

# USP 39, NF 34 General Chapter <800> Operator Protection from Hazardous Drugs

Presentation By:  
Krystina Ashe  
Product Manager  
AirClean® Systems, Inc.

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## Pharmacist Objectives:

- Identify hazardous drug substances used in compounding based on USP<800>
- Define USP<800> guidelines for compounding preparations containing hazardous drug substances
- Identify standard operating procedure requirements in USP <800>
- Describe training requirements needed for all personnel involved in the preparation and handling compounds containing hazardous drug substances
- List responsibilities for personnel involved in the preparation of hazardous drug compounds

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## Pharmacy Technician Objectives:

- Describe personal protective equipment required for compounders and handlers of hazardous drug compounds
- Identify hazardous drugs in prepared compounds as defined by USP<800>
- List responsibilities for personnel involved in the preparation of hazardous drug compounds

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## For the Newcomers...

Think of compounding in the following 4 categories:

- |                               |                 |
|-------------------------------|-----------------|
| 1. Non-sterile, Non-hazardous | (<795>)         |
| 2. Non-sterile, Hazardous     | (<800> + <795>) |
| 3. Sterile, Non-hazardous     | (<797>)         |
| 4. Sterile, Hazardous         | (<800> + <797>) |

\*Federal, State & other regulations apply, as well as other USP regulations. See section 13 for more info.

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## What is USP <800> & Where Can I Find It?

- USP <800> is a standard written to provide guidance when working with Hazardous Drugs (HDs), in an effort to mitigate worker exposure to HDs.
- <800> is located in the First Supplement to USP 39-NF 34
- Access to this standard can be purchased through the USP online store here: <http://www.usp.org/products>

**Pro Tip:** The online 1 year subscription keeps you up-to-date and allows for download capability.

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## In This Presentation...

### What's Covered:

- Comprehensive Overview of USP <800>
  - Including Sterile & Non-sterile HD Handling
  - LOTS OF QUOTATIONS – Get ready to read
- **Pro Tips** give the reader further guidance and commentary

### What's Not Covered:

- USP <797>
  - For the <797> update summary see our newly published <797> Update presentation

Disclaimer: This presentation is not a replacement for reading <800> in full. It is the responsibility of those bound to <800> compliance to read through the chapter and follow USP guidance accordingly.

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## USP <800> Sections

**Pro Tip:** All slides are labeled with <800> section references in the bottom, right-hand corner.

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# Section 1. Introduction & Scope



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## Who? – Regulation Reach

“This chapter applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs

(e.g., **pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices**).



United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 1. Introduction(2016), emphasis added

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## Examples of HD Handling



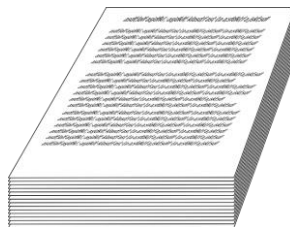
- “Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 1. Introduction(2016)

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## Section 2. List of Hazardous Drugs



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## What are HDs?

“The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs.”



Entity must maintain list of HDs used:

- “must be reviewed at least every 12 months” or “whenever a new agent or dosage form is used”

**Pro Tip:** The NIOSH list can be found here (look in Appendix A of document): <http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf> Proposed updates for 2016 available here: <http://www.cdc.gov/niosh/docket/review/docket233a/default.html>

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 2. List of Hazardous Drugs (2016)

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## HD Exceptions:

- “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...)”
- “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.”



United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 2. List of Hazardous Drugs (2016)

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## Section 3. Types of Exposure



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### Types of Exposure to HDs

- According to <800>, there are many “routes of unintentional entry of HDs into the body..”
- For examples, see the following slide:

#### Table 1. Examples of Potential Opportunities of Exposure Based on Activity

**Pro Tip:** Table 1 gives insight into what an inspector may look for

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 3. Types of Exposure (2016)

Next Slide:

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Table 1. Examples of Potential Opportunities of Exposure Based on Activity (2016)

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<b>Activity</b>	<ul style="list-style-type: none"> <li>• Potential Opportunity of Exposure</li> </ul>
<b>Receipt</b>	<ul style="list-style-type: none"> <li>• Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces, or floors</li> </ul>
<b>Dispensing</b>	<ul style="list-style-type: none"> <li>• Counting or repackaging tablets and capsules</li> </ul>
<b>Compounding and Other Manipulations</b>	<ul style="list-style-type: none"> <li>• Crushing or splitting tablets or capsules</li> <li>• Pouring oral or topical liquids from one container to another</li> <li>• Weighing or mixing components</li> <li>• Constituting or reconstituting powdered or lyophilized HDs</li> <li>• Withdrawing or diluting injectable HDs from parenteral containers</li> <li>• Expelling air or HDs from syringes</li> <li>• Contacting HD residue present on PPE or other garments</li> <li>• Deactivating, decontaminating, cleaning and disinfecting areas contaminated with or suspected to be contaminated with HDs</li> <li>• Maintenance activities for potentially contaminated equipment and devices</li> </ul>
<b>Administration</b>	<ul style="list-style-type: none"> <li>• Generating aerosols during administration of HDs by various routes (e.g., injection, irrigation, oral, inhalation, or topical application)</li> <li>• Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation)</li> <li>• Priming an IV administration set</li> </ul>
<b>Patient-care Activities</b>	<ul style="list-style-type: none"> <li>• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other materials</li> </ul>
<b>Spills</b>	<ul style="list-style-type: none"> <li>• Spill generation, management, and disposal</li> </ul>
<b>Transport</b>	<ul style="list-style-type: none"> <li>• Moving HDs within a healthcare setting</li> </ul>
<b>Waste</b>	<ul style="list-style-type: none"> <li>• Collection and disposal of hazardous waste and trace contaminated waste</li> </ul>

## Section 4. Responsibilities of Personnel Handling Hazardous Drugs



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## Responsibilities of 'HD Overseer'

- **“Each entity must have a designated person that is qualified and trained to:”**
  - Develop and implement “appropriate procedures”
  - Oversee “entity compliance”
  - Ensure “competency of personnel”
  - Ensure “environmental control of the storage and compounding areas”
  - Understand risks & responsibility to report potential hazards
- **“Must also be responsible for the oversight and monitoring of the facility and maintaining reports of testing/sampling performed in facilities and acting upon the results.”**

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 4. Responsibilities of Personnel Handling Hazardous Drugs (2016)

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## Responsibilities of Personnel Handling HDs

“All personnel who handle HDs are responsible for

**understanding the fundamental practices and precautions**

and for

**continually evaluating these procedures and the quality of the final HDs to**

- prevent harm to patients
- minimize exposure to personnel, and
- minimize contamination of the work and patient-care environment”



United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 4. Responsibilities of Personnel Handling Hazardous Drugs (2016)

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## Section 5. Facilities and Engineering Controls



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### General Requirements

“Designated areas must be available for:

- Receipt and Unpacking
- Storage of HDs
- Nonsterile HD compounding (if performed by entity)
- Sterile HD compounding (if performed by entity)”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 5. Facilities and Engineering Controls (2016)

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# Section 5.1 Receipt (and unpacking)



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## Receipt & Unpacking from External Shipping Containers

- “Antineoplastic HDs and all HD APIs **must be unpacked** ... in an area that is **neutral/normal or negative pressure** relative to the surrounding areas.”
- “HDs **must not be unpacked** ... in sterile compounding areas or **in positive pressure areas.**”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 5.1 Receipt (2016)

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# Section 5.2 Storage



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## Storage of HDs – General Requirements

- “HDs must be stored in a manner that prevents spillage or breakage if the container falls.”
- “Do not store HD’s on the floor.”
- The “manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.2 Storage (2016)

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## Storage: Separate HDs from Non-HDs

- **Exception:** “Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory.”
- Best location for Storage Cabinet? The C-SEC.
  - “These HDs must be stored in an externally ventilated, negative-pressure room with at least **12** air changes per hour (**ACPH**)”

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 5.2 Storage (2016)

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## Storage: Sterile HDs & Nonsterile HDs

- “Sterile and nonsterile HDs may be stored together, **but** HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding...”
- “Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.”

United States Pharmacopeia 39, National Formulary 34 (USP), General  
Chapter 800, Section 5.2 Storage (2016)

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## Now for a Closer Look at Compounding Areas...

“Designated areas must be available for:

- Receipt and Unpacking
- Storage of HDs
- *[If performed by the entity]:*
  - Nonsterile HD compounding
  - Sterile HD compounding”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 5. Facilities and Engineering Controls (2016)

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## Section 5.3 Compounding



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## Engineering Control Categories – General Terms

- **Primary: C-PEC**
  - The **enclosure**
- **Secondary: C-SEC**
  - The **room** containing the enclosure
- **Supplementary** levels of control
  - “...**adjunct controls** for additional layers of protection” ex: closed-system drug transfer device

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3 Compounding, (2016)

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## Engineering Control Definitions:

- **C-PEC:**
  - “A containment primary engineering control (C-PEC) is a **ventilated device** designed to minimize worker and environmental HD exposure when directly handling HDs.”
- **C-SEC:**
  - “Containment secondary engineering controls (C-SEC) is the **room** in which the C-PEC is placed.”
- **Supplemental engineering controls:**
  - “...**adjunct controls** to offer additional levels of protection.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3 Compounding, (2016)

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## General Plumbing Requirements:

- “A **sink** must be available for hand washing.”
- “An **eyewash station** and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available.”
- **Location Requirements:**
  - “...at least one meter away from the C-PEC” (the enclosure)
  - “..locate water sources and drains in areas where their presence will not interfere with required ISO classifications.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3 Compounding, (2016)

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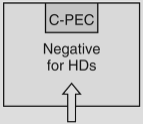
## Compounding Configurations

- Nonsterile HD Compounding ONLY
- Sterile HD Compounding ONLY
- Sterile HD + Sterile NON-HD Compounding
- Sterile HD + NON-Sterile HD Compounding

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# Section 5.3.1 Nonsterile Compounding

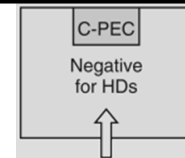
Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for Limitations
Nonsterile HD Compounding		12			

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas, (2016)

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## Enclosure & Room - Construction Requirements



- "...surfaces of ceiling walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding."  
(i.e. no paint chipping, no rust, etc.)
- **Pro Tip:** This applies to the room (C-SEC) and cabinet (C-PEC)

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.1 Nonsterile Compounding and Appendix 2, (2016)

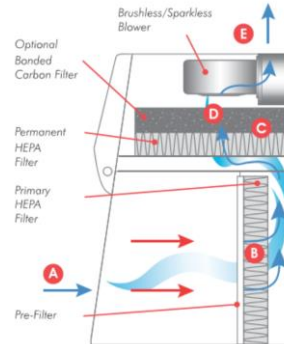
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# Nonsterile Enclosure [C-PEC] Requirements

- Externally vented or redundant-HEPA filtered in series
- The “critical environment does not need to be ISO classified.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.1 and Appendix 2, (2016)



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Redundant-HEPA design

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# Nonsterile Enclosure [C-PEC] Requirements

C-PEC  
Negative  
for HDs

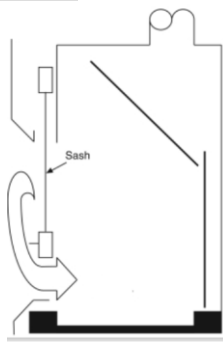
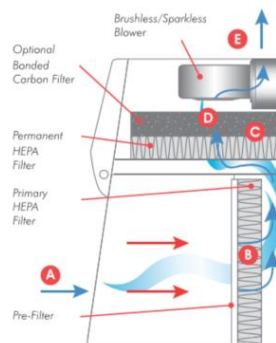


Figure 9.5. Prudent Practices in the Laboratory. 2011.  
Viewed Online. August 24, 2015.  
<http://www.ncbi.nlm.nih.gov/books/NBK55878/toc/?report=reader>



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## When is the Enclosure Required?

- **Always.** Unless the technician is handling “final dosage forms...that do not produce particles, aerosols, or gasses.”

**Pro Tip:** When utilizing redundant-HEPA designs, all chamber air must be filtered twice by HEPA filters *before* exhausting into the room.



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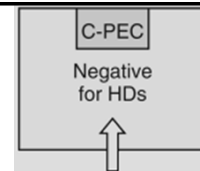
United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 5.3.1 Nonsterile Compounding, (2016)

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## Nonsterile HD Room [C-SEC] Requirements - Overview

- Externally vented
- Physically separated
- 12 ACPH
- Negative pressure between 0.01-0.03 inches of water column relative adjacent areas.
- \*published errata remove room HEPA requirement as air exits

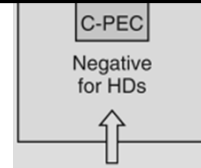


United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 5.3.1 and Appendix 2, (2016)

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## Can I Vent the Room (the C-SEC) Through the Enclosure (the C-PEC)?



- “C-PEC must be placed in a C-SEC that has at least 12 ACPH”
- “The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.”

**Pro Tip:** The answer according to <800> is ‘yes.’ AirClean® does provide vented units.

**However,** balances typically have problems taring out in enclosures that supply negative pressure to rooms. Why? This is a result of the venting which causes the airflow to become more turbulent within the enclosure. This problem becomes amplified with the practice of ‘chaining’ hoods up to the same ductwork.

**Furthermore,** you can’t ever turn off or turn down your C-SEC negative pressure if you vent your room through your hood. Turning down the ACPH at night or when the lab is unoccupied, will typically save an entity a surprising amount of HVAC cost in the long run. For more info on nighttime/unoccupied room ACPH see OSHA 1910.1450.

United States Pharmacopeia 39, National Formulary 34  
(USP), General Chapter 800, Sections 5.3 - 5.3.1, (2016)

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## Compounding Configurations

- Nonsterile HD Compounding ONLY
- Sterile HD Compounding ONLY
- Sterile HD + Sterile NON-HD Compounding
- Sterile HD + NON-Sterile HD Compounding

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# Section 5.3.2 Sterile Compounding



Following Slide: United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas. (2016)

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Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for Limitations
Sterile HD Compounding		30		12	Maximum BUD as described in <797> for segregated compounding area.
	OR		<p>This design is not recommended</p>	30	If this design is in place, measures must be taken to avoid contamination of the positive-pressure buffer room.
	OR		<p>Typically used in oncology clinic settings.</p>	30	Maximum BUD as described in <797>.

## Sterile HD Enclosure & Room - Construction Requirements

- “In addition to this chapter, sterile compounding must follow standards in <797>.”
- Smooth, non-shedding (no paint chipping), no rust, etc.

**Pro Tip:** USP <797> is currently going through an update.

Access is available here: <http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision>

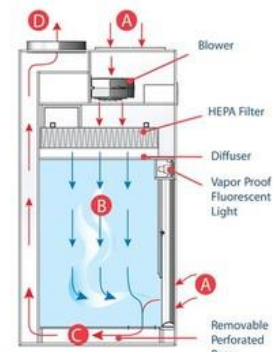
United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2 Sterile Compounding, (2016)

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## Sterile HD Enclosure

- Enclosure MUST
  - “Be externally vented”
  - “Operate continuously”
  - “ISO Class 5 or better air quality...”
  - Protect **Operator AND Process**
- What’s not allowed:
  - Laminar Airflow Workbench (LAFW)
  - Compounding Aseptic Isolator (CAI)
  - Class II Type A2 **without** external exhaust



1. Room air enters at "A"  
2. Clean, HEPA filtered air enters the chamber at "B"  
3. At "C", air is collected from chamber for exhaust to atmosphere at "D"

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DuraMax™ Hood

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Sections 5.3 & 5.3.2 emphasis added, (2016)

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## What Types of Sterile HD Enclosures Should I Look For?

- ISO 5, external vented enclosures:
  - EX: Class II BSCs B1 or B2, Class III BSCs, CACIs, etc.

**Pro Tip:** <800> lists Class II BSCs Type A2 cabinets as acceptable for sterile HD compounding.

**However,** Type A2 cabinets do not necessarily utilize duct exhaust, which is required for sterile compounding.

If you choose an A2 cabinet design, you will need to specifically check with the manufacturer to make sure you purchase the 100% exhaust version of an A2 cabinet.

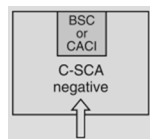
United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2 Sterile Compounding, (2016)

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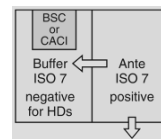
## BUD Times & Room Air Classification:

### C-SCA - Containment-Segregated Compounding Area



Category 1 CSPs

### ISO 7 Buffer Room with an ISO 7 ante-room



Category 2 CSPs

**Pro Tip:** How do you pick?

The USP <797> proposed update, classifies Compounded Sterile Products (CSPs) into 2 Categories. Category 1 having lower BUD (Beyond Use Date) times, but worse sterile room air quality. Category 2 requirements, have longer BUD times but require ISO 7 air. **See the following slide for more information.**

Sterile enclosure placement: United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2 Sterile Compounding and Appendix 2, (2016)

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## C-SCA vs. ISO 7 Buffer & Ante Room

**Pro Tip:** Max BUD times will depend on a variety of factors. For more info on BUD updates see Table 8 in the proposed <797> standard update.

- Step 1. Choose your goal CSP Category.
- Step 2. Follow the C-SEC (room) requirements for that Category

Image 1. CSP Categories & C-SEC Requirements				
CSP Category	Sterile C-SEC (Room) Air Quality Requirement	Up-Fit Cost	Max BUD Time (with refrigeration)	HD Categories
Category 1	Unclassified C-SCA	Low	24 hours	Low & Medium Risk Only
Category 2	ISO 7 Buffer Room + ISO 7 Ante-Room	High	45 days	All Legally Permitted

CSP Category Information: United States Pharmacopeia, Proposed Update to General Chapter <797>. Accessed Online, November 04, 2015.

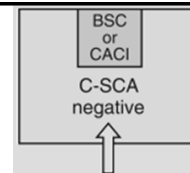
<http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision>

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## Containment-Segregated Compounding Area (C-SCA) Requirements

- Fixed walls
- Externally Vented
  - Negative pressure between 0.01 & 0.03 in of water column
  - Minimum of 12 ACPH
- Hand-washing sink at least 1 m from enclosure
  - Inside or directly outside the C-SCA



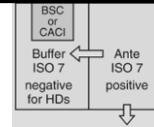
**Category 1 CSPs**

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2 Sterile Compounding and Appendix 2, (2016)

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## ISO 7 Buffer Room + Ante-Room Requirements



Category 2 CSPs

### ISO 7 Buffer Room

- ISO 7 Class Air
- Fixed Walls
- HEPA-filtered Supply Air
- **Negative pressure**
  - Between 0.01 & 0.03 in. of H<sub>2</sub>O column to all areas
  - Externally Vented
- Minimum of **30 ACPH**

### ISO 7 Ante-Room

- ISO 7 Class Air
- Fixed Walls
- HEPA-filtered Supply Air
- **Positive pressure**
  - At least 0.02 in. of H<sub>2</sub>O column to all adjacent unclassified areas
- **Sink** at least 1 m from entrance to buffer room

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 5.3.2 and Appendix 2, (2016)

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# Compounding Configurations

- ✓ Nonsterile HD Compounding ONLY
- ✓ Sterile HD Compounding ONLY
- Sterile HD + Sterile NON-HD Compounding
- Sterile HD + NON-Sterile HD Compounding

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# Sterile HD + Sterile NON-HD Compounding

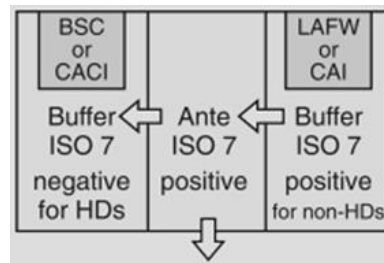
**Following Slide:** United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas, (2016)

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Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for Limitations
Sterile HD Compounding		30		12	Maximum BUD as described in <797> for segregated compounding area.
	OR			30	If this design is in place, measures must be taken to avoid contamination of the positive-pressure buffer room.
	OR		<p style="font-size: small;">Typically used in oncology clinic settings.</p>	30	Maximum BUD as described in <797>.

## Recommended Facility Design for Sterile HD & Sterile Non-HD Compounding



United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas, (2016)

### Pro Tip:

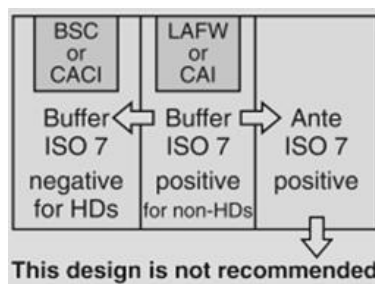
With recognition that this facility design may not be achievable, <800> has allowed for more configurations evaluated in the following slides.

These following configurations typically have some extra stipulation.

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## Sterile HD & Sterile Non-HD Alternative Design 1:



**Pro Tip:** This “alternative” configuration is listed as not recommended, but is accepted. What does this mean? There are extra stipulations and design requirements, evaluated on the next slide.

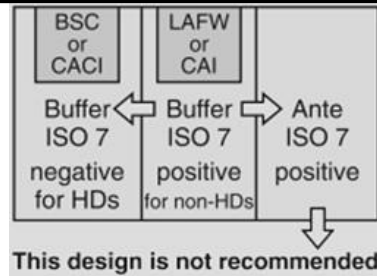
United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2, (2016)

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## Sterile HD & Sterile Non-HD Alternative Design 1: Requirements *Summary*

- PPE Demarcation Line
- A method to transport HDs, HD CSPs, & HD waste
  - *Pass-Through Chamber*
    - *Refrigerator pass-through must not be used*
    - *Must be included in facility's certification – ISO 7 air quality*
  - *Other containment methods (i.e. sealed containers)*



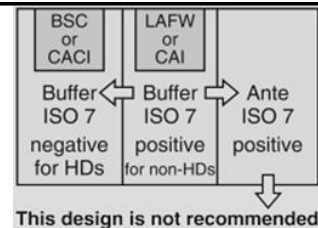
United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 5.3.2, (2016)

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## Sterile HD & Sterile Non-HD Alternative Design 1: Requirements *Cont.*

- “Although not a recommended facility design, if the negative-pressure HD buffer room is entered through the positive-pressure non-HD buffer room, the following is also required:
  - A line of demarcation must be defined within the negative pressure buffer room for donning and doffing PPE
  - A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination...”  
(see following slide)

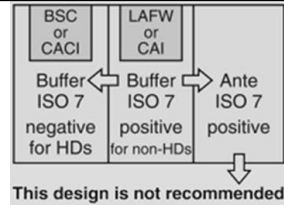


United States Pharmacopeia 39, National Formulary 34 (USP), General  
Chapter 800, Section 5.3.2 Sterile Compounding, (2016)

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## Sterile HD & Sterile Non-HD Alternative Design 1: Requirements Cont.



Methods of transporting HD/HD waste to/from HD Buffer Room:

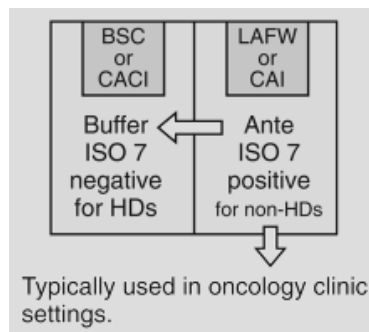
- **Pass-Through Chamber**
  - Located between negative-pressure buffer area and adjacent space
  - Chamber must be included in facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room
  - Refrigerator pass-through must not be used
- **Other methods of containment (i.e. sealed containers)**

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2 Sterile Compounding, (2016)

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## Sterile HD & Sterile Non-HD Alternative Design 2:

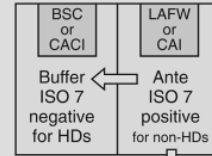


United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2. Examples of Designs for Hazardous Drug Compounding Areas, (2016)

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## Sterile HD & Sterile Non-HD Alternative Design 2:



Typically used in oncology clinic settings.

- Airflow Requirements:
  - Appendix 2 lists this design with a minimum of 30 ACPH in the ISO 7 Buffer Room
- BUD Limitations:
  - “maximum BUD as described in <797>”.

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2. Examples of Designs for Hazardous Drug Compounding Areas, (2016)

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## Sterile HD & Sterile Non-HD Compounding – Can I Use the Same Enclosure?

**Pro Tip:** Technically, yes, you can use the sterile HD enclosure for sterile non-HD compounding.

However, a BSC or CACI used for sterile HD prep, must not be used for sterile non-HD prep, “...unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC [the enclosure] and is labeled to require PPE handling precautions.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3.2 Sterile Compounding, (2016)

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# Compounding Configurations

- ✓ Nonsterile HD Compounding ONLY
- ✓ Sterile HD Compounding ONLY
- ✓ Sterile HD + Sterile NON-HD Compounding
- Sterile HD + NON-Sterile HD Compounding

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# Sterile HD + NON-Sterile HD Compounding

**Following Slide:** United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Appendix 2: Examples of Designs for Hazardous Drug Compounding Areas, (2016)

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Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for Limitations	
<b>Both Sterile HD and Nonsterile HD Compounding</b>	A separate room for sterile and nonsterile compounding is recommended.			30	For rooms used for both sterile and nonsterile compounding, particle-generating activity must not be performed when sterile compounding is in process. C-PECs must be at least one meter apart.	
			OR		12	Maximum BUD as described in <797> for segregated compounding area.
			OR		12	Maximum BUD as described in <797> for segregated compounding area.

## Recommended Facility Design for Sterile HD & Nonsterile HD Compounding

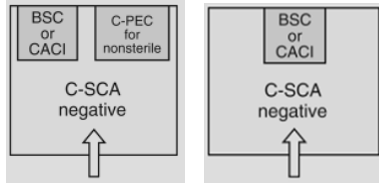
**Pro Tip:** It is recommended that the entity use two separate rooms.

However, these activities can be performed within the same room provided certain conditions are met.

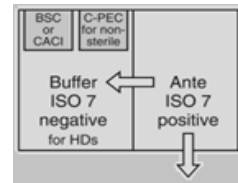
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## Combining Sterile HD & Nonsterile HD Activity



C-SCA Layouts



ISO 7 Buffer/Ante Layout

- “Maximum BUD as described in <797>”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3 and Appendix 2, (2016)

- Enclosures 1+ m apart
- ISO 7 classification during nonsterile compounding
- No particle-generating activity during sterile compounding

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## Compounding Configurations

- ✓ Nonsterile HD Compounding ONLY
- ✓ Sterile HD Compounding ONLY
- ✓ Sterile HD + Sterile NON-HD Compounding
- ✓ Sterile HD + NON-Sterile HD Compounding

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## Recalling Facility Design Requirements

- **C-PEC:**
  - “A containment primary engineering control (C-PEC) is a **ventilated device** designed to minimize worker and environmental HD exposure when directly handling HDs.”
- **C-SEC:**
  - “Containment secondary engineering controls (C-SEC) is the **room** in which the C-PEC is placed.”
- **Supplemental engineering controls:**
  - “...**adjunct controls** to offer additional levels of protection.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.3, (2016)

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## Section 5.4 Containment Supplemental Engineering Controls



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## What are Supplemental Engineering Controls?

- “adjunct controls to offer additional levels of protection during compounding or administration.”
  - EX: Closed System Transfer Device (CSTD)
- “A CSTD must not be used as a substitute for a C-PEC [an enclosure] when compounding.”
- “CSTDs must be used when administering antineoplastic HDs when the dosage form allows.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 5.4 Containment Supplemental Engineering Controls, (2016)

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## Section 6.

## Environmental Quality and Control



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## Environmental Quality & Control

- “Environmental wipe sampling for HD surface residue should be performed routinely”
  - “e.g. initially as a benchmark and at least every 6 months, or more often as needed, to verify containment.”
- “Surface wipe sampling should include:
  - Interior of the C-PEC and equipment contained in it
  - Pass-through chambers
  - Surfaces in staging or work areas near the C-PEC
  - Areas adjacent to the C-PECS
  - Areas immediately outside the HD buffer room or the C-SCA
  - Patient administration areas”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 6. Environmental Quality and Control, (2016)

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## Section 7. Personal Protective Equipment



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## Personal Protective Equipment (PPE)

- “The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings.”
- “Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 7. Personal Protective Equipment, (2016)

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## When to Wear PPE

- “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”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 7. Personal Protective Equipment, (2016)

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## Gloves – When to Wear

- “...two pairs of chemotherapy gloves are **required** for **compounding** sterile and nonsterile HDs.”
- “Chemotherapy gloves **should** be worn for **handling all HDs** including non-antineoplastics and for reproductive risk only HDs.”
- “Chemotherapy gloves **should** be **changed every 30 minutes** unless otherwise recommended” by the manufacturer... and must be changed when punctured/torn/etc.
  - Committee published response #27- If preparation takes longer than 30 minutes to **finish preparation** before changing gloves.

**Pro Tip:** You **MUST** comply with “**MUST**”/“**REQUIRED**” statements. “**SHOULD**” statements however, are recommendations.

i.e. **MUST** wear gloves when compounding HDs, **SHOULD** be changed every 30 minutes (or after finishing preparation)

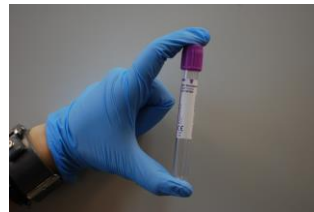
United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Sections 7 & 7.1, (2016), emphasis added

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## Gloves – What to Wear

- Chemotherapy gloves “...must meet ASTM standard D6978 (or its successor).”
- Gloves “...must be powder free...”
- Gloves “must be inspected for physical defects before use.”  
(holes/weak spots/etc.)
- “When used for sterile compounding, the outer chemotherapy gloves must be sterile”



United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Sections 7 & 7.1, (2016)

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## Gowns – What to Wear

- “Gowns must be selected based on the HDs handled.”
- When required, gowns “...must be disposable and shown to resist permeability by HDs.”
- “Gowns must close in the back, be long sleeved, and have closed cuffs that are elastic or knit.”

**Pro Tip:** <800> prefers “...disposable gowns made of polyethylene-coated polypropylene or other laminate materials...” to uncoated material.

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 7.2 Gowns, (2016)

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## Gowns – When to Wear

- “Gowns must be changed per the manufacturer’s information”
  - “If no permeation information is available...change them every 2-3 hours or immediately after a spill or splash”
- Gowns worn in HD areas must not be worn to other areas



United States Pharmacopeia 39, National Formulary 34  
(USP), General Chapter 800, Section 7.2 Gowns, (2016)

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## Head, Hair, Shoe, and Sleeve Covers

- “Head and hair covers (including beard and moustache, if applicable), shoe covers, and sleeve covers provide protection from contact with HD residue.”
- “When compounding HDs, a second pair of shoe covers **must** be donned before entering the C-SEC and doffed when exiting...” do **not** wear to other non-HD areas.
- “Disposable sleeve covers **may** be used to protect areas of the arm that may come in contact with HDs.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 7.3 Head, Hair, Shoe, and Sleeve Covers, (2016), emphasis added

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## Eye & Face Protection

### When Outside of a C-PEC (Enclosure):

- “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...”

### What to wear:

- Eye and Face Protection:
  - “A full-facepiece respirator”
  - “Face shields **in combination with goggles**”
- Eye Protection Only
  - Goggles
    - “Eye glasses alone or safety glasses with side shield do not protect the eyes adequately from splashes.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 7.4 Eye & Face Protection, (2016), emphasis added

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## Respiratory Protection

Follow OSHA 29 CFR 1910.134 Respiratory Protection Laws

**“Personnel who are unpacking HDs not contained in Plastic**

should wear an elastomeric half-mask with a multi-gas cartridge and P-100 filter until assessment of the packaging integrity can be made...”

**Particles Only:**

- NIOSH-certified N95 respirator is sufficient

**Splashes, Droplets, and Sprays:**

- Surgical N95 respirators provide a barrier
- Do not wear surgical masks for protection from HDs

**Large spills, Deactivating, Decontaminating, Cleaning, Etc.:**

- Full-facepiece, chemical cartridge-type respirators
- Powered-air purifying respirators

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 7.5 Respiratory Protection, (2016), emphasis added

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## PPE – Handling & Disposal

**How to Handle**

- “Consider all PPE worn when handling HDs to be contaminated with, at a minimum, trace quantities of HDs.”

**How to Dispose:**

- “PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC.”
- Dispose of gloves & sleeve covers inside the enclosure or place in sealed bag before removing from enclosure

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 7.6 Disposal of Used Personal Protective Equipment, (2016)

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# Section 8. Hazard Communication Program



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## Hazard Communication Program



United States Pharmacopeia 39, National Formulary  
34 (USP), General Chapter 800, Section 8. Hazard  
Communication Program, (2016)

“Entities are  
required to  
establish policies  
and procedures  
that ensure worker  
safety during all  
aspects of HD  
handling.”

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## Hazard Communication Program:

- Must include a written plan to implement <800>
- HD containers “must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings”
- “Entities must have an SDS for each hazardous chemical they use” – readily available during all shifts & at work area
- “Personnel who may be exposed to hazardous chemicals... must be provided information and training...” initially and when a change occurs
- “Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 8. Hazard Communication Program, (2016)

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## Section 9. Personnel Training



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## Personnel Training

### Who:

- “All personnel who handle HDs must be trained based on their job functions...”

### When:

- Personnel must be trained prior to the introduction of:
  - A new HD
  - New equipment
  - New or significant change in process or SOP.

### Reassessment:

- Competency “must be reassessed at least every 12 months”

### Documentation:

- All training and competency assessments

United States Pharmacopeia 39, National  
Formulary 34 (USP), General Chapter 800,  
Section 9. Personnel Training, (2016)

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## Training Requirements

### “The training must include at least the following:

- Overview of entity's list of HDs and their risks
- Review of the entity's SOPs related to handling of HDs
- Proper use of PPE
- Proper use of equipment and devices  
(e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials”

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United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 9. Personnel Training, (2016), emphasis added  
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# Section 10. Receiving



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## Receiving HDs

- **Receiving:**
  - “Antineoplastic HDs and all HD APIs must be unpacked (i.e. removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas..”
  - “HDs should be received...in impervious plastic”
  - “A spill kit must accessible in the receiving area.”
  - Receiving Damaged HD Shipping Containers
    - see Table 4. Summary of Requirements for Receiving and Handling Damaged HD Shipping Containers on following slide

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 10. Receiving, (2016), emphasis added

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Table 4. Summary of Requirements for Receiving and Handling Damaged HD Shipping Containers	
If the shipping container appears damaged	<ul style="list-style-type: none"> <li>• Seal container without opening and contact the supplier</li> <li>• If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous"</li> <li>• If the supplier declines return, dispose of as hazardous waste</li> </ul>
If a damaged shipping container must be opened	<ul style="list-style-type: none"> <li>• Seal the container in plastic or an impervious container</li> <li>• Transport it to a C-PEC and place on a plastic-backed preparation mat</li> <li>• Open the package and remove undamaged items</li> <li>• Wipe the outside of the undamaged items with a disposable wipe</li> <li>• Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"</li> <li>• If the supplier declines return, dispose of as hazardous waste</li> </ul>

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 10. Receiving, Table 4. Summary of Requirements for Receiving and Handling Damaged HD Shipping Containers, (2016)

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## Unpacking & Delivery



- **Unpacking:**
  - “PPE, including chemotherapy gloves, must be worn”
- **Delivery (After Unpacking):**
  - Deliver HDs “to storage area immediately”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 10. Receiving, (2016), emphasis added

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# Section 11. Labeling, Packaging, Transport and Disposal



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## Labeling, Packaging, Transport & Disposal



“The entity must establish SOP’s for the labeling, packaging, transport, and disposal of HDs.

The SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 11. Labeling, Packaging, Transport and Disposal, (2016)

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## HD Labeling & Packaging

### Labeling:

- HDs “must be clearly labeled” during transport

### Packaging Considerations During Transport:

- HD physical integrity, stability, and sterility
- Protecting workers during transport



United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 11. Labeling & Section 11.2 Packaging, (2016)

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## HD Transport & Disposal

### • Transport:

- Use containers that “minimize risk of breakage or leakage”
- Entity “...must consult Transportation Information on the SDS.”
- Label with:
  - Storage instruction
  - Disposal instruction
  - HD category

### • Disposal

- Personnel must be trained to protect themselves and prevent environmental HD contamination
- Disposal “...must comply with all applicable federal, state, and local regulations.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 11.3 Transport & Section 11.4 Disposal, (2016)

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# Section 12. Dispensing Final Dosage Forms

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## Dispensing Final Dosage Forms

"HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirement for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g. HD dust or leakage)."

- "Clean **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 counted or packaging machines..."

**Pro Tip:** Section 2 states: "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."

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 2. List of Hazardous Drugs and Section 12. Dispensing Final Dosage Forms, (2016), emphasis added

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# Section 13. Compounding



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## Compounding of HDs

- “Entities and personnel... must be compliant with the appropriate USP standards for compounding including <795> and <797>.”
- “Disposable or clean equipment for compounding must be **dedicated** for use with HDs.”
  - Mortars, pestles, spatulas, etc.

**Pro Tip:** According to Section 12, HD dedicated equipment must be decontaminated after each use.

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 13. Compounding, (2016), emphasis added

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## Compounding of HDs (Cont.)

- “A plastic-backed preparation mat should be placed on the work surface of the C-PEC.”
  - Change mat regularly during use & when spills occur
- “APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities  
(such as crushing tablets, opening capsules, and weighing powders).”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 13. Compounding, (2016), emphasis added

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## Section 14. Administering



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## Administering

- Use “...protective medical devices and techniques.”
  - Medical device ex: “needleless and closed systems”
  - Technique ex: Spiking/priming of IV tubing
- “Appropriate PPE must be worn when administering HDs.”
  - Discard after use at administration site
- Discard equipment properly (tubes, needles)
- “CSTDs must be used for administration of antineoplastic HDs when the dosage form allows.”

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 14. Administering, (2016)

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## Section 15. Deactivating, Decontaminating, Cleaning and Disinfecting

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## Deactivating, Decontaminating, Cleaning and Disinfecting

“The entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection.”

- Compounding area cleaning procedures must comply with:
  - <795> for nonsterile HDs
  - <797> for sterile HDs
- Written SOPs must include:
  - Cleaning Procedures
  - Agents used
  - Dilutions (if used)
  - Frequency
  - Documentation requirements



United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 15. Deactivating,  
Decontaminating, Cleaning and Disinfecting, (2016)

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## Deactivating, Decontaminating, Cleaning and Disinfecting

- All personnel who perform these activities must:
  - Be trained in SOPs
  - Wear appropriate PPE resistant to cleaners, including:
    - 2 pairs of chemotherapy gloves
    - Impermeable disposable gowns
    - Eye protection & face shields (if splashing is likely)
    - Respiratory protection (if required)
- Should use wetted wipes instead of spray bottles
- Discard materials according to EPA + entity policy

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800,  
Section 15. Deactivating, Decontaminating, Cleaning and Disinfecting, (2016)

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## Deactivating, Decontaminating, Cleaning and Disinfecting

Cleaning Step	Purpose	Example Agents
Deactivation	Render compound inert or inactive	As listed in the HD labeling or other agents which may incorporate EPA-registered oxidizers (e.g., peroxide formulations, sodium hypochlorite, etc.)
Decontamination	Remove HD residue	Materials that have been validated to be effective for HD decontamination, or through other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent
Disinfection (for sterile manipulations)	Destroy microorganisms	EPA-registered disinfectant and/or sterile alcohol as appropriate for use

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Table 5. Cleaning Steps, Section 15. Deactivating, Decontaminating, Cleaning and Disinfecting, (2016)

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## Deactivation & Decontamination

### Deactivation

- “Deactivation renders a compound inert or inactive.”
- “...residue must be removed by decontaminating the surface.”

### Decontamination

- “Decontamination occurs by inactivating, neutralizing, or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials...”

**Pro Tip:** For units where the work surface is removable, the user will have to abide by the following statement:

“C-PECs may have areas **under the work tray** where contamination can build up. These areas must be deactivated, decontaminated, and cleaned **at least monthly** to reduce contamination level in the C-PEC.”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 15.1 Deactivation & Section 15.2 Decontamination, (2016), emphasis added

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## Cleaning & Disinfecting

### Cleaning

- "...results in removal of contaminants from objects and surfaces..."
- "No cleaning step may be performed when compounding activities are occurring."

### Disinfection

- "...process of inhibiting or destroying microorganisms."
- Surfaces must be cleaned prior to disinfection
- "Disinfection must be done for areas intended to be sterile..."

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 15.3 Cleaning & Section 15.4 Disinfection, (2016), emphasis added

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## Section 16. Spill Control



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## Spill Control

- Train personnel managing spills on:
  - Spill management SOP
  - Use of PPE
  - Use of NIOSH-certified respirators
  - \*Personnel must be available when handling HDs
- “Signs must be available for restricting access to the spill area.”
- Spill kits “must be readily available” in common HD handling areas
  - Non-routine areas must have “a spill kit and respirator”

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 16. Spill Control, (2016)

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## Spill Control

“SOPs must be developed to prevent spills and to direct the clean up of HD spills.”

- SOPs must specify:
  - Person(s) “responsible for spill management”
  - The “location of spill kits and clean up materials”
  - Address “type of PPE required”
  - Address “size and scope of the spill”
  - The “capacity of the spill kit”
    - When exceeded, “...address use of appropriate full-facepiece or chemical cartridge-type respirators...”
- Must document spill circumstances + management

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 16. Spill Control, (2016)

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# Section 17. Documentation and Standard Operating Procedures



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## Documentation & Standard Operating Procedures

“The entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility.”

- **Yearly SOP Review:**
  - “The SOPs must be reviewed every 12 months by the designated person...”
  - The “...review must be documented.”
  - Communicate changes to “all personnel handling HDs”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 17. Documentation and Standard Operating Procedures, (2016)

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## SOP's Required By <800>

"The SOPs for handling HDs should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls  
(e.g., C-PECs, C-SECs, and CSTDs)
- Hand hygiene and use of PPE based on activity  
(e.g., receipt, transport, compounding, administration, spill, and disposal)
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring  
(e.g., wipe sampling)
- Disposal
- Spill control
- Medical surveillance"

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 17. Documentation and Standard  
Operating Procedures, (2016)

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## Training Documentation

- Personnel "must document their training" if they:
  - Transport HDs
  - Compound HDs
  - Administer HDs
- Document training according to:
  - OSHA standards
    - "...See OSHA 1910.120 Hazardous Waste Operations and Emergency Response."
  - Other applicable laws & regulations

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter  
800, Section 17. Documentation and Standard Operating Procedures, (2016)

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## Section 18.


# Medical Surveillance



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## Medical Surveillance

- “Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.”
- 
- General Purpose of Program:
    - “...minimize adverse health effects in personnel potentially exposed to HDs.”

United States Pharmacopeia 39, National Formulary 34 (USP),  
General Chapter 800, Section 18. Medical Surveillance, (2016)

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## Medical Surveillance Program

“Elements of a medical surveillance program should be consistent with entity’s HR policies and should include:”

- Method to “identify workers...potentially exposed to HDs”
- “Initial baseline assessment (pre-placement) of a worker’s health status and medical history.”
  - EX: lab testing, medical history, physical exam, & work history to assess HD exposure
  - Methods to asses HD exposure history include:
    - “Records of HDs handled with quantity and dosage forms”
    - “Estimated number of HDs handled per week”
    - “Estimates of hours spent handling HDs per week and/or per month”
    - “Performance of a physical assessment...”
- Monitoring through “periodic surveillance using the elements of data gathering” above

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 18. Medical Surveillance, (2016)

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## Medical Surveillance Program (Cont.)

“Elements of a medical surveillance program should be consistent with entity’s HR policies and should include:”

- Evaluation of engineering + administrative controls
- An “exit examination when a worker’s employment at the entity ends, to document the information on the employee’s medical, reproductive, and exposure histories. Examination and laboratory evaluation should be guided by the individual’s history of exposures and follow the outline of the periodic evaluation.”
- “Monitoring of the data to identify prevention failure...”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 18. Medical Surveillance, (2016)

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## Medical Surveillance Program (Cont.)

“Elements of a medical surveillance program should be consistent with entity’s HR policies and should include:”

- “Use of an entity-based or contracted employee health service...” that protects “the confidentiality of the employees’ personal medical information.”
- “Medical records of surveillance should be maintained according to OSHA regulation concerning access to employee exposure and medical records.”
- Include a “...follow-up plan for workers who have shown health changes...”

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 18. Medical Surveillance, (2016)

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## Medical Surveillance – Follow-Up (Part 1/3)

In cases of “exposure-related health changes,” the entity should take the following action:

- “Immediate re-evaluate of primary preventive measures...”
- Perform a “post-exposure examination tailored to the type of exposure...”
  - Confidential incident report assessing extent/involved area/organ systems commonly affected
  - “Treatment and laboratory studies will follow as indicated and be guided by emergency protocols.”
- Verify & document worker policy compliance.
  - Review PPE policy and availability

United States Pharmacopeia 39, National Formulary 34 (USP), General Chapter 800, Section 18.1 Follow-Up Plan, (2016)

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## Medical Surveillance – Follow-Up (Part 2/3)

In cases of “exposure-related health changes,” the entity should take the following action:

- “Ensure confidential, two-way communication between the worker and the employee health unit(s) regarding notification, discussions about a change in health condition, or detection of an adverse health effect.”
- “Ensure that any exposed worker receives confidential notification of any adverse health effect. Offer alternative duty or temporary reassignment.”

United States Pharmacopeia 39, National  
Formulary 34 (USP), General Chapter 800,  
Section 18.1 Follow-Up Plan, (2016)

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## Medical Surveillance – Follow-Up (Part 3/3)

In cases of “exposure-related health changes,” the entity should take the following action:

- “Compare performance of controls with recommended standards; conduct environmental sampling when analytical methods are available.”
- “Verify and document...engineering controls are in proper operating condition.”
- “Develop and document a plan....[to] prevent additional exposure of workers.”
- Provide and document follow-up medical survey demonstrating plan effectiveness
- “Provide ongoing medical surveillance of all workers at risk HD exposure to determine whether the plan implemented is effective.”

United States Pharmacopeia 39, National  
Formulary 34 (USP), General Chapter 800,  
Section 18.1 Follow-Up Plan, (2016)

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## The End!

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## Still Have Questions?

Feel free to contact us, we are happy to help!

**AirClean® Systems**  
2179 East Lyon Station Road  
Creedmoor, NC 27522

Phone: (919) 255.3220

Email: [contact@aircleansystems.com](mailto:contact@aircleansystems.com)

Presenter: Krystina Ashe, Product Manager  
KrystinaAshe@aircleansystems.com

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