Implementation Strategies for USP <800>

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Disclosure

The views and opinions expressed are those of the speaker and are not endorsed by or affiliated with USP.

Conflict of Interest

I have had no financial relationship over the past 12 months with any commercial sponsor with a vested interest in this presentation.

Pharmacist Learning Objectives

1. Explain the facility requirements for USP <800>.

2. List the requirements for an assessment of risk.

3. Describe the responsibilities of the designated person.

Technician Learning Objectives

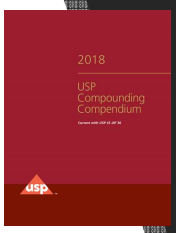
1. Describe how to identify if a drug is hazardous.

2. Describe additional PPE that is required for handling hazardous drugs in sterile compounding areas.

3. Differentiate between deactivation, decontamination, cleaning, and disinfection.

USP standards may be enforced at both state and federal levels and are often components of accreditation and credentialing standards.

Contains General Notices, General Chapters, and Compounded Preparation Monographs.

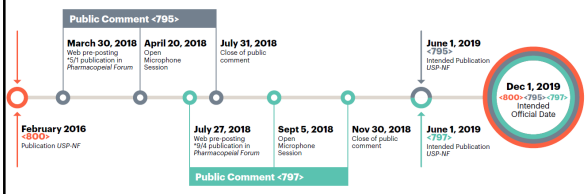


USP <795> Nonsterile
USP <797> Sterile
USP <800> Nonsterile & Sterile HDs
Related chapters
<51>, <71>, <85>, <1163>, etc.

Chapters <1000 are enforceable
Chapters >1000 are informational

Shall or Must = Required
Should = Recommended

Timeline associated for the proposed revisions to <795> and <797> and opportunities to engage with USP and provide input.



http://www.usp.org/compounding/updates-on-standards

Stay Informed

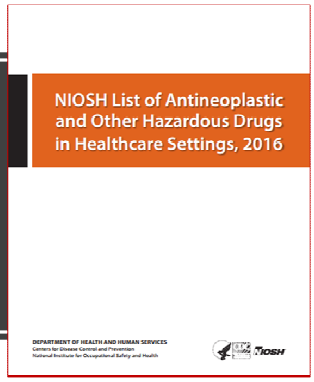
Pharmacopeial Forum (PF) is a free bimonthly online journal in which USP publishes proposed revisions to USP–NF for public review and comment.
http://www.uspnf.com/pharmacopeial-forum

Training and workshops available in person and online. Inaugural USP Workshop on Evolution and Advances in Compounding May 21- 22, 2018 Rockville, MD

Volunteer - Call for Candidates

NIOSH

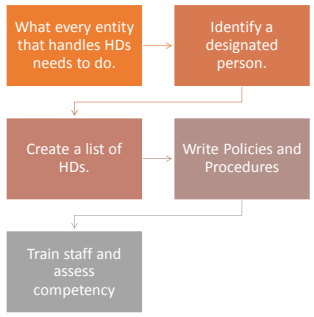
Table 1 Antineoplastic
Table 2 Non-antineoplastic
Table 3 Reproductive hazard
Table 5 Recommendations for Personal Protective Equipment (PPE)



Hazardous Drugs (HDs)

- Carcinogenicity
- Teratogenicity
- Reproductive Toxicity
- Organ Toxicity (at low doses)
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

Getting Started with USP <800>



Designated Person

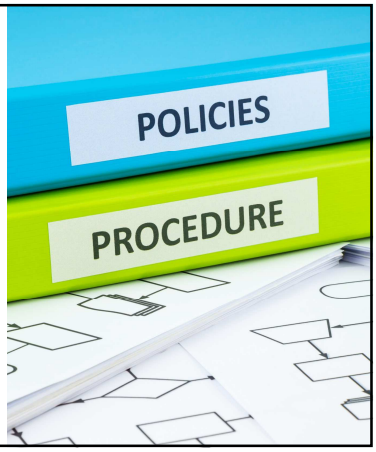
Each entity must have a designated person who is qualified and trained to be responsible for

- Developing and implementing appropriate procedures.
- Overseeing compliance.
- Ensuring competency of personnel.
- Ensuring environmental control of the storage and compounding areas.
- Understanding the rationale for risk-prevention policies, risks to themselves/others, risks of noncompliance, and the responsibility to report potentially hazardous situations to management.
- Oversight of monitoring the facility and maintaining reports of testing/sampling performed and acting on the results.

List of Hazardous Drugs (HDs)

- An entity must maintain a list of HDs, which must include any items on the current NIOSH list that it handles.
- The list must be reviewed at least every 12 months.
- Whenever a new agent or dosage form is used, it should be reviewed against the entity's list.
- The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. If the information available on a drug is deemed insufficient to make an informed decision, consider the drug hazardous until more information is available.

Review (and document review) at least every 12 months. Revisions in forms or records must be made as needed and communicated to applicable staff.



Policies and Procedures

Receipt of HDs

- Designated area for receipt and unpacking.
- Antineoplastic HDs and all HD APIs must be unpacked in an area that is neutral/normal or negative pressure.
- HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.
- PPE, including chemotherapy gloves, must be worn when unpacking HDs.
- Elastomeric half-mask with a multi-gas cartridge and P100-filter should be worn when unpacking HDs that are not contained in plastic.
- Include use of tiered approach, starting with visual examination of the shipping container.
- Handling of damaged packages.
- Spill kit must be accessible in the receiving area.

Policies and Procedures

Storage of HDs

- Designated area.
- Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.
- HDs must be stored in a manner that prevents spillage or breakage if the container falls. In areas prone to natural disasters the manner of storage must meet applicable safety precautions.
- Do not store HDs on the floor.

Policies and Procedures

Handling

- Consider patient safety, worker safety, and environmental protection.
- Receipt
- Storage
- Transport
- Compounding
- Dispensing
- Administering
- Disposal of HD waste
- Cleaning of Spills
- All other situations

Policies and Procedures

Equipment

- Disposable or clean equipment must be dedicated for compounding HDs.
- Counting or repackaging equipment should be dedicated for use with HDs and should be decontaminated after every use.
- Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines.
- Do not use pneumatic tubes for hazardous liquids or antineoplastic drugs.

Policies and Procedures

PPE

- Base on risk of exposure and activities performed including receipt, storage, transport, compounding, dispensing, administration, deactivation, decontamination, cleaning, and disinfecting, spill cleanup, and waste disposal.
- PPE, including chemotherapy gloves, must be worn when unpacking HDs.
- Elastomeric half-mask with a multi-gas cartridge and P100-filter should be worn when unpacking HDs that are not contained in plastic.
- Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs.

Policies and Procedures

PPE

- Two pairs of chemotherapy gloves are required for administering antineoplastic HDs.
- Chemo gown required for administering injectable antineoplastic HDs.
- Eye and face protection required when there is a risk for spills or splashes of HDs or HD waste when working outside of a C-PEC (e.g. administration in the surgical suite, working at or above eye level, or cleaning a spill).
- 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 cleaning HD spills larger than what can be contained with a spill kit, deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC and there is a known or suspected airborne exposure to powders or vapors.

Policies and Procedures

PPE

- Chemo gloves must meet ASTM D6978.
- Chemo gowns must be disposable and shown to resist permeability by HDs, close in the back, have long sleeves, closed cuffs, and no seams
- Fit test respirators and train workers to use respiratory protection. Follow all requirements in the OSHA respiratory protection standard (29 CFR 1910.134).
- Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.
- Additional PPE may be required to handle HDs outside of a C-PEC, such as treating a patient or cleaning a spill.
- NIOSH Table 5 provides general guidance on PPE.

Policies and Procedures

Cleaning and Prevention of HD contamination

- Include procedures, agents used, dilutions, frequency, and documentation requirements.
- Deactivate means to render inactive. Check labeling or SDS. If unknown use EPA-registered oxidizer.
- Decontaminate means to remove contamination by inactivating, neutralizing, or physically removing HD residue by transferring it to absorbent materials. Residue from deactivation must be removed by decontamination.
- Clean means to dissolve organic or inorganic matter using germicidal detergent.
- Disinfect means to destroy microorganisms using IPA or other non-residue disinfectant.

Policies and Procedures

Cleaning and Prevention of HD contamination

- All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned (and disinfected, when applicable)
- Area under the work tray of C-PEC must be deactivated, decontaminated, and cleaned at least monthly.
- Spill management dependent on the size and type of spill.
- Sufficient ventilation.
- Do not use a spray bottle to avoid spreading HD residue.
- All disposable materials must be discarded to meet EPA regulations.

Policies and Procedures

Cleaning and Prevention of HD contamination

- Decontaminate C-PEC at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
- C-PEC loss of power, repair or moving, stop all activities and decontaminate, clean, and disinfect before reuse.
- C-PEC work surface must be decontaminated between compounding of different HDs.
- For occasional nonsterile HD compounding, C-PEC used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding.
- Counting and repackaging equipment should be dedicated for use with HDs and should be decontaminated after every use.
- Reusable PPE must be decontaminated and cleaned after use.

Policies and Procedures

Compounding

- Comply with the appropriate USP standards for compounding.
- Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs.
- Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.
- Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs.
- Plastic-backed preparation mat should be placed on the work surface and should be changed immediately if a spill occurs, and regularly during use, and should be discarded at the end of the daily compounding activity.

Policies and Procedures

Compounding

- Decontaminate C-PEC at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
- C-PEC loss of power, repair or moving, stop all activities and decontaminate, clean, and disinfect before reuse.
- C-PEC work surface must be decontaminated between compounding of different HDs.
- For occasional nonsterile HD compounding, C-PEC used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding.
- A CSTD must not be used as a substitute for a C-PEC when compounding. CSTDs should be used when compounding HDs when the dosage form allows.

Policies and Procedures

Dispensing

- Appropriate PPE.
- Counting and repackaging equipment should be dedicated for use with HDs and should be decontaminated after every use.
- Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants.
- Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.

Policies and Procedures

Administration

- Appropriate PPE.
- Administering antineoplastic HDs – double chemo gloves.
- Administering injectable antineoplastic HDs – chemo gown.
- Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials
- Additional PPE may be required to handle HDs outside of a C-PEC (e.g. treating a patient or cleaning a spill).
- NIOSH Table 5 provides general guidance on PPE
- After use, remove and dispose of PPE as trace-contaminated HD waste at the site of drug administration.

Policies and Procedures

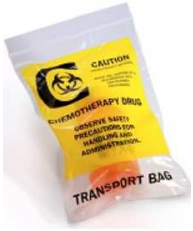
Administration

- Use protective medical devices and techniques.
  -Protective devices include needleless and closed systems.
  -Protective techniques include spiking or priming of IV tubing with a non- HD solution in a C-PEC & crushing tablets in a plastic pouch.
- Administration of antineoplastic HDs – CSTD if dosage form allows.
- Techniques and ancillary devices that minimize risk posed by open systems must be used.
- Avoid manipulating HDs (e.g. crushing tablets or opening capsules). If not possible, don appropriate PPE and use a plastic pouch to contain any dust or particles generated.
- Equipment and packaging materials must be disposed of properly.

Policies and Procedures

Labeling

- HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during transport.
- Personnel must ensure that the labeling processes do not introduce contamination into non-HD handling areas.



Policies and Procedures

Transport

- Address appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.
- Ensure labels include storage instructions, disposal instructions, and HD category information in a format consistent with the carrier's policies.
- Refer to SDS Section 14 for transport information.
- Examples of exposure-reducing strategies include small-bore connectors (such as Luer Lock) and syringes, syringe caps, CSTDs, the capping of container ports, sealed impervious plastic bags, impact-resistant and/or water-tight containers, and cautionary labeling.

Policies and Procedures

Disposal of HDs and trace-contaminated materials

- Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.
- PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations.
- Refer to SDS Section 13 for disposal considerations that meet federal requirements. Refer to state/local law for additional requirements.

HD disposal regulated by EPA (RCRA & state/local law)

- Refer to SDS Section 13 Disposal for federal requirements.
- Refer to state/local law for additional requirements.

HD transport regulated by DOT

- Refer to SDS Section 14 Transport for information.
- Refer to shipping vendor for additional requirements.

EPA and DOT HD are not the same as NIOSH HD.

Some drugs that are not required to be handled as hazardous may need to be disposed of or transported as hazardous.

Policies and Procedures

Spill management

- Spill kits containing materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled.
- Spill kit must be accessible in the receiving area.
- Include clean-up of spills (address the size and scope), use of spill kit, location of spill kits and clean-up materials, PPE requirements, and specify who is responsible for spill management.
- Prevention of accidental exposures or spills.
- Use of Safety Data Sheets (SDS).
- Response to known or suspected HD exposure.

Recommended Policies and Procedures

- Hazard communication program (required by federal law)
- Occupational safety program (required by federal law)
- Hand hygiene for each HD handling scenario.
- Washing of non-disposable clothing contaminated with HD residue

If performed

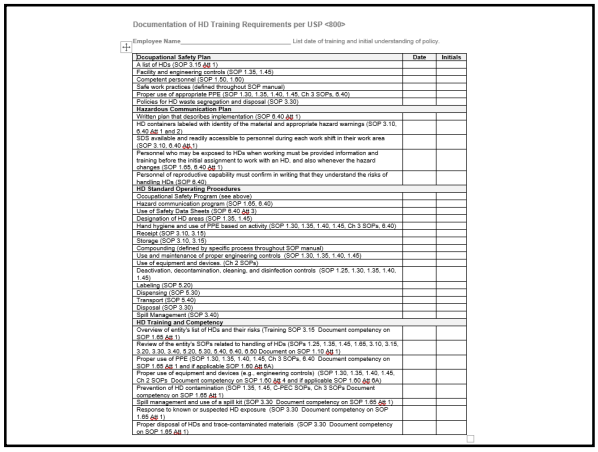
- Environmental monitoring (e.g., wipe sampling)
- Medical surveillance

Summary of Training Requirements

- All personnel who handle HDs or who perform custodial waste removal or cleaning activities must be trained based on job functions (receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs).
- Training must occur before independently handling HDs.
- Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP.
- Effectiveness of training must be demonstrated.
- Competency must be reassessed at least annually.
- All training and competency assessments must be documented according to OSHA standards and other applicable laws and regulations.

Training must include at least the following:

- Overview of HDs in use and their risks
- Use of Safety Data Sheets
- Storage
- Review of SOPs related to handling of HDs
- Use of equipment and devices.
- Use of PPE including use of NIOSH-certified respirators
- Prevention of HD contamination
- Labeling
- Transport
- Disposal of HDs and trace-contaminated materials
- Spill management and use of a spill kit
- Response to known or suspected HD exposure



Documentation of HD Training Requirements per USP <800>

Employee Name_____ List date of training and initial understanding of policy.

Occupational Safety Plan	Date	Initials
A list of HDs (SOP 3.15 Att 1)		
Facility and engineering controls (SOP 1.35, 1.45)		
Competent personnel (SOP 1.50, 1.90)		
Safe work practices (defined throughout SOP manual)		
Proper use of appropriate PPE (SOP 1.30, 1.35, 1.40, 1.45, Ch 3 SOPs, 6.40)		
Policies for HD waste segregation and disposal (SOP 3.30)		
Hazardous Communication Plan		
Written plan that describes implementation (SOP 6.40 Att 1)		
HD containers labeled with identity of the material and appropriate hazard warnings (SOP 3.10, 6.40 Att 1 and 2)		
SDS available and readily accessible to personnel during each work shift in their work area (SOP 3.10, 6.40 Att 1)		
Personnel who may be exposed to HDs when working must be provided information and training before the initial assignment to work with an HD, and also whenever the hazard changes (SOP 1.65, 6.40 Att 1)		
Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs (SOP 6.40)		
HD Standard Operating Procedures		
Occupational Safety Program (see above)		
Hazard communication program (SOP 1.65, 6.40)		
Use of Safety Data Sheets (SOP 6.40 Att 3)		
Designation of HD areas (SOP 1.35, 1.45)		
Hand hygiene and use of PPE based on activity (SOP 1.30, 1.35, 1.40, 1.45, Ch 3 SOPs, 6.40)		
Receipt (SOP 3.10, 3.15)		
Storage (SOP 3.10, 3.15)		
Compounding (defined by specific process throughout SOP manual)		
Use and maintenance of proper engineering controls (SOP 1.30, 1.35, 1.40, 1.45)		
Use of equipment and devices. (Ch 2 SOPs)		
Deactivation, decontamination, cleaning, and disinfection controls (SOP 1.25, 1.30, 1.35, 1.40, 1.45)		
Labeling (SOP 5.20)		
Dispensing (SOP 5.30)		
Transport (SOP 5.40)		
Disposal (SOP 3.30)		
Spill Management (SOP 3.40)		
HD Training and Competency		
Overview of entity's list of HDs and their risks (Training SOP 3.15 Document competency on SOP 1.65 Att 1)		
Review of the entity's SOPs related to handling of HDs (SOPs 1.25, 1.35, 1.45, 1.65, 3.10, 3.15, 3.20, 3.30, 3.40, 5.20, 5.30, 5.40, 6.40, 6.50 Document on SOP 1.10 Att 1)		
Proper use of PPE (SOP 1.30, 1.35, 1.40, 1.45, Ch 3 SOPs, 6.40 Document competency on SOP 1.65 Att 1 and if applicable SOP 1.60 Att 6A)		
Proper use of equipment and devices (e.g., engineering controls) (SOP 1.30, 1.35, 1.40, 1.45, Ch 2 SOPs Document competency on SOP 1.60 Att 4 and if applicable SOP 1.60 Att 5A)		
Prevention of HD contamination (SOP 1.35, 1.45, C-PEC SOPs, Ch 3 SOPs Document competency on SOP 1.65 Att 1)		
Spill management and use of a spill kit (SOP 3.30 Document competency on SOP 1.65 Att 1)		
Response to known or suspected HD exposure (SOP 3.30 Document competency on SOP 1.65 Att 1)		
Proper disposal of HDs and trace-contaminated materials (SOP 3.30 Document competency on SOP 1.65 Att 1)		

Drugs on the NIOSH list that must follow all <800> requirements:
- Any HD API
- Any antineoplastic HD requiring manipulation

Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented:

- Final dosage forms of compounded HD preparations and conventionally manufactured HD products that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).

For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices.

Facilities

- Designated areas must be available for:
  -Receipt and unpacking
  -Storage of HDs
  -Nonsterile HD compounding (if performed)
  -Sterile HD compounding (if performed)
- Certain areas are required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure.
- Consideration should be given to uninterrupted power sources (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.

Facilities

- Access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling.
- HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure.
- Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas.
- In addition to the previously mentioned PPE, when compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC. Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.

Engineering Controls (Containment)

- Engineering controls are required to protect the preparation from cross-contamination and microbial contamination (if preparation is intended to be sterile) during all phases of the compounding process.
- Containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs. Examples: BSC, CACI.
- The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed.
- Supplemental engineering controls [e.g., closed-system drug-transfer device (CSTD)] are adjunct controls to offer additional levels of protection.

Containment Secondary Engineering Control (C-SEC) used for Sterile Compounding

- C-PEC must be located in a C-SEC.
- ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA).
- Fixed walls are required for both scenarios.
- An eyewash station must be readily available.

ISO Class 7 buffer room requires external venting, minimum of 30 ACPH of HEPA-filtered supply air and negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.

ISO Class 7 ante-room requires minimum of 30 ACPH of HEPA-filtered supply air and positive pressure of at least 0.02 inches of water column relative to all adjacent areas.

- Hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room.
- HD CSPs prepared in an ISO Class 7 buffer room with an ISO Class 7 ante-room may use the BUDs described in USP <797>, based on the categories of CSP, sterility testing, and storage temperature.

If the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room (not recommended):

- A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE.
- A method is required to transport HDs and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer room and adjacent space but pass-through chambers must be included in certification. A refrigerator pass-through must not be used.

Containment segregated compounding area (C-SCA) requires external venting, minimum of 12 ACPH and negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.

- Hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA.
- Only low- and medium-risk HD CSPs may be prepared in a C-SCA.
- HD CSPs prepared in a C-SCA must not exceed the BUDs described in <797> for CSPs prepared in a segregated compounding area.

Containment Secondary Engineering Control (C-SEC) used for Nonsterile Compounding

- C-PEC must be located in a C-SEC with fixed walls.
- C-SEC requires external venting, minimum of 12 ACPH and negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- Hand-washing sink must be available and placed at least 1 meter from C-PEC
- An eyewash station must be readily available
- Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Containment Secondary Engineering Control (C-SEC) used for Storage of HDs

- C-SEC requires fixed walls, external venting, minimum of 12 ACPH and negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.
- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.
- If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.

Containment Primary Engineering Controls (C-PEC) used for Sterile Compounding

- HDs must be compounded in a C-PEC located in a C-SEC.
- C-PECs used for compounding sterile HDs must be externally vented, must provide ISO Class 5 or better air quality and must provide personnel and environmental protection.
- Class II BSC types A2, B1 or B2 or Class III BSC
- Compounding Aseptic Containment Isolator (CACI)

For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components.

Containment Primary Engineering Controls (C-PEC) for Nonsterile Compounding

- HDs must be compounded in a C-PEC located in a C-SEC.
- C-PECs used for compounding nonsterile HDs must be externally vented or have redundant HEPA filters in series.
- Containment Ventilated Enclosure (CVE)
- Class II BSC types A2, B1 or B2 or Class III BSC
- Compounding Aseptic Containment Isolator (CACI)

- The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC (not recommended) or if it is used for sterile compounding. If there is any loss of power to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately.
- For occasional nonsterile HD compounding, a C-PEC used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding.
- A LAFW or CAI must not be used for antineoplastic HDs.
- A C-PEC used for HDs must not be used for a non-HD unless it is placed in a protective outer wrapper during removal from the C-PEC & is labeled to require PPE handling precautions.

Containment Supplemental Engineering Controls (CSTD)

- Users should carefully evaluate the performance claims associated with available CSTDs.
- CSTD must not be used as a substitute for a C-PEC when compounding.
- CSTDs should be used when compounding HDs when the dosage form allows.
- CSTDs must be used when administering antineoplastic HDs when the dosage form allows.
- CSTDs known to be physically or chemically incompatible with a specific HD must not be used.

Drugs on the NIOSH list that must follow all <800> requirements:
Any HD API
Any antineoplastic HD requiring manipulation

Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented:

- Final dosage forms of compounded HD preparations and conventionally manufactured HD products that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).

For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices.

Assessment of Risk (AOR)

- If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter.
- Assessment of risk must, at a minimum, consider: type of HD, dosage form, risk of exposure, packaging, and any required manipulation.
- Document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure.
- Review at least every 12 months and document review.

Sample Assessment of Risk Form

Hazard □ Antineoplastic □ Non-Antineoplastic □ Reproductive Risk	
Drug:	
Dosage Form:	
Packaging:	
Manipulation:	
Risk of Exposure:	
Alternative containment strategies and/or work practices employed to minimize exposure:	
Implementation Date:	Approved by:
Annual Review:	Reviewed by:
Annual Review:	Reviewed by:
Annual Review:	Reviewed by:
Annual Review:	Reviewed by:
Annual Review:	Reviewed by:

Hazard □ Antineoplastic □ Non-Antineoplastic X Reproductive Risk

Teratogenic Effects: Pregnancy Category C– May cause fetal harm when administered to a pregnant woman. It is not known whether it is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised.
https://www.drugs.com/pro/chorionic-gonadotropin.html 10-30-17

Drug: Chorionic Gonadotropin, Human

Dosage Form: Injection

Packaging: Lyophilized powder in vial

Manipulation: (1) Reconstituting powdered or lyophilized HDs; (2) Withdrawing injectable HDs from parenteral containers

Risk of Exposure:

- Dermal and mucosal absorption by coming into contact with (1) HD residue on container or outer packaging; (2) spilled drug or during cleaning of spills.
- Inhalation from aerosolization (1) during manipulation; (2) from spilled drug or during cleaning of spills.
- Injection from accidental needlestick during (1) manipulation; (2) handling contaminated sharps.
- Ingestion from (1) mouth contact with contaminated hands; (2) contaminated food.

Alternative containment strategies and/or work practices employed to minimize exposure:

1. Pregnant women and nursing mothers should not handle, manipulate or perform spill cleaning.
2. Compounding

Alternative containment strategies – May be compounded in a LAFW or CAI located in a positive pressure buffer room or SCA if (1) manipulations are restricted to reconstituting drug vials and transferring contents to syringes or empty sterile vials; (2) a CSTD is used on the drug vial during reconstitution and withdrawing of contents; (3) negative pressure technique is used when adding reconstituted drug to empty sterile vial to minimize the chance of aerosolization; (4) Drug container is wiped with disposable wipe, enclosed in plastic and labeled with HD handling precautions when removed from PEC; (4) no other equipment or supplies are present in the PEC; (5) Sharps and waste is disposed of in appropriate containers; (5) PEC is deactivated, decontaminated, cleaned and disinfected after use; (6) non-HD sterile compounding is not occurring in the same area at the same time; (7) PPE follows <800> (and NIOSH) and includes chemo gown, head, hair, shoe covers, two pairs of chemotherapy gloves, eye protection and respiratory protection; (8) PPE is removed and discarded as trace HD in the sterile compounding area, reusable PPE is decontaminated, hand hygiene is performed.

Other activities must follow <800>.
1. Receipt – Follow <800> (and NIOSH)
Unpack in neutral/negative environment.
PPE – Chemo gown, single chemo glove. If not contained in plastic – respiratory protection.
2. Storage – Follow <800>

Store in HD nonsterile area refrigerator.
3. Dispensing – Follow <800>
Dispense in plastic bag with HD handling precautions.
4. Waste removal – Follow <800> (and NIOSH)
PPE – Chemo gown, double chemo gloves. Eye protection if splash concern. Respiratory protection if inhalation risk.
5. Spill cleaning – Follow <800> (and NIOSH)
PPE – Chemo gown, double chemo gloves, eye protection, respiratory protection.

In addition, personnel must follow institutional SOPs for PPE requirements in each specific work area (Nonsterile HD, Nonsterile Non-HD, Sterile).

Background info:

SDS says to wear impervious clothing, gloves, eye protection and (when required) N100 full face respiratory protection
http://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=CG10&brand=SIGMA&PageToGoToURL=http%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fproduct%2Fsigma%2Fcg10%3Flang%3Den 10-30-17

<800>
*Unpacking - PPE, including chemotherapy gloves.
*Compounding - Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves.

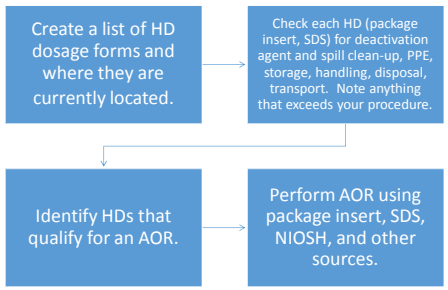
*Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill).

*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. For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles. However, N95 respirators offer no protection against gases and vapors and little protection against direct liquid splashes.

NIOSH
*Receiving/unpacking - Single chemo glove (protective gown and respirator protection when spills and leaks occur).
*Compounding – Gown, double chemo gloves. If not in containment device then eye protection and respiratory protection.
*Drug contaminated waste Gown, double chemo gloves. Eye protection if liquid that could splash. Respiratory protection if inhalation risk.
*Spills – Gown, double chemo gloves, eye protection and respiratory protection.

Implementation Date: | Approved by:

Getting started



Implementation

- Facility renovations (if needed)
- Identify a designated person.
- Create a list of HDs.
- Perform Assessments of Risk.
- Write policies and procedures.
- Train staff and assess competency.

Technician Learning Assessment

The NIOSH list is divided into categories that include all of the following except
A. Reproductive hazard
B. Antineoplastic
C. Fire hazard
D. Non-antineoplastic hazardous drug

Technician Learning Assessment

The NIOSH list is divided into categories that include all of the following except

C. Fire hazard

Pharmacist Learning Assessment

Hazardous drug compounding areas require a pressure of
A. 0.02 to 0.05 inch of water column
B. – 0.01 to – 0.03 inch of water column
C. – 0.02 to – 0.05 inch of water column
D. 0.01 to 0.03 inch of water column

Pharmacist Learning Assessment

Hazardous drug compounding areas require a pressure of

B. – 0.01 to – 0.03 inch of water column

Technician Learning Assessment

Two of the following PPE are required for sterile hazardous drug compounding.
A. Shoe covers
B. Hair covers
C. Mask
D. Goggles

Technician Learning Assessment

Two of the following PPE are required for sterile hazardous drug compounding.
A. Shoe covers

Pharmacist Learning Assessment

Drugs on the NIOSH list that do not have to follow all the containment requirements of <800> if an assessment of risk is performed and implemented include:
A. Any HD API.
B. Any antineoplastic requiring HD manipulation.
C. Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).
D. All of the above.

Pharmacist Learning Assessment

Drugs on the NIOSH list that do not have to follow all the containment requirements of <800> if an assessment of risk is performed and implemented include:

C. Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer).

Technician Learning Assessment

Sterile 70% IPA is used to clean the hood.
A. True
B. False

Technician Learning Assessment

Sterile 70% IPA is used to clean the hood.

B. False

Pharmacist Learning Assessment

The designated person must perform wipe sampling to ensure environmental control of the storage and compounding areas.
A. True
B. False

Pharmacist Learning Assessment

The designated person must perform wipe sampling to ensure environmental control of the storage and compounding areas.

B. False

Resources

- USP <800> FAQ
https://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings
- USP <800> HazRx Mobile App
https://www.usp.org/hazrx-app
- The Chapter <800> Answer Book by Patricia Kienle
https://store.ashp.org

References

- United States Pharmacopeia USP 41 - NF 36
app.uspnf.com
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016
https://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf

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