

UNIVERSITY OF TOLEDO

SUBJECT: HANDLING OF HAZARDOUS DRUGS (HD)
i.e., ANTINEOPLASTIC AND CARCINOGENIC AGENTS

Procedure No: HM-08-005

PROCEDURE STATEMENT

Hazardous drugs shall be handled in a manner so as to ensure the safety of the staff, patients, students, and faculty of the University of Toledo. Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH) and the United States Pharmacopoeia (USP) guidance have been used as a basis for this procedure.

PURPOSE OF PROCEDURE

To ensure protection of individuals working with hazardous drugs as defined by the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings document and 2020 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings.

PROCEDURE

1) RECEIVING, UNPACKING and STORING HAZARDOUS DRUGS

a) Required Facilities and Work Practices for Receiving, Unpacking and Storing Hazardous Drugs

i) A detailed list of required work facilities and safe work practices for receiving, unpacking and storing hazardous drugs can be found in the 2020 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings.

b) Personal Protective Equipment Required for Receiving, Unpacking and Storing Hazardous Drugs

i) Gloves

- (1) Chemotherapy gloves which meet the ASTM D6978 must be worn when receiving, unpacking and storing hazardous drugs.
- (2) Gloves shall be every 30 minutes or when punctured, torn or contaminated.
- (3) Hands must be washed after removing gloves.

ii) Gowns

- (1) Disposable gowns which are resistant to permeability by hazardous drugs must be worn when receiving, unpacking and storing hazardous drugs.
- (2) Gowns must be long sleeved, close in the back and have knit or elastic cuffs.
- (3) Gowns must be changed per manufacturer recommendations, or every 2-3 hours or after a spill or splash.
- (4) Gowns should not be worn outside the immediate area of use.

iii) Shoe Covers

- (1) Shoe covers shall be worn when receiving, unpacking and storing hazardous drugs.
- (2) Shoe covers must not be worn to other areas to avoid hazardous drug contamination.

iv) Respirators

- (1) A full face, powered air purifying respirator with appropriate vapor and particulate combination cartridges shall be worn when unpacking hazardous drugs until an assessment can be made to confirm that no breakage or spillage occurred in transport.

c) Disposal of Personal Protective Equipment (gloves, gowns and shoe covers) and Other Potentially Contaminated Materials when Receiving, Unpacking and Storing Hazardous Drugs

- i) Disposable personal protective equipment shall be removed and discarded into a biohazard – trace chemotherapy waste container (red bin with yellow sticker) prior to exiting the immediate area of use.
- ii) Potential residue on reusable personal protective equipment (respirators) shall be deactivated with an appropriate chemical, decontaminated, cleaned and disinfected prior to being returned to service.

2) COMPOUNDING HAZARDOUS DRUGS

a) Required Facilities and Work Practices Compounding Hazardous Drugs

- i) A detailed list of required work facilities and safe work practices for compounding hazardous drugs can be found in the 2020 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings.

b) Personal Protective Equipment Required for Compounding Hazardous Drugs

i) Gloves

- (1) Two pairs of chemotherapy gloves which meet the ASTM D6978 must be worn when compounding hazardous drugs.
- (2) Gloves shall be changed every 30 minutes or when punctured, torn or contaminated.
- (3) Hands must be washed after removing gloves.
- (4) Gloves shall be carefully removed inside of the Containment Primary Engineering Control (C-PEC) and contained in a sealed bag for disposal outside of the C-PEC.

ii) Gowns

- (1) Disposable gowns which are resistant to permeability by hazardous drugs must be worn when compounding hazardous drugs.
- (2) Gowns must be long sleeved, close in the back and have knit or elastic cuffs.
- (3) Gowns must be changed per the manufacturer's recommendations, or every 2-3 hours or after a spill or splash.
- (4) Gowns should not be worn outside of the immediate area of use.

iii) Shoe Covers

- (1) Two pairs of shoe covers shall be worn when compounding hazardous drugs.
- (2) The second pair of shoe covers shall be donned prior to entering the Containment Secondary Engineering Control (C-SEC) and removed prior to exiting the C-SEC.
- (3) Shoe covers must not be worn to other areas to avoid hazardous drug contamination.

iv) Disposable Sleeve Covers

- (1) Disposable sleeve covers shall be used when compounding hazardous drugs in the C-PEC.
- (2) Disposable sleeve covers shall be carefully removed inside of the C-PEC and contained in a sealed bag for disposal outside of the C-PEC.

v) Other PPE

- (1) Hair and beard cover, if applicable
- (2) Surgical masks must be worn for sterile compounding preparations
- (3) Sterile gloves must be worn for sterile compounding preparations
- (4) Eye and respiratory protection are needed if not compounded in a contained primary engineering control

c) Disposal of Personal Protective Equipment (gloves, gowns and shoe/sleeve covers) and Other Potentially Contaminated Materials when Compounding Hazardous Drugs

- i) Disposable personal protective equipment shall be removed and discarded into a biohazard – trace chemotherapy waste container (red bin with yellow sticker) prior to exiting the immediate area of use.

3) TRANSPORT AND DISTRIBUTION of HAZARDOUS DRUGS

a) Requirements for Transportation and Distribution of Hazardous Drugs

- i) Hazardous drugs must be packaged in a secured area limited to authorized personnel and **clearly labeled** in order to prevent contamination to any person distributing the drug from the pharmacy to any clinical area.
- ii) Department managers or principal investigators will ensure that personnel involved in transporting hazardous drugs are trained in the necessary procedures should a spill occur.
- iii) The pneumatic tube system should not be used to transport highly hazardous drugs that are not in intact tablets or capsules.
- iv) Specimens from patients who have received antineoplastics (chemotherapy, immunotherapy) within the previous 48 hours, should be labeled with a yellow sticker stating "Caution: Antineoplastic Material."
- v) Any material generated in the research areas transferred from original containers shall be labeled as a carcinogen or suspected carcinogen (i.e., syringe, diet).
- vi) Appropriate notification shall be given to DLAR personnel when animals are administered hazardous drugs.

b) PPE for transporting hazardous drugs

- i) Chemotherapy gloves which meet the ASTM D6978

4) ADMINISTRATION of HAZARDOUS DRUGS

a) Required Facilities and Work Practices for Administering Hazardous Drugs

- i) A detailed list of required work facilities and safe work practices for administering hazardous drugs can be found in the 2020 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. These procedures include:

- (1) Using protective medical devices and techniques, such as:
 - (a) Using needless and closed systems
 - (b) Spiking or priming IV tubing with a non-HD solution inside of a C-PEC
 - (c) Crushing tablets inside of a plastic pouch

b) Personal Protective Equipment Required to Administer Hazardous Drugs

i) Gloves

- (1) Chemotherapy gloves which meet the ASTM D6978 must be worn when administering hazardous drugs.
- (2) Gloves shall be every 30 minutes or when punctured, torn or contaminated.
- (3) Hands must be washed after removing gloves.

ii) Gowns

- (1) Disposable gowns which are resistant to permeability by hazardous drugs must be worn when administering hazardous drugs not in intact unit-dose tablets/capsules.
- (2) Gowns must be long sleeved, close in the back and have knit or elastic cuffs.
- (3) Gowns must be changed per the manufacturer's recommendations, or every 2-3 hours or after a spill or splash.
- (4) Gowns should not be worn outside of the immediate area of use.

iii) Respirators

- (1) A full face, powered air purifying respirator with appropriate vapor and particulate combination cartridges shall be worn when administering hazardous drugs where open administration of hazardous drugs is unavoidable or where administration may result in uncontained, open hazardous drugs in the clinical environment.

iv) Eye and Face Protection

- (1) Eye (indirectly vented goggles) and face (face shield) protection must be worn in combination when administering liquid hazardous drugs where a respirator is not necessary.

c) Disposal of Personal Protective Equipment (gloves, gowns) and Other Potentially Contaminated Materials when Administering Hazardous Drugs

- i) Disposable personal protective equipment shall be removed and discarded into a biohazard – trace chemotherapy waste container (red bin with yellow sticker) prior to exiting the immediate area of use. If a red bin is not available, PPE and other contaminated or potentially contaminated items should be disposed into a sealed plastic bag and transported to the chemotherapy waste container.
- ii) Potential residue on reusable personal protective equipment (respirators) shall be deactivated with an appropriate chemical, decontaminated, cleaned and disinfected prior to being returned to service.

5) CLEANING AREAS WHERE HAZARDOUS DRUGS ARE ADMINISTERED

a) Personal Protective Equipment Required to Clean in Areas Where Hazardous Drugs have been Unpacked, Stored, Compounded or Administered

b) When cleaning the area where drugs have been unpacked or stored, the C-SEC and Administration Areas

i) Gloves

- (1) 2 pairs of chemotherapy gloves which meet the ASTM D6978 must be worn when cleaning areas used for hazardous drugs.
- (2) Gloves shall be every 30 minutes or when punctured, torn or contaminated.
- (3) Hands must be washed after removing gloves.

ii) Gowns

- (1) Disposable gowns which are resistant to permeability by hazardous drugs must be worn when cleaning areas used for hazardous drugs.
- (2) Gowns must be long sleeved, close in the back and have knit or elastic cuffs.
- (3) Gowns must be changed per the manufacturer's recommendations, or every 2-3 hours or after a spill or splash.
- (4) Gowns should not be worn outside of the immediate area of use.

iii) Shoe Covers

- (1) Shoe covers shall be worn when cleaning areas used for hazardous drugs.
- (2) 2 pairs of shoe covers shall be worn when cleaning areas inside the C-SEC.
- (3) Shoe covers must not be worn to other areas to avoid hazardous drug contamination.

iv) Eye and Face Protection

- (1) Eye (indirectly vented goggles) and face (face shield) protection must be worn in combination when cleaning areas used for hazardous drugs.

v) Respiratory Protection

- (1) Respiratory protection must be worn when cleaning under

c) Disposal of Personal Protective Equipment (gloves, gowns) and Other Potentially Contaminated Materials when Administering Hazardous Drugs

- i) Disposable personal protective equipment shall be removed and discarded into a biohazard – trace chemotherapy waste container (red bin with yellow sticker) prior to exiting the immediate area of use

d) When cleaning the C-PEC

i) Gloves

- (1) 2 pairs of chemotherapy gloves which meet the ASTM D6978 must be worn when cleaning areas used for hazardous drugs.
- (2) Gloves shall be every 30 minutes or when punctured, torn or contaminated.
- (3) Gloves shall be carefully removed inside of the Containment Primary Engineering Control (C-PEC) and contained in a sealed bag for disposal outside of the C-PEC.
- (4) Hands must be washed after removing gloves.

ii) Gowns

- (1) Disposable gowns which are resistant to permeability by hazardous drugs must be worn when cleaning the C-PEC.
- (2) Gowns must be long sleeved, close in the back and have knit or elastic cuffs.
- (3) Gowns must be changed per the manufacturer's recommendations, or every 2-3 hours or after a spill or splash.
- (4) Gowns should not be worn outside of the immediate area of use.

iii) Shoe Covers

- (1) 2 pairs of shoe covers shall be worn when cleaning areas inside the C-SEC.
- (2) Shoe covers must not be worn to other areas to avoid hazardous drug contamination.

iv) Eye and Face Protection

- (1) Eye (indirectly vented goggles) and face (face shield) protection must be worn in combination when cleaning the C-PEC

v) Respirators

- (1) A full face, powered air purifying respirator with appropriate vapor and particulate combination cartridges shall be worn when cleaning under the tray of the C-PEC.

e) Disposal of Personal Protective Equipment (gloves, gowns) and Other Potentially Contaminated Materials when Cleaning the C-PEC.

- i) Disposable personal protective equipment shall be removed and discarded into a biohazard – trace chemotherapy waste container (red bin with yellow sticker) prior to exiting the immediate area of use.

- ii) Potential residue on reusable personal protective equipment (respirators) shall be deactivated with an appropriate chemical, decontaminated, cleaned and disinfected prior to being returned to service.

6) SPILL CONTAINMENT

- a) Refer to EHRS Procedure [HM-08-013](#), *Hazardous Material Spill Procedures*. Spills must be reported to 419-530-2600) for management and cleanup.
- b) Each area in which hazardous drugs are handled shall contain a small spill clean-up kit. These kits are available from Central Stores and are made up of the following items: 1 disposable chemo-safety gown, 2 pair chemotherapy gloves, 1 Chux spill absorbent, 1 small scoop/scrapper, 1 small sealable and 1 large yellow polyethylene bag for disposal of contaminated absorbent, 1 stack paper towels, and spill procedure sheet.
- c) Overt contamination of gloves or gowns, or direct skin contact should be treated as follows: Immediately remove gloves or gown, wash the affected skin area immediately with soap and water, and complete an injury/incident report. If eye or skin contact or if irritation develops, seek medical attention. If eye contact occurs, flush eyes for at least 15 minutes with water or isotonic eyewash. Seek medical attention immediately.
- d) All contaminated absorbents should be disposed of as described in Section 7 below.

7) DISPOSAL OF HAZARDOUS DRUG (Carcinogen Waste) WASTE

- a) Contaminated sharps used in the preparation or administration of a hazardous drug shall be placed in sharps containers which are clearly marked chemotherapy waste and/or color-coded yellow. Full sharps containers, I.V. tubing and supplies used in the preparation or administration of hazardous drugs (including post-administration liquid wastes from bladder instillations or interperitoneal) and spent spill clean-up supplies shall be placed in 2 mil polypropylene or 4 mil thick polyethylene disposal bags, preferably color-coded yellow. (These supplies are available through Central Stores.) Hazardous drug waste must be placed into a 28-gallon red infectious waste tub. These wastes shall be collected by Environmental Services. Generators of the waste (typically nurses) are responsible for informing Environmental Services that individual containers of infectious waste contain hazardous drug waste and must receive a yellow sticker. Environmental Services will label the waste for incineration by affixing

a yellow sticker to the outside of the red container. Carcinogens generated on the college side should either be disposed of in the Department of Lab Animal Research or by contacting Environmental Health and Radiation Safety at 419-530-3600. These wastes will be disposed of by high-temperature incineration through the Environmental Health and Radiation Safety Department.

- b) Personnel dealing with blood, vomitus, or excreta from patients who have received antineoplastic drugs in the last 48 hours should wear latex gloves and disposable gowns, to be discarded after each use. Eye/Face protection should be worn if vomit or potential to spit up is suspected. Standard precautions will provide appropriate protection.
 - c) Linen contaminated with antineoplastic drugs, blood, vomitus, or excreta from a patient who has received antineoplastic drugs in the last 48 hours should be first bagged in a clear plastic liner, then in a blue linen bag, and then placed in a 4 mil, yellow polyethylene bag for disposal. Bags are available from Central Distribution.
 - d) Certain classes of hazardous drugs provided through the hospital Pharmacy are considered "hazardous waste" when destined for disposal. These drugs will be identified by the Pharmacy. Nursing will be required to collect the waste and place it in a black container found in dirty utility rooms in clinical areas. Nursing staff should contact Environmental Health and Radiation Safety to retrieve these wastes for disposal through a licensed hazardous waste treatment facility. Disposal can be requested at 419-530-3600 or via the chemical waste disposal request form at <http://utoledo.edu/depts/safety/forms.html>
- 8) DISPOSAL OF NON-HAZARDOUS DRUG WASTE
- a) Liquid non-hazardous drug waste (drugs which are not considered "hazardous", "carcinogen" or "controlled substances") shall be wasted to the greatest extent possible down a sanitary drain system (sink or toilet), and empty containers disposed of in the solid waste receptacle (trash) or broken glass disposal container as appropriate. Solid non-hazardous drug waste shall be disposed of in the solid waste receptacle or broken glass container as appropriate.
- 9) PERSONNEL POLICY RECOMMENDATIONS
- a) All personnel in affected areas shall receive special training in working with hazardous drugs. Each department manager shall have the responsibility for either obtaining or providing the necessary training on an annual basis. Documentation of this training shall be maintained in the department. Training is also available from the Oncology Clinical Nurse Specialist and Department of Nursing Resources.
 - b) It is the responsibility of the departmental managers to assure compliance with established procedures/ policies for handling of hazardous drugs.
 - c) Pregnant employees should be informed of the potential reproduction hazard, and if they so request, staff members who are pregnant or breastfeeding should be transferred to comparable duties that do not involve handling hazardous drugs. At the discretion of the department manager, a similar policy may be followed among male or female personnel who are actively trying to conceive a child. (See Procedure [HM-08-028](#).)

Source: Safety & Health Committee

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