General pharmacy (no sterile or nonsterile compounding) – this means only handles HDs in final dosage forms and does NO manipulation of antineoplastic HDs (cutting tablets, etc.). Manipulation of table 2 and 3 HDs is addressed in the assessment of risk.

## 5.35 (Choice A): Hazardous Drug Handling

1. **Purpose:** This procedure describes the handling of hazardous drugs (HDs) which includes receipt, storage, dispensing, and disposal to promote personnel and environmental safety.
2. **Scope:** This procedure applies to all personnel in a pharmacy that receives, stores, prepares and dispenses HDs as they may potentially be exposed to HDs.
3. **Definitions:**
   * Hazardous drug (HD): Any drug identified by at least one of the following criteria:

• Carcinogenicity, teratogenicity, or developmental toxicity

• Reproductive toxicity in humans

• Organ toxicity at low dose in humans or animals

• Genotoxicity or new drugs that mimic existing HDs in structure or toxicity

1. **Safety Requirements:** All personnel who handle HDs are responsible for understanding and following HD handling practices and precautions to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work environment.
2. **Procedure**
3. **Hazard communication program**

* The pharmacy has warning signs designating the hazard prominently displayed before the entrance to the areas where hazardous drugs are stored or handled. These areas are only accessed by authorized personnel.
* All containers of hazardous chemicals or drugs are labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
* The pharmacy has a Safety Data Sheet (SDS) for each hazardous drug or chemical in the pharmacy and the SDSs are readily available in all areas where HDs are handled. Annual review of file to ensure all HDs have an SDS. SDSs will be added when new HDs are added to inventory.
* All personnel who may be exposed to hazardous chemicals when working are required to successfully complete training and assessments before working with HDs, annually, and whenever the hazard changes. Training includes:
  + Overview of the pharmacy list of HDs and the assessment of risk.
  + Review of the pharmacy policies and procedures for handling HDs.
  + Proper use of personal protective equipment (PPE)
  + Proper use of equipment and devices
  + Response to known or suspected HD exposure
  + Spill management
  + Proper disposal of HDs and trace-contaminated materials
* All personnel of reproductive capability [NOTE: best practice is for all personnel, not limited to reproductive age] must confirm in writing that they understand the risks of handling HDs. See attachment “Hazardous Drug Handling and Exposure Acknowledgement”.

1. **Occupational safety program**
   * HD list. The pharmacy maintains a list of all HDs in the pharmacy. The list is reviewed and revised at least every 12 months.

HDs include:

* Drugs listed in the most current National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings
* Any new drug that enters the market since the most recent NIOSH list was published that meets the criteria for an HD.
* Investigational drugs that meet the criteria for an HD.
* Drugs for which there is not sufficient information to determine if hazardous.
  + Assessment of Risk. The pharmacy performs an Assessment of Risk (AOR) for each HD drug and dosage form. In the absence of an AOR, all HDs must be handled under the full containment requirements required by USP Chapter <800> Hazardous Drugs.

The assessment of risk includes:

* The name of the HD (note: must be a line for each drug, not general categories like “estrogens”, etc.)
* Type of HD according to the NIOSH table (antineoplastic, non-antineoplastic, reproductive risk only)
* Dosage form (note: each dosage form of the same HD must be addressed on a separate line).
* Risk of exposure
* Packaging
* Manipulation
* Alternative containment strategies and/or work practices that are employed for specific dosage forms to minimize occupational exposure.

The AOR is reviewed and revised at least every 12 months.

The AOR is readily available to employees in all areas where HDs are handled.

* + Facility and engineering controls
    - HDs are handled under conditions that promote patient safety, worker safety, and environmental protection.
    - HD handling areas are located away from breakrooms and refreshment areas for personnel or visitors to reduce the risk of exposure.
  + Competent personnel
    - All personnel are trained and have successfully completed competency assessments for handling HDs.
  + Safe work practices
    - Policies and procedures are in place and reviewed annually.
    - Appropriate engineering controls are maintained, and PPE are available.
    - Appropriate action is taken when personnel fail to follow policies and procedures or engage in behavior that puts personnel or the environment at risk of exposure.
  + Personal Protective Equipment (PPE)
    - The use of PPE is specific to the HD and activity being performed. Refer to the AOR for information on the PPE required for handling the specific HD and dosage form.
    - Gloves
      1. Chemotherapy gloves meet the American Society for Testing and Materials (ASTM) standard D6978 (or its successor), or better.
      2. Selection of gloves also includes evaluating the HD to be handled and the permeability characteristics of the glove material (PVC, latex, nitrile rubber, polyurethane, neoprene, etc.).
      3. Gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs.
      4. Gloves must be inspected for physical defects before use. Do not use gloves with pin holes or weak spots.
      5. Chemotherapy gloves must be changed when torn, punctured, or contaminated.
      6. Hands must be washed with soap and water after removing gloves.
    - Gowns (if used)
      1. Gowns are disposable and shown to resist permeability by HDs and selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.
      2. Gowns close in the back (i.e., no open front), are long sleeved, and have closed cuffs that are elastic or knit. Gowns do not have seams or closures that could allow HDs to pass through.
      3. Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs because they permit the permeation of HDs and can hold spilled drugs against the skin, thereby increasing exposure. Clothing may also retain HD residue from contact and may transfer to other personnel or surfaces.
      4. Potentially contaminated clothing must not be taken home under any circumstances.
      5. Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other personnel.
    - Shoe covers (if used)
      1. When appropriate, shoe covers are worn to protect shoes from HD residue.
      2. Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other personnel.
    - Eye protection
      1. Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs, and when cleaning up spills.
      2. Gogglesare used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes.
      3. Face shieldsalone do not provide full eye and face protection.
      4. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes.
      5. Also, a full-facepiece respirator (if used) provides eye and face protection.
    - Respiratory Protection
      1. When to use a respirator
         1. Unpacking shipments of antineoplastic HDs not contained in plastic
         2. Working on HD spills larger than the spill kit can contain
      2. Types of respiratory protection
         1. N-95 respirators and N-95 surgical masks – for particle protection only
         2. Elastomeric half-mask respirators with P100 filters or targeted cartridges
         3. Full-facepiece chemical cartridge respirators
         4. Full-facepiece powered air-purifying respirator (PAPR)
      3. Personnel who will use respirators must provide a medical evaluation indicating they are not prohibited from using a respirator due to a medical condition (which may include COPD, asthma, lung or heart conditions, etc.).
      4. Personnel who will be using respirators will be fit tested to ensure proper functioning of the respirator and protection of the personnel.
  + Policies for HD waste segregation and disposal
    - The facility has a hazardous waste disposal system in place that segregates and handles waste
    - The facility works with a knowledgeable vendor for hazardous waste handling and destruction.
    - The facility accurately describes EPA waste and hazardous drugs.
      1. EPA lists (P, U, K, F)
      2. NIOSH list
      3. The facility follows all requirements for limits and recordkeeping for their type of a hazardous waste generator.
         1. The facility is registered as a large quantity generator (LQG) if more than 2.2 pounds of EPA listed acute hazardous waste (nicotine gum, warfarin, etc.) been accumulated on site. LQG has a 90-day limit on accumulating waste.
         2. Small quantity generators (SQG) have a 180-day limit on accumulation.
    - The hazardous waste is segregated by (at a minimum):
      1. Red containers: biohazardous or infectious waste – sharps, syringes/needles, live attenuated vaccines, blood products, globulins, etc.
      2. Yellow containers: trace contaminated waste – PPE, general cleaning materials (may have trace HD residue), empty containers, syringes or vials that contained hazardous drugs, etc.
      3. Black containers: contaminated PPE, spill clean-up materials, bulk powders, hazardous drugs, wipes used when decontaminating packages of HDs received, etc.
    - If a hazardous waste vendor is not used, the facility appropriately documents and destroys hazardous waste according to local, state and federal regulations (taken care of by the hazardous waste vendor)

1. **Designation of HD areas**

* Receipt and unpacking
  + Hazardous drugs and APIs must be unpacked in a designated area that is neutral or negative pressure.
* General Storage
  + All drug products are stored under appropriate USP or product-specific temperature and humidity conditions.
  + HDs are stored to prevent breakage. In earthquake prone areas, HDs are stored on shelves with raised lips or other secure storage that will prevent HDs from falling and breaking.
  + HDs are not stored on the floor.
  + Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs (does not need manipulation or compounding) may be stored with regular stock according to the direction in the pharmacy hazardous drug list and assessment of risk alternative containment requirements.

1. **Receipt**

* There is a designated area for the receipt of antineoplastic HDs.
* Appropriate PPE is available and used when unpacking HDs. At a minimum, gloves or chemo gloves will be donned, HDs unpacked, and the exterior of the packages wiped down to remove any HD residue before transporting to the appropriate storage area.
* PPE is discarded as trace contaminated (yellow bin) and the wipes used to remove HD residue from the outer packages received are discarded as contaminated (black bin).
* Remove the PPE after handling the HD and BEFORE traveling to other areas where the PPE may spread HD contaminants. For example, remove the gloves and discard appropriately, then wash your hands before answering the phone or handling other items in the pharmacy.
* If HDs are received damaged, handle as a spill (see 12.0 Spill Control), donning appropriate additional PPE and taking steps to prevent HD residue from contaminating the pharmacy.

1. **Handling and Dispensing Finished Dosage Forms**

* The final dosage form of a medication is that form which requires no further manipulation before administration. For example, just counting out tablets or capsules and putting in a vial or dispensing an entire tube of an HD cream. If any manipulation of the HD is required (such as cutting tablets in half or pouring an HD liquid into a bottle for dispensing) it must be addressed in the assessment of risk and may be required to be treated as nonsterile compounding with appropriate controls.
* Finished or final dosage forms of HDs may be stored separately in a designated, marked area or stored with regular (non-HD) stock on the shelves, with the additional containment required as indicated in the assessment of risk.
* Finished dosage forms are prepared for dispensing (counted out, etc.) in a designated area using designated equipment (counting tray, spatula). The equipment and area are cleaned after use.
* Antineoplastic HDs are not counted out using automation. Other HDs are not counted out using automation unless there is a plan to contain any HD residue and a plan for cleaning of the equipment and this is addressed in the assessment of risk.
* Appropriate PPE is worn when handling HDs in final dosage forms and will be indicated in the assessment of risk. PPE is discarded as trace contaminated (yellow bin).
* Remove the PPE after handling the HD and BEFORE traveling to other areas where the PPE may spread HD contaminants. For example, after filling a prescription for an HD, remove the gloves and discard appropriately, then wash your hands before answering the phone or handling other items in the pharmacy.
* For spills, leaks or damage, see 12.0 Spill Control.
* Cleaning equipment and the area where HDs are handled occurs daily and after each HD is prepared to dispense. CLEANING AGENTS MUST NOT BE SPRAYED onto contaminated areas as this may spread HD residue. Personnel must wear appropriate PPE when cleaning. First a deactivating agent is used to break down any HD residue (an oxidizer such as peroxide agent or sodium hypochlorite), then the area, or tray and spatula is decontaminated and cleaned (with a soap or detergent) to remove the deactivated HD material and other contaminants. Cleaning may be followed by a purified water rinse to remove cleaning product residue and/or an alcohol wipe or rinse to disinfect the equipment and area.

1. **Nonsterile Compounding - this pharmacy performs no nonsterile compounding.**
2. **Sterile Compounding – this pharmacy performs no sterile compounding.**
3. **Labeling, Packaging and Transport**

* Labeling: All HDs identified in the risk assessment as requiring special handling must be clearly labeled with cautionary labeling. Labels and accessory labeling for the HDs include storage instructions, any special handling instructions, and disposal instructions.
* Packaging: Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting personnel who transport HDs from HD residue or leakage.
* Transport: HDs must be transported in containers that minimize the risk of breakage or leakage.
  + Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.
  + If HDs are being delivered, the delivery employee must have a spill kit and appropriate PPE available and be trained in using them if there is a spill or leak.
  + If shipping HDs to locations outside the pharmacy, the pharmacy must follow the transportation information SDS and the requirements of the carrier. The HDs must have all appropriate labeling including the HD category.

1. **[Administering – this pharmacy does not administer any HDs.]** 
   1. HDs must be administered safely using protective medical devices (needleless systems and CSTDs, etc.) and techniques (spiking and priming IV tubing in a C-PEC or crushing tablets in a plastic bag, etc.)
   2. Appropriate PPE must be worn when administering HDs.
   3. PPE, packaging materials, tubing, needles, etc. used for administration are appropriately disposed of as hazardous waste.]
2. **Environmental Monitoring** (e.g., wipe sampling)

Note: This is a “should” item – not required. May not be necessary if the pharmacy does no compounding or manipulation of HDs. The pharmacy should determine if the amounts and types of HDs handled would warrant this type of monitoring.

* Environmental wipe sampling for HD surface residue should be performed initially, then at least every 6 months to verify containment of HD residue in areas where HDs are handled.
* Surface wipe sampling is performed on the:
  + Surfaces in the HD counting and preparation areas
  + Areas adjacent to preparation areas
  + [Patient administration areas]
* Common marker HDs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. Many more are being developed. Research suppliers to ensure appropriate residues will be detected if present.
* If any measurable contamination is found, the designated person must identify, document, and contain the cause of contamination. This may include:
  + Performing thorough deactivation, decontamination and cleaning
  + Reevaluating work practices
  + Re-training personnel
  + Repeating the wipe sampling to validate that the deactivation/decontamination and cleaning steps have been effective.

1. **Disposal**
   1. The pharmacy has contracted with a hazardous waste disposal company.
   2. The company has provided color-coded bins in which to put hazardous waste and trace-contaminated materials. Black for contaminated or bulk HD waste, yellow for trace-contaminated materials, and red for biohazardous or sharps.
   3. HD waste bins are located in all areas where HDs are handled.
   4. All personnel are trained in the appropriate procedures to identify and handle HD waste, and in cleaning of areas that may be contaminated with HD residue. This includes all housekeeping and custodial personnel that perform cleaning or waste removal from the pharmacy.
   5. Appropriate disposal of HD waste is handled by the contracted HD waste disposal company.
   6. If the pharmacy does not contract with a company, the pharmacy must comply to all local, state, and federal (including EPA) regulations for the segregation, handling, and disposal of HD waste.
2. **Spill control**
   1. Spill kits are of the appropriate size and composition to contain and clean up a spill of HDs handled by the facility.
   2. A spill kit must be available in areas where HDs are received, stored, handled, and with delivery drivers.
   3. All employees are trained in handling spills, including employees that are delivery drivers, initially and annually.
   4. A “spill” of an HD includes dropping solid dosage forms, spilling of liquid HDs, damaged or leaking containers of HDs received, HD packaging damaged when handling, etc.
   5. Procedure
      1. A spill is identified.
      2. Signage is posted or other means used to alert staff to the spill and restrict access to the spill area until clean-up is complete.
      3. The appropriate personnel (or spill team, if you have one) dons PPE and retrieves the spill kit. PPE includes a cartridge-type respirator or, if the capacity of the spill kit is exceeded or there is potential exposure to vapors or gases, a full-facepiece, chemical cartridge-type respirator is used.
      4. The materials in the spill kit are used to contain and soak up any HDs, and to collect any solids, packaging and broken glass for disposal.
      5. The spill area is then thoroughly cleaned by deactivating the HD, decontaminating the area, cleaning and sanitizing.
      6. All spill and clean-up materials are placed in the bag(s) supplied with the spill kit, sealed, and disposed of as contaminated or bulk hazardous waste (black bin).
      7. The spill and actions taken afterward are documented.
   6. Personnel and others who are exposed during the spill or clean-up, or who have direct skin or eye contact with HDs require immediate evaluation.
      1. Provide a copy of the HD SDS to medical personnel performing the evaluation for reference to the specific HD the person was exposed to.
      2. Document the exposure
      3. Monitor for exposure-related health changes (see 13.0 Medical surveillance)
   7. All spills and any related incidents of exposure are evaluated as part of the pharmacy quality program and may include re-evaluation of:
      1. Administrative controls
      2. Engineering controls
      3. PPE and spill kits available
      4. SOPs
      5. Training
3. **Medical surveillance** (optional)

Note: This is a “should” item – not required. May not be necessary if the pharmacy does no compounding or manipulation of HDs. May be used for acute spills and exposures of certain HDs. The pharmacy should determine if the amounts and types of HDs handled would warrant this type of monitoring

* 1. Pharmacy personnel who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program. It is part of a comprehensive exposure control program along with engineering controls, safe work processes, and use of PPE. It is a secondary prevention tool that may provide early detection if health problems develop.
  2. Medical surveillance programs involve assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood counts) to determine whether there is a deviation from the expected norms.
  3. The data-gathering elements of a medical surveillance program are used to establish a baseline of workers' health and then to monitor their future health for any changes that may result from exposure to HDs.
  4. Medical surveillance programs also look for trends in populations of workers. Examining grouped data compared with data from unexposed workers may reveal a small alteration or increase in the frequency of a health effect that would be obscured if individual workers' results alone were considered.
  5. Procedure:
     1. Identify personnel who are potentially exposed to HDs as part of their regular job duties.
     2. Contract with a health service to perform the tests while protecting the employee medical information.
     3. Have a baseline assessment performed.
        1. Medical and reproductive history
        2. Physical examination including lab tests linked to target organs based on the types of HDs handled
        3. Exposure history (HDs handled, dosage forms, quantities, estimated time handling HDs weekly or monthly, etc.)
        4. Blood or urine levels of a specific HD only with acute spills and exposure to the specific HD.
        5. Monitoring and documentation maintained according to OSHA.
        6. Prospective periodic surveillance performed and monitoring for changes.
        7. Develop follow-up plan for changes suggesting toxicity or for those with acute exposure. The occurrence of exposure-related health changes should prompt immediate re-evaluation of primary preventive measures (including administrative and engineering controls, PPE, etc.).
        8. Completion of an exit examination when an employee leaves employment at the pharmacy to document the information on the employee's medical, reproductive, and exposure histories.

1. **References**
   * USP Chapter <800> Hazardous Drugs
   * NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings <https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf> [note that current edition is 2016, the 2018 revision is anticipated to be released in early 2019]
   * Respirators: <https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html>
   * Respirator Fit Testing: <https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html>
   * Medical Surveillance: <https://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf>

[NOTE: should the respirator and medical surveillance references be incorporated directly into the specific sections or stay here with the references?]

1. **Attachments**
   * Hazardous Drug Handling and Exposure Acknowledgement

**Hazardous Drug Handling and Exposure Acknowledgement**

Employee Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I understand that this pharmacy handles and prepares hazardous drugs.

Hazardous drugs are those drugs that have one or more of the following characteristics: carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity at low doses or genotoxicity.

I have been provided training that includes review of the pharmacy’s Standard Operating Procedures (SOPs) and agree to comply with them.

I have taken and passed the assessment questions for hazardous drug training, and successfully demonstrated competency in the handling of hazardous drugs.

I am familiar with SDS and the assessment of risk for the hazardous drugs handled at this pharmacy.

I acknowledge that exposure to hazardous drugs may cause acute and chronic effects including skin rashes, infertility, miscarriage, birth defects and possibly cancer. Failure to follow pharmacy policies and procedures may put me at greater risk of exposure to hazardous drugs.

Employee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

PIC Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_