EVOLUTION OF FACILITY MANAGEMENT

MARCH 24-27, 2024 | HOUSTON, TEXAS

USP 797 & 800

Presentation for:
TAHFM – Evolution of Facility Management 2024

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THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center®

EAB
ENGINEERED AIR BALANCE

March 26, 2024

Session Overview

- FDA Section 503A
- Common Terms
- USP Chapters
- Certification Requirements
- Facilities & Design Requirements

United States Pharmacopeia (USP)

- The United States Pharmacopeia is an independent, scientific nonprofit organization
- USP was founded in 1820 by eleven physicians with the goal of protecting patients from poor-quality medicines
- USP is governed by three bodies: the USP Convention membership, the Board of Trustees, and the Council of Experts and its Expert Committees.
- Standards are produced by Expert Committees from around the world.

Source: https://www.usp.org/about

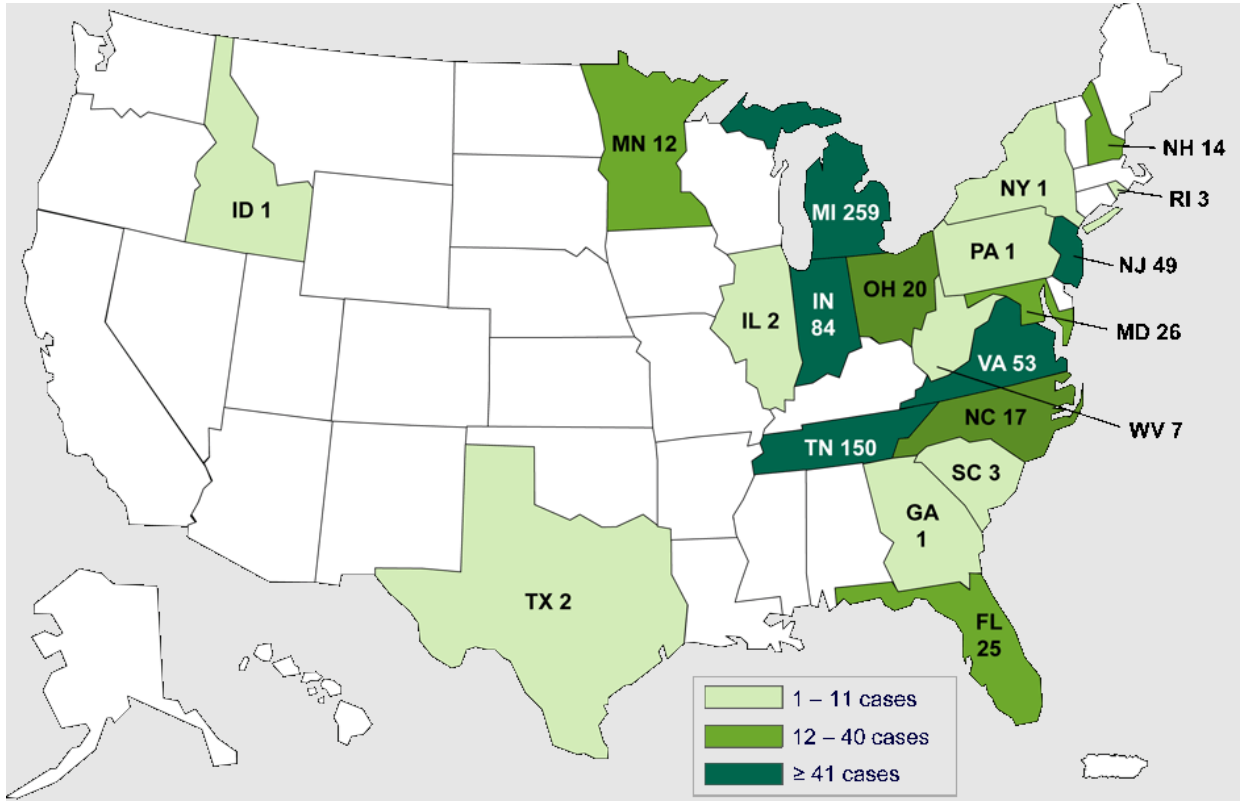
Food, Drug and Cosmetic Act (FDCA) Section 503A

- **What is a 503A Compounding Pharmacy?**
  - 503A compounding pharmacies are what you know as ‘traditional’ patient-focused compounding facilities in that they:
  - Fulfill individual patient-specific prescriptions approved by a prescribing practitioner.
  - Comply with state boards of pharmacy regulations.
  - **Produce compounds in compliance with United States Pharmacopeia (USP) chapters** or the National Formulary (NF) monograph. These compliance standards ensure patient safety and maintain drug quality and purity. For human sterile medications, these chapters are called USP <795> and <797>.

Source: https://newdrugloft.com/prescribers/503a-503b-compounding-pharmacies/

NECC Fungal Meningitis Outbreak

- 2012 New England Compounding Center (NECC) fungal meningitis outbreak due to contaminated steriod injections.
- Greater than 700 patients were diagnosed with a fungal infection after receiving injections of methylpredinisolone acetate (MPA) prepared by NECC across 20 states, many being fatal.
- Due to improper sterilization, failure to verify the sterilization process, and improper testing to ensure sterility.

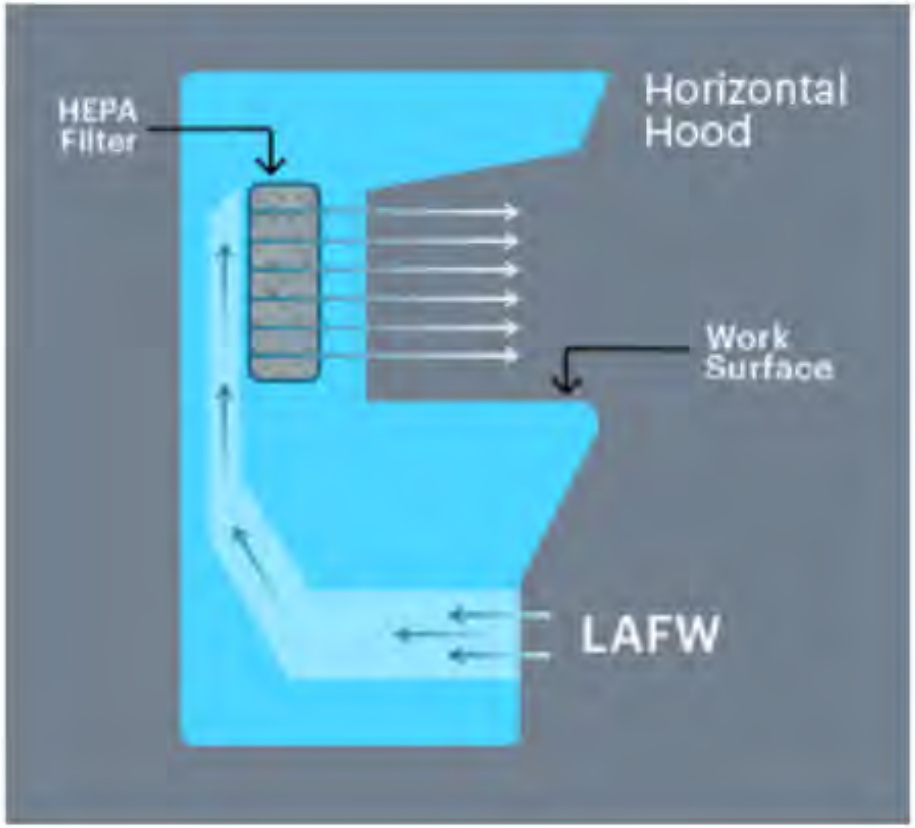


USP Common Terms

- **Primary engineering control (PEC):** A device or zone that provides an ISO Class 5 air quality environment for sterile compounding. These include BSCs, LAFWs, CACIs etc..
- **Secondary engineering control (SEC):** The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.
- **Buffer room:** An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
- **Compounded sterile preparation (CSP):**A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
- **Critical site:** A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.
- **Direct compounding area (DCA):**A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

Primary Engineering Controls (PECs)

- The unidirectional airflow within PECs must have sufficient velocity to sweep particles away from the DCA protecting the DCA from process-generated contamination
- Proper design, control, and use minimize turbulence and creation of eddies or stagnant air in the PEC
- PECs must be certified to meet ISO Class 5 or better conditions during compounding



Primary Engineering Controls (PECs)

Sources: https://www.nuaire.com/products/biosafety-cabinets
https://www.labconco.com/product/purifier-horizontal-clean-benches/45

USP Chapter Overviews

- **USP <795>:** Pharmaceutical Compounding – Non-Sterile Preparations
- **USP <797>:** Pharmaceutical Compounding – Sterile Preparations
- **USP <800>:** Hazardous Drugs – Handling in Healthcare Settings

USP <795> Pharmaceutical Compounding – Nonsterile Preparations

- **Section 4: Buildings and Facilities**

4.1 Compounding Area

- An **area** must be **designated for nonsterile compounding**. The method of designation must be described in the facility's SOPs. Other activities must not be occurring in the compounding area at the same time as compounding. The compounding area must be **well lit** and must be **maintained in a clean, orderly, sanitary condition** and in a **good state of repair**. There should not be carpet in the compounding area. The compounding area must provide for the orderly placement of equipment and materials to prevent mix-ups among components, containers, labels, in-process materials, and finished CNSPs. The **area** should be **designed, arranged, and used in a way that minimizes cross contamination** from non-compounding areas.

USP <795>

4.2 Storage Area

Compounding personnel must **monitor temperatures in the storage area(s)** either manually **at least once daily** on days that the facility is open, **or continuously with a temperature recording device** to ensure the temperature remains within the appropriate range for the CNSPs and components. The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable. All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer. The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s). When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised, and, if so, the CNSP or component must be discarded. All CNSPs, components, equipment, and containers must be stored off the floor in a manner that prevents contamination and permits inspection and cleaning of the storage area(s).

4.3 Water Sources

A **source of hot and cold water and an easily accessible sink must be available**. The sink must be emptied of all items unrelated to compounding and must be cleaned if visibly soiled before being used to clean any equipment used in nonsterile compounding. The plumbing system must be free of defects that may contribute to the contamination of any CNSP. *Purified Water* (see *Water for Pharmaceutical Purposes ⟨1231⟩, 3.1.1 Purified Water*), distilled water, or reverse osmosis water should be used for rinsing equipment and utensils.

USP <795>

Section 6: Equipment and Components

6.1 Equipment:

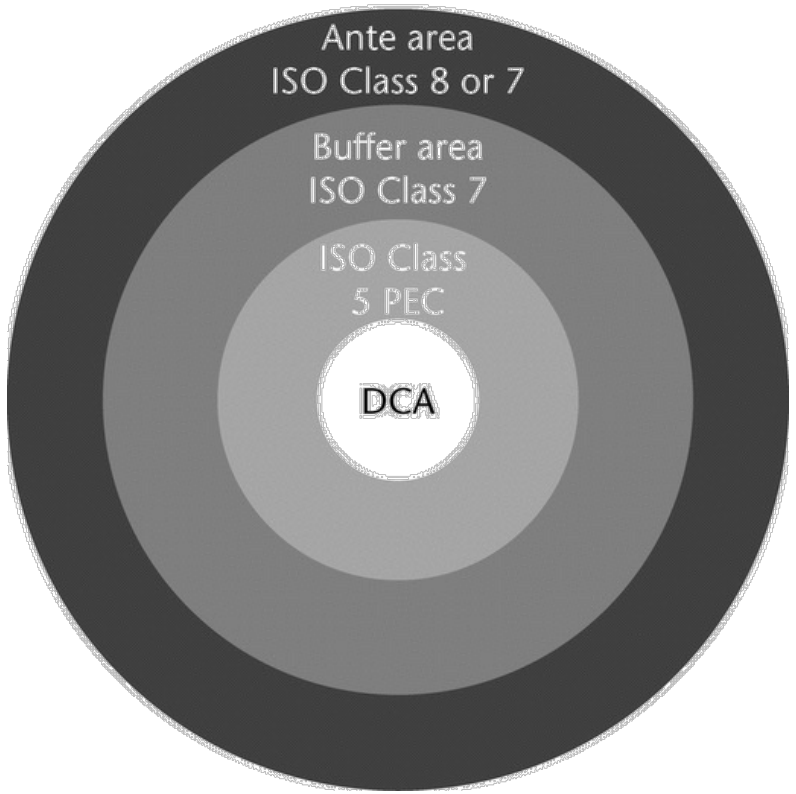
The equipment and components used for compounding a CNSP must be suitable for the specific compounding process. **Equipment surfaces that contact components must not be reactive, additive, or sorptive,** and must not alter the quality of the compounded non-sterile preparation (CNSP). Disposable or dedicated equipment may be used to reduce the chance of bioburden and cross contamination. Equipment must be stored in a manner that minimizes the risk of contamination and must be located to facilitate equipment use, maintenance, and cleaning. **Equipment** and devices used in the compounding or testing of compounded preparations must be **inspected** prior to use and, if appropriate, **verified for accuracy** as recommended by the manufacturer at the frequency recommended by the manufacturer or **at least every 12 months**, whichever is more frequent. After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation. Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of **closed-system processing devices** include **containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags**. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented. **If a CVE or BSC is used, it must be certified at least every 12 months** according to manufacturer specifications or other laws and regulations of the applicable regulatory jurisdiction.

USP <797> Pharmaceutical Compounding – Sterile Preparations

Section 4: Facilities & Engineering Controls

Sterile compounding facilities must be designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs. The required air quality must be achieved and maintained through PECs and secondary engineering controls (SECs). The anteroom, buffer room, and SCA must be separated from areas not directly related to compounding. The anteroom and buffer room must be appropriately controlled to achieve and maintain the required air quality classifications. The design of the facility should take into account the number of personnel and their movements, and the impact the placement of equipment, supplies, and components could have on the maintenance of air quality. The number of operations being performed, the equipment (e.g., PECs, carts, computers), the personnel in the compounding area (and in adjacent areas), and the complexity of the compounding procedures are critical considerations for maintaining control of environmental conditions in the facility.

Conceptual representation of USP Chapter <797> facility requirements



The Ultimate Goal of USP <797> Facility Design Requirements

- Patient safety
- To protect the critical sites at the direct compounding area (DCA)
- The air change rate , pressure, HEPA filtration, temperature, and humidity requirements are all in place to help prevent microbial growth and prevent product contamination like the fungal growth at NECC.

Source: https://www.labconco.com/news/48-hour-xpress-helps-pharmacy-compounding

USP <797>

- **Section 5. Certification and Re-Certification**
  - Before a compounding area is used to compound either Category 1, Category 2, or Category 3 CSPs, it must be independently certified using the requirements in this chapter and when applicable, manufacturer specifications. Certification indicates that the compounding area is meeting its design and air quality specifications. (see *Table 4*).

  - **Certification of the classified areas** including the PEC must be performed initially, and recertification must be performed at least **every 6 months** and must include:
    - ***Airflow testing:*** Airflow testing is performed to determine acceptability of the air velocity, the room air exchange rate, and the room pressure differential in doorways between adjacent rooms to ensure consistent airflow and that the appropriate quality of air is maintained under dynamic operating conditions. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report.
    - ***HEPA filter integrity testing:*** HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of recertification.
    - ***Total particle count testing:*** (See *5.1 Total Airborne Particle Sampling*.) Total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment.
    - ***Dynamic airflow smoke pattern test:*** Smoke pattern tests must be performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).

USP <797>

- **Section 4.1: Protection from Airborne Contaminants**
  Sterile compounding facilities must be designed to minimize the risk of airborne contamination of the area in which sterile compounding occurs. Proper design and controls are required to minimize the risk of exposure of CSPs to airborne contaminants.

- **Section 4.1.1: Air Quality Standards**

Table 4. ISO Classification of Particulate Matter in Room Air[a]

ISO Class	Particle Count per Cubic Meter[b]
3	35.2
4	352
5	3520
6	35,200
7	352,000
8	3,520,000

[a] Adapted from ISO 14644-1, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness by particle concentration.
[b] Limits for number of particles ≥0.5 µm measured under dynamic operating conditions.

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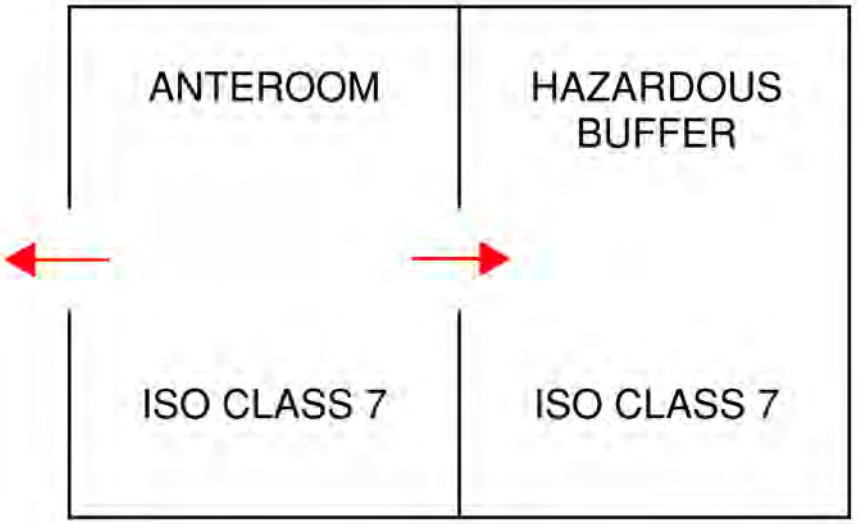
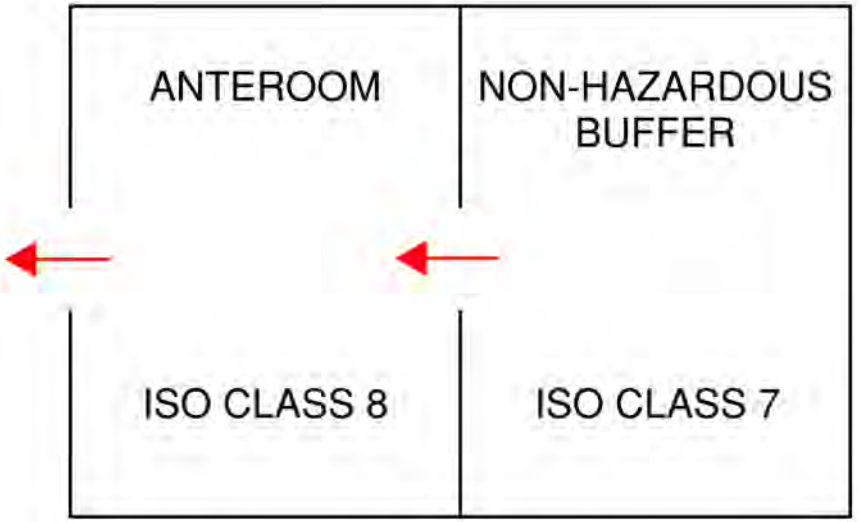
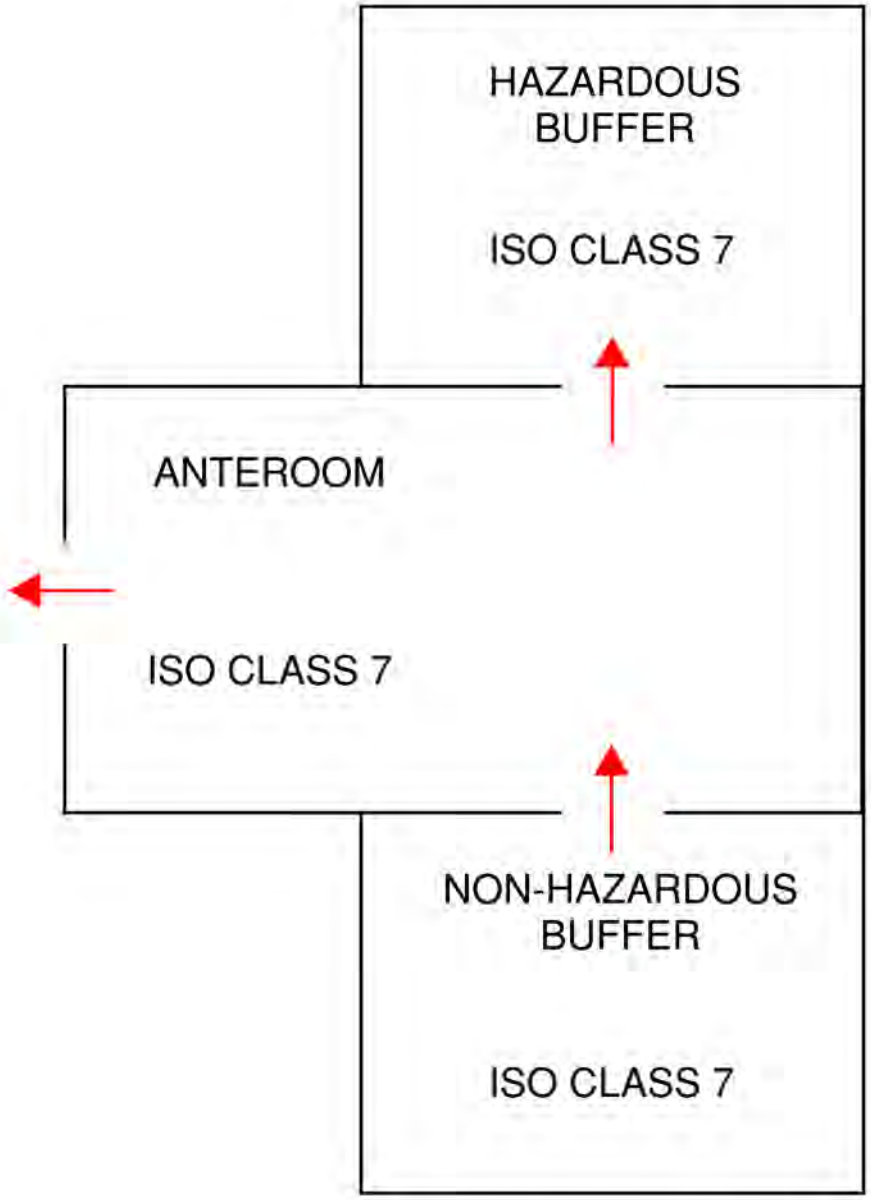
4.1.2 Design requirements to maintain air quality:

- Classified areas in which the air quality is controlled include anterooms, buffer rooms, and PECs.
- Anterooms providing access only to positive-pressure buffer rooms must meet at least ISO Class 8 classification.
- Anterooms providing access to negative-pressure buffer rooms must meet at least ISO Class 7 classification
- Buffer room must meet at least ISO Class 7 air quality. Activities in the buffer room must be controlled to minimize any effects on air quality in the area where CSPs are prepared.


ANTEROOM
HAZARDOUS BUFFER
ISO CLASS 7
ISO CLASS 7


ANTEROOM
NON-HAZARDOUS BUFFER
ISO CLASS 8
ISO CLASS 7


HAZARDOUS BUFFER
ISO CLASS 7
ANTEROOM
ISO CLASS 7
NON-HAZARDOUS BUFFER
ISO CLASS 7

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- **Section 4.2: Facility Design and Environmental Controls**
  - **Temperature and Humidity**

- The cleanroom suite should be maintained at a **temperature of 20°C (68 °F) or cooler** and a **relative humidity of 60% or less** to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb.

- Temperature and humidity must be monitored in each room of the cleanroom suite each day that compounding is performed.
  - Can be monitored manually or by a continuous recording device.
  - Must be documented at least once daily or stored in the continuous recording device and must be retrievable.
  - **Free-standing air conditioners, humidifiers, and dehumidifiers must not be used within the classified area or the SCA.**
  - Temperature and humidity monitoring devices must be verified for accuracy at least every 12 months or as required by the manufacturer.

Temperature and Humidity

- Redundancy and built-in additional capacity
- Types of supplemental systems: Dessicant dehumidification, glycol coil and DX coil.
- Dealing with existing systems

USP <797>

Section 4.2: Types of SECs and Design

Cleanroom Suite Continued:

- The **anteroom must have a line of demarcation** to separate the clean side from the dirty side. The anteroom is entered through the dirty side, and the clean side is the area closest to the buffer room. Alternatively, facilities may be designed with two separate anterooms—a dirty anteroom and a clean anteroom. The anteroom is entered through the dirty anteroom, and the clean anteroom is the area closest to the buffer room.
- Airlocks and interlocking doors may be used to facilitate better control of air balance between areas of differing ISO classification (e.g., between the buffer room and anteroom) or between a classified area and an unclassified area (e.g., between the anteroom and a hallway). If a pass-through chamber is used, both doors must never be opened at the same time, and doors should be interlocking. Due to the interdependence of the various rooms or areas that make up a sterile compounding facility, it is essential to carefully define and control the dynamic interactions permitted between areas and rooms. Consider the placement of door closures, door surfaces, and the movement of the doors, all of which can affect airflow.
- **Seals and sweeps should not be installed** at doors **between buffer rooms and anterooms**. Access doors should be hands-free.
- **Tacky mats must not be placed within ISO-classified areas**.
- If compounding both sterile and nonsterile preparations the respective PECs must be placed in separate rooms unless those PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification. If the PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 m apart, and particle-generating activity must not be performed when sterile compounding is in process.

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Section 4.2: Types of SECs and Design

Types of SECs and design:

- The PEC must be located in the buffer room of the cleanroom suite or the SCA in a manner that minimizes conditions that could increase the risk of microbial contamination. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open-faced PEC such as a laminar airflow workbench (LAFW).

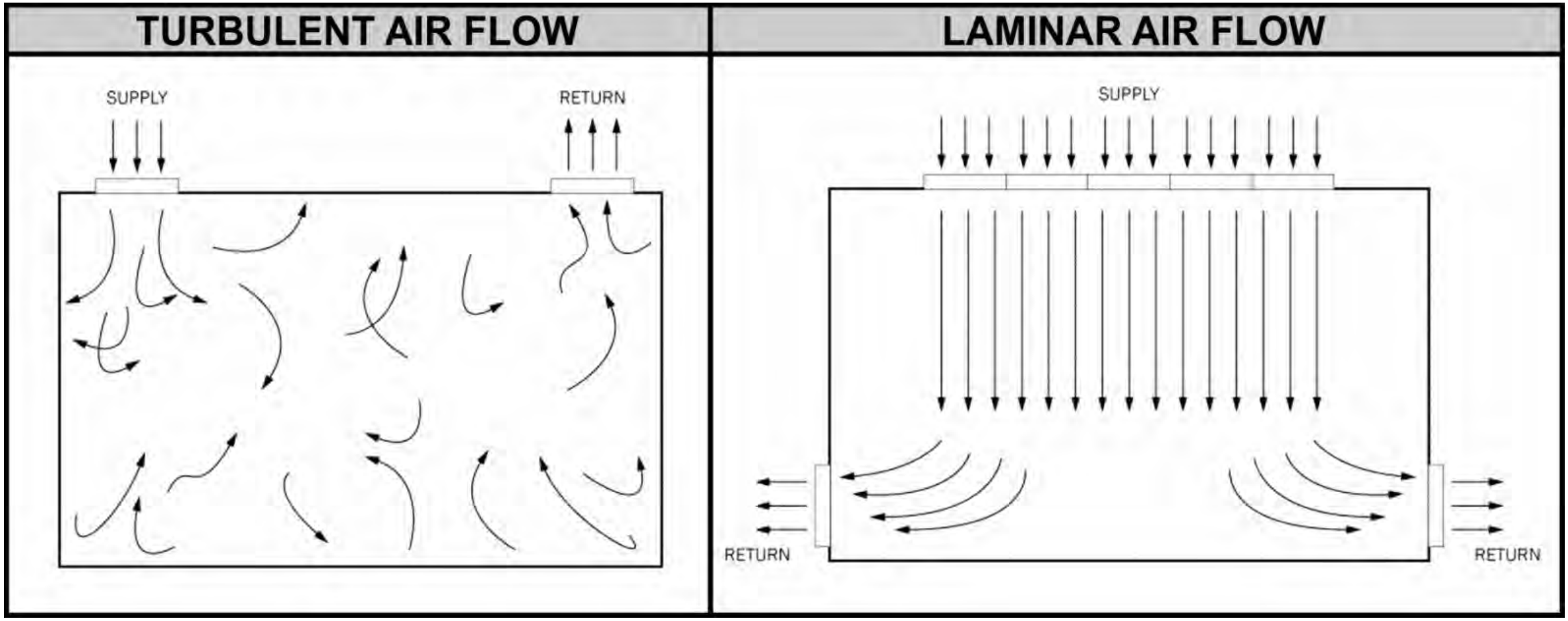
Cleanroom suite:

- The ISO-classified anteroom and buffer room must be separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls must be in place to minimize the flow of lower-quality air into the more controlled areas.

- The classified rooms must be equipped with a pressure-differential monitoring system. **Air supplied to** the **cleanroom** suite **must be introduced through HEPA filters that are located in the ceiling** of the buffer room and anteroom.

- Air **returns** in the cleanroom suite **must be low on the wall** unless a visual smoke study demonstrates an absence of stagnant airflow. This smoke study along with environmental monitoring must be repeated whenever a change is made to the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (e.g., HVAC alterations, change of HEPA filter units).

USP <797>



Source: https://www.climet.com/accessories/isoprobes.html

USP <797>

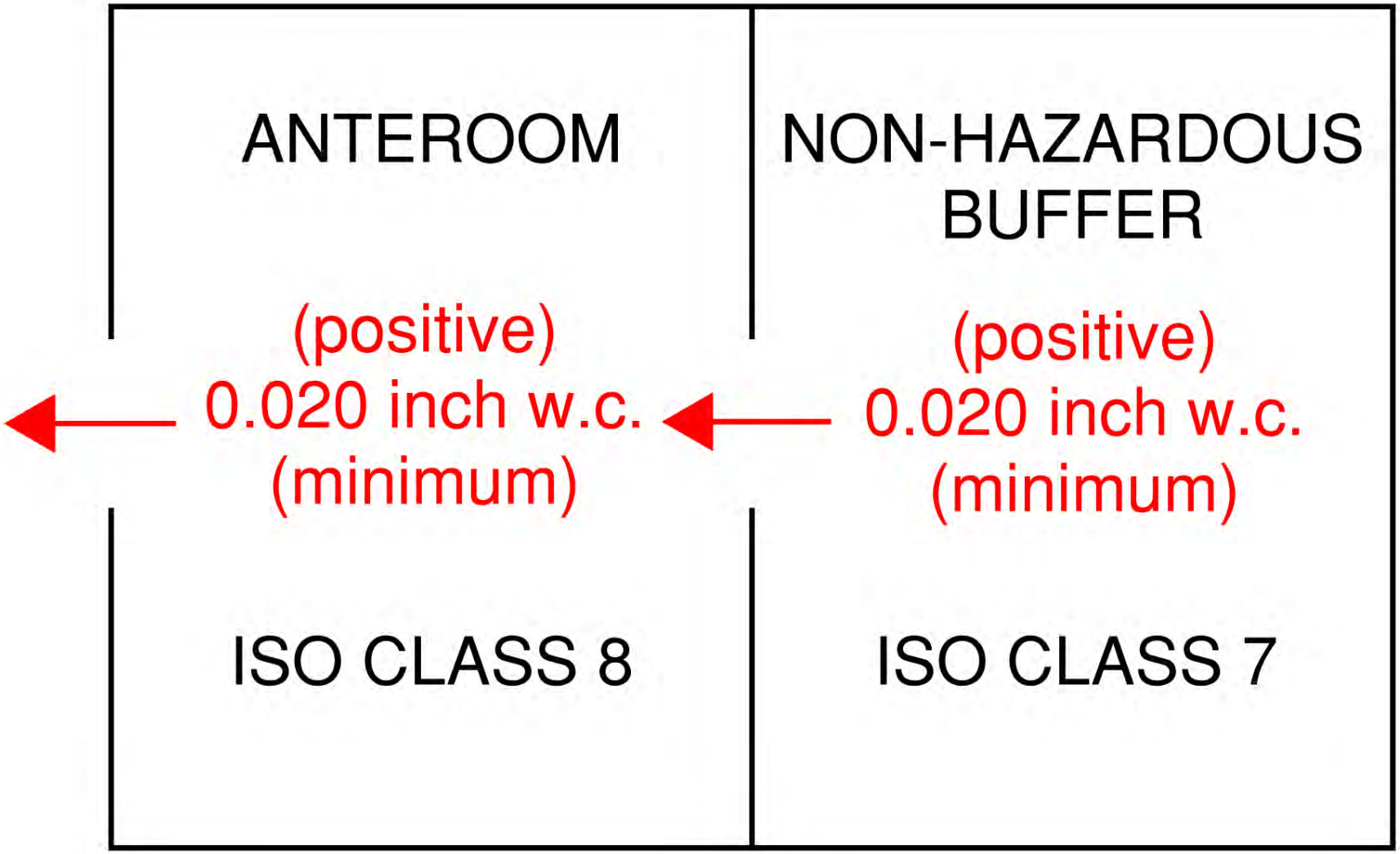
Tab Name	Tab Text
ISO Class 7 Rooms	A minimum of 30 total HEPA-filtered ACPH must be supplied to ISO Class 7 rooms: • The total HEPA-filtered air change rate must be adequate to maintain ISO Class 7 during dynamic operating conditions considering the factors listed above • At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling • The HEPA-filtered air from the PEC, when added to the HVAC-supplied HEPA-filtered air, increases the total HEPA-filtered ACPH to at least 30 ACPH • If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off except for maintenance • Rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 7 air quality under dynamic operating conditions • The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report
ISO Class 8 Rooms	A minimum of 20 total HEPA-filtered ACPH must be supplied to ISO Class 8 rooms: • The total HEPA-filtered air change rate must be adequate to maintain ISO Class 8 under dynamic operating conditions considering the factors listed above • At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling • Rooms where activity levels are high may require more HEPA-filtered ACPH to maintain ISO Class 8 air quality under dynamic operating conditions • The total ACPH must be documented on the certification report

USP <797>

Section 4.2.5: Establishing and Maintaining Pressure Differentials

Non-Hazardous

- In a cleanroom suite, a **minimum** differential **positive pressure** of **0.020 - inches of water column** is required between adjacent ISO-classified areas (e.g., **between** the **buffer room** and **anteroom**).
- The **pressure** differential **between** the **anteroom** and the **unclassified area** must **not** be **less than 0.020-inch water column**.
- Where pressure differentials are required, a pressure differential **monitoring device** must be **used to continuously monitor** the pressure differentials. The quantitative results from the pressure monitoring device must be reviewed and **documented at least daily** on the days when compounding is occurring.
- See USP <800> for differential pressure requirements for hazardous compounding.


ANTEROOM
NON-HAZARDOUS BUFFER
(positive)
0.020 inch w.c.
(minimum)
(positive)
0.020 inch w.c.
(minimum)
ISO CLASS 8
ISO CLASS 7

Plumbing Systems

Area	Location of Sink	Cleaning and Disinfecting Requirements	Additional Water Source Requirements
Segregated Compounding Areas			
Segregated Compounding Area	• Either inside or near the perimeter of the SCA • At least 1 meter away from the PEC	• Clean and disinfect each day of use • Apply sporicidal agent monthly	Sink should be hands free
Cleanroom Suites			
Outside of Anteroom	In a clean space	• Clean and disinfect each day of use • Apply sporicidal agent monthly	Sink should be hands free
Inside of Anteroom	Either clean side or dirty side	• Clean and disinfect each day of use • Apply sporicidal agent monthly for Category 1 and Category 2 or weekly for Category 3	• Sink should be hands free • No floor drains • If installed, sprinkler systems should be recessed and covered. Covers should be easily cleanable.
Buffer Room	Not permitted	Not applicable	• No plumbed water sources (e.g., sinks, showers, eyewashes) • No floor drains

*The order of hand washing and garbing will depend on the placement of the sink and must be described in the facility's standard operating procedures (SOPs).
*If compounding is not performed daily, cleaning and disinfecting of the sink must be completed before initiating compounding.

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Section 4.3: Creating Areas to Achieve Easily Cleanable Conditions

4.3.1 Cleanroom suite:

- The **surfaces** of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area must be **smooth, impervious, free from cracks and crevices, and non-shedding** so they can be cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.
- Surfaces should be resistant to damage (e.g., rust) by cleaning agents, sporicidal and other types of disinfectants, and tools used to clean.
- **Junctures between the ceiling and the walls and between the walls and the floor must be sealed to eliminate cracks and crevices where dirt can accumulate**.
- If **ceilings** consist of **inlaid** panels, the **panels must be caulked** around each panel to seal them to the support frame.
- Walls must be constructed of, or may be covered with, durable material (e.g., epoxy painted walls or heavy-gauge polymer) and the integrity of the surface must be maintained. Panels must be joined together and sealed to each other and the support structure.
- **Floors must include coving to the sidewall**, or the juncture between the floor and the wall must be caulked. Classified areas should minimize dust-collecting overhangs, such as utility pipes, and ledges, such as windowsills. If overhangs or ledges are present, they must be easily cleanable.
- **The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed**. Any other penetrations through the ceiling or walls must be sealed.

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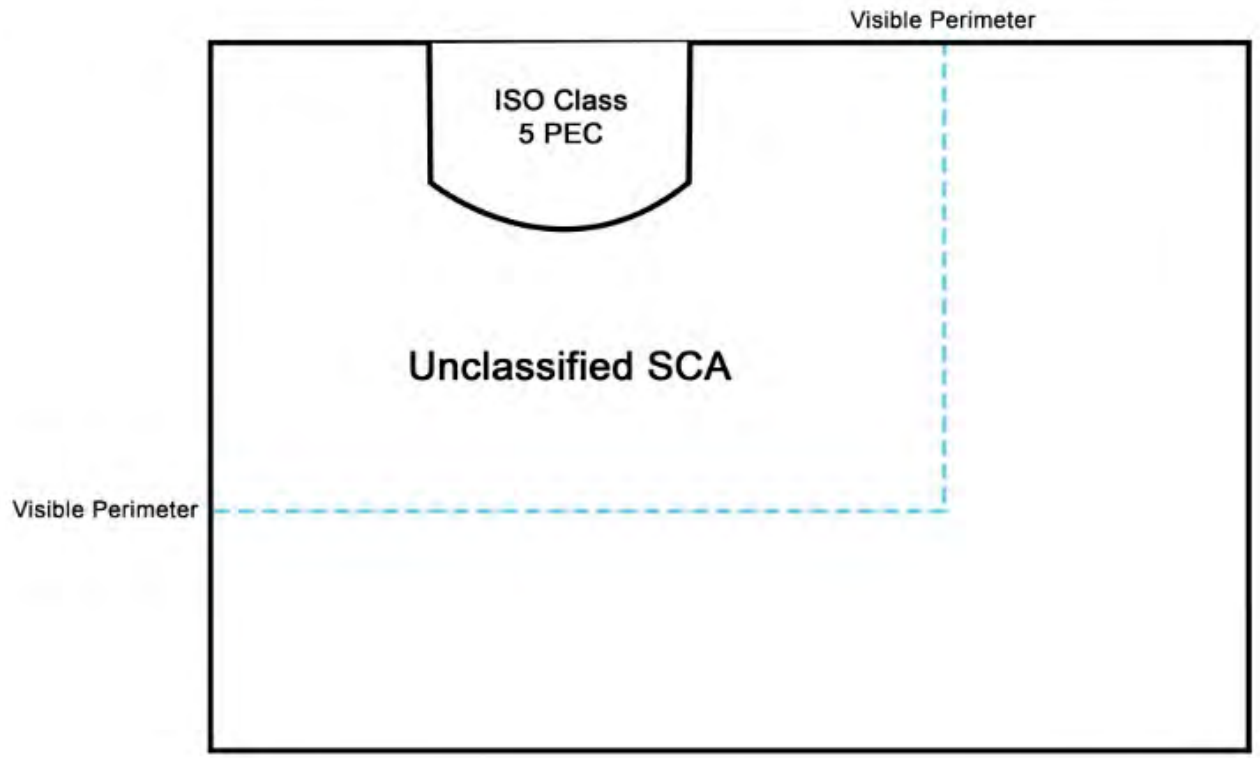
Segregated Compounding Areas (SCAs)

- An ISO Class 5 PEC in an unclassified area is known as an SCA
- Only Category 1 CSPs can be compounded in an SCA
- SCAs must be located away from areas and activities that may affect the air quality in the PEC
- A visible perimeter must establish the boundaries of the SCA



Goals of USP <800>

- To reduce risks associated with hazardous drugs (HDs)
- To protect healthcare workers and patients from accidental exposure to HDs

USP <800> Hazardous Drugs – Handling in Healthcare Settings

Section 5: Facilities & Engineering Controls

- HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. 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.

- Designated areas must be available for:
  - Receipt and unpacking
  - Storage of HDs
  - Nonsterile HD compounding (if performed by the entity)
  - Sterile HD compounding (if performed by the entity)

- 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.

USP <800>

Section 5.1: Receipt

- 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 must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.

Section 5.2 Storage

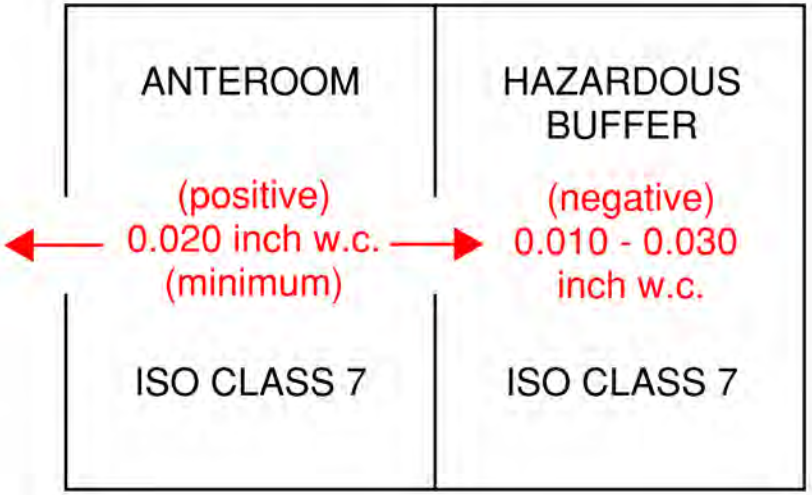
- HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.
- Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These **HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).** Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.
- 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** [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. **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.**

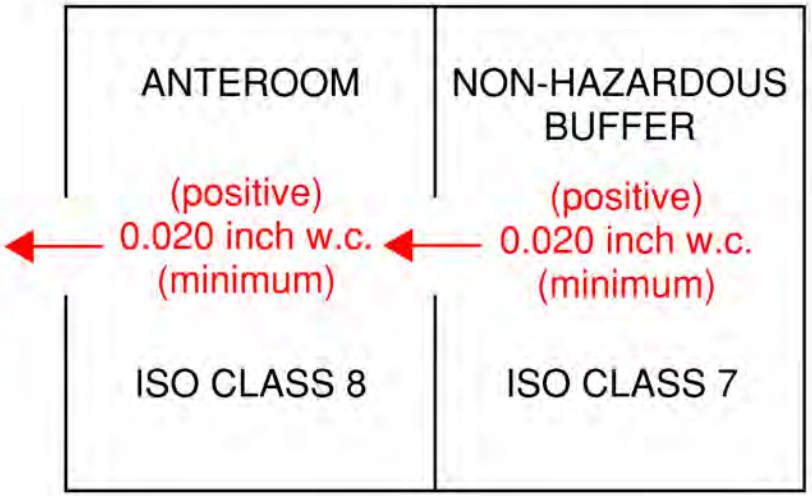
USP <800>

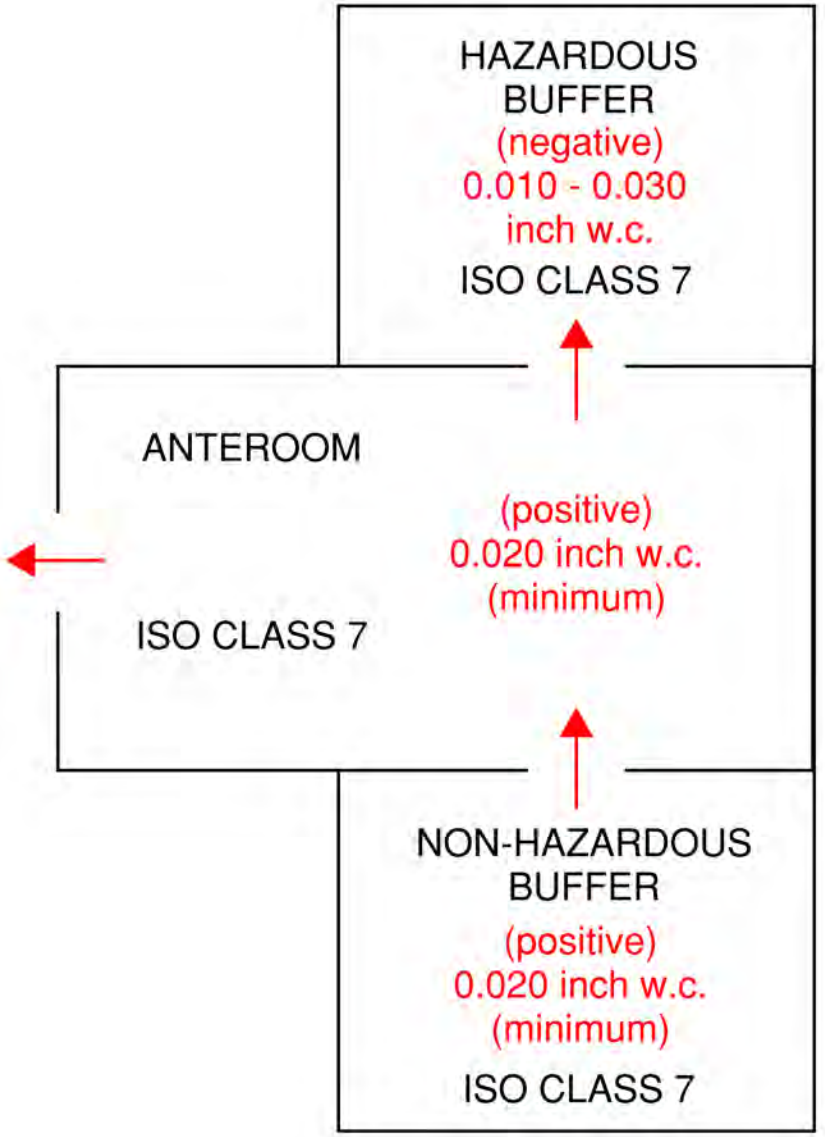
Section 5.3.2 Sterile HD Compounding

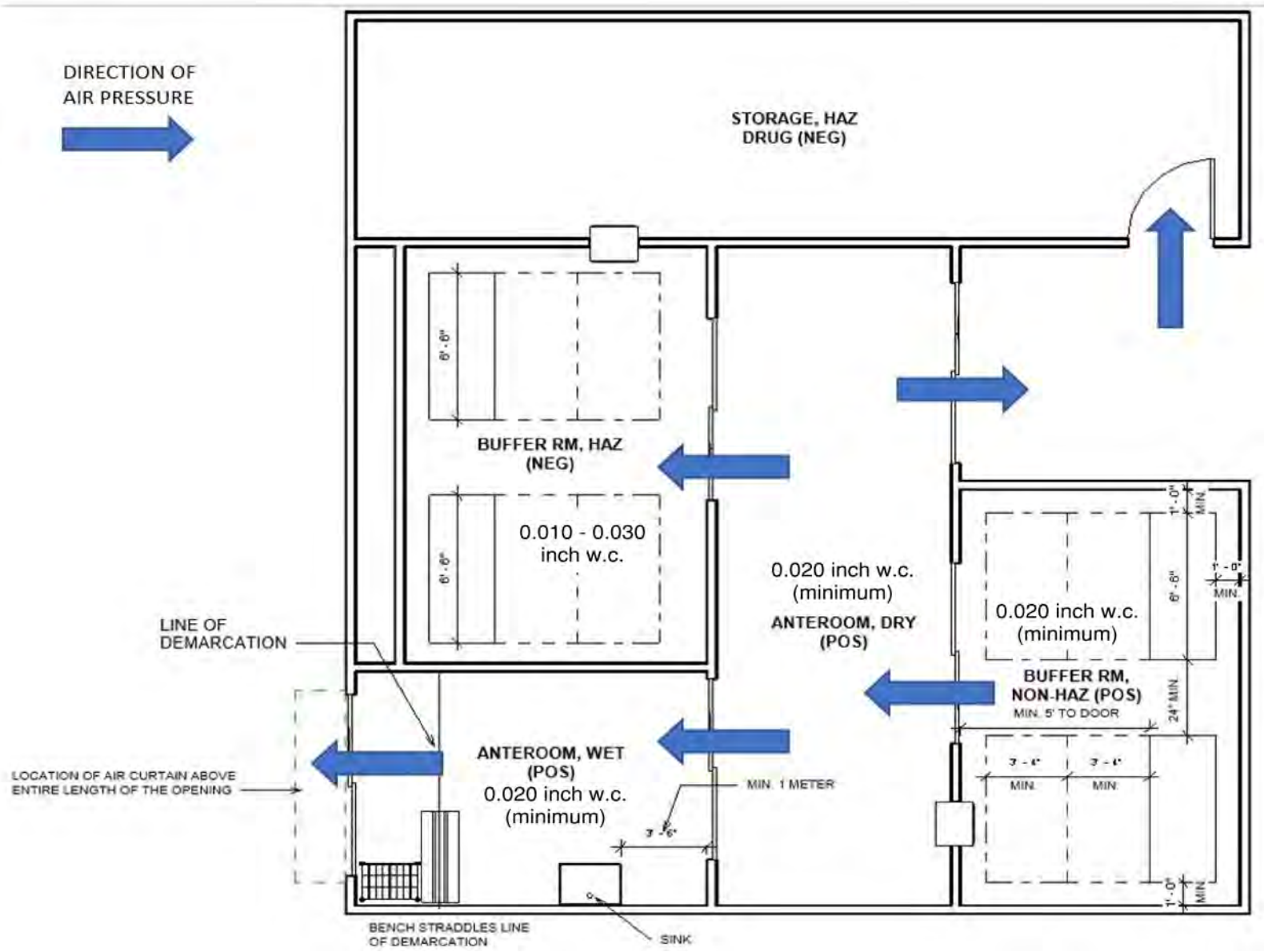
Table 3. Engineering Controls for Sterile HD Compounding

Configuration	C-PEC	C-SEC
ISO Class 7 buffer room with an ISO Class 7 ante-room	•Externally vented •Examples: Class II BSC or CACI	•Externally vented •30 ACPH •Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas
Unclassified C-SCA	•Externally vented •Examples: Class II BSC or CACI	•Externally vented •12 ACPH •Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas


ANTEROOM
HAZARDOUS BUFFER
(positive)
0.020 inch w.c.
(minimum)
(negative)
0.010 - 0.030
inch w.c.
ISO CLASS 7
ISO CLASS 7


ANTEROOM
NON-HAZARDOUS BUFFER
(positive)
0.020 inch w.c.
(minimum)
(positive)
0.020 inch w.c.
(minimum)
ISO CLASS 8
ISO CLASS 7


HAZARDOUS BUFFER
(negative)
0.010 - 0.030
inch w.c.
ISO CLASS 7
ANTEROOM
(positive)
0.020 inch w.c.
(minimum)
ISO CLASS 7
NON-HAZARDOUS BUFFER
(positive)
0.020 inch w.c.
(minimum)
ISO CLASS 7


DIRECTION OF AIR PRESSURE
STORAGE, HAZ DRUG (NEG)
BUFFER RM, HAZ (NEG)
0.010 - 0.030 inch w.c.
0.020 inch w.c. (minimum)
ANTEROOM, DRY (POS)
LINE OF DEMARCATION
0.020 inch w.c. (minimum)
BUFFER RM, NON-HAZ (POS)
MIN. 5' TO DOOR
LOCATION OF AIR CURTAIN ABOVE ENTIRE LENGTH OF THE OPENING
ANTEROOM, WET (POS)
0.020 inch w.c. (minimum)
MIN. 1 METER
BENCH STRADDLES LINE OF DEMARCATION
SINK

USP <800>

Section 5.3: Compounding

- **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.** 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.

- **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 . A **hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer** room to avoid contamination migration into the negative pressure HD buffer room.

“Life is like riding a bicycle. To keep your balance, you must keep moving.”

-Albert Einstein

Thank You for Your Time

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ENGINEERED AIR BALANCE