



# Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 913  
VERSION: 7

## **SUBJECT: Handling of Hazardous Drugs**

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### **PURPOSE:**

To establish guidelines for the safe handling of hazardous drugs. Hazardous drugs, such as antineoplastic agents, are known to be carcinogenic, teratogenic or mutagenic. Their toxicity dictates that exposure to the pharmacy staff, other medical personnel, and patients be minimal. Contamination can arise from several sources and multiple points. All personnel involved in the preparation of antineoplastic agents shall take appropriate steps to minimize self and environmental contamination.

### **POLICY:**

- All manipulation of hazardous drugs (other than counting or pouring) shall occur in the ChemoShield.
- Pharmacy staff shall not manipulate hazardous drugs in final dosage forms other than counting/filling and will use appropriate Personal Protective Equipment (PPE) to minimize self and environmental contamination.
- The use of PPE is mandatory when handling and disposing hazardous medications in any form. Disposable PPE should be placed in appropriately identified hazardous waste containers after use.
- Pharmacy staff routinely exposed to hazardous drugs will be identified by their Service Area Managers/Supervisors to be enrolled and monitored as part of the Hazardous and Antineoplastic Drug Surveillance Program per policy and procedure and shall be fit tested.
- Pregnant personnel, those attempting to become pregnant, those suspected of being pregnant, and nursing mothers should avoid handling hazardous medications.
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling hazardous drugs.
- Eating, drinking and the presence of food is prohibited in areas where hazardous drugs are prepared and stored.

### **DEFINITIONS:**

**Hazardous Antineoplastic Medications:** medications used in the direct treatment of cancer or autoimmune disorders that produce its effects via a cytotoxic mechanism. In addition to being cytotoxic, many of these medications may pose an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, or breast feeding.

**Hazardous Non-Antineoplastic Medications:** medications classified as carcinogenic, teratogenic, developmentally toxic, reproductive toxic or end organ toxic, but do not produce their effects via a cytotoxic mechanism. Some of these medications may pose an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, or breast feeding.

**Reproductive Risk:** medications with a potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, or breast feeding.

**Chemo safe gloves:** gloves that meet American Society for Testing and Materials standard D6978 or successor.

**Deactivation:** Deactivation renders a compound inert or inactive. Residue from deactivation must be removed by decontaminating the surface.

**Decontamination:** inactivating, neutralizing, or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned

**Cleaning:** process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals.

## **PROCEDURES:**

### **Training/Competency**

- Pharmacy staff members who engage in receiving, handling, and compounding of all hazardous drugs shall have training and demonstrated competence in the proper handling of hazardous drugs (HD's)

### **List of Hazardous Drugs**

- HDRHC Pharmacy shall maintain a list of hazardous drugs, in accordance to NIOSH recommendations, and categorize the drugs identified as antineoplastic, non-antineoplastic, or reproductive risk.
  - The list must be reviewed at least every 12 months

### **Receiving**

- A spill kit shall be accessible in the receiving area
- Antineoplastic HDs must be unpacked in a designated area that is neutral/normal pressure relative to surrounding areas.
- When receiving hazardous drug, pharmacy staff shall wear double chemo safe gloves. If a leak is suspected, in addition to double chemo safe gloves, staff members shall don a chemo safe gown, and a N95 respirator.
- When received from a supplier, containers containing HD's received from a supplier shall be received in dedicated area
  - Containers and packaging shall be inspected for damage prior to opening (signs of leakage or sounds of broken glass)
    - If shipping container appears damage, contact the supplier and safety officer for further instruction
    - Handle spills per policy and procedures

- After opening the shipping container, HD drugs shall be retained in sealed plastic container until delivery to storage area
  - If damage/spill is suspected within the bag and leaking is apparent, do not open the bag. Transfer plastic container into another sealed plastic bag and container and contact supplier and safety officer for further instructions
  - Handle spills per policy and procedures

### **Storage**

- Antineoplastic hazardous drugs in final dosage forms shall be separated from other drugs
- Non-antineoplastic and reproductive risk only hazardous drugs in final dosage forms may be stored with other inventory.
- All hazardous drug that require manipulation (other than counting and pouring) shall be stored in the negative pressure chemo room with at least 12 air changes per hour.
- Antineoplastic hazardous drugs requiring refrigeration shall be stored in a dedicated refrigerator in the negative pressure chemo room with at least 12 air changes per hour.
- Drug packages, bins, shelves, and all storage areas of hazardous drugs shall bear distinctive labels identifying them as requiring special precautions.
- Hazardous drugs shall be protected from potential breakage by storing in bins that have high fronts and on shelves that have guards to prevent accidental falling. The bins must also be appropriately sized so as to properly contain all stock

### **Handling of Hazardous Drugs in Final Dosage Forms**

- A dedicated area in the pharmacy will be used to prepare hazardous drugs that are in final dosage forms into a prescription container.
  - A chemosorb mat shall be placed on the counter of this area. All counting and preparing shall be done above this mat. This mat shall be replaced at the end of the day and with any signs of contamination.
- Pharmacy staff shall wear two pairs of chemo safe gloves when handling hazardous drugs
- Pharmacy staff shall wear two pairs of chemo safe gloves when counting or transferring hazardous drugs from the manufacturer's package to a prescription container. Chemo safe gloves are recommended but not required when handling these drugs in the final dispensed non-alterable form (i.e. prescription container).
- Pharmacy staff shall never crush tablets or open capsules containing hazardous drugs
- Tablet and capsule forms of hazardous drugs shall not be placed in automated counting machines

- Hazardous drugs shall be counted on trays designated for hazardous drugs. These trays shall be decontaminated (wiped down with sterile water and gauze) after each use. The gauze and rinse should be contained and disposed of as contaminated hazardous waste.
- Contaminated equipment should be cleaned with gauze saturated with sterile water after each use (i.e. counting trays and spatula). The gauze and rinse should be contained and disposed of as contaminated hazardous waste.

### **Sterile compounding of injectable hazardous drugs**

- All hazardous drugs that require compounding must be prepared/compounded in the chemoSHIELD Barrier Isolator (see chemoShield policy 02-47). This isolator is placed in a negative pressure room with at least 12 ACPH and a negative pressure of 0.01 to 0.03 inches of water column.
- IVPB preparations of sterile compounded hazardous drugs shall be primed with medication administration sets by the pharmacy staff in the chemoSHIELD.
- Luer-lock syringes and IV sets are used for all admixtures when possible
- A chemosorb pad is placed on the hood surface during the mixing of antineoplastic agents. The drape is exchanged whenever substantial spillage occurs or at the end of each production sequence
- External surfaces of final compounded products shall be wiped with sterile water prior to removing from the isolator

### **Personal Protective Equipment**

- Disposable, ASTM- tested, powder free chemo safe gloves must be worn for handling hazardous drugs (including counting and transferring hazardous from the manufacturers packaging to a prescription container). Double gloving shall be practiced. Change gloves every 30 minutes or immediately when damaged or contaminated. Hands shall be washed after removing gloves. When used for sterile compounding, the outer chemotherapy glove must be sterile.
  - Wash hands each time gloves are removed. Gloves are not a replacement for hand washing.
- Disposable chemo gowns shall have a closed front, long sleeves, and closed cuff (either elastic or knit). These shall be worn in the event of a suspected vial breakage of a hazardous drug, a hazardous drug spill, and during compounding activities involving hazardous drugs. Chemo gowns shall be changed and used for no longer than 3 hours.
- Head and hair and double shoe covers shall be worn when compounding hazardous drugs.
- Eye and face protection shall be worn when handling spills outside of the isolator.

- All potentially contaminated barrier garments or gloves **MUST** be immediately discarded in appropriate bins.
- Gloves and barrier garments shall be disposed of in the appropriate waste container.

### **Labeling Requirements**

- HD shall be labeled as such at all times during transport.
- In addition to compounded sterile preparation IV label requirements, sterile compounded hazardous drug products shall also have the following warning label: ***“Chemotherapy - Dispose of Properly”*** or similar verbiage.

### **Pregnant Employee or Nursing Mother**

- Pregnant personnel, those attempting to become pregnant, those suspected of being pregnant, and nursing mothers should avoid preparing and handling all antineoplastic drugs. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. Attestation shall be kept in each employee personal file.

### **Order Verification and Dispensing**

- All orders compounded sterile chemotherapy agents shall be checked and calculated by the pharmacist. To ensure medication safety a **DOUBLE CHECK shall be performed by another pharmacist**
- Labs are to be checked before dispensing chemotherapy. Documentation of checks and progress notes are to be kept on records in a patient profile in the Pharmacy.

### **Transportation of hazardous compounded sterile preparation to nursing areas**

- All hazardous compounded sterile preparations shall be placed in a sealed zipped chemobloc bag. These preparations shall be double bagged. The inner bag shall hold each admixture separately. Labels identifying drug name shall be placed on the inner bag and the outer bag shall be labeled with the patient name and MRUN.
- Alert personnel with appropriate labeling. Label shall include the statement **“CAUTION – CANCER CHEMOTHERAPY – DISPOSE OF PROPERLY”**
- All final compounded antineoplastic drugs must be transported in a sealed container.
- Chemo safe gloves shall be worn when transporting antineoplastic drugs to nursing station.

### **Deactivation and Decontamination**

- All areas where HDs are handled and all reusable equipment must be deactivated/decontaminated at the end of the day or if visible contamination occurs

- Handle hazardous drug spill per policy and procedures
- PeridoxRTU or a low concentration of sodium hypochlorite may be used for deactivation
- Personnel performing these activities must wear appropriate PPE including two pairs of chemotherapy gloves, chemo safe gown, eye protection, and respiratory protection.
- All disposable materials must be discarded in appropriate waste bins (i.e. black bins)

**Attachments**

- **Hazardous drug list**

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