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<b>4. Responsibilities of Personnel Handling HDs</b>				
<i>Rationale: All personnel who handle HDs are responsible for practices and precautions to prevent patient harm, minimize worker exposure, and minimize environmental contamination.</i>				
		Yes	No	
1.	Entity designates a person to oversee compliance			
2.	Designated person is qualified and trained			
3.	Designated person monitors compliance, maintains reports of testing/ sampling			
<b>Additional Notes:</b>				

<b>5. Facilities and Engineering Controls</b>				
<i>Rationale: HDs are handled under conditions that promote patient safety, worker safety and environmental protection.</i>				
		Yes	No	Comments
1.	HD Receiving area(s):			
a.	Signs designating the hazard are displayed at entrance			
b.	Neutral or negative pressure relative to surrounding areas			
c.	No unpacking from shipping containers in sterile compounding area			
2.	HD Storage area(s):			
a.	Signs designating the hazard are displayed at entrance			
b.	No HD drugs stored on the floor			
c.	Manner of storage prevents spills and breakage			
d.	HDs stored separately from non-HDs			
e.	Refrigerated HDs stored in dedicated refrigerator			
f.	HDs stored in externally vented, negative pressure room w/ 12 ACPH			
3.	Compounding – Sterile products			<input type="checkbox"/> N/A
a.	Containment primary engineering control (C-PEC) (type: _____)			
b.	C-PEC externally vented			
b.	C-PEC operates continuously			
c.	Containment secondary engineering control (C-SEC)(room where C-PEC placed)			
d.	C-SEC externally vented through HEPA filtration			
e.	Physically separate from other preparation areas			
f.	Appropriate air exchange			
g.	Negative pressure relative to surrounding areas (0.01-0.03 in. water)			

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<b>5. Facilities and Engineering Controls</b>			
h.	Sink for handwashing		
i.	Eyewash station		
5.3.1	Compounding – Nonsterile products		<input type="checkbox"/> N/A
a.	Dedicated C-PEC (Type: _____)		
b.	C-PEC externally vented <i>or</i> redundant-HEPA filters in series		
c.	Located in C-SEC		
	C-SEC externally vented		
d.	Minimum 12 air changes per hour		
e.	Supplemental Engineering Controls used: <input type="checkbox"/> Compounding <input type="checkbox"/> Administration		

<b>6. Environmental Quality and Control</b>				
<i>Rationale: Environmental sampling for contamination is used to verify containment of HDs</i>				
		Yes	No	Comments
1.	Environmental wipe sampling is performed at baseline and every 6 months			
2.	The designated person takes action to identify, document and contain the cause when measurable contamination is found			
3.	Assesses facility & personnel compliance with USP <797> (sterile compounding)			
a.	<input type="checkbox"/> Total particle counts <input type="checkbox"/> Viable air sampling <input type="checkbox"/> Surface sampling <input type="checkbox"/> Gloved fingertip sampling <input type="checkbox"/> Appropriate growth media used			
b.	Documents facility and personnel compliance with USP <797>			
	<input type="checkbox"/> When sampling occurs <input type="checkbox"/> Where sampling occurs <input type="checkbox"/> Number of samples <input type="checkbox"/> Conditions under which sampling occurs <input type="checkbox"/> Materials required <input type="checkbox"/> Action levels			

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<b>7. Personal Protective Equipment</b>				
<i>Rationale: Appropriate PPE provides worker protection when handling HDs.</i>				
		Yes	No	Comments
7.0	SOP describes PPE to be worn for HD handling activities			
1.	Chemotherapy gloves provided			
a.	Chemotherapy gloves meet ASTM standard D6978			
b.	Sterile gloves provided for sterile compounding			
c.	Double gloves worn for HD administration			
2.	Chemotherapy gowns provided			
a.	Gowns shown to resist HD permeation			
b.	Disposable gowns provided			
3.	Head, hair, shoe, and sleeve covers provided for HD preparation			
4.	Eye and face protection provided			
5.	Respiratory protection provided			
6.	Used PPE is discarded according to local, state, and federal regulations			
Additional notes				

<b>8. Hazard Communication Program</b>				
<i>Rationale: Workers who handle HDs are informed of the risks and method of reducing exposure.</i>				
		Yes	No	Comments
1.	Written hazard communication program in place			
2.	All HD containers are labeled with a hazard warning			
3.	SDS onsite for each hazardous chemical			
4.	SDSs accessible to personnel in all locations and at all times			
5.	Personnel receive initial and updated information and training			
6.	Personnel of reproductive capability confirm understanding of risks in writing			
<b>Additional Notes</b>				

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**9. Personnel Training**

*Rationale: All personnel who handle HDs are trained based on their job functions*

		Yes	No	Comments
1.	Initial training for HD handling is provided and documented			
2.	Initial HD handling competency is evaluated			
3.	HD handling competency is validated at least every 12 months			
4.	Other potential competencies			
	<input type="checkbox"/> Environmental sampling			
	<input type="checkbox"/> Material handling			
	<input type="checkbox"/> Use of SEC			

**Additional Notes**

**10. Receiving**

*Rationale: HDs are handled safely in receiving and internal transfer process.*

		Yes	No	Comments
1.	SOPs are in place for receiving HDs			
2.	HDs are segregated from other drugs			
a.	Supplier clearly marks outer container			
b.	Single container should contain only HDs			
c.	HDs in marker container should be enclosed in impervious plastic			
3.	PPE is provided and worn by workers unpacking HDs			
4.	HDs are delivered to HD storage area immediately after unpacking			
5.	Policies address handling damaged or broken HD containers			
6.	Spill kit available in receiving			

**Additional Notes**

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### 11. Labeling, Packaging, Transport, and Disposal

*Rationale: Policies specify that HDs are labeled, packaged, and transported in a manner to minimize worker exposure*

		Yes	No	Comments
1.	HDs are clearly labeled at all times during transport			
2.	HDs are packaged to maintain integrity, stability, and sterility during transport			
3.	HDs are transported in a manner to minimize breakage, leakage			
a.	Consideration given to who transports			
b..	Pneumatic tubes are not used to transport HDs			
4.	Policies address HD waste handling based on local, state, and federal regulations			
<b>Additional Notes</b>				

### 12. Dispensing Final Dosage Forms

*Rationale: Dosage forms that are not manipulated may not need all containment requirements*

		Yes	No	Comments
1.	Dedicated equipment is used for counting and repackaging HDs			
2.	Automated counting or packaging machines are not used for solid HD forms			
3.	IV tubing attached and primed prior to adding HD's to infusion container			
4.	Designated decontamination agent used to wipe final CSP surface prior to transfer out of C-PEC			
5.	Final containers have luer lock or CSTD systems in place			
6.	Final CSP placed in zip-locked bag clearly marked			
<b>Additional Notes</b>				

### 13. Compounding

*Rationale: Compounding is performed in accordance with USP standards including 795 and 797*

		Yes	No	Comments
1.	Compounding is performed in proper engineering controls			
2.	Plastic-backed preparation mats are used on work surface of C-PEC			
3.	Equipment used for compounding HDs is dedicated for use with HDs			
<b>Additional Notes</b>				

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**14. Administering**

*Rationale: HDs are administered safely.*

		Yes	No	Comments
1.	Needleless system used			
2.	Closed System Transfer Devices (CSTDs) used when dosage form allows			
3.	Spiking and priming IV tubing <i>not</i> performed at administration site			
4.	Manipulation of dosage forms limited			
5.	All appropriate PPE available and used			
6.	Designated waste containers available			
7.	Spill kit available at sites of administration			

Additional Notes:

**15. Deactivating, Decontamination, Cleaning and Disinfecting**

*Rationale: Deactivating, decontaminating, cleaning and disinfecting reduce environmental contamination with HDs*

		Yes	No	Comments
1.	Written procedures exist for decontamination, deactivation, cleaning and for sterile compounding areas, disinfection			
2.	Policies specify agents, dilutions, frequency, and documentation requirements			
a.	Decontamination agent is EPA registered oxidizing agent			
b.	Cleaning agent contains a surfactant			
c.	Sporicidal agent is used weekly			
d.	Sterile IPA 70% used as disinfectant			
e.	Contact time documented for all agents used			
f.	Manufacturer instructions followed for use of all agents			
g.	MSDS available for all cleaning agents			
h.	Documentation of non RTU solutions available			
i.	Cleaning performed from cleanest to dirtiest			
j.	Monitoring program exists for compliance with PnP			
k.	Appropriate cleaning supplies used (mops, buckets etc.)			
l.	Cleaning equipment stored appropriately			
3.	Personnel performing activities are trained and wear appropriate PPE			
a.	Only authorized pharmacy personnel clean PEC			

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<b>15. Deactivating, Decontamination, Cleaning and Disinfecting</b>				
b.	Eye/face protection worn when cleaning and disinfection performed			
c.	Respiratory protection utilized			
d.	Gown, double gloves worn			
<b>Additional Notes:</b>				

<b>16. Spill Control</b>				
<i>Rationale: Qualified personnel available to manage HD spills; SOPs describe spill management procedures.</i>				
		Yes	No	Comments
1.	SOP for spill management in place			
2.	Spill training provided			
a.	Spill drills performed			
3.	Spill kits available in all areas where HDs are handled			
4.	Spill reporting process in place			
<b>Additional Notes</b>				

<b>17. Documentation and Standard Operating Procedures</b>				
<i>Rationale: Standard operating procedures describe the safe handling of HDs throughout the facility</i>				
1.	SOPs address entire HD safety program			
2.	SOPs are reviewed every 12 months and the review is documented			
3.	Updates to SOPs are communicated to all personnel handling HDs			
	SOP's are: <ul style="list-style-type: none"> <li><input type="checkbox"/> Clear and concise</li> <li><input type="checkbox"/> Complete with all necessary information</li> <li><input type="checkbox"/> Are objective not opinion</li> <li><input type="checkbox"/> Coherent sequential steps</li> <li><input type="checkbox"/> Consistent and used to train new staff</li> <li><input type="checkbox"/> Accessible for reference</li> </ul>			
	SOP format <ul style="list-style-type: none"> <li><input type="checkbox"/> Header that clearly identifies information</li> </ul>			



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	<ul style="list-style-type: none"> <li><input type="checkbox"/> Sections             <ul style="list-style-type: none"> <li><input type="checkbox"/> Definitions and Purpose</li> <li><input type="checkbox"/> Policy Statement</li> <li><input type="checkbox"/> Reference other Documents (internal and/or external)</li> <li><input type="checkbox"/> Procedures</li> <li><input type="checkbox"/> Documentation (sample forms)</li> </ul> </li> <li><input type="checkbox"/> Footers             <ul style="list-style-type: none"> <li><input type="checkbox"/> Page numbers</li> <li><input type="checkbox"/> Confidentiality statement</li> </ul> </li> </ul>			
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**Additional Notes:**

**18. Medical Surveillance**

*Rationale: Medical surveillance is used to minimize adverse health effects in personnel potentially exposed to HDs*

		Yes	No	Comments
1.	Entity has process to identify workers who are potentially exposed to HDs			
2.	Medical surveillance services are available onsite or by contract			
3.	Entity provides pre-placement assessment of workers who handle HDs (health history, HD exposure history, physical examination, laboratory testing).			
4.	Entity provides periodic surveillance (health history, exposure history, physical assessment, and laboratory testing if appropriate)			
5.	Entity monitors surveillance data			
6.	Entity provides exit health assessment for workers who handle HDs			
7.	Entity has plan for post-exposure follow up			
8.	Entity uses medical surveillance data to evaluate effectiveness of HD program			

Additional Notes