ASHRM
AMERICAN SOCIETY FOR HEALTH CARE RISK MANAGEMENT

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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