe Handling and Disposal of Occupationally Hazardous Drugs and Environmentally Hazardous Drugs

1. Purpose. To provide policy and guidelines for Bureau of Medicine and Surgery (BUMED) activities in controlling occupational exposures to hazardous drugs, as defined by the American Society of Health-System Pharmacists and modified by the National Institute for Occupational Safety and Health (NIOSH), reference (a), Section VI, Chapter 2: https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html, and in managing ashore disposal of drugs including those classified as hazardous wastes per the Resource Conservation and Recovery Act (RCRA), other state and local regulation, or foreign government requirements (i.e., host nation). This instruction is not intended to guide afloat drug disposal which is governed by OPNAV P-45-113-3-99, Afloat Medical Waste Management Guide. This instruction incorporates the latest industry standards, regulatory guidance, and other updated documents, per references (a) through (t). Enclosure (1) is a list of references and enclosure (2) is a list of acronyms found within this instruction.

2. Cancellation. BUMEDINST 6570.3 and previous versions of the BUMED Pharmaceutical Waste Management Guidelines.

3. Scope. This instruction applies to settings where personnel may be exposed to occupationally hazardous drugs (OHDs) in the workplace, and to ashore settings where activities generate waste containing environmentally hazardous drugs (EHDs).

4. Background

a. Preparation, transportation, administration, and disposal of OHDs or certain EHDs may expose pharmacy personnel, nurses, physicians, and other health care workers or facility staff to potentially hazardous levels of these chemicals through acute and chronic workplace exposure. Routes of exposure include inhalation of dusts or aerosols, dermal absorption, ingestion, self-inoculation, and contact with excreta or body tissue from patients treated with these drugs.

b. OHDs are characterized by genotoxicity, carcinogenicity, teratogenicity, reproductive toxicity, or serious organ toxicity at low doses (reference (i): http://www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx). OHDs include new drugs with structure and toxicity profiles that mimic existing OHDs (reference (a)). Lists of OHDs have been compiled by OSHA, enclosure (3), and NIOSH, reference (l): http://www.cdc.gov/niosh /docs/2014-138/pdfs/2014-138.pdf; updated biennially at: http://www.cdc.gov/niosh/topics/ hazdrug/. These lists serve as references for organizations creating their own lists of OHDs (i.e., those OHDs to which workers at those work sites may be exposed). As explained herein, medical facilities must create local OHD lists, as determined by risk analysis of pharmaceuticals used; such lists may group OHDs into tiers based on risk.

c. Mitigating occupational risk requires a deliberate strategy to eliminate or minimize exposure to OHDs through a comprehensive program of administrative and engineering controls, use of personal protective equipment (PPE), and education and training of supervisors and employees. References (a) through (m) can assist in developing this program. Reference (k), the safe handling of hazardous drugs is located at: http://www.pharmacypracticenews.com/download/Safe_handling_ppnse12_WM.pdf.

d. A number of pharmaceuticals and formulations of pharmaceuticals are identified as pharmaceutical waste that is hazardous to the environment (i.e., EHDs), and their management and disposal are regulated by the Environmental Protection Agency (EPA), other state/local environmental agencies, or host nations. Examples of these EHDs are provided in enclosure (4). These drugs are classified as hazardous waste under the applicable regulations, and while they may or may not pose an occupational hazard to workers, they do have additional regulations regarding their management and disposal (references (n) through (p)). While there is overlap between referenced lists of OHDs and EHDs, there are many pharmaceuticals that fall only into one category.

5. Policy. It is BUMED policy to eliminate or, when elimination is not feasible, to minimize employee exposure to OHDs and to properly manage and transfer EHDs for hazardous waste disposal. Per best management recommendations from the EPA, BUMED also elects to manage all non-hazardous pharmaceutical waste in a manner to prevent it from entering sewers or landfills untreated.

6. Action. Activities handling OHDs or rendering health care to patients who may have been administered OHDs will implement a comprehensive program to eliminate or minimize employee exposure to OHDs per enclosure (5). Activities generating waste containing EHDs will implement a comprehensive program to appropriately manage disposal of EHDs per enclosures (4) and (5). Variations to this policy to allow for less stringent management practices for EHDs (e.g., longer accumulation times or variation to containers) based on site-specific requirements may be requested in writing from BUMED Headquarters Environmental Program Manager (EPM) via the chain of command.

7. Responsibilities. Commanding officers or officers in charge of any activity handling OHDs or generating waste containing EHDs must:

a. Appoint a pharmacist as the Hazardous Drugs Officer and establish a multi-disciplinary or joint hazardous drugs committee. The Committee will be chaired by the Hazardous Drugs Officer, and will consist of representatives from safety, industrial hygiene, occupational medicine, pharmacy, nursing, environmental management, and others, as appropriate. The committee will, in partnership with supervisors and appropriate specialists, develop an OHD safety and health plan as described in reference (a), section VI, chapter 2, paragraph V.A.2. This plan must be reviewed and its effectiveness evaluated at least annually and updated as necessary. A key element of this plan will be to perform and document multi-disciplinary risk assessments to determine who is enrolled in the OHD medical surveillance program, as noted in enclosure (5).

b. Identify a department, clinic, or location as the emergency treatment facility that will provide evaluation and care of workers with skin or eye exposures to OHDs immediately after initial flushing of the affected area(s).

c. Appoint a member of the pharmacy staff as the primary point of contact (POC) for the management of pharmaceutical waste. The pharmaceutical waste POC will have oversight for each area in which pharmaceutical waste is generated (e.g., pharmacies, treatment areas, etc.) and the responsibility to ensure written procedures are developed, implemented, and maintained. The pharmaceutical waste POC must receive the appropriate training, as delineated in enclosure (5), paragraph 11. The pharmaceutical waste POC must work with the facility EPM and host installation Hazardous Waste Manager (HWM) to ensure proper pharmaceutical waste management and disposal per enclosures (4) and (5).

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/s/
C. FORREST FAISON III

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REFERENCES

(a) OSHA Technical Manual
(b) 29 CFR 1910.133
(c) DoD Instruction 6050.05 of 15 August 2006
(d) International Safety Equipment Association Z358.1-2014, Emergency Eyewash and Shower Equipment
(e) NMCPHC-TM OM 6260, Medical Surveillance Procedures Manual and Medical Matrix, July 2011
(f) OPNAVINST 5100.23G
(g) OPNAVINST 6000.1C
(h) NMCPHC-TM-OEM 6260.01C, Reproductive and Developmental Hazards: A Guide for Occupational Health Professionals, April 2010
(i) American Society of Health-System Pharmacists Guidelines on Handling Hazardous Drugs, 2004
(j) NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings, DHHS, 2004
(k) Safe Handling of Hazardous Drugs: Reviewing Standards for Worker Protection, Power LA, Polovich M, Pharmacy Practice News, 2012
(l) NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014
(m) U.S. Pharmacopeial Convention General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings
(n) 40 CFR 260-273
(o) OPNAV M-5090.1 of January 2014
(p) DoD Instruction 4715.05 of 1 November 2013
(q) 21 CFR 1300, 1301, 1304, 1305, 1307, and 1317
(r) U.S. Department of Justice, Drug Enforcement Administration, Letter to Practitioners, 17 October 2014
(s) BUMEDINST 6220.14
(t) 29 CFR 1910.1030

ACRONYMS

BSC	Biological Safety Cabinet
BUMED	Bureau of Medicine and Surgery
CACI	Compounding Aseptic Containment Isolator
DEA	Drug Enforcement Administration
DLA-TS	Defense Logistics Agency - Troop Support
DOT	Department of Transportation
EHD	Environmentally Hazardous Drugs
EPA	Environmental Protection Agency
EPM	Environmental Program Manager
HEPA	High Efficiency Particulate Air
HWM	Hazardous Waste Manager
IV	Intravenous
MTF	Medical Treatment Facility
NIOSH	National Institute for Occupational Safety and Health
OHD	Occupationally Hazardous Drugs
OSHA	Occupational Safety and Health Administration
POC	Point of Contact
PPE	Personal Protective Equipment
RCRA	Resource Conservation and Recovery Act
SAA	Satellite Accumulation Area
SDS	Safety Data Sheet
SOP	Standard Operating Procedure

COMMON DRUGS CONSIDERED OCCUPATIONALLY HAZARDOUS BY THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

This list is not all-inclusive, should not be construed as complete, and represents an assessment of some, but not all, marketed drugs at this time. See also NIOSH lists, references (j): http://www. cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf and (l).

ALTRETAMINE
AMINOGLUTETHIMIDE
AZATHIOPRINE
BLEOMYCIN
BUSULFAN
CARBOPLATIN
CARMUSTINE
CHLORAMBUCIL
CHLORAMPHENICOL
CHLOROTIANISENE
CHLOROZOTOCIN
CISPLATIN
CYCLOSPORIN
CYCLOPHOSPHAMIDE
CYTARABINE
DACARBAZINE
DACTINOMYCIN
DAUNORUBICIN
DIETHYLSTILBESTROL
DOXORUBICIN
ESTRADIOL
ESTRAMUSTINE
ETHINYL ESTRADIOL
ETOPOSIDE
FLOXURIDINE
FLUOROURACIL
FLUTAMIDE
GANCICLOVIR
HYDROXYUREA
IDARUBICIN
IFOSFAMIDE
INTERFERON-A
ISOTRETINOIN
L-ASPARAGINASE
LEUPROLIDE
LEVAMISOLE
LOMUSTINE
MECHLORETHAMINE
MEDROXYPROGESTERONE
MEGESTROL
MELPHALAN
MERCAPTOPURINE
METHOTREXATE
MITOMYCIN
MITOTANE
MITOXANTRONE
NAFARELIN
PIPOBROMAN
PLICAMYCIN
PROCARBAZINE
RIBAVIRIN
STREPTOZOCIN
TAMOXIFEN
TESTOLACTONE
THIOGUANINE
THIOTEPA
URACIL MUSTARD
VIDARABINE
VINBLASTINE
VINCRISTINE
ZIDOVUDINE (AZT)

PHARMACEUTICAL WASTE MANAGEMENT

1. Background. Some pharmaceuticals and pharmaceutical metabolites meet the definition of hazardous waste. The EPA and other regulatory agencies, both in the United States and overseas, address the management of wastes from pharmacies. Surveyors for the Joint Commission include pharmaceutical waste management in their surveys. Because of the risks associated with the improper disposal of both regulated and non-regulated pharmaceutical waste, a program to properly manage and dispose of these wastes is required.

2. Purpose. These guidelines supplement the safe handling and disposal procedures in enclosure (5) by providing detailed information for the pharmaceutical waste POC and the facility EPM or host installation HWM regarding the pharmaceutical waste management program. Much of the information contained herein, including the requirement to make waste determinations, is required by Federal, state, local, host nation, or Department of Defense environmental regulations. The intent of the information provided is to assist facilities in implementing a strategy for compliance. These are minimum requirements; states or other localities (e.g., host nations) may have other standards that must be met in addition to or in lieu of these standards. Variations to this policy to allow for less stringent management practices for EHDs (e.g., longer accumulation times or variation to containers) based on site-specific requirements may be requested in writing from BUMED Headquarters EPM via the chain of command.

3. Scope and Classifications. There are five categories of pharmaceutical waste that require management as part of a pharmaceutical waste management program:

a. Non-regulated pharmaceutical waste: pharmaceuticals that must be wasted out, but that are not classified as hazardous waste or chemotherapy waste (i.e., not classified in paragraphs 3b through 3c of enclosure (4)).

b. Non-chemotherapy hazardous pharmaceutical waste (also commonly known as "RCRA waste"): listed or characteristic hazardous wastes, not including antineoplastics.

c. Trace chemotherapy (antineoplastic) waste: empty (less than 3 percent of the original full volume) containers or equipment used in the preparation or delivery of antineoplastics.

d. Bulk chemotherapy (antineoplastic) waste: full or partially full (greater than or equal to 3 percent of the original full volume) containers or equipment used in the preparation or delivery of antineoplastics. This may also contain PPE (e.g., gowns or gloves) used during the handling of these medications that are too bulky for management as trace chemotherapy waste.

e. Dual waste: a mixture of both hazardous pharmaceutical waste and medical waste.

4. Pharmaceutical Waste Determinations. Per reference (n) and/or applicable site-specific waste regulations, the facility must be able to demonstrate to a regulator or other inspector that waste determinations have been made for each pharmaceutical that is stocked. It is strongly recommended that the individual tasked with making formulary-based waste management determinations use suitable software (capable of creating a table, spreadsheet, or database) into which he or she can insert and manipulate associated data and notes. The following guidelines in this section are based on this recommendation. If other tracking methods are used, the strategy for making and periodically reviewing these waste determinations must be documented to demonstrate environmental compliance to a regulator or inspector.

a. Create a table or spreadsheet with the following headers:

(1) National drug code

(2) Brand name

(3) Generic name

(4) Manufacturer

(5) Strength

(6) Dosage form

(7) Package size

(8) Antineoplastic (yes/no)

(9) Hazardous waste code (Federal/state/local/host nation)

(10) Non-regulated pharmaceutical (yes/no)

b. Obtain the complete pharmacy formulary. If no formulary is available, one option may be to request a one-year purchase history. Items (1) through (7) of paragraph 4.a, above, should be readily obtainable from the formulary or purchase history.

c. Enter each formulary item into the spreadsheet and make the appropriate determinations for items (8) through (10) of paragraph 4.a, above. Keep in mind that the hazardous waste code may be a Federal, state, local, or overseas waste code depending on location and site-specific regulations. Pharmaceuticals to consider when making the determinations for items (8) through (10) include, but are not limited to:

(1) Common P-listed pharmaceuticals (identified as acutely hazardous wastes, per reference (n)), including empty containers and packaging, which must be considered for management as hazardous waste:

(a) P042 – Epinephrine

(b) P075 – Nicotine and salts

(c) P081 – Nitroglycerin

(d) P204 – Physostigmine

(e) P188 – Physostigmine salicylate

(f) P001 – Warfarin and salts, when present at concentrations greater than 0.3%

(g) P012 – Arsenic trioxide

(2) Common U-listed pharmaceuticals (identified as toxic wastes, per reference (n)) that must be considered for management as hazardous waste:

(a) U034 – Chloral (as the hydrate)

(b) U035 – Chlorambucil

(c) U058 – Cyclophosphamide

(d) U059 – Daunomycin

(e) U075 – Dichlorodifluoromethane

(f) U089 – Diethylstilbestrol

(g) U129 – Lindane

(h) U150 – Melphalan

(i) U151 – Mercury

(j) U010 – Mitomycin C

(k) U200 – Reserpine

(l) U201 – Resorcinol

(m) U205 – Selenium sulfide

(n) U206 – Streptozotocin

(o) U121 – Trichloromonofluoromethane

(p) U248 – Warfarin and salts, when present at concentrations of 0.3% or less

(3) Common pharmaceuticals that may be classified as characteristic hazardous wastes, as defined in reference (n), include:

(a) Lantus

(b) Humalog

(c) Humulin N

(d) Humulin R

(e) Centrum Silver

(f) Flovent

(g) Taxol

(h) Atrovent

(i) Zinc shampoo

(j) Selenium

(k) Collodion

d. States and other regulatory entities (e.g., host nations) may have additional pharmaceuticals defined as hazardous wastes that must be considered in the pharmaceutical waste management program.

e. Whenever a new drug or material is received for use in the pharmacy, a waste determination must be made.

f. The determination spreadsheet should be reviewed at least annually for accuracy and to confirm appropriate waste disposal procedures, typically in conjunction with the annual formulary review.

5. Hazardous Waste Profiles

a. Any pharmaceutical waste requiring management as hazardous waste (e.g., non-chemotherapy hazardous pharmaceutical waste or bulk chemotherapy waste) must be profiled for proper disposal. This responsibility will fall to either the facility EPM or the host installation HWM, depending on the party responsible for the disposal of hazardous wastes (see below).

b. In locations where the host installation retains responsibility for the disposal of hazardous wastes, the generation of hazardous waste profiles shall be performed by or coordinated with the host installation HWM, and the facility EPM must notify the host installation HWM of any changes to the waste determinations that will impact the hazardous waste profiles.

c. In locations where the facility EPM has the responsibility to generate hazardous waste profiles, the EPM must do so based on the information obtained from the waste determination process and must retain updated copies of the hazardous waste profiles.

6. Informing the Staff Who Handle EHDs. Health care staff who handle EHDs must be made aware of the proper mechanisms by which to dispose of their pharmaceutical wastes. These staff must be trained at the time of assignment and annually thereafter, and this training must be documented. In addition to the management and disposal requirements of this instruction, other best management practices may be employed to further streamline the process for the user. Recommended practices include:

a. Place labels/stickers on the pharmacy shelves to identify the disposal mechanism for pharmaceuticals. One option to identify pharmaceuticals requiring special management and disposal requirements would be to place a specific color label on the shelf (e.g., black for non-chemotherapy hazardous waste and yellow for chemotherapy waste). The shelves for all other pharmaceuticals would have no labels as an indication that they are permissible in the non-regulated pharmaceutical waste container.

b. For medications issued from the pharmacy to another treatment space, place labels/stickers on the issued product to provide an indication regarding the appropriate disposal of that pharmaceutical, if wasted. This will minimize the likelihood that medication will be wasted to a sink or to the general trash.

c. Develop a system for labeling all compounded items and intravenous mixtures that require special management and disposal.

7. Container Selection and Management

a. The color-coding system established in this instruction has been designed to standardize the management of the various categories of pharmaceutical waste and is required at all Navy pharmacy locations. This color-coding system is modeled after current industry practice, and appropriate containers are readily available through various supply chains.

(1) Blue or white: non-regulated pharmaceutical waste for incineration (defined in paragraph 3.a.)

(2) Black: non-chemotherapy hazardous pharmaceutical waste (defined in paragraph 3.b.)

(3) Yellow: chemotherapy (antineoplastic) waste, both trace and bulk (defined in paragraphs 3.c. and 3.d., respectively)

b. Containers must meet applicable regulatory standards (EPA, Department of Transportation (DOT), host nation, etc.) for the collection and transport of the waste being containerized.

c. Containers must be properly labeled per requirements of this instruction and other applicable regulatory standards (EPA, DOT, OSHA, host nation, state, etc.). Labels must be readily visible to workers in the area.

d. Some locations may elect to more stringently manage all of their non-chemotherapy pharmaceutical waste as hazardous waste (black containers). In these cases, the pharmaceutical waste POC and the EPM must document this decision, including the rationale for cost-benefit considerations, in the site-specific pharmaceutical waste standard operating procedure (SOP).

e. Some locations will be subject to site-specific requirements that will not allow for the use of this color-coding system. In such cases, the facility EPM must coordinate with their regional EPM to request a policy waiver from the BUMED Headquarters EPM. This request must include the regulatory driver and a description of the alternative strategy to be employed. The BUMED Headquarters EPM will provide written response and the approved strategy must be documented in the site-specific pharmaceutical waste SOP.

8. Accumulation Points

a. Accumulation points must be established for the collection of pharmaceutical waste. These points must be at or near the point of generation and under the control of the user.

b. If pharmaceutical waste is generated in other locations throughout the facility, determine the need for additional waste accumulation points at these other locations (e.g., treatment areas).

c. Satellite Accumulation Areas (SAA) for hazardous waste may not exceed a total collection capacity of 55 gallons. For acutely hazardous waste (e.g., P-listed hazardous waste), the total collection capacity may not exceed one quart. Segregation of incompatible wastes must be considered when determining the number and capacity of collection containers provided for hazardous waste management in the SAA. There are no Federal volume restrictions for

non-hazardous pharmaceutical waste; however, consideration should be given to state and local regulations, the ease of management, and accumulation time restrictions in selection of container size.

d. It is recommended that as few points as possible be established within the pharmacy to facilitate management of the areas and to minimize worker exposure.

e. It is BUMED policy to ensure that all pharmaceutical wastes are removed from the site within 1 year of becoming a waste. To achieve this requirement, when a container in the accumulation point becomes approximately three-quarters (75 percent) full or when the container has been in use for 9 months, the pharmaceutical waste POC must remove the container from service, provide a "closed" date, properly label the container for storage and shipment, and process it for appropriate disposal per internal and host installation processes.

9. Inspections

a. While there is no Federal requirement for periodic inspections of the pharmaceutical waste containers and documentation in SAAs, the collection of these wastes may present a significant risk of noncompliance to the facility. As such, the facility EPM and pharmaceutical waste POC should consider implementation of an inspection program for pharmaceutical waste SAAs as described below. Consideration should also be given to more stringent site-specific requirements for inspections (e.g., state or local regulation).

b. If implemented, the inspections should be documented and include, at a minimum:

(1) Condition of the containers

(2) Appropriate placement of pharmaceutical waste containers throughout the facility

(3) Proper segregation of the wastes

(4) Proper container labeling

(5) Dates on container within the required timeline for accumulation and removal

(6) Appropriate completion and maintenance of log sheets

(7) Initial and refresher training of personnel

10. Disposal of Controlled Substances

a. Requirements for the disposal of controlled pharmaceuticals are delineated in reference (q). Per that reference, the U.S. Drug Enforcement Administration (DEA) requires that controlled substances in schedules II through V that are categorized and treated as "pharmaceutical wastage" at a health care facility be destroyed per Federal, state, tribal, and local laws and regulations. The process must be witnessed and documented by two health care professionals.

b. Disposal of controlled substances that have been dispensed to a patient, partially administered, or otherwise wasted at the point of patient care, through flushing into the sewer system or through discarding into the landfill are no longer acceptable to the DEA, and are not environmentally sound disposal methods. The DEA requires these controlled substances be disposed of so they are non-retrievable; however, current DEA guidance allows for these residues to be placed into a pharmaceutical waste container. The DEA clarified, in a letter to practitioners, reference (r): http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf, that once a medication has been dispensed to a patient in the institutional setting, pursuant to an order for immediate administration, the medication is considered decremented from inventory. Thus, any unused portion of these dosage forms (e.g., partial quantity remaining in prefilled syringes, half tablets, etc.) does not require disposal as directed by Title 21 CFR part 1317. In this manner, the DEA advises that remaining substances be destroyed per Federal, state, tribal and local laws and regulations. Disposal of controlled substances in the institutional setting pursuant to an order for immediate patient administration will require documentation and witnessing by two authorized health care professionals and must be disposed of per Federal, state, tribal, and local laws and regulations. The DEA also strongly encourages all institutions and practitioners to continue to implement and adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted.

c. The disposal of unwanted, unused, or unusable controlled substances (inventory/stock) may be transferred to a DEA-registered reverse distributor who is authorized to accept the items for the purpose of destruction. This is considered a transfer between DEA registrants as defined in reference (q), and all required paperwork and inventory requirements must be followed. Medical treatment facilities (MTF) are strongly encouraged to consult local EPA officials for exact determination of medications that are considered "viable pharmaceuticals" eligible for credit return status by the reverse distributor versus medications that are deemed waste and not eligible for credit return. Loose pills that must be disposed of, but have not been dispensed, including those that fall on the floor or are spilled in robotics, must be treated as a loss of inventory. Mandatory reporting and recordkeeping requirements are delineated in reference (q).

d. In the event that no disposal options are made available to the facility due to conflicting regulation, the local DEA field office should be contacted for guidance on disposal.

PROCEDURES FOR SAFE HANDLING AND DISPOSAL OF OCCUPATIONALLY HAZARDOUS DRUGS AND ENVIRONMENTALLY HAZARDOUS DRUGS

1. Safety Data Sheets (SDS). Per requirements in references (a) and (c), SDSs for certain OHDs used at the activity must be maintained and readily accessible to employees. This includes those OHDs that are not in solid, final form, such as liquids or powders, or drugs that are in solid final form (e.g., tablets) but may be manipulated (i.e., crushed) prior to administration. Each area where OHDs are stored, prepared, or administered will maintain the appropriate SDS(s). A listing of the OHDs present at the facility must be included on the command's authorized use list or in the pharmacy formulary.

2. OHD Preparation Precautions

a. OHD preparation must be performed in an area with access limited to authorized personnel only. OHDs may contaminate surfaces in preparation areas. Eating, drinking, smoking, chewing gum, taking or administering medications, applying cosmetics, and storing food in the preparation area must be prohibited. Procedures for spills and emergencies must be posted in the preparation area. Appropriate personal protective equipment (PPE) must be worn during preparation (see paragraph 5, below) per reference (m) and a risk assessment performed by the Hazardous Drugs Committee.

b. Only Class II, Type B, or Class III Biological Safety Cabinets (BSC) that meet the current National Sanitation Foundation Standard, or negative pressure Compounding Aseptic Containment Isolators (CACI) that meet International Standards Organization 14644 Class 5, Air Quality Standards, must be designated for preparation of OHDs. Internal and external exhausts for the hoods must have high efficiency particulate air (HEPA) filters. Pharmacies that compound one or fewer OHD per day on average may use a negative pressure CACI that is not externally vented only if a secondary engineering control such as a closed system transfer device is used in addition to the hood for compounding. All OHDs other than commercially available oral dosage forms must be prepared in designated hoods. When possible, a BSC should be dedicated for use with OHDs only. Refer to paragraph 2.g. in this enclosure for guidance in preparation of commercially available oral OHD products. The interior of isolators and their contents (e.g., infusion bags and syringes) are readily contaminated by aerosols and spills, and are a potential secondary source of exposure to pharmacy personnel, nurses and cleaning staff. Appropriate care must be taken to avoid exposures from these routes.

c. The exhaust fan or blower on the hood must be on at all times, except when the hood is being mechanically repaired or moved. If the blower is turned off, the hood must be decontaminated before reuse. Any time the cabinet is turned off or transported, it should be sealed with plastic. Each hood must be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance. The outside exhaust of these hoods must be vented away from air intake units. Backup (emergency) electrical power must be available and automatically engaged when needed.

d. The cabinet must be cleaned/decontaminated as frequently as the manufacturer's instructions recommend, but at least weekly, as well as whenever spills occur or when the cabinet requires moving, service, or certification. Decontamination must consist of surface cleaning with water and detergent followed by thorough rinsing. Do not use spray cleaners or germicidal fumigants. During the cleaning, the worker must wear appropriate PPE per reference (m) and a risk assessment performed by the Hazardous Drugs Committee. Ideally, the sash on BSCs should remain down during cleaning. A NIOSH-approved respirator and gown appropriate for the hazard must be worn by the worker if the sash will be lifted at any time during the process. Cleaning will proceed from least to most contaminated area. The drain spillage trough area should be cleaned at least twice since it can be heavily contaminated. All materials from the decontamination process must be handled as hazardous waste, and disposed of per applicable regulations as coordinated with the facility EPM or the host installation HWM.

e. Hoods that are being used must be serviced and certified by a qualified technician at the frequency recommended by the manufacturer, but not less frequently than every 6 months or any time the cabinet is moved or repaired. HEPA filters must be changed when air flow is restricted (as indicated by the continuous monitor), or when the filters are contaminated by an accidental spill, or according to the manufacturer's instructions, whichever is sooner. Used filters must be disposed of appropriately.

f. All contaminated needles, syringes, and intravenous (IV) tubing used to prepare OHDs will be disposed of intact. Clipping, crushing, or recapping is prohibited. Priming IV sets or expelling air from syringes must be carried out in the designated hood. If done at the administration site, the line will be primed with a non-drug containing solution, or a back-flow closed system must be used. Filter needles are recommended to prevent the aerosolization of OHDs during the preparation process. IV containers with venting tubes should not be used.

g. Handling of OHD tablets and other final dosage forms must follow the guidance provided in reference (m), which is located at: http://www.usp.org.

3. Transportation and Storage

a. In addition to standard pharmacy labeling practices, all syringes and IV bags containing OHDs must be labeled with a distinctive warning label identifying it as an OHD.

b. Access to areas where OHDs are stored must be limited to authorized personnel with signs restricting entry. A list of drugs covered by OHD policies and information on spill and emergency contact procedures must be posted or easily available to staff. Storage should be per reference (m). If not present from the manufacturer, warning labels will be applied to all OHD containers identifying that they contain OHDs.

c. Transport must occur in sealed plastic bags and in containers to avoid breakage. Personnel involved with transporting OHDs and/or EHDs will be trained in spill procedures (see paragraph 9 of this enclosure).

4. Drug Administration. Only appropriately qualified/certified personnel will administer OHDs.

a. Personnel administering OHDs must wear appropriate PPE, per reference (m) and a risk assessment performed by the Hazardous Drugs Committee. Preparation for administration of OHDs on the ward or clinic will be carried out on trays lined with a plastic-backed absorbent pad (e.g., Chux®) so the plastic can be gathered as waste for appropriate disposal at the end of the procedure.

b. Contaminated needles, syringes, and IV tubing will be disposed of intact. Clipping, crushing, or recapping is prohibited. Only when a procedure specifically requires recapping will the one-handed method be used.

c. The administration of aerosolized OHDs requires special engineering controls and PPE to prevent exposure to health care workers and others in the vicinity. PPE should be per reference (m) and a risk assessment by the Hazardous Drugs Committee.

5. PPE

a. The PPE required to safely handle each OHD in each process will be determined by both reference (m) and a risk assessment performed by the Hazardous Drugs Committee. The Committee should consider information from the Industrial Hygiene survey in its risk assessment.

b. Gloves. The type of material used in gloves for handling OHDs is important. Gloves must be powder free because powder can contaminate the work area and adsorb and retain OHDs. Gloves specifically made for handling hazardous drugs must be used (e.g., Chemobloc® gloves) and must conform to the American Society for Testing and Materials standard D6978 (or its successor). Certain activities may require double gloving, based on the risk of exposure, per reference (m) and a risk assessment by the Hazardous Drugs Committee. Because all gloves are permeable to some extent and their permeability increases with time, they must be changed every 30 minutes or immediately if they are torn, punctured, or contaminated with a spill. Hands must be washed with soap and water before gloves are put on and after they are removed.

c. Gowns. Gowns must be selected and worn based on the OHDs being handled. Guidance on gown selection is found in reference (m). A protective disposable gown made of polyethylene-coated polypropylene or other laminate material with a closed front, long sleeves, and elastic or knit-closed cuffs will be worn. The cuffs will be tucked under the gloves unless

double gloving is specified. If double gloves are worn, the outer glove will be worn over the gown cuff and the inner glove under the gown cuff. Gowns and gloves used in the preparation area will not be worn outside the OHD preparation area.

d. Chemical Goggles and Face Shields. Whenever splashes, sprays, or aerosols of OHDs may be generated, chemical-barrier face and eye protection will be used per reference (b). Eyewash facilities meeting reference (d) requirements must also be available.

e. Respirator. Personnel administering aerosolized OHDs must wear a NIOSH-approved respirator appropriate for each OHD as determined by the Industrial Hygienist. Treatment areas should be designed to protect health care workers administering such drugs. Personnel required to wear a respirator must be enrolled in the Respirator User Certification Exam Program (Matrix Program 716, reference (e): http://go.usa.gov/366dd).

6. Caring for Patients Receiving OHDs. Per references (s) and (t), appropriate precautions must be observed to prevent contact with blood or other potentially infectious materials.

a. Personnel dealing with any blood, body fluids, urine, or excreta from patients who have received OHDs within the last 48 hours must wear appropriate PPE, per reference (m) and a risk assessment by the Hazardous Drugs Committee. Hands must be thoroughly washed after removal of PPE or after contact with the above substances.

b. Linen contaminated with OHDs, urine, or excreta from patients who have received OHDs within the last 48 hours must be placed in specially marked impervious plastic laundry bags. Linen soiled with blood or other potentially infectious materials as well as contaminated with urine or excreta must also be managed per reference (s).

c. Reusable items such as glassware must be washed twice by trained employees using appropriate PPE, per reference (m) and a risk assessment by the Hazardous Drugs Committee.

7. Medical Surveillance

a. Those personnel with potential exposure to OHDs will be considered for placement in the medical surveillance program per reference (a), section VI, based on the recommendations of the Hazardous Drugs Committee using a multi-disciplinary risk assessment process. Required elements of OSHA, reference (a), and other pertinent regulations and guidance are contained in the Hazardous Drugs Medical Surveillance Program (Matrix Program 110) of reference (e). Selection of individuals for medical surveillance must be based on exposure assessment performed by Industrial Hygiene (ashore) or the medical department representative (shipboard), worksite visits, and a deliberate and collaborative risk assessment process performed by the Hazardous Drugs Committee.

(1) All personnel who directly handle OHDs, including nurses, pharmacists, and pharmacy technicians, must be considered for enrollment in medical surveillance. Enrollment

decisions will be based on the results of a multidisciplinary risk assessment by the Hazardous Drugs Committee. Handling OHDs may include preparing, dispensing, and administering oral medications, IV solutions, or nebulized treatments, or similar activities.

(2) In addition, other workers (e.g., nurses' aides, laundry workers, shipping and receiving personnel, housekeeping personnel) who may come directly into contact with hazardous agents or with patient wastes within 48 hours after a patient has received a hazardous drug should be considered for inclusion in a medical surveillance program, based on documented risk assessment.

(3) Medical surveillance consists of pre-placement, periodic, and termination examinations per reference (e). An attempt should be made to minimize the number of personnel who work with these agents.

b. In situations involving pregnant or breastfeeding personnel, references (e) through (h) should be consulted for guidance. Reproductive health issues must be incorporated into the hazard communication training for personnel with potential exposure to OHDs.

(1) Pregnant or breastfeeding women must be informed of the hazards that OHDs may pose to the health of their children. Staff members who are pregnant, actively trying to conceive, or breastfeeding will be offered a transfer to duties that do not involve preparation or administration of OHDs, if such a position is available. Military members who are pregnant or breastfeeding will be transferred to duties not involving exposure to OHDs, as long as mission readiness is not impaired. Civilians will be informed of the risks of exposure to OHDs, but cannot be required to be transferred.

(2) The hazards of occupational exposure to antineoplastic agents were addressed by the National Study Commission on Cytotoxic Exposure, as noted in reference (h): http://www.med.navy.mil/sites/nmcphc/Documents/oem/Repro2010d2.pdf. The following are excerpts from the Commission's statement on the handling of cytotoxic agents by women who are attempting to conceive, are pregnant, or are breastfeeding:

> "There are substantial data regarding the mutagenic, teratogenic and abortifacient properties of certain cytotoxic agents both in animals and humans who have received therapeutic doses of these agents. Additionally, the scientific literature suggests a possible association of occupational exposure to certain cytotoxic agents during the first trimester of pregnancy with fetal loss or malformation. These data suggest the need for caution when women who are pregnant or attempting to conceive, handle cytotoxic agents. …it is prudent that women who are breastfeeding should exercise caution in handling cytotoxic agents…. Personnel should be provided with information to make an individual decision. This information should be provided in written form and it is advisable that a statement of understanding be signed…. It is essential to refer to individual state right-to-know laws to ensure compliance."

8. Post Exposure Actions

a. In case of skin contact with OHDs, follow the manufacturer's instructions per the SDS. This generally involves immediately removing contaminated clothing, flushing the affected area with water, and washing the area with soap or other inactivator as specified by the manufacturer.

b. In case of eye contact with OHDs, flush with water for a minimum of 15 minutes using equipment that meets reference (d) standards. Continue irrigation until ophthalmologic examination is obtained.

c. Report to the emergency treatment facility for additional treatment and documentation of the exposure. Particular attention to the eyes, buccal (mouth) and nasal mucous membranes, and the skin will be included in the physical examination for acute exposures.

d. Workers who do not routinely work with OHDs (i.e., who are not enrolled in Hazardous Drugs Medical Surveillance) that have had a situational exposure to OHDs should be evaluated and followed on an individual basis. Although the treating physician may elect to incorporate all elements of Hazardous Drugs Medical Surveillance in the evaluation of workers who have had such a situational exposure, enrollment in Hazardous Drugs Medical Surveillance should be reserved for workers who handle or may be exposed to OHDs, and have undergone risk assessment by the Hazardous Drugs Committee.

9. Spill Control

a. A spill clean-up kit, clearly labeled, will be kept in each area where OHDs are prepared, administered, or accumulated for disposal or transport. When transporting OHDs or patients under active treatment with OHDs, activities must maintain a spill kit on the vehicle or cart for immediate access. See reference (a), section VI, chapter 2, paragraph V.C.5.e. for guidance on assembling spill kits.

b. Clean-up of spills. The American Society of Health-System Pharmacists considers small spills to be those less than 5 ml. The 5 ml threshold should be used to categorize spills as large or small. Small spills, large spills, and spills in BSCs must be cleaned following reference (a), section VI, chapter 2, paragraphs V.C.5.b-d. Trained personnel (trained in both spill cleanup and handling of OHDs) wearing appropriate PPE, per reference (m) and the risk assessment by the Hazardous Drugs Committee, should clean up small spills.

c. When a large spill occurs, the area should be isolated and aerosol generation avoided. The clean-up personnel should wear appropriate PPE, as noted above, including a NIOSH-approved respirator if there is any suspicion of airborne powder or that an aerosol has been or will be generated. The cleanup personnel must be trained to clean up large spills. The training must include both spill cleanup and handling of OHDs. Large spills must be immediately reported to the safety officer.

d. Disposal of materials used during spill clean-up of any size must be coordinated with the facility EPM or the host installation HWM to ensure compliance with applicable regulations and policies.

10. Waste Management and Disposal Procedures

a. The following procedures target appropriate management of pharmaceutical waste. Supplemental guidelines and requirements intended for the pharmaceutical waste POC and the facility EPM or host installation HWM are contained in enclosure (4).

b. These are minimum requirements for the management and disposal of pharmaceutical waste. States and other localities (e.g., host nations) may have other standards that must be met in addition to or in lieu of these standards.

c. MTFs are eligible to participate in the reverse distribution program for unused or expired pharmaceuticals, to the extent that Federal, state, local, or host nation regulations allow. The reverse distribution contract is centrally managed and funded by Defense Logistics Agency - Troop Support (DLA-TS) Medical Supply Chain. MTFs will manage medications that are expired or near expiration according to the DLA-TS managed reverse distribution contract. In general, the reverse distribution contractor will collect the medications from the MTF and ship the items to their central facility for credit return processing and disposition. MTFs will maintain all applicable environmental and security controls on these medications until the reverse distribution contractor assumes possession of the material.

d. The pharmaceutical waste POC must, in conjunction with appropriate pharmacy staff (knowledgeable about the pharmacology of the drugs on the formulary), review the pharmaceutical formulary at least once per year to validate or determine the proper disposal of each product. Whenever the pharmacy acquires a new medication, the pharmaceutical waste POC must review the drug to determine the proper disposal mechanism. Assistance may be required from the facility EPM or the host installation HWM. Examples of hazardous drugs and drugs that are classified as hazardous waste are identified in enclosures (3) and (4); however, these are general lists and may not be comprehensive.

e. A site-specific SOP must be developed by the pharmaceutical waste POC, in conjunction with the pharmacy staff and facility EPM, to document the proper management of all pharmaceutical wastes. If there are multiple points of generation for pharmaceutical wastes (e.g., pharmacy, emergency room, operating room, or other treatment areas), the requirements for each location must be addressed in an SOP.

f. Non-regulated pharmaceutical waste (see waste category classifications in enclosure (4))

(1) The pharmaceutical waste POC must work with the facility EPM to establish a collection point for non-regulated pharmaceutical waste. These wastes include pharmaceuticals that must be wasted out, but are not classified as hazardous waste or chemotherapy waste. No pharmaceuticals should ever be placed in the regular trash.

(2) The collection of these medications must be in a rigid blue or white sharps-like container. This container must be labeled as "non-regulated pharmaceutical waste" and must be marked "for incineration only." It must also be labeled as "open" with the date on which the container was put into use. The lids must be closed except when actively in use.

(3) The users generating the non-regulated pharmaceutical waste must be trained by the pharmaceutical waste POC or the facility EPM regarding the proper management of these wastes. This training must include the appropriate segregation of the wastes.

(4) When the container becomes approximately three-quarters (75 percent) full or when the container has been in use for 9 months, the pharmaceutical waste POC must remove the container from service, label it as "closed" with the date the container was taken out of service, properly secure and label it for disposal, and process it for proper disposal as non-regulated waste. Some locations have more stringent regulations for the time that a waste container may be in-use at an accumulation point. The pharmaceutical waste POC must work with the EPM or host installation HWM to determine if more stringent requirements apply.

g. Non-chemotherapy hazardous pharmaceutical waste

(1) The pharmaceutical waste POC must work with the EPM or the host installation HWM to establish a Satellite Accumulation Area (SAA) for the non-chemotherapy hazardous pharmaceutical wastes, allowing for appropriate segregation. These SAAs must adhere to the storage capacity restrictions of reference (n), and multiple SAAs may be needed for multiple points of generation throughout the facility.

(2) Rigid black sharps-like containers will be used to collect the non-chemotherapy hazardous pharmaceutical wastes. The pharmaceutical waste POC must work with the EPM or the host installation HWM to clearly designate each container regarding which waste type(s) can be accumulated in each (e.g., P-list/toxic, U-list, ignitable, corrosive, etc.) and must properly label each container per the requirements of reference (n). It should be noted that there are chemotherapy drugs that are also U-listed hazardous waste. These drugs must be managed as part of the chemotherapy waste program as outlined below in sections 10.h and 10.i.
All lids must be closed except when actively in use.

(3) The pharmaceutical waste POC must ensure a log sheet is maintained for each container at the SAA. Anyone placing an item in the container for non-chemotherapy hazardous pharmaceutical waste must document each item on the log sheet, to include the identity of the

item(s), the date, and the name and phone number of the individual who placed the item(s) in the container. The accuracy of this log sheet is critical for proper profiling and disposal of this waste, and to demonstrate hazardous waste compliance to a regulatory agency.

(4) The users generating the non-chemotherapy hazardous pharmaceutical waste must be trained by the pharmaceutical waste POC or facility EPM regarding the proper management of their pharmaceutical wastes. This training must include what medications they are required to collect, the process of logging the waste, required PPE, and the appropriate segregation of the wastes.

(5) When the container becomes approximately three-quarters (75 percent) full or when the container has been in use for 9 months based on the first date entered on the log sheet (whichever comes first), the pharmaceutical waste POC must remove the container from service, properly secure and label it for disposal (including the date of closure), and turn it in with its associated log sheet for proper disposal as hazardous waste utilizing the site-specific processes for the transfer and disposal of hazardous waste. Some locations have more stringent regulations for the time that a waste container may be in-use at a SAA. It is critical that the pharmaceutical waste POC work with the EPM or host installation HWM to determine if more stringent requirements apply.

h. Trace chemotherapy (antineoplastic) waste

(1) The pharmaceutical waste POC must work with the facility EPM to establish an accumulation point (or multiple accumulation points, as appropriate) for trace chemotherapy wastes.

(2) Rigid yellow sharps-like containers will be used to collect trace chemotherapy wastes, including items such as syringes, vials, and tubing used in chemotherapy preparation or delivery.

(3) To qualify as trace chemotherapy waste, the chemotherapy vial, bag, other receptacle, or associated delivery equipment must be “RCRA empty” (less than 3 percent of the full volume remaining).

(4) The pharmaceutical waste POC must properly label each container as “trace chemotherapy waste.” It must also be labeled as “open” with the date on which the container was put into use. Lids must be closed except when actively in use.

(5) The users generating the trace chemotherapy waste must be trained by the pharmaceutical waste POC or facility EPM regarding the process of disposing of these wastes. This training must include what medications they are required to collect, the required PPE, and which container to use for disposal.

(6) When the container becomes approximately three-quarters (75 percent) full or when the container has been in use for nine months, the pharmaceutical waste POC must remove the

container from service, provide a "closed" date, properly label it for disposal, and process it for disposal as trace chemotherapy waste, as appropriate. Trace chemotherapy waste is typically disposed through the regulated medical waste program as reflected in this guidance. Since the items in this waste stream are considered "RCRA empty," they are exempt from the requirements for disposal as hazardous waste. Some states or overseas locations may have variations to this rule, and proper disposal mechanisms must be verified, often with the host installation HWM. These disposal mechanisms must be documented as part of the pharmaceutical waste SOP. Additionally, some locations have more stringent regulations for the time that a waste container may be in-use at an accumulation point. It is critical that the pharmaceutical waste POC work with the EPM to determine if more stringent requirements apply.

i. Bulk chemotherapy (antineoplastic) waste

(1) The pharmaceutical waste POC must work with the facility EPM or the host installation HWM to establish an SAA (or multiple SAAs, as appropriate) for bulk chemotherapy wastes. Although there are antineoplastics that are not classified as hazardous waste for disposal, BUMED has made the decision to manage all bulk chemotherapy waste as hazardous waste per the best management practices for increased worker safety and decreased liability.

(2) Yellow collection bags that are at least 4 mils (4 thousandths of an inch) thick, inside a rigid container, and properly labeled must be used to collect bulk (greater than or equal to 3 percent of the full volume remaining), non-sharp chemotherapy waste. Additionally, items such as gloves or gowns that are too bulky for the trace chemotherapy waste container are to be collected as bulk chemotherapy waste. These bags must be properly containerized and managed as a hazardous waste per reference (n) and paragraph 10.g. of this enclosure, including quantity restrictions, container specifications, and labeling requirements. This waste must be labeled as hazardous waste rather than medical waste.

(3) In addition to the labeling requirements of reference (n), the pharmaceutical waste POC must properly label each container as "bulk chemotherapy waste." The container must also be labeled as "open" with the date on which the container was put into use. Lids must be closed except when actively in use.

(4) The users generating the bulk chemotherapy waste must be trained by the pharmaceutical waste POC or facility EPM regarding the process of disposing of these wastes. This training must include what medications they are required to collect, the required PPE, and which container to use for disposal.

(5) When the container becomes approximately three-quarters (75 percent) full or when the container has been in use for 9 months, the pharmaceutical waste POC must remove the container from service, provide a "closed" date, properly label it for disposal, and process it for disposal as bulk chemotherapy waste. Bulk chemotherapy waste is typically disposed as

hazardous waste as reflected in this guidance. Some states or overseas locations may have variations to this rule, and proper disposal mechanisms must be verified, often with the host installation HWM. The disposal process must be documented as part of the pharmaceutical waste SOP. Additionally, some locations have more stringent regulations for the time that a waste container may be in-use. The pharmaceutical waste POC must work with the host installation HWM to determine if more stringent requirements apply.

j. Dual waste

(1) Waste may be generated that exhibits characteristics of both a hazardous waste and a regulated medical waste (e.g., a syringe and needle that was used to transfer P-listed pharmaceutical).

(2) When dual waste is generated, the pharmaceutical waste POC must coordinate with the EPM and/or host installation HWM to ensure the waste is managed on-site per the applicable regulations.

(3) The pharmaceutical waste POC must coordinate with the EPM or host installation HWM to ensure that the transporter and receiving facility are permitted to transport and properly dispose of both hazardous waste and regulated medical waste, per applicable regulations.

11. Training and Information Dissemination

a. Per references (a) and (c), all personnel involved in any aspect of the handling of covered OHDs will receive training on the hazards, appropriate handling, and disposal procedures of OHDs present in the work area. This includes physicians, nurses, pharmacy personnel, housekeepers, and employees involved in receiving, transport, or storage of OHDs. This training will cover topics including the use of appropriate PPE, medical surveillance, post-exposure actions, spill control, etc. Such information will be provided at the time of an employee's initial assignment to a work area where OHDs are present and prior to assignments involving new hazards. Annual refresher training is required.

b. Reference (a), section VIII provides the essential elements required for employee training. Training records should be recorded in the Enterprise Safety Applications Management System and maintained for 5 years from the date on which training occurred per reference (f).

c. The pharmaceutical waste POC must be properly trained in the management and disposal of waste in their area(s) by either the facility EPM or by the host installation HWM, as appropriate. This training must occur at the time of assignment, and annual refresher training is required. At a minimum, this training must include information required by regulation (e.g., hazardous waste generator training) and information specific to the contents of this instruction and site-specific pharmaceutical waste SOPs. This training must be documented and records must be maintained per reference (o).

d. This instruction and the site-specific SOP for the management and disposal of pharmaceutical waste must be made available to users. The pharmaceutical waste POC, in conjunction with the EPM, must ensure that appropriate personnel are properly trained on the requirements.