

# Compounding Pharmacy Design for USP-797 and USP-800 Compliance

## Mechanical Perspective

Alaska Society of Healthcare Managers and Engineers  
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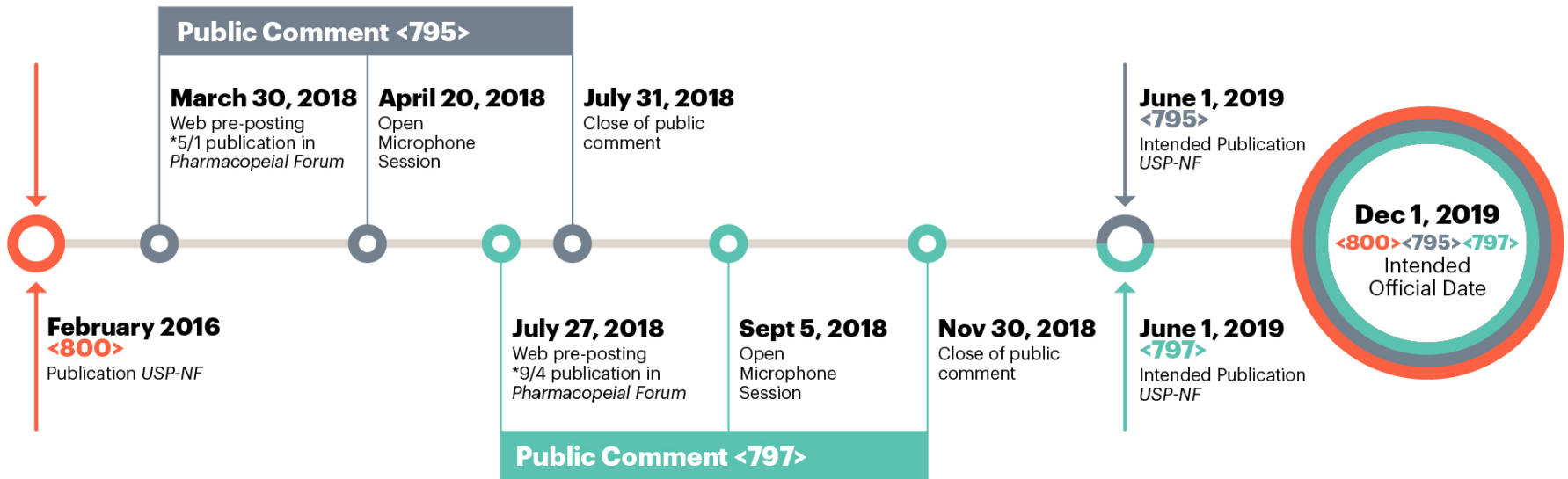
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# New Standard USP-800 Hazardous Drugs Handling in Healthcare Setting Updates to USP-795 Non-Sterile Preparations and USP-797 Sterile Preparations



**Note:** The current version of General Chapters <795> and <797> published in USP-NF are official.

Source: USP website. [www.usp.org/compounding/updates-on-standards](http://www.usp.org/compounding/updates-on-standards)



## Critical Initial Steps for Project Success

- Develop Owner's Project Requirements (OPR)
  - Phasing Considerations
  - Space Limitations
  - Budgets
- Generate List of Applicable Codes and Standards
  - **United States Pharmacopeia (USP) Standards**
  - **Facilities Guidelines Institute (FGI)**
  - **ASHRAE Standard 170**
  - Authority Having Jurisdiction (AHJ) adopted codes: ICC Codes & UPC
  - Owner's Insurance Agency Criteria
  - Accreditation Agency Criteria
  - NFPA Codes and Standards
  - Owner Design Standards
  - FDA Standards
- Develop Basis of Design (BOD) to Address OPR and Codes and Standards
- Customize Project to Meet Specific and Unique Criteria

## Determining Applicable USP Compounding Standards

	Non-Sterile Preparations	Sterile Preparations
Non-Hazardous Drugs	USP-795	USP-797
Hazardous Drugs	USP-800 USP-795	USP-800 USP-797

# Determining Compounding Suite Facility Requirements for Sterile Compounding

## Two Important Terms and Their Definitions

### **BUD – Beyond Use Date**

The date or time beyond which a compounded preparation cannot be used and must be discarded. The date or time is determined from the date or time when the preparation was compounded.

### **CSP (Compounded Sterile Preparation) Categories - Risk Categories**

*Categories 1 or 2* are primarily based on the conditions under which they are made, the probability for microbial growth, and the time period within which they must be used. Generally: *Category 1 CSPs* are those assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. *Category 2 CSPs* are those that may be assigned a BUD greater than 12 hours at controlled room temperature or greater than 24 hours if refrigerated.

Note: CSP Category 1 and 2 classifications are new to the updated draft USP-797 standard. Previous USP-797 used 'Low', 'Medium', and 'High' Microbial Contamination Risk Levels.

**Pharmacy personnel to define these criteria based on their program requirements.**

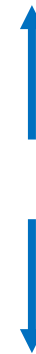


# Classification of Air Cleanliness

## ISO Classifications for Air Quality Standards

**Table 1. ISO Classification of Particulate Matter in Room Air**  
 (limits are in particles of 0.5  $\mu\text{m}$  and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])\*

Class Name		Particle Count	
ISO Class	U.S. FS 209E	ISO, $\text{m}^3$	FS 209E, $\text{ft}^3$
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000



Increasing Air Quality  
(Cleaner)

Decreasing Air Quality  
(Dirtier)

\* Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5  $\mu\text{m}$  per  $\text{m}^3$  or larger (ISO Class 5) is equivalent to 100 particles per  $\text{ft}^3$  (Class 100) ( $1 \text{ m}^3 = 35.2 \text{ ft}^3$ ).

Source: USP General Chapter 797, 2015 United States Pharmacopeia Convention

Increased space air quality achieved through high efficiency particulate air (HEPA) filtration and increased room air exchange rates of HEPA filtered air.

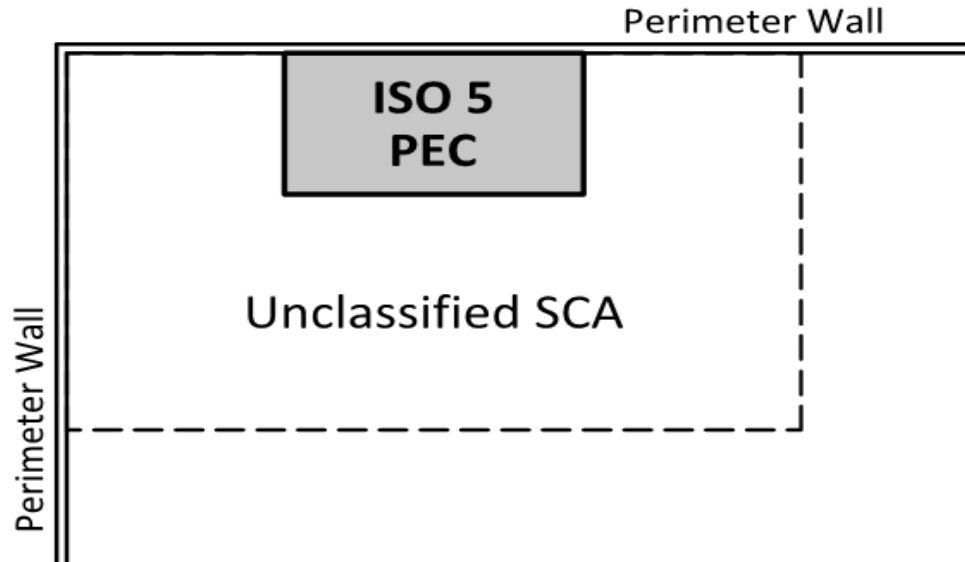
## USP-797 and USP-800 Engineering Controls

Engineering controls are required to protect compounded preparations from contamination. For hazardous drug (HD) compounding, engineering controls are also required to protect workers from exposure.

Three identified levels of engineering controls:

- Primary Engineering Controls (PECs) for Sterile Compounding:
  - For Sterile Compounding: Device or zone that provides an ISO Class-5 air quality.
  - For HDs: Containment Primary Engineering Controls (C-PECs).
    - Ventilated device that minimizes worker and environmental exposures to the HDs.
    - For sterile HD compounding this device provides ISO Class-5 air quality and also provides worker and environmental protection from the HDs.
- Secondary Engineering Controls (SECs) for Sterile Compounding:
  - Space where the PEC is located.
  - For HDs: Containment Secondary Engineering Controls (SECs).
    - Room with fixed walls where the C-PEC is located.
- Supplemental Engineering Controls:
  - Additional measures which may be used concurrently with PECs and SECs providing additional levels of protection, especially when handling HDs outside of the PECs and SECs.  
Example: Closed-System Drug-Transfer Device (CSTD).

## Types of Secondary Engineering Controls Sterile Non-HDs – Low Risk Category

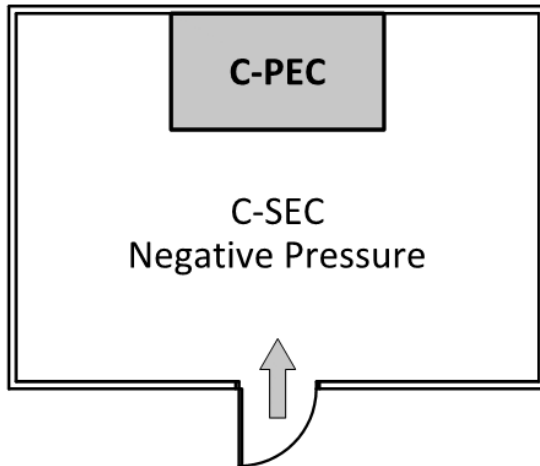


### Segregated Compound Area (SCA)

- Sterile non-HDs.
- Risk category 1, limited BUD.
- ISO Class 5 PEC.
- Non-classified space.
- HEPA filtered supply air not required.
- No specific air exchange rate.
- No space pressure requirements.

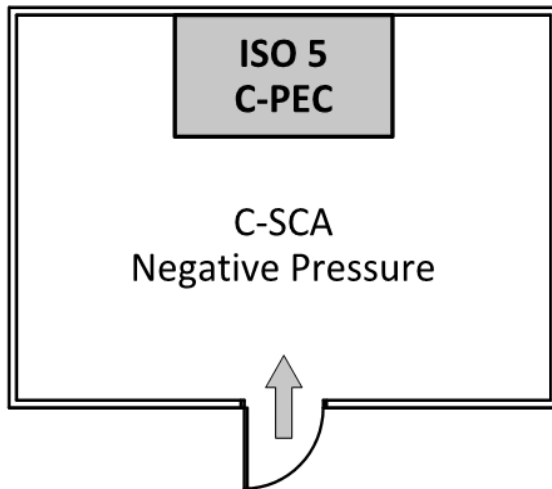


## Types of Secondary Engineering Controls Non Sterile and Sterile HDs – Low Risk Category



### Containment Secondary Engineering Control (C-SEC)

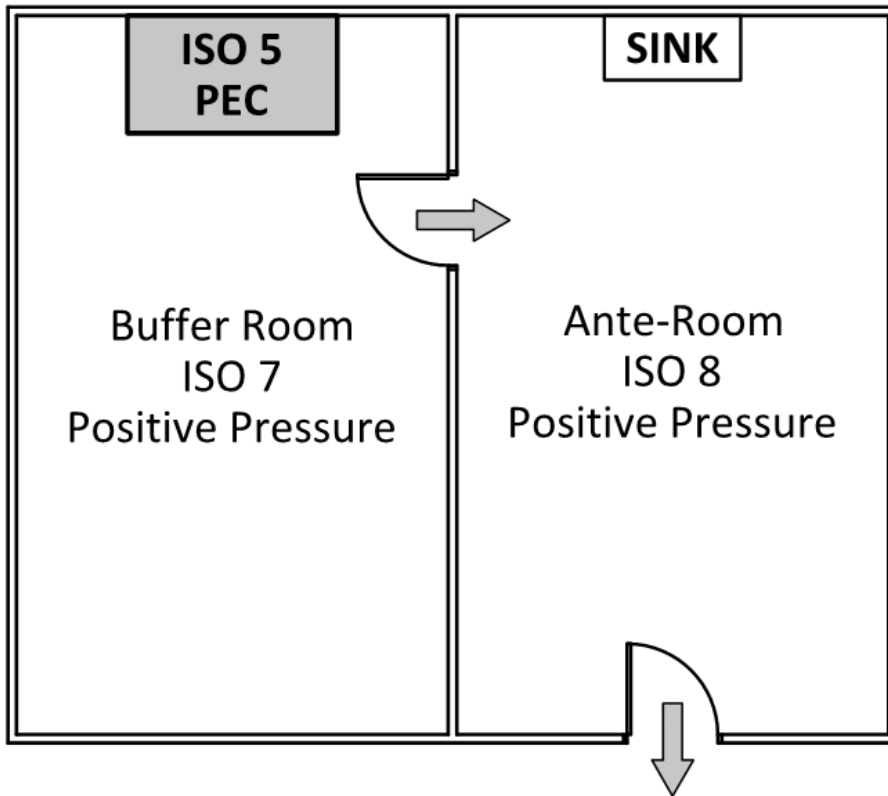
- Non Sterile HDs.
- Non-ISO classified PEC.
- Non-classified space.
- HEPA filtered supply air not required.
- Minimum 12 ACPH.
- Exhausted to outdoors.
- Negative pressure to adjacent spaces.
- Hand wash sink and emergency eyewash available.



### Containment Segregated Compound Area (C-SCA)

- Sterile HDs.
- Low and Medium Risk CSPs, limited BUD.
- ISO Class 5 PEC.
- Non-classified space.
- HEPA filtered supply air not required.
- Minimum 12 ACPH.
- Exhausted to outdoors.
- Negative pressure to adjacent spaces.
- Hand wash sink and emergency eyewash available.

## Types of Secondary Engineering Controls Sterile Non-HDs – Higher Risk Category



### Cleanroom Suite for Non-HDs

- Buffer + Ante-room.
- Sterile non-HDs.
- Risk category 2, extended BUD.
- ISO classified spaces.
- HEPA filtered supply air introduced at ceiling.
- Low wall return grilles.

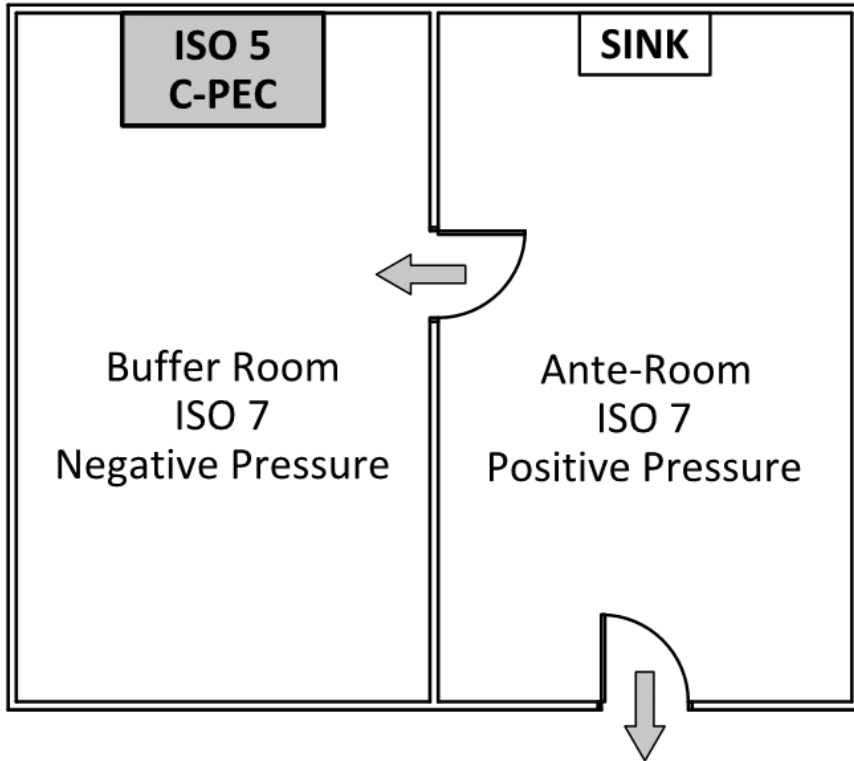
### Buffer Room

- ISO Class 5 PEC.
- ISO Class 7 or better room.
- Minimum 30 ACPH of HEPA filtered supply air.
  - PEC can account for up to 15 ACPH.
- Positive pressure to anteroom.

### Ante-Room

- ISO Class 8 or better.
- Minimum 20 ACPH of HEPA filtered supply air.
- Positive pressure to general pharmacy space.
- Hand wash sink.
  - Typically includes emergency eyewash.

## Types of Secondary Engineering Controls Sterile HDs – Higher Risk Category



### Cleanroom Suite for HDs

- Buffer + Ante-room.
- Sterile HDs.
- Required for high risk, extended BUD.
- ISO classified spaces.
- HEPA filtered supply air introduced at ceiling.

### Buffer Room

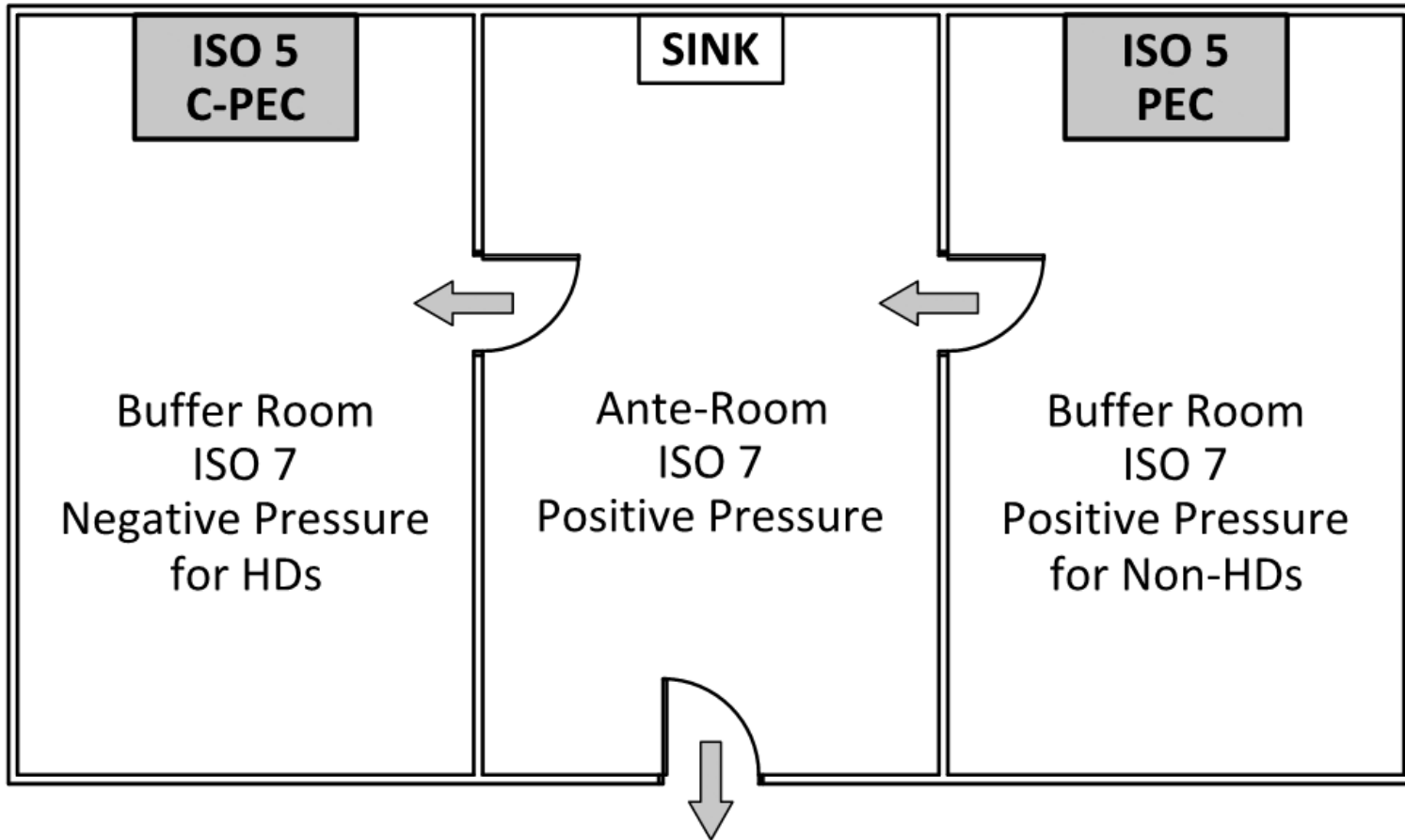
- ISO Class 5 C-CPEC.
- ISO Class 7 or better room.
- Minimum 30 ACPH of HEPA filtered supply air.
- Negative pressure to anteroom.
- Exhausted to outdoors.
  - Low wall exhaust grilles (if provided).

### Ante-Room

- ISO Class 7 or better.
- Minimum 30 ACPH of HEPA filtered supply air.
- Positive pressure to general pharmacy space.
- Low wall return grilles.
- Hand wash sink.
  - Typically includes emergency eyewash.

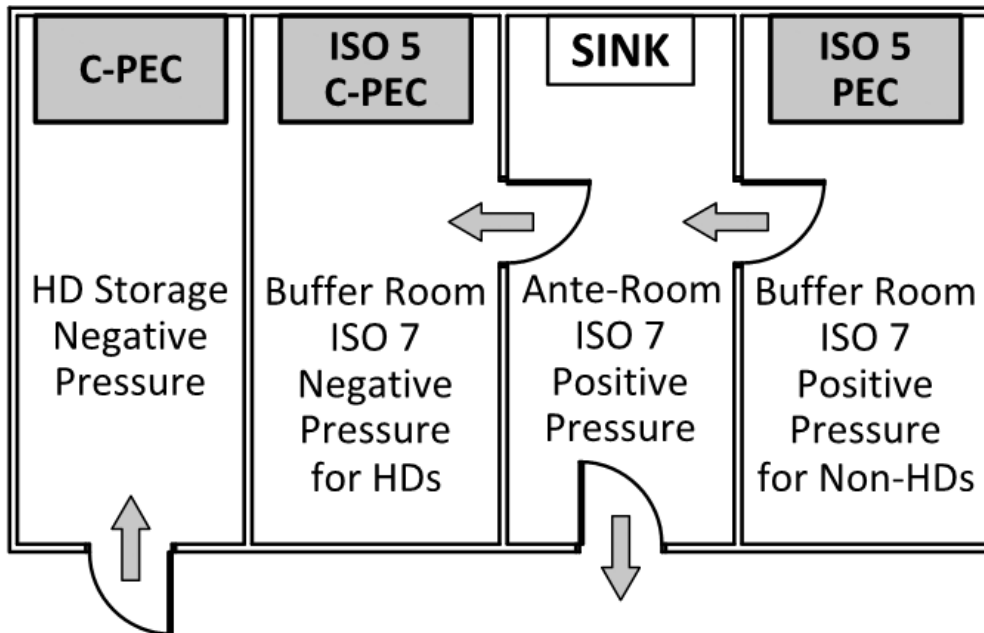
## Types of Secondary Engineering Controls Sterile Non-HDs and Sterile HDs – Higher Risk Category

Recommended compounding cleanroom suite layout for both HDs and non-HDs



## Considerations for Storage of Hazardous Drugs

HD's may be stored in the HD buffer room used for sterile compounding, though a separate HD storage room is preferred.



### HD Storage Rooms

- Non-classified space.
- HEPA filtered supply air not required.
- Minimum 12 ACPH.
- Space exhausted to outdoors.
- Negative pressure to adjacent spaces.
- May also be equipped with a non ISO classified C-PEC for non-sterile HD compounding.

## Ventilation Systems for the Pharmacy Compounding Clean Room Suite

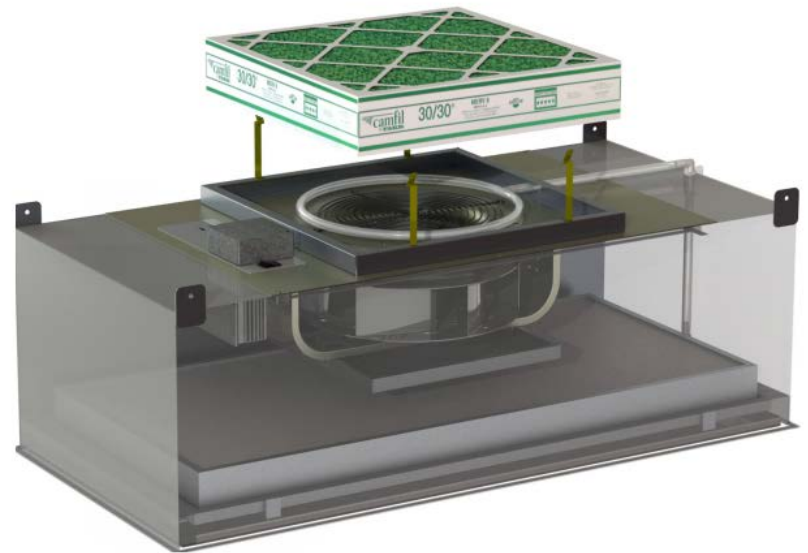
- Temperature and humidity control provided via central equipment.
  - Portable in-room space heaters, humidifiers, or dehumidifiers prohibited.
  - Maximum of 68 degrees F. and maximum of 60% relative humidity.
- Space pressure controls and monitoring.
- Controllability of both supply and return air to spaces.
  - Recommend use of air terminal units on both supply and return systems.
- Constant volume airflow to compounding suite is recommended.
- HEPA filtered ceiling supply air grilles.
- Low wall returns/exhausts for buffer and anterooms.
  - Locate returns/exhaust near potential sources of contamination.
    - Printers, computers.
    - Refrigerators, freezers.
    - Scrub sinks.

## Ventilation Systems for the Pharmacy Compounding Clean Room Suite

- HEPA filtered ceiling supply air grilles.
  - Unidirectional downward airflow and minimal diffusion.
  - Gel seal around filter for air-tight seal.
  - Means for HEPA filter integrity/leak testing; aerosol injection ports/systems.
  - Recommend supply grilles with room-side replaceable filters.
  - Consider Fan Filter Units (FFUs) for retrofit applications.



Camfil Pharmaseal HEPA Ducted Ceiling Module



Camfil Pharmaseal FFU

## Exhaust Fan Systems for HDs

- Negative pressure ductwork in building.
  - Roof-mounted fans when possible.
  - Positive pressure ductwork allowed inside mechanical rooms only.
- Discharge exhaust vertically upward minimum 10 feet above roof.
- Locate discharge minimum 25 feet from intakes or openings into building.





## Miscellaneous Mechanical Design Considerations

- Air Change per Hour (ACH) requirements stated in USP are **minimums** and higher rates may be required.
- Emergency power critical or equipment branch for Primary (PEC) and Secondary (SEC) equipment.
- Redundancy considerations for mechanical equipment.
- Seismic restraints and equipment seismic certifications.
- Emergency eyewash locations.
- Deep scrub sink for washing to elbows with hands-free faucet.
- Concealed-type sprinkler heads in pharmacy areas.
- Interlocking anteroom and buffer room doors.
- Equipment locations for serviceability with minimal disruptions to pharmacy operations.
- Commissioning of ventilation systems before initial certification of PECs, hoods, and pharmacy compounding suite.

# Thank You

# Questions?

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