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Monograph

Physical Environment Provisions of USP <800> "Hazardous Drugs — Handling in Healthcare Settings"

Mike Zorich

AHA Data & Insights

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ASHE Disclaimer

USP <800> Monograph Executive Summary

- The intent of USP <800> is to protect health care workers and patients from harm associated with exposure to hazardous drugs (HDs).
- USP <800> covers in detail requirements for all potential tasks where exposure can occur.
- This monograph intends to support those preparing for compliance with USP <800> by:
  - Defining HDs
  - Comparing to USP <797>
  - Explaining enforceability
  - Planning & budgeting
  - Physical environment considerations including room finishes and HVAC layout
  - Reviewing initial certification process and ongoing compliance requirements
  - Providing a plan review checklist

Physical Environment Provisions of USP <800> "Hazardous Drugs — Handling in Healthcare Settings"

Introduction

The intent of USP <800> is to protect health care workers and patients from harm associated with exposure to hazardous drugs (HDs). According to the Centers for Disease Control and Prevention (CDC), eight million health care workers are potentially exposed to hazardous drugs every year. This exposure can occur with workers who are unaware of their exposure and in departments outside of the pharmacy. Studies have shown low-level work-related exposure to HDs can lead to acute and chronic issues including nausea, hair loss, rashes, kidney damage, infertility and increased risk of cancer.

Other risks associated with HDs include compounding errors that pose additional risk of microbial contamination to patients. Medication compounding-related infections (MCRI) are unwanted consequences when drugs are mixed incorrectly or in nonsterile environments, leading to many types of infections such as blood stream infections or fungal meningitis. The number of MCRIs in the U.S. health care industry is unknown, but regulatory bodies such as The Joint Commission (TJC) have started compounding certificate programs to ensure safe procedures are met. These programs, in addition to USP <800>, were established to help reduce these compounding errors.

The Purpose of USP <800>

USP <800> was developed to define the quality standards for the handling of HDs and the proper environmental controls for compounding to protect health care workers and patients. Under the premise of protecting the health care worker and the patient, the chapter covers in detail requirements for all potential tasks where exposure can occur. Aspects of handling HDs covered in USP <800> where exposure can occur include the following:

- Receiving
- Transporting
- Storing
- Compounding
- Dispensing
- Administering
- Spills
- Cleaning
- Waste Disposal

Definition of Hazardous Drugs

A clear definition of HDs is critical so that health care workers can recognize the drugs they are handling, understand the risks, and take proper actions to eliminate their exposure. The most commonly referenced HDs in many health care settings are chemo agents as they are associated with cancer risk, but several other hazardous drugs that workers are exposed to can cause adverse health effects.

USP <800> utilizes the list of HDs identified by the National Institute for Occupational Safety and Health (NIOSH). Drugs are classified as hazardous if they possess any of the following characteristics:

- Genotoxicity
- Organ toxicity
- Teratogenicity or development toxicity
- Reproductive toxicity
- Carcinogenicity

NIOSH is a federal agency and part of the CDC. The organization establishes — through research and third-party review — a list of drugs that exhibit the hazardous characteristics noted above. As new drugs enter the market, NIOSH will update its list of HDs to include in the next publication cycle. If new drugs enter the market prior to a NIOSH HD update, health care providers are to determine if the drug is similar to an existing HD in structure or toxicity; if so, the drug should be considered hazardous until it is further evaluated.

Health care providers are required to develop and keep a list of HDs utilized at their facility on file and available for surveyors.

Relation to USP <797> Pharmaceutical Compounding — Sterile Preparations

Prior to the development of USP <800>, the main guidance related to the handling of HDs was covered in USP <797>. In simple terms, the main intent of USP <797> was to protect hazardous and non-hazardous drugs from contamination. Standards for preparing sterile drugs to reduce the risk for contamination, infection or incorrect dosing are defined throughout USP <797>. What USP <797> did not cover was the handling of HDs and the associated risk of exposure of patients and health care workers. USP <800> was developed for this reason and to provide guidance on protecting any individual who may have exposure to HDs.

Enforceability

Similar to USP <797>, USP <800> is a set of rules and standards written in a context that could be enforced, but neither chapter has authority until it is adopted by an authority having jurisdiction such as the state board of pharmacists. However, both USP <797> and USP <800> are identified as the standard of care for the industry, and many health care organizations voluntarily follow the chapters to ensure patient and staff safety is met while also reducing their liability.

In 2012, a fungal meningitis outbreak in a New England compounding center infected 778 patients and resulted in 76 deaths. The source of the infection was determined to be drugs that were contaminated by improper compounding in a nonsterile condition. In 2017, TJC called on health care workers to eliminate medication compound-related infections (MCRI) and recognize that the standard of care for compounding medications was USP <797> and USP <800>.

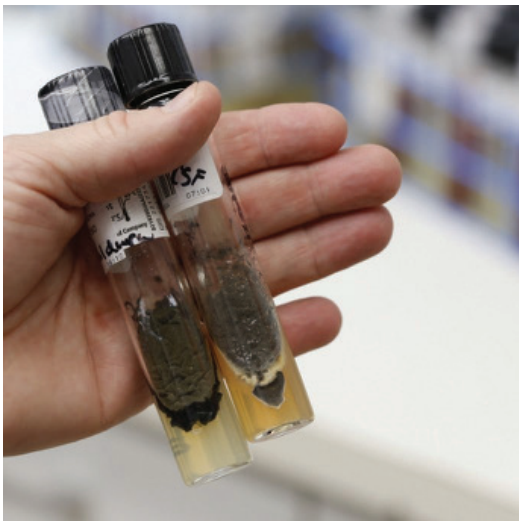

Figure 1: Researcher shows samples of Cladosporium species, left, and Aspergillus fumigatus — two of the fungi attached to the meningitis outbreak.

In January of 2017, TJC established a new Medication Compounding (MCC) program. One of the goals of the MCC is to ensure compliance with USP and TJC.

In August of 2018, TJC announced they would be enhancing their on-site evaluations and increasing their focus on compounding areas due to the increase in regulations and the incidents of contamination. TJC added that they would be providing more information on how the recent release of chapter revisions to USP would impact their surveys.

Planning and Budgeting

As pharmacies look to modify their current operations to ensure compliance with USP <800>, it is recommended traditional $/sq-ft values are not utilized for initial budgeting until the entire scope of construction is understood. Many factors can impact the overall renovation cost for compliance.

One of the biggest challenges for a pharmacy renovation is keeping the existing pharmacy operational while the spaces are being renovated. Some locations have the luxury of soft space that allows for smoother construction with the establishment of a temporary pharmacy that can be utilized during construction, but this is not always the case. It is important that construction phasing be evaluated during the planning process and that the quantity of phases be balanced between limiting staff disruption and construction cost.

Another item that can greatly impact construction cost and schedule is the condition and capacity of the existing HVAC system. The airflow, air quality, pressurization, temperature and humidity requirements in USP <800> make it risky to assume the existing infrastructure is adequate to comply with the guideline. Therefore, pre-measurement and verification of the HVAC systems is highly recommended to identify all deficiencies prior to establishing a construction budget. The cost for addressing the deficiencies can be substantial depending on their magnitude.

In instances where the cost of compliance is either too disruptive to existing operations or not cost-effective, some health systems have taken a hard look to

determine if their compounding needs are better served at a different location. Many systems have decided to move their compounding needs to an off-site location such as a medical office building, which is a less expensive occupancy.

Physical Environment Considerations

The common spaces found in a working pharmacy include the general pharmacy, anteroom and buffer room(s); sometimes a storage room or HD storage room are included. Before understanding when these spaces are required and how they interact with one another, it is important to understand a few basic definitions and terminology utilized in USP <800>.

ISO Classification

Cleanrooms are classified based upon the cleanliness of the air within the space. The lower the ISO classification number, the cleaner the air quality; ISO 1 is the cleanest and ISO 9 is the least clean. The ISO classifications common in compounding pharmacies are shown in **Figure 2**. The figure was taken from USP <797>; its intent is to show the "nesting" in which each ISO item must be contained within other associated ISO classes. For example, an ISO Class 5 PEC must be contained within an ISO Class 7 environment.

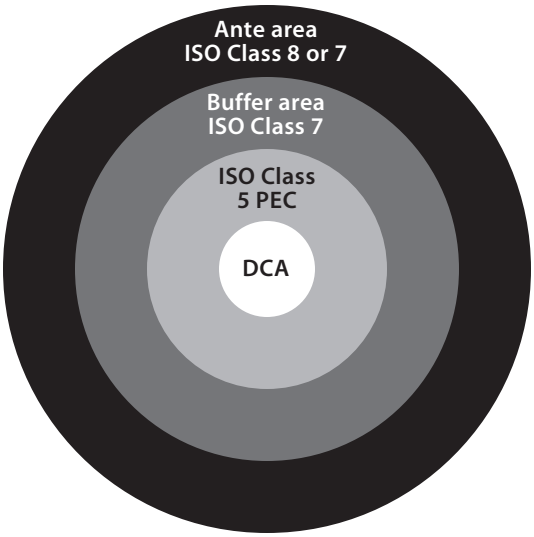

Figure 2: ISO class nesting

Direct Compounding Area (DCA)

The DCA is the critical area within the ISO Class 5 hood where the compound is being prepared.

ISO 5

The C-PEC or hood where the compounds are mixed.

ISO 7

Buffer area where C-PEC is located.

ISO 8 or ISO 7

The classification of the anteroom directly adjacent to the buffer room.

Beyond Use Date (BUD)

BUD is the time after which a compounded preparation cannot be used or stored. Compounded preparations that have a 12-hour or less BUD have less restrictive requirements for the classification of the room where the compounding occurs. This is described in the Containment Segregated Compounding Area (C-SCA) section.

Containment Primary Engineering Control (C-PEC)

C-PEC is the device, commonly referred to as the hood, where compounds are mixed. The C-PEC includes containment ventilated enclosures (CVE) known as powder hoods, biological safety cabinet (BSC), and compounding aseptic containment isolators (CACI).

The National Sanitation Foundation (NSF) classifies safety cabinets to differentiate their containment capabilities and performance levels. Compounding pharmacies in a health care application utilize a Class II and either a Type A2 or B2 for the C-PECs. **Table 1** shows the classification types.

Classification	Intent
I	Designed to protect personnel and environmental.
II	Designed to protect product, personnel and environmental.

Type	Description
A2	70% of airflow recirculated to the space; 30% of airflow directly exhausted.
B2	0% of airflow recirculated to the space; 100% of airflow directly exhausted.

Table 1: Classification types

Containment Secondary Engineering Control (C-SEC)

C-SEC is the room where the C-PEC device is located. The C-SEC may be an ISO 7 buffer room with an ISO 7 anteroom or an unclassified containment segregated compounding area (C-SCA). The rooms are often referred to as the "positive" room or the "negative" room, but the terminology utilized in USP <800> is the buffer room, and more specifically, the non-HD buffer room and HD buffer room.

- Non-HD Buffer Room (Positive):
  - Non-HD buffer room is the location where pharmacy staff prepares sterile non-hazardous compounding preparations.
  - Room requirements include an ISO Class 7 buffer room with fixed walls, a positive pressure of at least 0.02 inches water column (W.C.) to adjacent spaces, and a minimum of 30 air changes per hour (ACH) of HEPA filtered supply air. Inches of water column is a unit for measuring pressure differential between two locations.

- HD Buffer Room (Negative):
  - HD buffer room is the location where sterile and/or nonsterile hazardous drug compounding preparations are mixed. Currently USP <800> allows the preparation of sterile and nonsterile hazardous drugs to be prepared within the same hood if the C-PEC's performance is adequate to ensure the HD buffer room maintains an ISO 7 classification throughout the duration of the nonsterile compounding efforts. Staff must then adequately clean and disinfect the C-PEC between each use before resuming compounding.
  - Many health care facilities that perform both sterile and nonsterile hazardous drug compounding have chosen to utilize two separate C-PECs, or at minimum, plan their HD buffer rooms for a future additional C-PEC. Many are doing this to provide flexibility in the future, should their caseloads increase or should USP, FDA or other regulating bodies discontinue the allowance of sterile and nonsterile HD compounding within the same room.
  - Room requirements include an ISO Class 7 buffer room with fixed walls, a negative pressure between 0.01 and 0.03 in. W.C. to adjacent spaces, and a minimum of 30 ACH of HEPA filtered supply air.
  - Hazardous preparations compounded in the HD buffer room can be assigned the full BUD listed in USP <797>.

- Containment Segregated Compounding Area (C-SCA)
  - C-SCA is a type of C-SEC, or a non-classified room with lower airflow requirements. USP <800> eliminated the low-volume exemption in USP <797> that allowed the placement of a C-PEC in a non-negative pressure room for facilities that prepare a low volume of HDs. All HD compounding must now occur in a separate, designated compounding area. The guideline does allow for compounding to occur in a C-SCA (**Figure 3**) for applications where only low- and medium-risk preparations are compounded, and the BUD is less than 12 hours for non-refrigerated compounds or less than 24 hours for refrigerated compounds.
  - The non-classified room has fixed walls, a negative pressure between 0.01 and 0.03 in. W.C. to adjacent spaces, and a minimum of 12 ACH of supply air.
  - A hand wash sink is required to be placed no less than one meter from the C-PEC. The sink may either be located within the non-classified room or directly outside the C-SCA.

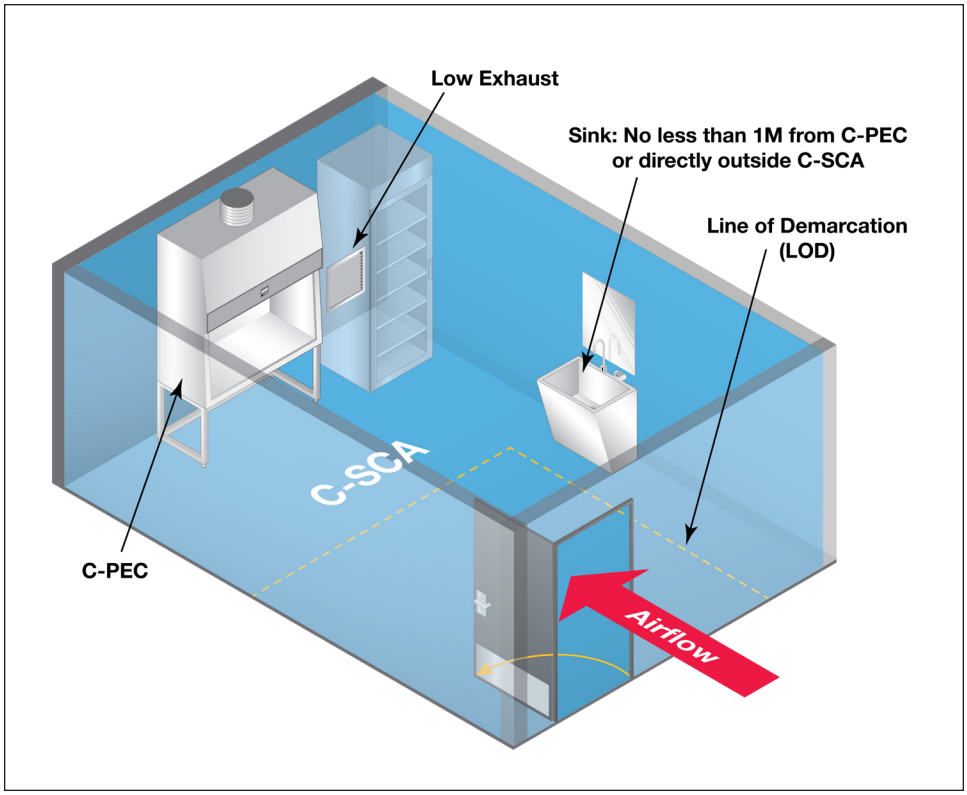

Figure 3: Compounding in a C-SCA

- Anteroom
  - The anteroom is the transition area between unclassified support spaces and classified rooms where compounding occurs. The anteroom is the space where pharmacy staff perform particle-generating activities such as hand-washing, donning personal protective equipment (PPE), documenting or order entry. A line of demarcation within the anteroom helps separate the anteroom functions and distinguishes the clean side from the dirty side.
  - Room requirements include an ISO Class 7 room with fixed walls, a positive pressure of at least 0.02 in. W.C. to adjacent spaces, and a minimum of 30 ACH of HEPA filtered supply air.
  - A hand wash sink is required to be placed no less than one meter from the entrance of the HD buffer room door to reduce the risk of contamination.

Compounding Room Arrangements

The most common and recommended compounding arrangement defined in USP <800> is shown in **Figure 4**, where HD buffer and non-HD buffer share an anteroom. In this configuration, staff enters the clean room by entering the anteroom. From this location — after donning PPE — staff can enter either compounding room. The anteroom often has windows, allowing staff to see into both compounding rooms to see if they are occupied prior to entering.

The second compounding arrangement discussed in USP <800> — though noted as not recommended, but allowed — is shown in **Figure 5**, where the HD buffer room is entered through the non-HD buffer room. Operationally, this configuration presents many challenges to pharmacy staff. Precautions must be made when transporting HDs and HD waste through the non-HD room to minimize the risk of cross-contamination. This is achieved through sealed containers and carts or the use of "pass throughs" from the HD buffer room to an adjacent space. Beside the potential risk for cross-contamination, this arrangement is disruptive to staff in the non-HD buffer room every time staff passes through to the HD buffer room. This arrangement may be useful in an existing condition where a pharmacy is planning a renovation. If their current configuration or other space restrictions do not allow them the preferred arrangement in **Figure 4**, this arrangement may be useful to help minimize construction phasing and disruption to operations.

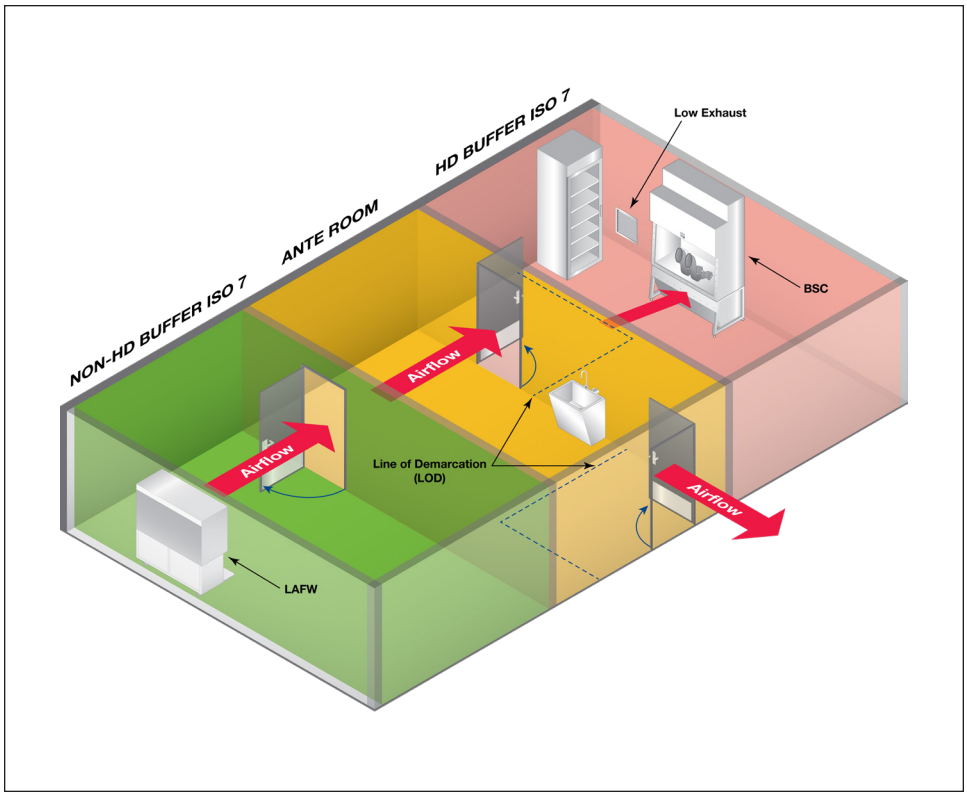

Figure 4: HD buffer and non-HD buffer share an anteroom

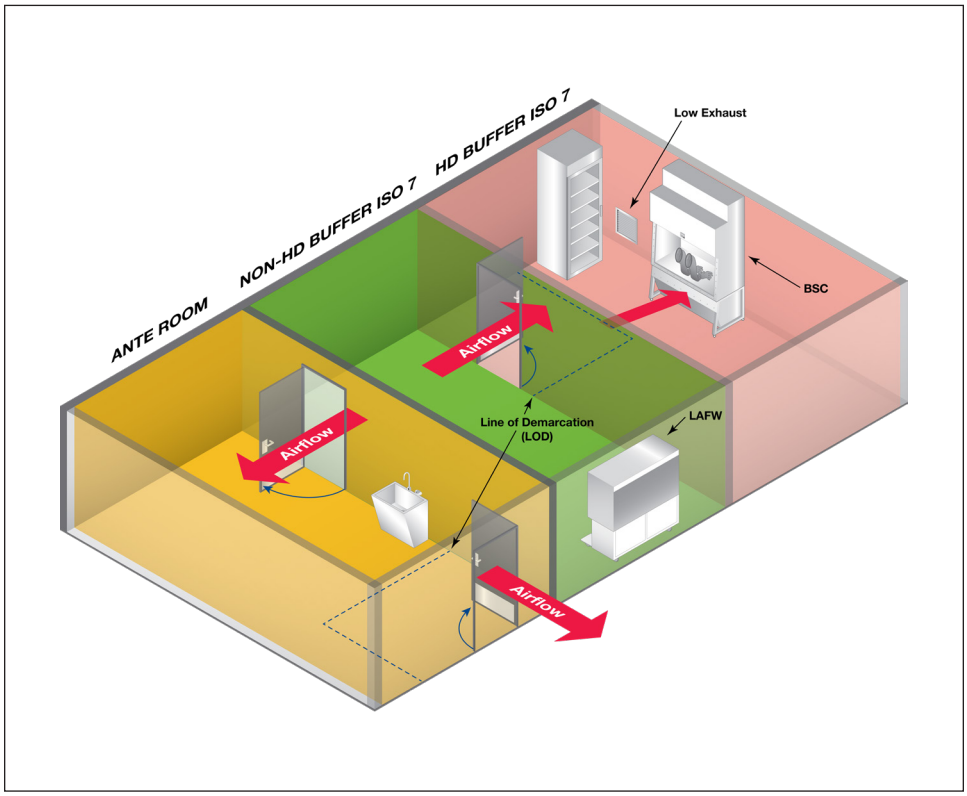

Figure 5: The HD buffer room is entered through the non-HD buffer room

Hazardous Drug Storage

One of the biggest impacts USP <800> has on many current operations is the requirement related to HD storage. To prevent cross-contamination and potential staff exposure, USP <800> does not allow non-HDs and HDs to be stored within the same room. HDs must be stored in a negative pressure room with a minimum of 12 ACH. Prior to USP <800>, it was common to have HDs and non-HDs stored in refrigerators in the anteroom. This is no longer allowed with the issuance of USP <800>.

Options to address this change are either storing the HDs within the HD buffer room or providing a dedicated HD storage room. Often the HD storage room is preferred because it allows for a location to unbox and store the HD, but this does require the planning of an additional room.

A key item related to HD storage that is often misunderstood and is found in section 5.2 of USP <800> states:

> *"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."*

Under this requirement, if a pharmacy will be conducting both nonsterile and sterile HD compounding, it will need a dedicated HD storage room.

HD Storage Room Options

- Store HDs in HD buffer room (or C-SCA if applicable)
  - HDs received and unboxed elsewhere
  - Nonsterile HDs cannot be stored in hazardous compounding room

- Dedicated HD Storage Room
  - HDs may be unboxed in this room
  - Sterile and nonsterile HDs can be stored in this room
  - A negative pressure to adjacent spaces and minimum of 12 ACH of exhaust air

Under either HD storage room option, USP <800> requires all refrigerated antineoplastic HDs to be stored in a dedicated refrigerator. USP <800> states that if a refrigerator is located in the HD buffer room, an exhaust located

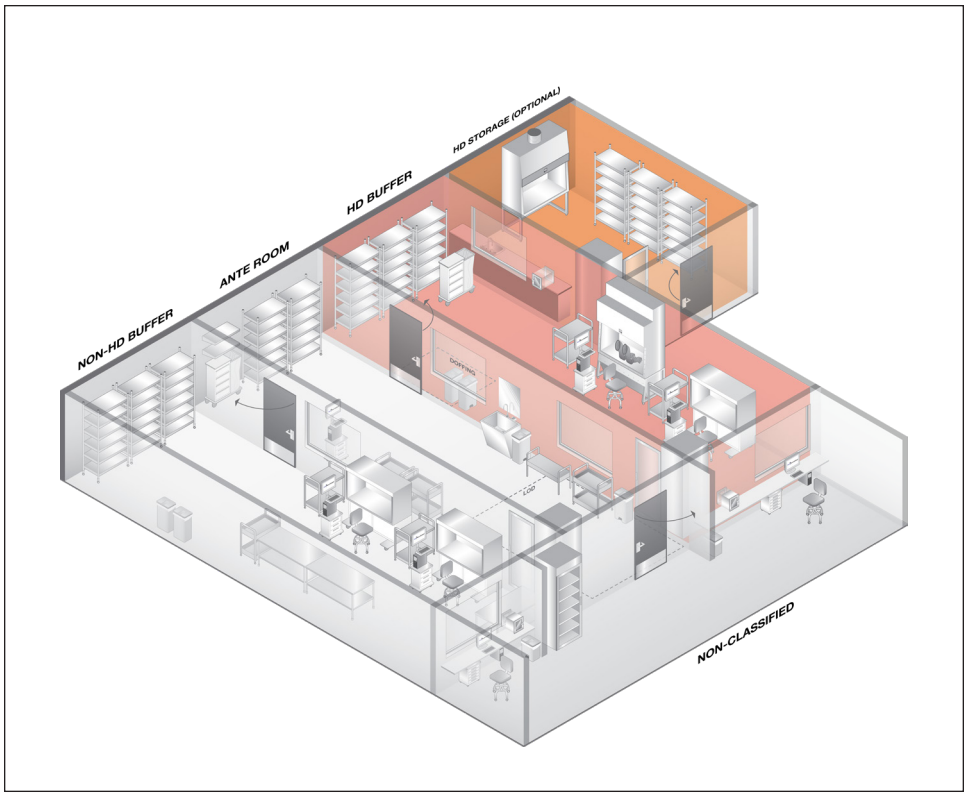

Figure 6: Compounding pharmacy with option HD storage room

adjacent to the refrigerator's compressor and behind the refrigerator should be considered. The intent of this recommendation is to place a low wall exhaust to help draw out any particulates from the fridge or spillage from its contents. Though not clearly stated in USP <800>, it is best practice to have this low wall exhaust behind the refrigerator for both a dedicated HD storage room and when HDs are stored in the HD buffer room.

Pass Throughs

Pass throughs are enclosures with interlocking doors that are utilized in clean room spaces. They are common between the anteroom and buffer rooms or between the HD storage room and HD buffer room. Pass throughs are discussed in both USP <797> and UPS <800>. Important items to note include:

- Pass throughs serving negative pressure rooms need to have sealed doors.
- Pass throughs serving a storage room, such as the HD storage room that may be fire rated, need to be a rated assembly.
- Refrigerated pass throughs are no longer allowed into the HD buffer room.

HVAC Considerations

The intent of the HVAC design for the compounding areas — which consist of the HD buffer, anteroom and non-HD buffer — should be to meet clean room fundamentals. In basic terms, this means to provide a large amount of HEPA filtered supply air at a low velocity at the ceiling and then remove the air with low return grilles to sweep out any particulates in the space.

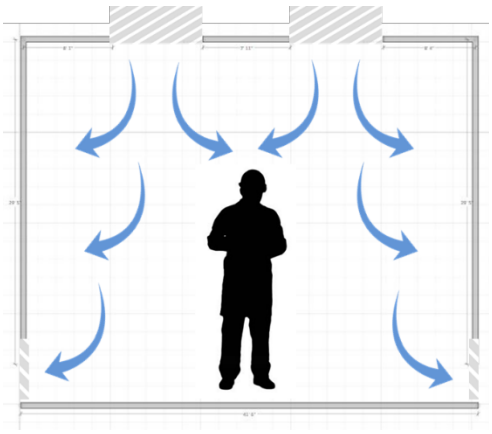

Figure 7: HVAC considerations

The ISO 7 and ISO 8 rooms will require a laminar airflow diffuser (LAF) with HEPA filters at the ceiling to provide clean and low-velocity air. LAF provides unidirectional airflow that does not introduce turbulence and provides additional protection from bacterial shedding associated with personnel or surfaces in the space. Low wall returns are required for all the compounding areas to draw the air downward.

One challenge that USP <800> has introduced is defining a negative pressure range for the HD buffer room and the Segregated Compounding Area (C-SCA). It is important that the HVAC design be flexible and resilient to meet these requirements. Construction quality can have a big impact on the relative tightness of the room, so this should be considered when the HVAC systems are selected.

Other HVAC items to consider:

- Temperature and humidity must be monitored and documented for every day compounding occurs.
- Compounding rooms must be equipped with a pressure monitoring system to notify occupants if spaces are within tolerance.

Table 2 identifies the HVAC requirements for the pharmacy spaces:

Room	Temp [°F]	RH	Pressure	Air Changes	ISO Class
HD Buffer (C-SEC)	Max 68	60%	-0.01″ to -0.03″	30 ACH Supply	7
Non HD Buffer (C-SEC)	Max 68	60%	> +0.02″	30 ACH Supply1	7
Anteroom	NR	NR	> +0.02″	30 ACH Supply	7 or 8 2
HD Storage Room	NR	NR	Negative	12 ACH Exhaust	NR
General Pharmacy 3	NR	NR	Positive	4 Total ACH 2 OA ACH	NR
HD Compounding (C-SCA)	Max 68	60%	-0.01″ to -0.03″	12 ACH Supply	NR

Table 2: HVAC requirements

Notes
1. 15 ACH can be recirculated in the room.
2. ISO Class 7 if opening into HD Buffer Room. ISO Class 8 if only connected to non-HD buffer room.
3. From ASHRAE-170 — 2017 Table 7.1.

Certification: What to Expect

The requirement for certification of the air quality, airflow and pressurization in the compounding areas is still found in Section 4 of USP <797>, but the similar physical environment requirements of the HD compounding area defined in USP <800> will be reviewed in the certification process as well. Certification is required at least every six months using procedures defined by the current Controlled Environment Testing Association (CETA) certification guide for "Sterile Compounding Facilities." The certification of the space includes the following:

- Airflow Testing
  - Performed to determine proper ACH and space pressurization.
- HEPA Filter Testing
  - Performed to determine integrity and condition of HEPA filters to determine performance is met and leakage is not occurring.

- Total Particulate Count Testing
  - Performed under dynamic operating conditions, air and surface, to provide information on environmental quality of the spaces. Determine both viable and non-viable particulates.
- Other Certification Tasks
  - Certification of C-PEC.
  - Cytotoxic Residue Sampling.

Plan Review Checklist for Compounding Rooms

The pharmacy staff should be highly engaged by the design and construction team early in the planning stages for compliance with USP <800>. These discussions should start with understanding the entire process for how staff receives, transfers, stores, delivers and administers HDs to patients. These discussions also should include the techniques the pharmacy staff will utilize for HD compounding. It's critical the designers understand how soon medications will be administered following compounding, and if the pharmacy staff will be performing nonsterile compounding, sterile compounding or both. Knowing these differences will allow for planning a compliance solution that meets the pharmacy's specific needs. Below is a suggested checklist for use during design

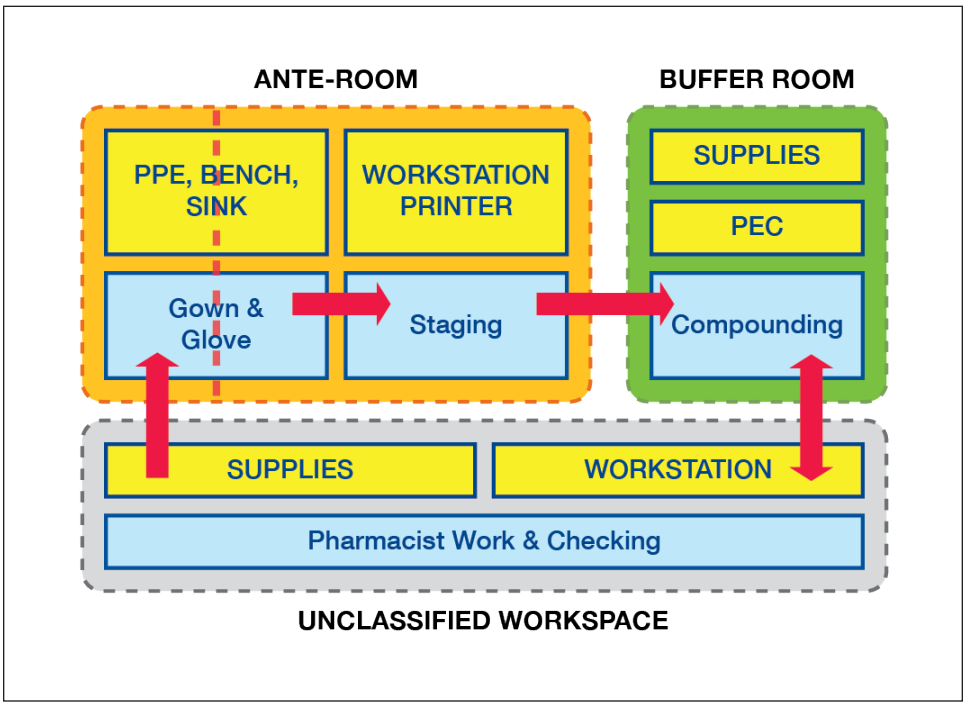

Figure 8: Typical flow diagram for planning a compounding pharmacy

and plan review. The checklist may not be all-inclusive, and the regulations should be consulted for further detail.

Containment Primary Engineering Control (C-PEC)

- ☐ The hood can be certified as ISO Class 5.
  - ○ This includes powder hoods, biological safety cabinets (BSC) or compounding aseptic containment isolators (CACI).
- ☐ Hood selection is identified as Class II and one of the following types:
  - ○ Type A2: 70% of airflow recirculated; 30% of airflow directly exhausted
  - ○ Type B2: 0% of airflow recirculated; 100% of airflow directly exhausted
- ☐ The hood is in an area without traffic.

HD Buffer Area (Negative)

- ☐ The HD buffer area can be certified as ISO Class 7.
- ☐ HEPA-filtered supply air is provided at the ceiling.
- ☐ Low exhaust grilles are provided.
- ☐ If refrigerator for antineoplastic HDs is provided in HD buffer room, the following are met:
  - ○ Both sterile and nonsterile compounding are not being conducted in the buffer room.
  - ○ A low exhaust is located behind the refrigerator and near the compressor.
- ☐ Proper air changes are provided:
  - ○ Minimum 30 ACH of supply air.
- ☐ Space conditions are recommended to be designed to maintain the following:
  - ○ Maximum space temperature of 68°F.
  - ○ Maximum space relative humidity of 60%RH.
- ☐ The HD buffer room is separated from other areas with a negative pressure between -0.01" W.C. and -0.03" W.C.
- ☐ An installed pressure differential monitoring device must be used to continuously monitor all required pressure differentials (recorded daily). *Note: It is recommended to have a visual pressure monitoring station located outside the cleanroom suite.*

- ☐ No sinks or floor drains are included in the HD buffer.
- ☐ Surfaces of ceilings, walls, floors, fixtures, cabinets, etc., are impervious, free from cracks and crevices and made of non-shedding material.
- ☐ Work surfaces are constructed of stainless steel or molded plastics.
- ☐ Doors between HD buffer and anteroom do not have seals or sweeps.
- ☐ Doors shall be of non-shedding material. Wood doors are not allowed unless coated with epoxy paint.
- ☐ Junctures of ceilings and walls are coved or caulked.
- ☐ Junctures of floors and walls are coved.
- ☐ Ceiling surfaces are hydrophobic.
- ☐ Walls are constructed of epoxy coated gypsum, heavy-gauge polymer or stainless steel.
- ☐ Penetrations through walls or ceilings are sealed.

Non-HD Buffer Area (Positive)

- ☐ The non-HD buffer area can be certified as ISO Class 7.
- ☐ HEPA-filtered supply air is provided at the ceiling.
- ☐ Low exhaust grilles are provided.
- ☐ Proper air changes are provided:
  - ○ Minimum 30 ACH of supply air.
  - ○ 15 ACH with open circulating hood (hood must provide 15 ACH).
- ☐ Space conditions are recommended to be designed to maintain the following:
  - ○ Maximum space temperature of 68°F.
  - ○ Maximum space relative humidity of 60%RH.
- ☐ The ante-room must maintain a differential pressure > 0.02" W.C with all unclassified areas.
- ☐ A differential positive pressure > +0.02" W.C with all ISO classified areas from higher air-quality to an area of lower air-quality.

- ☐ An installed pressure differential monitoring device must be used to continuously monitor all required pressure differentials (recorded daily). *Note: It is recommended to have a visual pressure monitoring station located outside the cleanroom suite.*
- ☐ No sinks or floor drains are included in the non-HD buffer.
- ☐ Surfaces of ceilings, walls, floors, fixtures, cabinets, etc., are impervious, free from cracks and crevices, and made of non-shedding material.
- ☐ Work surfaces are constructed of stainless steel or molded plastics.
- ☐ Doors between non-HD buffer and anteroom do not have seals or sweeps.
- ☐ Doors shall be of non-shedding material. Wood doors are not allowed unless coated with epoxy paint.
- ☐ Junctures of ceilings and walls are coved or caulked.
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- ☐ Walls are constructed of epoxy coated gypsum, heavy-gauge polymer or stainless steel.
- ☐ Penetrations through walls or ceilings are sealed.

Containment Segregated Compounding Area: C-SCA (Negative)

- ☐ Pharmacy staff has documented their intended use of the space meets the following:
  - ○ Compounding only low- and medium-risk preparations.
  - ○ BUD is < 12 hours for non-refrigerated compounds.
  - ○ BUD is < 24 hours for refrigerated compounds.
- ☐ The C-SCA can be a non-classified room.
- ☐ Low exhaust grilles are provided:
  - ○ If refrigerator for antineoplastic HDs is provided in C-SCA, a low exhaust is located behind the refrigerator and near the compressor.
- ☐ Proper air changes are provided:
  - ○ Minimum 12 ACH of supply air

- ☐ Space conditions are recommended to be designed to maintain the following:
  - ○ Maximum space temperature of 68°F.
  - ○ Maximum space relative humidity of 60%RH.
- ☐ The C-SCA room is separated from other areas with a negative pressure between -0.01" W.C. and -0.03" W.C.
- ☐ A hand wash sink is provided meeting one of the following:
  - ○ Within the C-SCA room no less than 1 meter from the C-PEC
  - ○ Directly outside the C-SCA

Anteroom

- ☐ The anteroom can be certified as ISO Class 7 if the following is met:
  - ○ Anteroom opens into HD buffer room
- ☐ The anteroom can be certified as ISO 8 if the following is met:
  - ○ Anteroom is only connected to non-HD buffer room
- ☐ HEPA-filtered supply air is provided at the ceiling.
- ☐ Low exhaust grilles are provided.
- ☐ Proper air changes are provided:
  - ○ Minimum 30 ACH of supply air
- ☐ The anteroom is separated from other areas with a positive pressure > +0.02" W.C.
- ☐ A line of demarcation is provided to separate clean and dirty room functions.
- ☐ An installed pressure differential monitoring device must be used to continuously monitor all required pressure differentials (recorded daily). *Note: It is recommended to have a visual pressure monitoring station located outside the cleanroom suite.*
- ☐ A sink is provided no less than one meter from the door to the HD buffer room.
- ☐ Surfaces of ceilings, walls, floors, fixtures, cabinets, etc. are impervious, free from cracks and crevices, and made of non-shedding material.
- ☐ Work surfaces are constructed of stainless steel or molded plastics.

- ☐ Doors between anteroom and any buffer room do not have seals or sweeps.
- ☐ Doors shall be of non-shedding material. Wood doors are not allowed unless coated with epoxy paint.
- ☐ Junctures of ceilings and walls are coved or caulked.
- ☐ Junctures of floors and walls are coved.
- ☐ Ceiling surfaces are hydrophobic.
- ☐ Walls are constructed of epoxy coated gypsum, heavy-gauge polymer or stainless steel.
- ☐ Penetrations through walls or ceilings are sealed.

HD Storage Room

- ☐ The HD storage room can be a non-classified room.
- ☐ Low exhaust grilles are provided.
  - ○ A low exhaust is located behind the refrigerator and near the compressor.
- ☐ Proper air changes are provided:
  - ○ Minimum 12 ACH of exhaust air
- ☐ The HD Storage room is separated from other areas with a negative pressure between -0.01" W.C. and -0.03" W.C.

Other Considerations

Below are several items that are not specifically called out in <800> or <797>, but which should be considered during the planning stages.

Pressure Ports

As part of the six-month certification process, the pharmacy certifier will be testing the pressure drop across the HEPA filtered diffusers to determine effectiveness. It is recommended as part of the design, tubing be ran from the HEPA filtered diffusers to a common test port located in the ceiling of the general pharmacy or non-classified space. This allows testing of the HEPA filters be done without disruption to the compounding areas.

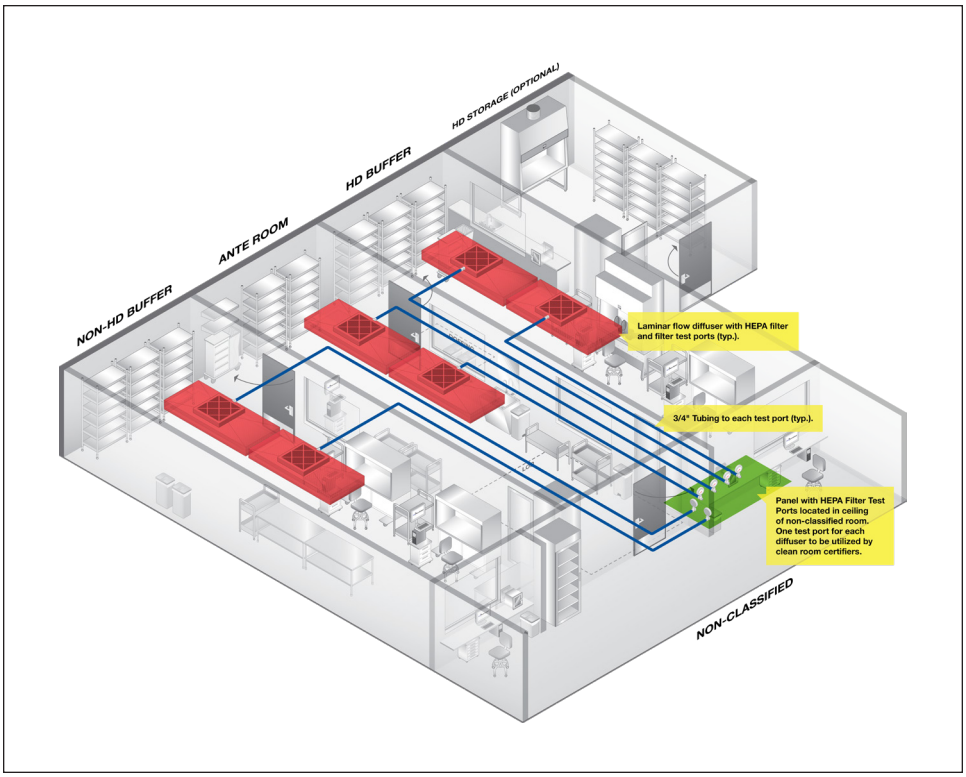

Figure 9: Pressure ports

Cameras

Cameras for security and monitoring are common requests within the general pharmacy and compounding areas. Oftentimes the compounding hoods are provided with internal cameras for monitoring of preparations. Any camera that is selected must be able to stand up to routine cleaning.

Music

There is a debate within the pharmacy industry on whether music should be allowed to be played in the compounding rooms. Some believe staff should be focusing on their preparations rather than music playing in the room, while others feel music improves alertness. If music is allowed by the pharmacy department it is important staff does not bring in their own personal music devices. This will be a source for outside contaminants and a potential particle generator. Many pharmacies are utilizing smart speakers that remain in the compounding room. The smart speakers can be voice controlled by the occupants, leaving the occupants' hands free. Whichever device is selected, it should be able to stand up to routine cleaning.

Compounding Room: Doors

Hands-free swinging or sliding doors are acceptable in the compounding area. When utilizing swinging doors, the direction of door swing is not defined in either <797> or <800>, but it is recommended consideration be made for the movement of the doors and its impact on airflow. Some pharmacies have utilized interlocks that only allow one door to be open at a time to minimize impact on airflow and pressurization. Other items to consider is the door swing direction's impact on staff flow and usable space. For example, an inward swinging door to the anteroom needs to be carefully coordinated with the gowning and line of demarcation space to ensure adequate space is provided. Whether a swinging or sliding door is utilized, it is important to review the needs of the occupants and factor in the impact on space and airflow.

Air Changes per Hour: ISO 7

For ISO 7 spaces, the minimum ACH is 30. A system that is provided with just the minimum ACH at start-up may not be able to provide that minimum over the life of the system. It is recommended designers factor in filter loading and duct leakage when sizing the HVAC systems. Depending on system type and the size of the area served, designers may consider designing the space above the minimum 30 ACH to ensure compliance over a reasonable time period.

Conclusion

USP <800> was developed to define the standards for the handling of HDs and the proper environmental controls to protect health care workers and patients. It is intended to be utilized with USP <797> to improve safety and quality for all those impacted by the pharmacy operations. When discussing compliance needs, it is important to include individuals from not only the pharmacy department, but also facilities, administration, and design and construction to ensure all needs are represented and understood.

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