

# RECEIVING PERSONNEL: HAZARDOUS DRUG PRECAUTIONS



(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.