WA Pharmacy Quality Assurance Commission

2021 Responsible Manager
Pharmacy Self-Inspection Worksheet
USP 800 – Hazardous Drugs Addendum

ATTENTION: Responsible Manager or Equivalent

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this addendum within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. This worksheet does not replace **U.S. Pharmacopeia (USP) <800> Hazardous Drugs – Handling in Healthcare Settings**. (NOTE: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

This self-inspection worksheet applies only to activities performed by pharmacy personnel. Other healthcare professionals are regulated by their own boards and commissions.

Date responsible manager/change of responsible manager inspection was performed: _____

Signature of responsible manager: _____

General Rule Reference - Applies to all questions through worksheet.
RCW 18.64.270(2) "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products."

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
List of Hazardous Drugs								
			1.			Is there a list of HDs that the entity handles? ****Items on the current NIOSH list must be included.****	**USP Chapter 800- 2 LIST OF HAZARDOUS DRUGS** The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity's list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity's list. The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. Drugs on the NIOSH list that must follow the requirements in this chapter include: any HD API, any antineoplastic requiring HD manipulation… If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter. The assessment of risk must, at a minimum, consider the following: type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only); dosage form; risk of exposure; packaging; manipulation. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. If used, the assessment of risk must be reviewed at least every 12 months and the review documented.	
			2.			Is this list reviewed at least every 12 months?		
			3.			Are newly identified HDs added to the entity list of HDs?		
			4.			Is an assessment of risk performed on all HDs?		
			5.			If an assessment is not completed, are all HDs handled with all containment strategies defined in this chapter?		
			6.			Does the assessment of risk include the following:		
			6.	a		Type of HD		
			6.	b		Dosage form		
			6.	c		Risk of exposure		
			6.	d		Packaging		
			6.	e		Manipulation		
			7.			If an assessment of risk approach is taken, does the entity document what alternative containment strategies and/or work practices are being employed for specific		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				dosage forms to minimize occupational exposure?		
			8.	Is the assessment of risk reviewed at least every 12 months?		
Responsibilities of Personnel Handling Hazardous Drugs						
			9.	Does the entity have a qualified and trained designated person responsible for oversight of the entity's HD program?	**USP Chapter 800- 4 RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS** Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas. The designated person must thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team. The designated person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results. All personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.	
			10.	Does the designated person thoroughly understand the rationale for risk-prevention policies, risks to themselves and others, risks of non-compliance that may compromise safety, and the responsibility to report potentially hazardous situations to the management team?		
			11.	Is the designated person responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results?		
Facilities and Engineering Controls						
			12.	Are HDs handled under conditions that promote patient safety, worker safety, and environmental protection?	**USP Chapter 800- 5 FACILITIES AND ENGINEERING CONTROLS** HDs must be handled under conditions that promote patient safety, worker safety, and environmental	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			13.		Do areas were HDs are handled have a hazard sign displayed before the entrance?	protection. Signs designating 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 risk of exposure. Designated areas must be available for: receipt and unpacking; storage of HDs; nonsterile HD compounding (if performed by the entity); sterile HD compounding (if performed by the entity). Certain areas are required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure. Consideration should be given to uninterrupted power sources (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.	
			14.		Does the HD handling area have restricted access?		
			15.		Are HD handling areas located away from breakrooms and refreshment areas for personnel, patients, or visitors?		
			16.		Does the facility have areas designated for:		
			16.	a	Receipt and unpacking		
			16.	b	Storage of HDs		
			16.	c	Nonsterile HD compounding (if performed by the entity)		
			16.	d	Sterile HD compounding (if performed by the entity)		
			17.		Are antineoplastic HDs and HD APIs unpacked in neutral/normal or negative pressure areas?	**USP Chapter 800- 5.1 RECEIPT** Antineoplastic HDs and all HD APIs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.	
			18.		Does the facility ensure that HDs are not unpacked in sterile compounding areas or in positive pressure areas?		
			19.		Are HDs stored in a manner to prevent spills or breaks?	**USP Chapter 800- 5.2 STORAGE** HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet	
			20.		Do you have antineoplastic and API HDs stored separately from non-HDs?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			21.		Are antineoplastic HDs that require manipulation and all HD APIs stored separately from non-HDs in an externally ventilated, negative-pressure room with at least 12 ACPH?	applicable safety precautions, such as secure shelves with raised front lips. 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 air changes per hour (ACPH). Nonantineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy. Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. 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 containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.	
			22.		Are refrigerated antineoplastic HDs stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH?		
			23.		Does sterile or nonsterile compounding occur in a C-PEC located in a C-SEC?	**USP Chapter 800- 5.3 COMPOUNDING** Sterile and nonsterile HDs must be compounded within a C-PEC located in a 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 an appropriate air exchange (e.g., ACPH); have a 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 loss of power to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately. If necessary, protect the unit by covering it appropriately	
			24.		Does the C-SEC used for sterile and nonsterile compounding include:		
			24.	a	External ventilation		
			24.	b	Physical separation		
			24.	c	Appropriate air exchange		
			24.	d	Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			25.	Does the C-PEC operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding?	per the manufacturer's recommendations. Once the C-PEC can be powered on, decontaminate, clean, and disinfect (if used for sterile compounding) all surfaces and wait the manufacturer-specified recovery time before resuming compounding. A sink must be available for hand washing. An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. 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 C-PEC. 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. 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.	
			26.	Is the C-PEC decontaminated, cleaned, and disinfected prior to use if not operated continuously?		
			27.	Is a sink available for handwashing?		
			28.	Are eyewash stations and/or other emergency or safety precautions readily available?		
			29.	Are water sources and drains located to prevent interference with required ISO classifications?		
			30.	Are water sources and drains at least 1 meter from the C-PEC?		
			31.	If compounding nonsterile and sterile HDs in the same room, is the C-PEC able to maintain ISO 7 classification?		
			32.	If the C-PECs used for sterile and nonsterile compounding are placed in the same room, are they placed at least 1 meter apart and is particle-generating activity not occurring when sterile compounding is in process?		
			33.	Does the facility follow <795> for nonsterile compounding?	**USP Chapter 800- 5.3.1 NONSTERILE COMPOUNDING** In addition to this chapter, nonsterile compounding must follow standards in Pharmaceutical Compounding—Nonsterile Preparations <795>. A C-PEC is not required if manipulations are limited to handling of final dosage	
			34.	Do C-PECs used for manipulation of nonsterile HDs have either		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				external ventilation or redundant–HEPA filters in series?	forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses. The C-PECs used for manipulation of nonsterile HDs must be either externally vented (preferred) or have redundant–HEPA filters in series. Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC used only for nonsterile compounding does not require unidirectional airflow because the critical environment does not need to be ISO classified. The C-PEC must be placed in a C-SEC that has at least 12 ACPH. Table 2 summarizes the engineering controls required for nonsterile HD compounding. Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.	
			35.	Is nonsterile HD compounding performed in a C-PEC that provides personnel and environmental protection? ****A Class I Biological Safety Cabinet (BSC), Containment Ventilated Enclosure (CVE), Class II BSC, or a compounding aseptic containment isolator (CACI) may be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding is acceptable but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.****		
			36.	Is the C-PEC placed in a C-SEC that has at least 12 ACPH?		
			37.	Are surfaces in the nonsterile compounding area smooth, impervious, free from cracks and crevices, and non-shedding?		
			38.	If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, does it have a line of demarcation?	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING** Although not a recommended facility design, if the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room, the following is also required: a line of demarcation must be defined	

Compliant			#				USP Reference	Notes/Corrective Actions
Yes	No	N/A						
			39.			If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, is there a method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room that minimizes the spread of HD contamination?	within the negative-pressure buffer room for donning and doffing PPE; a method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of 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 of the negative-pressure buffer room. A refrigerator pass-through must not be used. Other methods of containment (such as sealed containers) may be used.	
			40.			Does the C-SCA meet the following:	**USP Chapter 800- 5.3.2 STERILE COMPOUNDING: CONTAINMENT SEGREGATED COMPOUNDING AREA (C-SCA)** 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. The C-SCA must be externally vented. 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. Only Category 1 HD CSPs may be prepared in a 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.	
			40.	a		Fixed walls		
			40.	b		Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas		
			40.	c		Minimum of 12 ACPH		
			40.	d		Externally vented		
			40.	e		Hand-washing sink is placed at least 1 meter from C-PEC ****The sink may be located inside the C-SCA or directly outside the C-SCA.****		
			41.			Are only Category 1 HD CSPs prepared in the C-SCA?		
			42.			Do HD CSPs comply with the BUDs in <797> for CSPs prepared in a SCA?		
			43.			Are CSTDs used when administering antineoplastics?	**USP Chapter 800- 5.4 CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS**	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
						CSTDs must be used when administering 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.	
Personal Protective Equipment							
			44.	Is disposable PPE discarded after a single use?		**USP Chapter 800- 7 PERSONAL PROTECTIVE EQUIPMENT** Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.	
			45.	Is reusable PPE decontaminated and cleaned after use?			
			46.	Is appropriate PPE worn during handling of HDs when receiving, storing, transporting, compounding, cleaning and disinfecting, administering, spill control, and waste disposal?		**USP Chapter 800- 7 PERSONAL PROTECTIVE EQUIPMENT** Gowns, head, hair, 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 injectable antineoplastic HDs. Gowns shown to resist permeability by HDs are required when administering injectable antineoplastic HDs. For all other activities, the entity's 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 exposure (see Types of Exposure) and activities performed. Appropriate PPE must be worn when handling HDs including during: receipt; storage; transport; compounding (sterile and nonsterile); administration deactivation/decontamination, cleaning, and disinfecting; spill control; waste disposal.	
			47.	If chemotherapy gloves are used, do they meet the following:		**USP Chapter 800- 7.1 GLOVES** When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor). Chemotherapy gloves should be worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs. Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs. Gloves must be inspected for physical defects before use. Do not use gloves with pin holes or	
			47.	a	ASTM standard D6978		
			47.	b	Powder-free		
			47.	c	Inspected for defects before use		
			47.	d	Sterile outer gloves used when sterile compounding		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			47.	e	Changed every 30 minutes unless otherwise recommended by the manufacturer's documentation	weak spots. When used for sterile compounding, the outer chemotherapy gloves must be sterile. Chemotherapy gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. Hands must be washed with soap and water after removing gloves.	
			47.	f	Changed when torn, punctured, or contaminated		
			48.		Are hands washed with soap and water after removing gloves?		
			49.		Do gowns meet the following requirements:	**USP Chapter 800- 7.2 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. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials. Gowns must close in the back (i.e., no open 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. 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 spill or splash. Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.	
			49.	a	Disposable		
			49.	b	Resist permeability by HDs		
			49.	c	Close in the back		
			49.	d	Long sleeved		
			49.	e	Closed cuffs that are elastic or knit		
			49.	f	Does not have seams or closures that could allow HDs to pass through		
			50.		Is potentially contaminated clothing not taken home under any circumstances?		
			51.		Are gowns changed per the manufacturer's information for permeation of the gown? ****If no permeation information is available for the gowns used, changing them every 2–3 hours or immediately after a spill or splash is acceptable.****		
			52.		Are gowns only worn in the HD handling areas?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			53.	Are two pairs of shoe covers only worn in the C-SEC?	**USP Chapter 800- 7.3 HEAD, HAIR, SHOE, AND SLEEVE COVERS** 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 areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.	
			54.	Is eye and face protection worn when there is a risk of a spill or splash?	**USP Chapter 800- 7.4 EYE AND FACE PROTECTION** Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill). A full-face piece respirator provides eye and face protection. Goggles must be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes. Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.	
			55.	If required, is appropriate respiratory protection provided and used?	**USP Chapter 800- 7.5 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.	
			56.	Is PPE placed into an appropriate waste container and disposed of per local, state, and federal regulations?	**USP Chapter 800- 7.6 DISPOSAL OF USED PERSONAL PROTECTIVE EQUIPMENT** Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.	

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			57.		Are chemotherapy gloves and sleeve covers carefully removed and discarded immediately into an approved waste container? ****Trace contaminated waste must be disposed inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.****	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. 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 waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	
Hazard Communication Program							
			58.		Does the entity have established policies and procedures that ensure worker safety during HD handling?	**USP Chapter 800- 8 HAZARD COMMUNICATION PROGRAM** Entities are required to establish policies and procedures that ensure worker safety during all aspects of HD handling. 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: a 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 that the SDSs 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 that they understand the risks of handling HDs.	
			59.		Does the entity have HD SOPs for the following:		
			59.	a	Labeling		
			59.	b	Transport		
			59.	c	Storage		
			59.	d	Disposal		
			59.	e	Use of Safety Data Sheets (SDS)		
			60.		Does the hazard communication program plan include the following:		
			60.	a	A written plan describing how the standard will be implemented		
			60.	b	Labeling, tagging, or marking of hazardous chemical containers that identify the material and include appropriate hazard warnings		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			60.	c	SDSs for each hazardous chemical used are readily available to personnel		
			60.	d	Information and training for personnel before initial assignment to work with a hazardous chemical and whenever the hazard changes		
			60.	e	Written confirmation from personnel of reproductive capability understanding the risks of handling HDs		
Personnel Training							
			61.		Are all personnel who handle HDs trained for their job functions?	**USP Chapter 800- 9 PERSONNEL TRAINING** All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of 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 process or SOP. All training and competency assessment 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.	
			62.		Does training occur before the employee independently handles HDs?		
			63.		Is effectiveness of training demonstrated by each employee?		
			64.		Is personnel competency reassessed at least every 12 months?		
			65.		Are personnel trained prior to the following:		
			65.	a	Introduction of a new HD		
			65.	b	Introduction of new equipment		
			65.	c	New or significant change in process or SOP		
			66.		Are all training and competency assessments documented?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			67.	Does the training include the following:			
			67.	a	Overview of entity's list of HDs and their risks		
			67.	b	Review of the entity's SOPs related to handling of HDs		
			67.	c	Proper use of PPE		
			67.	d	Proper use of equipment and devices		
			67.	e	Response to known or suspected HD exposure		
			67.	f	Spill management		
			67.	g	Proper disposal of HDs and trace-contaminated materials		
Receiving							
			68.	Does the entity establish SOPs for receiving HDs?		**USP Chapter 800- 10 RECEIVING** 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 visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass). When opening damaged shipping containers, they should preferably be transported to a C-PEC designated for nonsterile compounding. If a C-PEC designated for sterile compounding 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	
			69.	Are HDs delivered to the HD storage area immediately after unpacking?			
			70.	Is PPE worn when unpacking HDs?			
			71.	Is a spill kit accessible in the receiving area?			
			72.	Does the entity enforce policies regarding HD receiving?			
			73.	Is a spill kit available in the receiving area?			
			74.	If a sterile compounding C-PEC is used when opening damaged shipping containers, is it disinfected after decontamination,			

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
				deactivation, and cleaning before returning to sterile compounding activity?		person and managed according to the entity's SOPs. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. Clean-up must comply with established SOPs.	
			75.	Are damaged packages or shipping cartons:			
			75.	a	Considered spills		
			75.	b	Reported to the designated person		
			75.	c	Managed according to the entity's SOPs		
			76.	Does clean-up comply with established SOPs?			
Labeling, Packaging, Transport and Disposal							
			77.	Does the entity have SOPs for HD:		**USP Chapter 800- 11 LABELING, PACKAGING, TRANSPORT AND DISPOSAL** The entity must establish SOPs for the labeling, packaging, transport, and disposal of HDs. The SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit.	
			77.	a	Labeling		
			77.	b	Packaging		
			77.	c	Transporting		
			77.	d	Disposal		
			78.	Are HDs labeled to include special handling precautions during transport?		**USP Chapter 800- 11.1 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.	
			79.	Do labeling processes prevent introduction of contamination in non-HD handling areas?			
			80.	Does packaging maintain physical integrity, stability, and sterility during transport?		**USP Chapter 800- 11.2 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 materials must protect the HD from damage,	
			81.	Does packaging protect the HD product from damage, leakage,			

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
				contamination, and degradation during transport?	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.	
			82.	Are there written SOPs for appropriate shipping containers and insulating materials?		
			83.	Are transported HDs labeled, stored, and handled in accordance with applicable regulations?	**USP Chapter 800- 11.3 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 because of the potential for breakage and contamination. 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 storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.	
			84.	Are HDs transported in containers that minimize the risk of breakage or leakage?		
			85.	Does the entity not use pneumatic tubes to transport liquid or antineoplastic HDs?		
			86.	Does the entity consult the SDS when shipping HDs?		
			87.	Does the entity's HD labeling include storage, disposal, and HD category information consistent with the carrier's policies?		
			88.	Are personnel trained to properly dispose of HDs?	**USP Chapter 800- 11.4 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.	
			89.	Does HD disposal comply with all applicable regulations?		
Dispensing Final Dosage Forms						
			90.	Is counting or repackaging of HDs done carefully?	**USP Chapter 800- 12. DISPENSING FINAL DOSAGE FORMS**	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			91.	Does the facility not place HDs in automated counting or packaging machines?	Counting or repackaging of HDs must be done carefully. Clean equipment should be dedicated for use with HDs and should be decontaminated after every use. 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.	
Compounding						
			92.	Are the entity and personnel compliant with USP <795> and/or <797>?	**USP Chapter 800- 13 COMPOUNDING** Entities and personnel involved in compounding HDs must be compliant with the appropriate USP standards for compounding including <795> and <797>. Compounding must be done in proper engineering controls as described in Compounding. When compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC. The mat should be changed immediately if a spill occurs and regularly during use, and should be discarded at the end of the daily compounding activity. Disposable or clean equipment for compounding (such as mortars and pestles, and 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 to protect against occupational exposure, especially during particle-generating activities (such as crushing tablets, opening capsules, and weighing powder).	
			93.	Is compounding performed in proper engineering controls?		
			94.	Does the entity have equipment dedicated to HD compounding?		
			95.	Are bulk containers of liquid and API HD handled carefully to avoid spills?		
			96.	Are APIs and powdered HDs handled in a C-PEC to protect against occupational exposure?		
Are HDs administered at the facility? If yes, continue to question _____. If no, skip to question _____.						
Administering						
			97.	Are HDs administered safely using protective medical devices and techniques?	**USP Chapter 800- 14 ADMINISTERING** HDs must be administered safely using protective medical devices and techniques. Appropriate PPE must be worn	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			98.	Is appropriate PPE worn when administering HDs?	when administering HDs. After use, PPE must be removed and disposed of in a waste container approved for trace-contaminated 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.	
			99.	Is PPE removed and disposed of in an approved HD waste container at the site of drug administration?		
			100.	Are equipment and packaging materials disposed of properly after administration?		
			101.	Are CSTDs used for administration of antineoplastic HDs when the dosage form allows?		
			102.	Are techniques and ancillary devices that minimize risk from open systems used when administering HDs through certain routes?		
			103.	Do personnel don appropriate PPE and use a plastic pouch for HD manipulation?	**USP Chapter 800- 14 ADMINISTERING** If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) 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						
			104.	Are HD areas, equipment, and devices deactivated, decontaminated, and cleaned?	**USP Chapter 800- 15 DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING** All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Additionally, sterile compounding areas and devices must be subsequently disinfected. The entity must establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection. Additionally, cleaning of nonsterile compounding areas must comply	
			105.	Are sterile compounding areas and devices disinfected after cleaning?		
			106.	Does the entity have written procedures for decontamination, deactivation, cleaning, and sterile compounding area disinfection?		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			107.	Does cleaning of nonsterile compounding areas comply with <795> and cleaning of sterile compounding areas comply with <797>?	with <795> and cleaning of sterile compounding areas must comply with <797>. Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and 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 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). Additionally, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used. The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials.	
			108.	Do written procedures for cleaning include procedures, agents used, dilutions (if used), frequency, and documentation requirements?		
			109.	Are personnel who perform deactivation, decontamination, cleaning, and disinfection in HD handling areas trained?		
			110.	Do personnel wear appropriate PPE?		
			111.	Are deactivating, decontaminating, cleaning, and disinfecting agents selected appropriate?		
			112.	Are products used compatible with surface material?	**USP Chapter 800- 15 DEACTIVATING, DECONTAMINATING, CLEANING, AND DISINFECTING** The products used must be compatible with the surface material. Consult manufacturer or supplier information for compatibility with cleaning agents used. Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid spreading HD residue. All disposable materials must be discarded to meet EPA regulations and the entity's policies. Perform cleaning in areas that are sufficiently ventilated.	
			113.	Does the disposal of materials meet EPA regulations and the entity's policies?		
			114.	Is the surface decontaminated after deactivation?	**USP Chapter 800- 15.1 DEACTIVATION** Residue from deactivation must be removed by decontaminating the surface… To prevent corrosion,	

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
			115.	Is a neutralizing agent used to remove the sodium hypochlorite?	sodium hypochlorite must be neutralized with sodium thiosulfate or by following with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water, germicidal detergent, or sporicidal agent).	
			116.	Do solutions used for wiping HD packaging not alter the product label?	**USP Chapter 800- 15.2 DECONTAMINATION** The solution used for wiping HD packaging must not alter the product label. The work surface of the C-PEC must be decontaminated between compounding of different HDs. The 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-PECs may have areas under the work tray where contamination can build up. These areas must be deactivated, decontaminated, and cleaned at least monthly to reduce the contamination level in the C-PEC.	
			117.	Are work surfaces decontaminated between compounding different HDs?		
			118.	Is the C-PEC 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?		
			119.	Are areas under the work tray deactivated, decontaminated, and cleaned at least monthly in the C-PEC?		
			120.	Are surfaces cleaned before disinfection?	**USP Chapter 800- 15.4 DISINFECTION** Before disinfection can be adequately performed, surfaces must be cleaned. Disinfection must be done for areas intended to be sterile, including the sterile compounding areas.	
			121.	Are areas that are intended to be sterile disinfected?		
Spill Control						
			122.	Do personnel receive proper training in HD spill management, use of PPE, and NIOSH-certified respirators?	**USP Chapter 800- 16 SPILL CONTROL** All personnel who may be required to clean up a spill of HDs must receive proper 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	
			123.	Are spills contained and cleaned immediately by qualified personnel with appropriate PPE?		

Compliant			#			USP Reference	Notes/Corrective Actions
Yes	No	N/A					
			124.		Are qualified personnel available at all times while HDs are being handled?	all times while HDs are being handled. Signs must be available for restricting access to the spill area. Spill kits containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled. If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and respirator must be available. All spill materials must be disposed of as hazardous waste. The circumstances and management of spills must be documented. SOPs must be developed to prevent spills and to direct the cleanup of HD spills. SOPs must address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required. The management of the spill (e.g., decontamination, deactivation, and cleaning) may be dependent on the size and type of spill. The SOP must address the location of spill kits and clean-up materials as well as the capacity of the spill kit.	
			125.		Are signs available for restricting access to the spill area?		
			126.		Are spill kits readily available in all areas where HDs are routinely handled?		
			127.		If HDs are being prepared or administered in a non-routine healthcare area, is a spill kit and respirator available?		
			128.		Are spill materials disposed of as hazardous waste?		
			129.		Are the circumstances and management of spills documented?		
			130.		Do HD SOPs include the following:		
			130.	a	Spill prevention		
			130.	b	Direct the cleanup of spills		
			130.	c	Address the size and scope of the spill		
			130.	d	Specify who is responsible for spill management		
			130.	e	Type of PPE required		
			130.	f	Address the location of spill kits and clean-up materials		
			130.	g	Capacity of the spill kit		

Compliant			#		USP Reference	Notes/Corrective Actions
Yes	No	N/A				
Documentation and Standard Operating Procedures						
			131.	Does the entity have SOPs for the safe handling of HDs?	**USP Chapter 800- 17 DOCUMENTATION AND STANDARD OPERATING PROCEDURES** The entity must maintain SOPs for the safe handling of HDs for all situations in which these HDs are used throughout a facility. The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.	
			132.	Are the SOPs reviewed at least every 12 months by the designated person?		
			133.	Is the SOP review documented?		
			134.	Are revisions in forms or records made as needed and communicated to all personnel handling HDs?		
			135.	Is training documented for all personnel who handle HDs according to OSHA standards and applicable regulations?	**USP Chapter 800- 17 DOCUMENTATION AND STANDARD OPERATING PROCEDURES** 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.	