RECEIVING PERSONNEL: HAZARDOUS DRUG PRECAUTIONS

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(See Sections 5 and 10 in USP <800>.)

APIs of any type of HD and antineoplastic agents must be received using the containment strategies and work practices defined in <800>. <800> allows the entity to perform an Assessment of Risk to evaluate exempting specific dosage forms of HDs from the containment strategies and/or work practices. Non-antineoplastic agents and reproductive hazards may be considered for the entity's Assessment of Risk if alternative containment strategies and/or work practices are identified and implemented.

9.1 What training is required for receiving personnel?

Occupational Safety and Health Administration (OSHA) Hazard Communication Standards and <800> require personnel who handle hazards to be knowledgeable about the risks. Although receiving personnel may not be involved in compounding or administering hazardous drugs (HDs), they need to be aware of occupational risks. The entity's policies need to define the expectations of receiving functions concerning HDs, and they should include the following for receiving personnel:

- Identifying HDs, organizational policies and procedures.
- Use of personal protective equipment (PPE).
- Use of engineering controls and other devices.
- Response to exposure to HDs, spill management, and proper disposal of HDs.

Personnel must document competency prior to independently handling HDs. Personnel training must occur before a new HD or new equipment is used, and competency must be documented at least every 12 months.

9.2 Why is delivery and acceptance of HDs covered under <800>?

The purpose of <800> is to minimize the occupational risk of handling HDs to healthcare personnel. The scope of <800> is wider than in <795> or <797>. <800> is intended to protect healthcare personnel from the time a HD arrives at the organization.

9.3 Where do I open the HDs I receive from suppliers?

If you have a designated negative pressure area for receipt of HDs, open them there. If not, you can open the totes and other packages in your normal receiving area. <800> allows the receiving area to be either negative or neutral/normal pressure. You ***cannot*** receive HDs in a positive pressure area; that would spread contamination if it is present.

9.4 How do I know if a container includes a HD?

Ideally, your supplier will mark the outside of the container with an indication that a HD is inside. This will probably be limited to antineoplastic HDs, as those are the agents that all entities—even those who have performed an Assessment of Risk to exempt some dosage forms of non-antineoplastics or reproductive hazards—will need to handle as HDs.

9.5 Are suppliers required to label HD containers?

<800> does not have the scope to require suppliers to label the containers. However, you can choose to request this from your supplier.

9.6 Do I need a designated room for unpacking? Does it have to be negative?

<800> does not require a designated room, although having a dedicated space to do this is a safe practice that you may want to implement. The space does not have to be negative, but it can be. It ***cannot*** be positive pressure because that would spread contamination if it is present.

9.7 Should I unpack the wholesaler tote in the chemo room?

No. Do not take the tote or any other outside shipping container into the containment secondary engineering control (C-SEC) (room). These containers have been in dirty environments; you do not want to bring any containers with potential microbial contamination into your International Standards Organization (ISO)-classified areas or into the containment segregated compounding area (C-SCA). Corrugated cardboard can contain mold spores, so you don't want to expose your anteroom or buffer room to that potential contamination. However, if your supplier provides the HDs contained in plastic (e.g., inside a chemo bag) inside your tote, you can remove the plastic bag of HDs and take that bag containing HDs into your negative pressure cleanroom suite or C-SCA.

9.8 Won't I contaminate my C-SEC if I take the wrapped HDs into it?

A compliant C-SEC (room) is designed with negative pressure, external venting, and frequent air changes. This serves to sweep away any particles or contamination.

9.9 Could we use a powder hood to open the packages?

Yes. A containment ventilated enclosure (CVE)—commonly called a powder hood—or a Class I biological safety cabinet (BSC) or other containment primary engineering control (C-PEC) dedicated to receiving and opening HDs would be an ideal situation. This provides a negative pressure device to sweep away the particles.

9.10 What regulations do manufacturers have to control the hazardous residue on the outside of their products?

There are no requirements for suppliers or manufacturers to do this, and requiring it is beyond the scope of <800>. It certainly would improve the safety.

9.11 Do HD totes have to be delivered to the chemo room?

No, and you don't want that to occur. Outside shipping containers or any corrugated cardboard should never be taken into the ISO-classified areas or C-SCAs.

9.12 Would the individual taking the plastic-wrapped package into the buffer room have to be garbed?

Yes. Anyone going into the buffer room needs to be garbed.

9.13 How should the packages of HDs be taken into the chemo room?

Ideally, your supplier wraps the HDs in impervious plastic (e.g., a chemo bag) inside the shipping container. You can take that plastic-wrapped package to the anteroom for receipt by properly garbed compounding personnel. If you have a cleanroom pass-through chamber that goes from the pharmacy into either the anteroom or buffer room, you can take the plastic-wrapped package to that point. If you don't have a pass-through chamber, you could designate cleanable containers (e.g., a tackle box) in which to place the HDs for transport to the anteroom.

9.14 Is there a requirement for pressure monitoring in the receiving area to demonstrate neutral or negative air?

<800> does not require pressure monitoring of the receiving area.

9.15 How should I handle receipt of antineoplastics that will be dispensed without manipulation (e.g., unit-of-use methotrexate tablets)?

This should be evaluated in your Assessment of Risk and a policy developed and in-serviced to staff.

Because packages of oral and topical antineoplastics have the same risk of contamination by HD residue and injections, you might consider these options:

- If you have a designated negative pressure storage area for those antineoplastics that are used for nonsterile compounding, you could take the packages directly to that area.
- If you don't have an area for nonsterile HD compounding, consider keeping them with the injectable antineoplastics that have been received and take all of them into the negative pressure cleanroom. After the compounding staff members have wiped off the containers, use a designated cleanable transport box (e.g., a small tackle box) to move those agents out of the negative pressure cleanroom to the area where they will be stored.
- If you don't have an area for nonsterile HDs and need to package the oral HD into unit-dose or unit-of use containers, consider keeping the unopened bottle in the negative pressure storage area until you first need it. At that point, package the entire bottle using the alternative containment strategies you identify in your Assessment of Risk. After packaging and containment of the entire bottle, you may be able to move the packaged stock into your general storage area if your Assessment of Risk allows.

9.16 What PPE should be available to receiving personnel?

Your policy and procedure need to define what PPE is required for receiving personnel. Chemotherapy gloves tested to American Society for Testing and Materials (ASTM) standard D6978 must be required. The National Institute for Occupational Safety and Health (NIOSH) list of HDs[7] includes a table of suggested PPE for receiving.

<800> requires use of chemotherapy gloves when unpacking HDs. Many personnel in receiving areas wear work gloves; if work gloves are worn, they should be worn over the chemotherapy gloves. If the items received are not enclosed in plastic, <800> recommends wearing an elastomeric half-mask with a multi-gas cartridge and P100 filter until the packaging can be checked to be sure it is not damaged. Protective gowns and respiratory protection are needed if spills or leaks occur, and a spill kit must be available in the receiving area.

9.17 Do I need to wash my hands after I remove the chemo gloves I wear when receiving and stocking chemo agents?

Yes. You need to wash your hands with soap and water any time you remove (doff) any PPE worn when handling HDs. Use of alcohol hand rub alone is ***not*** sufficient.

9.18 How should damaged or broken HD containers be handled?

The entity needs to have a policy and procedure in place for this situation, and receiving personnel must have documented competency. A stratified approach is needed. See **Table 9-1** for policy requirements and recommendations.

9.19 What happens if a damaged package needs to be opened?

The entity must have a policy and procedure in place for this situation, and receiving personnel need to have documented competency. A stratified approach is necessary. See Table 9-1 for policy requirements and recommendations.

9.20 We segregate antineoplastic deliveries from our wholesaler by using a unique PO number. Do non-antineoplastics (e.g., warfarin, estrogen, fluconazole) need to be in separate totes?

It depends on your Assessment of Risk. If you have identified alternative containment strategies (e.g., purchasing manufacturer unit dose, premixed infusions), you may choose to handle the non-antineoplastic agents and reproductive hazards that are in final dosage forms the same way as you handle non-HDs. If you use a process to separate antineoplastics from other agents by using a separate purchase order (PO) number, you could use the same process to separate out the other HDs.

9.21 Will wholesalers designate hazardous items in their ordering system?

That is up to the wholesaler or other supplier. There is no requirement to do this in <800>, since that is out of scope of <800>.

9.22 Do I have to receive HDs in a negative pressure area?

No. The HDs can be received in either a neutral/normal pressure area or in a negative pressure area. No corrugated cardboard or external shipping containers should be brought into a negative pressure area.

TABLE 9-1 Requirements and Recommendations for Receiving Hazardous Drugs

Observe Contents of Package	Minimum PPE Required	Receiving Area	Recommended Procedure
All intact and enclosed in impervious plastic bag	1 pair chemotherapy gloves	Can be received in neutral/normal, or negative pressure, but the negative pressure area cannot be the sterile compounding negative pressure room. DO NOT receive this in a positive pressure area.	Remove bag of HDs from the external container, then take the unopened bag to be placed in the negative pressure storage area
All intact but not enclosed in an impervious plastic bag	2 pairs chemotherapy gloves, impervious gown, shoe covers, respiratory protection	Ideally, in a separate negative pressure area. Neutral/normal pressure area is acceptable. DO NOT receive this in a positive pressure area.	Contain the HD by placing it in plastic or another impervious container, then place the container in the negative pressure storage area
Damaged and will not be opened	2 pairs chemotherapy gloves, impervious gown, shoe covers, respiratory protection		Seal the container and contact the supplier. Ideally, the supplier will provide credit and tell you to discard the package as hazardous waste. If the package must be returned to the supplier, enclose it in an impervious container and label the outer container as hazardous. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. Report the damaged package as a spill, using your organization's procedure for reporting spills.
Damaged but need to open the package to retrieve one or more undamaged product	2 pairs chemotherapy gloves, impervious gown, shoe covers, respiratory protection		Seal the container in plastic or in an impervious container. Take it to a C-PEC (preferably one used only for nonsterile preparations), open the package on a disposable plastic mat, and remove the undamaged items. Wipe the outside of the undamaged items with a disposable wipe. Place the undamaged items in the negative pressure storage area. Decontaminate and clean the C-PEC. Discard the wipes and mat as hazardous waste. Ideally, the supplier will provide credit for the damaged items and tell you to discard the package as hazardous waste. If the package must be returned to the supplier, enclose it in an impervious container and label the outer container as hazardous. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. Report the damaged package as a spill, using your organization's procedure for reporting spills.

C-PEC: containment primary engineering control; HD: hazardous drug; HDs: hazardous drugs; PPE: personal protective equipment

9.23 How can I identify HD containers when they come in from suppliers?

Your supplier should identify the outside of the container if antineoplastic agents are included in a package. Ideally, only antineoplastics will be in a tote or other container separate from other drugs. Some pharmacies separate their supplier orders so only antineoplastics are ordered on a single PO; that generally forces the supplier to package them separately.

9.24 How should HDs be packaged by suppliers?

Because most organizations are expected to use an Assessment of Risk approach, only the antineoplastic agents are likely to be segregated. Your supplier should identify the container by a different color tote or a distinctive label on the outside of the container and should wrap the antineoplastic agents inside the marked container in impervious plastic.

9.25 Where should HD shipments be received?

HD containers should be delivered to the area where they will be used. In most pharmacies, this means to the general pharmacy receiving area (not a loading dock). The HDs have to be delivered to the HD storage area immediately after they are received and unpacked.

9.26 What garb needs to be worn by receiving personnel?

At least one pair of chemotherapy gloves must be worn when receiving HDs. Facility policy may require other PPE for routine use and must require additional PPE if HDs are received not in impervious plastic or are damaged. The receiving area must have a spill kit.

9.27 What is the ideal process for receiving HDs?

Ideally, all totes and other containers arrive with an identifiable marking, indicating that antineoplastic HDs—and only antineoplastic HDs—are inside. The properly garbed receiving person opens the container and finds the antineoplastic HDs wrapped in a sealed, impervious plastic wrap. The drugs are visible through the plastic, so the receiving list can be checked without opening the sealed plastic bag. Once the contents are reconciled, the sealed plastic bag is transported into the negative pressure buffer room or C-SCA through a pass-through that meets <797> and <800> criteria. The bag of antineoplastic HDs is then opened in the negative pressure storage room, the negative pressure buffer room, or C-SCA and placed in stock in plastic bins in that room.

9.28 Should receiving personnel open up all the boxes of chemotherapy?

External shipping containers and any corrugated cardboard should be removed by receiving personnel. Smooth coated cardboard boxes in which many antineoplastic vials are packaged can remain unopened. Smooth, coated cardboard packaging is acceptable to be placed in the negative pressure area as long as the negative pressure area can maintain the required controls (e.g., ISO classification).

9.29 What should be done when broken or damaged HDs are received?

The entity must have a policy and procedure in place for this situation, and receiving personnel need to have competency documented concerning it. A stratified approach is necessary. See Table 9-1 for policy requirements and recommendations.