**TB MED 515**

TECHNICAL BULLETIN

OCCUPATIONAL AND ENVIRONMENTAL HEALTH

# OCCUPATIONAL HEALTH AND INDUSTRIAL HYGIENE
# GUIDANCE FOR THE MANAGEMENT, USE AND DISPOSAL OF HAZARDOUS DRUGS

APPROVED FOR PUBLIC RELEASE, DISTRIBUTION IS UNLIMITED
HEADQUARTERS, DEPARTMENT OF THE ARMY

22 April 2014

TECHNICAL BULLETIN
MEDICAL 515

HEADQUARTERS
DEPARTMENT OF THE ARMY
Washington, DC, 22 April 2014

# GUIDANCE FOR THE MANAGEMENT, USE AND DISPOSAL OF HAZARDOUS DRUGS

You can help to improve this bulletin. If you find any mistakes or have a recommendation to improve procedures, please let us know. Mail a memorandum or DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to Office of the Surgeon General, ATTN: DASG-PPM-NC, 7700 Arlington Boulevard, Falls Church, VA 22042-5143.

## List of Figures



## List of Tables

# CHAPTER 1

# INTRODUCTION

## 1–1. Purpose and scope

This bulletin consolidates numerous regulations and standards published by Federal agencies and national consensus groups into a single, comprehensive document to provide military treatment facilities (MTFs), dental treatment facilities (DTFs), and veterinary treatment facilities (VTFs) the safety and health precautions needed for the safe management, use, and disposal of hazardous drugs (HDs). These precautions apply to Army MTFs (medical centers; community hospitals; ambulatory care centers), DTFs, and VTFs that employ healthcare workers (HCWs) who are potentially exposed to HDs in the workplace. This bulletin provides guidance on—

*a.* Characteristics of HDs.
*b.* Written Hazardous Drug Safety and Health Plan (HDSHP).
*c.* Worker education and training.
*d.* Hazardous drugs.
*e.* Aerosolized drugs.

## 1–2. References

Appendix A provides a list of required and related references.

## 1–3. Explanation of abbreviations and terms

The glossary contains a list of abbreviations as they are used in this publication.

## 1–4. Functions

*a.* The MTF Commanders have the following responsibilities:

(1) Appoint on orders an individual from the Preventive Medicine Occupational Health, Industrial Hygiene, or the Environmental Health Section to act as the Hazardous Drug Officer (HDO).

(2) Establish a HDSHP for the safe management, use, and disposal of HDs and to keep occupational exposures as low as reasonably achievable (ALARA).

(3) Monitor the HDSHP's effectiveness and identify opportunities for program improvement. The Environment of Care/Safety Committee oversees the implementation of the HDSHP under the purview of the Hazardous Materials and Waste Management Plan. Commanders may designate a separate multidisciplinary HD Committee to oversee the HDSHP when the size of the MTF or the quantity of HDs used warrants a separate committee.

*b.* Commanders of DTFs and VTS have the following responsibilities:

(1) Appoint on orders an individual who is knows the safety and health risks associated with HDs used in the DTF or VTF and the safety precautions that prevent/minimize occupational exposure(s) to act as the Hazardous Drug Officer (HDO).

(2) Establish a HDSHP for the safe management, use, and disposal of HDs and to keep occupational exposures as low as reasonably achievable (ALARA).

(3) Monitor the HDSHP's effectiveness and identify opportunities for program improvement.

*c*. The HDO has the following responsibilities:

(1) Set up and carry out the HDSHP.

(2) Evaluate the HDSHP's effectiveness, at least annually, and report the evaluation results to the Environment of Care/Safety Committee.

(3) Advise the Environment of Care/Safety Committee and staff on all matters related to the safe storage, use, handling, and disposal of HDs.

(4) Coordinate the collection of information about the safety and health risks, deficiencies including HD spills, and opportunities for improvement regarding the safe use of HDs.

(5) Verify that safety precautions recommended by the Environment of Care/Safety Committee are implemented as designed and that they are effective.

(6) Review all reports of occupational exposure, spill incidents, and near misses; and recommend measures to prevent reoccurrence. A near miss is an unplanned event that did not result in injury, illness, or damage but had the potential to do so.

(7) Assist work-area supervisors in conducting and documenting safety and health risk assessments.

*d*. The Environment of Care/Safety Committee has the following responsibilities:

(1) Develop a HD list according to the criteria presented in Chapter 2.

(2) Serve as the MTF's HD safety and health resource and form policies for distributing, using, and disposing HDs.

(3) Monitor and document the HDSHP's effectiveness.

(4) Evaluate reports of unsafe conditions and acts, hazard surveillance data, accident and injury data, and incident reports involving HDs; identify opportunities for improvement.

(5) Develop and approve recommendations that will prevent occupational exposure to HDs.

(6) Review organization-wide and department-specific standing operating procedures (SOPs) whenever there is a process change or as needed, but at least once every 3 years; verify that the SOPs contain current, complete, and accurate information.

(7) Recommend effective HD education and training programs for all potentially exposed HCWs.

(8) Review proposals for introducing new HDs into the workplace, and verify that the proposals address necessary safety measures to prevent occupational exposure to HDs.

*e*. When the MTF has a separate HD Committee, the Environment of Care/Safety Committee has responsibility for reviewing the HD Committee minutes and recommending and approving improvements that will prevent occupational exposure to HDs.

*f*. The Logistics Division has the following responsibilities:

(1) Chief, Supply Chain Management has the following responsibilities:

(*a*) Properly label, package, and handle all HD waste; complete the appropriate documentation; and arrange for disposal through the Installation's Environmental Office or through appropriate U.S. Army Medical Command disposal channels.

(*b*) Maintain the 90-day storage area for hazardous waste (HW), if applicable, according to the requirements provided in the Installation's Hazardous Waste Management Program and local, state, and Federal regulations.

(2) Chief, Medical Maintenance Branch has responsibility for verifying that engineering controls, such as compounding aseptic containment isolators (CACIs) and biological safety cabinets (BSCs), used to compound sterile HDs, are maintained and certified. Certified means that a trained individual conducted a routine inspection and test according to strict protocols and verified that the cabinet was working properly.

(3) Facility Manager has responsibility for verifying that clean rooms and buffer zones meet at least U.S. Pharmacopeia (USP) General Chapter 797 recommendations.

*g.* Preventive Medicine Service has the following responsibilities:

(1) Occupational Health Section has responsibility for—

(*a*) Conducting initial and periodic medical surveillance for HCWs who are potentially exposed to HDs in the workplace.

(*b*) Maintaining exposure records on all HCWs handling these substances for the duration of employment plus 30 years.

(*c*) Evaluating HCWs following acute exposures, with documentation in each occupational health record.

(2) Environmental Health Section has responsibility for—

(*a*) Surveying the work areas where HDs are stored, compounded, and administered to monitor the timely collection, transportation, treatment, storage, and disposal of HD waste according to the Installation's Hazardous Waste Management Program and local, state, and Federal regulations at least annually.

(*b*) Maintaining a log of HD spills, and sharing relevant information with the HDO and Environment of Care/Safety Committee.

(3) Environmental Science and Engineering Officer (ESEO) has responsibility for surveying HD waste storage areas and work areas where HDs are stored, compounded, and administered at least annually to—

(*a*) Identify waste streams and determine disposal methods and procedures for all HD wastes.

(*b*) Train waste handlers and staff on proper disposal procedures.

(4) Industrial Hygiene Section has responsibility for surveying the work areas where HDs are stored, compounded, and administered according to Department of Army Pamphlet (DA Pam) 40–503 at least annually to—

(*a*) Evaluate engineering controls for proper operation (that is, clean rooms, ventilation systems, and booths).

(*b*) Aid in selecting personal protective equipment (PPE) and training HCWs in its use.

(*c*) Document potential for HCWs' exposure to HDs in the workplace and the engineering, administrative, safe-work practice controls, and PPE used in the Defense Occupational and Environmental Health Readiness System-Industrial hygiene (DOEHRS-IH) database. The Industrial Hygiene Program Manager shares survey results with the Occupational Health Section.

(*d*) Assist work-area supervisors in conducting and documenting safety and health risk assessments.

(*e*) Perform environmental wipe sampling according to instructions provided in Appendix B.

*h.* Deputy Commander for Clinical Services has the following responsibilities:

(1) Implement a training program for medical practitioners who handle and administer HDs.

(2) Verify that each department, clinic, or ward has a current SOP for medical practitioners who administer HDs.

(3) Notify the Hazardous Drug Officer (HDO) and industrial hygienist when work processes involving HDs change and when department-specific HD SOPs are updated.

*i.* The Deputy Commander for Nursing Services has the following responsibilities:

(1) Maintain a log of nursing personnel preparing and administering HDs, dates of preparation, and drugs prepared.

(2) Implement a training program for nursing personnel who handle and administer HDs.

(3) Verify that each department, clinic, or ward has a current SOP for nursing personnel administering HDs.

(4) Notify the HDO and industrial hygienist when work processes involving HDs change and when department-specific HD SOPs are updated.

(5) Verify that each department, clinic, or ward maintains safety data sheets (SDSs) for HDs handled within their work areas according to the MTF's Hazard Communication (HAZCOM) Program.

*j.* Chief, Pharmacy has the following responsibilities:

(1) Maintain a log of pharmacy personnel preparing HDs, dates of preparation, and drugs prepared.

(2) Maintain a separate inventory of HDs with corresponding SDSs.

(3) Maintain, prepare, and dispense HDs safely.

*k.* Work-area supervisors have the following responsibilities:

(1) Identify the locations where HDs are received, stored, prepared or compounded, and where HD waste is stored.

(2) Coordinate with the HDO and Industrial Hygiene Section to identify, evaluate, eliminate or manage, and document the safety and health risks associated with HDs in the workplace. Documentation may include Department of the Army (DA) Form 7566 (Composite Risk Management Worksheet), job hazard analyses, proactive risk assessments, and root-cause analyses.

(3) Develop safe-work practices and department-specific HD SOPs; review and update them as needed but at least once every 3 years.

(4) Notify the HDO and Industrial Hygiene Section when work processes involving HDs change and when department-specific HD SOPs are updated.

(5) Confirm that HCWs receive education and training on the HDSHP; job-specific HD hazards, engineering and administrative controls, safe-work practices, and PPE; actions to take to eliminate, minimize, or report hazards; and procedures to report accidents, spills, and exposures.

(6) Verify and document staff competency in personnel competency-based files.

(7) Confirm that HCWs participate in the Medical Surveillance Program.

(8) Confirm that engineering and administrative controls, safe-work practices, and PPE are functional, used, and effective.

(9) Investigate all accidents/incidents involving HDs, record/report all occupational injuries and illnesses as required, and share relevant information with the HDO.

(10) Report HD spills to the Preventive Medicine Environmental Health Section.

*l.* The HCWs have responsibility for complying with all requirements in the MTF's HDSHP and in their department-specific safety SOPs.

*m.* Contractors having workers who are potentially exposed to HDs in the workplace have the following responsibilities:

(1) Develop and implement a Safety and Occupational Health Program that applies to the work and tasks performed by their employees.

(2) Require their employees work safely and follow applicable contract provisions and safety, health, and environmental regulations and standards.

(3) Take meaningful and effective action to hold employees accountable for noncompliance with applicable contract provisions and safety, health, and environmental regulations and standards.

### 1–5. Technical assistance

Requests for additional assistance and guidance may be addressed to: Industrial Hygiene and Medical Safety Management Program (MCHB-IP-OMS), U.S. Army Public Health Command, 5158 Blackhawk Road Aberdeen Proving Ground, MD 21010-5403 or by calling commercial 410-3161, DSN 584-3161.

# CHAPTER 2

# CHARACTERISTICS OF HAZARDOUS DRUGS

## 2–1. Background

*a.* Hazardous drugs.

(1) Exhibit one or more of the following six characteristics in humans or animals:

(*a*) Carcinogenicity.

(*b*) Teratogenicity or other developmental toxicity.

(*c*) Reproductive toxicity.

(*d*) Organ toxicity at low doses.

(*e*) Genotoxicity.

(*f*) Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria.

(2) Pose a health hazard when they are present in the workplace in such a manner that HCWs may be exposed under normal conditions of use or in a foreseeable emergency.

*b*. All workers with job duties that include the preparation, administration, transportation, handling, or disposal of HDs risk occupational exposure to HDs. These workers include shipping and receiving personnel, pharmacists, pharmacy technicians, nursing staff and medical practitioners, respiratory therapists, operating room staff, housekeeping personnel, medical equipment repairers, HW handlers, dental workers, and veterinary care workers. In addition to the type of procedures performed, some other factors that influence potential for worker exposure are the volume, frequency, and form of the HD handled and the safe-handling practices used.

*c.* Most exposures occur through eye and skin absorption through direct contact and contact with contaminated surfaces such as the outside of the drug vials received from the manufacturer; inhalation of dust or aerosols during drug preparation or administration; ingestion through contact with contaminated foods, drinks, cigarettes, and cosmetics (cosmetics include skin-care creams, lotions, powders, perfumes, lipsticks, lip balms, fingernail and toenail polishes, and eye and facial makeup); or injection through a needle stick or sharps injury.

*d.* Workers follow safe-handling practices from the time an HD enters the MTF until proper disposal. Safe handling practices include—

(1) *Engineering controls*. Use of engineering controls is preferred since they control HCWs' exposures by containing the contaminants at their source and by reducing the quantity of contaminants released into the work environment. The CACIs, BSCs, and puncture-resistant HD disposal containers are examples of engineering controls that enclose a process or a hazard to mitigate occupational exposure to HDs.

(2) *Administrative controls*. Administrative controls include education and training to increase awareness and limiting worker exposures by reducing the time workers spend in contaminated areas. Examples of administrative controls include orientation and refresher training, job rotation, job transfer, and modified work schedules.

(3) *Safe-work practices*. Safe-work practices are designed to prevent worker injuries or exposures to known hazards. Examples of safe-work practices include good housekeeping, sanitation and hygiene, and handling techniques that minimize/prevent the generation of aerosols or dusts.

(4) *Personal protective equipment*. The PPE must be used in conjunction with engineering and administrative controls, as well as safe-work practices whenever work exposures cannot be reduced to acceptable limits. Examples of PPE include splash goggles, face shields, gloves, gowns, and respirators. The PPE is further described in paragraphs 5–20 through 5–25.

**2–2. Categories of hazardous drugs**

*a. Cytotoxic drugs or antineoplastic drugs, Therapeutic Class (10:00)*. The American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System is used to classify drugs commonly used in North America. This system is updated once a year, and is published as a book by the American Society of Health-System Pharmacists (http://www.ashp.org/ ). The AHFS code is a 6 digit number which includes three levels of information arranged in a step-up/step-down manner. All AHFS codes starting with 10:00 represent a broad class of drugs known as antineoplastic agents otherwise known as cytotoxic drugs (CDs). Antineoplastic agents/CDs make up the majority of the HDs. They are used to treat cancer, neoplasms, and more recently non-malignant rheumatologic and immunologic diseases. The CDs are capable of causing organ toxicity, fertility problems, genetic damage, birth defects, and cancer (leukemia).

*b. Other therapeutic classes of hazardous drugs*. In addition to CDs, the National Institute for Occupational Safety and Health (NIOSH) HD list includes some drugs from the following Therapeutic Categories: antibiotics and anti-infectives (08:12, 08:40), antivirals (08:18), androgens (68:08), estrogens (68:16:04), gonadotropins (68:18), oxytocics (76:00), some vaccines (80:12), topical retinoids (84:36), immunosuppressive agents (92:00), and other unclassified agents (92:00).

*c. Safety precautions*. Chapter 5 of this bulletin describes safety precautions for preventing occupational exposure to HDs.

*d. Aerosolized drugs*.

(1) Aerosolized drugs include pentamidine and ribavirin. Pentamidine is used to treat *Pneunocystis carinii* pneumonia in immunosuppressed patients, and ribavirin is used to treat severe respiratory syncytial virus in infants and young children. Some HCWs exposed to aerosolized pentamidine (AP) and ribavirin noted symptoms of respiratory and eye irritation, sharp pains around the eyes and nose, and headaches.

(2) Chapter 6 of this bulletin describes safety precautions for preventing occupational exposure to these two aerosolized drugs.

*e. Waste anesthetic gases*.

(1) Waste anesthetic gases (WAG) (such a nitrous oxide, halothane, enflurane, methoxyflurane, sevoflurane, and isoflurane) are used to anesthetize patients who are undergoing surgery. Exposure to the WAG may cause drowsiness, headache, nausea, fatigue, and impaired

judgment and coordination. Chronic exposure to WAG has been associated with infertility, infants with low-birth weight and congenital abnormalities, and an increased risk of spontaneous abortion in exposed female HCWs as well as the wives of exposed male HCWs.

(2) Safety precautions for preventing occupational exposure to the WAG are described in Technical Bulletin, Medical (TB MED) 510.

*f. Estrogens and opiates.*

(1) Estrogens and opiates have caused a variety of adverse health effects in workers in the pharmaceutical manufacturing industry.

(2) The manufacturer's data or SDSs provide the detailed safety precautions for preventing occupational exposures to these types of drugs.

*g. Investigational drugs.*

(1) Investigational drugs are under review in clinical studies.

(2) Army Regulation (AR) 40–7 contains detailed policies for using investigational drugs. In addition, the manufacturer's data or SDSs provide the detailed safety precautions for preventing occupational exposures to these drugs. Handle all investigational drugs according to the manufacturers' recommended safety and health precautions since their hazards may not be fully known.

**2–3. Hazardous drug list**

*a*. Create a unique list of hazardous drugs used at each MTF.

*b*. Consider the following characteristics when deciding whether to designate a drug as hazardous:

(1) The American Hospital Formulary Service Drug Information lists the drug as Therapeutic Category 10:00 (antineoplastic).

(2) The drug is a known—

(*a*) Human mutagen, carcinogen, teratogen, or reproductive toxicant.

(*b*) Animal carcinogen or teratogen.

(3) The drug is known to be acutely toxic to an organ system.

*c*. Resources that may be used to evaluate the hazard potential of a drug include but are not limited to—

(1) Safety Data Sheets.

(2) Product labeling approved by the U.S. Food and Drug Administration (FDA) (package inserts).

(3) Special health warnings from drug manufacturers, FDA, and other professional groups and organizations.

(4) Reports and case studies published in medical and other healthcare profession journals.

(5) Evidence-based recommendations from other facilities that meet the criteria defining hazardous drugs.

(6) The NIOSH's list of drugs by chemical/generic name that are commonly considered hazardous can be found on line at NIOSH List of Antineoplastic and Other Hazardous Drugs in Health Care Settings 2012. This list is not exhaustive, and it is updated by NIOSH periodically.

## 2-4. Permissible exposure limits

*a.* The Occupational Safety and Health Administration (OSHA) has not set specific permissible exposure limits (PEL) or standards for most HDs; however, it has issued guidelines (OSHA Technical Manual, Directive Number TED 01-001-005) urging employers to establish a HDSHP and to keep occupational exposures ALARA. A violation of such guidelines or equivalent procedures could result in a citation under the General Duty Clause of the OSH Act (Public Law (PL) 91–596).

*b.* Hazardous drugs with established limits are—

(1) Cisplatin (Platinol®) (exposure limit for Platinum, soluble salts as Platinum) OSHA PEL 0.002 milligrams per cubic meter ($mg/m^3$) and American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Value (TLV®) 0.002 $mg/m^3$. (Platinol® is a registered trademark of Bristol-Myers Company; ACGIH® and TLV® are registered trademarks of the American Conference of Governmental Industrial Hygienists.)

(2) Carboplatin (Paraplatin®) (exposure limit for Platinum, soluble salts as Platinum) OSHA PEL 0.002 $mg/m^3$ and ACGIH TLV 0.002 $mg/m^3$. (Paraplatin® is a registered trademark of Bristol-Myers Company.)

(3) Arsenic trioxide OSHA PEL 0.01 $mg/m^3$ and ACGIH TLV 0.01 $mg/m^3$.

(4) Nitrous oxide ACGIH TLV 50 parts per million (or ppm).

*c.* Some pharmaceutical manufacturers have developed occupational exposure limits (OELs) for use in their manufacturing facilities. The OELs are based on pharmaceutical workers' exposure to single drugs that are handled in an automated production line. In healthcare, workers may come in direct contact with a variety of HD liquids, dusts, and aerosols when caring for patients. Therefore, using the OELs to limit HCWs' occupational exposure to HDs is not as protective as keeping their occupational exposures ALARA.

*d.* In the absence of OELs and where validated sampling and analytical methods have been developed, the OELs for mutagens, teratogens, and carcinogens should be based on risk evaluations using human or animal health effects data, as well as on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques.

## 2–5. Exclusion

The Environment of Care/Safety Committee may approve the pharmacy's request to exclude a drug from the hazardous drug inventory when the pharmacy provides evidence that there is no potential for occupational exposure. For example, HDs in solid tablet or pill form may be exempted when HCWs administer them in prepackaged, individual prescriptions directly to patients.

# CHAPTER 3

## HAZARDOUS DRUG SAFETY AND HEALTH PLAN

### 3–1. Purpose

*a.* The HDSHP defines the essential actions to eliminate or effectively manage health hazards associated with HDs and to keep occupational exposures to HDs ALARA.

*b.* The HDSHP is a local regulation, signed by the MTF Commander.

### 3–2. Hazardous drug safety and health plan components

The HDSHP addresses the following elements:

*a. Personnel*. Designating personnel responsible for developing and implementing the HDSHP.

(1) The HDO.

(*a*) The ideal candidates for this position include representatives from the Preventive Medicine Occupational Health, Industrial Hygiene, or the Environmental Health Section.

(*b*) More important, the HDO knows the safety and health risks associated with HDs used in the MTF and the safety precautions that prevent/minimize occupational exposure(s).

(2) The Environment of Care/Safety Committee. The committee includes representatives or has a mechanism in place to share information from the following regarding the use of HDs in the workplace:

(*a*) Medical and nursing staffs.

(*b*) Pharmacy.

(*c*) Oncology.

(*d*) Operating room personnel.

(*e*) Respiratory Therapy.

(*f*) Ophthalmology.

(*g*) Dental.

(*h*) Veterinary Services.

(*i*) Preventive Medicine Services Occupational, Environmental, and Industrial Hygiene Sections.

(*j*) Nursing education and training.

(*k*) Logistics, to include medical supply, housekeeping, and medical maintenance.

*b.* Managing risk. To minimize occupational exposures to HDs and consequent health and safety risks, each MTF develops and implements a risk management process that includes—

(1) A written list of all HDs and identification of all work locations where HDs are present.

(2) Identification of the safety and health hazards associated with HD receipt, storage, preparation, administration, and disposal.

(3) Risk assessment of the identified safety and health hazards associated with HDs.

(4) Development and implementation of appropriate control measures to manage risk.

(5) Periodic testing and evaluation of control measures to validate that they are implemented, effective, and that they do not introduce additional hazards into the workplace.

(6) Documentation of criteria used to determine, implement, and assess control measures to prevent occupational exposures, such as results of—

(*a*) Annual HDSHP assessments.

(*b*) Safety and health risk assessments (DA Form 7566).

(*c*) General safety inspections.

(*d*) Industrial hygiene surveys.

(*e*) Medical equipment and facilities maintenance activities.

(*f*) Reviews of employee reports of unsafe or unhealthy working conditions (DA Form 4755 (Employee Report of Alleged Unsafe or Unhealthy Working Condition), accident and incident reports, and OSHA Form 300 (Log of Work-Related Injuries and Illness Entries).

*c*. The availability of SOPs related to HD handling. Examples of related SOPs include—

(1) Hazard communication.

(2) Emergency management.

(3) Hazardous material spill prevention and response.

(4) Waste disposal.

(5) Linen management.

(6) Medical surveillance.

(7) Accident reporting.

(8) Organization-wide and departmental-specific HD SOPs.

(9) HD transport.

(10) Inventory tracking.

*d*. The procedures for certifying, maintaining, and testing ventilation systems that are used to contain and remove hazardous aerosols (such as, CACIs, BSCs, negative-pressure isolation rooms, and negative chamber booths).

*e*. The protocols for using investigational drugs.

*f*. The procedures for conducting employee training and providing information.

*g*. The procedures for providing medical surveillance examinations.

### 3–3. Hazardous drug safety and health plan management

*a*. Provide all potentially exposed HCWs free access to the HDSHP (such as, access to hard copy, trained on equipment and procedures to access electronic copies, trained on the back-up system for accessing electronic copies, and so forth).

*b*. The HDO—

(1) Serves as an advisor to the Environment of Care/Safety Committee.

(2) Reviews the HDSHP, evaluates the plan's effectiveness, and reports the results to the Environment of Care/Safety Committee at least annually.

(3) Coordinates the collection of information about deficiencies and opportunities for improvement regarding the MTF's safe use of HDs.

(4) Verifies that safety precautions recommended by the Environment of Care/Safety Committee are implemented and effective.

*c*. The Environment of Care/Safety Committee—

(1) Establishes policy and serves as the MTF's HD safety and health resource.

(2) Establishes and implements a comprehensive and effective HDSHP.

(3) Recommends changes to existing safety regulations, rules, and procedures and hazard elimination and control measures.

(4) Evaluates reports of unsafe conditions and acts, hazard surveillance data, accident and injury data, and incident reports.

(5) Reviews the HDSHP at least once every 3 years to verify that it contains current, complete, and accurate information.

(6) Monitors effectiveness, and develops and approves recommendations and improvements to the HDSHP.

(7) Develops effective safety and health training programs to communicate safety and health information to all potentially exposed workers.

(8) Documents HDSHP performance.

*d*. Work-area supervisors—

(1) Implement the safety precautions recommended by the Environment of Care/Safety Committee and monitor them to make sure they are effective.

(2) Review and update department-specific HD SOPs, when processes change, as needed, and at least once every 3 years.

(3) Notify the HDO and industrial hygienist when work processes involving HDs change and when department-specific HD SOPs are updated.

(4) Confirm that HCWs receive education and training on the HDSHP; job-specific HD hazards; actions to take to eliminate, minimize or report hazards; and procedures to report accidents, spills, and exposures.

(5) Confirm that HCWs participate in the medical surveillance program.

*e*. The HCWs comply with all requirements in the HDSHP and in department-specific safety SOPs.

### 3–4. Recordkeeping

*a.* The HDO maintains comprehensive records showing that the HDSHP is carried out as it was designed and maintained. At a minimum, records include—

(1) Results of annual program assessments.

(2) Certification, maintenance, and testing records for engineering controls (CACIs and BSCs) and ventilation systems.

(3) The HCWs' medical, education, and training records.

(4) Investigational HD approvals and reports if applicable.

*b.* Keep annual program assessment records for 5 years.

# CHAPTER 4

# TRAINING AND INFORMATION

## 4–1. Supervisors

Supervisors of affected HCWs (such as, temporary, permanent, and contractor) are trained to—

*a*. Regularly evaluate the work area and work procedures to detect and eliminate or effectively manage safety and health hazards.

*b*. Verify control measures (such as, engineering, administrative, safe-work practices and PPE) are functional, effective, and properly used.

*c*. Assess worker competency, and reinforce worker knowledge and proficiency in techniques and procedures for the safe handling of HDs.

(1) Supervisors assess HCWs' knowledge and competency after the initial orientation when new hazards or techniques are introduced into the work area and yearly, thereafter, or more frequently if performance problems occur.

(2) Competency assessments include written examinations, an observed demonstration of safe-handling skills, or a combination of both.

## 4–2. Healthcare workers

*a*. All HCWs involved in any aspect of handling HDs receive discipline-appropriate training and education before beginning any work with HDs.

*b*. Orientation and annual refresher training is sufficient to meet the HAZCOM or "worker-right-to-know" statutes and regulations and cover the following:

(1) The known risks of handling HDs.

(2) The relevant techniques and procedures for the safe handling of HDs.

(3) The proper care and use of engineering controls, specialized equipment, and PPE.

(4) The spill reporting and cleanup procedures.

(5) The medical policies (including those dealing with pregnancy, breast feeding, and with HCWs actively trying to conceive children).

(6) The waste disposal procedures.

## 4–3. Hazard communication

*a*. *The Occupational Safety and Health Administration hazard communication standard*. The HCWs who risk occupational exposure to HDs are covered by OSHA's HAZCOM standard (Title 29 Code of Federal Regulations (CFR) Part 1910, Section 1200).

*b*. *The hazard communication program requirements*.

(1) *Written program and inventories*. The written HAZCOM program explains the MTF's procedures for maintaining warning labels and SDSs, conducting worker information and training, performing non-routine tasks, and sharing information with contract workers. In addition, the written program includes a list of all the hazardous chemicals, including HDs, used at the facility.

(2) *Warning labels*. Original packages containing HDs list the name of the material, the physical and health hazards, and the name of the manufacturer.

(3) *Safety Data Sheets*.

(*a*) Drug manufacturers and importers obtain or develop SDSs for each HD that they produce/import, and they send a copy of the SDS to their customers with all initial shipments.

(*b*) The MTFs maintain a SDS on hand for each HD that they use and make sure that the SDSs are accurate and that all potentially exposed HCWs have free access to the SDSs (such as, access to hard copies, trained on equipment and procedures to access electronic copies, trained on the back-up system for accessing electronic copies, and so forth).

(4) *Information and training*.

(*a*) Work-area supervisors review the SDS for each HD and explain the following essential information to HCWs: health hazards; primary exposure routes; carcinogenic, mutagenic, and teratogenic evaluations; reproductive toxicity; acute exposure treatment; chemical inactivators; and solubility, stability, and volatility.

(*b*) Work-area supervisors make sure that HCWs know the requirements and location of the MTF's HAZCOM program, the operations/procedures in their work area(s) where HDs are present, and the location of SOPs regarding HDs.

(*c*) The MTFs train HCWs in procedures for detecting the presence of HDs in their work area(s); the physical, health, and reproductive hazards of HDs in their work area(s); the engineering controls, administrative controls, safe-work practices, and PPE used to prevent exposure(s); the symptoms of exposure; the location of spill kits and emergency spill response procedures; and proper disposal of HD wastes. Workers receive specific training on the proper use of engineering controls such as CACIs, BSCs, clean-room technology, and closed-system-transfer devices (CSTDs) when used in the workplace.

(*d*) The HCWs who prepare compounded sterile products (CSPs) are trained in aseptic and negative pressure techniques for working with HDs.

## 4–4. Occupational health and safety consultation

*a.* The Occupational Health Section and/or Industrial Hygiene Section may be consulted for technical assistance on the occupational safety and health issues related to HDs.

*b.* The Occupational Health Section may also be contacted for technical assistance on medical surveillance and other medical-related issues involving HDs.

## 4–5. Recordkeeping

*a.* The HAZCOM and HD orientation and annual refresher training records are maintained for 3 years from the date of training.

*b*. The HD training records includes the following:

(1) Training date.

(2) Summary of the training session, such as a lesson plan or training outline.

(3) Name(s) and qualifications of the instructor(s).

(4) Names(s) and job title(s) of all HCWs attending the training session.

*c*. Competency assessments should be completed and documented in HCW's competency folders.

# CHAPTER 5

# HAZARDOUS DRUGS

## Section I
## Engineering Controls and Safety Equipment

### 5–1. Clean rooms, buffer areas, ante-areas, and negative pressure rooms

*a. Clean rooms and buffer areas.*

(1) Clean rooms and buffer areas are controlled areas where CACIs or BSCs are used for preparing CSPs.

(2) The USP General Chapter 797 provides the mandatory requirements for CSPs and addresses environmental design, quality, and control of the CSP preparation areas.

(3) Clean rooms and buffer areas used to prepare HD CSPs meet the following requirements:

*(a)* They are physically separated (walls, doors, and pass-throughs) from other non-hazardous preparation areas. Hazardous and non-hazardous compounding areas may share an anteroom.

*(b)* Air quality is at least International Organization of Standardization (ISO) Class 7 (ISO Class 7 is equivalent to 352,000 particles of 0.5 micrometer (μm) and larger per cubic meter ($m^3$) or 100,000 particles per cubic foot ($ft^3$). (See ISO Standard 14644-1.)

*(c)* Air pressure is negative (not less than 0.01-inch water column negative pressure) relative to the adjacent positive pressure ante-areas to allow inward airflow and contain any airborne HDs.

*(d)* The high-efficiency particulate air (HEPA) air is introduced at the ceiling and returns are mounted low on the wall, creating a general top-down dilution of area air.

*(e)* Room air changes are ≥ 30 room air changes per hour (ACH).

*b. Ante-areas.*

(1) Ante-areas are transition areas designed to maintain pressure relationships so that air flows from clean to dirty areas.

(2) Ante-areas are physically separated (walls, doors, and pass-throughs) from clean rooms and buffer areas.

(3) Air quality is at least ISO Class 7.

(4) Air pressure is positive relative to all adjacent areas, including the clean rooms and buffer areas. The buffer area or clean room should be negative in relation to the ante-area. A positive pressure differential of not less than 0.01-inch water column is required to allow air to flow inward from the ante-area to the buffer area or clean room. A positive pressure differential between the ante-areas and general pharmacy is not less than 0.02-inch water column.

(5) Room air changes are ≥ 30 room ACH. Industrial Hygiene evaluates ACH at least annually and documents the evaluation results in DOEHRS-IH.

*c. Negative pressure rooms.*

(1) The CACIs and BSCs used outside of a clean room or buffer area are placed in a negative pressure room that maintains a minimum negative pressure of 0.01-inch water column and the room air changes are ≥ 12 ACH.

(2) Use of a BSC or CACI located in a non-negative pressure room is acceptable when all of the following are met:

(*a*) The MTF prepares a low volume of HDs (≤ 5 per week).

(*b*) The CACI or BSC is vented 100 percent to the outside.

(*c*) A CSTD is used within the CACI or BSC.

(*d*) The room air changes are ≥ 12 ACH.

*d. Exhaust air*. One hundred percent of the air from the clean rooms, buffer areas, ante-areas, and negative pressure rooms is exhausted outdoors through a dedicated exhaust system.

*e*. *Room temperature and humidity control.* For the HCWs' comfort, temperatures within the clean rooms, buffer areas, and ante-areas are maintained at ≤ 68 degrees Fahrenheit (°F) year round. Relative humidity is maintained at 55 percent in the summer and 40 percent in the winter.

*f. Pressure differential monitoring.* Pressure indicators to monitor the pressure differentials or airflow and air conditioning and humidity controls must be in place. Trained HCWs document pressure differentials on a daily log at the beginning of every work shift or a continuous monitoring device records pressure differential.

*g. Certifying clean rooms and buffer rooms.* Qualified individuals certify clean rooms and buffer rooms according to the Controlling Environment Testing Association (CETA) Certification Guide for Sterile Compounding Facilities (CAG-003-2006, Revised January 2012). Certification occurs every 6 months and whenever the CACIs or BSCs are relocated, when the room is altered, or when major services are performed.

*h. Environmental sampling*.

(1) Trained industrial hygienists conduct surface-wipe sampling initially to: (1) establish a baseline that documents that work areas have been cleaned and results are comparable to what would be found in locations that have never had exposure to HDs and (2) detect uncontained HDs. Common HDs that can be assayed are cyclophosphamide, ifosfamide, methotrexate, and fluorouracil.

(2) Sampling locations include high or frequently contacted areas such as HD dispensation areas, the working areas (all horizontal and vertical spaces within the main chamber, except the plenums and diffusers) of the CACIs and BSCs, the floors directly under the working areas, the areas adjacent to the BSCs and CACIs, counter tops where finished HD CSPs are placed, and doorknobs. Appendix B provides more information on procedures for collecting and analyzing wipe samples.

(3) Whenever wipe-sample results show that measurable contamination above the baseline is present, the MTF identifies, documents, and contains the cause of the contamination.

(4) The presence of measureable HD contamination in wipe samples indicates poor work practices, malfunctioning controls, and/or inadequate cleaning of work surfaces. These results require supervisory oversight and more frequent worksite inspections as well as HCW retraining to reduce contamination levels to below detectable limits.

## 5–2. Compounding aseptic containment isolators

*a*. *System*. A CACI is a closed system made up of four solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed to provide cleanable surfaces with coving between all wall junctures. The air-handling system provides HEPA filtration of both inlet and exhaust air. Transfer of materials is accomplished through air locks, glove rings, or pass-through ports to minimize potential for HD CSP contamination. Manipulations can take place through either glove ports or half suits.

*b*. *Preparation of hazardous drugs*. The CACIs used for preparing HDs meet the following requirements:

(1) Air quality is at least ISO Class 5 (ISO Class 5 is equivalent to 3520 particles of 0.5 μm and larger) (per $m^3$ or 100 particles per $ft^3$) environment if used for sterile preparations. (See ISO Standard 14644-1.)

(2) Air pressure within the CACIs is negative relative to the surrounding space. Airflow within the CACIs is unidirectional.

(3) They are designed for asepsis, containment, and worker comfort (adjustable height, sized glove ports, and front view screens).

(4) Non-recirculating CACIs are used when compounding volatile HDs. The exhaust system is a dedicated exhaust system, directly vented to the outside and, thus, will not recirculate air back into the building or nearby buildings.

(5) They are equipped with a continuous monitoring device to allow confirmation of adequate airflow prior to each use.

*c*. *Exhaust systems*.

(1) Exhaust is HEPA-filtered and exhausted 100 percent to the outside.

(2) Exhaust systems are equipped with a direct-drive motor to avoid failure due to belt slipping, stretching, or breaking.

(3) Fan placement is downstream of the HEPA filter so that contaminated ducts are maintained under negative pressure.

(4) The exhaust system does not recirculate air back into the building or nearby buildings.

(5) Blowers are operated continuously during HD preparation. Fans and exhaust blowers are connected to the MTF's emergency power supply to maintain critical operations during a power outage.

*d*. *Placement*. The CACIs are located out of traffic patterns and away from room air currents that could disrupt airflow patterns.

*e*. *Maintenance*.

(1) The CACIs are maintained according to the manufacturer's instructions and certified by qualified individuals according to Compounding Isolator Testing Guide, CETA CAG-002-2006, revised December 2008 and Unidirectional Flow Clean Air Devices, Institute of Environmental Sciences and Technology (IEST) RP CC002.3-2009. Certification occurs upon initial installation, every 6 months thereafter, and whenever the CACI is moved or repaired and HEPA filters are replaced.

(2) Trained personnel clean and decontaminate the CACIs before maintenance personnel begin carrying out any maintenance or repairs.

(3) Maintenance personnel—

(*a*) Presume that all internal components of the CACIs are contaminated with HDs.

(*b*) Wear PPE described in chapter 5, section III, to include gloves, gown, respirator and a plastic face shield or splash goggles.

(*c*) Expose only those hand tools and materials necessary to complete repairs, maintenance, or certifications; avoid using power tools since these tools may not be easily decontaminated.

(*d*) Receive information and training as discussed in chapter 3.

(*e*) Change HEPA filters when they restrict airflow using a "bag-in-bag-out" type filter, and dispose of filters as a HD waste; if the HD is a Resource Conservation Recovery Act (RCRA) HW, dispose of filters as a HW as described in paragraph 5-19.

(*f*) Decontaminate and bag any equipment or parts removed for replacement/repair before removing them from the work area.

(*g*) Decontaminate hand tools and equipment with an appropriate decontamination solution. Place any tools, equipment, and parts that cannot be decontaminated in sealed, ≥ 4-mil, disposable, plastic bags before removing them from the work area.

(4) Post the following information on the front of the CACIs in a location visible to the user:

(*a*) Date tested.

(*b*) Reference report number.

(*c*) Due for retest date (month and year).

(*d*) Tested by (Name printed) and (signature).

(*e*) Notice of pass/failure of the Preparation Ingress and Egress Test.

(*f*) Whether or not the CACI is designed for use with volatile HDs, toxic, flammable, or explosive materials.

(*g*) Results of the Recovery Time Determination Test.

*f. Surface decontamination*.

(1) Work area supervisors establish cleaning schedules according to the CACI manufacturer's instructions and the USP 797 requirements for compounding CSPs. The HCWs always decontaminate CACIs before the CACIs are moved, serviced, or certified and whenever a spill occurs.

(2) Trained HCWs—

(*a*) Don PPE as described in paragraphs 5–20, 5–21, 5–22, and 5–23 as appropriate.

(*b*) Decontaminate surfaces from the least to the most contaminated areas.

(*c*) Use detergent, sodium hypochlorite, and a neutralizer or use a deactivating agent recommended by the drug manufacturer to decontaminate the potentially contaminated surfaces at the end of the batch, shift, or day.

(*d*) Thoroughly clean and rinse surfaces with sterile water at least twice before disinfecting surfaces with a disinfectant approved by the Infection Control Committee.

(*e*) Decontaminate the gloves of the fixed-glove assembly before the first batch or preparation of the day and after each batch. Use sodium hypochlorite and a neutralizer and then wipe off gloves with gauze moistened with sterile water.

(*f*) Dispose materials used during decontamination as a HD waste, or if the HD is a RCRA-HW, dispose as a HW as described in paragraph 5–19.

(*g*) Maintain a log to document when decontamination is completed.

## 5–3. Biological safety cabinets

*a. Class I.* Use of Class I BSCs (figure 5–1) is unacceptable for sterile HD preparations because unfiltered air continually enters through the cabinet front and flows across the work surface which can contaminate the preparations.

*b. Class II and Class III BSCs.* Properly installed and maintained Class II and Class III BSCs that meet the current National Sanitation Foundation (NSF® is a registered trademark of the National Sanitation Foundation) International Standard 49 may be used to protect workers when working with HDs because the—

(1) Inward airflow into the BSC's front grill protects the HCW.

(2) Downward laminar flow of HEPA-filtered air within the BSC protects the compounded drug.

(3) HEPA filters installed in the exhaust ducts protect the environment from particulates.

*c. Class II, BSCs.* Class II BSCs have an open front, an inward air flow with downward HEPA-filtered laminar air flow, and HEPA-filtered exhaust. Class II BSCs are classified according to the venting of the exhaust air. There are four types of Class II BSCs: A1 (formerly designated as Type A), A2 (formerly designated as Type A/B3), B1, and B2.

(1) Class II, Type A1, BSCs (figure 5–2). Class II, Type A1, BSCs produce a minimum average inflow air velocity of 75 feet per minute (fpm) at the face opening of the cabinet. Room air is drawn in through the sash opening, and HEPA-filtered air flows down through the work area. Both bodies of air are mixed and drawn into the BSC's blowers located under the work area. About 30 percent of the air flows out of the cabinet via an exhaust HEPA filter, and the remaining 70 percent of the air is recirculated through the supply HEPA filter before flowing down through the work area. To avoid disturbing the balance of the cabinet by fluctuations in the building exhaust system, the Class II, Types A1 and A2, BSCs are connected to the building exhaust system by means of a canopy (thimble) unit (figure 5–4) when used to prepare HDs. The canopy unit is designed to allow for proper certification of the cabinet (that is, provide access to permit scan testing of the HEPA filter). All contaminated ducts and plenums are under negative pressure or surrounded by negative pressure ducts and plenums.

(2) Class II, Type A2, BSCs (figure 5–3). The difference between the Type A1 and A2 cabinets is that the A2 produces an average minimum air-inflow velocity of 100 fpm at the face opening of the cabinet.

(3) Class II, Type B1, BSCs (figure 5–5). Class II, Type B1, BSCs produces a minimum average inflow air velocity of 100 fpm at the face opening of the cabinet. Room air is drawn in through the sash opening, HEPA filtered, and then drawn to the top of the cabinet where about 30 percent of the air is HEPA-filtered a second time before it flows down through the work area. The remaining 70 percent of the air is exhausted to the outside through an exhaust HEPA filter and dedicated exhaust duct. All contaminated ducts and plenums are under negative pressure or surrounded by negative pressure ducts and plenums.

(4) Class II, B2, BSCs (figure 5–6). The difference between the B1 and B2, BSCs is that 100 percent of the air in the Type B2 cabinet is exhausted to the outside without recirculation. The Class II, B2, BSC is the best choice when working with HDs because air is not recirculated onto the work surface.

*d. Class III BSCs*. Class III BSCs (figure 5–7) are totally enclosed and gas-tight with HEPA-filtered supply and exhaust air. Work is performed with attached long-sleeved gloves. Class III BSCs are primarily designed for work with biosafety level 4 microbiological agents and are rarely used in hospital pharmacies.

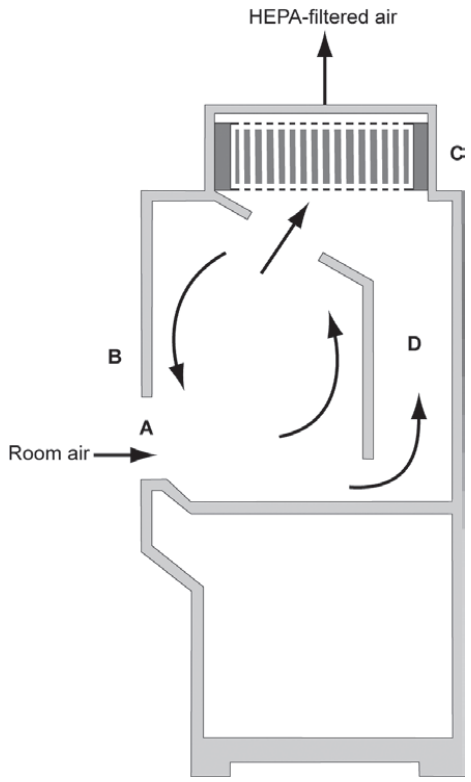



***Figure 5–1. Class I biological safety cabinet***
*(source: U.S. Department of Health and Human Services (DHHS), 2009 Biosafety in Microbiological and Biomedical Laboratories (BMBL) U.S. Department of Health and Human Services Public Health Service Centers for Disease Control and Prevention and National Institutes of Health Fifth Edition 2009 U.S. Government Printing Office)*

Legend:
A. Front Opening
B. Sash
C. Exhaust HEPA Filter
D. Exhaust Plenum

Note: Toxic vapors must be exhausted to the outdoors (per the BMBL) and not reconditioned/ recirculated within the building.

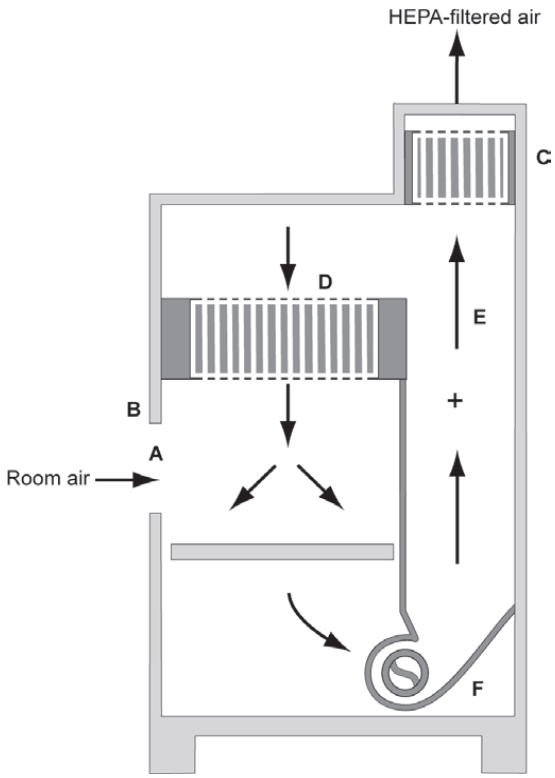



***Figure 5–2. Class II, type A1, biological safety cabinet (source: DHHS 2009)***

Legend:
- A. Front Opening
- B. Sash
- C. Exhaust HEPA Filter
- D. Supply HEPA Filter
- E. Common Plenum
- F. Blower

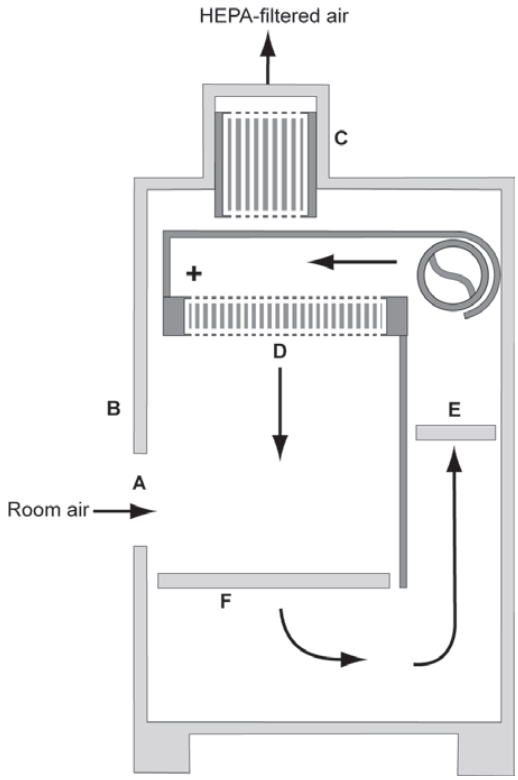



***Figure 5–3. Class II, type A2, biological safety cabinet (source: DHHS 2009)***

Legend:
- A. Front Opening
- B. Sash
- C. Exhaust HEPA Filter
- D. Supply HEPA Filter
- E. Positive Pressure Common Plenum
- F. Negative Pressure Common Plenum

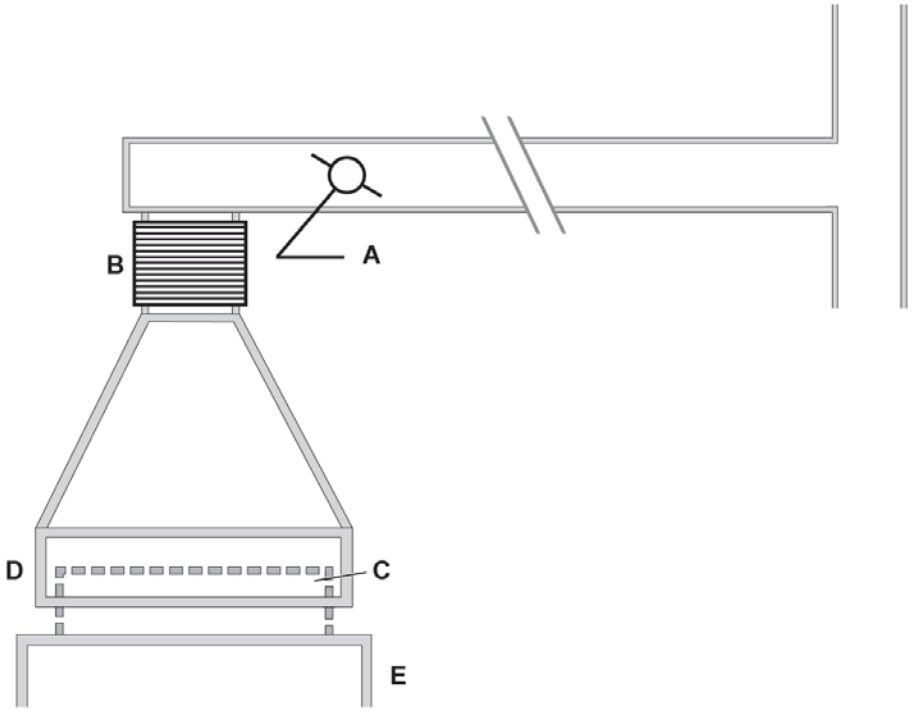



***Figure 5–4. Canopy (Thimble) Unit for Ducting Class II, Type A1 and A2, biological safety cabinets***
***(source: DHHS 2009)***

Legend:

A. Balancing Damper
B. Flexible Connector to Exhaust System
C. Cabinet Exhaust HEPA Filter Housing
D. Canopy Unit
E. BSC

Note: there is a 1-inch gap between the canopy unity (D) and the exhaust filter housing (C) through which room air is exhausted.

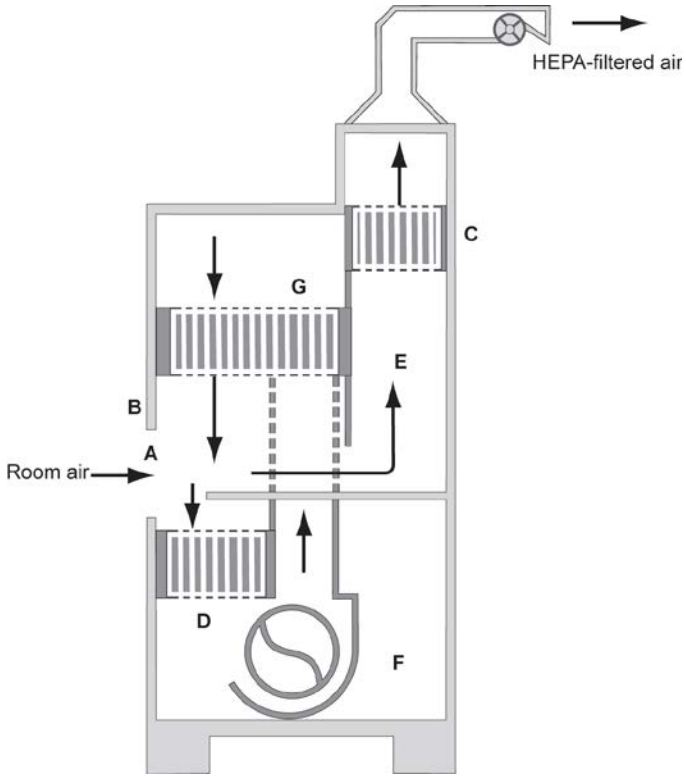



***Figure 5–5. Class II, type B1, biological safety cabinet (source: DHHS 2009)***

Legend:

A. Front Opening
B. Sash
C. Exhaust HEPA Filter
D. Supply HEPA Filter
E. Negative Pressure Dedicated Exhaust Plenum
F. Blower
G. Additional HEPA Filter for Supply Air

Note: The BSC needs to be hard connected to the building exhaust system.

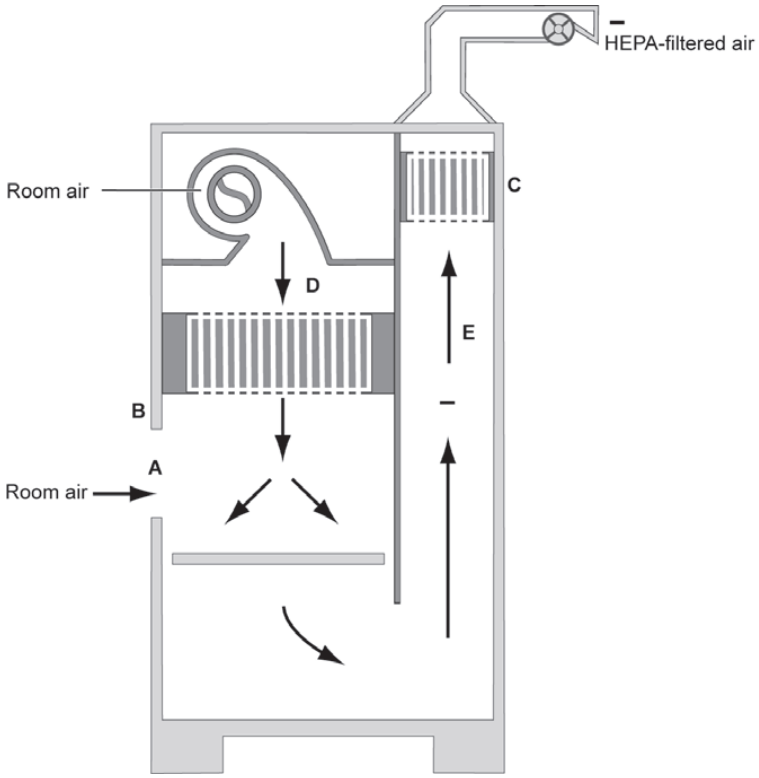



***Figure 5–6. Class II, type B2, biological safety cabinet (source: DHHS 2009)***

Legend:
A. Front Opening
B. Sash
C. Exhaust HEPA Filter
D. Supply HEPA Filter
E. Negative Pressure Exhaust Plenum

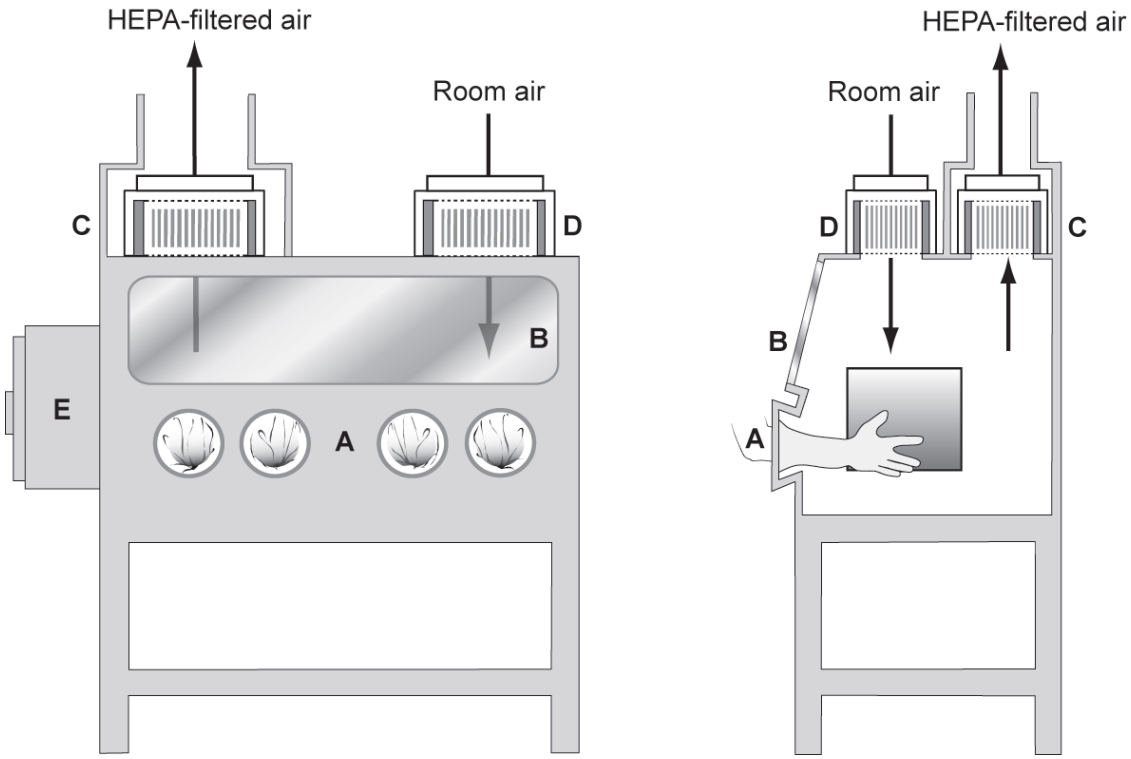



***Figure 5–7. Class III biological safety cabinet***
***(Source: DHHS 2009)***

Legend:
A. Glove Ports with O-Ring For Attaching Arm-Length Gloves to Cabinet
B. Sash
C. Exhaust HEPA Filter
D. Supply HEPA Filter
E. Double-Ended Autoclave or Pass-Through Box

(1) Regardless of type BSC used, each cabinet is equipped with a continuous monitoring device to allow confirmation of adequate air flow before each use.

(2) Air quality must be at least ISO Class 5 environment if used for CSPs.

*e. Exhaust systems*.

(1) If possible, keep the BSC's exhaust fan on at all times (24 hours a day, 7 days a week).

(2) If the exhaust fan must be turned off, decontaminate the BSC before reuse. Also, let the fan operate 3 to 5 minutes (30 minutes when compounding sterile preparations) before beginning work to allow the BSC to purge any particulates present inside the BSC.

(3) When separate fans are used for recirculated and exhaust air, the fans must be interlocked so that—

(*a*) If the exhaust fan fails, the supply fan shuts off and triggers an alarm.

(*b*) If the supply fan fails, the exhaust fan must continue to operate after the alarm sounds.

(4) If the BSC is exhausted by a remote blower, the unit is equipped with a sensor, an audible alarm, and a warning light to indicate when the remote blower is nonoperational.

(5) Fans and exhaust blowers are connected to the MTF's emergency power supply to maintain critical operations during a power outage.

(6) If the BSC is vented to the outside—

(*a*) Discharge the exhaust air at an appropriate height, with a minimum stack height of 10 feet.

(*b*) Prohibit rain caps and other obstructions on the exhaust ducts.

(*c*) Direct the airflow away from air-intake units.

(*d*) Provide a stack velocity of approximately 3000 fpm.

*f. Placement*.

(1) BSCs are located according to NIH Guidelines: "Biosafety Cabinet (BSC) Placement Requirements for new Buildings and Renovations." (See NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (Appendix I.))

(2) BSCs are located in the rear of the room away from entrances, traffic, open windows, air supply registers, and laboratory equipment that create air movement. The BSCs used for preparing HD CSPs are installed within a buffer area or clean room with ISO Class 7 air quality.

(3) If possible, maintain a 12-inch clearance behind and on each side of the BSC to allow easy access for maintenance. A 12- to 14-inch clearance may be required above the BSC to allow accurate air-velocity measurement across the exhaust filter surface.

*g. Maintenance*.

(1) Follow the manufacturer's instructions and the specifications listed in the NSF International Standard 49 and Unidirectional Flow Clean Air Devices, IEST RP 002-2009 for maintaining and evaluating BSCs. The BSCs are certified only by qualified technicians who are trained in BSC design theory. Certifications occur upon initial installation, every 6 months thereafter, and whenever the BSC is moved or repaired and HEPA filters are replaced.

(2) Certified maintenance workers who maintain BSCs used for HD preparation should—

(*a*) Presume that all internal components of the BSCs are contaminated with HDs.

(*b*) Wear PPE described in chapter 5, section III, to include gloves, gown, respirator, and a plastic face shield or splash goggles.

(*c*) Expose only those hand tools and materials necessary to complete repairs, maintenance, or certifications, and avoid using power tools since these tools may not be easily decontaminated.

(*d*) Change HEPA filters when they restrict airflow. After placing a "DO NOT USE—CONTAMINATED" label on the BSC, maintenance workers change the filter using a "bag-in-bag-out" type filter, and dispose of filters as a HD waste; or if the HD is a RCRA-HW, dispose of filters as a HW as described in paragraph 5–19.

(*e*) Decontaminate and bag any equipment or parts removed for replacement or repair before removing them from the work area.

(*f*) Decontaminate hand tools and equipment with an appropriate decontamination solution. Place any tools, equipment, and parts that cannot be decontaminated in sealed, ≥ 4-mil, disposable, plastic bags before removing them from the work area.

*h. Cleaning and disinfecting*.

(1) Work area supervisors establish a cleaning schedule according to the BSC manufacturer's instructions and the USP 797 requirements for compounding CSPs. The HCWs always decontaminate BSCs before the BSCs are moved, serviced, or certified and whenever a spill occurs.

(2) Trained HCWs—

(*a*) Decontaminate the BSC at least weekly and anytime a spill occurs, before and after maintenance and certification, and anytime the device is moved.

(*b*) Don PPE as described in paragraphs 5–20, 5–21, 5–22, and 5–23. Keep the exhaust fan/blower on and the sash down during decontamination.

(*c*) Decontaminate surfaces from the least to the most contaminated areas.

(*d*) Use detergent and sodium hypochlorite and a neutralizer or use a deactivating agent recommended by the drug manufacturer to clean the potentially contaminated surfaces at the end of the batch, shift, or day.

(*e*) Apply the cleaning and decontamination solutions to a disposable wipe to avoid damaging the HEPA filter.

(*f*) Lift and clean the back and sump located under the removable work trays. Clean the drain spillage area at least twice, since it may be heavily contaminated.

(*g*) Thoroughly clean and rinse surfaces with sterile water at least twice, before disinfecting surfaces with a disinfectant approved by the Infection Control Committee.

(*h*) Discard materials used during decontamination as a HD waste, or if the HD is a RCRA-HW, dispose as a HW as described in paragraph 5–19.

(*i*) Maintain a log to document when weekly decontamination is completed.

## 5–4. Sinks

*a*. Install a sink for hand washing near the HD preparation area, (such as, in the anteroom). Sinks should have hot and cold running water and hands-free faucets. Stock plenty of disposable towels and soap near the sink.

*b*. Require HCWs to wash their hands before gloving, after removing gloves, and before leaving the preparation area.

### 5–5. Emergency eyewash stations

*a.* Install a stand-alone, plumbed emergency eyewash station, complying with the American National Standards Institute (ANSI) Z358.1–2009, in an accessible location that requires no more than 10 seconds to reach from the preparation area. The path of travel between the preparation area and the emergency eyewash station must be free of obstructions.

*b*. The HCWs should activate the device at least weekly and let the water run for at least 3 minutes to ensure proper operation and to flush stagnant water from the water supply lines. In addition, the device must be inspected annually to verify that it is operational, meets ANSI Z358.1-2009 requirements, and that it is installed according to the manufacturer's instructions. All tests and inspections are documented.

## Section II
## Safe-Work Practices

### 5–6. Introduction

*a*. Allow only trained and competent HCWs to prepare HDs.

*b*. Prepare HDs in one restricted, centralized area within the pharmacy. Use a designated CACI or BSC when preparing HDs.

*c.* Request the drug manufacturer/distributor to provide a SDS when it is not received with the initial shipment.

*d*. Minimize the number of HCWs working with HDs, and limit access to HD storage and preparation areas to authorized personnel.

*e*. Secure areas used to store HD-contaminated equipment, waste, and linen to prevent unauthorized access.

*f*. Post the HD storage and preparation areas with—

(1) A large warning sign bearing the legend—

| **"**CAUTION: RESTRICTED ACCESS—AUTHORIZED PERSONNEL ONLY" |
|---|

(2) A list of all HDs covered by the MTF's HDSHP.

(3) A sign detailing procedures for reporting spills, as well as procedures for providing first-aid after accidental skin and eye contact.

*g*. Keep SDSs, spill cleanup procedures, and a HD spill kit as described in paragraph 5–18, as well as waste disposal materials in a readily accessible location in or near the receiving, storage, preparation, and HD dispensation/treatment areas.

*h.* Prohibit eating, drinking, smoking, chewing gum or tobacco, applying cosmetics, or storing food in or near the HD receiving, storage, preparation, and dispensation areas. In addition, staff is prohibited from eating, drinking, smoking, chewing gum or tobacco, applying cosmetics, or storing food in adjacent office spaces near these areas due to potential for HD contamination. Appropriate signs are posted to warn HCWs of prohibited practices.

*i.* Signs are prominently displayed and designed to alert HCWs of regulated areas, restricted access, and required PPE.

(1) *Designated work areas*. All areas handling HDs are posted with appropriate warning signage at the entrance—

> "WARNING:
> Hazardous Drug Handling Area, Restricted Access,
> Authorized Personnel Only"

(2) *Personal protective equipment*. All areas requiring HD-specific PPE have signage posted at the entrance—

> "WARNING:
> Chemotherapy Double Gloves, Gown, Eye Protection and
> Shoe Covers Required for Entry when
> Compounding Hazardous Drugs"

(3) *Work practices*. All areas handling HDs or potentially contaminated with HDs have appropriate signage posted—

> "WARNING:
> Hazardous Drug Handling Area
> Eating, Drinking, Smoking, Chewing Gum or Tobacco,
> Or Applying Cosmetics is Prohibited"

(4) *Engineering controls*. All engineering controls such as CACIs and BSCs used for handling HDs are labeled with the following signage—

> "WARNING:
> Potentially Contaminated with Hazardous Drugs,
> Use Appropriate PPE and Work Practices"

(5) *Storage areas*. All areas storing HDs are posted with appropriate signage—

> "WARNING:
> Hazardous Drug Storage Area,
> Authorized Access Only"

(6) *Spill areas*. Whenever HDs are spilled, the area is portioned off and access restricted. A temporary warning sign is posted at the perimeter until the clean-up is complete—

| |
|---|
| "WARNING:<br>Restricted Access<br>Hazardous Drug Spill" |

**5–7. Receiving, storing, and handling hazardous drugs**

*a*. Wear two pairs of chemotherapy gloves, a gown, and eye protection as described in paragraphs 5–20, 5–21, and 5–23 when receiving, unpacking, stocking and inventorying HDs since the outside of the packages may be contaminated. Change gloves at least every 30 minutes, and immediately change gloves or gowns if they become damaged or contaminated with HDs.

*b*. Verify that all incoming HD containers are clearly labeled with the identity of the hazardous drug, appropriate hazard warnings, and name and address of the drug manufacturer.

*c*. Visually inspect packages for signs of damage.

*d*. Use caution when handling damaged HD containers.

(1) Wear two pairs of chemotherapy gloves and gown as described in paragraphs 5–20 and 5–21. Wear a respirator as described in paragraph 5–22 when there is potential for exposure to airborne HDs.

(2) Isolate the damaged HD container, and leave it unopened.

(3) Place the damaged HD container into a closeable, leak-proof, HD waste container.

(4) Place a hazardous waste warning label on the HD waste container if the HD is a RCRA-HW (see table 5–2).

(5) Transport the closed waste container to a designated HD waste collection area.

(6) Remove outer gloves first, then the gown, and then the inner gloves and place them in a HD waste container. Wash hands with soap and water after removing gloves.

(7) Notify the shipper immediately.

*e.* Decontaminate all HD containers with wipes that have been sprayed with alcohol or pre-moistened towelettes (such as Wet-Ones®) prior to placing the vials in storage. Do not spray alcohol directly on to the vials to avoid damaging the labels. (Wet Ones® is a registered trademark of Energizer Battery Company, Inc.)

*f.* Transport HDs to administration areas in a manner that will prevent damage and protect the drug, HCWs, and the environment from contamination.

(1) Never use a pneumatic tube system to transport HDs.

(2) Package final HD containers in labeled, sealed, leak-proof secondary containers that protect the HD from breakage and contain leakage if breakage occurs. The warning label on the containers should bear the legend—

| |
|---|
| "CAUTION:<br>HAZARDOUS DRUG.<br>HANDLE WITH GLOVES.<br>DISPOSE OF PROPERLY." |

(3) Train HCWs who transport HDs how to—

(*a*) Recognize HD warning labels.

(*b*) Control and report spills.

(*c*) Access PPE and a HD spill kit.

(*d*) Deliver HDs directly to the administration areas via designated routes.

*g*. Store HDs separately from other medications in a manner to prevent contamination of work surfaces and exposure to workers.

(1) Verify that the storage room is under negative pressure and that the general exhaust ventilation provides at least 12 air changes per hour to dilute and remove any airborne contaminants. In lieu of separate storage rooms, anterooms serving clean rooms used to prepare HDs may be used for storing the HDs. Note: Buffer areas and clean rooms used to compound HDs should be under negative pressure in relation to the anterooms.

(2) Label the shelves and bins where HD containers are permanently stored with a HD hazard warning sign.

(3) Prevent HD containers from falling off shelves by installing guards on storage shelves and arranging containers neatly on the shelves or in bins.

**5–8. Preparing hazardous drugs in compounding aseptic containment isolators**

Use aseptic techniques with the following safe-work practices when preparing HD CSPs:

*a*. Check labels and complete calculations before accessing the CACI.

*b.* Don two pairs of gloves and a gown as described in paragraphs 5–20 and 5–21. Change gloves at least every 30 minutes, and immediately change gloves or gowns if they become damaged/contaminated with HDs.

*c.* Verify that the CACI is working properly, and notify the proper authorities (such as, logistics or biomedical maintenance) when the CACI is not working properly.

*d.* Inspect the gauges, and verify that the CACI is ready for use. If the CACI was turned off, allow the blower to run for the time specified by the manufacturer before beginning work.

*e*. Inspect the fixed-glove and sleeve assemblies for tears or damage. Follow the manufacturer's instructions, and replace damaged gloves and sleeves before beginning work. Make sure that the connections between the gloves, sleeves, and CACI are intact.

*f*. Gather all items (HD vials and supplies) before beginning work. Before placing the HD vials in the CACI's pass-through, wipe them down with moist gauze to remove any drug residue. Discard the gauze in an HD waste container.

*g.* Wear at least one pair of fresh gloves inside the CACI's glove assembly and a gown as described in paragraphs 5–20 and 5–21.

*h.* Place only those items needed to compound the dose or batch in the isolator. Never place transport bags in the main chamber of the CACI during compounding.

*i.* After compounding the dose or batch, decontaminate the fixed-glove assembly, don fresh gloves, decontaminate the outer surfaces of the prepared drug containers, affix labels to the container, and then place the container into the CACI's pass-through ports.

*j.* Label all prepared drug containers with patient-specific data and a warning label bearing the legend—

| |
|---|
| **"**CAUTION: HAZARDOUS DRUG<br>HANDLE WITH GLOVES<br>SPECIAL HANDLING/DISPOSAL PRECAUTIONS" |

*k.* Don fresh gloves, and place the securely sealed, capped, or clamped-prepared drug containers in sealable bags or leak-proof, secondary containers for transport. Whenever possible, use clear bags or transport containers so that before administration, doses can be verified without removing the contents from the bags or transport containers.

*l.* Discard used syringes and needles in a puncture-resistant HD waste container to avoid drug aerosolization and needle-stick injuries. Never crush, clip, or recap needles or syringes before disposal. Place HD-contaminated waste into a sealable container before removing it from the CACI.

*m.* Remove outer gloves first, then the gown, and then the inner gloves and place them in the HD waste container.

*n.* Always wash hands before donning and after removing gloves and before leaving the preparation area.

*o.* Decontaminate all work surfaces of the CACI according to paragraph 5–2.

*p*. When reusable protective goggles and face-shields are worn, clean them with detergent, and rinse them with clean water. Store reusable PPE in a manner which preserves its cleanliness and functionality.

### 5–9. Preparing hazardous drugs in biological safety cabinets

Use aseptic techniques with the following safe-work practices when compounding sterile HD preparations:

*a.* Check labels, and complete calculations before accessing the BSC.

*b.* Before using any chemical in the BSC, consult its SDS for reactivity, corrosivity, and flammability. Check the BSC user's manual for restrictions on the use of flammable liquids and other chemicals inside the unit. Some BSCs are not intrinsically safe and may present a fire or explosion hazard when certain chemicals are used within the unit.

*c.* Don two pairs of gloves and a gown as described in paragraphs 5–20 and 5–21. Change gloves at least every 30 minutes and immediately change gloves or gowns if they become damaged or contaminated with HDs.

*d*. Verify that the BSC is working properly, and notify the proper authorities (such as, logistics or biomedical maintenance) when the BSC is not working properly.

*e*. Position the moveable sash at the designated height to ensure sufficient airflow and to allow comfortable access to the work surface inside the BSC.

*f.* Adjust stool height so that workers' faces are above the front opening of the BSC.

*g.* Gather all items (HD vials and supplies) before beginning work. Wipe down HD vials with moist gauze to remove any drug residue before disinfecting them and placing them in the BSC.

*h.* Place only the necessary drugs and supplies inside the BSC before beginning work to minimize disturbance of the laminar airflow. Never place transport bags in the BSC during compounding.

*i.* Delay beginning work for about 1 minute after placing hands and arms inside the BSC to allow the BSC to stabilize and to remove surface microbial contaminants from the hands and arms.

*j.* Keep the front and back grills free of obstructions. Perform manipulations at least 4 inches behind the front grill and by keeping arms slightly raised above the grill.

*k.* Move arms in and out slowly and perpendicular to the front opening to avoid disrupting the cabinet air barrier.

*l.* Immediately place used syringes and needles in a puncture-resistant HD waste container for disposal to avoid drug aerosolization and needle-stick injuries. Never crush, clip, or recap needles or syringes before disposal.

*m.* Don fresh gloves and decontaminate the outer surfaces of the prepared drug container with moist gauze, and affix the label.

*n.* Label all prepared drug containers with patient-specific data and a warning label bearing the legend–

| |
|---|
| **"**CAUTION: HAZARDOUS DRUG<br>HANDLE WITH GLOVES<br>SPECIAL HANDLING/DISPOSAL PRECAUTIONS" |

*o.* Don fresh gloves, and place the securely sealed, capped, or clamped-prepared drug containers inside a plastic bag or a leak-proof, secondary container for transport. Whenever possible, use clear bags or transport containers so that before administration, doses can be verified without removing the contents from the bag or transport container.

*p.* Place contaminated materials, including used gauze and alcohol wipes, in a HD waste container. Remove outer gloves first, then the gown, and then the inner gloves and place them in the HD waste container.

*q.* Always wash hands before donning and after removing gloves and before leaving the preparation area.

*r.* Decontaminate all work surfaces of the BSC according to paragraph 5–3h.

*s.* When worn, clean reusable protective goggles and face-shields with detergent, and rinse them with clean water. Store reusable PPE in a manner which preserves its cleanliness and functionality.

### 5–10. Closed-system transfer devices

A CSTD is a drug transfer device and a mechanically closed system that prohibits the escape of HD or HD vapor concentrations outside the system and prohibits the transfer of environmental contaminants into the device.

*a*. Use CSTDs when transferring HDs from vials to dosing equipment (infusion, bags, bottles, or pumps) to limit aerosol generation and exposing HCWs to sharps.

*b*. Always attach CSTDs to the final HD containers within a CACI or BSC.

**5–11. Syringes and intravenous (IV) sets**

*a*. If possible, standardize IV equipment with equipment used in the HD administration areas.

*b.* Whenever possible, use needleless systems and sharps with engineered sharps injury protection. Note: Pharmacy has an exemption from using needleless systems when preparing HDs.

*c*. Use Luer-Lock® fittings for needleless systems, syringes, needles, infusion tubing, and pumps since these fittings are less likely to separate during use. (Luer-Lock® is a registered trademark of Becton Dickinson.)

*d*. Attach and prime appropriate IV sets to the final containers within a BSC or a CACI before adding the HDs. An alternative is to use a CSTD to achieve a dry connection between the administration set and the final container; this allows the container to be spiked with a secondary IV set and the set to be primed by backflow from the primary nonhazardous solution.

*e*. Select appropriate syringes for the dose, and fill the syringes no more than three-fourths full.

*f.* Never transport HD-filled syringes with needles attached.

*g.* Discard IV bags with tubing intact whenever possible; thoroughly flush tubing with a non-toxic solution before disconnecting tubing at other points in the system.

**5–12. Vials**

Use the following precautions when withdrawing HDs from vials:

*a*. Use a CSTD when transferring HDs from a vial to administration equipment. If a CSTD is not available, use a venting device (such as hydrophobic filter needle) or use the negative-pressure technique to withdraw HDs from vials.

*b*. Discard empty vials with the CSTDs and venting devices intact.

*c*. Measure the exact volume of HD needed while the needle is in the vial. Any excess drug should remain in the vial.

**5–13. Ampules**

Use the following precautions when withdrawing HDs from ampoules:

*a*. Gently tap down any material from the neck and top portion of the ampule. Use an ampule breaker or wrap-sterile gauze around the neck of the ampule while breaking it to prevent cuts and to capture any spillage.

*b*. Use a filtering device when withdrawing the HD to prevent glass particles from being drawn into the syringe.

*c*. Eject any air and excess HD into a sterile vial.

### 5–14. Solid hazardous drugs

Use the following precautions when handling solid HDs:

*a*. Whenever possible, purchase capsules and tablets packed in individual doses to allow patients to self-administer.

*b.* Wear two pairs of gloves as described in paragraph 5–20.

*c*. Examine HD containers before opening them to detect broken tablets or capsules. If some of the tablets or capsules are broken, carefully remove the desired quantity of the product, keeping any powders in the original container. If too many of the tablets or capsules are broken, return the unopened container to the manufacturer.

*d*. Handle gel capsules and coated tablets with care to prevent breakage. Count coated tablets and gel capsules in a designated HD area away from the main work area, which has minimal air movement (such as, away from open doors and windows or foot traffic). If there is any possibility that dusts will be generated during the counting process, use a CACI or a BSC designated for HDs.

*e*. Avoid using automated pill- or capsule-counting machines unless the process is enclosed to contain any aerosols and dusts that may be generated during the counting process.

*f.* Use clean-counting equipment dedicated for use with HDs.

*g*. Following the counting procedure, wipe equipment with gauze saturated with sterile water; decontaminate the equipment with detergent, sodium hypochlorite, and neutralizer; then rinse the equipment with water.

*h.* Discard materials used during decontamination and any dropped tablets as a HD waste; if the HD is a RCRA-HW, dispose as a HW as described in paragraph 5–19.

### 5–15. Administering hazardous drugs

*a. Dispensing/treatment areas*. Whenever possible, centralize dispensing areas on inpatient wards and outpatient clinics to ensure the safe handling and disposal of all HDs.

*b. Dispensing/treatment area equipment*. Equip dispensing areas with the following equipment and supplies:

(1) The PPE.
(2) Disposable, plastic-backed, absorbent liners, and gauze for cleanup.
(3) Sterile gauze pads, tape, and alcohol swabs.
(4) Leak-proof linen bags and appropriate warning labels.
(5) An HD spill kit as described in paragraph 5–18.
(6) A puncture-resistant HD waste container.
(7) A hand-washing sink as described in paragraph 5–4.
(8) Emergency eyewash equipment as described in paragraph 5–5.

*c*. *Posting procedures in administration area*. In the dispensing area, post a sign detailing procedures for cleaning up and reporting spills as well as procedures for providing first-aid after accidental skin and eye contact.

*d. Dispensing hazardous drugs*. Only HCWs having specialized knowledge and skills and who demonstrate competency in HD administration shall dispense HDs.

(1) *General*.

(*a*) Assemble all necessary equipment and supplies including PPE.

(*b*) Don PPE before removing the HD from the transport bag. Wear two pairs of gloves, a gown, and eye and face protection (when there is potential for splashing) as described in paragraphs 5–20, 5–21, and 5–23.

(*c*) Change gloves at least every 30 minutes; immediately change gloves or gowns if they become damaged or contaminated with HDs.

(*d*) Perform all work below eye level.

(*e*) Use needleless systems and sharps with engineered sharps injury protection, and use Luer-Lock fittings for needleless systems, syringes, needles, infusion tubing, and pumps.

(*f*) Visually inspect sealed bags and final containers used to transport HDs; do not open them if visible leakage is present. Report the leakage to the pharmacy.

(*g*) Remove disposable PPE before leaving the administration unit. Remove outer gloves first, then the gown, and then the inner gloves.

(*h*) Always wash hands before donning and after removing gloves as well as before leaving the dispensing area.

(*i*) Use HD waste containers that are sufficiently large to hold all discarded material, including PPE. Never push/force materials in the HD waste container.

(*j*) Place linen contaminated with HDs or body fluids from patients having received HDs within the last 48 hours into a specially marked laundry bag, which is then placed in a labeled (biohazard symbol or color-coded) impervious bag.

(*k*) Manage unused HDs intended for disposal as described in paragraph 5–19.

(*l*) Wash surfaces that come into contact with HDs with detergent, sodium hypochlorite solution, and a neutralizer or use a deactivating agent recommended by the drug manufacturer.

(*m*) Clean reusable protective goggles and face-shields with detergent, and rinse them with clean water. Store reusable PPE in a manner that preserves its cleanliness and functionality.

(2) *Intravenous infusions*.

(*a*) Securely attach the IV tubing to the patient's venous access device or, if using a secondary set, to the primary tubing.

(*b*) Place a disposable, plastic-backed absorbent liner under the connection site.

(*c*) Place a gauze pad under the connection at injection ports during administration to catch leaks.

(*d*) Discard the final containers with the administration sets intact in a puncture-resistant HD waste container.

(3) *Intravenous injections*.

(*a*) Place a disposable, plastic-backed absorbent liner under the patient's arm.

(*b*) Remove the syringe cap, and attach the appropriate safety needle.

(*c*) Do not expel air from the syringe or prime the safety needle.

(*d*) Wrap sterile gauze around injection ports during IV push procedures to reduce the potential for spraying the HD when attaching or removing the syringe.

(*e*) Discard the needles and syringes directly into a puncture-resistant HD waste container.

(4) *Oral hazardous drugs.*

(*a*) Open packaging carefully, and avoid touching the tablet or capsule. Place the HD directly into a medicine cup for administration. Discard disposable items in an HD waste container as described in paragraph 5–19.

(*b*) Perform any manipulation of oral drugs (such as crushing, breaking, or mixing tablets with food or fluids) in a BSC or CACI designed for HD preparation.

(5) *Topical applications*. Cover all topical applications (creams and lotions) with bandages to protect clothing and linen.

**5−16. Housekeeping**

*a*. Wear two pairs of gloves and a gown as described in paragraphs 5–20 and 5–21 when handling linen and cleaning equipment and surfaces contaminated with urine, blood, feces, vomit, and other body fluids or from patients who have received HDs in the last 48 hours. Also, wear a face shield and splash goggles, as described in paragraph 5–23, whenever splashes, sprays, or aerosols of HDs may be generated. The HCWs should notify housekeeping personnel when PPE is required to be worn.

*b*. Clean reusable protective goggles and face-shields with detergent, and rinse them with clean water. Store reusable PPE in a manner which preserves its cleanliness and functionality.

*c*. Trained personnel follow established protocols and use approved cleaning and disinfecting agents when cleaning surfaces and equipment in the HD storage, preparation, and dispensing areas.

(1) Avoid cleaning during HD preparation.

(2) Use dedicated cleaning materials (such as, wipes, sponges, and mops), and discard cleaning materials after one use as a HD waste.

(3) Clean counters, work surfaces, and floors daily. Clean walls, ceilings, and storage shelving monthly.

(4) In the event of a spill, suspend routine cleaning until the area has been properly decontaminated.

*d*. Only trained workers wash contaminated, reusable items, and glassware twice with mild detergent and rinse them with clean water. During cleaning procedures, workers wear gloves and a face shield and splash goggles as described in paragraphs 5–20 and 5–23. If splashing is likely, wear double gloves and a gown as described in paragraph 5–21.

*e.* Wash hands after removing gloves.

**5−17. Managing linen**

*a*. Use disposable linen or absorbable, leak-proof pads for incontinent and vomiting patients.

*b*. Manage contaminated disposable pads as a HD waste as described in paragraph 5–19.

*c*. Handle soiled linen as little as possible and with minimum agitation.

*d*. Always bag soiled linen at the location where it was used. Never sort or prerinse soiled linen in patient-care areas.

*e*. Place linen contaminated with HDs or excreta from patients who have received HDs in the past 48 hours in a color-coded or otherwise specially identified bag, which is then placed in a

labeled (that is, biohazard symbol or color-coded) container with a closed lid for transportation to the laundry-processing facility.

*f.* Laundry workers must—

(1) Wear two pairs of gloves and a gown as described in paragraphs 5–20 and 5–21 when handling contaminated linen before the prewash cycle.

(2) Place the laundry bag and its contents into a laundry machine for a separate prewash, and then add it to the other laundry for a second wash.

(3) Follow the same laundering procedures for linens contaminated with bloodborne pathogens.

*g*. Protect mattresses, pillows, chairs, and other large items from contamination by using waterproof mattress covers, plastic coated pillows, and vinyl, or nonabsorbent chair cushions.

**5−18. Cleaning up hazardous drug spills**

*a*. *Healthcare workers*. Only those HCWs specifically trained in HD spill cleanup procedures should cleanup HD spills.

(1) Call a trained spill response team to clean up HD spills whenever the size and scope of the spill exceed their capability to safely clean up the spill.

(2) Ensure the HCWs and spill response teams have ready access to copies of the HD SDSs.

*b. Hazardous drug officer.* The HDO or a qualified alternate, such as an industrial hygienist, will oversee all HD spill cleanup events.

*c*. *Spill kits*.

(1) Use commercially available or locally made up spill kits.

(2) Spill kits must contain the following items:

(*a*) Written instructions for use of the spill kit and a spill report form.

(*b*) Warning signs to alert others of the hazard and to isolate the spill.

(*c*) Two pairs of appropriate thickness, chemotherapy-type gloves as described in paragraph 5–20.

(*d*) A protective, disposable gown as described in paragraph 5–21.

(*e*) Splash goggles and plastic face shield as described in paragraph 5–23.

(*f*) Shoe coverings as described in paragraph 5–24.

(*g*) A NIOSH-approved respirator. The HCWs should only wear the respirators that they have been fit-tested and trained to use when cleaning up HD spills.

(*h*) Sufficient supplies to absorb a spill of about 1000 milliliter (mL) (volume of one IV bag or bottle). Absorbents should be incinerable.

(*i*) A small scoop or dust pan, scraper, and puncture-resistant HD container to collect broken glass.

(*j*) Sodium hypochlorite solution, neutralizer, detergent, and absorbent pads.

(*k*) A color-coded or otherwise specially identified linen bag.

*d*. *Spills outside the CACI or BSC.*

(1) Assess the size and scope of the spill and call for trained help, if necessary (such as, clean-up requires two or more spill kits).

(2) Remove patients and visitors from the area until the cleanup procedure is completed.

(3) Post signs according to paragraph 5–6, and isolate areas of the spill so that it is not disturbed by other personnel.

(4) Provide first-aid to exposed individuals as described in chapter 5–27.

(5) After donning the PPE, including a respirator—

(*a*) Contain the spill.

(*b*) Pick up broken glass with a small scoop, and place broken glass fragments in a puncture-resistant HD container.

(*c*) Absorb liquids with a sponge or absorbent pads, and absorb powders with damp disposable pads or soft toweling.

(*d*) Cleanup will proceed progressively from the areas with the least contamination to the areas with the greatest contamination. Wash the spill area with sodium hypochlorite solution and a neutralizer or use a deactivating agent recommended by the drug manufacturer followed by washing the area with detergent followed by several rinses with clean water.

(*e*) Call housekeeping to perform a final cleaning after the spill is cleaned up.

(*f*) Place the puncture-resistant HD container in a HD waste container or bag along with the used absorbent pads and contaminated materials.

(*g*) Discard spill clean-up materials as a HD waste, or if the HD is a RCRA-HW, dispose as a HW as described in paragraph 5–19.

(*h*) Wash reusable items and PPE twice with a mild detergent solution, and rinse with water. Store reusable PPE in a manner which preserves its cleanliness and functionality.

(6) Document the spill.

(*a*) Spill reports include the following:

*1*. The name of the agent or the HD and approximate volume spilled.

*2*. How the spill occurred.

*3*. Spill-management procedures followed.

*4*. Personnel, patients, and others exposed to the spill.

*5*. Personnel notified about the spill.

(*b*) At least annually, the HDO reviews the spill reports for trends and the root causes, and establishes new measures such as procuring safety equipment, revising procedures, and conducting training to reduce or eliminate future spills. This annual review is formally documented and archived.

(7) Replace the spill kit.

*e. Spills inside the BSC or CACI.*

(1) Clean up spills in the BSC or CACI immediately.

(2) Use a spill kit if the volume of the spill exceeds 30 mL or the contents of one drug vial or ampule.

(3) Thoroughly clean all interior surfaces, including the spillage trough by following procedures in paragraph 5–2 for CACIs and paragraph 5–3 for BSCs.

(4) If the spill contaminates the HEPA filter, suspend use of the BSC or CACI until the filter can be changed by a certified technician.

(5) Discard spill clean-up materials as a HD waste, or if the HD is a RCRA-HW, dispose as a HW as described in paragraph 5–19.

(6) Document the spill according to paragraph 5–18(d)

*f.* Report all spills according to paragraph 5–18.d(6) and 1–4.g(2)(b) to Preventive Medicine Environmental Health Section.

**5−19. Managing hazardous drug waste**

*a. Coordination.* Coordinate HD waste disposal with preventive medicine service personnel and Chief, Supply Chain Management.

*b. Waste classification.*

(1) *Unused hazardous drugs*. An unused HD is a product that is in its original container or a dispensing instrument (syringe, IV bag, administration set) and was not physically connected to or used on a patient. Unused HDs include HDs that were hydrated with saline/dextrose for delivery purposes but were not used on a patient.

(2) *Used hazardous drugs*. Used HDs include residues contained in dispensing devices that have been physically introduced into a patient.

(3) *RCRA hazardous waste hazardous drugs*. The EPA's P-list and U-list regulate discarded commercial chemical products, manufacturing chemical intermediates, and off-specification commercial chemical products that contain certain ingredients, and any soil or debris contaminated by spills of those products or intermediates. The P- and U-lists can be found in the EPA regulations at 40 CFR §261.33. They include specific commercial chemical products in an unused form, including some pharmaceutical products.

(4) *Non-RCRA hazardous drugs*. These are drugs that are not defined by the Environmental Protection Agency (EPA) as an HW but will require special management procedures to limit human exposures and to ensure proper destruction[1].

(5) *Chemotherapy waste*. Chemotherapy waste includes chemotherapy drug residuals; items contaminated with minuscule droplets or minor splashes of HDs (such as, gloves, gowns, masks, gauze pads, alcohol wipes, chucks, pads, linen, empty drug vials and bottles, syringes, IV tubing, hood filters); and non-RCRA spill clean-up material.

(6) *RCRA empty*. All possible HD contents were removed leaving residual amounts less than a measurable dose and less than 3 percent by weight of total volume or less than 1 inch.

*c. Disposal procedures* (see Figure 5–8).

(1) *Unused hazardous drugs*.

(*a*) Return unopened (the manufacturer's seal must be intact), expired non-RCRA HDs to the manufacturer through the Pharmaceutical Returns Vendor Program.

(*b*) In states that permit the return of expired RCRA-HW HDs to the manufacturer, return the unopened containers to the manufacturer through the Pharmaceutical Returns Vendor Program. Contact the Installation or Garrison Environmental Office to verify that your state allows the return of expired RCRA-HW HDs.

(*c*) In states that do not permit the return of expired RCRA-HW HDs to the manufacturer, dispose of unopened containers as a HW.

[1] Contact the Army Institute of Public Health, Hazardous and Medical Waste Program at DSN 584-3651 or commercial 410-436-3651 for information on HD disposal procedures; or access the Military Item Disposal Instructions on line at http://usaphcapps.amedd.army.mil/MIDI; or call 1-800-276 MIDI (6434).

(*d*) Dispose of dispensing instruments containing RCRA-HW HDs that were not administered to a patient as a HW.

(2) *Used hazardous drugs*.

(*a*) Dispose of opened containers (bottles, vials) with measurable amounts of RCRA-HW HDs as a HW.

(*b*) Dispose of RCRA-HW HDs generated as a result of a spill cleanup as a HW.

(3) *Empty containers*.

(*a*) Dispose of empty vials and dispensing instruments that contained a P-listed waste and were connected to patients in EPA Region 2 as a HW.

(*b*) Dispose of empty vials and dispensing instruments that contained P-listed waste and were connected to patients in all other EPA Regions as a solid waste.

(*c*) Dispose of empty vials and dispensing instruments that contained a U-listed waste as a solid waste.

(d) Dispose of empty chemotherapy vials and dispensing units in chemotherapy waste containers. See Tables 5–1 and 5–2 for P and U listed HDs.

(4) *Chemotherapy waste*. Dispose of used, non-RCRA chemotherapy waste in designated HD collection containers (chemotherapy containers) for removal via the regulated medical waste (RMW) contract or other designated waste contract when the RMW contract cannot incinerate the waste. Mark or otherwise manage the containers to indicate that incineration is required.

(5) *Non-RCRA HDs*. Dispose of used, non-RCRA HDs that have been declared an exposure hazard as a chemotherapy waste to prevent exposure and to ensure incineration.

(6) *Non-RCRA HD spill materials*. Dispose of non-RCRA HD spill cleanup materials resulting from small spills as a chemotherapy waste to prevent exposure and to ensure incineration.

*d. Hazardous drug collection containers.*

(1) At the point of generation, use sealable, leak-proof, and puncture-proof containers and write the following words or attach a label with the following words on the outside of the container–

| |
|---|
| "REGULATED MEDICAL WASTE, UN3291<br>CHEMO WASTE<br>INCINERATION REQUIRED" |

(2) Typically HD collection containers are yellow in color; however, a RMW container may be used as long as the outside of the container indicates that it contains an HD waste by attaching a label that is described in paragraph 5-19.d.(1).

(3) Keep exterior surfaces of waste containers free of contamination as much as possible. If exterior surfaces do become contaminated, place the contaminated container inside a second HD waste container for disposal.

(4) Place HD waste containers in an approved Department of Transportation shipping container separate from RMW and write the following words or attach a label that is described in paragraph 5-19.d.(1).

(5) Always store RMW and HD waste containers awaiting disposal in a secure area (that is, in a locked area or limited to authorized personnel only).

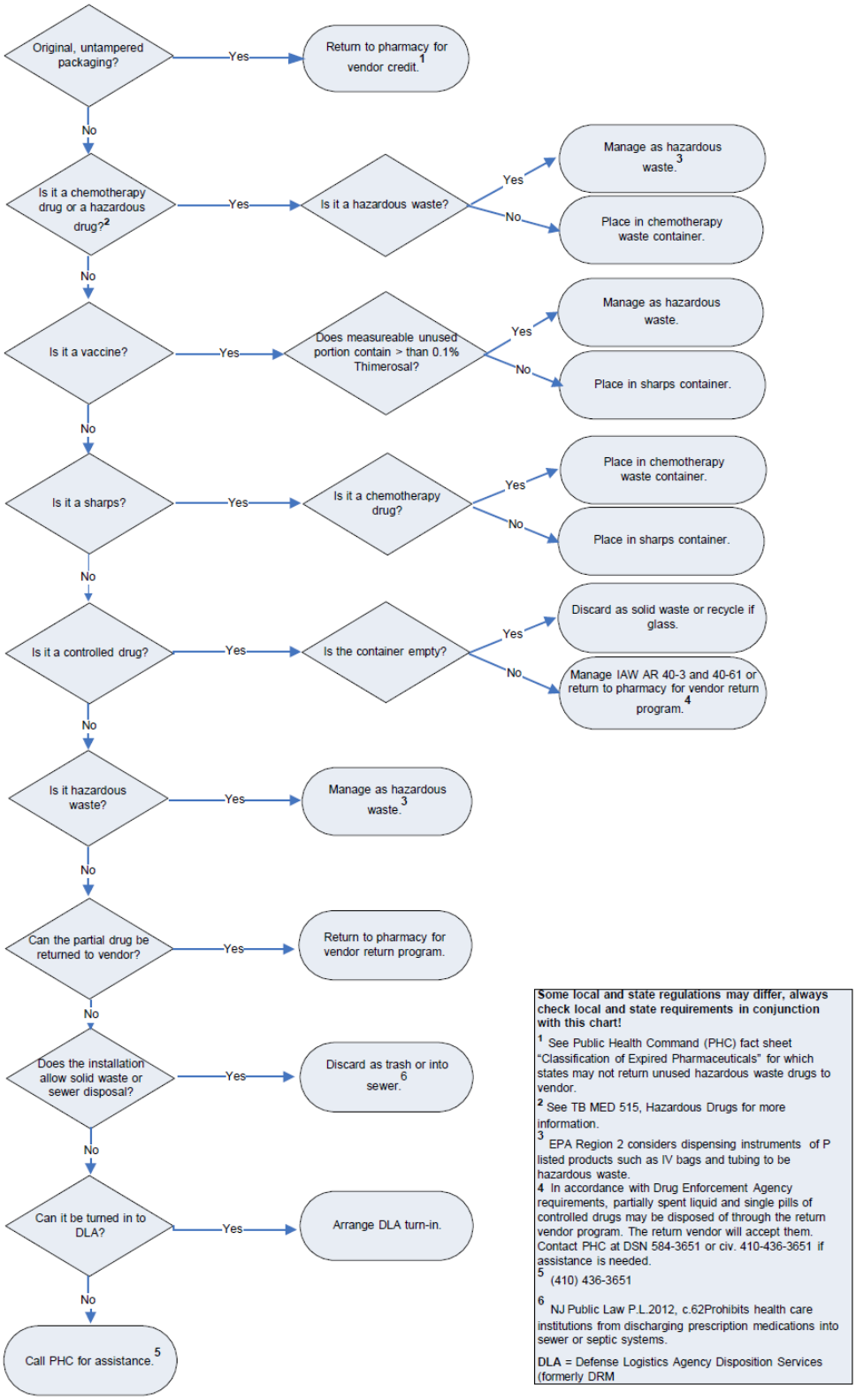



***Figure 5-8. Hazardous waste management flow chart***

**Table 5-1. Partial List of Hazardous Waste Chemotherapy Pharmaceuticals**

| Name | Brand or Trade Name/Synonym | EPA HW # |
|---|---|---|
| Arsenic trioxide | Trisenox | P012<br>D004 |
| Azaserine | Azaserin, L-Azaserine | U015 |
| Chlorambucil Tablets and Powder | Leukeran, Chlorambucil Powder | U035 |
| Chlornaphazine | Erysan, Chlornaphazin | U026 |
| Cyclophosphamide Injection and Tables | Cytoxan, Neosar, CTX, Procytox | U058 |
| Daunorubicin | Daunomycin, Liposomal Daunorubidin, Cerubidine, DaunoXome, Rubidomycin HCL, Daunorubicin HCL | U059 |
| Diethylstibestrol | DES, Stilbestrol, Stilbesterol, Stilphostrol | U089 |
| Melphalan | Alkeran, Melphalan Hydrochloride, L-PAM, L-Sarcolysin, Phenylalanine Mustard | U150 |
| Mitomycin-C | Mutamycin, Mitomycin, Azirino | U010 |
| Streptozotocin | Zanosar, SZNO, Streptozocin | U206 |
| Uracil Mustard | Aminouracil Mustard, Chlorethaminacil, Demethyldopan, Desmethyldopan, Nordopan, Uramustin, Uramustine | U237 |

**Table 5-2. Partial List of Hazardous Waste Pharmaceuticals**

| Name | EPA HW # |
|---|---|
| Alcohol Pads | D001 |
| Aluminum Chloride Solution 20% | D001 |
| BD Single Use Swab | D001 |
| Clobetasol | D001 |
| Condylox Topical | D001 |
| Coumadin | P001 |
| Cyclophosphamide | U058 |
| Isopropyl Alcohol | D001 |
| Nicotine Patch, Spray, Gum, Lozenges | P075 |
| Olux Foam | D001 |
| Podofilox | D001 |
| Selenium Sulfide | D010 |
| Silvadene 1% | D011 |
| Silver Sulfadiazine 1% | D011 |
| Testim 1% | D001 |
| Warfarin | P001 |

## Section III
## Personal Protective Equipment

### 5−20. Gloves
For all activities involving HDs—

*a.* Selection.

(1) Select gloves recommended by the manufacturer for the specific type of HDs used and that are chemically resistant to the detergents, disinfectants, and decontaminants used.

(2) Verify gloves have a chemotherapy-claim compliant with the FDA's Medical Glove Guidance Manual; ASTM® D6978-05; or an equivalent test method. (ASTM® is a registered trademark of the American National Standards Institute.)

*b*. Wear two pairs of chemotherapy gloves for all activities involving HDs.

*c*. Workers with latex sensitivity should wear gloves made of an alternate material such as nitrile, polyurethane, neoprene, or other materials recommended by the HD manufacturer.

*d.* Consider using chemotherapy gloves when working with HDs that are not chemotherapy drugs or for which no information is available.

*e.* Sterile chemotherapy gloves are required for CSPs under USP Chapter 797. Sanitize gloves with sterile 70 percent alcohol spray or gel and allow them to dry; make sure that the selected gloves are not degraded by alcohol.

*f*. When using a CACI, wear an additional pair of chemotherapy gloves within the fixed-glove assembly. Clean fixed gloves after compounding to avoid spreading HD contamination to other surfaces.

*g*. Always wash hands before donning and after removing gloves.

*h*. Inspect gloves for visible defects before donning them.

*i*. Wear two pairs of chemotherapy gloves when compounding, dispensing, and disposing HDs.

*j.* Wear the inner gloves under the gown cuff and the outer gloves over the cuff.

*k.* Place gloves with long cuffs over the cuff of the gown to protect the wrist and forearm.

*l.* Change gloves at least every 30 minutes and immediately if they are torn, punctured, or contamination is suspected.

*m.* After wiping down the final preparation but before labeling or removing the preparation from the BSC or CACI, remove the outer gloves by turning them inside-out so that contaminated glove surfaces do not touch uncontaminated surfaces. Place the gloves in an appropriate disposal container. Don fresh gloves for completing the final check and placing the preparation into a transport container.

*n.* Never wear contaminated gloves outside the immediate work area.

*o*. Never use powdered latex gloves since the powder can contaminate the sterile processing area and absorb HDs which may increase potential for skin contact. Also, powder-free gloves may reduce exposures to latex protein and reduce the risk of latex allergy.

### 5−21. Disposable gowns
*a*. Wear a protective, disposable gown that—

(1) Is made of a lint-free, non-absorbent fabric (such as, polyethylene-coated polypropylene material) or a gown that provides equivalent protection.

(2) Has a solid front with back closure.

(3) Has long sleeves with elastic or closed-knit cuffs.

*b*. When wearing gloves, ensure they are doubled, and tuck one glove under the cuff and one glove over the cuff.

*c*. Change gowns whenever they are contaminated or whenever gloves are removed.

*d*. Dispose gowns after each use since the practice of hanging up a gown between uses may lead to surface contamination.

*e*. Never wear contaminated gowns outside the immediate work area.

**5−22. Respirators**

Where a CACI or a BSC is not currently available, and whenever sprays, splashes, or aerosols of HDs may be generated—

*a*. Use only NIOSH-approved respirators according to OSHA (29 CFR 1910.134 and AR 11–34).

(1) The Installation Respiratory Protection Program Manager, Industrial Hygiene Office, or Safety Office should select respirators and filter materials based on the identity and the nature of the HDs and the potential level of exposure. The NIOSH Respirator Selection Logic provides a process that qualified individuals having sufficient knowledge of respiratory protection can use to select appropriate respirators for the protection of workers in specific workplaces.

(2) Ensure that all HCWs, who are required to wear respirators or who are allowed to wear respirators under the voluntary respiratory program, are placed on the Installation Respiratory Protection Program that includes: medical evaluation, fit-testing, and education and training.

(*b*) Where respirators are required, never wear surgical masks in place of respirators since surgical masks DO NOT protect against breathing HD aerosols.

(*c*) Keep assigned respirators in an accessible location within the immediate work area.

(*d*) Clean and decontaminate reusable respirators according the respirator manufacturers' directions after use.

(*e*) Store respirators in a manner that protects them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and prevents deformation of the facepiece and exhalation valve.

**5−23. Face shields and splash goggles**

*a*. Wear a face shield and chemical splash goggles complying with ANSI Z87.1–2010 whenever splashes, sprays, or aerosols of HDs may be generated. Eyeglasses with temporary side shields do not provide adequate protection against splash hazards.

*b*. Wear splash goggles to protect eyes whenever half-mask respirators are used.

*c*. Clean reusable face shields and splash goggles with mild detergent and clean water after use; disinfect the areas in direct contact with the wearer's skin (temples, frame, nose pads and/or headbands) with appropriate solutions recommended by the manufacturer of the device. Store

reusable eye protection in a manner which preserves its cleanliness and functionality. If indicated and when possible, provide HCWs their own eye and face protection.

**5-24. Sleeve, shoe, and hair coverings**

*a*. Wear hair coverings during the sterile compounding process to minimize particulate contamination of the critical work zone and the preparation.

*b*. Wear sleeve covers constructed of coated materials to provide additional protection from the areas of the arms and wrists that come in contact with the BSC.

*c*. Wear shoe coverings in compounding and dispensing areas to control spread of contamination from any HDs that may have settled on the floor.

*d.* Wear shoe coverings when there is potential to contaminate footwear during HD spill clean-up procedures.

**5-25. Sequence and procedures for removing personal protective equipment**

Remove PPE in a manner that prevents any contamination from being transferred to the worker or the work environment–

*a*. *Pharmacy*.

(1) Remove outer gloves by gently rolling them off the hands, so they are inside out.

(2) Remove hair cover, gown, inner pair of gloves, and shoe covers.

(*a*) Remove gown by unfastening the ties and pulling the gown away from the neck and shoulders, touching the inside of the gown only. Turn the gown inside out, and fold it or roll into a bundle.

(*b*) When removing inner gloves, do not allow the unprotected skin of fingers to touch the contaminated side of the glove. Pinch the first glove with the gloved fingers of the opposite hand; carefully remove the glove then turn that glove inside out to contain the residue. Place ungloved fingers inside the wrist of the second glove, and remove the glove by sliding it off and turning it inside out.

(*c*) When removing shoe covers, place the feet one after the other in the clean area.

*b*. *Drug administration area*.

(1) Remove outer pair of gloves in the same manner as described above.

(2) Remove gown in the same manner as described above.

(3) Remove inner pair of gloves in the same manner as described above.

(4) If worn, remove eye and face protection by grasping the head band or ear pieces.

(5) If worn, remove respirator by loosening the bottom then the top elastics. Handle the respirator by the elastics only.

## Section IV
## Medical Surveillance

### 5−26. Preplacement and termination examinations

*a*. The following personnel should have preplacement and termination medical examinations:

(1) All HCWs with potential for exposure to HDs through preparation, dispensing, housekeeping, waste disposal, transport, storage, or spill cleanup.

(2) Maintenance and service personnel with potential for exposure to HDs while performing repairs on contaminated medical equipment, CACIs, and BSCs; replacing CACI and BSC filters; or conducting CACI and BSC certification.

*b*. Occupational medicine physicians should collect medical and occupational histories and tailor medical examinations and laboratory studies to the HCW's potential for exposure and the specific toxic profiles of the HDs handled (such as, hematological studies for Antineoplastic agents). Preplacement medical histories should be very detailed, while periodic examinations may be less detailed (focus on the signs and symptoms related to exposure to HDs and changes in health status).

(1) Medical history should focus on known target organ systems of the HDs handled (hematopoietic, hepatic, reproductive, skin, and urologic), symptoms thought to be caused by exposure to HDs (significant, unintentional weight loss; fever; malaise; and unexplained fatigue, headaches; hair loss; lightheadedness; dizziness), and information from previous medical examinations. Special consideration should be given to the HCW's reproductive history (general questions regarding problems conceiving, spontaneous abortions, fetal malformations, and so forth). Female HCWs should be asked to provide a complete reproductive history of each pregnancy (dates, outcome, work history during pregnancy) and menstrual irregularities. Male HCWs should provide information about reproductive histories of their partners.

(2) Work history should include a description of the worker's job duties related to exposure to HDs such as the names of the HDs handled, the quantities handled, hours spent handling HDs per week, and number of preparations or administrations per week. Work history should also include a description of the engineering and administrative controls, work practices, and PPE used when handling HDs.

(3) Physical examinations should be complete with emphasis on the skin, mucous membranes, cardiopulmonary and lymphatic systems, and liver.

(4) Suggested laboratory tests include a complete blood count with differential, reticulocyte count, liver transaminase concentrations (aspartate aminotransferase (or AST), alanine aminotransferase (or ALT), and urine microscopy or dipstick for blood.

### 5−27. Periodic examination

*a*. All personnel working with HDs should receive a medical examination at least every 2 years or on an annual basis at the discretion of the occupational medicine physician( based on the worker's potential for exposure, duration of exposure, history, and age) as well as an incidental examination as required (such as, after an acute exposure).

*b*. These examinations may detect changes in—

(1) The HCW's general health as might be affected by subsequent exposure to HDs.

(2) Specific diagnoses secondary to exposure to HDs.

**5−28. Acute exposures**

*a*. Acute exposures include, but are not limited to—

(1) A needle-stick from a needle attached to a syringe or IV catheter containing an HD.

(2) A spill or splash on exposed skin or in the eye(s).

(3) Ingestion resulting from inadvertent hand contact with HDs when handling food, drink, cosmetics, and smoking materials.

(4) Inhalation of aerosols or droplets.

*b*. First-aid for an acute exposure requires immediate action to include decontamination and medical care or evaluation.

**5−29. Personnel contamination**

*a*. Treat overt contamination of gloves or gown and direct skin or eye contact as follows—

(1) Immediately remove contaminated PPE and any underlying clothing that is contaminated due to soak through. Discard disposable items in a HD waste container as described in paragraph 5–18.

(2) Wash contaminated skin with soap and water. For splashes to the eye(s), rinse the affected eye(s) with tepid water for at least 15 minutes or until the pH of the conjunctival surface is neutral; then refer to an eye-care provider.

(3) Refer to the manufacturer's SDS for additional emergency and first-aid procedures.

(4) Follow-up with medical attention, especially for inhalation of HDs in powder form.

*b*. Following an acute exposure, the treating medical practioner must document acute exposure evaluations in the HCW's medical record. Also, the HCW's immediate supervisor must investigate the accident according to the facility's accident reporting procedures, and send a copy of the accident report to the safety manager.

**5−30. Pregnancy**

Workers, both male and female, starting any job that requires routine handling of HDs should be fully informed of the potential reproductive and other health hazards. Additionally, HCWs who are pregnant, breast-feeding, or are trying to conceive a child should be given the option of being transferred to other comparable duties that do not involve handling HDs.

**5−31. Recordkeeping**

*a.* The HCW's medical records and exposure records must be kept for the duration of employment plus 30 years. The HCWs must have access to their medical records.

*b.* The industrial hygiene section maintains HCWs' exposure records in the DOEHRS-IH data base. Documentation includes—

(1) All work areas where HDs are present.

(2) The identity and quantity of HDs handled.

(3) The identity of the HCWs/personnel that handle the HDs (the hours spent handling HDs per week, and the number of preparations/administrations performed per week) or who are potentially exposed to HDs.
(4) A description of the HCW's job duties.
(5) Engineering and administrative controls, work practices, and PPE used.
(6) Environmental sampling data.

**5−32. Exposure-related disease/adverse health effects**
Any occurrence of exposure-related disease or adverse health effects should initiate an immediate investigation into the effectiveness of the safety precautions currently in use.

# CHAPTER 6

# AEROSOLIZED DRUGS

## 6–1. Pentamidine

*a*. *Engineering controls*.

(1) Use a Respirgard® II nebulizing system that is equipped with one-way valves, expiratory filters, and a cut-off switch actuated by the patient and/or automatic shut-down when the mouth piece is removed from the patient's mouth. (Respirgard® is a registered trademark of Marquest Medical Products, Inc.)

(2) When administering Aerosolized Pentamidine (AP), use local exhaust ventilation (such as, an aerosol treatment chamber) to capture air contaminants at or near the source and remove them from the patient area.

(*a*) Place patients in the chamber or other enclosure designed for AP administration. Chambers are under negative pressure with respect to adjacent areas. The exhaust air passes through a HEPA filter and is exhausted directly to the outside away from all windows, air-intake ducts, and occupied areas.

(*b*) Follow the manufacturer's operations manual for proper installation and maintenance of the chamber to prevent aerosol contaminants from escaping into the environment. Test and evaluate the chamber's performance after initial installation, at least annually, whenever the HEPA filters are changed, following maintenance and repairs, and whenever the chamber is moved. Wear respiratory protection and gloves when performing maintenance and testing procedures.

(3) Administer AP in a negative-pressure isolation room.

(*a*) Because of the high potential for exposure to mycobacterium tuberculosis (MTB) during cough-inducing and aerosol-delivery procedures, the treatment room is designed, cleaned, decontaminated, and maintained according to OSHA Enforcement and Compliance (CPL) 02-00-106 or latest standard for preventing occupational exposure to MTB even when local exhaust ventilation is used.

(*b*) Rooms are under negative pressure with respect to adjacent areas and provide a minimum of 6 ACHs for existing facilities and 12 ACHs for new and renovated facilities. Air from these rooms is exhausted directly to the outside, away from all windows, air-intake ducts, and occupied areas.

(*c*) Personnel must install windows for visual surveillance and provide a system to permit active communication between patients and HCWs to allow HCWs to remain outside the treatment room during AP administration (aside from brief interventions for assistance or control purposes).

*b*. *Administrative controls*.

(1) Instruct patients prior to AP treatment—

(*a*) To remain in the isolation booth/administration room for a short period following treatment and until coughing subsides to minimize the spread of contaminants into the room

when the door is opened. The time that the patient is to remain in the booth should be sufficient to remove at least 99 percent of the airborne contaminants (such as, 2–5 minutes).

(*b*) In the proper use of the nebulizer and the actions to take in the case of a coughing fit.

(*c*) To limit the number of disconnections, and to shut off the nebulizer before calling for staff assistance at the time of a coughing fit.

(2) Before beginning AP administration, install a warning sign at the treatment room entrance to warn all who enter of the potential hazards and to discourage non-essential persons from entering the administration room.

(3) Enroll all HCWs who administer AP in a medical surveillance program, and screen them according to procedures provided in OSHA CPL 02-00-106.

(4) Instruct women to avoid exposure to pentamidine during pregnancy and within 8 weeks of becoming pregnant. Give pregnant HCWs and HCWs who are trying to conceive a child the option of being transferred to other comparable duties that do not involve handling of pentamidine.

(5) Determine the effectiveness of engineering, administrative, and work-practice controls by conducting air sampling using NIOSH Method No. 5032, periodically and when changes in procedures or equipment occur.

*c. Safe-work practices*.

(1) Keep doors and windows to administration rooms closed during AP administration to maintain negative pressure and to minimize potential for contamination of air in surrounding areas.

(2) Avoid window air conditioners and personal cooling fans.

(3) Verify that administration rooms are under negative air pressure each day before AP administration is started by using pressure-sensing devices, non-irritating smoke trails, or some other indicator to demonstrate that direction of airflow is from the corridor into the administration room with the door closed. If an anteroom exists, direction of airflow must be demonstrated at the inner door between the administration room and the anteroom.

(4) Keep local exhaust systems in operation after treatment is completed.

(5) If AP must be administered without the use of a chamber, tent, hood, or booth but inside a negative-pressure isolation room, prohibit HCWs from entering the room without respiratory protection until sufficient time has passed to remove at least 99 percent of the airborne contaminants (Centers for Disease Control and Prevention (CDC), 2005). Also, HCWs wear a half-face respirator with organic vapor and P100 cartridges when they are in the room with a pediatric patient being administered AP. Parents should wear respiratory protection when they are in the treatment room during AP administration.

(6) Complete scheduled inspections, tests, and maintenance of ventilation systems and nebulizers to verify they are functional.

(7) Follow schedules established by infection control for cleaning and disinfecting equipment and room surfaces. Use wet-cleaning methods to avoid raising dust.

(8) Clean up spills properly. In the event of a spill, a trained HCW—

(*a*) Puts on appropriate PPE as described in paragraph 6–1d.

(*b*) Dampens solid spill material with water, or wipes up liquids with absorbent materials.

(*c*) Transfers the spill materials to a waste container for disposal.

(*d*) Wipes the area with absorbent paper dampened with water to pick up any remaining material, and then washes all contaminated surfaces with soap and water.

(*e*) Places contaminated disposable clothing in a sealable plastic bag for disposal.

(*f*) Properly disposes of waste as a non-RCRA HD waste according to Federal, state and local regulations as described in paragraph 5–19.

(*g*) Documents the spill as described in paragraph 5–18.

(*h*) Should an accidental exposure occur, provides first-aid for—

i. *Skin contamination*. Immediately rinse affected skin with water, remove contaminated clothing, and wash affected skin with soap and water for 15 minutes.

ii. *Eye contamination*. Flush eyes with tepid water for 15 minutes or until the conjunctival surface is neutral and refer to an eye care provider.

iii. *Inhalation*. Immediately leave the contaminated area, and take deep breaths of fresh air. Give cardiopulmonary resuscitation (or CPR) if required.

iv. *Ingestion*. Do not induce vomiting. If the victim is conscious and not convulsing, give him/her one to two glasses of water to drink. Contact your local poison control center for additional instructions.

v. *Documentation*. Document the exposure in the HCW's health record.

*d*. *Personal protective equipment*. Whenever there is potential for eye or skin contact or inhalation of dusts, fumes, mists, or vapors, HCWs wear—

(1) Disposable latex gloves or gloves made of an alternate material such as nitrile, polyurethane, neoprene or other materials recommended by the HD manufacturer.

(2) Long-sleeved disposable gowns.

(3) Respirator as described in paragraph 5–22.

(4) Splash goggles as described in paragraph 5–23.

**6–2. Ribavirin**

*a. Engineering controls*.

(1) Conduct aerosolized ribavirin administration in a separate negative-pressure room with the door closed.

(2) Use an aerosol generator, such as the Small Particle Aerosol Generator (SPAG®–2), along with a vacuum scavenger system. (SPAG® is a registered trademark of ICN Pharmaceuticals, Inc.)

(3) Provide means, such as a remote switch, that allows HCWs to turn off the SPAG–2 before entering the room.

*b. Administrative-controls*.

(1) Before beginning therapy, install a warning sign at the treatment room entrance to warn all who enter, including visitors, of the potential health hazards.

(2) Limit access to only essential HCWs during aerosolized ribavirin administration.

(3) Give pregnant HCWs and HCWs who are trying to conceive a child the option of being transferred to other comparable duties that do not involve handling ribavirin.

(4) Determine the effectiveness of engineering, administrative, and work-practice controls by conducting air sampling using NIOSH Method No. 5027 (Ribavirin) periodically and when changes in procedures or equipment occur.

*c. Safe-work practices*. HCWs—

(1) Turn off the SPAG–2 at least 5 minutes before entering the room to provide routine care. If emergent or urgent problems require immediate access to the patient, HCWs wear a respirator as described in paragraph 5–22.

(2) Shut off the aerosol generator when attending patients and while handling respiratory equipment.

(3) Complete scheduled inspections, tests, and maintenance of administration and scavenging equipment.

(4) Follow schedules established by infection control for cleaning and disinfecting equipment and room surfaces.

(5) Handle linens with a minimum of shaking to reduce the risk of ribavirin from being released into the room.

(6) Cleanup spills properly. In the event of a spill follow procedures in Section 6–1(c)(8).

(7) Prohibit wearing contact lenses when working with ribavirin.

(8) Properly dispose of waste as a non-RCRA HD waste according to Federal, state and local regulations as described in paragraph 5–19.

*d. Personal protective equipment*. Whenever there is potential for eye or skin contact or inhalation of dusts, fumes, mists, or vapors, HCWs wear—

(1) Air-tight chemical splash goggles as described in paragraph 5–23.

(2) Disposable latex gloves or gloves made of an alternate material (such as, nitrile, polyurethane, neoprene or other materials) recommended by the HD manufacturer.

(3) Long-sleeved disposable gowns.

(4) Hair and shoe covers.

(5) Respirator as described in paragraph 5–22.

# APPENDIX A

## REFERENCES

### Section I
### Required Publications

Except as noted below, ARs, DA Pams, and TB MEDs are available online from the U.S. Army Publishing Directorate (APD) website: http://www.apd.army.mil/. ANSI standards are available online from the ANSI website: http://www.ansi.org/library/overview.aspx?menium=11. Code of Federal Regulations are available online from the Government Printing Office website: http://gpoaccess.gov/CFR/index.html.

**AR 11–34**
The Army Respiratory Protection Program. (Cited in para 5–16a., 5-22a)

**AR 40–7**
Use of U.S. Food and Drug Administration-Investigational Products in Humans Including Schedule I Controlled Drug Substances. (Cited in para 2–2g(2).)

**DA Pam 40–11**
Preventive Medicine. (Cited in para 5–13b(c)(2).)

**DA Pam 40-503**
The Army Industrial Hygiene Program. (Cited in para 1-4f(4).)

**TB MED 510**
Guidelines for the Evaluation, and Control of Occupational Exposure to Waste Anesthetic Gases. (Cited in para 2–2f(1).)

**ANSI Z87.1–2010**
American National Standard for Occupational and Educational Eye and Face Protection. (cited in para 5–23a)

**ANSI Z358.1–2009**
American National Standard for Emergency Eyewash and Shower Equipment. (Cited in para 5–5a; 5–5b.)

**ASTM D 6978-05**
American Standard Test Method, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs". (Cited in para 5-20a(2).)

**CETA CAG-002-2006**
Compounding Isolator Testing Guide, 2008. (Cited in para 52e(1).)
http://www.cetainternational.org/

**CETA CAG-003-2006**
Certification Guide for Sterile Compounding Facilities, 2012. (Cited in para 5-1g.)
http://www.cetainternational.org/

**FDA**
Medical Glove Guidance Manual, January 22, 2008. (Cited in para 5-20a(2).)
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm150053.htm

**IEST RP CC002.3-2009**
Unidirectional Flow Clean Air Devices. (Cited in para 5–2e(1) and 5–3g(1).)

**ISO Standard 14644-1:1999**
Classification of Air Cleanliness. (Cited in para 5–1c(2); 5–2b(1).)
http://www.iest.org/Standards-RPs/ISO-Standards/ISO-14644-Standards/ISO-14644-1

**NIH**
Design Requirements Manual for Biomedical Laboratories and Research Facilities. (Appendix I, Biosafety Cabinets (BSC) Placement Requirements for new Buildings and Renovations Division of Technical Resources; Office of Research Facilities). 2008. (Cited in para. 5–3f(1).)
http://orf.od/nih/gov/policiesandguidelines

**NIOSH Method 5027**
NIOSH Manual of Analytical Methods, Ribavarin. (Cited in para 6–2b(4).)
(http://www.cdc.gov/Niosh/nmam/pdfs/5027.pdf.)

**NIOSH Method No. 5032**
NIOSH Manual of Analytical Methods for Testing Air Quality, Method No. 5032 relating to Pentamidine Isetheone, 15 August 1994. (Cited in para 6–1b(5).)
(http://www.cdc.gov/NIOSH/nmam/pdfs/5032.pdf.)

**NSF/ANSI International Standard 49**
Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. (Cited in para 5–3b; 5–3g(1).)
http://www.nsf.org/business/biosafety_cabinetry/standards.asp?program=BiosafetyCab

**TB MED 515**

**OSHA Enforcement and Compliance (CPL) 2.106**
Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis. Washington, District of Columbia, OSHA 9 February 1996 (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1586). (Cited in para 6–1a(3)(a).) (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1586.)

**OHSA CPL 02-00-106 [Directive Number: CPL 02-00-106]**
Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis. (Cited in paras 6-1a(3)(a) and 6-1b(3).)
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=1586

**PL 91–596**
Occupational Safety and Health Act of 1970. (Cited in para 2–4a.)
(http://www.usbr.gov/ssle/safety/PublicLaw91-596.pdf.)

**U.S. Pharmacopeia USP 797**
U.S. Pharmacopeial Convention. 2008. (Cited in para 5-2f(1).)
http://www.usp797.org/USP797-2008Guidelines.htm

**USP General Chapter 797**
Pharmaceutical Compounding–Sterile Preparations. (2008). Rockville, MD: U.S. Pharmacopeia. (Cited in paras 1–4e(3); 5–1b; and 5–20c; and 5–3h(1).)
(http://jnm.snmjournals.org/cgi/reprint/45/6/20N.pdf.)

**29 CFR 1910.134**
Respiratory Protection. (Cited in para 5–22a.)

**29 CFR 1910.1200**
The OSHA Hazard Communication Standard (HCS). (Cited in para 4–3a.)

**40 CFR 261 Subpart C**
Identification and Listing of Hazardous Waste; Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof. (Cited in para 5-19b(3))

## Section II
## Related Publications

**AR 40–5**
Preventive Medicine

**AR 385–40**
Army Accident Investigations and Reporting

**DA Pam 40-506**
The Army Vision Conservation and Readiness Program

**DHHS Publication No. (CDC) 21-1112**
Biosafety in Microbiological and Biomedical Laboratories

**DHHS**
Public Health Service Centers for Disease Control and Prevention and National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories*. U.S. Government Printing Office, Washington, District of Columbia. 2009.

**DHHS**
Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.* U.S. Government Printing Office, Washington, District of Columbia. 1995.

**ANSI Z9.5–1992**
American National Standard for Laboratory Ventilation

**ASHP: American Society of Health-System Pharmacists**
ASHP Guidelines on Handling Hazardous Drugs: Am J of Health-Syst Pharm. 2006; 63:1172-1191.

**ASTM F 739-99a**
American Standard Test Method, "Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquid and Gases Under Condition of Continuous Contact".

**CDC**
Mobidity and Mortality Weekly Report (MMWR), 43/RR-13/October 28, 1994. Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994, Table S3–1.

**CDC**
MMWR, 54/RR-17/December 30, 2005. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005.

**CETA CAG-001-2005**
Compounding Aseptic Isolators in Compounding Sterile Preparations in Healthcare Facilities. December 2008

**CETA CAG-005-2007**
Servicing Hazardous Drug Compounding Primary Engineering Controls

**NIOSH Publication No. 88–119**
Guidelines for Protecting the Safety and Health of Health Care Workers

**NIOSH Publication No. 97-135**
NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace

**NIOSH Publication No. 2004–165**
NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings

**NIOSH Publication No. 2005-100**
NIOSH Respirator Selection Logic

**NIOSH Publication No. 2009-106**
Workplace Solutions: Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs

**NIOSH Publication No. 2012-150**
NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012

**NIOSH Publication No. 2013-103**
Workplace Solutions: Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs

**NIOSH Respirator Selection Logic**
http://www.cdc.gov/niosh/docs/2005-100/pdfs/2005-100.pdf

**OSHA Technical Manual [Directive Number: TED 01-001-015]**
Controlling Occupational Exposures to Hazardous Drugs. January 20, 1999
https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#1

**OSHA Technical Manual [Directive Number: TED 01-001-015, Chapt II]**
Categorization of drugs as hazardous. January 20, 1999.
https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html#1

*American Hospital Formulary Service Drug Information.* (1992). American Society of Hospital Pharmacists, Inc., Bethesda, Maryland.

ASHP Guidelines on Handling Hazardous Drugs. (2006). American Society of Health System Pharmacists, Bethesda, Maryland.

ASHP Safe Handling of Hazardous Drugs Video Training Program. (2006). American Society of Health System Pharmacists, Bethesda, Maryland.

Charney, W. & Schirmer, J. (1990). *Essentials of Modern Hospital Safety.* Chelsea: Lewis Publishers, Inc.

Charney, W. & Schirmer, J. (1993). *Essentials of Modern Hospital Safety Volume 2.* Chelsea: Lewis Publishers, Inc.

*Comprehensive Accreditation Manual for Hospitals: The Official handbook.* (2010). Joint Commission on Accreditation of Healthcare Organizations, Chicago, Illinois.

Connor TH, McDiarmid MA. Preventing occupational exposures to antineoplastic drugs in health care settings. *CA Cancer J Clin*. 2006;56:354–365.

"Controlling Occupational Exposure to Hazardous Drugs," *American Journal Health-Syst Pharm* Volume 53 (July 1996): 1669–1685.

Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities. Biosafety Cabinet (BSC) Placement Requirements for new Buildings and Renovations (Appendix I), National Institutes of Health (2011), Bethesda, Maryland.

"Exposures of Health-Care Workers to Ribavirin Aerosol: A Pharmocokinetic Study," *Archives of Environmental Health* Volume 50, Number 6 (November/December 1995): 445–451.

*1995 Handbook–HVAC Applications.* Atlanta: American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE).

*1997 Handbook–Fundamentals.* ASHRAE, Atlanta, Georgia.

"Hazardous Drugs," Occupational Medicine: State of the Art Reviews. Volume 12, Number 4 (October–December 1997): 669-685.

"Health Care Worker Exposure to Aerosolized Ribavirin: Biological and Air Monitoring." *Journal of Occupational and Environmental Medicine*. Volume 38, Number 3 (March 1996): 257–263.

*Industrial Ventilation: Manual of Recommended Practice*, 23rd ed. (1998). ACGIH, Cincinnati, Ohio.

McDiarmid, M.A. 1990. "Medical surveillance for antineoplastic drug handlers." *Am. J. Hosp. Pharm*. 47:1061–1066.

National Institutes of Health (NIH) Warren Grant Magnuson Clinical Center Nursing Department. *Safe Handling and Disposal of Hazardous Drugs.* NIH, Bethesda, Maryland. 1997.

"Pentamidine Aerosols and Environmental Contamination: Healthcare Workers at Risk," *Pharmacy World & Science*. Volume 18, Number 4 (August 1996): 148–152.

Pentamidine Isethionate Material Safety Data Sheet (MSDS), Fujisawa, April 18, 1995.

Pentamidine Isethionate MSDS, NTP Chemical Repository, Radian Corporation, August 29, 1991.

"Pharmaceuticals as Hospital Hazards: Managing the Risks," *Journal of Occupational Medicine*, Volume 33, Number 2 (February 1991): 155–158.

Polovich M, Bolton DL, Eisenberg S, Glynn-Tucker EM, Howard-Ruben J, McDiarmid MA, Power LA and Smith CA. Safe handling of hazardous drugs. Oncol Nurs Society. Second Edition. February, 2011.

Pretty JR, Connor TH, Spasojevic I, Kurtz KS, McLaurin JL, B' Hymer C, Debord DG. Sampling and mass spectrometric analytical methods for five antineoplastic drugs in the healthcare environment. *J Oncol Pharm Pract*. 2010; 18:23-36.

"Respiratory Effects of Occupational Exposure to Aerosolized Pentamidine," *Journal of Occupational Medicine*, Volume 37, Number 2 (February 1995): 145–150.

"Ribavirin-Exposure to Healthcare Workers," *American Industrial Hygiene Association Journal*. Volume 49 (January 1988): A13–A14.

Ribavirin Material Safety Data Sheet (MSDS), NTP Chemical Repository, Radian Corporation, August 29, 1991.

Safe Handling of Hazardous Drugs (2nd ed.). (2003). Oncology Nursing Press, Inc., Pittsburg, Pennsylvania.

Schierl R, Bohlandt A, and Nowak D. Guidance values for surface monitoring of antineoplastic drugs in German pharmacies. *Ann Occup Hyg*. 2009; 53(7):703-711.

Sessink PJM. Environmental contamination with cytostatic drugs: past, present, future. *Saf Considerations Oncol Pharm* (Special edition) Fall 2011); http://www.ppme.eu.

Turci R, Sottani C, Spagnoli G and Minoia C. Biological and environmental monitoring of hospital personnel exposed to antineoplastic agents: a review of analytical methods. *J Chromatog B*. 2003; 789:169-209.

Tweedy, J.T. (1997). Healthcare Hazard Control and Safety Management. St. Lucie Press, Delray Beach, Florida.

"Get Ready for 2010" Critical Access Hospital Teleconference-Environment of Care, The Joint Commission, December 15, 2009.

**Section III**
**Prescribed Forms**

This section contains no entries.

**Section IV**
**Referenced Forms**

**DA Form 4106**
Quality Assurance/Risk Management Report

**DA Form 2028**
Recommended Changes to Publications and Blank Forms

**DA Form 4755**
Employee Report of Alleged Unsafe or Unhealthy Working Conditions

**DA Form 7566**
Composite Risk Management Worksheet

**OSHA No. 300**
Log of Work-Related Injuries and Illness Entries

# APPENDIX B

## A GUIDE FOR THE COLLECTION AND ANALYSIS OF WIPE SAMPLING FOR POTENTIAL HAZARDOUS DRUG CONTAMINATION IN HEALTHCARE FACILITIES

### B–1. General

This document recommends that healthcare facilities that handle chemotherapy drugs conduct wipe sampling of work surfaces where these hazardous drugs (HDs) are handled to determine the level of contamination and effectiveness of engineering controls, work practices, and cleanup procedures.

### B–2. Sampling strategy

*a.* The Industrial Hygiene Office or the Hazardous Drug Officer (HDO) sets up the wipe sampling surveillance strategy. Wipe sampling is conducted initially and repeated periodically. The frequency of repeated sampling is based on changes to the drugs used, procedures, operations and equipment, and engineering controls used. Sampling frequency is also based on previous sampling results and the industrial hygienist's professional judgment. Since there are hundreds of chemotherapy drugs currently in use, select the single drug handled in the healthcare facility which has the highest potential for contamination based on physical characteristics (e.g., solid, liquid, or vapor pressure), frequency of handling, and potential for contamination of the work place. Use this drug as an indicator of potential work surface contamination.

*b.* Develop a process flowchart to determine potential sources of contamination to HCWs and personnel and work surfaces from HD receipt to patient treatment and final disposal. Refer to the HD wipe decision logic provided in Figure 9 for sampling guidance.

### B–3. Sampling

*a. Step 1. Screening wipe sampling.* Initial screening sampling is conducted in the highest risk areas for potential drug contamination, which is usually the HD buffering/compounding area. Each buffering/compounding area usually contains at least one biological safety cabinet (BSC); however, there may be more. Each of the screening sample wipes will be analyzed for one HD (e.g., cyclophosphamide, ifosfamide, paclitaxel, doxorubicin, and 5-fluorouracil), as determined by industrial hygiene personnel based on hazard analysis. Wipe sampling is conducted on surfaces in the HD buffering/compounding area of the pharmacy to include one inside the horizontal working surface of each BSC or compounding aseptic containment isolator (CACI) (primary work surface), one on the floor in front of each BSC or CACI, and an additional horizontal work surface within this area, such as a countertop, and an appropriate number of blanks. If no laboratory results are above the limit of detection (LOD), resample periodically. If at least one sample result is above the LOD, re-clean all areas, review work practices and cleaning processes, and retrain staff. Re-clean the work areas that exceed the LOD and resample. Proceed to Step 2.

*b. Step 2. Specific wipe sampling.* When any screening wipe sample laboratory result is above the LOD of the HD analyte, additional HD-specific wipe sampling is performed at the next step in the process which is normally transportation to the location where the HDs are administered to

patients. Samples are collected from the shipping container (e.g., plastic basket), floor near the treatment chair, at least one treatment chair arm rest, and a horizontal work surface such as a table, desk, or computer work station in the patient treatment/drug administration areas. If any wipe sample result is above the LOD, hospital/clinic and pharmacy supervisors review their employee work practices, retrain employees as needed, and determine and eliminate actions that contribute to contamination of the workplace. If sample results exceed the LOD in any area, then all areas are re-cleaned.

*c. Sampling method*.

(1) Contact the Client Services Division (CSD), Army Institute of Public Health (AIPH) for detailed guidance on wipe sampling collection, storage, handling shipping and analysis. Generally, a wipe sampling kit containing instructions along with templates, sampling media (filler and solvent) and sample containers will be shipped to the requestor.

(2) All chemotherapy wipe samples must be analyzed by an American Industrial Hygiene Association-accredited laboratory using approved sampling and analytical methods (for example, NIOSH methods). Any alternate sampling and analytical methods must be approved by the Portfolio of Laboratory Sciences, AIPH.

(3) Follow laboratory requirements for storing and shipping samples. Provide CSD, AIPH advance notification if the number of samples is expected to exceed 25. Consult the Chief, CSD, AIPH, at 410-436-2208 or DSN 584-2208 for additional information and recommendations on sample methodology and laboratory analysis.

*d. Result interpretation*. The wipe sample is determined to be positive for a chemotherapy drug when laboratory results report values greater than the LOD for the HD analytical method.

e. *Baseline*. Whenever the industrial hygienist or HDO cannot determine the highest use area that has the highest potential for surface contamination, they conduct baseline sampling. Conduct baseline sampling in all high hazard areas or locations having potential for surface contamination. Set up future sampling requirements based on the baseline sampling results.

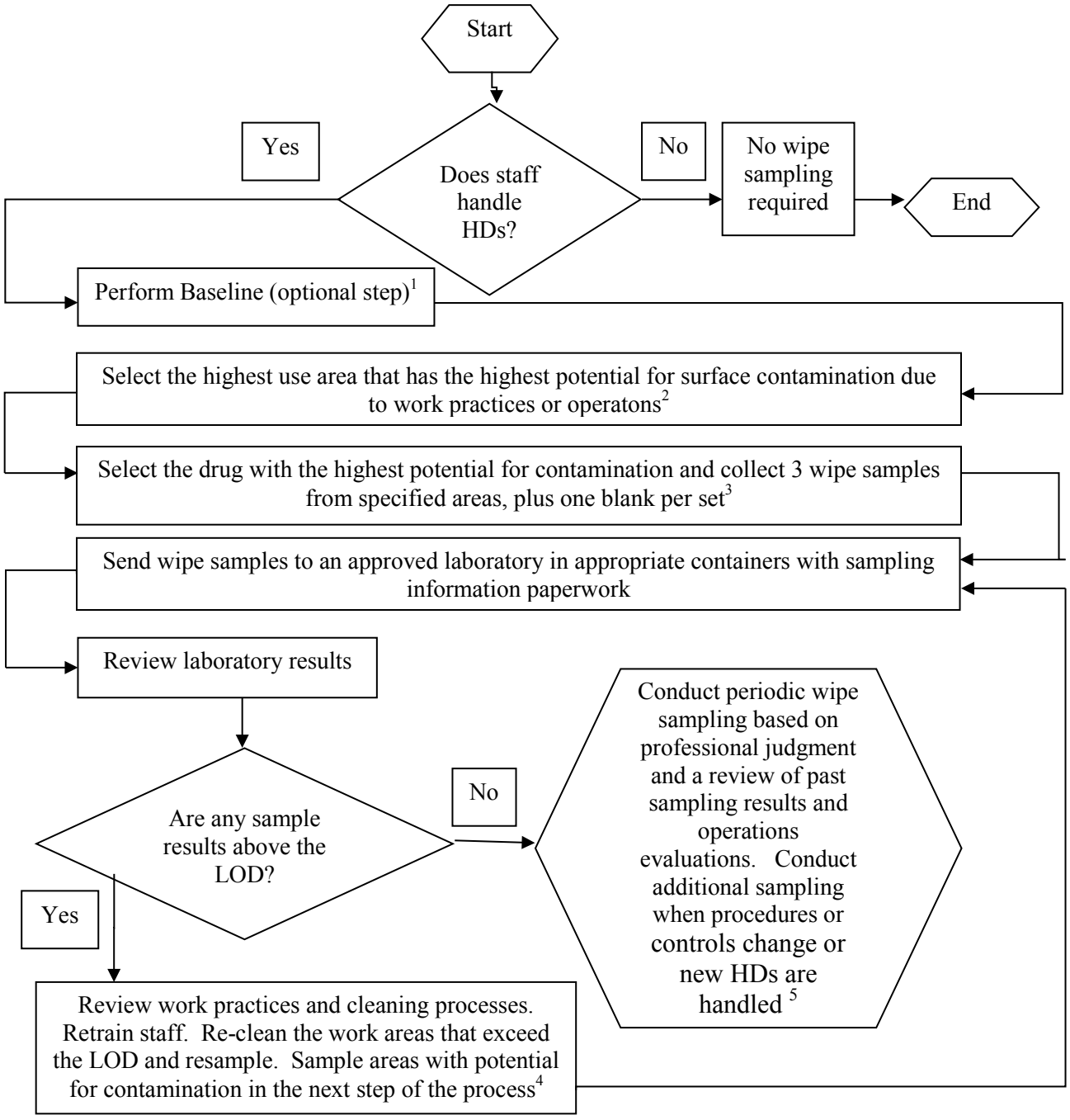



***Figure B–1. Hazardous drug wipe decision logic***

**Note 1.** Whenever the industrial hygienist or HDO cannot determine the highest use area that has the highest potential for surface contamination, they conduct baseline sampling. Conduct baseline sampling in all high hazard areas or

locations having potential for surface contamination. Set up future sampling requirements based on the baseline sampling results.
**Note 2.** Select the one area that contains the highest potential for having contaminated work surfaces. If there are multiple areas with similar potential for contamination, sample all of them or select areas by some random procedure or based on the industrial hygienist's or HDO's professional judgment, ensuring all areas of concern are addressed.
**Note 3.** Select the drug for sampling that has the highest use rate or has the highest potential for contaminating work surfaces. In each area, select three surfaces for wiping: the primary work surface ( e.g., BSC, CACI or bench top) where the compounding/preparation operation is performed, a horizontal work surface next to the primary work surface, and the floor in front of the primary work surface (where the worker stands).
**Note 4.** If any positive wipe sample results are above the LOD, collect additional samples in the next step in the HD handling process such as the equipment used to transport HDs or the administration area or treatment room.
**Note 5.** The industrial hygienist or HDO use their knowledge and evaluation of the HD process, and past sampling results to determine the frequency of conducting surveillance wipe sampling. At a minimum, sampling should be conducted once every 2 years. When no past data or knowledge is available, conduct wipe sampling every 6 months.

# GLOSSARY

## ABBREVIATIONS

**ACGIH**
American Conference of Governmental Industrial Hygienists

**ACH**
air changes per hour

**AIPH**
Army Institute of Public Health

**ALARA**
as low as reasonably achievable

**ANSI**
American National Standard Institute

**AP**
Aerosolized Pentamidine

**AR**
Army Regulation

**BSC**
biological safety cabinet

**CACI**
compounding aseptic containment isolator

**CD**
cytotoxic drug

**CDC**
Centers for Disease Control and Prevention

**CETA**
Controlled Environment Testing Association

**CFR**
Code of Federal Regulations

**CPL**
compliance

**CSPs**
compounding sterile preparations

**CSTD**
closed-system transfer device

**DA**
Department of the Army

**DA Pam**
Department of Army Pamphlet

**DHHS**
U.S. Department of Health and Human Services

**DOEHRS-IH**
Defense Occupational and Environmental Health Readiness System-Industrial Hygiene

**EPA**
Environmental Protection Agency

**FDA**
Food and Drug Administration

**fpm**
feet per minute

**$ft^3$**
cubic foot

**HAZCOM**
hazard communication

**HCW**
healthcare worker

**HD**
hazardous drug

**HDO**
Hazardous Drug Officer

**HDSHP**
Hazardous Drug Safety and Health Plan

**HEPA**
high-efficiency particulate air

**HW**
Hazardous waste

**IEST**
Institute of Environmental Sciences and Technology

**ISO**
International Organization of Standardization

**IV**
intravenous

**LOD**
limit of detection

**$m^3$**
cubic meter

**$mg/m^3$**
milligrams per cubic meter

**mL**
milliliter

**MMWR**
Morbidity and Mortality Weekly Report

**MTB**
mycobacterium tuberculosis

**MTF**
military treatment facility

**NIOSH**
National Institute for Occupational Safety and Health

**NSF**
National Sanitation Foundation

**OEL**
occupational exposure limit

**OSHA**
Occupational Safety and Health Administration

**PEL**
permissible exposure limits

**PL**
Public Law

**PPE**
personal protective equipment

**RCRA**
Resource Conservation and Recovery Act

**RMW**
regulated medical waste

**SDS**
safety data sheet

**SOP**
standing operating procedure

**SPAG**
Small Particle Aerosol Generator

**TB MED**
Technical Bulletin, Medical

**TLV**
threshold limit value

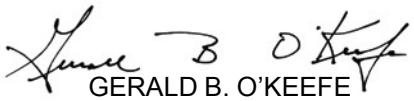
**USP**
US Pharmacopeia

**WAG**
waste anesthetic gases

By Order of the Secretary of the Army:

RAYMOND T. ODIERNO
*General, United States Army*
*Chief of Staff*

Official:



GERALD B. O'KEEFE
*Administrative Assistant to the*
*Secretary of the Army*

Distribution:

This publication is available in electronic media only and is intended for command levels C, D, and E for the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve.