



Joint Task Force National Capital Region Medical **INSTRUCTION**

NUMBER 6050.02

December 12, 2011

Incorporating Change 1, July 29, 2013

J-3B

SUBJECT: Hazardous Drugs (HDs) Safety Plan

References: See Enclosure 1

1. PURPOSE. This Instruction, based on the authority of References (a) through (d), shall:

a. Establish policy and guidelines for the Joint Task Force National Capital Region Medical (JTF CapMed) in controlling occupational exposures to HDs, as defined by the American Society of Hospital Pharmacists (ASHP), including cytotoxic drugs (CDs) per Occupational Safety and Health Administration (OSHA) Technical Manual TED I-O.15A and Sections 1910.133, 1910.1030, and 1910.1200 of title 29, Code of Federal Regulations (References (e) and (f)).

b. List some common drugs that are considered hazardous by OSHA (Enclosure 2).

c. Provide a list of Environmental Protection Agency (EPA)-regulated HDs (Enclosure 3).

d. Cancel and reissue JTF CapMed Instruction 6050.02 (Reference (g)) to update handling requirements and guidance in accordance with References (h) through (m).

2. APPLICABILITY. This Instruction applies to:

a. The JTF CapMed Headquarters, Fort Belvoir Community Hospital (FBCH), Walter Reed National Military Medical Center (WRNMMC), and the Joint Pathology Center. Hereafter, FBCH and WRNMMC are referred to as Joint Medical Treatment Facilities (MTFs).

b. All settings where personnel may be occupationally exposed to HDs.

3. POLICY. It is the policy of JTF CapMed to handle all HDs according to protocols outlined in this Instruction and References (e), (f), and (i) through (m). All HDs dispensed by the Pharmacy

Departments will bear a label reading "Handling/Disposal - Special Precautions Necessary." Caution shall be exercised when handling or manipulating all HDs. Appropriate personal protective equipment (PPE) (such as nitrile gloves rated for chemotherapy and other HDs) must be worn for all procedures involving the handling and/or administration of HDs; or the handling of excreta and other body fluids from patients who have received a HD within the previous 48 hours. HDs must not be handled, prepared, or manipulated in the immediate vicinity where food and drink are consumed. Handwashing will be enforced to prevent unintentional exposure after handling. All spills of HDs must be cleaned up immediately by a properly trained person utilizing the appropriate procedure (e.g., hazardous spill kits). All exposures to hazardous materials must be reported and treated immediately utilizing the protocols outlined in this Instruction.

4. RESPONSIBILITIES. Joint MTF Commanders and Center Directors. Joint MTF Commanders and Center Directors must:

a. Appoint an HD officer (who is a nurse or pharmacist) and, if appropriate, establish an HD Committee or a joint HD/Hazardous Materials Committee (to be determined by the Executive Committee of the Medical Staff).

b. Develop an HD Safety and Health Plan as described in paragraph V.A.2 of chapter 2 of section VI of Reference (c). This plan must be reviewed and its effectiveness reevaluated at least annually and updated as necessary.

5. PROCEDURES. See Enclosures 2, 3, and 4.

6. RELEASABILITY. UNLIMITED. This Instruction is approved for public release and is available on the JTF CapMed Website at: www.capmed.mil.

7. EFFECTIVE DATE. This Instruction:

a. Is effective upon publishing to the JTF CapMed Website; and

b. Must be reissued, cancelled, or certified current within 5 years of its publication in accordance with JTF CapMed Instruction 5025.01 (Reference (h)). If not, it will expire effective 10 years from the publication date and will be removed from the JTF CapMed Website.


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Acting Commander

Enclosures

1. References
2. Procedures
3. Common Drugs Considered Hazardous by OSHA
4. EPA-Regulated HDs

Glossary

ENCLOSURE 1

REFERENCES

- (a) Deputy Secretary of Defense Memorandum, "Authorities for Joint Task Force National Capital Region Medical (JTF CapMed)," February 7, 2012
- (b) Deputy Secretary of Defense Action Memorandum, "Civilian and Military Personnel Management Structures for the Joint Task Force National Capital Region Medical," January 15, 2009
- (c) Comprehensive Master Plan for the National Capital Region Medical, April 23, 2010
- (d) Supplement to the Comprehensive Master Plan for the National Capital Region Medical, August 31, 2010
- (e) Occupational Safety and Health Administration Technical Manual TED I-O.I5A, current version¹
- (f) Sections 1910.133, 1910.1030, and 1910.1200 of title 29, Code of Federal Regulations, July 1, 2010²
- (g) JTF CapMed Instruction 6050.02, "Hazardous Drugs (HDs) Safety Plan," December 12, 2011 (hereby cancelled)
- (h) JTF CapMed Instruction 5025.01, "Formats and Procedures for the Development and Publication of Issuances," March 5, 2012
- (i) Biosafety in Microbiological and Biomedical Laboratories Appendix A-Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, 2nd edition, CDC/NIH 2000
- (j) Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings, NIOSH Alert, Department of Health and Human Services Centers for Disease Control and Prevention National Institute for Occupational Safety and Health, September, 2004
- (k) ASHP Guidelines on Handling Hazardous Drugs, American Society of Health-System Pharmacists, 2006
- (l) American National Standards Institute Z358.1 – 9, "Emergency Eyewash and Shower Equipment," as revised³
- (m) Section 172.101 of title 49, Code of Federal Regulations, October 1, 2010⁴

¹ This information is available at the following Web Site:

<http://www.sfu.ca/content/dam/sfu/ehs/chemsafety/Laboratory%20Safety%20Manual%20May%202011.pdf>

² This information is available at the following Web Site:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10147

³ This information is available at the following Web Site: <http://gesafety.com/downloads/ANSIGuide.pdf>

⁴ This information is available at the following Web Site: <http://cfr.vlex.com/vid/172-101-purpose-hazardous-materials-table-19941866>

ENCLOSURE 2

PROCEDURES

1. HD-DISPENSING PREPARATION PRECAUTIONS

a. HD-dispensing preparation must be performed in an area with access limited to authorized personnel only. Eating, drinking, smoking, chewing gum, applying cosmetics, and storing food in the preparation area is absolutely prohibited. Procedures for spills and emergencies must be posted in the preparation area.

b. Only Class II, Type A or B or Class III Biological Safety Cabinets (BSC), vented to the outside, that meet the current National Sanitation Foundation Standard, or negative-pressure Containment Aseptic Isolators (CAI) that meet International Standards Organization 14644 Class 5 Air Quality Standards may be designated for preparation of HDs (References (i) through (k)). Internal and external exhausts for the hoods must have High Efficiency Particulate Air (HEPA) filters. Pharmacies that compound one or fewer HD per day on average may use a negative-pressure CAI 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 HDs other than commercially available oral dosage forms must be prepared in designated hood. Using a dedicated BSC for HDs, when possible, is prudent practice. Refer to paragraph 1.g. of this enclosure for guidance in preparation of commercially available oral HD products.

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. Ensure that the outside exhaust of the hoods is vented away from air intake units. The exhaust stacks must be labeled of the hazard to protect hospital maintenance workers. 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 should wear PPE similar to that used for spills. Ideally, the sash on BSCs should remain down during cleaning; however, a National Institute of Occupational Safety and Health (NIOSH)-approved respirator appropriate for the hazard must be worn by the worker if the sash will be lifted at any time during the process. Cleaning should proceed from least to most contaminated areas. 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 HDs and disposed of following Federal, State, and local laws.

e. Hoods that are being used must be serviced and certified by a qualified technician as recommended by the manufacturer, but not less frequently than every 6 months and any time the cabinet is moved or repaired. HEPA filters should be changed when air flow is restricted (as indicated by the continuous monitor), or when the filters are contaminated by an accidental spill.

f. All contaminated needles, syringes, and intravenous (IV) tubing used to prepare HDs will be disposed of intact. Clipping, crushing, or recapping is prohibited. Priming IV sets or expelling air from syringes should 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 HDs during the preparation process. IV containers with venting tubes should not be used.

g. The handling of non-liquid forms of HDs requires special precautions. HD tablets which may produce dust or potential exposure to the handler should be counted in a hood. Non-sterile fume hoods that are vented to the outside may be used for oral dosage forms in lieu of an aseptic hood. Special work practices should be followed when handling these HDs to ensure tablets and capsules are not crushed or broken. Automated counting devices are discouraged unless the process is enclosed and isolates the hazard from employees. Trays and counting equipment should be cleaned with alcohol. Equipment used for counting whether done by hand or automated should be dedicated to counting HDs only.

2. TRANSPORTATION AND STORAGE

a. In addition to standard pharmacy labeling practices, all syringes and IV bags containing HDs should be labeled with a distinctive warning label, such as: CYTOTOXIC AGENT/ DISPOSAL PRECAUTIONS. EPA-regulated HDs listed in Reference (f), must have labels following the standard to warn personnel of the hazards associated with handling these drugs.

b. Access to areas where HDs are stored should be limited to authorized personnel, with signs restricting entry. A list of drugs covered by HD policies, and information on spill and emergency contact procedures should be posted or easily available to staff. Facilities used for storing HDs should not be used for other drugs. These facilities should also be designed to prevent containers from falling to the floor (e.g., bins and shelves with barrier fronts). Warning labels should be applied to all HD containers, as well as the bins and shelves where these containers are stored.

c. Transport must occur in sealed plastic bags and in containers to avoid breakage. Shipped HDs that are subject to EPA regulation as hazardous waste are also subject to Department of Transportation regulations as specified in Section 172.101 of title 49, Code of Federal Regulations (Reference (m)). Personnel involved with transporting HDs should be trained in spill procedures (see section 7).

3. APPROPRIATELY QUALIFIED/CERTIFIED PERSONNEL ADMINISTRATION OF HDs

a. Gloves, goggles, gowns, and other PPE as described in section 4 of this enclosure must be worn when administering HDs. Preparation for administration of HDs on the ward or clinic will be carried out on trays lined with a plastic-backed absorbent pad (Chux) so that at the end of the procedure the plastic can be gathered as waste for appropriate disposal.

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, the one-handed method will be used.

c. The administration of aerosolized HDs requires special engineering controls to prevent exposure to health care workers and others in the vicinity. In the case of pentamidine, these controls include treatment booths with local exhaust ventilation and negative-pressure isolation rooms designed specifically for its administration.

4. PPE

a. Gloves. The thickness of the gloves used in handling HDs is more important than the type of material, although the best results have been observed with latex gloves. Gloves specifically made for handling HDs shall be used (e.g., Chemobloc® gloves). Make sure that the gloves are labeled as chemotherapy gloves and make sure this information is available on the box (meets American Society for Testing and Materials standards) or from the manufacturer. Wear double gloves for all activities involving HDs. Because all gloves are permeable to some extent and their permeability increases with time, they should be changed regularly (i.e., hourly) or immediately if they are torn, punctured, or contaminated with a spill. Wash hands before gloves are put on and after they are removed.

b. Gowns. A protective disposable gown made of lint-free, low-permeability fabric 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 HD preparation area.

c. Chemical Goggles and Face Shields. Whenever splashes, sprays, or aerosols of HDs may be generated, chemical-barrier face and eye protection will be used per Reference (f). Eyewash facilities in accordance with American National Standards Institute Z358.1 – 9 (Reference (l)) must also be available.

d. Respirator. Personnel administering aerosolized HDs should wear NIOSH-approved N95, or greater, particulate respirator. Treatment areas should be designed to protect health care workers administering such drugs (see section 3).

5. CARING FOR PATIENTS RECEIVING HDs. Per Reference (l), universal precautions must be observed to prevent contact with blood or other potentially infectious materials.

a. Personnel dealing with any body fluids or excreta from patients who have received HDs within the last 48 hours must wear approved gloves, face shields, and disposable gowns. Hands must be thoroughly washed after removal of PPE or after contact with the above substances.

b. Linen contaminated with HDs, or excreta from patients who have received HDs 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 excreta must also be managed according to Reference (m).

c. Reusable items such as glassware should be washed twice by trained employees using double gloving and a gown.

6. FIRST AID AND MEDICAL SURVEILLANCE

a. In case of skin contact with HDs, do the following:

(1) Remove contaminated clothing immediately.

(2) Flush affected area with water for 15 minutes.

(3) Wash area with soap or other inactivator if the manufacturer specifies one.

(4) In case of eye contact with HDs, flush with water for a minimum of 15 minutes using equipment that meets specifications in Reference (l). Continue irrigation until ophthalmologic examination is obtained.

(5) Report to an occupational health or emergency medicine provider for additional treatment and documentation of the exposure.

(6) Particular attention to the eyes, buccal (mouth) and nasal mucous membranes, and the skin will be included in the physical examination for acute exposures.

(7) All exposures and spills will be reported immediately to the Safety Office.

b. Those personnel exposed to HDs will be placed in the Medical Surveillance Program per section VI of Reference (f). Selection of individuals for medical surveillance will be a collaborative effort between supervisors, safety, industrial hygiene, and occupational health. Medical surveillance will consist of pre-placement, periodic, situational (after acute exposure), and termination examinations. An attempt should be made to minimize the number of personnel who work with these agents.

c. Reproductive health issues will be incorporated into the hazard communication training for personnel with potential exposure to HDs.

(1) Breastfeeding women should not handle antineoplastics or work in areas where they are handled. These agents may contaminate surfaces in pharmacy drug preparation areas and drug administration areas, and even occasionally penetrate gloves. The assessment of any of these types of exposures should be performed by a qualified industrial hygienist in consult with appropriate medical staff (Office of Emergency Management, Obstetrics/Gynecology, and Doctor of Pharmacy).

(2) The hazards of occupational exposure to antineoplastic agents were addressed by the National Study Commission on Cytotoxic Exposure (Reference (e)). 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 breast feeding 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.”

(3) Staff members who are pregnant, actively trying to conceive a child or breastfeeding may be offered a transfer to duties that do not involve preparation or administration of HDs.

7. SPILL CONTROL

a. A spill clean-up kit, clearly labeled, will be kept in each area where HDs are prepared, administered, or accumulated for disposal or transport. Vehicles transporting patients under active treatment with HDs will maintain the spill kit on the vehicle. See paragraph V.C.5.e of chapter 2 of section VI of Reference (f) for guidance on assembling spill kits.

b. ASHP considers small spills to be those less than 5 milliliters (ml). The 5 ml volume of material should be used to categorize spills as large or small. Small spills, large spills, and spills in BSCs must be cleaned following paragraphs V.C.5.b-d of chapter 2 of section VI of Reference (f). Trained personnel wearing gowns, gloves, and splash goggles 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 protective apparel available in the spill kit (including a NIOSH-approved respirator if there is any suspicion of airborne powder or that an aerosol has been or will be generated). Specific individuals should be trained to clean up large spills. Large spills should be immediately reported to the safety officer.

8. DISPOSAL PROCEDURES

a. Thick, leak-proof plastic bags, colored differently from other hospital trash bags, should be used for the collection of used containers, discarded gloves, gowns, and any other disposable HD-contaminated material. Bags containing hazardous chemicals, as defined by section 6 of Reference (f), must be labeled. Where Reference (f) does not apply, labels should indicate that bags contain HD-related waste.

b. Needles, syringes, and breakable items should be placed in a sharps container before the container is placed in the waste bag. The waste bag should be kept in a covered container that is clearly labeled "HD Waste Only." At least one such receptacle should be located in every area where HDs are prepared or administered.

c. HD-related wastes should be handled separately from other hospital trash and disposed of following EPA, State, and other local regulations for hazardous waste. While awaiting removal, the waste should be held in a secure area in covered, labeled drums with plastic liners.

d. Per requirements in Reference (e) and section 1910.1200 of Reference (f), Material Safety Data Sheets (MSDSs) for all covered HDs used at the activity must be maintained and readily accessible to employees. Each area where HDs are prepared or administered will maintain the appropriate MSDSs.

9. TRAINING AND INFORMATION DISSEMINATION

a. In compliance with Reference (e) and section 1910.1200 of Reference (f), all personnel involved in any aspect of the handling of covered HDs (physicians, nurses, pharmacists, housekeepers, employees involved in receiving, transport, or storage) will receive information and training to apprise them of the hazards of HDs present in the work area. Such information will be provided at the time of an employee's initial assignment to a work area where HDs are present and prior to assignments involving new hazards. Annual refresher information and training should be provided as well.

b. Section VIII of Reference (e) provides the essential elements required for employee training. Training records should be maintained for 3 years from the date on which training occurred.

ENCLOSURE 3

COMMON DRUGS CONSIDERED HAZARDOUS BY OSHA

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.

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

ENCLOSURE 4

EPA-REGULATED HDs

These HDs are CDs and are classified as hazardous wastes when they are to be discarded or are intended to be discarded. Any spill debris and the first voided urine from patients given bladder irrigation with these materials is also a hazardous waste and must be handled accordingly. These drugs are not to be intermingled. Each must be in a properly labeled container. The label must say "Hazardous Waste" and the name of the material. The containers are 1 to 5-gallon Department of Transportation-approved plastic pails with lids.

<u>Table. CDs</u>	
<u>DRUG</u>	<u>EPA WASTE NUMBER</u>
Clorambucil (Leukeran)	U035
Cyclophosphamide (Cytosan)	U058
Daunorubicin (Daunomycin)	U059
Diethylstilbestrol (Stilphostrol)	U089
Melphalan (Alkeran)	U150
Mitomycin C (Mutamycin)	U010
Dichlorodiphenyldichloroethane (ODD)	U060
Streptozocin	U206
Uracil Mustard	U237

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

ASHP	American Society of Hospital Pharmacists
BSC	Biological Safety Cabinets
CAI	Containment Aseptic Isolators
CDs	cyotoxic drugs
EPA	Environmental Protection Agency
FBCH	Fort Belvoir Community Hospital
HD	hazardous drugs
HEPA	High Efficiency Particulate Air
IV	intravenous
JTF CAPMED	Joint Task Force National Capital Region Medical
ml	milliliters
MSDAs	Material Safety Data Sheets
MTF(s)	Medical Treatment Facility/Facilities
NIOSH	National Institute of Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PPE	Personal Protective Equipment
WRNMMC	Walter Reed National Military Medical Center

PART II. DEFINITIONS

hazardous drug. An HD is a drug, which poses a significant risk to a healthcare worker (or patient) by virtue of its teratogenic, mutagenic, carcinogenic, or reproductive toxicity potential, as well as acute toxicity to an organ system.