



USP <800> FAQs

USP provides answers to Frequently Asked Questions (FAQs) as a service to stakeholders and others who are seeking information regarding USP's organization, standards, standards-setting process, and other activities. These are provided for informational purposes only, and should not be construed as an official interpretation of USP text, or be relied upon to demonstrate compliance with USP standards or requirements.

USP <800> is currently informational only.

USP recognizes that entities and/or jurisdictions may be implementing <800>. In that case, USP provides the following FAQs as technical support for entities implementing <800>.

Table of Contents

- ▶ Status and Compendial Applicability
- ▶ Implementation
- ▶ Introduction and Assessment of Risk
- ▶ Personnel
- ▶ Facilities and Engineering Controls
- ▶ Containment Supplemental Engineering Controls
- ▶ Environmental Quality and Control
- ▶ Personal Protective Equipment (PPE)
- ▶ Compounding
- ▶ Hazard Communication Program
- ▶ Receiving
- ▶ Labeling, Packaging, Transport, and Disposal
- ▶ Dispensing Final Dosage Forms
- ▶ Medical Surveillance

Status and Compendial Applicability

1. How can I obtain a copy of USP <800>?

You may [download a free copy of USP <800>](#).

2. What is the scope of USP <800>?

USP <800> only applies to handling of hazardous drugs (HDs) where there is a risk of exposure to patients, healthcare workers, and the environment. USP <795> and <797> were intended to contain reference to <800>, which would make <800>



apply to compounding. For HDs, this means only when a practitioner is “compounding” (as that term is defined in <795> and <797>) would <800> be applicable. For example, since administration and dispensing final dosage forms is out of scope of <795> and <797>, <800> would not apply in this context (see [FAQ #65](#)).

3. What is the compendial status of USP <800> and when will it become official?

On December 1, 2019, when USP <800> becomes official, it will be informational and not [compendially applicable](#).

USP <800> is intended to balance patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs in healthcare facilities. Facilities should perform an assessment of risk to determine alternative containment strategies and/or necessary work practices. This is intended to be a specific evaluation of the type of HD, dosage form, risk of exposure, packaging, and manipulation. However, facilities may determine that there are no containment requirements for an assessment of risk of final dosage forms that are dispensed without further manipulation (see [FAQ #65](#)).

4. What is the purpose of this chapter?

The known risks associated with HD exposure present a compelling public health challenge. USP <800> was developed with the goal of protecting the health and safety of healthcare workers and patients who may be exposed to HDs. Official standards that provide best practices for the handling of HDs serve an important public health need.

The chapter was developed based on public health need and potential exposure of approximately [8 million U.S. healthcare workers to HDs each year](#). The public health need for developing <800> was based on published reports of adverse effects in healthcare personnel from occupational exposure to HDs.¹ USP <795> and <797> contained some information on handling of HDs. Based on the public health need and stakeholder input, the Compounding Expert Committee began developing a general chapter specific to HDs by incorporating the principles of HD compounding established in <795> and <797>. USP <800> was first published for public comment in 2014 and was based on existing guidance documents published by the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH), the American Society of Health-System Pharmacists (ASHP), and the Oncology Nursing Society (ONS). ASHP published a Technical Assistance Bulletin in 1986 and NIOSH published an alert on preventing occupational exposure in 2004. There was a known risk of HD exposure in healthcare settings from published medical reports, but there was no public standard to minimize the potential risk of exposure.

Implementation

5. How can facilities implement USP <800> in light of conflicts with provisions in currently official USP <797>?

For facilities that implement USP <800>, there are two sections that are not harmonized between the currently official <797> and <800>: 1) Segregated Compounding Area and 2) “Low volume” HD compounding. Below we point out the differences between <800> and currently official <797>. States, regulators, and accreditation bodies may make their own

¹Sessink PJ, Bos RP. Drugs hazardous to healthcare workers. Evaluation of methods for monitoring occupational exposure to cytostatic drugs. *Drug Saf.* April 1999; 20(4): 347-59.

Venitt S, Crofton-Sleigh C, Hunt J, Speechley V, Briggs K. Monitoring exposure of nursing and pharmacy personnel to cytotoxic drugs: urinary mutation assays and urinary platinum as markers of absorption. *Lancet.* Jan 1984;1(8368): 74-7.

See also <https://www.cdc.gov/niosh/topics/antineoplastic/default.html>.



determination on implementation and enforcement of USP standards. Stakeholders should speak with the appropriate regulators in their state to determine what may be required.

1. Segregated Compounding Area (SCA)

Currently official <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area.

USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 12 air changes per hour (ACPH) and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.

Note the differences in terminology and requirements in the SCA in currently official <797> and C-SCA in <800>.

- ▶ Under <800>, low- and medium- risk level HDs may be prepared in a C-SCA provided it meets the requirements in <800> and the CSP is assigned a BUD of 12 hours or less.
- ▶ If not implementing <800>, only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA (as described in <797>).

2. “Low volume” HD compounding

Currently official <797> allows facilities that prepare a “low volume” of HDs to compound these drugs in a non- negative pressure room if “two tiers of containment [e.g., closed-system drug-transfer device (CSTD) within a BSC or CACI that is located in a non-negative pressure room]” are used.

USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.

- ▶ Under <800>, HDs must be prepared in a C-SEC meeting the requirements in <800>.
- ▶ If not implementing <800>, facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) are used.

Introduction and Assessment of Risk

6. What is a hazardous drug?

A HD is any drug identified as hazardous or potentially hazardous by the [National Institute for Occupational Safety and Health \(NIOSH\)](#) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing HDs in structure or toxicity. [NIOSH maintains a list](#) of antineoplastic and other hazardous drugs used in healthcare settings.



7. What is an assessment of risk?

The assessment of risk is consideration of the type of HD, dosage form, risk of exposure, packaging, and manipulation. The chapter describes containment requirements for HD APIs and antineoplastic drugs requiring manipulation. For all dosage forms of other HDs, facilities should perform an assessment of risk to determine alternative containment strategies and/or work practices, if necessary, to minimize the risk exposure to HDs. However, during an assessment of risk of final dosage forms that are dispensed without further manipulation, facilities may determine that there are no containment requirements necessary (see [FAQ #65](#)).

8. Can I perform an assessment of risk for an entire group of HDs (i.e. Group 1, Group 2, or Group 3) instead of listing each individual HD?

No. The assessment of risk must list each drug and dosage form individually. Dosage forms of drugs within the same group might not have the same risk of exposure. For example, priming an intravenous line may have more risk of exposure than dispensing tablets without further manipulation. HDs appear on the NIOSH list based on different characteristics, such as specific reproductive risks. The facility may have the same information for several drugs or dosage forms, but the facility's list needs to be specific to the drug and dosage form.

9. What are alternative containment strategies that may be employed under an assessment of risk?

The purpose of an assessment of risk is to identify mitigation (alternate) strategies for handling dosage forms of HDs to minimize exposure to personnel in the healthcare setting and preserve patient access to medicines. Some examples of alternative strategies include purchasing HDs in unit-of-use packaging or unit-dose packaging, reassignment of pregnant personnel, and use of additional personal protective equipment (PPE).

10. Can repackaging containers of commercially available HD oral liquids into prescription containers or unit-dose packages be considered under an assessment of risk?

Yes, final dosage forms of commercially available HD oral liquids that do not require any further manipulation other than pouring and repackaging may be considered under an assessment of risk.

11. Can the reconstitution, mixing, and diluting of Group 2 and 3 HDs on the NIOSH list be performed under an assessment of risk?

Yes. The reconstitution, mixing, and dilution of dosage forms of Group 2 and 3 HDs may be considered under an assessment of risk.

12. If a NIOSH Group 1 HD is supplied as a ready to administer injection, does expelling air from the syringe prior to administration require following all of the containment requirements in the chapter?

No. If the NIOSH Group 1 HD is a final dosage form that is being prepared for immediate administration, an assessment of risk may be performed to determine alternative containment strategies and/or work practices (see USP <800> 14. Administering).



13. Can an assessment of risk be performed on concentrated solutions of HDs (i.e. hormone concentrates)?

No, concentrated solutions of HDs (i.e., hormone concentrates) are considered HD APIs that are further manipulated into a final dosage form and are subject to the containment requirements in USP <800>. USP <800> defines an API as “any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.”

Personnel

14. How much training should be required of a designated person?

The chapter does not specify a minimum number of training hours nor the type of training required. The designated person must have a thorough understanding of the chapter to be able to develop and implement appropriate procedures; oversee entity compliance with the chapter and other applicable laws, regulations, and standards; ensure competency of personnel; and ensure environmental control of the storage and compounding areas.

Facilities and Engineering Controls

15. Are there requirements for posting signs that HDs are being handled in the facility?

Yes. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. Additionally, signs must be available for restricting access to areas where HD spills occur. However, signs are not required to be posted at the entrance of facilities.

16. Can sterile and nonsterile HDs be stored together?

Yes. Sterile and nonsterile HDs may be stored together. However, HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding in order to minimize traffic into the sterile compounding area (see USP <800> 5.2 *Storage*). Additionally, antineoplastic HDs requiring manipulation (other than counting or repackaging of final dosage forms) and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 ACPH. Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy. Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (e.g., storage room, buffer room, or C-SCA).

17. Can refrigerated non-antineoplastic HDs be stored with antineoplastic HDs?

Yes, a refrigerator must be dedicated to HD storage and located in a negative pressure room with at least 12 ACPH. Refrigerated antineoplastic HDs must be stored in this dedicated refrigerator. HD APIs requiring refrigeration must also be stored according to USP <800>. Other HDs may be stored in this dedicated refrigerator or may be stored with other inventory if an assessment of risk has been performed and implemented.

18. Where should the sink be located?

Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications. Water sources and drains must be located at least 1 meter away from the Containment Primary



Engineering Control (C-PEC). Within an ISO classified area, a hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room. Within an unclassified C-SCA, a hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA.

19. Is the Containment Secondary Engineering Control (C-SEC) required to be externally vented through high-efficiency particulate air (HEPA) filtration?

No, the C-SEC must be externally vented but it does not have to be externally vented through HEPA filtration.

20. Is the C-PEC used for sterile compounding required to be exhausted to the outside or can the C-PEC be recirculated into the negative pressure C-SEC which is exhausted to the outside of the building?

USP <800> requires that all C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class II or III biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI). Class II BSC types A2, B1, or B2 are acceptable. C-PECs used for pre-sterilization procedures such as weighing and mixing must be either externally vented (preferred) or have redundant-HEPA filters in series and must provide personnel and environmental protection, such as a Class I BSC or Containment Ventilated Enclosure (CVE). A Class II BSC or a CACI may also be used.

21. Can non-HDs and HDs be compounded in C-PECs located in the same C-SEC?

Separate rooms (C-SECs) are required for sterile, nonsterile, HD, and non-HD compounding with two exceptions:

1. For entities that compound both nonsterile and sterile 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 (see USP <800> 5.3 Compounding). If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process; and
2. A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions (see USP <800> 5.3.2 *Sterile Compounding*).

22. Can a Laminar Airflow Workbench (LAFW) or compounding aseptic isolator (CAI) be used for compounding a non-antineoplastic HD?

A LAFW cannot be used for compounding an antineoplastic HD (see USP <800> 5.3.2 *Sterile Compounding*). However, for handling non-antineoplastic and reproductive risk HDs, each facility may conduct an assessment of risk and implement alternative containment strategies and/or work practices. A LAFW does not provide any protection for the worker from the HD. A LAFW or CAI may be used for non-antineoplastic HDs, however, alternative containment strategies and/or work practices must be determined during the assessment of risk.

23. Can a BSC or CACI used for compounding HDs be used for compounding non-HDs?

If a non-HD is prepared in a C-PEC where HDs have been prepared, then the non-HD must be handled and labeled as an HD. The non-HD preparation must be placed into a protective outer wrapper during removal from the C-PEC and must be labeled to require PPE handling precautions. All associated materials and wrappers should be discarded as HD waste



because the preparation and associated materials have potentially been contaminated by exposure to HDs.

24. Can the negative pressure to the C-SEC be reduced or turned off when the room is not in use?

No, the C-SEC must maintain a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent areas at all times.

25. Can the ACPH in the C-SEC be set below the minimum requirement when the C-SEC is not in use?

No, the C-SEC must have an appropriate air exchange (e.g., 12 or 30 ACPH) at all times.

26. May a CACI, isolator, robotic device, or similar device be used to compound a sterile HD outside of a C-SEC?

No. A CACI, isolator, robotic device, or similar device may act as the C-PEC if it meets the containment requirements of USP <800> as well as the requirements listed in <797>. However, the device must be placed in C-SEC meeting the requirements in <800>.

27. Can the C-PEC be used to create 100% of the external venting for the C-SEC?

Yes, if that C-PEC can function appropriately as the sole source of exhaust from a room.

28. What is meant by “fixed walls”?

Fixed walls are solid hard wall modular or ‘stick-build’ construction. Fixed walls are required to prevent the egress of HD contamination from the C-SEC (either a C-SCA or HD buffer room) as well as ingress of contamination into the ISO Class 7 HD buffer room.

29. What kind of materials may be used for the cabinets and counters in the nonsterile compounding room?

Cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding but does not limit or define the specific materials that may be used.

30. Are pressure gauges required to monitor the pressure differential between the C-SEC and the adjacent areas?

A pressure gauge and at least daily monitoring is currently required for sterile compounding in USP <797>. However, pressure monitoring is not addressed in nonsterile compounding in USP <795>, so entities should follow applicable federal, state, and local regulations. Presence of a pressure gauge and at least daily monitoring of negative pressure storage areas and nonsterile compounding areas helps ensure pressure requirements are continually maintained in these areas.



Containment Supplemental Engineering Controls (e.g., CSTDs)

31. Are CSTDs (Closed System Drug-Transfer Device) required for compounding HDs?

No, USP <800> does not require a CSTD for compounding HDs, although it is recommended. However, CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.

32. Are CSTDs required for administering HDs?

CSTDs are required for administering antineoplastic HDs when the dosage form allows as there are no other containment engineering controls protecting healthcare workers and patients. The CSTD used must be physically and chemically compatible with the specific HD. From a compendial perspective, USP <800> is not applicable to administration.

33. Is there a protocol for evaluating the performance of the different CSTDs available?

No. NIOSH initially created a draft containment test protocol for barrier-type CSTDs which it released for public comment in September 2015. Following substantial comment, NIOSH announced its intent to develop a second draft protocol, applicable to both barrier and air-cleaning (filtration) CSTDs in September 2016 and held a public meeting on the topic in November 2016. The comment period for this universal protocol has been extended several times. Neither protocol has been released in final form.

34. How can a CSTD be chemically incompatible with a HD?

Depending on the chemical composition of the drug being compounded and the composition of the CSTD device, chemical incompatibilities may exist. For example, in March 2015, FDA warned against the use of bendamustine with CSTDs, syringes, and adapters containing polycarbonate or acrylonitrile-butadiene-styrene (ABS). The component in bendamustine (N, N-dimethylacetamide (DMA)) dissolved the ABS or polycarbonate on contact.

Environmental Quality and Control

35. Is environmental wipe sampling required?

No, USP <800> recommends but does not require the performance of environmental wipe sampling. Some common marker HDs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. If no wipe sampling kit is available for the specific HDs used by the entity, the performance of environmental wipe sampling would not be appropriate.

36. Why is environmental wipe sampling recommended when there is currently no standard for acceptable limits on HD surface contamination?

Environmental wipe sampling for HD surface residue can verify the effectiveness of containment strategies and work practices. Wipe sampling kits need to be evaluated to ensure they are appropriate for HDs used by the entity. If contamination is found, the designated person must identify, document, and contain the cause of contamination. Such action may include reevaluating work practices, re-training personnel, performing thorough deactivation, decontamination, cleaning, and improving engineering controls. Wipe sampling should be repeated to validate that the deactivation/decontamination and cleaning steps have been effective.

**37. Does every area where HDs are handled require environmental sampling?**

No, USP <800> recommends, but does not require, the performance of environmental wipe sampling. The term “sampling” indicates that a portion, or sample, of the entire population be tested.

38. What are the acceptable limits for HD surface contamination?

There is currently no standard for acceptable limits for HD surface contamination. Wipe sampling helps establish a baseline and to verify containment of HDs.

Personal Protective Equipment (PPE)**39. What PPE is required for compounding HDs?**

Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are required for compounding sterile and nonsterile HDs.

40. When compounding sterile preparations in a CACI, is three pairs of gloves required?

No. Some RABS (Restricted Access Barrier System) such as gauntlet sleeves and gloves meet American Society for Testing and Materials (ASTM) D6978 (i.e., are chemotherapy rated) standards. When compounding HDs, two pairs of chemotherapy gloves are required to be worn.

41. Can gowns be re-worn during the same day if a compounder leaves the HD compounding area?

No. Disposable PPE must not be re-used. Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations. PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC.

42. What PPE is required for administering HDs?

For administering antineoplastic HDs, two pairs of chemotherapy gloves tested to American Society for Testing and Materials (ASTM) D6978 standard must be worn. For administering injectable antineoplastic HDs, gowns shown to resist permeability by HDs must be worn in addition to two pairs of chemotherapy gloves. For administering other HDs, the PPE requirements should be specified in the entity’s policies.

43. Are compounders required to remove all PPE when leaving the compounding area?

Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. The gown and outer pair of shoe covers need to be removed in the doffing area prior to leaving the negative pressure room. Other garb may remain, depending on the facilities policies and work practices. The goal is to contain all hazardous contamination within the negative pressure room.

44. Are the PPE and Engineering Controls specified in Table 5 of the current NIOSH list required?

No, the list of PPE and engineering controls in Table 5 of the 2016 NIOSH list is a recommendation and may be used to help guide the development of the entity’s policy. For all other activities, the entity’s Standard Operating Procedures



(SOPs) must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk. The entity must develop SOPs for PPE based on the risk of exposure and activities performed.

45. USP <800> does not specify PPE requirements for all HD handling activities, where can I find additional PPE recommendations?

USP <800> provides minimum PPE requirements (see <800> 7. *Personal Protective Equipment*). Facilities must determine appropriate PPE based on the HD handling activity and the facility's assessment of risk. Table 5 of the NIOSH List additionally provides recommendations to help guide the facility's PPE requirements.

46. Does USP certify or validate PPE or equipment for HD handling?

No, USP does not validate or certify PPE, equipment, or other products for compliance with USP <800>.

47. Is it required to fit-test a N95 respirator?

Yes, if a surgical N95 respirator is used, it must be fit-tested.

48. What is required to show that a gown will resist permeability by HDs?

Gowns used for HD handling must be shown to resist permeability by HDs which can be determined by testing against ASTM F739-12. Manufacturers of gowns used for handling HDs should provide results of ASTM F739-12 testing. The gown manufacturer should be able to provide permeability data for commonly used HDs.

Compounding

49. Can NIOSH listed Table 2 or 3 HDs be compounded in a positive pressure C-SEC, and if so, what are the labeling requirements?

Yes, Table 2 and 3 HDs may be compounded in a positive pressure C-SEC if an assessment of risk is performed. Facilities may determine alternative containment and work practices for HDs eligible for an assessment of risk (see USP <800> Box 1. *Containment Requirements*).

The facility must establish policies and procedures for labeling HDs. If a BSC or CACI used for the preparation of HDs is used for the preparation of a non-HD, the non-HD preparation must be placed into a protective outer wrapper during removal from the C-SEC and be labeled to require PPE handling precautions.

50. Is an entity required to have two sets of equipment, one set for compounding HDs and a second set for compounding non-HDs?

Disposable or clean equipment for compounding (such as mortars and pestles, and spatulas) must be dedicated for use with HDs. Equipment (or parts of equipment) that comes in direct contact with HDs must be dedicated for use with HDs. Equipment that does not come in direct contact with HDs may be shared between HD and non-HD compounding areas provided it is deactivated, decontaminated, and cleaned before it is removed from the HD area. Equipment used in HD compounding must be operated in the C-SEC unless it is operated as a closed system (e.g., certain mixers, terminal sterilization using an autoclave, or convection oven).



51. During nonsterile compounding with HD APIs, are all steps of the compounding process required to be performed in the C-PEC?

APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder). USP <800> requires bulk containers of liquid and API HD to be handled carefully to avoid spills. It is recognized that under some circumstances, it is not possible to perform all steps of the compounding process in the C-PEC (e.g., due to equipment size or function). For example, once nonvolatile, non-antineoplastic, powdered HDs are wet, alternative containment strategies and/or work practices may be used when using ointment mills or closed-system mixers that do not fit in the C-PEC. It is important for the safety of personnel that powdered HDs be weighed and mixed to the wet stage or made into capsules in the C-PEC. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings including instances where a C-PEC cannot be used.

52. Where should HD APIs be handled prior to sterilization when compounding sterile HDs?

Per USP <800>, presterilization procedures for high-risk level HD CSPs can occur in the HD ISO Class 7 negative pressure buffer room if the C-PEC used for the nonsterile presterilization procedures is sufficiently effective that the room can continuously maintain ISO 7 classification. In addition to <800>, sterile compounding must follow standards in USP <797> which states that presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment. If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process. Alternatively, an ISO Class 8 or better negative pressure room could be used. An ISO Class 7 negative pressure room would be necessary if it leads directly into the HD ISO 7 negative pressure buffer room.

Hazard Communication Program

53. Do personnel of reproductive capability include both male and females since the chapter requires personnel of reproductive capability confirm in writing that they understand the risks of handling HDs?

Yes, the requirement applies to anyone capable of reproduction.

Receiving

54. What PPE is required for receiving HDs?

If the HD is not eligible for an assessment of risk, at least one pair of chemotherapy gloves tested to ASTM D6978 standard must be worn when unpacking HDs (see USP <800> 10. *Receiving*). The entity's policies must address if any additional PPE is required. Table 5 of the 2016 NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings provides additional recommendations for PPE and engineering controls based the formulation of HD and the activity. The entity's policy should address situations where HDs are received in intact containers and where HDs are received in containers that may be damaged.

55. Are suppliers required to ship HDs in impervious plastic?

No. The chapter recommends that suppliers ship HDs in impervious plastic to segregate them from other drugs and allow for safety in the receiving and internal transfer process.

**56. Does the HD return waiting area have to be separate from the regular HD storage area?**

No. A separate area is not required. If the HD is not eligible for an assessment of risk, HDs waiting to be returned to the supplier must be segregated in a designated negative pressure area. The regular HD storage area may be designated for this purpose. If the HD is eligible for an assessment of risk, the facility may determine alternative containment requirements or work practices.

57. Can my unpacking or receiving area be within an existing room of my pharmacy?

Yes. Antineoplastic HDs and all HD APIs must be unpacked in an area that is normal or negative pressure relative to the surrounding areas. This can be a designated area and is not required to be a separate room.

58. What container materials are considered impervious?

The type of impervious packaging will vary with the situation and type of HD. Impervious packaging may be soft or firm. HDs must be transported in containers that minimize the risk of breakage or leakage.

59. What is the tiered approach for receiving HDs?

The tiers will be defined by the entity's SOPs based on considerations such as the facility design and types of HDs being handled.

Labeling, Packaging, Transport, and Disposal**60. Where do I find labeling requirements for HDs?**

Labeling must be compliant with federal, state, and local regulations and the appropriate USP standards for compounding including USP <795> and/or <797>, if applicable. HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport.

61. What kind of packaging containers can be used for HDs?

Packaging containers and materials that maintain physical integrity, stability, and sterility (if needed) of the HDs during transport should be used. Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. The entity must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport. Other sources of information may include the chemical or formula and the safety data sheet (SDS).

62. What are the labeling requirements when transporting HDs outside of my facility?

The facility must establish policies and procedures for labeling and transport of HDs. The required labels and labeling for the HDs include, but are not limited to, storage instructions, disposal instructions, and HD category information. This must also be consistent with the carrier's policies.

**63. Can HDs be transported in pneumatic tubes, robots, or patient carts?**

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 because of the potential for breakage and contamination.

Each facility must conduct an assessment of risk and develop SOPs accordingly.

64. Are personnel involved in waste removal and cleaning required to use PPE?

Yes, personnel must wear appropriate PPE based on their assigned tasks and as described in the entity's policies.

Dispensing Final Dosage Forms**65. What are the requirements for dispensing final dosage form HDs (e.g., conventionally manufactured products that do not require further manipulation)?**

Final dosage forms of HDs that do not require any further manipulation may be dispensed without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage). These do not require any additional storage or handling requirements according to USP <800> unless otherwise required by the manufacturer.

66. Our entity does not compound HDs but may handle final dosage forms. Are we required to have engineering controls (i.e., negative pressure storage rooms, negative pressure compounding areas)?

No. HDs that do not require further manipulation may be prepared for dispensing without further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (see USP <800> 12. *Dispensing Final Dosage Forms*).

67. Does a pre-filled syringe with an existing system of reconstitution need to be manipulated inside a C-PEC?

No. A syringe that is designed to be prefilled and/or have a self-contained system of reconstitution may be considered a final dosage form. Final dosage forms may be dispensed without additional requirements for containment (see USP <800> 12. *Dispensing Final Dosage Forms*).

68. Can automated counting and packaging machines be used to count antineoplastic HDs?

No, USP <800> states that tablets and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines, which subject them to stress and may create powdered contaminants. If permitted by the facility's assessment of risk, tablets and capsules forms of non-antineoplastic HDs may be placed in automated counting or packaging machines.

69. Can bottles of final dosage from HDs be placed on conveyor belts in a central fill pharmacy?

Facilities may determine that final dosage forms of HDs may be placed on conveyor belts based on their assessment of risk.



Medical Surveillance

70. Can an employee keep their medical records private from the employer?

Medical surveillance is recommended but not required. The entity may choose to use a contracted employee health service to perform the medical surveillance while protecting the confidentiality of the employees' personal medical information.

71. In a medical surveillance program, how does an employer obtain data from the unexposed workers for comparison to the exposed workers?

The chapter recommends an initial baseline assessment (pre-placement) of a worker's health status, medical history, and collection of data elements including a medical (including reproductive) history and work history to assess exposure to HDs, physical examination, and laboratory testing. Methods used to assess exposure history include a review of:

- ▶ Records of HDs handled, with quantities and dosage forms
- ▶ Estimated number of HDs handled per week
- ▶ Estimates of hours spent handling HDs per week and/or per month
- ▶ Performance of a physical assessment and laboratory studies linked to target organs of commonly used HDs such as a baseline complete blood count.