



**HAZARDOUS DRUGS:
ENGINEERING CONTROLS, SAFE WORK PRACTICES
AND PERSONAL PROTECTIVE EQUIPMENT**

TECHNICAL INFORMATION PAPER No. 55-083-0817

PURPOSE

This Technical Information Paper (TIP) provides guidance regarding the selection of engineering controls, safe work practices and personal protective equipment (PPE) for the safe handling of the National Institute for Occupational Safety and Health (NIOSH) list of Hazardous Drugs (HD). This TIP does not change any existing Department of the Army (DA) directives, policies, or procedures related to handling of HD or HD usage at DA medical treatment facilities (MTF).

REFERENCES

U.S. Army Technical Bulletin-Medical (TB-MED) 515. *Occupational Health and Industrial Hygiene Guidance for the Management, Use, and Disposal of Hazardous Drugs*, 22 April 2014.

Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016*. <https://www.cdc.gov/niosh/docs/2016-161/default.html>

USP Compounding Compendium. Chapter <800> Hazardous Drugs – Handling in Healthcare Settings, November 2016.

National Institute for Occupational Safety and Health (NIOSH) Publication No. 2009-106—Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs, 2008.

Army Regulation 11-34, The Army Respiratory Protection Program.

Oncology Nursing Society (ONS), *Safe Handling of Hazardous Drugs, Second Edition*. 2011. Oncology Nursing Society, Pittsburgh, PA.

ENGINEERING CONTROLS

Engineering controls must ensure the quality of the compounding of HD as well protect workers from HD exposure. They provide the most reliable protection from unintended exposure to HD. Depending on the type of work, different engineering controls are needed.

General hazardous drug storage

All HD should be segregated from the general drug population within the MTF. This location should be well labeled with general signage, and each HD should be prominently labeled as HD. For HD requiring refrigeration, the refrigerator must be located in a negatively pressured room, with a minimum of twelve (12) air exchanges an hour.

General counting of hazardous drugs

For HD that are not manipulated (that is those HD that are counted or dispensed without producing particles), no engineering controls are necessary. A separate counting tray must be used only for HD. This tray should be well labeled and stored in a unique location away from general drug counting trays.

Compounding of hazardous drugs

While compounding activities occur, USP <800> requires both primary and secondary engineering controls to be in place. Two types of compounding are recognized by USP <800>, sterile and non-sterile, each with different requirements. Follow the requirements below regardless of type of HD compounding:

- Primary engineering controls (PEC) should be located within a secondary engineering control (SEC).
- The SEC should be externally vented.
- Exhaust from the engineering controls should be high-efficiency particulate air (HEPA) filtered prior to venting.
- The SEC, which is an identified, signed room, should be physically separated from other preparation areas.
- The SEC should be at negative pressure relative to all adjacent areas.

Non-sterile compounding of hazardous drugs

For compounding of HD that does not require a sterile environment, the SEC should have at minimum 12 air exchanges an hour. Additionally, the PEC should be externally vented or at minimum have exhaust air redundant HEPA filtered in series. The PEC can be a Class I or Class II biological safety cabinet (BSC) or a compounding aseptic containment isolator (CACI).

Sterile compounding of hazardous drugs

The preferred SEC environment is a certified International Organization of Standardization (ISO) Class 7 room, referred often to as a “Clean Room”. The non-preferred SEC environment is an unclassified dedicated room containing a PEC. In either type of SEC, the room must be externally ventilated and negatively pressurized relative to adjacent rooms. For an ISO Class 7 room, a minimum of 30 air exchanges per hour is required. For a non-classified SEC room, a minimum of 12 air exchanges per hour is required.

Sterile compounding of HD requires the PEC either be a Class II BSC or a CACI. With either a Class II BSC or a CACI, maintaining an ISO Class 5 environment within the PEC must occur to ensure sterile compounding. The PEC must be negatively pressured relative to the SEC. Additionally, after each use, deactivation, decontamination and sterilization of work surfaces is required.

Supplemental engineering controls

Used in tandem with a PEC, closed system transfer devices (CSTD) are the most common supplemental engineering control. A CSTD captures vaporized HD during transfer from one system or another, to include administration of medication. CSTD's add an additional means of protection for workers during compounding or administration of HD. However, it is important to note that it does not replace other engineering controls or PPE.

Automated Dispensing Devices

Use of automated capsule or tablet counting, packaging or dispensing devices for HD is prohibited.

SAFE WORK PRACTICES

While it is impossible to remove all potential exposure while working with HD, elimination of the most common exposures can occur by employing safe work practices. It is important to identify all possible locations where an exposure to HD may occur within the MTF; this allows for development and implantation of a comprehensive plan for safely handling all HD.

HD Designated Areas

All HD work conducted within a MTF must be done within a designated HD area, labeled with appropriate signage (see HD Signage). These areas must be clearly demarcated for work only with HD. They include, but are not limited to, the following locations:

- HD Storage
- HD Sterile Compounding (If conducted by the MTF)
- HD Non-Sterile Compounding (If conducted by the MTF)
- HD Counting
- HD Patient Treatment Facilities

Access to these designated HD locations must be limited to properly trained authorized personnel. These areas must be located away from break areas, and general MTF population areas.

HD Signage

As part of a HD Safe Work Practices plan, proper signage must be displayed where HD are present for any portion of the workday. These signs must be prominently displayed and readable in all the languages officially spoken at the MTF. Signs should be yellow with black writing, and use proper pictographs. See Figure 1 for an example of HD signage.



Figure 1: HD Warning

HD Storage

All storage of HD must conform to the following items:

- HD must be segregated within the pharmacy. A dedicated HD storage location is required.
- Secondary containment for HD is required.
- Secondary containment cannot be cardboard or other absorbent materials. It must be made from impermeable materials, capable of containing the entire contents of stored items.
- Storage of HD for compounding must be located in an externally ventilated, negatively pressurized (relative to surrounding rooms) room, which has a minimum of twelve (12) air exchanges an hour.
- All HD storage areas must have warning signage posted.
- Storage of HD on floor is not permitted.

HD Cleaning

Maintenance of a clean workspace free of residual HD contamination is critical to the reduction of worker HD exposure. Find guidance for deactivation, decontamination and cleaning of work surfaces exposed to HD in the U.S. Army Public Health Center (APHC) Deactivating, Decontaminating and Cleaning of Surfaces Contaminated with Hazardous Drugs Standard Operating Procedure. Use of Compressed air to clean HD contaminated areas is prohibited.

HD Compounding

- All compounding of HD must take place within proper engineering controls and PPE.
- All HD compounding engineering controls must be properly signed
- All HD compounding engineering controls must be used only for HD and never for general medication compounding.

HD Counting

All counting of HD must conform to the following items:

- Perform all HD counting in HD designated area. This will help reduce HD contamination. (Figure 2)
- Use proper signage to designate the HD counting area. This area should be easily identifiable.

- Employ proper PPE for all HD counting.



Figure 2: Designated HD Counting Area

- Conduct all HD counting on designated HD counting trays reserved for that purpose. (Figure 3)
- Non-HD functions may not be conducted within the HD designated counting area



Figure 3: Designated HD Counting Tray

HD Transport

Handle carefully all HD materials transported throughout the MTF. For HD that is dispensed without manipulation, standard medication handling should be observed. Those medications that are manipulated or dispensed for use within the MTF should be placed into a chemotherapy rated bag and placed within a transport container for movement within the MTF. The transport container should be clearly labeled for HD use only and should never be employed to transport

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other medications or materials. An example of a HD transport container can be seen in Figure 4.



Figure 4: Designated HD Transport Container

HD Hazard Communication

A MTF specific Hazard Communication (HazCom) Program is required. For information regarding HD HazCom please see APHC Technical Information Paper 55-074-0517: Safe Handling of Hazardous Drugs Hazard Communication. In addition to a written HazCom, per paragraph 8 of USP <800>, signed documentation indicating understanding of the risks associated with handling HD is required of all personnel of reproductive capability.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) must ensure the quality of the compounding of HD's as well protect workers from HD exposure. PPE provides reliable protection from unintended exposure to HD, when it is properly selected, worn and maintained. Depending on the type of work, different PPE is needed.

Gloves

Handling of any HD must be conducted wearing powder-free and ASTM-tested chemotherapy gloves. Two pairs are required for compounding, administering, managing a spill, and disposal of HDs. The information about the ASTM testing is available on the box or from the manufacturer. Gloves are required for handling of shipping and other exterior boxes. Double gloves are required for the handling of the actual drug bottles, bags or other containers. Appropriate gloves for cleaning HD areas should also be selected. These cleaning gloves must be

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both ASTM-tested for chemotherapy and appropriate for the cleaning agents used in the HD areas. A glove chart, usually available on the glove manufacturer's website, must be used to select the appropriate gloves for the chemical components of the cleaning agents. If one glove cannot be found, an ASTM-tested chemotherapy glove can be worn under the appropriate glove for the cleaning chemicals.

Protective Clothing

For HD that are not manipulated (that is those HD that are counted or dispensed without producing particles), a laboratory coat should be used to help keep worker's street clothing clean.

Gowns are required for any compounding, administering or spill cleanup. Gowns must be disposable, long-sleeved and cuffed gowns, with a solid front and closure in the back, made of polyethylene coated polypropylene or other laminate material.

Hair, Face, Beard, Shoe Covers must be worn for HD compounding, administering or spill cleanup.

Eye and Face Protection

Eye and face protection must be used when manipulating HDs outside of a PEC and working at or above eye level, cleaning a PEC, or cleaning a spill. Face shields with goggles will provide protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection

Respiratory Protection

Some HD activities require respiratory protection. Anyone using respiratory protection must be enrolled in the Installation's respiratory protection program; where they are part of medical surveillance, and are fit tested for the specific respirator they are using. For most HD activities, a NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles; however, these respirators offer no protection against gases and vapors and little protection against direct liquid splashes. Surgical masks do not provide respiratory protection from drug exposure and should not be used to compound or administer drugs. A surgical N95 respirator provides the respiratory protection of an N95 respirator and the splash protection provided by a surgical mask.

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CONCLUSION

The engineering controls, safe work practices and personal protective equipment described in this TIP outline a number of ways to reduce the occupational exposure to HD. Engineering controls will always be the preferred method to reduce exposure; they have limited human dependence and are not easily avoided. However, engineering controls can be hard to place in existing MTF locations and can be cost prohibitive. Therefore, a combination of administrative controls, PPE and general safe work practices in addition to engineering controls will help to protect the worker from occupational exposure to HD.

POINT OF CONTACT

For more information, contact the U.S. Army Public Health Center, Industrial Hygiene Field Services Division at commercial 410-436-3118 or DSN 584-3118.

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