

## USP <800> “Should(s)”

### 2. List of Hazardous Drugs

Whenever a new agent or dosage form is used, it **should** be reviewed against the entity's list.

### 5. Facilities and Engineering Controls

HDs used for nonsterile compounding **should** not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

CSTDs **should** be used when compounding HDs when the dosage form allows.

### 6. Environmental Quality and Control

Environmental wipe sampling for HD surface residue **should** be performed routinely.

### 7. Personal Protective Equipment

Chemotherapy gloves **should** be worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs.

Chemotherapy gloves **should** be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated.

Personnel who are unpacking HDs that are not contained in plastic **should** wear an elastomeric half-mask with a multi-gas cartridge and P100-filter until assessment of the packaging integrity can be made to ensure no breakage or spillage occurred during transport.

An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) **should** be worn when there is a risk of respiratory exposure to HDs, including when:

- Attending to HD spills larger than what can be contained with a spill kit.
- Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC.
- There is a known or suspected airborne exposure to powders or vapors.

PPE worn during compounding **should** be disposed of in the proper waste container before leaving the C-SEC.

## 10. Receiving

HDs **should** be received from the supplier in impervious plastic to segregate them from other drugs and to allow for safety in the receiving and internal transfer process.

When opening damaged shipping containers, they **should** preferably be transported to a C-PEC designated for nonsterile compounding.

## 12. Dispensing Final Dosage Forms

Clean equipment **should** be dedicated for use with HDs and should be decontaminated after every use.

## 13. Compounding

A plastic-backed preparation mat **should** be placed on the work surface of the C-PEC.

- The mat **should** be changed immediately if a spill occurs and regularly during use and **should** be discarded at the end of the daily compounding activity.

## 14. Administering

Healthcare personnel **should** avoid manipulating HDs, such as crushing tablets or opening capsules if possible.

## 15. Deactivating, Decontaminating, Cleaning, and Disinfecting

Agents used for deactivation, decontamination, and cleaning **should** be applied through the use of wipes wetted with an appropriate solution and not delivered by a spray bottle to avoid spreading HD residue.

Products with known deactivation properties (EPA-registered oxidizing agents that are appropriate for the intended use) **should** be used when possible.

Because of the growing number of assays available for HDs, additional surface wipe sampling is now possible and **should** be done to document the effectiveness of any agent used for the decontamination of HD residue from work surfaces.

Written procedures **should** address the use of appropriate full-facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

### **18. Medical Surveillance**

Healthcare workers who handle HDs as a regular part of their job assignment **should** be enrolled in a medical surveillance program.

The occurrence of exposure-related health changes **should** prompt an immediate re-evaluation of primary preventive measures.

See below for Medical Surveillance information:

#### **18. Medical Surveillance is a “should”**

Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and the use of PPE. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program. The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs. Medical surveillance programs involve the assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.

Medical surveillance can also be viewed as a secondary prevention tool that may provide a means of early detection if a health problem develops. Tracking personnel through medical surveillance allows the comparison of health variables over time in individual workers, which may facilitate early detection of a change in a laboratory value or health condition. 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.

Medical surveillance evaluates the protection afforded by engineering controls, other administrative controls, safe work processes, PPE, and worker education about the hazards of the materials they work with in the course of their duties. 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.

Elements of a medical surveillance program should be consistent with the entity's Human Resource policies and should include:

- Development of an organized approach to identify workers who are potentially exposed to HDs on the basis of their job duties.
- Use of an entity-based or contracted employee health service to perform the medical surveillance while protecting the confidentiality of the employees' personal medical information
- Initial baseline assessment (pre-placement) of a worker's health status and medical history. Data elements collected include a medical (including reproductive) history and work history to assess exposure to HDs, physical examination, and laboratory testing. Methods used to assess exposure history include a review of:
  - Records of HDs handled, with quantities and dosage forms
  - Estimated number of HDs handled per week
  - Estimates of hours spent handling HDs per week and/or per month
  - Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs, such as a baseline complete blood count. Biological monitoring to determine blood or urine levels of specific HDs is not currently recommended in surveillance protocols but may have a role in the follow-up of acute spills with a specific agent.
- Medical records of surveillance should be maintained according to OSHA regulations concerning access to employee exposure and medical records
- Monitoring workers' health prospectively through periodic surveillance using the elements of data gathering described above (updated health and exposure history, physical assessment, and laboratory measures, if appropriate)
- Monitoring of the data to identify prevention failure leading to health effects; this monitoring may occur in collaboration with the employee health service
- Development of a follow-up plan for workers who have shown health changes suggesting toxicity or who have experienced an acute exposure. This follow-up should include evaluation of current engineering and administrative controls and equipment to ensure that all systems are appropriately and accurately implemented (see Follow-Up Plan)
- Completion of an exit examination when a worker's employment at the entity ends, to document the information on the employee's medical, reproductive, and exposure histories. Examination and laboratory evaluation should be guided by the individual's history of exposures and follow the outline of the periodic evaluation.