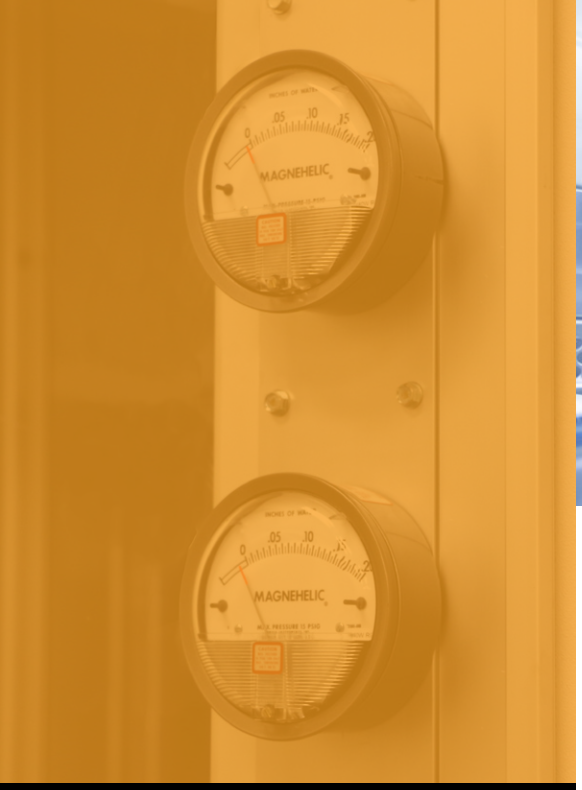

CONSIDERATIONS ON FACILITY AND ENGINEERING CONTROLS IN THE WAKE OF **USP <800>**

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An exploration of the challenges imposed by USP <800> Section 5: Facilities and Engineering Controls and potential considerations to overcome them.

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In February 2016, the US Pharmacopeial Convention (USP), a non-profit organization that sets health care activity standards enforceable by the Food and Drug Administration (FDA), adopted a new regulation to address concerns over the handling of hazardous drugs. The regulation, USP <800>, seeks to "identify the requirements for receipt, storage, compounding, dispensing, and administration of hazardous drugs (HDs) to protect the patient, healthcare personnel, and environment."

The USP <800> chapter builds on current compounding standards by incorporating information contained in USP <795> and USP <797>, adding the element of containment of hazardous drugs. The philosophy of the chapter is that there is no acceptable level of exposure to hazardous drugs and that exposure should be limited to the lowest possible level by using engineering controls and personal protective equipment.

USP <800> provides recommendations on the handling of hazardous drugs through various phases of the handling process, including receipt, unpacking, compounding, dispensing and administering. It includes both non-sterile and sterile products and preparations, and the standard applies to all personnel who compound these drug preparations and all places where they are prepared, stored, transported and administered.

It's clear that USP <800> is an important step in protecting healthcare workers and the environment. Since the chapter's publication in 2016, however, it has also become clear that achieving USP <800> compliance can be a formidable and expensive task for many healthcare institutions from a facility design and building infrastructure standpoint. Facilities currently designed to comply with USP <795> and USP <797>, for example, are most likely out of compliance with numerous facility requirements of USP <800>.

To further complicate matters, the December 1, 2019 enforceable deadline for USP <800> means there is little time for many of these facilities to make the necessary upgrades and modifications to their facilities to achieve USP <800> compliance.

This whitepaper serves to explore USP <800> Section 5: Facilities and Engineering Controls, the challenges imposed by this section on existing facilities and potential considerations on how to overcome them.

ACRONYM REFERENCE AND DEFINITION

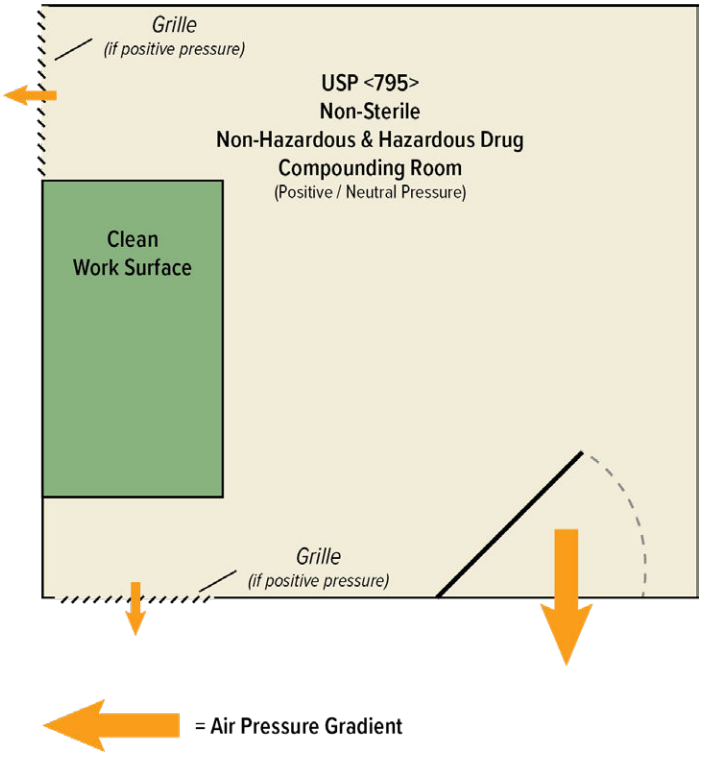
ACPH	Air Changes per Hour
BSC	Biological Safety Cabinet; a ventilated cabinet often used for the preparation of hazardous drugs. Note: there are different classes of BSCs.
CACI	Compounding Aseptic Containment Isolator; a specific type of CAI that is designed for the compounding of sterile hazardous drugs. Ventilated outside of the building.
C-PEC	Containment Primary Engineering Control; the device in which the compounding will occur (e.g. CACI, BSC, CVE).
C-SCA	Containment Segregated Compounding Area; a type of C-SEC, limited for use with a BSC when preparing low or medium risk compounded sterile products with a 12-hour or less beyond use date (BUD) or for preparing non-sterile hazardous drugs in a C-PEC.
C-SEC	Containment Secondary Engineering Control; the room in which the C-PEC is placed.
CVE	Containment Ventilated Enclosure; i.e. powder containment hood.
HD	Hazardous Drug
Ante-Room	The transitional room between the general area and the buffer room containing the C-PEC where particle-generating activities can take place (e.g. hand hygiene, garbing, staging of components, and order entry).
Buffer Room	A type of C-SEC where the C-PEC is located.
USP	United States Pharmacopeia; a non-profit organization that sets standards for various activities and areas of health care, which are enforceable by the Federal Drug Administration (FDA).

INTRODUCTION

USP <800> builds on the standards set forth in USP <795> "Pharmaceutical Compounding – Non-Sterile Preparations" and USP <797> "Pharmaceutical Compounding – Sterile Preparations," with an emphasis on protecting personnel through limiting hazardous drug exposure to as low a level as reasonably achievable.

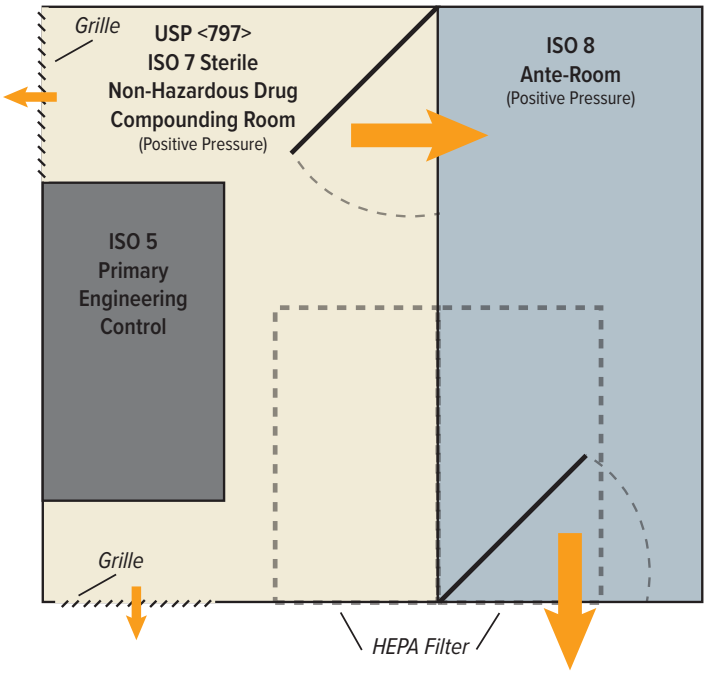
From a facility design standpoint, USP <795> does not mandate any specific requirements for non-sterile hazardous or non-hazardous drugs. The compounding space should be separated from sterile compounding areas and must be climate controlled (Figure 1). Prior to USP <800>'s publishing, non-sterile hazardous and non-hazardous drugs could be handled in a shared space under USP <795>.

Figure 1: USP <795>-Compliant Non-Sterile Non-Hazardous and Hazardous Drug Compounding Layout. Neutral or Positive pressure differential to adjacent areas.



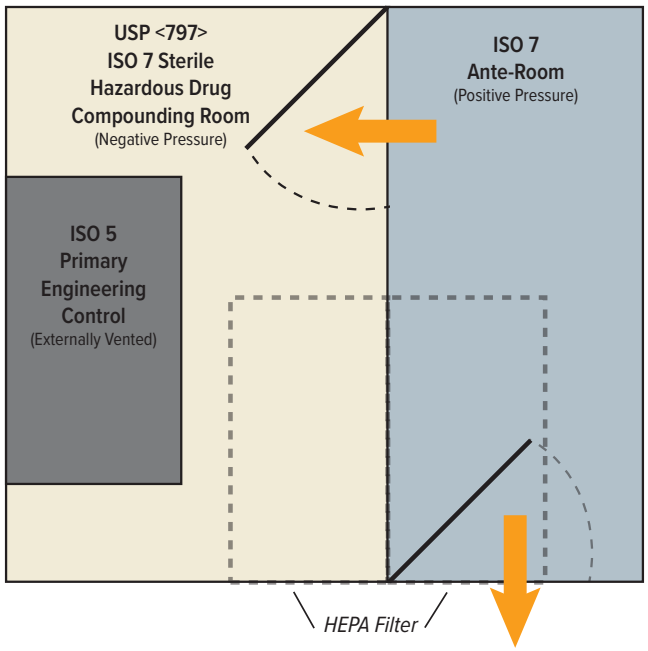
USP <797>, alternatively, has facility requirements for non-hazardous compounding aimed at creating positively pressurized ISO 5, 7 and 8 environments (Figure 2)—ISO 5 for Primary Engineering Controls, ISO 7 for buffer rooms and ISO 8 for ante-rooms.

Figure 2: USP <797>-Compliant Sterile Non-Hazardous Drug Compounding Layout. Min 30 ACPH, Min 0.02" water column positive pressure differential to adjacent areas.



Additionally, USP <797> provides facility requirements for the compounding of hazardous drugs (Figure 3). These requirements were the same as non-hazardous, with the exception that the Primary Engineering Control would be externally vented, the layout would include an ISO 7 buffer room and ISO 7 ante-room and the buffer room would maintain 0.01" of water column relative to the adjacent area. USP <797> also dictated that hazardous drug compounding should be separated from non-hazardous drug compounding. USP <800> clarifies and expands upon the hazardous drug guidelines found in USP <797>.

Figure 3: USP <797>-Compliant Sterile Hazardous Drug Compounding Layout. Min 30 ACPH, Min 0.02" water column negative pressure differential to adjacent areas.



USP <800>

The key directives of USP <800> Section 5: Facilities and Engineering Controls, are to ensure the handling of hazardous drugs is considered in a way that promotes the safety for all employees, patients and the surrounding environment. Access to hazardous drug handling spaces must be restricted to authorized personnel and signs designating the hazard must be prominently displayed before the entrance to the hazardous drug space.

Clear separation should be provided for the following operations:

- Receipt and unpacking of hazardous drugs
- Storage of hazardous drugs
- Non-sterile hazardous drug compounding (if performed)
- Sterile hazardous drug compounding (if performed)

RECEIPT AND UNPACKING OF HAZARDOUS DRUGS

Hazardous drugs should not be unpacked or removed from external shipping containers in any area that is positively pressurized relative to the surrounding area. USP <800> advises that the receipt and unpacking of hazardous drugs are to take place in an area that is neutral / normal or in an area that is negatively pressurized relative to the surrounding area. However, in accordance with USP <800> this negative pressure area cannot be where sterile compounding takes place to prevent contamination of the sterile environment.

Impact on existing facilities: Facilities currently designed to comply with USP <795> and USP <797> that are also handling hazardous drugs, would more than likely be unpacking hazardous drugs within a positive pressurize ante room or just outside the ante room in a neutral or negative pressure space.

Since there is no mandated pressure differential or air change rate requirement, unpacking hazardous drugs in a facility space that is designed with neutral or negative pressurization is allowable per USP <800> and would not require any change in procedure or to the environment.

If the facility is currently unpacking hazardous drugs within a positive pressure ante room or facility space that is positively pressurized, then some modifications will be required to meet USP <800> unpacking area requirements.

Potential modifications include:

- Designating an existing neutral room or space within the facility for the unpacking of hazardous drugs.
- Constructing a modular enclosure to accommodate for the unpacking of hazardous drugs.
- Utilizing space in a negatively pressurized storage room.

STORAGE OF HAZARDOUS DRUGS

USP <800> mandates a clear space separation for the storage of hazardous drugs and non-hazardous drugs. An exception is made for hazardous drugs that already exist in their final unit dose or unit-of-use packaging, which may be stored alongside non-hazardous drugs if they are labeled as hazardous in nature.

Hazardous drugs that are separated from other drug inventory should be stored at or below level (but never on the floor) in a negatively pressurized room that is externally ventilated and has a minimum of 12 air changes per hour. Stowage should be in a manner that prevents spillage in the event the container falls and breaks.

While there is no mandated separation between the storage of sterile hazardous drugs and non-sterile hazardous drugs, hazardous drug storage within a sterile compounding area is limited to sterile hazardous drugs only.

Refrigerated hazardous drugs require storage in their own dedicated refrigerator that must be in a negatively pressurized area, which may be the hazardous drug storage room, buffer room or other segregated area. If located in the negative pressure buffer room, the placement of an exhaust next to the compressor should be considered to meet the external ventilation requirement.

Impact on existing facilities: Facilities currently in compliance with USP <795> and USP <797> are most likely storing hazardous and non-hazardous inventory in a shared, positive-pressure environment. The necessary separation between hazardous and non-hazardous drug storage will require facilities to evaluate their current storage conditions and overall facility square footage.

A non-sterile hazardous drug buffer room is the ideal place to store both sterile and non-sterile hazardous drugs. These rooms meet the requirement for external ventilation, negative pressure and at least 12 ACPH. However, if square footage within the buffer room is limited, then separate spaces will need to be either converted or constructed to meet the hazardous drug store requirements.

Potential modifications include:

- Converting an existing room into a negative pressure, externally vented storage area for hazardous drugs.
- Building a new, USP <800>-compliant room to accommodate the storage of hazardous drugs.

NON-STERILE / STERILE HAZARDOUS DRUG COMPOUNDING

USP <800> outlines three types of containment engineering controls that should be present when compounding hazardous drugs: primary, secondary and supplemental. A containment primary engineering control (C-PEC) is the hood or work surface in which hazardous drugs are manipulated, a containment secondary engineering control (C-SEC) is the room in which the C-PEC is located and the supplemental engineering control refers to items such as closed-system drug-transfer devices (STDs).

As with the separation of hazardous drug receipt, unpacking and storage, USP <800> also requires hazardous drug preparation areas to be separated from non-hazardous drug preparation areas. All hazardous drugs must be compounded within a C-PEC located in a C-SEC that is physically separated from other rooms, externally vented and negatively pressurized to maintain 0.01 and 0.03 inches of water column. The C-SEC must also have a minimum of 12 air changes per hour.

For facilities that process both non-sterile hazardous and sterile hazardous drugs, the regulation allows the C-PECs to be located in the same C-SEC room if the devices are at least 1 meter apart, the C-SEC is able to maintain the ISO 7 classification throughout non-sterile compounding operations and no particle-generative activity is performed during sterile compounding activities.

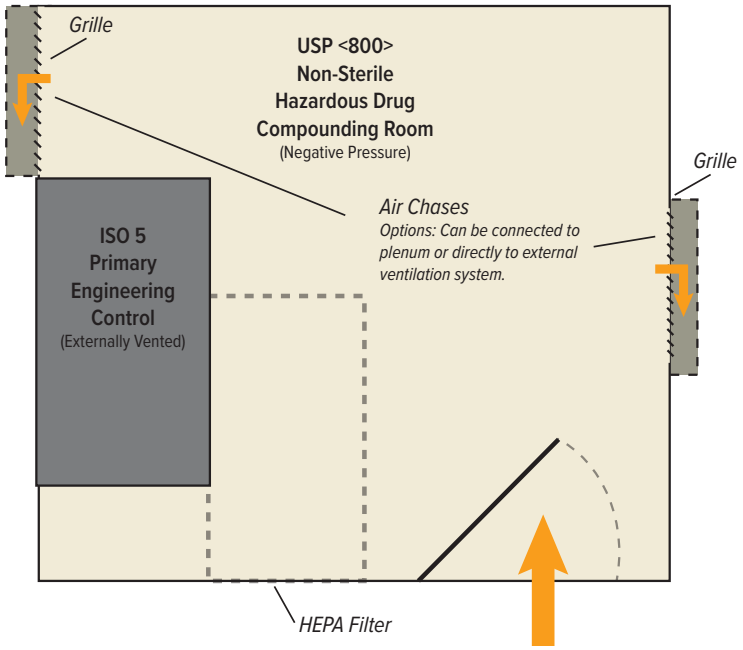
If these specifications cannot be met, non-sterile hazardous and sterile hazardous drug compounding should be confined to separate C-SECs.

Engineering controls for non-sterile hazardous drug compounding: A C-PEC for the manipulation of non-sterile hazardous drugs is required for any compounding activity that generates aerosols, gases or particles. This C-PEC must be either externally vented or use redundant HEPA filtration in series.

The C-PEC used for preparation of non-sterile hazardous drugs must provide personnel and environmental protection. Appropriate devices include a Class I Biological Safety Cabinet (BSC) or a Containment Ventilated Enclosure (CVE), more commonly referred to as a powder hood. A Class II BSC or Compounding Aseptic Containment Isolator (CACI) may also be used for non-sterile hazardous drug compounding if dedicated only to non-sterile hazardous drug compounding.

There is no mandated air classification requirement for the C-SEC in which the C-PEC is located. However, the room must meet the requirements of a USP <800>-compliant C-SEC, such as segregation from other areas, appropriate air changes per hour and maintenance at negative pressure. (Figure 4 and Table 1). In addition, the surfaces within the C-SEC are required to comply with recommendations listed in USP <797>. This includes smooth, seamless and impervious architectural finishes.

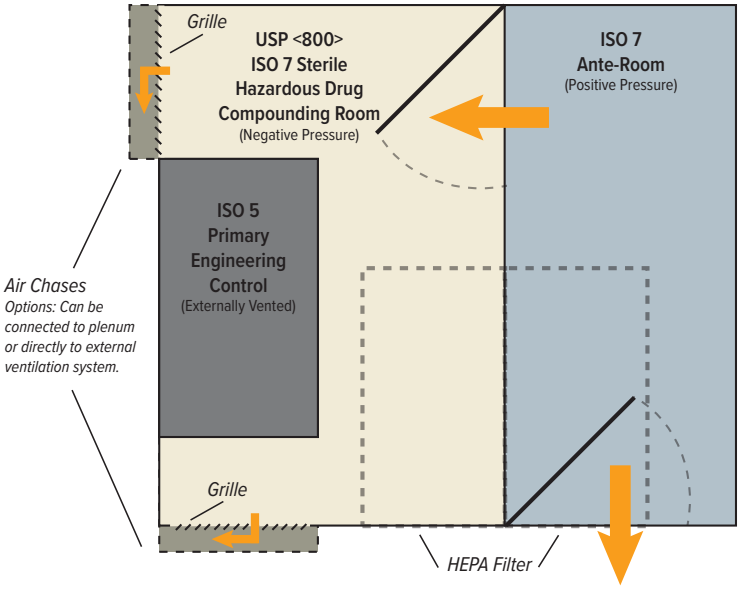
Figure 4: USP <800>-Compliant Non-Sterile Hazardous Drug Compounding Layout. Min 12 ACPH. Between 0.01" and 0.03" water column negative to adjacent areas. Externally vented.



Engineering controls for sterile hazardous drug compounding: As with non-sterile hazardous drug compounding, the C-PEC used for sterile hazardous drug manipulation must be externally vented, but must also meet ISO 5 air. Appropriate devices include a Class II BSC or CACI.

The preferred placement of a C-PEC used for sterile hazardous drug compounding is in an ISO 7 classification buffer room maintained at a minimum of 30 ACPH of HEPA filtered air and a negative pressurization of 0.01" – 0.03" water column with respect to adjacent areas. The ante-room through which the buffer room is entered must be positively pressurized with a minimum of 0.02" of water column, contain a minimum of 30 ACPH of HEPA filtered air and meet ISO 7 air classification. A hand-washing sink must be available and should be placed in the ante-room at least 1 meter from the entrance to the buffer room (Figure 5).

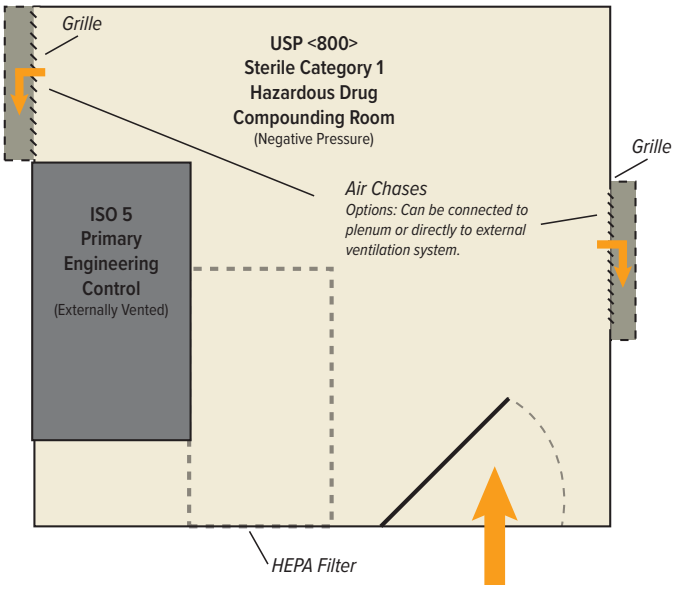
Figure 5: USP <800>-Compliant Sterile HD Compounding Layout. Buffer Room: Min 30 ACPH, Between 0.01" and 0.03" water column negative to adjacent areas. Externally vented. Ante-Room: Min 30 ACPH, positive pressure with respect to Buffer Room.



Recognizing that an ISO 7 environment may not always be available—especially in a healthcare facility with limited space or a smaller institution without a dedicated cleanroom—USP <800> alternatively allows the C-PEC used for Category 1 sterile hazardous drug compounding to be placed in a Containment Segregated Compounding Area (C-SCA), provided the beyond use date does not exceed those denoted in USP <797>.

While there is no mandated air quality classification, the C-SCA will still need to meet all requirements for a USP <800>-compliant C-SEC, such as segregation from other areas, appropriate air changes per hour and maintenance at negative pressure (Figure 6 and Table 1). It is important to note that this directive differs from a previous recommendation published in USP <797> allowing facilities that compound a small volume of hazardous drugs to have a BSC or CACI for hazardous drug compounding in a non-negative pressure room. USP <800> eliminates this previous allowance for low-volume hazardous drug compounding (referred to as the "low-volume exception"), clearly requiring that all hazardous drug compounding is to take place in a negative pressure room, regardless of the type of C-SEC.

Figure 6: USP <800>-Compliant Category 1 Sterile HD Compounding Layout. Min 12 ACPH, Between 0.01" and 0.03" water column negative to adjacent areas. Externally vented. Ante-Room: Min 30 ACPH, positive pressure with respect to Buffer Room.



Impact on existing facilities: Depending on the facility's compounding activities, separate spaces for hazardous drug compounding will need to be configured. Modifications required to achieve compliance with USP <800> will vary greatly from building to building; however, facilities that handle sterile hazardous drugs, non-sterile hazardous drugs, non-hazardous sterile drugs and non-hazardous non-sterile drugs will be the most impacted since separate activity spaces—each with unique pressurization differentials, ACPH and ISO classification requirements—will be required.

In addition to the equipment needed to achieve the correct pressurization differentials, ACPH and ISO classification requirements (i.e. HEPA filters, temperature / humidity gauges) for each space, facilities will also need to furnish the new C-SECs with the appropriate primary engineering controls (BSCs, CACIs and CVEs) used exclusively for hazardous drug compounding.

Collaboration between building design professionals, general contractors and the healthcare facility staff are essential to determine the appropriate solution.

Figure 7 demonstrates the layout of a healthcare facility that handles both hazardous and non-hazardous sterile drugs. This layout is both USP <797> and USP <800>-compliant.

Figure 7: USP <797>-Compliant Sterile Non-HD to <USP> 800 Sterile HD Compounding Layout. HD Buffer Room: Min 30 ACPH, Between 0.01" and 0.03" water column negative to adjacent areas. Externally vented. Ante-Room: Min 30 ACPH, positive pressure with respect to HD Buffer Room. Non-HD Buffer Room: Positive Pressure.

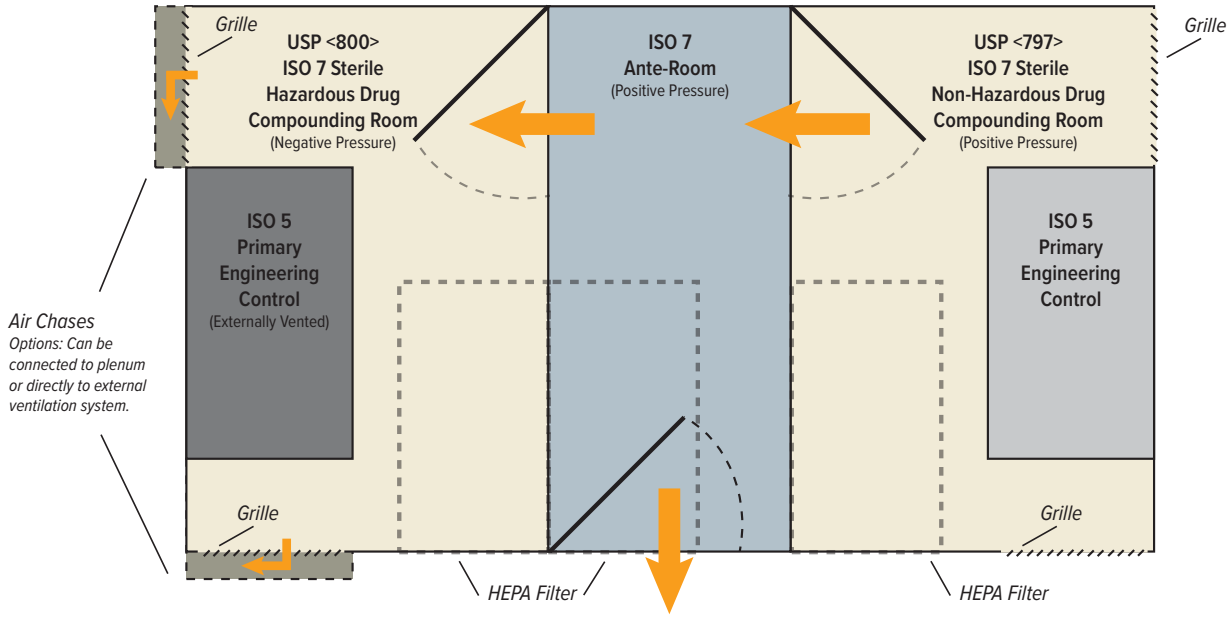


Figure 8 demonstrates the layout of a healthcare facility that handles hazardous and non-hazardous sterile and non-sterile drugs. This layout uses a 3 ante-room configuration to properly contain contaminants during the transition from non-hazardous to hazardous compounding. This layout is USP <795>, USP <797> and USP <800>-compliant.

Figure 8: USP <795>, USP <797> and USP <800>-Compliant Sterile/Non-Sterile Non-HD/HD Compounding Layout.

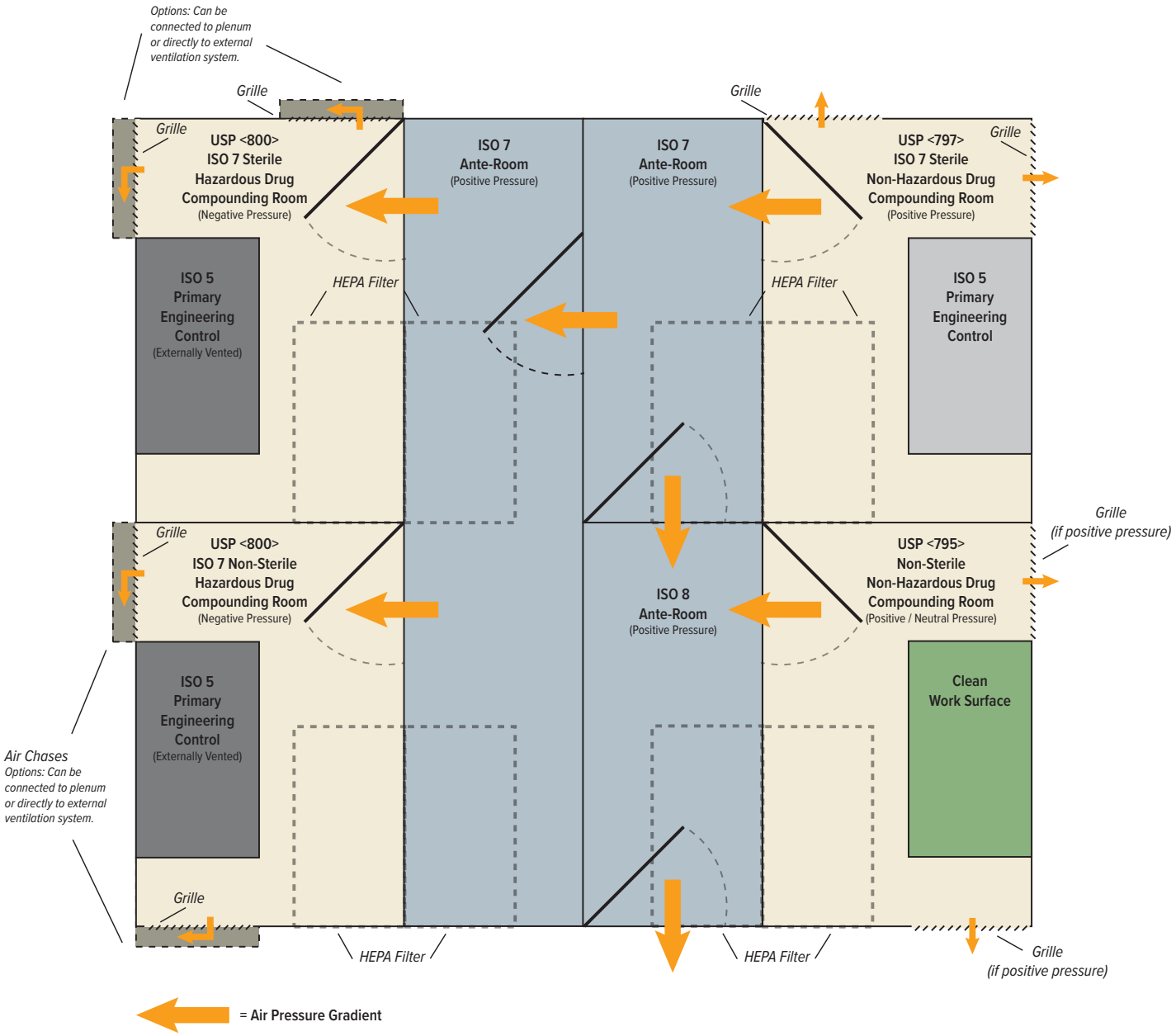


Table 1: Consolidated Engineering Controls for Hazardous Drug Operations

	HD Receipt / Unpacking	HD Storage	Non-Sterile HD Compounding	Sterile HD Compounding		
				Ante-Room	Buffer Room	C-SCA *(Category 1 Risk)*
C-SEC OR ROOM REQUIREMENTS						
ACPH	No Requirement	Min 12	Min 12	Min 30	Min 30	Min 12
External Ventilation	Not Required	Required	Required	Not Required	Required	Required
Room Pressure	Neutral / Negative with respect to adjacent areas	Negative with respect to adjacent areas	Negative with respect to adjacent areas *(0.01 – 0.03" water column)*	Positive with respect to Buffer	Negative with respect to adjacent areas *(0.01 – 0.03" water column)*	Negative with respect to adjacent areas *(0.01 – 0.03" water column)*
ISO Classification	No Requirement	No Requirement	No Requirement	ISO 7	ISO 7	No Requirement
Sink Placement	Not Allowed	Not Allowed	Min. 1 meter from C-PEC or directly outside C-SEC	Min. 1 meter from Buffer Room entrance	Not Allowed	Min. 1 meter from C-PEC or directly outside C-SEC
Surfaces	Smooth, Seamless, Impervious	Smooth, Seamless, Impervious	USP <797>-Compliant *(Smooth, Seamless, Impervious)*	USP <797>-Compliant *(Smooth, Seamless, Impervious)*	USP <797>-Compliant *(Smooth, Seamless, Impervious)*	Smooth, Seamless, Impervious
C-PEC REQUIREMENTS						
Class I BSC / CVE	Not Allowed	Not Allowed	Externally Vented or Redundant HEPA Filtration in Series	Not Allowed	Not Allowed	Not Allowed
Class II BSC	Not Allowed	Not Allowed	Externally Vented or Redundant HEPA Filtration in Series	Not Allowed	Externally Vented	Externally Vented
CACI	Not Allowed	Not Allowed	Externally Vented or Redundant HEPA Filtration in Series	Not Allowed	Externally Vented	Externally Vented

MODULAR C-SECS / ROOMS VERSUS TRADITIONAL STICK-BUILT

When building a new room or converting an existing space into a USP <800>-compliant C-SEC or room, healthcare institutions can consider either modular or traditional stick-built construction. Modular enclosures are pre-fabricated and built off-site. These cleanrooms offer a quality finish, professional look and can be custom built to meet the needs of the application. Modular cleanrooms can be integrated into current architecture and mechanical systems.

Stick-built construction consists of modifying the current facility architecture (e.g. fixed walls, doors, flooring) with a construction manager and subcontractors. This approach offers the flexibility of choosing the building materials like flooring and cabinetry. Depending on the square footage available, anticipation of growth in the future and overall desired look, the healthcare institution can determine which application is the best fit.

Table 2: Advantages and Disadvantages of Modular and Stick-Built Cleanrooms

	Modular Cleanroom	Stick-Built Construction
Affordability	More affordable than traditional stick-built. Modular cleanrooms can be considered capital equipment rather than capital improvements; therefore, can be depreciated at an accelerated rate. This results in tax savings.	Being complicated construction projects, these rooms require permits and renovating the entire building structure, which can bring a high cost and extended depreciation periods.
Compliance	Many cleanroom manufacturers guarantee to pass certification.	Local contractors generally don't understand USP compliance and will not offer any certification guarantees. This could potentially cost more in the long term if the C-SEC(s) don't pass as expected.
Scalability	Can be easily expanded or reconfigured.	Facilities with already limited space lose additional flexibility for growth. Scalability is limited and varies on available square footage.
Installation Time	Manufactured off-site, shipped and then installed on-site. Typically completed 30% - 50% faster than conventional construction.	Time frame varies, but generally take longer to complete due to material lead times and subcontractor scheduling.
Relocatability	Can be disassembled and moved in its entirety.	Designed and constructed to be immovable.

FACILITY INFRASTRUCTURE CHALLENGES

Facility infrastructure and mechanical modifications can be equally as challenging as the necessary space reconfigurations needed to achieve USP <800> compliance. Since USP <800> has differing air pressurization requirements than those imposed by the USP <795> and USP <797> chapters, healthcare facilities will need to examine current air handling systems. These systems generally include:

- Air Conditioning Unit(s) – exterior mounted system that supplies conditioned air.
- Duct System – the collection of conduit passages that distribute air from the air conditioning unit to the room, or from the room to the exhaust fan.
- HEPA Fan Filter Unit(s) – A positive pressure fan that receives air from the external mounted air handling / air conditioning unit and pushes the air through a HEPA filter directly into the room.
- Differential Pressure Gauge(s) – a visual indicator, designed to measure and display the difference between two pressure points.
- Temperature / Humidity Gauge(s) – a visual indicator, designed to measure and display the temperature and moisture level within a space.
- Exhaust Fan(s) – a fan that moves air out of an enclosure.

Though modifications can vary from minimal equipment upgrades to routing new ductwork to create dedicated exhaust systems, some level of facility modification will most likely be needed for facilities that handle hazardous drugs in their compounding activities to be USP <800>-compliant.

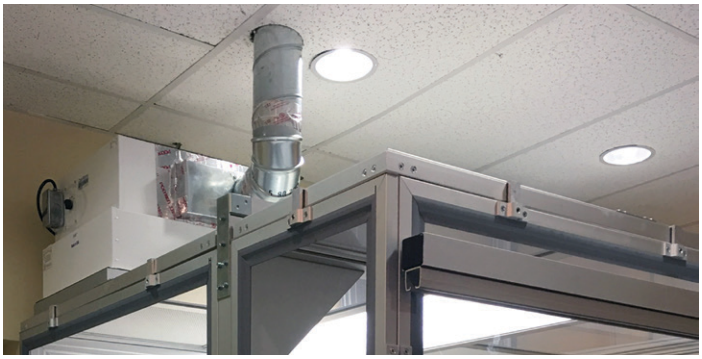
External Ventilation: Notably, one of the most daunting challenges is the overhaul of current air handling systems to achieve the negative pressurization requirement mandated by the chapter. Hazardous drug C-SECs must maintain a negative pressure between .01 and .03 inches of water column relative to adjacent areas. This means that there must be less air supplied to the C-SEC than the air that is exhausted, which will create a low-pressure vacuum from the adjoining room.

Facilities currently designed for non-hazardous drugs may have limited or no exhaust systems serving the space and therefore are not in compliance if hazardous drugs are also being used. Because USP <800> mandates that 100% of the airflow from the C-PEC, C-SEC and negative pressure storage room be externally ventilated, it would be recommended to install a system or modify the current system to accommodate all spaces requiring external ventilation (i.e. compounding room, C-PEC and storage rooms for hazardous drugs).

Depending on the location of the existing healthcare operation within the building, the impact of routing new exhaust ductwork through existing spaces can be substantial, especially if the organization is on the first floor of a multi-story building. Where upgrades to current exhaust systems are not an option, an alternative would include outfitting the C-PEC, C-SEC and negative pressure storage rooms with reverse HEPA fan filter units. These units can be ducted directly to the building's exterior (Figure 9).

Note: The original proposed draft of USP <800> required that C-SECs be externally vented through HEPA filtration. However, the final publication of USP <800>, Section 5.3, Facilities and Engineering Controls, was revised to indicate that C-SECs used for sterile and non-sterile compounding must be externally vented, but do not need to be vented through HEPA filtration.

Figure 9: Reverse HEPA fan filter ducted to the building's exterior. This meets USP <800>'s external ventilation requirement.



Air Supply: With additional ventilation and fan filter equipment, comes the accompanying challenge of forcing enough air into the cleanrooms to maintain USP <800>'s required air change per hour, ISO air classification as well as a consistent negative pressure. Most common commercial HVAC systems are inadequate for meeting these standards and can result in starved fan filter units and burnt out fan motors. System modifications to maintain equipment functionality and meet the airflow requirements for compliance can include rebalancing the existing system or increasing the HVAC fan motor size.

Where upgrades to the current air conditioning system are not an option, an alternative would be to reposition the fan filter units that outfit the C-PEC, C-SEC and negative pressure storage rooms six to eight inches below the air registers that supply air to these spaces. This will allow the fan filter units to supplement air intake with the surrounding ambient air rather than pulling exclusively from the facility's system. This alternative can provide enough air supply to meet USP <800>'s air change per hour and ISO air standards while allowing the fan filter equipment to operate efficiently.

Pressurization Challenges: Even with adequate exhaust and air supply systems in place, balancing the pressurization between spaces can be a challenge. Factors such as work flow, equipment and people variables will need to be taken into consideration when testing and balancing the C-SEC. It is also important to understand that the C-SEC and C-PEC affect each other's engineering performance, especially since USP <800> mandates that both the C-PEC and C-SEC be externally vented.

Unlike non-hazardous positive pressure gradients associated with USP <795> and USP <797>, more negative pressure than what is required in a hazardous drug buffer room can be detrimental. Negative pressures should not exceed 0.03" water column negative. If the pressure is too negative, it results in dirty air and particles from the adjoining area being drawn into the space. There should be a visual pressure gauge between the buffer area and ante-room, as well as the ante-room and adjacent space.

ADDITIONAL CONSIDERATIONS

Energy: Additional air conditioning, fan filter units and external exhaust can increase energy usage and costs. Researching and implementing more energy efficient equipment, such as energy efficient HEPA filters and C-PECs with high efficiency motors.

Sanitation: The ante-room plays an important role in overall contamination control. Since the C-SEC is negatively pressurized, air from the ante-room will be drawn into the hazardous drug buffer room. For this reason, it is imperative that the ante-room air quality be at least as clean as the air in the hazardous drug buffer room (i.e. ISO 7). This inward air migration of equal air quality allows for the containment of any airborne hazardous drugs. Therefore, cleaning in the ante-room that serves the hazardous drug buffer room becomes as critical as cleaning the buffer room itself.

Additionally, facilities currently designed for compliance for non-hazardous positive pressure environments may need to address any issues with surface and wall integrity. From a positive pressure standpoint, cracks in the walls are not a critical issue since airflow is being forced out of the enclosure and containment is not a priority. Per USP <800>, however, walls and surfaces must be smooth, seamless and impervious to ensure the containment of hazardous contaminants.

Local / State Regulations: To certify that all procedures and configurations comply with USP <800>, it is recommended to consult the state or local pharmacy board or regulating authority. These authorities often enforce stricter regulations than the US Pharmacopeial Convention (USP) when pertaining to the application and implementation of USP <795>, USP <797> and USP <800>. It is also important to note that these organizations may adopt USP <800> standards in whole or in part and may establish implementation dates that start before or after the USP's December 1, 2019 implementation date.

The California Board of Pharmacy, for example, updated its compounding regulations to include certain requirements for engineering controls consistent with USP <800>, but the regulations did not adopt USP <800> in its entirety. These updated regulations went into effect on January 1, 2017.

Production Impact: Another, often overlooked challenge, is the maintenance of current healthcare operations while modifications are underway. Existing facilities with traditional stick-built rooms will be the most impacted, as on-site construction can disrupt compounding production and day-to-day operations. Depending on the extent of the construction project, it is likely that these healthcare facilities will need to designate a temporary space for compounding, or even pause operations while construction modifications take place. Modular cleanrooms are an ideal solution to this challenge as the installation has minimal impact to the business.

ABOUT SIMPLEX

Simplex Isolation Systems is a prominent leader in critical environment solutions. With over 35 years of industry expertise, Simplex designs and manufactures custom cleanrooms and enclosure systems that are robust, modular and expandable. Simplex's complete line of cleanrooms are ideal for compounding sterile injectables and other critical operations.

Allow Simplex to assist with your next USP <800> compliant cleanroom project to ensure satisfaction from initial concept through installation.

SUMMARY

USP <800> builds on the suggestions set forth by USP <795> and USP <797> with specific directives for the handling of hazardous drugs in the healthcare setting. As opposed to the USP <795> and USP <797> chapters, which are exclusive to compounding activities, USP <800> spans the entire hazardous drug handling process.

From a facility design and building infrastructure standpoint, USP <800> compliance can mean costly renovations for healthcare institutions whose current facilities present major design flaws such as limited square footage or inadequate air handling systems. With the approaching December 1, 2019 implementation date, healthcare institutions should begin evaluating their space and infrastructure needs as soon as possible if they have not already done so.

Consulting a cleanroom specialist would be in any healthcare institution's best interest and can help alleviate many of the challenges associated with compliance. In addition to detecting the potential space or building infrastructure modifications needed, a cleanroom specialist can help to identify which approach—modular or stick-built construction—is the best fit. Factors such as budget, work flow and anticipated future growth will be taken into consideration and accounted for.

It is recommended for healthcare administrators and employees involved in the hazardous drug process to read USP <800> in its entirety and understand all requirements and recommendations set forth by the chapter. Though USP <800> will impact many healthcare institutions, it is undisputed that the guidelines set forth by the chapter for the handling of hazardous drugs are an important step for protecting healthcare workers and the environment moving forward.

As a disclaimer, this whitepaper is intended to provide an overview of USP <800> Section 5: Facilities and Engineering Controls. Simplex Isolation Systems makes no claims as to the final interpretations from regulatory organizations such as the State Boards of Pharmacy and / or the FDA or the final interpretation of USP <800> recommendations from the United States Pharmacopeia (USP).

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