USP <800> FAQs

Updated: November 1, 2023

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 provides the following FAQs as technical support.

Table of Contents

Status and Compendial Applicability

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

USP provided free access to <800> on the USP website while it was an informational chapter. All compendially applicable compounding standards are available through *USP-NF* or the *USP Compounding Compendium*. As of November 1, 2023, <800> is compendially applicable thus only available through the *USP Compounding Compendium* or *USP-NF*. To learn more or purchase a subscription, please visit https://www.usp.org/products/usp-compounding-compendium.

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* <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.

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

<800> became official on December 1, 2019, and became compendially applicable to the extent to which <795> and <797> apply on November 1, 2023.

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. Based on the public health need and stakeholder input, in 2010, 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 1985 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 help minimize the potential risk of exposure.

Implementation

5. How can facilities implement <800> requirements that mention risk levels in light of the revision to <797>?

Risk levels are mentioned in <800> when describing that only low and medium-risk HD CSPs may be prepared in a C-SCA. <797> risk levels have been replaced with Category 1, 2, and 3 CSPs. Only Category 1 CSPs (both sterile-to-sterile and nonsterile-to-sterile) may be compounded in segregated compounding areas.

Introduction and Assessment of Risk

6. What is a hazardous drug?

An 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 other 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. These drugs are listed in the current NIOSH list of antineoplastic and other hazardous drugs used in healthcare settings.

7. What is the most current NIOSH list of hazardous drugs?

NIOSH maintains a list of antineoplastic and other hazardous drugs used in healthcare settings. The most current NIOSH list is the 2016 List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. Entities should consult with their regulators and oversight agencies regarding any allowance for an implementation period.

8. What does the revision bulletin, which became official on July 1, 2020, mean for entities that are implementing <800>?

USP published a revision bulletin which became official on July 1, 2020, to clarify that for the purposes of the chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH list. This revision bulletin will not result in any changes for entities implementing <800> with the 2016 NIOSH List.

9. 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 of exposure to HDs.

10. Can I perform an assessment of risk for an entire group of HDs (i.e., Table 1, Table 2) 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, crushing HD tablets or opening capsules 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.

11. 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 (alternative) 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).

12. 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.

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

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

14. If a NIOSH Table 1 Antineoplastic 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 Table 1 Antineoplastic 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*).

15. 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

16. 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 applicable laws, regulations, and standards; ensure competency of personnel; and ensure environmental control of the storage and compounding areas.

17. Is more than one designated person permitted for <800>?

Yes. The designated person is one or more individuals assigned by the facility to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded preparations. Facilities must determine whether they have one or more designated person(s), select the designated person(s), and determine how to allocate responsibility if there is more than one designated person. The designated person(s) can delegate activities to an assigned trainer provided that is described in the organization's policies.

18. Can a designated person be responsible for more than one site?

<800> does not restrict a designated person to one site. This must be determined by the facility's SOPs.

19. Does the designated person need to be a pharmacist?

There is not a requirement for the designated person to be a pharmacist.

Facilities and Engineering Controls

20. 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.

21. 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, Table 1 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. NIOSH HDs other than Table 1 antineoplastics that must be manipulated may be stored with other inventory if permitted by entity policy. Refrigerated Table 1 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).

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

Except for HDs exempted by the entity's assessment of risk, a refrigerator must be dedicated to HD storage and located in a negative pressure room with at least 12 ACPH. Refrigerated NIOSH Table 1 antineoplastic HDs must be stored in this dedicated refrigerator. HD APIs requiring refrigeration must also be stored according to *USP* <800>.

23. Can I store all my compounding components (for both non-HD and HD preparations) in the negative pressure room?

<800> requires designated areas for HD storage. Non-HD components stored in negative pressure rooms should be dedicated to use only for HD compounded preparations.

24. Can the negative pressure to the HD storage room be reduced or turned off when not in use?

No, the HD storage room must remain under negative pressure at all times.

25. 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 unclassified C-SCA, and may be either inside the C-SCA or directly outside of the C-SCA.
- Water sources and drains must be located at least 1 meter away from the door to the negative pressure buffer room to avoid contamination migration into the negative pressure HD buffer room.
- <797> allows the sink to be placed inside or outside the anteroom. When the sink is present in the anteroom, follow Section *5.3.2* of <800>.

26. What does external venting mean?

When external venting is required, it means the air must be exhausted outside of the building.

27. 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.

28. Is the C-PEC used for nonsterile compounding or weighing nonsterile ingredients to be used as components of CSPs 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?

C-PECs used for nonsterile compounding and pre-sterilization procedures such as weighing and mixing must be either externally vented (preferred) or have redundant–HEPA filters in series (that can be separately tested) 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.

29. 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 biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI). 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 (that can be separately tested) 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.

30. 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*).

31. Can a laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) be used for compounding a non-antineoplastic HD?

An LAFW cannot be used for compounding a NIOSH Table 1 antineoplastic HD (see *USP* <800> *5.3.2 Sterile Compounding*). However, for handling other HDs, each facility may conduct an assessment of risk and implement alternative containment strategies and/or work practices. An LAFW does not provide any protection for the worker from the HD. An LAFW or CAI may be used for non-antineoplastic HDs, however, alternative containment strategies and/or work practices must be documented in the assessment of risk.

32. 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 with PPE precautions. 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.

33. 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 0.010 to 0.030 inches of water column relative to all adjacent areas at all times.

34. 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.

35. 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>.

36. 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. But it may not be the best option. It depends on the air handling system, the type of C-PEC you have, the room size, and other factors.

37. What is meant by "fixed walls"?

Fixed walls are rigid 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.

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

Shelving 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.

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

A pressure gauge and at least daily monitoring is currently required for sterile compounding in *USP* <797>. A pressure gauge is required to monitor that the C-SEC for compounding nonsterile HDs is maintained at a negative pressure relative to adjacent areas.

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

40. Are closed-system drug-transfer devices (CSTDs) required for compounding HDs?

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.

41. Are CSTDs required for administering HDs?

Yes. CSTDs are required for administering Table 1 antineoplastic HDs when the dosage form allows. The CSTD used must be physically and chemically compatible with the specific HD.

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

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.

43. 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.

Environmental Quality and Control

44. Is HD environmental wipe sampling required?

USP <800> recommends but does not require the performance of HD environmental wipe sampling. Some common marker HDs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, fluorouracil, and platinum-containing drugs. Some hormones can also be assayed.

45. 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.

46. 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 HD handling area be tested.

47. 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)

48. What PPE is required for compounding HDs?

Gowns, head, hair, shoe covers, and two pairs of gloves that meet the American Society for Testing and Materials (ASTM) standard D6978 are required for compounding sterile and nonsterile HDs. ASTM has published F3267-22 (Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs) standard for chemotherapy gowns which is gaining wide acceptance in the industry.

49. When compounding sterile preparations in a CACI, are three pairs of gloves required?

When compounding HDs, two pairs of gloves that meet ASTM standard D6978 are required. When using a CACI, that means one pair on the sleeve assembly and one pair passed through the antechamber and placed over the gloves on the sleeve assembly. Depending on the CACI used and your organizational policy, some entities use an additional glove to place on the hands prior to accessing the gloves on the sleeve assembly.

50. 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.

51. 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 NIOSH Table 1 antineoplastic HDs, gowns shown to resist permeability by HDs must be worn in addition to two pairs of chemotherapy gloves. ASTM has published F3267-22 (Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs) standard for chemotherapy gowns which is gaining wide acceptance in the industry. For administering other HDs, the PPE requirements should be specified in the entity's polices.

52. 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 HD 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 facility's polices and work practices. The goal is to contain all hazardous contamination within the negative pressure room.

53. When do HD PPE components need to be removed?

The outer pair of sterile HD gloves (tested to ASTM D6978) are removed inside the C-PEC prior to leaving the C-PEC. They must be placed in a trace HD container (such as a bag or small rigid yellow bin) inside the hood.

Each negative-pressure room should have a doffing area, near the door leading to the anteroom (for a cleanroom suite) or the general area (if leaving a C-SCA). Remove the outer pair of shoe covers and the HD gown in the doffing area and discard it inside a trace HD container in the negative-pressure room just prior to leaving the room. Discard the remaining PPE in the anteroom (for a cleanroom suite) or just outside the general area (for a C-SCA) in a trace HD container.

54. Are the PPE and Engineering Controls specified in the new NIOSH document "Managing Hazardous Drug Exposure: Information for Healthcare Settings" required?

No, the list of PPE and engineering controls in "Managing Hazardous Drug Exposure: Information for Healthcare Settings" 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.

55. *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. 'Managing Hazardous Drug Exposure: Information for Healthcare Settings' additionally provides recommendations to help guide the facility's PPE requirements.

56. 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>.

57. Does an N95 respirator require fit-testing?

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

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

Manufacturers of gowns should provide this information. Gowns used for HD handling must be shown to resist permeability by HDs. The gown manufacturer should be able to provide permeability data for commonly used HDs.

Compounding

59. Can HDs that are not Table 1 antineoplastics be compounded in a positive-pressure C-SEC?

Yes, HDs that are not NIOSH Table 1 antineoplastics may be compounded in a positive-pressure C-SEC if an assessment of risk is performed. Facilities may determine alternative containment and/or 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-PEC and be labeled to require PPE handling precautions.

60. 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).

61. 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 HDs to be handled carefully to avoid spills. 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 a 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.

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

Per *USP* <800>, presterilization procedures for nonsterile-to-sterile 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 nonsterile-to-sterile CSPs, such as weighing and mixing, must 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

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

Yes, the requirement applies to anyone capable of reproduction.

Receiving

64. What PPE is required for receiving HDs?

At least one pair of chemotherapy gloves tested to ASTM D6978 standard must be worn when unpacking NIOSH Table 1 antineoplastic HDs (see *USP* <800> *10. Receiving*). The entity's policies must address PPE requirements for other HDs. NIOSH's Managing Hazardous Drug Exposure document provides additional recommendations for PPE and engineering controls based on 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 unprotected or damaged.

65. 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.

66. 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.

67. 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.

68. 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.

69. What is the tiered approach for receiving HDs?

Entities should establish safe methods to evaluate the integrity of HDs received. A tiered approach should establish if the container is damaged, and if so, the actions that need to be taken should be defined in SOPs. Examples are provided in the chapter. 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

70. 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> 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.

71. What kind of packaging containers can be used for prepackaging 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. Prepackaging tablet and capsule forms of Table 1 Antineoplastic HDs for dispensing to patients should be done using a manual system to eliminate the risk of contaminating automated systems if the HD would break.

72. What kind of packaging containers can be used for packaging HDs for transportation within the healthcare institution?

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's SOPs should describe the practices for transporting hazardous drugs within the healthcare setting (e.g., use of cleanable transport containers) and ensure safe work practices (e.g., training, access to spill kits).

73. What kind of packaging containers can be used for shipping HDs outside of the healthcare setting?

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).

74. 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.

75. What are the labeling requirements for HDs that are not Table 1 antineoplastics that are compounded in a positive-pressure C-SEC?

HDs identified by the entity as requiring special HD handling precautions must be clearly labeled at all times during their transport.

76. 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 Table 1 antineoplastic HDs because of the potential for breakage and contamination.

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

77. 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

78. 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.

79. 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*).

80. 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 as listed in its FDA-approved labeling 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*).

81. Can automated counting and packaging machines be used to count NIOSH Table 1 antineoplastic HDs?

No, *USP* <800> states that tablet 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, tablet and capsule forms of HDs that are not NIOSH Table 1 antineoplastics may be placed in automated counting or packaging machines.

82. Can bottles of final dosage form 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.

Deactivating, Decontaminating, Cleaning, and Disinfecting

83. <800> lists four steps in the cleaning process: deactivation, decontamination, cleaning, and disinfecting. What is the correct solution to use for deactivation?

Check the HD labeling for specific agents. If no specific agent is listed, use an EPA-registered oxidizer (e.g., peroxide formulations, sodium).

Medical Surveillance

84. Is a medical surveillance program required?

USP <800> recommends, but does not require, a medical surveillance program.

85. 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.