NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Hazardous Drug Compounding Inspection: Instruction Sheet and Form

(12/16/24)

The NVBOP's established self-assessment inspection process provides management the opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services.

Please have the self-assessment form completed and available for review by the first day of the month listed on your inspection notice. An inspector will review the form with you and inspect your facility during the month listed on your inspection notice.

To minimize any disruption to your facility during the inspection process please have the following available:

1. Completed Hazardous Drug Compounding Inspection form along with prior year inspection form.
2. List of compounding personnel approved to compound hazardous products.
3. Prior 12 months of competency documentation for hazardous compounding personnel.
4. Initial training documentation for all hazardous drug compounding personnel.
5. List of hazardous drugs handled at facility.
6. Stand Operating Procedures related to hazardous drugs.
7. Current assessment of risk documentation if applicable.

USP-800 became official as of July 1st, 2020.

General Information:

USP 800 applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs.

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

A list of HDs

Facility and engineering controls

Competent personnel

Safe work practices

Proper use of appropriate Personal Protective Equipment

Policies for HD waste segregation and disposal

Pharmacy Information	
Date Completed:	
Pharmacy Name:	
Pharmacy License #:	
Pharmacy Address:	
Pharmacy Telephone #:	
Pharmacy Fax #:	
Pharmacy Email:	
Managing Pharmacist Name:	
Managing Pharmacist start date:	
Name of Designated Person:	

List of Personnel Approved for Hazardous Drug Compounding

#	Name (First, Last)	License Number	Sterile/Non-Sterile/Both
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

General Information				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800	Pharmacy compounds hazardous non-sterile drugs?			
USP 800	Pharmacy compounds hazardous sterile drugs?			

List of Hazardous Drugs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 2	Does the facility maintain a list of hazardous drugs which includes any items on the current NIOSH list that the entity handles?			
USP 800 Section 2	Is the list reviewed as least every 12 months?			
USP 800 Section 2	Drugs on the NIOSH list that must follow the requirements in USP 800 include: Any HD API and any antineoplastic requiring HD manipulation.			
USP 800 Section 2	Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include: Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer)			
USP 800 Section 2	For dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and/work practices.			

USP 800 Section 2	If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in USP 800.			
USP 800 Section 2	Has the pharmacy performed an assessment of risk for any HDs?			
USP 800 Section 2	If yes, does the assessment of risk consider all of the following items: Type of HD (i.e. antineoplastic, non-antineoplastic, reproductive risk only) Dosage form Risk of exposure Packaging Manipulation			
USP 800 Section 2	Does the assessment of risk document alternative containment strategies and/or work practices employed for specific dosage forms to minimize occupational exposure?			
USP 800 Section 2	Are all assessment of risks reviewed at least every 12 months and the review documented?			

Responsibilities of Personnel Handling Hazardous Drugs				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 4	Pharmacy has a designated person who is trained and qualified to be responsible for development, oversight, and monitoring of compliance with USP 800 standards?			

Facilities and Engineering Controls				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 5	The pharmacy has a sign designating the hazard prominently displayed before the entrance to the HD handling areas?			
USP 800 Section 5	Are all HD designated areas located away from breakrooms and refreshment areas?			
USP 800 Section 5	Does the pharmacy have a designated area for all of the following? Receiving and unpacking HDs Storage of HDs Nonsterile HD compounding (if applicable) Sterile compounding (if applicable)			
USP 800 Section 5	Is access to the HD areas restricted to authorized personnel?			
Receipt				
USP 800 Section 5.1	Are antineoplastic HD and HD API unpacked in an area that is neutral/normal or negative pressure relative to the surrounding areas?			
USP 800 Section 5.1	HDs are not unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas?			
Storage				
USP 800 Section 5.2	Is all HD stock stored in a manner that prevents its spillage or breakage?			
USP 800 Section 5.2	Are all antineoplastic HDs requiring manipulation and HD API's stored separately from non-HDs?			
USP 800 Section 5.2	Are all antineoplastic HDs requiring manipulation and HD API's stored in an externally ventilated, negative pressure room with at least 12 air exchanges per hour?			
USP 800 Section 5.2	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 air exchanges per hour?			
Compounding - General				
USP 800 Section 5.3	All sterile and non-sterile compounding is performed within a C-PEC located in a C-SEC?			

USP 800 Section 5.3	Does the HD buffer room have both external ventilation and a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent unclassified areas?			
USP 800 Section 5.3	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?			
USP 800 Section 5.3	Is an eyewash station readily available?			
USP 800 Section 5.3	Waters sources and drains are located at least 1 meter away from the C-PEC?			
USP 800 Section 5.3	Does the pharmacy compound both non-sterile and sterile HDs in the same room?			
USP 800 Section 5.3	If yes to the above question are the C-PECs used for sterile and non-sterile compounding placed at least 1 meter apart and particle generating activity is not performed when sterile compounding is in process?			
Compounding – Non-Sterile				
USP 800 Section 5.3.1	The C-PECs used for manipulation of non-sterile HDs are either externally vented or have redundant-HEPA filters in series?			
USP 800 Section 5.3.1	Non-sterile compounding is performed in either a Class I biological safety cabinet, a containment ventilated enclosure, or a compounding aseptic containment isolator?			
USP 800 Section 5.3.1	The C-PEC is placed in a C-SEC that has at least 12 air exchanges per hour?			
USP 800 Section 5.3.1	Surfaces of ceilings, wall, floors, fixtures, shelving, counters, and cabinets in the non-sterile compounding area are smooth, impervious, free from cracks and crevices, and non-shedding?			
Compounding – Sterile				
USP 800 Section 5.3.2	In addition to USP 800 the pharmacy is following all of the requirements of USP 797 for sterile compounding?			
USP 800 Section 5.3.2	All C-PECs used for manipulation of sterile HDs are externally vented?			
USP 800 Section 5.3.2	Sterile HD compounding is performed in a C-PEC that provides ISO Class 5 or better air quality, such as a Class II or III BSC or CACI?			
USP 800 Section 5.3.2	The C-PEC is located in a C-SEC which is either an ISO Class 7 buffer room with an ISO Class 7 ante room or an unclassified containment segregated compounding area (C-SCA)?			
USP 800 Section 5.3.2	If the C-PEC is placed in a C-SCA then the BUD of all products is limited as described in USP 797?			
USP 800 Section 5.3.2	The C-SEC is externally vented and has a minimum of 30 air exchanges per hour?			
USP 800 Section 5.3.2	The C-SCA is externally vented and has a minimum of 12 air exchanges per hour?			
USP 800 Section 5.3.2	The ante-room has a minimum of 12 air exchanges per hour, maintains a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas, and maintains an air quality of ISO Class 7 or better?			
USP 800 Section 5.3.2	The sink in the ante-room is at least 1 meter from the entrance to the HD buffer room?			
USP 800 Section 5.3.2	Both the buffer room and ante room have fixed walls?			
Containment Supplemental Engineering Controls				
USP 800 Section 5.4	CSTD (closed system transfer device) are used when compounding and administering antineoplastic HDs when the dosage form allows?			

Environmental Quality and Controls				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 6	Does your facility conduct sampling for HD surface residue (listed as should in USP 800)?			

Personal Protective Equipment				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 7	Pharmacy has policies and procedures which describe the appropriate PPE to be worn when handling HDs and HD API's?			
USP 800 Section 7	Disposable PPE is not reused?			
USP 800 Section 7	Reusable PPE is decontaminated and cleaned after use?			
USP 800 Section 7	Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are used for compounding sterile and non-sterile HDs?			
Gloves				
USP 800 Section 7.1	Are the chemotherapy gloves worn powder free?			
USP 800 Section 7.1	The facility uses chemotherapy gloves that meet the American Society for Testing Materials (ASTM) standard D6978?			
USP 800 Section 7.1	Gloves are inspected for physical defects before use?			
USP 800 Section 7.1	When performing sterile compounding the outer glove used is sterile?			
USP 800 Section 7.1	Chemotherapy gloves are changed every 30 minutes unless otherwise recommended by the manufacturer?			
Gowns				
USP 800 Section 7.2	Gowns are disposable and shown to resist permeability by HDs?			
USP 800 Section 7.2	Gowns are closed in the back?			
USP 800 Section 7.2	Gowns have long sleeves with wrist cuffs?			
USP 800 Section 7.2	Gowns are changed every 2-3 hours or immediately after a spill or splash?			
Head, Hair, Shoe, and Sleeve Covers				
USP 800 Section 7.3	Are outer shoe covers doffed when exiting the C-SEC?			
Eye and Face Protection				
USP 800 Section 7.4	Goggles are used when eye protection is needed?			
Respiratory Protection				
USP 800 Section 7.5	Does the pharmacy provide fit tested NIOSH-certified N95 respirators to the compounding staff?			
Disposal of Used Personal Protection Equipment				
USP 800 Section 7.6	Is a designated waste container approved for trace contaminated waste used for disposal of all gloves and sleeve covers used during the compounding process?			
USP 800 Section 7.6	If the designated waste container is located outside the C-PEC are the chemo gloves and sleeve covers (if applicable) placed in a sealable bag for discard outside the C-PEC?			

Hazard Communication Program				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 8	The pharmacy has a Hazard Communication Program with written policies in place?			
USP 800 Section 8	All hazardous chemical containers are properly labeled with identity of material and appropriate hazard warning?			
USP 800 Section 8	SDS for all hazardous chemicals that are used are readily accessible to personnel during each work shift?			
USP 800 Section 8	The pharmacy has a written confirmation from all employees of reproductive capability that they understand the risks of handing HDs?			

Personnel Training				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 9	Do all personnel who handle HDs receiving training in the handling of HDs based on their job function?			
USP 800 Section 9	Are all employees reassessed every 12 months and is this documented?			
USP 800 Section 9	Does the training include all of the following: Overview of entity's list of HDs and their risks Review of SOPs related to handling of HDs Proper use of PPE Proper use of equipment and devices Spill management Proper disposal of HDs and trace-contaminated materials			

Receiving				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 10	Is PPE, including chemotherapy gloves, worn when unpacking HDs?			
USP 800 Section 10	Is there a HD spill kit in the area designated for receiving HDs?			
USP 800 Section 10	Are HDs received in a neutral/negative storage area immediately after unpacking?			
USP 800 Section 10	Does the pharmacy have a policy on HD receiving related to what steps are to be taken if a HD shipment is damaged?			
USP 800 Section 10	Are damaged HD packages considered spills and reported to the designated person and managed according to SOPs?			

Labeling, Packaging, Transport, and DIsposal				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 11.1	Are HDs requiring special handling precautions clearly labeled at all times during their transport?			
USP 800 Section 11.2	Are packaging containers and materials used that maintain the physical integrity, stability, and sterility (if needed) of the HDs during transport?			
USP 800 Section 11.3	Are HDs transported in containers that minimize the risk of breakage or leakage?			
USP 800 Section 11.3	Are pneumatic tubes ever used to transport any liquid or antineoplastic HDs?			
USP 800 Section 11.4	Are all personnel who perform routine waste removal in HD handling areas trained in appropriate procedures to protect themselves and the environment from HD contamination?			

Dispensing Final Dosage Forms				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 12	Are any neoplastic HDs ever placed in automated counting or packaging machines?			
USP 800 Section 12	Is equipment for counting or repackaging of HDs dedicated for such use and decontaminated after every use?			

Compounding				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 13	Is the pharmacy and personnel involved in compounding HDs also compliant with the appropriate USP 795 and USP 797 standards?			
USP 800 Section 13	Is all compounding of HDs and handling of HD APIs done in proper C-PEC and C-SEC engineering controls?			
USP 800 Section 13	Is a plastic backed preparation mat used when compounding HDs in a C-PEC?			

Administering				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 14	Is appropriate PPE used during the administration of HDs?			
USP 800 Section 14	Are HDs administered using protective medical devices and techniques such as needleless systems and closed system transfer devices when the dosage form allows?			
USP 800 Section 14	Are HD infusions spiked in the C-PEC?			
USP 800 Section 14	Are HD infusions primed with a non-HD solution in a C-PEC?			

Deactivating, Decontaminating, Cleaning, and Disinfecting				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 15	Does the facility have SOPs for decontamination, deactivation, cleaning, and disinfection for sterile compounding areas?			
USP 800 Section 15	Do written procedures for cleaning include: Procedures, agents used, dilutions (if used), frequency, and documentation requirements?			
USP 800 Section 15	Is written documentation available for training of all personnel who perform deactivation, decontamination, cleaning, and disinfection?			
USP 800 Section 15	Is deactivation, decontamination, and cleaning performed in all areas where non-sterile HDs are handled?			
USP 800 Section 15	Is deactivation, decontamination, cleaning, and disinfection performed in all sterile HD compounding areas?			
USP 800 Section 15	Is appropriate PPE resistant to cleaning agents used, including two pair of chemotherapy gloves and impermeable disposable gowns used when cleaning HD areas?			
USP 800 Section 15	Is appropriate eye protection, face shields, and respiratory protection used when warranted by activity?			
USP 800 Section 15	Is an EPA-registered oxidizing agent with known deactivation properties used?			
USP 800 Section 15	Are materials that have been validated to be effective for HD decontamination, or proven to be effective through testing used?			

Handling HD Spills				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 16	Does the pharmacy have SOPs developed to prevent spills and to direct the cleanup of HD spills?			
USP 800 Section 16	Do established SOPs address: The size and scope of the spill, who is responsible for spill management, type of PPE required, and location of spill kits and cleanup materials?			
USP 800 Section 16	Are personnel who may be required to clean up a spill of HD trained in spill management, the use of PPE, and a NIOSH-certified respirator?			
USP 800 Section 16	Are qualified spill cleaning personnel available at all times while HD are being handled?			
USP 800 Section 16	Are all HD spills reported to the designated person?			
USP 800 Section 16	Are spill kits containing all the materials needed to clean HD spills available in all areas where HDs are routinely handled?			

Documentation and Standard Operating Procedures				
Citation	**Question**	**Yes**	**No**	**NA**
USP 800 Section 17	Does the pharmacy have SOPs for the safe handling of HDs for all situations in which HDs are used throughout the facility?			
USP 800 Section 17	Are SOPs reviewed at least every 12 months by the designated person and the review documented?			

Notes

Your location will be inspected by an agent of the Nevada Board of Pharmacy. **All unsatisfactory conditions must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business. Please attach a copy of any documentation and corrective action you have taken to this inspection form for future review on inspection.**

Date:	
Pharmacist Printed Name:	

Pharmacist Signature:	