



USP800 PPE

 The US Oncology
Network

Why?

1. Practices need to be USP800 compliant by December 1, 2019. Non compliance could result in potential fines, penalties, or facility closure.
2. Potential fines from OSHA
 1. \$12,600 per site for infraction
 2. \$126,000 per site for willful infraction
 3. \$126,000 per site for repeat infraction
3. Employee recruitment of quality clinical staff (nurses, pharmacists, technicians) will be negatively impacted by substandard compliance with USP800 guidelines.
4. Provide healthier working environment for employees



Today's discussion

- Personal Protective Equipment
 - Simplest to implement if most stringent interpretation used (not necessarily easiest)
 - Assessment of Risk may result in less stringent PPE requirement for certain tasks
 - Visible to Patients (administration)
 - Ongoing expense
 - Use must match policies
- Engineering (BSC, HVAC, Negative Pressure etc.)
- Policies and Procedures



PPE

What does USP 800 say?

Personal Protective Equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues. Additional PPE may be required to handle the HDs outside of a C-PEC, such as treating a patient or cleaning a spill. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings. Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.

Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs. Two pairs of chemotherapy gloves are required for administering antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs.

These are really the only absolutes



PPE

For all other activities, the entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk (if used).

This is your opportunity to refine PPE requirements

The entity must develop SOPs for PPE based on the risk of exposure (see *Types of Exposure*) and activities performed. Appropriate PPE must be worn when handling HDs including during:

- Receipt • Storage • Transport • Compounding (sterile and nonsterile) • Administration • Deactivation/decontamination, cleaning, and disinfecting • Spill control • Waste disposal

There are some minimum requirements.



PPE

Receipt

- Undamaged container
 - Chemotherapy gloves (single)
- Damaged container
 - Chemotherapy gloves (single)
 - Other considerations based on risk type
 - Gown
 - Eye protection
 - Respiratory

Storage and Transport

- SOP reflecting consideration of exposure risks



PPE

Compounding

- Gloves (chemotherapy gloves)
 - 1st pair under cuff
 - 2nd pair over cuff
 - Changed every 30-60 minutes, between patients or tasks
- Gown (Low-permeability)
- Gloves and gown removed and placed in proper waste receptacle prior to leaving HD area.
 - Inner glove removed last
- Hair/head cover
 - Don in ante room
- Double shoe covers
 - Don first pair in ante room
 - 2nd pair in HD clean room
 - Outer pair removed prior to exiting HD room
 - Inner pair removed before leaving ante room



PPE

Administration

- From USP800 - Two pairs of chemotherapy gloves are required for administering antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs.
- Table 5 of the 2016 NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings provides additional recommendations for PPE and engineering controls based the formulation of HD and the activity.
 - Table 5 reflects recommendations not mandates. You should design SOP around exposure type risks
 - Consideration of aerosol, dust, splash, body fluid/excretion etc. need to be reflected in PPE SOP.
 - When to where eye/face protection
 - Frequency of changing
 - HD PPE should never be worn into non HD Area



PPE

Deactivation/decontamination, cleaning, and disinfecting

From USP800 –

- All personnel performing these activities must wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns (see *Personal Protective Equipment*). Additionally, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used.
- SOP should reflect when respiratory protection indicated.
- Any activity where eye level work is being done should include eye/face protection



PPE

Spill Control

- Generally spills will occur in environment where personnel are already wearing at least some PPE
- SOP needs to reflect PPE requirements based on size of spill
 - Spills of less than 5 mL or 5 gm outside a BSC should be cleaned up immediately by personnel wearing gowns, double latex gloves, and splash goggles
 - When a large (larger than 5 mL or 5 gm) spill occurs, the area should be isolated and aerosol generation avoided
 - Protective apparel, including appropriate respirators, should be used if there is any suspicion of airborne powder or aerosol
 - Major Spills
 - In the unusual circumstance of a major spill (e.g., > 1000 mL spill, the breakage of a large container or entire carton of a hazardous drug, or a significant portion of the work area is involved.) should occur, the area should be quarantined to avoid further contamination and spread of aerosolized particles. It is recommended that a local (city or county) EPA or Hazardous Material Team be called to clean-up/decontaminate the affected work area.



PPE

Waste Disposal

- Personnel disposing of hazardous drug/waste should wear gowns and protective gloves when handling waste containers with contaminated exteriors. Furthermore, a container with a contaminated exterior should be placed in a second container in a manner that eliminates the possibility of contaminating the second container.



PPE

Other considerations:

- Lab Personnel
 - SOP to reflect risk of exposure
 - Chemo gloves likely not necessary
 - Offsite lab would not use
 - Gown? (consideration of splash potential)
 - Changing of PPE between patients
- Linens and things
 - If contaminated with body fluids/excreta within 48 hours of chemotherapy these should be washed once separately from other linens/garments and then again either separately or combined.
 - Placed in separate marked bag and in impervious bag set aside for prewash.
 - Other contaminated reusable items, such as glassware or other patient care equipment, should be washed twice with detergent and water. Staff washing these items should be trained in handling these items and wear double latex gloves and a gown.



PPE

Assessment of risk

From USP800

Some dosage forms of drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (e.g., tablets or capsules—solid, intact medications that are administered to patients without modifying the formulation). However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation. An assessment of risk may be performed for these dosage forms to determine alternative containment strategies and/or work practices. If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter. The assessment of risk must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.



PPE

General guide

Summary Recommendations	
Gloves	Gowns
Surgical latex (or nitrile if allergic to latex)	Disposable
<ul style="list-style-type: none"> • Powder free • 0.6 mm – 0.9 mm thickness 	<ul style="list-style-type: none"> • Lint-free • Low permeability fabric • Solid front
Practice double gloving	Long sleeves
<ul style="list-style-type: none"> • Long cuffs – to cover gown cuff • Change gloves frequently (at least hourly) 	Elastic or knit cuffs
<ul style="list-style-type: none"> • Wash hands before gloves are put on and after removed 	Do not wear outside the designated hazardous area
<ul style="list-style-type: none"> • Use sterile alcohol periodically to sterilize gloves 	
Use of Personal Protective Equipment	
Wear gloves and gowns when preparing, administering or handling cytotoxic drugs.	
Wear gloves and gowns when handling contaminated items (drug vials, IV bags, tubing, syringes, linens, emesis basins, etc.).	
<ul style="list-style-type: none"> • Wear gloves and gowns when handling excreta (urine, stool, etc.) from patients who received chemotherapy within the last 48 hours. • Respirator masks or eye and face protection may be indicated when there is potential for aerosolization or splashes. 	
Personal protective equipment should be removed immediately after use and before leaving the admixture or infusion area.	
Gloves and gowns should be discarded in appropriate waste receptacles for hazardous waste.	
<ul style="list-style-type: none"> • Non-disposable respirator masks, goggles and eye and face shields should be washed twice with detergent and water by trained personnel wearing double gloves. 	

