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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>.

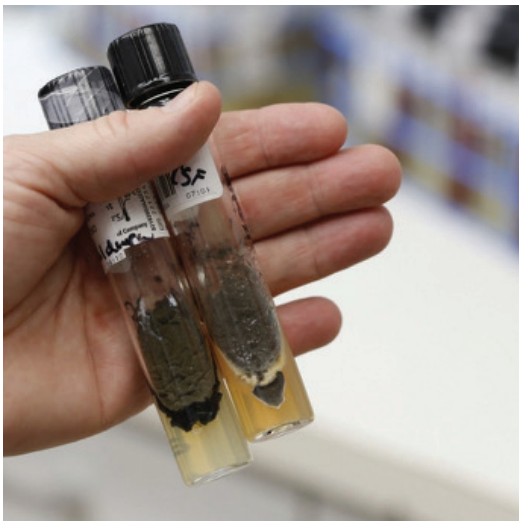

Figure 1: Researcher shows samples of Cladosporium species, left, and Aspergillus fumigatus — two of the fungi attached to the meningitis outbreak.

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.

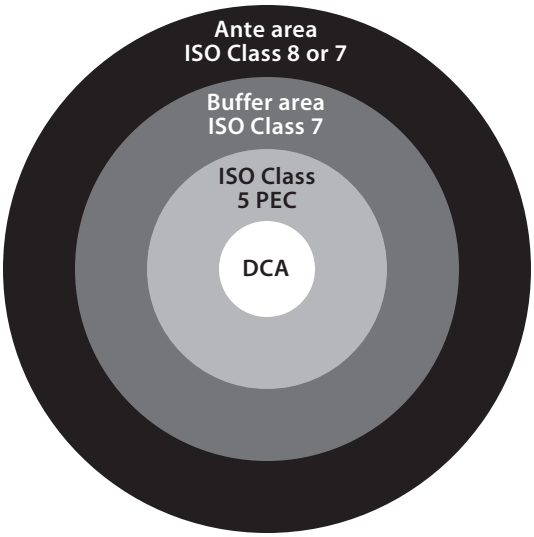

Figure 2: ISO class nesting

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.

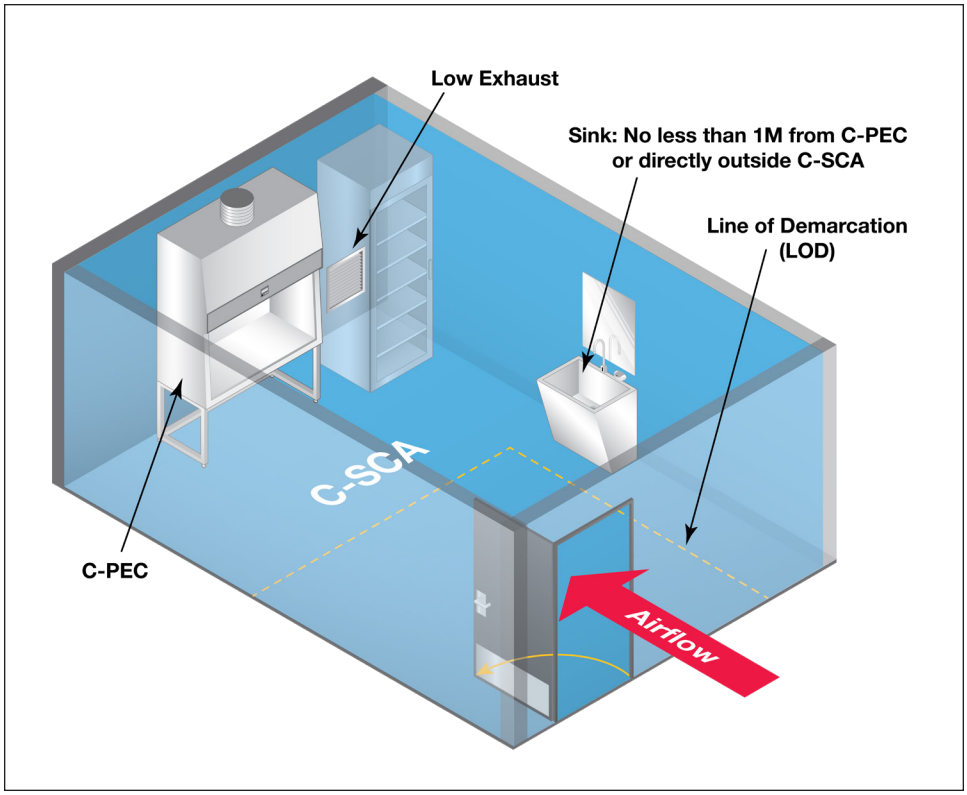

Figure 3: Compounding in a C-SCA

- 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.

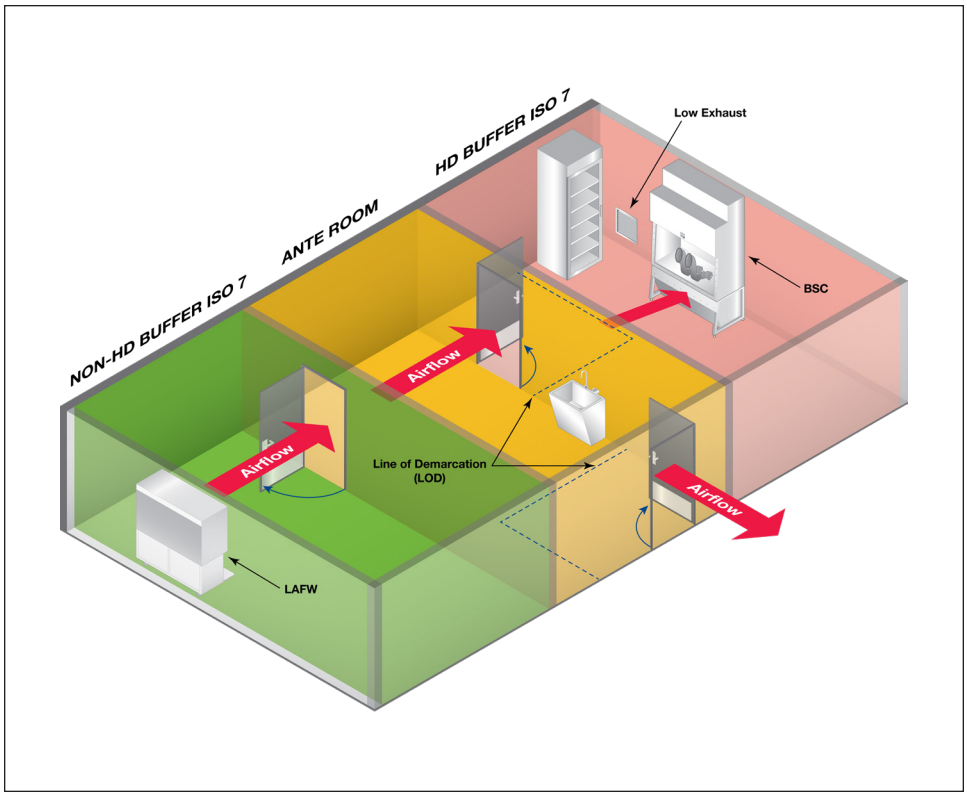

Figure 4: HD buffer and non-HD buffer share an anteroom

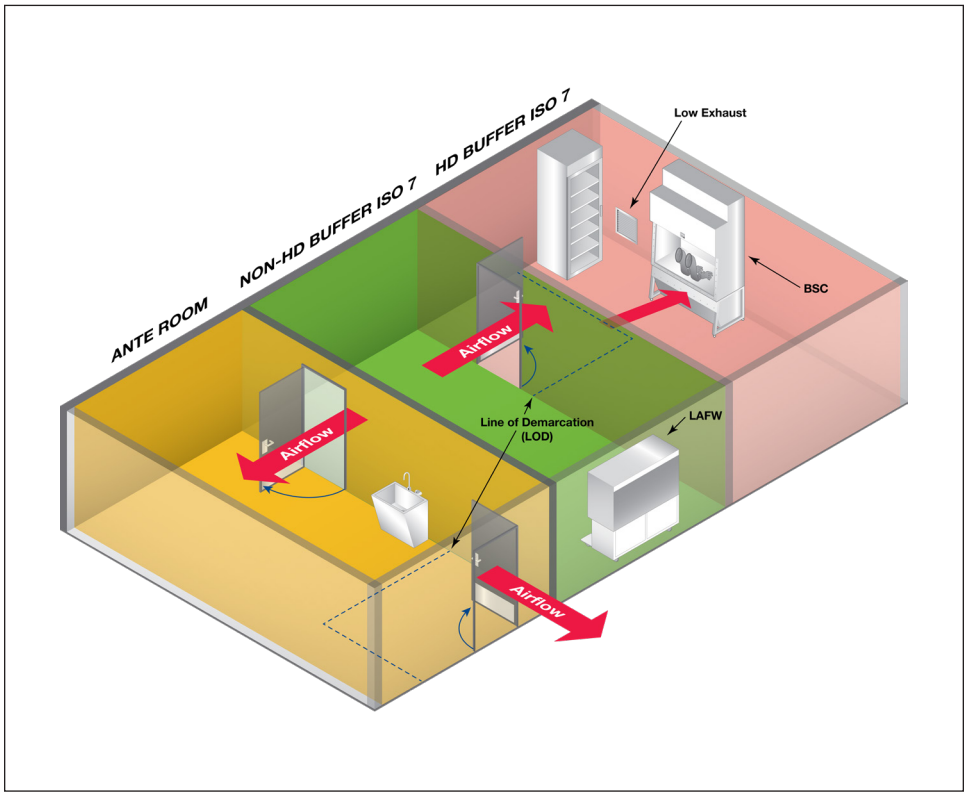

Figure 5: The HD buffer room is entered through the non-HD buffer room

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

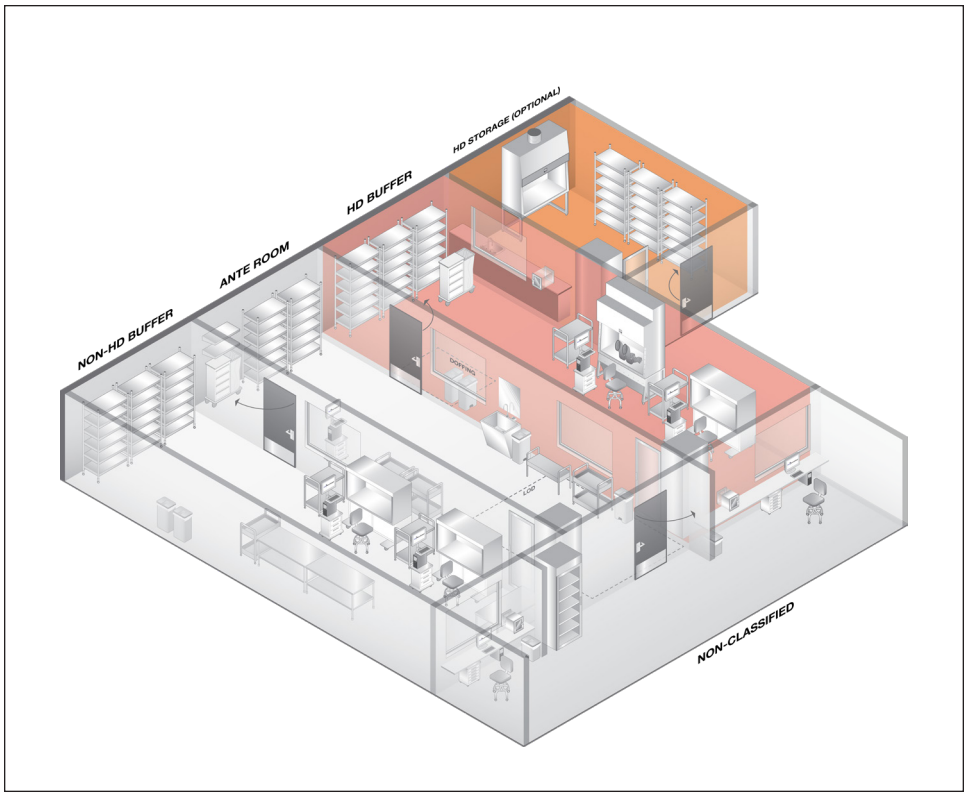

Figure 6: Compounding pharmacy with option HD storage room

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.

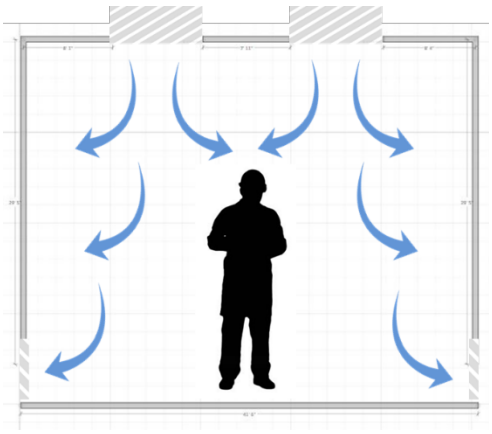

Figure 7: HVAC considerations

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

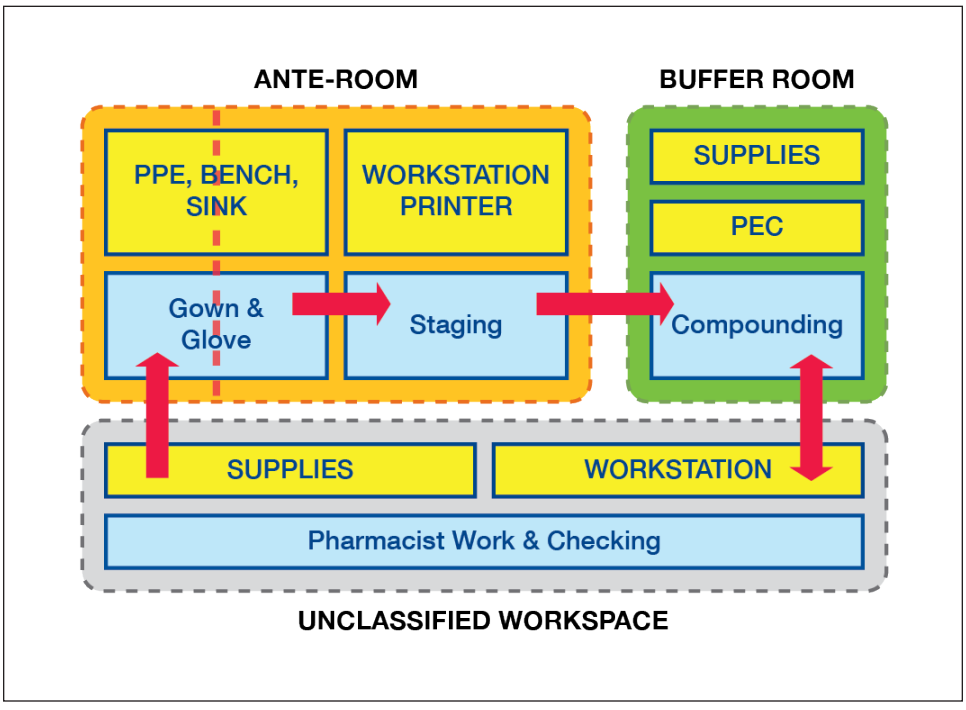

Figure 8: Typical flow diagram for planning a compounding pharmacy

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.

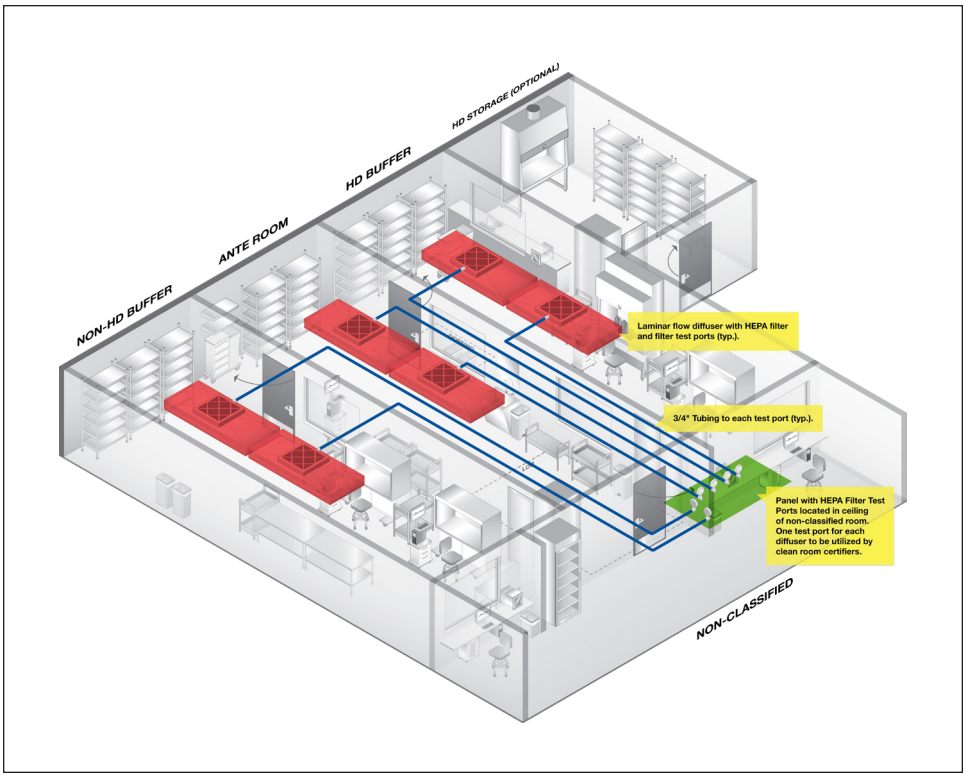

Figure 9: Pressure ports

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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USP <800> Hazardous Drugs Risk Readiness Checklist

Implementation Date December 1, 2019

AHA Data & Insights

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USP <800> Hazardous Drugs Risk Readiness Checklist

Implementation Date December 1, 2019

USP <800> Hazardous Drugs – Handling in Health Care was published on February 1, 2016 with an **implementation date of December 1, 2019**. The purpose of the <800> chapter is to describe practice and quality standards for handling hazardous drugs (HD) in health care settings and help promote patient safety, worker safety and environmental protection. The scope of chapter <800> is very broad and this checklist will assist in identifying areas where opportunities exist to become compliant in these standards where required.

The intent of this USP <800> Hazardous Drugs Risk Readiness Checklist is to help you gain information regarding your organization's readiness to implement USP <800> standards. Once you complete the checklist, review your assessment and focus on the areas that need to be addressed (red), continue moving areas in progress (yellow) to be completion, and confirm all areas are completed (green).

- Green – Completed
- Yellow – In Progress
- Red – To Be Addressed

According to The National Institute for Occupational Safety and Health (NIOSH), health care workers who prepare or administer hazardous drugs (e.g., those used for cancer therapy, and some antiviral drugs, hormone agents and bioengineered drugs) or who work in areas where these drugs are used may be exposed to these agents in the workplace. About 8 million U.S. health care workers are potentially exposed to hazardous drugs, including pharmacy and nursing personnel, physicians, operating room personnel, environmental services workers, workers in research laboratories, veterinary care workers and shipping and receiving personnel.[i]

NIOSH goes on to state, "Exposure to HDs can result in adverse health effects in health care workers. In fact, published studies have shown that workplace exposures to hazardous drugs can cause both acute and chronic health effects such as skin rashes, adverse reproductive outcomes (including infertility, spontaneous abortions and congenital malformations), and possibly leukemia and other cancers. The health risk depends on how much exposure a worker has to these drugs and how toxic they are. Workers can be protected from exposures to hazardous drugs through engineering and administrative controls, and proper protective equipment."[ii]

It is also important to note that USP <797> Pharmaceutical Compounding – Sterile Preparations has also been revised. Both USP <797> and <800> are standards and not enforced by USP; however, 28 states have adopted <797> and CMS recently adopted most provisions of the chapter and is enforcing these standards.

These standards are taken directly from www.usp.org document *2017 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings* and are reflective of all required and must standards.

Important Dates:

USP <800> and the revised <797> chapter will become final in June of 2019 and are set for implementation in December of 2019.

Scope

> Chapter <800> applies to all health care personnel who handle HD preparation and all entities that store, prepare, transport or administer HDs (e.g., pharmacies, hospitals and other health care institutions, patient treatment clinics and physicians' practices facilities.[iii]

Entities that handle HDs **must** incorporate the standards in chapter <800> into their occupational safety plan. The plan's health and safety management must, at a minimum, include:

- List of Hazardous Drugs
- Types of Exposure
- Responsibilities of Personnel Handling Hazardous Drugs
- Facilities and Engineering Controls
- Environmental Quality and Control
- Personal Protective Equipment
- Hazard Communication Program
- Personnel Training
- Receiving
- Labeling, Packaging, Transport and Disposal
- Dispensing Final Dosage Forms
- Compounding
- Administrating
- Deactivating, Decontaminating, Cleaning and Disinfecting
- Spill Control
- Documentation and Standards Operating Procedures (SOPs)
- Medical Surveillance

List of Hazardous Drugs

NIOSH maintains a list of antineoplastic and HDs utilized in health care. The health care entity **must** be reviewed at least every 12 months or it **should** be reviewed whenever a new agent is added or a new dosage form is used.

The most recent NIOSH list of antineoplastic and other HDs provides criteria to identify a HD and **must** be used.

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Drugs on the most recent NIOSH list **must** follow chapter <800> containment requirements: • Any HD and/or active pharmaceutical ingredient (API) is contained within the entity's HD list • Any antineoplastic requiring HD manipulation is contained within the entity's HD list	☐ ☐	☐ ☐	☐ ☐	
Drugs on the NIOSH list that do not have to follow all the containment requirements of chapter <800> if a risk assessment is performed and implemented include: • Final dosage forms of compounded HD preparations and conventionality manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repacking (unless required by the manufacturer)				
The risk assessment **must**, at a minimum, include: • Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only) • Dosage form • Risk of exposure • Packing • Manipulation If utilizing a risk assessment, the entity **must** document: • Alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure • Reviewed at least every 12 months • Documentation of the review at least every 12 months	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	

Types of Exposure

Unintentional routes of HDs into the body via dermal and mucosal absorption, inhalation, injection and ingestion (e.g., contamination of food, spills, or mouth contact with contaminated hands). HDs have been shown to be contaminated upon receipt. Personnel both clinical and non-clinical may be exposed to HD when contaminated surfaces are touched or while handling HDs.

Potential opportunities of exposure are listed as:

Examples of Potential Opportunities of Exposure Based on Activity[iv]	
Administration	• Generating aerosols during administration of HDs by various routes (e.g., injection, oral, inhalation or topical application) • Performing certain specialized procedures (e.g., intraoperative intraperitoneal injections or bladder instillation) • Priming an IV line
Compounding and other manipulations	• Crushing or splitting tablets or opening capsules • Pouring oral or topical liquids from one container to another • Weighting or mixing components • Constituting or reconstituting powdered or lyophilized HDs • Withdrawing or diluting injectable HDs from parenteral containers • Expelling air or HDs from syringes • Contacting HD residue present on PPE or other garments • Deactivating, decontaminating, cleaning and disinfecting areas contaminated with our suspected to be contaminated with HDs • Maintenance activities for potentially contaminated equipment and devices
Dispensing	Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces or floors
Patient-care activities	Handling body fluids (e.g., urine, feces, sweat or vomit) or body-fluid contaminated clothing, dressings, linens and other materials
Receipt	Contacting HD residues present on drug containers, individual dosage units, outer containers, work surfaces or floors
Spills	Spill generation, management and disposal
Waste	Collection and disposal of hazardous waste and trace contaminated waste
Transport	Moving HDs within a health care setting

Source: USP, *2017 USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings*, www.usp.org. Downloaded March 11, 2019.

Responsibilities of Personnel Handling Hazardous Drugs

There **must** be a designated person who is qualified and trained to be responsible for:

Developing and implementing appropriate procedures
Overseeing entity compliance with chapter <800> and other applicable laws, regulations and standards
Ensuring competency of personnel
Ensuring environmental control of the storage and compounding areas
Understanding rationale of risk-prevention policies, risks to themselves and others, risk of non-compliance that may compromise safety, responsibility to report potentially hazardous situations to the management team
Overseeing monitoring of the facility
Maintaining reports of test/sampling performed in the facility and acting on results

Facilities and Engineering Controls

Facilities and engineering controls are set forth to provide enhancement of conditions to promote patients' and workers' safety as well as environmental protections.

	Completed	In Progress	To Be Addressed	Responsible Indivdual
HDs **must** be handled under conditions that promote patient safety, worker safety and environmental protection	☐	☐	☐	
Signs designing 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 exposure likelihood	☐	☐	☐	
Designated areas **must** be available for: • Receipt and unpacking • Storage of HDs • Nonsterile HD compounding – if performed in the entity • Sterile HD compounding – if performed in the entity	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
Negative pressure in certain areas is **required** to contain HDs and minimize risk of exposure	☐	☐	☐	
Receipt				
Antineoplastic HDs and all HD APIs **must** be unpacked in an area that is neutral/normal or negative pressure relative to its surroundings	☐	☐	☐	
HDs **must not** be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas	☐	☐	☐	
Storage				
HDs **must** be stored in a manner that prevents spillage or breakage of containers if they fall	☐	☐	☐	
In areas with risk of natural disasters (e.g., earthquakes) the storage practice **must** meet applicable safety precautions (e.g., secured shelving and raised front lips shelving)	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD APIs **must** be stored separately from non-HDs in a manner that prevents contamination and personnel exposure	☐	☐	☐	
The above HDs and HD APIs **must** be stored in an externally ventilated, negative pressure room with at least 12 air exchanges per hour (ACPH)	☐	☐	☐	
Refrigerated antineoplastic HDs **must** be stored in a dedicated refrigerator in a negative pressure area with at least 12 air changes per hour (ACPH) (e.g., containment segregated compounding area (C-SCA) or storage room)	☐	☐	☐	
Compounding				
Engineering controls are required to protect the preparation from cross-contamination and if sterile, microbial contamination. Engineering controls for containment are divided into three categories of engineering control: 1. Primary – The primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs 2. Secondary – The secondary engineering control (C-SEC) is the room in which the C-PEC is placed 3. Supplementary – An example of a supplementary engineering control is a closed-system drug transfer device				
Sterile and Nonsterile Compounding				
Sterile and nonsterile HDs **must** be compounded within the C-PEC located in the C-SEC. The C-SEC used for sterile and nonsterile compounding **must**:				
Be externally vented	☐	☐	☐	
Be physically separated (i.e., a different room from other preparation areas)	☐	☐	☐	
Have appropriate air exchange (e.g., ACPH)	☐	☐	☐	
Have negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas	☐	☐	☐	
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 power loss to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC **must** be suspended immediately (If necessary, follow the manufacturer's recommendations for closure and restart)	☐	☐	☐	
A sink **must** be available for hand-washing	☐	☐	☐	
An eyewash station and/or emergency or safety precautions that meet applicable laws and regulations **must** be readily accessible	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Water sources and drains **must** be located at least 1 meter (3.28084 feet) away from the C-PEC	☐	☐	☐	
Compounding sterile and nonsterile HDs:				
The respective C-PECs **must** be placed in separate rooms (unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity)	☐	☐	☐	
Sterile and nonsterile compounding are done in the same room • They **must** be at least 1 meter (3.28084 feet) apart and particle-generating activity **must** not be performed when sterile compounding is in process	☐	☐	☐	
Nonsterile Compounding				
In addition to the <800> chapter standards, nonsterile compounding **must** follow the standards in USP <795> Pharmaceutical Compounding – Nonsterile Preparations. Engineering controls C-PEC **are not required** if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets or capsules) that do not produce particles, aerosols or gases.				
C-PECs used for manipulation of nonsterile HDs: C-PEC **must** be place in a C-SEC that has at least 12 ACH	☐	☐	☐	
Surfaces such as ceilings, walls, floors, fixtures, shoveling, counters and cabinets **must** be smooth, impervious, free from cracks and crevices and non-shedding to allow cleaning of the area	☐	☐	☐	
HDs **must** be: Vented – externally preferred or have redundant-HEPA filters in a series	☐	☐	☐	
Performed in a C-PEC that provides personnel and environmental protection, such as Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE)	☐	☐	☐	
Sterile Compounding				
NOTE: In addition to this <800> chapter, sterile compounding **must** follow standards in <797>.				
All C-PECs used for manipulation **must** be externally vented	☐	☐	☐	
Sterile HD compounding **must** be performed in a C-PEC that provides an ISO Class 5 or better air quality	☐	☐	☐	
Laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) **must not** be used for the compounding of an antineoplastic HD	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
The C-PEC **must** be located in a C-SEC (ISO Class 7 anteroom preferred)	☐	☐	☐	
If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared **must** be limited as described in <797> for CSP prepared in a segregated compounding area. (See Engineering Controls for Sterile HD Compounding in <800> for more information.)	☐	☐	☐	
ISO Class 7 Buffer Room with an ISO Anteroom				
NOTE: The C-PEC is placed in an ISO Class 7 room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACH.				
Buffer room **must** be externally vented	☐	☐	☐	
The following is **required**: Minimum of 30 ACH of HEPA-filtered supply air	☐	☐	☐	
Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent areas	☐	☐	☐	
Maintain an air quality of ISO Class 7 or better	☐	☐	☐	
NOTE: An ISO Class 7 anteroom with fixed walls is necessary to provide inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD.				
Hand-washing sink **must** be placed in the anteroom at least 1 meter (3.28084 feet) from the entrance to the HD buffer room	☐	☐	☐	
Although not recommended by facility design, if the negative-pressure buffer room is entered through a positive-pressure non-HD buffer room, the following is **required**: Line of demarcation **must** be defined within the negative-pressure buffer room for donning and doffing PPE	☐	☐	☐	
A method of transportation HDs, HD CSP and HD waste in and out of the buffer room to minimize contamination. This may be accomplished by a pass through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber **must** be included in the facility's certification to ensure that particles are not compromising the air quality in the negative-pressure buffer room	☐	☐	☐	
A refrigerator pass-through **must not** be used	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Containment Segregated Compounding Area (C-SCA)				
NOTE: The C-PEC is placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 12 ACPH.				
C-SCA **must** be externally vented	☐	☐	☐	
Containment segregated compounding area **must** have a hand-washing sink 1 meter (3.28084 feet) from C-PEC and may be either inside the C-SCA or directly outside the C-SCA	☐	☐	☐	
HD CSPs prepared in the C-SCA **must not** exceed the BUDs described in <797> for CSPs prepared in a segregated compounding area	☐	☐	☐	
Containment Supplemental Engineering Controls				
NOTE: Containment supplemental engineering controls, such as closed-system drug-transfer devices (CSTD), provide adjunct controls to offer an additional level of protection during compounding or administration. However, there is no certainty that all CSTDs will perform adequately. Until a published universal performance standard for evaluation of CSTD containment is available, users should carefully evaluate the performance claims associated with available CSTDs based on independent, peer-reviewed studies and demonstrated containment reduction.				
CSTD **must not** be used as a substitute for a C-PEC when compounding	☐	☐	☐	
CSTD **must** be used when administrating antineoplastic HDs when the dosage form allows	☐	☐	☐	
CSTDs known to be physically or chemically incompatible with a specific HD **must not** be used for that HD	☐	☐	☐	

Environmental Quality and Control

Environmental wipe sampling for HD should be performed (i.e., initially as a benchmark and at least every six months, or more often if needed, to verify containment).

A list of surface wipe sample suggestions can be found in Engineering Controls for Sterile HD Compounding, USP <800> Hazardous Drugs — Handling in Healthcare Settings (pgs. 5-6).

There are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination. There is currently no standard for acceptable limits for HD surface contamination.

Personal Protective Equipment

Personal protective equipment (PPE) provides worker protection to reduce exposure to HD aerosols and residues. Additional PPE may be required to handle the HDs outside of a C-PEC, such as patient treatment or cleaning a spill. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in health care settings.

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Disposable PPE **must not** be reused	☐	☐	☐	
Reusable PPE **must** be decontaminated and cleaned after use	☐	☐	☐	
Gowns, head, hair and shoe covers, and two pairs of chemotherapy gloves are **required** for compounding sterile and nonsterile HDs	☐	☐	☐	
Two pairs of chemotherapy gloves are **required** for administering antineoplastic HDs	☐	☐	☐	
Gowns shown to resist permeability by HDs are **required** when administering injectable antineoplastic HDs	☐	☐	☐	
For all other activities, the entity's standard operating procedure (SOP) **must** describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk, if used	☐	☐	☐	
The entity **must** develop SOPs for PPE based on the risk of the exposure and activities performed	☐	☐	☐	
Appropriate PPE **must** be worn when handling HDs including during: • Receipt • Storage • Transport • Compounding both sterile and nonsterile • Administration • Deactivation, decontamination, cleaning and disinfecting • Waste disposal • Spill control	 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	
Gloves				
When chemotherapy gloves are **required**, they **must** meet American Society for Testing and Materials (ASTM) standards D6978 (or its successor)	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Chemotherapy gloves **must** be worn and **must** be powder free because powder can contaminate the work area and can absorb and retain HDs	☐	☐	☐	
Gloves **must** be inspected for physical defects before use (Do not use gloves with pin holes or weak spots)	☐	☐	☐	
In sterile compounding, the outer chemotherapy gloves **must** be sterile	☐	☐	☐	
Gloves **must** be changed when torn, punctured or contaminated	☐	☐	☐	
Hands **must** be washed with soap and water after removing the gloves	☐	☐	☐	
Gowns				
When gowns are required, they **must** be disposable and shown to resist permeability by HDs	☐	☐	☐	
Gowns **must** be selected based on the HDs handled	☐	☐	☐	
Gowns **must** close in the backs (not in the front), be long sleeved and have closed cuffs that are elastic or knit	☐	☐	☐	
Gowns **must not** have seams or closures that could allow HDs to pass through (Cloth laboratory coasts, surgical scrubs, isolation gowns or other absorbent materials are not appropriate protective outerwear)	☐	☐	☐	
Potentially contaminated clothing **must not** be taken home under any circumstances.	☐	☐	☐	
Gowns **must** be changed per the manufacturer's information for permeation of the gown (If no permeation information is available for the gowns used, change them every 2-3 hours or immediately after a splash or spill)	☐	☐	☐	
Gowns worn in the HD handling areas **must not** be worn to other areas	☐	☐	☐	
Head, Hair, Shoe and Sleeve Covers				
Head and hair covers (including beards and moustaches), shoe covers, and sleeve covers provide protection from contact with HD residue.				
When compounding HDs a second pair of shoe covers **must** be donned before entering the C-SEC and doffed when exiting the C-SEC	☐	☐	☐	
Shoe covers worn in HD handling area **must not** be worn to other areas	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Eye and Face Protection				
Many HDs are eye and mucus membrane irritating.				
Appropriate eye and face protection **must** be worn when there is a risk for spills or splashes of HDs or HD waste outside of a C-PEC (Face shields alone do not provide full eye and face protection)	☐	☐	☐	
Goggles **must** be used when eye protection in needed (Safety glasses with side shields are not adequate)	☐	☐	☐	
Respiratory Protection				
Surgical masks do not provide respiratory protection from drug exposure and **must not** be used when respiratory protection from HD exposure is required	☐	☐	☐	
Fit test the respirator and train workers to use respiratory protection following all requirements in the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134)	☐	☐	☐	
Disposal of Used Personal Protection Equipment				
PPE **must** be placed in an appropriate waste container and further disposed of per local, state and federal regulations	☐	☐	☐	
Chemotherapy gloves and sleeve covers (if used) worn during compounding **must** be carefully removed and discarded immediately into a waste container approved for trace contaminated wasted inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC	☐	☐	☐	

Hazard Communication Program

Entities are required to have established policy and procedures that ensure worker safety during all aspects of HD handling.

	Completed	In Progress	To Be Addressed	Responsible Indivdual
The entity **must** develop SOPs to ensure effective training regarding proper labeling, transport, storage and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS)	☐	☐	☐	
Elements of the hazard communication program plan **must** include:				
• Written plan that describes how the standard will be implemented	☐	☐	☐	
• All containers of hazardous chemicals **must** be labeled, tagged or marked with the identity of the material and appropriate hazard warnings	☐	☐	☐	
• Entities **must** have an SDS for each hazardous chemical they use (29 CFR 1910.1200)	☐	☐	☐	
• Entities **must** ensure the SDS for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas	☐	☐	☐	
• Personnel who may be exposed to hazardous chemicals when working **must** be provided information and training before the initial assignment to work with a hazardous chemical and also whenever the hazard changes	☐	☐	☐	
• Personnel of reproductive capability **must** confirm in writing they understand the risks of handling HDs	☐	☐	☐	

Personnel Training

All personnel who handle HDs **must** be trained based on their job function (e.g., the receipt, storage, compounding, repackaging, dispensing, administrating and disposing of HDs).

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Training **must** occur before the employee independently handles HDs	☐	☐	☐	
The effectiveness of the training for HD handling competencies **must** be demonstrated by each employee	☐	☐	☐	
Personnel competency **must** be reassessed at least every 12 months	☐	☐	☐	
Personnel **must** be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in the process or SOP	☐	☐	☐	
All training and competency assessments **must** be documented	☐	☐	☐	
The training **must** include at least the following: • Overview of entity's list of HDs and their risks • Review of the entity's SOPs related to handling of HDs • Proper use of PPE • Proper use of equipment and devices (e.g., engineering controls) • Response to known or suspected HD exposure • Spill management • Proper disposal of HDs and trace-contaminated materials	 ☐ ☐ ☐ ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐ ☐ ☐ ☐	

Receiving

The entity **must** establish standard operating procedures (SOPs) for receiving HDs

	Completed	In Progress	To Be Addressed	Responsible Indivdual
The entity **must** establish SOPs for receiving HDs	☐	☐	☐	
HDs **must** be delivered to the HD storage area immediately after unpacking	☐	☐	☐	
PPE, including chemotherapy gloves, **must** be worn when unpacking HDs (see "Personal Protective Equipment")	☐	☐	☐	
A spill kit **must** be accessible in the receiving area	☐	☐	☐	
The entity **must** enforce policies that include a tiered approach, starting with a visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass)	☐	☐	☐	

Requirements for Receiving and Handling Damaged HD Shipping Containers				
If the shipping container appears damaged:				
Seal container without opening and contact the supplier	☐	☐	☐	
If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous"	☐	☐	☐	
If the supplier declines return, dispose of as hazardous waste	☐	☐	☐	
If a damaged shipping container must be opened:				
Seal the container in plastic or impervious container	☐	☐	☐	
Transport it to a C-PEC and place on a plastic-backed preparation mat	☐	☐	☐	
Open the package and remove undamaged items	☐	☐	☐	
Wipe the outside of the undamaged items with a disposable wipe	☐	☐	☐	
Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"	☐	☐	☐	
If the supplier declines return, dispose of as hazardous waste	☐	☐	☐	
Deactivate, decontaminate and clean the C-PEC (see *Deactivating, Decontaminating, Cleaning and Disinfecting*) and discard the mat and cleaning disposables as hazardous waste	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
When opening damaged shipping containers, they should preferably be transported to a C-PEC designated for nonsterile compounding. If a C-PEC designated is the only one available, it **must** be disinfected after the decontamination, deactivation and cleaning step before returning to any sterile compounding activity	☐	☐	☐	
Damaged packages or shipping cartons must be considered spills that **must** be reported to the designated person and managed according to the entity's SOPs	☐	☐	☐	
Cleanup **must** comply with established SOPs	☐	☐	☐	

Labeling, Packaging, Transport and Disposal

	Completed	In Progress	To Be Addressed	Responsible Indivdual
The entity **must** establish HD SOPs for: • Labeling • Packaging • Transport • Disposal	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	
SOPs **must** address: • Prevention of accidental exposures or spills • Personnel training on response to exposure and use of spill kit • Examples of exposure-reducing strategies include small-bore connectors (such as lure-lock) and syringes, syringe caps, CSTDs, the capping of container ports, sealed impervious plastic bags, impact-resistant and/or water-tight containers and cautionary labels	☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐	
Labeling				
HDs identified by the entity as requiring special HD handling precautions **must** be clearly labeled at all times during their transport	☐	☐	☐	
Personnel **must** ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas	☐	☐	☐	
Packaging				
Personnel **must** select and use packaging containers and materials that will maintain physical integrity, stability and sterility (if needed) of the HDs during transport	☐	☐	☐	
Packaging material **must** protect the HD from damage, leakage, contamination and degradation, while protecting health care workers who transport HDs	☐	☐	☐	
The entity **must** have written SOPs to describe appropriate shipping containers and insulating material, based on information from product specifications, vendors and mode of transport	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Transport				
HDs that need to be transported **must** be labeled, stored and handled in accordance with applicable federal, state and local regulations	☐	☐	☐	
HDs **must** be transported in containers that minimize the risk of breakage or leakage	☐	☐	☐	
Pneumatic tubes **must not** be used to transport any liquid HDs or any antineoplastic HDs	☐	☐	☐	
When shipping HDs to locations outside the entity the entity **must** consult the Transport Information on the SDS	☐	☐	☐	
The entity **must** ensure that labels and accessory labeling for the HDs include the following in a format that is consistent with the carrier's polices: • Storage instructions • Disposal instructions • HD category information	 ☐ ☐ ☐	 ☐ ☐ ☐	 ☐ ☐ ☐	
Disposal				
All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas **must** be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination	☐	☐	☐	
Disposal of all HD waste, including but not limited to unused HDs and trace-contaminated PPE and other materials, **must** comply with all applicable federal, state and local regulations	☐	☐	☐	

Dispensing Final Dosage Forms

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Counting or repacking **must** be done carefully	☐	☐	☐	
Tablet and capsule forms of the antineoplastic HDs **must not** be placed in automated counting or packaging machines	☐	☐	☐	

Compounding

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Entities and personnel involved in compounding HDs **must** be complaint with the appropriate USP standards for compounding including <795> and <797>	☐	☐	☐	
Compounding **must** be done in proper engineering controls as described in Compounding 5.3 section of *USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Setting*.	☐	☐	☐	
Disposable or clean equipment for compounding (such as mortars and pestles, or spatulas) **must** be dedicated for use with HDs	☐	☐	☐	
Bulk containers of liquid and API HD **must** be handled carefully to avoid spills	☐	☐	☐	
If used, APIs or other powdered HDs **must** be handled in a C-PEC, especially during particle-generating activities (such as crushing tablets, opening capsules and weighting powder)	☐	☐	☐	

Administering

	Completed	In Progress	To Be Addressed	Responsible Indivdual
HDs **must** be administered safely using protective medical devices and techniques	☐	☐	☐	

- Examples of protective medical devices include needleless and closed systems
- Examples of protective techniques include spiking or priming of IV tubing with a non-HD solution in a C-PEC and crushing tablets in a plastic pouch

Appropriate PPE **must** be worn when administering HDs	☐	☐	☐	
PPE **must** be removed and disposed of in a waste container approved for trace-contaminate HD waste at the site of drug administration.	☐	☐	☐	
Equipment, such as tubing and needles, and packaging materials **must** be disposed of properly, such as in HD waste containers after administration	☐	☐	☐	
CSTDs **must** be used for administration of antineoplastic HDs when the dosage form allows	☐	☐	☐	
Techniques and ancillary devices that minimize the risk posed by open systems **must** be used when administering HDs through certain routes	☐	☐	☐	
If HD dosage forms do require manipulation, such as crushing tablets or opening capsules for a single dose, personnel **must** don appropriate PPE and use a plastic pouch to contain any dust or particles generated	☐	☐	☐	

Deactivating, Decontaminating, Cleaning and Disinfecting

	Completed	In Progress	To Be Addressed	Responsible Indivdual
All areas where HDs are handled and all reusable equipment and devices **must** be deactivated, decontaminated and cleaned	☐	☐	☐	
Sterile compounding areas and devices **must** be subsequently disinfected	☐	☐	☐	
The entity **must** establish written procedures for decontamination, deactivation and cleaning for disinfection of sterile compounding areas	☐	☐	☐	
Cleaning of nonsterile compounding areas **must** comply with <795>	☐	☐	☐	
Cleaning of sterile compounding areas **must** comply with <797>	☐	☐	☐	
Written procedures for cleaning **must** include: • Procedure • Agents used, dilutions (if used) • Frequency requirements • Documentation requirements	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
All personnel who perform deactivation, decontamination, cleaning and disinfection activities in HD handling areas **must** be trained in appropriate procedures to protect themselves and the environment from contamination.	☐	☐	☐	
All personnel performing these above activities **must** wear appropriate PPE resistant to the cleaning agents used, including two pairs of chemotherapy gloves and impermeable disposable gowns (see "Personal Protective Equipment")	☐	☐	☐	
Eye protection and face shield **must** be used if splashing is likely	☐	☐	☐	
Respiratory protection **must** be worn if warranted by the activity	☐	☐	☐	
Deactivating, decontaminating, cleaning and disinfecting agents selected **must** be appropriate for the type of HD contaminant(s), location and surface material	☐	☐	☐	
Products **must** be compatible with the surface material (consult manufacturer or supplier information for compatibility with cleaning agents)	☐	☐	☐	
All disposable materials **must** be discarded to meet EPA regulations and entity's policies	☐	☐	☐	

	Completed	In Progress	To Be Addressed	Responsible Indivdual
Deactivation – Deactivation renders a component inert or inactive. There is no one proven method for deactivating all compounds.				
Residue from deactivation **must** be removed by decontaminating the surface	☐	☐	☐	
Decontamination – Decontamination occurs by inactivating, neutralizing or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, towels) appropriate to the area being cleaned.				
C-PEC **must** be decontaminated at least daily, when used, any time a spill occurs, before and after certification, any time voluntary interruption occurs and if the ventilation tool is moved	☐	☐	☐	
C-PES may have areas under the work tray where contamination may build – these areas **must** be deactivated, decontaminated and cleaned at least monthly	☐	☐	☐	
Cleaning – Cleaning is the process that results in the removal of contaminates (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergent, surfactant, solvents and/or other chemicals.				
No cleaning step may be performed when compounding activities are occurring	☐	☐	☐	
Disinfection – Disinfection is a process of inhibiting or destroying microorganisms.				
Before disinfection can be adequately performed surfaces **must** be cleaned	☐	☐	☐	
Disinfection **must** be done for areas intended to be sterile, including sterile compounding areas	☐	☐	☐	

Spill Control

	Completed	In Progress	To Be Addressed	Responsible Indivdual
All personnel who may be required to clean up a spill of HDs **must** receive training in spill management and the use of PPE and NIOSH-certified respirators (see "Personal Protective Equipment")	☐	☐	☐	
Spills **must** be contained and cleaned immediately only by qualified personnel with appropriate PPE	☐	☐	☐	
Qualified personnel **must** be available at all time while HDs are being handled	☐	☐	☐	
Signs **must** be available for restricting access to the spill area	☐	☐	☐	
Spill kits containing all the materials needed to clean HD spills **must** be available in all areas where HDs are routinely handled	☐	☐	☐	
If HDs are being prepared or administered in a non-routine health care area, a spill kit and respirator **must** be available	☐	☐	☐	
All spill materials **must** be disposed of as hazardous waste	☐	☐	☐	
Circumstance of the spill **must** be documented	☐	☐	☐	
Personnel who are potentially exposed during a spill or spill cleanup who have direct skin or eye contact with HDs **require** immediate evaluation	☐	☐	☐	
SOPs **must** be developed to prevent spills and to direct the cleanup of HD spills and must address: • The size and scope of the spill • Who is responsible for spill management • The type of PPE required • The location and capacity of spill kits and cleanup materials	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	☐ ☐ ☐ ☐	

Documentation and Standard Operating Procedures (SOPs)

	Completed	In Progress	To Be Addressed	Responsible Indivdual
The entity **must** maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility	☐	☐	☐	
SOPs **must** be reviewed at least every 12 months, by a designated person	☐	☐	☐	
SOPs review **must** be documented	☐	☐	☐	
Revisions in forms or records **must** be made as needed and communicated to all personnel handling HDs	☐	☐	☐	
Personnel who transport, compound or administer HDs **must** document their training according to OSHA standards (see OSHA standard 1910.120 Hazardous Waste Operations and Emergency Response) and other applicable laws and regulations	☐	☐	☐	
See USP <800> for suggested SOPs for handling HDs (pgs. 11-12).				

Medical Surveillance

Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes and use of PPE.

Elements of a medical surveillance program should be consistent with the entity's human resource polices. Suggestions can be found in USP <800> (pgs. 12-13).

Follow-up Plan – The occurrence of exposure-related health changes should prompt immediate re-evaluation of primary preventive measures (e.g., administrative and engineering controls, PPE, etc.). Entity action suggestions can be found in USP <800> (pg. 13).

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[i] The National Institute for Occupational Safety and Health (NIOSH), *Hazardous Drug Exposures in Healthcare*, https://www.cdc.gov/niosh/topics/hazdrug/default.html. Accessed 3/11/2019.
[ii] Ibid.
[iii] USP, 2017 *USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings*, www.usp.org. Downloaded March 11, 2019.
[iv] USP, 2017 *USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings*, www.usp.org. Downloaded March 11, 2019.


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