

PERSONAL PROTECTIVE EQUIPMENT

8

(See Section 7 in USP <800>.)

PPE listed in <800> must be used for handling API of any type of hazardous drug and for antineoplastic agents. The entity's policies and procedures must list the requirements in addition to what is listed in <800> as requirements.

8.1 GENERAL INFORMATION

8.1-1 What does <800> require for PPE?

Depending on the activities performed, <800> requires chemotherapy gloves tested to meet American Society for Testing and Materials (ASTM) standard D6978; gowns that are long-sleeved impermeable and close in the back (no opening in the front) and have closed cuffs that are elastic or knit; hair covers; beard covers; shoe covers; face and eye protection; and respiratory protection.

8.1-2 What are the benefits of PPE?

Personal protective equipment (PPE) limits the amount of exposure to hazardous drug (HD) aerosols and particles.

8.1-3 Are all the components of PPE needed for every activity when handling HDs?

Not necessarily. Different functions have different PPE requirements. See the National Institute for Occupational Safety and Health (NIOSH) list of HDs⁷ for recommended PPE based on the activity performed.

8.1-4 What does *donning* and *doffing* mean?

Don means to put on PPE; *doff* means to remove it.

8.1-5 What does *hand hygiene* mean?

The Centers for Disease Control and Prevention (CDC) defines *hand hygiene* as “cleaning your hands by using either handwashing (washing hands with soap and water), antiseptic hand wash, antiseptic hand rub (i.e., alcohol-based hand sanitizer including foam or gel), or surgical hand antiseptis.” For HD handling, you need to wash your hands with soap and water because the mechanical process of rubbing your hands together helps to remove any HD contamination. Use of only hand rubs is not sufficient to remove HD contamination. See the CDC Hand Hygiene Guideline at www.cdc.gov/handhygiene for further information.

8.1-6 When gloves are mentioned in <800>, does that mean chemo gloves?

Yes. *Gloves* means chemotherapy gloves that have been tested to meet ASTM standard D6978.

8.1-7 What PPE needs to be worn by receiving personnel?

<800> requires use of chemotherapy gloves when unpacking HDs. Many personnel in receiving areas wear work gloves; if these are worn, the work gloves should be 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.

The entity's policies and procedures must describe the appropriate PPE to be worn based on its occupational safety plan, which must address the risk of exposure and activities performed. See the PPE recommendations in the NIOSH list of HDs⁵ and the NIOSH Workplace Solutions document *Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs*¹³ for additional information.

If the entity has performed an Assessment of Risk and identified alternative containment strategies and/or work practices for agents that are listed in the NIOSH HD list as non-antineoplastic or reproductive hazards, those strategies and work practices concerning PPE may differ from the requirements for antineoplastic agents or active pharmaceutical ingredients (APIs).

Also see information under Section 9, Receiving Personnel: Hazardous Drug Precautions.

8.1-8 What PPE needs to be worn by personnel who are transporting HDs?

<800> doesn't specify the PPE requirements for transporting HDs, but similar protection as used for receiving is logical. Those transporting HDs should use chemotherapy gloves. Protective gowns and respiratory protection are needed if spills or leaks occur, and a spill kit should be accessible.

The entity's policies and procedures must describe the appropriate PPE to be worn based on its occupational safety plan, which must address the risk of exposure and activities performed. See the PPE recommendations in the NIOSH list of HDs⁵ and the NIOSH Workplace Solutions document *Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs*¹³ for additional information.

If the entity has performed an Assessment of Risk and identified alternative containment strategies and/or work practices for agents that are listed in the NIOSH HD list as non-antineoplastic or reproductive hazards, those strategies and work practices concerning PPE may differ from the requirements for antineoplastic agents or APIs.

8.1-9 What PPE needs to be worn by personnel who are packaging HDs?

Personnel who are unit-dose packaging oral HDs that are not intact (e.g., those containers with broken tablets or extraneous powder) require similar PPE as used for compounding: chemotherapy gloves, impervious gown, hair covers, shoe covers, and, if not packaging the agents in a containment primary engineering control (C-PEC), eye and respiratory protection.