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## BRIEFING

⟨ 800 ⟩ **Hazardous Drugs—Handling in Healthcare Settings**, *PF* 40(3) [May–Jun. 2013]. Based on the public comments received for the proposed ⟨ 800 ⟩ in *PF* 40(3), the USP Compounding Expert Committee has developed a revised chapter. This chapter has been created to identify the requirements for receipt, storage, compounding, dispensing, and administration of hazardous drugs (HDs) to protect the patient, healthcare personnel, and environment. Facility requirements that differ from [Pharmaceutical Compounding—Sterile Preparations](#) ⟨ 797 ⟩ and this chapter will be harmonized through an upcoming revision of ⟨ 797 ⟩, which will include the following:

- Elimination of the current allowance in ⟨ 797 ⟩ for facilities that prepare a low volume of HDs that permits placement of a Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) in a non-negative pressure room. All HD compounding must be done in a separate area designated for HD compounding.
- Addition of an allowance in ⟨ 800 ⟩ for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use when compounding HDs. Low- and medium-risk HD compounded sterile preparation (CSP) may be prepared in a BSC or compounding aseptic containment isolator (CACI) located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours.

Major changes from the proposal of ⟨ 800 ⟩ in *PF* 40(3) include:

- Clarified wording in many sections.
- Removed statement concerning no acceptable level of HDs.
- Revised section on list of HDs, to allow entities to perform an assessment of risk for non-antineoplastic drugs and final dosage forms to determine alternative containment strategies and/or work practices.
- Clarified that HDs may be unpacked in either a neutral/normal or negative pressure area.
- Allowance for either external venting or redundant high-efficiency particulate air (HEPA) filtration of containment primary engineering controls (C-PECs) used for nonsterile compounding.

The proposed chapter is posted online at [www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings](http://www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings) with line numbers. Please provide the line numbers corresponding to your comments when submitting comments to [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org).

(CMP: J. Sun.) Correspondence Number—C151881

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*Add the following:*

# ◁ 800 ▷ HAZARDOUS DRUGS— HANDLING IN HEALTHCARE SETTINGS

## 1. INTRODUCTION AND SCOPE

This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.

This chapter applies to all healthcare personnel who handle HD preparations and all entities which store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.

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

- Engineering controls
- Competent personnel
- Safe work practices
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies for HD waste segregation and disposal

The chapter is organized into the following main sections:

1. [Introduction and Scope](#)
2. [List of Hazardous Drugs](#)
3. [Types of Exposure](#)
4. [Responsibilities of Personnel Handling Hazardous Drugs](#)
5. [Facilities](#)
6. [Environmental Quality and Control](#)
7. [Personal Protective Equipment](#)
8. [Hazard Communication Program](#)
9. [Personnel Training](#)
10. [Receiving](#)
11. [Labeling, Packaging, and Transport](#)
12. [Dispensing Final Dosage Forms](#)
13. [Compounding](#)

- 37 14. [Administering](#)
- 38 15. [Deactivation/Decontamination, Cleaning, and Disinfection](#)
- 39 16. [Spill Control](#)
- 40 17. [Disposal](#)
- 41 18. [Documentation and Standard Operating Procedures](#)
- 42 19. [Medical Surveillance](#)

43 [Appendix A: Acronyms and Definitions](#)

44 [Appendix B: Examples of Design for Hazardous Drugs Compounding Areas](#)

45 [Appendix C: Types of Biological Safety Cabinets](#)

46 [Appendix D: Bibliography](#)

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## 2. LIST OF HAZARDOUS DRUGS

49 The National Institute for Occupational Safety and Health (NIOSH) maintains a list of  
50 antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs,  
51 which may include items on the current NIOSH list in addition to other agents not on the  
52 NIOSH list. The entity's list must be reviewed at least annually and whenever a new  
53 agent or dosage form is used.

54 The NIOSH list of antineoplastic and other HDs provides the criteria used to identify  
55 HDs. These criteria must be used to identify HDs that enter the market after the most  
56 recent version of the NIOSH list, or that enter the entity as an investigational drug. If the  
57 information available on this drug is deemed insufficient to make an informed decision,  
58 consider the drug hazardous until more information is available.

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### Box 1: Containment Requirements

- Any antineoplastic HD requiring manipulation and HD Active Pharmaceutical Ingredients (API) on the NIOSH list must follow the requirements in this chapter.
  - Final antineoplastic dosage forms that do not require any further manipulation other than counting final dosage forms may be dispensed without any further requirements for containment unless required by the manufacturer.
- 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.

60 Some dosage forms of drugs defined as hazardous may not pose a significant risk of  
61 direct occupational exposure because of their dosage formulation (e.g., tablets or  
62 capsules—solid, intact medications that are administered to patients without modifying  
63 the formulation). However, dust from tablets and capsules may present a risk of  
64 exposure by skin contact and/or inhalation. An assessment of risk may be performed for  
65 these dosage forms to determine alternative containment strategies and/or work  
66 practices.

67 The assessment of risk must, at a minimum, consider the following:

- 68 • Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk)
- 69 • Risk of exposure
- 70 • Packaging
- 71 • Manipulation

72 If an assessment of risk approach is taken, the entity must document what alternative  
 73 containment strategies and/or work practices are being employed for specific dosage  
 74 forms to minimize occupational exposure. If used, the assessment of risk must be  
 75 reviewed at least annually and the review documented.

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### 3. TYPES OF EXPOSURE

78 Routes of unintentional entry of HDs into the body include dermal and mucosal  
 79 absorption, inhalation, injection, and ingestion (e.g., contaminated foodstuffs, spills, or  
 80 mouth contact with contaminated hands). Both clinical and nonclinical personnel may be  
 81 exposed to HDs when they handle HDs or touch contaminated surfaces. [Table 1](#) lists  
 82 examples of potential routes of exposure based on activity.

83 **Table 1. Examples of Potential Routes of Exposure Based on Activity**

Activity	Potential Route of Exposure
Dispensing	<ul style="list-style-type: none"> <li>• Counting tablets and capsules from bulk containers</li> </ul>
Compounding	<ul style="list-style-type: none"> <li>• Crushing tablets or opening capsules</li> <li>• Pouring oral or topical liquids from one container to another</li> <li>• Weighing or mixing components</li> <li>• Constituting or reconstituting powdered or lyophilized HDs</li> <li>• Withdrawing or diluting injectable HDs from parenteral containers</li> <li>• Expelling air or HDs from syringes</li> <li>• Contacting HD residue present on PPE or other garments</li> <li>• Deactivating, decontaminating, cleaning, and disinfecting areas contaminated with or suspected to be contaminated with HDs</li> <li>• Maintenance activities for potentially contaminated equipment and devices</li> </ul>
Administration	<ul style="list-style-type: none"> <li>• Generating aerosols during administration of HDs by various routes (e.g. injection, irrigation, oral, inhalation, or topical application)</li> <li>• Performing certain specialized procedures (e.g., intraoperative intraperitoneal injection or bladder instillation)</li> <li>• Priming an IV administration set</li> </ul>
Patient-care activities	<ul style="list-style-type: none"> <li>• Handling body fluids (e.g., urine, feces, sweat, or vomit) or body-fluid-contaminated clothing, dressings, linens, and other</li> </ul>

Activity	Potential Route of Exposure
	materials
Spills	<ul style="list-style-type: none"> <li data-bbox="508 333 1154 367">• Spill generation, management, and disposal</li> </ul>
Receipt	<ul style="list-style-type: none"> <li data-bbox="508 415 1386 520">• Contacting with HD residues present on drug container, individual dosage units, outer containers, work surfaces, or floors</li> </ul>
Transport	<ul style="list-style-type: none"> <li data-bbox="508 575 1084 609">• Moving HDs within a healthcare setting</li> </ul>

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#### 4. RESPONSIBILITIES OF PERSONNEL HANDLING HAZARDOUS DRUGS

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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 individual 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 individual must also be responsible for the continuous monitoring of the facility and maintaining reports of testing/sampling performed in facilities.

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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 care environment.

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#### 5. FACILITIES

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HDs must be handled under conditions that promote patient safety, worker safety, environmental protection, and infection prevention. 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. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas.

Designated areas must be available for:

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- Receipt and unpacking of antineoplastic HDs or HD API
- Storage of HDs
- Nonsterile HD compounding (if performed by the entity)
- Sterile HD compounding (if performed by the entity)

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### 5.1 Receipt

115 Antineoplastic HDs and APIs must be unpacked (i.e., removal from external shipping  
116 containers) in an area that is neutral/normal or negative pressure relative to the  
117 surrounding areas. HDs must not be unpacked from their shipping containers in sterile  
118 compounding areas or in positive pressure areas.

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### 5.2 Storage

120 HDs must be stored in a manner that prevents spillage or breakage if the container  
121 falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters  
122 (e.g., earthquakes) the manner of storage must meet applicable safety precautions,  
123 such as secure shelves with raised front lips.

124 Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic  
125 HDs may be stored with other inventory. Antineoplastic HDs requiring manipulation  
126 other than counting final dosage forms and any HD API must be stored separately from  
127 non-HDs in a manner that prevents contamination and personnel exposure. These HDs  
128 must be stored in a negative-pressure room with at least 12 air changes per hour  
129 (ACPH).

130 Sterile and nonsterile HDs may be stored together. Depending upon facility design,  
131 HDs may be stored within a negative pressure buffer room with at least 12 ACPH.  
132 However, only HDs used for sterile compounding may be stored in the negative  
133 pressure buffer room.

134 Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a  
135 negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or  
136 containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a  
137 negative pressure buffer room, an exhaust located adjacent to the refrigerator's  
138 compressor and behind the refrigerator should be considered.

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### 5.3 Compounding

140 Engineering controls are required to protect the preparation from cross-contamination  
141 and microbial contamination (if preparation is intended to be sterile) during all phases of  
142 the compounding process. Engineering controls for containment are divided into three  
143 categories representing primary, secondary, and supplementary levels of control. A  
144 containment primary engineering control (C-PEC) is a ventilated device designed to  
145 minimize worker and environmental HD exposure when directly handling HDs.  
146 Containment secondary engineering controls (C-SEC) is the room in which the C-PEC  
147 is placed. Supplemental engineering controls [e.g., closed-system drug-transfer device  
148 (CSTD)] are adjunct controls to offer additional levels of protection. *Appendix B* provides  
149 examples for designs of HD compounding areas.

150 Sterile and nonsterile HDs must be compounded within a C-PEC located in a C-SEC.  
151 The C-SEC used for sterile and nonsterile compounding must:

- 152 • Be externally vented through high-efficiency particulate air (HEPA) filtration
- 153 • Be physically separated (i.e., a different room from other preparation areas)
- 154 • Have a negative pressure between 0.01 and 0.03 inches of water column

155 The C-PEC must operate continuously if used for sterile compounding or if the C-PEC  
156 supplies the negative pressure. If there is any loss of power to the unit, or if repair or  
157 moving occurs, all activities occurring in the C-PEC must be suspended immediately. If  
158 necessary, protect the unit by covering it appropriately per the manufacturer's  
159 recommendations. Once the C-PEC can be powered on, decontaminate, clean, and  
160 disinfect (if used for sterile compounding) all interior surfaces and wait the  
161 manufacturer-specified recovery time before resuming compounding.

162 A sink must be available for hand washing as well as emergency access to water for  
163 removal of hazardous substances from eyes and skin. An eyewash station and/or other  
164 emergency or safety precautions that meet applicable laws and regulations must be  
165 readily available. However, care must be taken to locate them in areas where their  
166 presence will not interfere with required ISO classifications.

167 For entities that compound both nonsterile and sterile HDs, the respective C-PECs  
168 must be placed in segregated rooms separate from each other, unless those C-PECs  
169 used for nonsterile compounding are sufficiently effective that the room can  
170 continuously maintain ISO 7 classification throughout the nonsterile compounding  
171 activity. If the C-PECs used for sterile and nonsterile compounding are placed in the  
172 same room, they must be placed at least 1 meter apart and particle-generating activity  
173 must not be performed when sterile compounding is in process.

#### 174 **5.3.1 NONSTERILE COMPOUNDING**

175 In addition to this chapter, nonsterile compounding must follow standards in  
176 [Pharmaceutical Compounding—Nonsterile Preparations](#) ( 795 ). A C-PEC is not  
177 required if manipulations are limited to handling of final dosage forms (e.g., tablets and  
178 capsules) that do not produce particles, aerosols, or gasses.

179 The C-PECs used for manipulation of nonsterile HDs must be either externally vented  
180 (preferred) or redundant–HEPA filtered in series. Nonsterile HD compounding must be  
181 performed in a C-PEC that provides personnel and environmental protection, such as a  
182 Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A  
183 Class II BSC or a compounding aseptic containment isolator (CACI) may be also be  
184 used. For occasional nonsterile HD compounding, a C-PEC used for sterile  
185 compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated,  
186 cleaned, and disinfected before resuming sterile compounding in that C-PEC. A C-PEC  
187 used only for nonsterile compounding does not need to have unidirectional airflow  
188 because the critical environment does not need to be ISO classified.

189 The C-PEC must be placed in a C-SEC that has at least 12 ACPH. [Table 2](#)  
190 summarizes the engineering controls required for nonsterile HD compounding.

191 Due to the difficulty of cleaning HD contamination from surfaces, the architectural  
192 finish requirements (e.g., smooth, seamless, and impervious surfaces) described in  
193 [Pharmaceutical Compounding—Sterile Preparations](#) ( 797 ) also apply to nonsterile  
194 compounding areas.

195 **Table 2. Engineering Controls for Nonsterile HD Compounding**

<b>C-PEC</b>	<b>C-SEC Requirements</b>
• Externally vented (preferred) or redundant–HEPA filtered in series	• 12 ACPH • Externally vented

C-PEC	C-SEC Requirements
<ul style="list-style-type: none"> <li>Examples: CVE, Class I or II BSC, CACI</li> </ul>	<ul style="list-style-type: none"> <li>Negative pressure between 0.01 and 0.03 inches of water column</li> </ul>

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### 5.3.2 STERILE COMPOUNDING

In addition to this chapter, applicable sterile compounding standards in [\( 797 \)](#) must be followed.

All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides a Class 5 or better air quality, such as a Class II or III BSC, or CACI. Class II BSC types A2, B1, or B2 are all acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components. *Appendix C* describes the different types of BSCs.

A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic HD. A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.

The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room (preferred) or an unclassified containment segregated compounding area (C-SCA). 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 defined in [\( 797 \)](#) for CSPs prepared in a segregated compounding area. *Table 3* summarizes the engineering controls required for sterile HD compounding.

**Table 3. Engineering Controls for Sterile HD Compounding**

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 Buffer Room	<ul style="list-style-type: none"> <li>Externally Vented</li> <li>Examples: Class II BSC or CACI</li> </ul>	<ul style="list-style-type: none"> <li>30 ACPH</li> <li>Externally vented</li> <li>Negative pressure between 0.01 and 0.03 inches of water column</li> </ul>	As described in <a href="#">( 797 )</a>
C-SCA	<ul style="list-style-type: none"> <li>Externally Vented</li> <li>Examples: Class II BSC or CACI</li> </ul>	<ul style="list-style-type: none"> <li>12 ACPH</li> <li>Externally vented</li> <li>Negative pressure between 0.01 and 0.03 inches of water column</li> </ul>	As described in <a href="#">( 797 )</a> for segregated compounding area

218 **ISO class 7 buffer room:** The C-PEC may be placed in an ISO Class 7 buffer room  
219 that has a negative pressure between 0.01 and 0.03 inches of water column and has a  
220 minimum of 30 ACPH of HEPA-filtered supply air.

221 Because the room through which entry into the HD buffer room (e.g., ante-area or non-  
222 HD buffer room) plays an important role in terms of total contamination control, the  
223 following is required:

- 224 • Minimum of 30 ACPH of HEPA-filtered supply air
- 225 • Maintain a positive pressure of 0.02 inches of water column relative to all  
226 adjacent unclassified spaces
- 227 • Maintain an air quality of ISO Class 7 or better

228 This provides for inward air migration of equal cleanliness classified air into the  
229 negative pressure buffer room to contain any airborne HD. A hand-washing sink must  
230 be placed at least 1 meter from the entrance of the buffer room to avoid contamination  
231 migration into the negative pressure HD buffer room.

232 Although not a recommended facility design, if the negative-pressure HD buffer room  
233 is entered though the positive-pressure non-HD buffer room, the following is required:

- 234 • A line of demarcation must be defined within the negative-pressure buffer area  
235 for garbing and degarbing
- 236 • A method to transport HDs, CSPs, and waste into and out of the negative  
237 pressure buffer room to minimize the spread of HD contamination. This may be  
238 accomplished by use of a pass-through between the negative-pressure buffer  
239 area and adjacent space. The pass-through must be included in the facility's  
240 certification to ensure that particles are not compromising the air quality of the  
241 negative-pressure buffer room. Do not use a refrigerator pass-through. Other  
242 methods of containment (such as sealed containers) may be used if the entity  
243 can demonstrate HD containment and appropriate environmental control.

244 HD CSPs prepared in an ISO Class 7 buffer room may use the BUDs described in {  
245 [797](#)}, based on the categories of CSP, sterility testing, and storage temperature.  
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247 **Containment segregated compounding area (C-SCA):** The C-PEC may be placed  
248 in an unclassified C-SCA that has a negative pressure between 0.01 and 0.03 inches of  
249 water column relative to all adjacent spaces and has a minimum of 12 ACPH of HEPA-  
250 filtered supply air. A hand-washing sink must be placed at least 1 meter from C-PEC.

251 Only low- and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs  
252 prepared in the C-SCA must not exceed the BUDs described in { [797](#) } for CSPs  
253 prepared in a segregated compounding area.

#### 254 **5.4 Containment Supplemental Engineering Controls**

255 Containment supplemental engineering controls, such as CSTDs, provide adjunct  
256 controls to offer additional levels of protection during compounding or administration.  
257 Some CSTDs have been shown to limit the potential of generating aerosols during  
258 compounding. However, there is no certainty that all CSTDs will perform adequately.

259 Since there is no published universal performance standard for evaluation of CSTD  
260 containment, users should carefully evaluate the performance claims associated with  
261 available CSTDs based on independent studies and demonstrated containment  
262 reduction.

263 A CSTD must not be used as a substitute for a C-PEC when compounding. CSTDs  
264 should be used when compounding HDs when the dosage form allows. CSTDs must be  
265 used when administering HDs when the dosage form allows.

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## 6. ENVIRONMENTAL QUALITY AND CONTROL

268 Environmental wipe sampling should be performed routinely (e.g., initially as a  
269 benchmark and at least every 6 months, or more often as needed, to verify  
270 containment). Surface wipe sampling should include:

- 271 • Interior of the C-PEC and equipment contained in it
- 272 • Staging or work areas near the C-PEC
- 273 • Areas adjacent to C-PECs (e.g., floors directly under staging and dispensing  
274 area)
- 275 • Patient administration areas

276 There are currently no studies demonstrating the effectiveness of a specific number or  
277 size of wipe samples in determining levels of HD contamination. Wipe sampling kits  
278 should be verified before use to ensure the method and reagent used have been tested  
279 to recover a specific percentage of known marker drugs from various surface types  
280 found in the sampled area. There are currently no certifying agencies for vendors of  
281 wipe sample kits.

282 There is currently no standard for acceptable limits for HD surface contamination.  
283 Common marker HDs that can be assayed include cyclophosphamide, ifosfamide,  
284 methotrexate, fluorouracil, and platinum-containing drugs. An example of measurable  
285 contamination would be cyclophosphamide levels  $>1.00 \text{ ng/cm}^2$ , which were shown in  
286 some studies to result in uptake of the drug in exposed workers. If any measurable  
287 contamination is found, the compounding supervisor must identify, document, and  
288 contain the cause of contamination. Such action may include reevaluating work  
289 practices, re-training personnel, performing thorough deactivation/decontamination and  
290 cleaning, and improving engineering controls. Repeat the wipe sampling to validate that  
291 the deactivation/decontamination and cleaning steps have been effective.

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## 7. PERSONAL PROTECTIVE EQUIPMENT

294 Personal Protective Equipment (PPE) provides worker protection to reduce exposure  
295 to HD aerosols and residues. When performing a task in situations where C-PECs are  
296 not generally available, such as treating a patient or cleaning a spill, additional PPE may  
297 be required. The NIOSH list of antineoplastic and other HDs provides some general  
298 guidance on PPE for possible scenarios that may be encountered in healthcare  
299 settings.

300 Gloves, gowns, head, hair, and shoe covers are required for compounding sterile and  
301 nonsterile HDs. Gloves are required for administering antineoplastic HDs. Gowns are

302 required when administering injectable antineoplastic HDs. For all other activities, the  
303 entity's SOP must describe the appropriate PPE to be worn based on its occupational  
304 safety plan and assessment of risk (if used). The entity must develop SOPs for PPE  
305 based on the risk of exposure (see *Types of Exposure*) and activities performed.

306 Appropriate PPE must be worn when handling HDs including during:

- 307 • Receipt
- 308 • Storage
- 309 • Transport
- 310 • Compounding (sterile and nonsterile)
- 311 • Administration
- 312 • Deactivation/Decontamination, Cleaning, and Disinfecting
- 313 • Spill Control

### 314 **7.1 Gloves**

315 When required, chemotherapy gloves must be tested to American Society for Testing  
316 and Materials (ASTM) standard D6978 (or its successor). Chemotherapy gloves must  
317 be powder-free because powder can contaminate the work area and can adsorb and  
318 retain HDs. Gloves must be inspected for physical defects before use. Do not use  
319 gloves with pin holes or weak spots.

320 Chemotherapy gloves must be changed every 30 min or when torn, punctured, or  
321 contaminated.

### 322 **7.2 Gowns**

323 When required, disposable gowns must be tested and shown to resist permeability by  
324 HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of  
325 polyethylene-coated polypropylene or other laminate materials offer better protection  
326 than those made of uncoated materials. Gowns must close in the back (i.e., no open  
327 front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not  
328 have seams or closures that could allow HDs to pass through.

329 Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials  
330 are not appropriate outerwear when handling HDs because they permit the permeation  
331 of HDs and can hold spilled drugs against the skin, thereby increasing exposure.  
332 Clothing may also retain HD residue from contact, and may transfer to other healthcare  
333 workers or various surfaces. Washing of non-disposable clothing contaminated with HD  
334 residue may transfer drug residue to other clothing.

335 Gowns must be changed per the manufacturer's information for permeation of the  
336 gown. If no permeation information is available for the gowns used, change them every  
337 2–3 hours or immediately after a spill or splash. Gowns worn in HD handling areas must  
338 not be worn to other areas in order avoid spreading HD contamination and exposing  
339 other healthcare workers.

### 340 **7.3 Head, Hair, Shoe, and Sleeve Covers**

341 Head and hair covers (including beard and moustache, if applicable) and shoe covers  
342 provide protection from contact with HD residue on surfaces and floors. When  
343 compounding sterile HDs, a second pair of shoe covers must be donned before entering

344 the buffer room and removed when exiting the buffer room. Shoe covers worn in HD  
345 handling areas must not be worn to other areas to avoid spreading HD contamination  
346 and exposing other healthcare workers.

347 Disposable sleeve covers constructed of coated materials may be used to protect  
348 areas of the arm that may come in contact with HDs. If used, sleeve covers must be  
349 carefully removed and properly disposed of after the task is completed.

#### 350 **7.4 Eye and Face Protection**

351 Many HDs are irritating to the eyes and mucous membranes. Appropriate eye and face  
352 protection must be worn when there is a risk for spills or splashes of HDs or HD waste  
353 materials when working outside of a C-PEC (e.g., administration in the surgical suite,  
354 working at or above eye level, or cleaning a spill). A full-facepiece respirator provides  
355 eye and face protection. Goggles must be used when eye protection is needed. Eye  
356 glasses alone or safety glasses with side shields do not protect the eyes adequately  
357 from splashes. Face shields in combination with goggles provide a full range of  
358 protection against splashes to the face and eyes. Face shields alone do not provide full  
359 eye and face protection.

#### 360 **7.5 Respiratory Protection**

361 For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or  
362 more protective respirator is sufficient to protect against airborne particles. However,  
363 N95 respirators offer no protection against gases and vapors and little protection  
364 against direct liquid splashes (see the Centers for Disease Control and Prevention's  
365 (CDC's) Respirator Trusted-Source Information).

366 Surgical masks do not provide respiratory protection from drug exposure and must not  
367 be used when respiratory protection is required. A surgical N95 respirator provides the  
368 respiratory protection of an N95 respirator, and like a surgical mask, provides a barrier  
369 to splashes, droplets, and sprays around the nose and mouth.

370 Personnel who are unpacking HDs that are not contained in plastic should wear an  
371 elastomeric half-mask with a multi-gas cartridge and P100-filter. If the type of drug can  
372 be better defined, then a more targeted cartridge can be used.

373 Fit test the respirator and train workers to use respiratory protection. Follow all  
374 requirements in the Occupational Safety and Health Administration (OSHA) respiratory  
375 protection standard (29 CFR 1910.134). An appropriate full-facepiece, chemical  
376 cartridge-type respirator must be worn when attending to HD spills larger than what can  
377 be contained with a spill kit, or when there is a known or suspected airborne exposure  
378 to powders or vapors.

#### 379 **7.6 Disposal of Used Personal Protective Equipment**

380 Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace  
381 quantities of HDs. PPE must be placed in an appropriate waste container and further  
382 disposed of per local, state, and federal regulations. PPE used during compounding  
383 should be disposed of in the proper waste container before leaving the C-SEC.  
384 Chemotherapy gloves worn during compounding must be carefully removed and  
385 discarded immediately in an approved HD waste container inside the C-PEC or  
386 contained in a sealable bag for discarding outside the C-PEC. Potentially contaminated  
387 clothing must not be taken home under any circumstances.

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## 8. HAZARD COMMUNICATION PROGRAM

390 Entities are required to establish policies and procedures that ensure worker safety  
391 during all aspects of HD handling. The entity must develop SOPs to ensure effective  
392 training regarding proper labeling, transport, and storage of the HDs and use of Safety  
393 Data Sheets (SDS), based on the Globally Harmonized System of Classification and  
394 Labeling of Chemicals (GHS).

395 Elements of the plan must include:

- 396 • A written plan that describes how the standard will be implemented.
- 397 • All containers of hazardous chemicals must be labeled, tagged, or marked with  
398 the identity of the material and appropriate hazard warnings.
- 399 • Entities must have an SDS for each hazardous chemical they use.
- 400 • Entities must ensure that the SDSs for each hazardous chemical used are readily  
401 accessible to personnel during each work shift and when they are in their work  
402 areas.
- 403 • Personnel who may be exposed to hazardous chemicals when working must be  
404 provided information and training before the initial assignment to work with a  
405 hazardous chemical, and also whenever the hazard changes.

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## 9. PERSONNEL TRAINING

408 All personnel who handle HDs must be fully trained based on their job functions (e.g.,  
409 in the receipt, storage, handling, compounding, dispensing, and disposal of HDs).  
410 Training must occur before the employee independently handles HDs. The  
411 effectiveness of training for HD handling competencies must be demonstrated by each  
412 employee. Personnel competency must be reassessed at least every 12 months and  
413 when a new HD or new equipment is used or a new or significant change in process or  
414 SOP occurs. All training and competency assessment must be documented.

415 The training must include at least the following:

- 416 • Overview of entity's list of HDs and their risks
- 417 • Review of the entity's SOPs related to handling of HDs
- 418 • Proper use of PPE
- 419 • Proper use of equipment and devices (e.g., engineering controls)
- 420 • Spill management
- 421 • Response to known or suspected HD exposure

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## 10. RECEIVING

424 The entity must establish SOPs for receiving HDs. HDs should be received from the  
425 supplier sealed in impervious plastic to segregate them from other drugs and to improve  
426 safety in the receiving and internal transfer process. HDs must be delivered to the HD  
427 storage area immediately upon arrival.

428 PPE, including ASTM-tested, powder-free chemotherapy gloves, must be worn when  
429 unpacking HDs (see *Personnel Protective Equipment*). A spill kit must be accessible in  
430 the receiving area.

431 The entity must enforce policies that include a tiered approach, starting with visual  
432 examination of the shipping container for signs of damage or breakage (e.g., visible  
433 stains from leakage, sounds of broken glass containers). [Table 4](#) summarizes the steps  
434 for receiving and handling of damaged shipping containers.

435 **Table 4. Summary of Requirements for Receiving and Handling Damaged HD**  
436 **Shipping Containers**

If the shipping container appear damaged	<ul style="list-style-type: none"><li>• Seal container without opening and contact the supplier for instructions</li><li>• If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous"</li><li>• If the supplier declines return, dispose of properly</li></ul>
If a damaged shipping container must be opened	<ul style="list-style-type: none"><li>• Seal the container in plastic or an impervious container</li><li>• Transport it to a C-PEC and place on a plastic-backed preparation mat</li><li>• Open the package and remove usable items.</li><li>• Wipe the outside of the usable items with a disposable wipe.</li><li>• Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"</li><li>• If the supplier declines return, dispose of properly</li><li>• Decontaminate/deactivate and clean the C-PEC (see <i>Deactivation/Decontamination, Cleaning, and Disinfection</i>) and discard the mat and cleaning disposables as hazardous waste</li></ul>

437 When opening damaged shipping containers, they should preferably be transported to  
438 a C-PEC designated for nonsterile compounding. If a C-PEC designated for sterile  
439 compounding is the only one available, it must be thoroughly disinfected after the  
440 decontamination/deactivation and cleaning step before returning to any sterile  
441 compounding activity.

442 Damaged packages or shipping cartons must be considered spills that must be  
443 reported to the designated person and managed according to the entity's SOPs. Clean-  
444 up must comply with established SOPs.

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## 11. LABELING, PACKAGING, AND TRANSPORT

447 The entity must establish SOPs for the labeling, handling, packaging, and transport of  
448 HDs. The SOPs must address prevention of accidental exposures or spills, personnel  
449 training on response to exposure, and use of a spill kit. Examples of special exposure-  
450 reducing strategies include small-bore connectors (such as Luer Lock) and syringes,

451 syringe caps, CSTDs, the capping of container ports, sealed impervious plastic bags,  
452 impact-resistant and/or water-tight containers, and cautionary labeling.

### 453 **11.1 Labeling**

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

### 456 **11.2 Packaging**

457 Compounding personnel must select and use packaging containers and materials that  
458 will maintain physical integrity, stability, and sterility (if needed) of the HDs during  
459 transport. Packaging materials must protect the HD from damage, leakage,  
460 contamination, and degradation, while protecting healthcare workers who transport  
461 HDs. The entity must have written SOPs to describe appropriate shipping containers  
462 and insulating materials, based on information from product specifications, vendors,  
463 mode of transport, and experience of the compounding personnel.

### 464 **11.3 Transport**

465 HDs that need to be transported must be labeled, stored, and handled in accordance  
466 with applicable federal, state, and local regulations. HDs must be transported in  
467 containers that minimize the risk of breakage or leakage. Pneumatic tubes must not be  
468 used to transport any liquid or antineoplastic HDs because of the potential for breakage  
469 and contamination.

470 When shipping HDs to locations outside the entity, the entity must consult the  
471 Transport Information on the SDS. The entity must ensure that labels and accessory  
472 labeling for the HDs include storage instructions, disposal instructions, and HD category  
473 information in a format that is consistent with the courier's policies.

## 474 **12. DISPENSING FINAL DOSAGE FORMS**

476 HDs that do not require any further manipulation other than counting final dosage  
477 forms may be dispensed without any further requirements for containment unless  
478 required by the manufacturer or if visual indicators of HD exposure hazards (e.g., HD  
479 dust or leakage) are present.

480 Counting of HDs should be done carefully. Clean equipment should be dedicated for  
481 use with these drugs. Tablet and capsule forms of HDs must not be placed in  
482 automated counting or packaging machines, which subject them to stress and may  
483 introduce powdered contaminants into the work area.

## 484 **13. COMPOUNDING**

486 Entities and personnel involved in compounding HDs must be compliant with the  
487 appropriate USP standards for compounding including [795](#) and [797](#).  
488 Compounding must be done in proper engineering controls as described in  
489 *Compounding*. When compounding nonsterile and sterile HD preparations in a C-PEC,  
490 a plastic-backed preparation mat must be placed on the work surface of the C-PEC.  
491 The mat should be changed immediately if a spill occurs and regularly during use, and  
492 should be discarded at the end of the daily compounding activity. Disposable or clean

493 equipment for compounding (such as mortars and pestles, and spatulas) must be  
494 dedicated for use with HDs. Compounding personnel must ensure that the labeling  
495 processes for compounded preparations do not introduce contamination into non-HD  
496 handling areas.

497 When compounding nonsterile HD preparations, use commercially available products  
498 as starting ingredients whenever possible. Liquid formulations are preferred over  
499 crushing tablets or opening capsules. APIs should only be used when there are no other  
500 options. When compounding sterile HD preparations, APIs should be avoided if a  
501 suitable manufactured product is available and appropriate for use (e.g., use an  
502 injectable product rather than API).

503 Bulk containers of liquid and API HD must be handled carefully to avoid spills. If used,  
504 APIs should be handled in a C-PEC to protect against occupational exposure,  
505 especially during particle generating activities (such as crushing tablets, opening  
506 capsules, and weighing powder).

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#### 14. ADMINISTERING

509 HDs must be administered safely using protective medical devices and techniques.  
510 Examples of protective medical devices include needleless and closed systems.  
511 Examples of protective techniques include spiking or priming of IV tubing in a C-PEC  
512 and crushing tablets in plastic sleeves.

513 Appropriate PPE must be worn when administering HDs. After use, PPE must be  
514 removed and disposed of in an approved HD waste container at the site of drug  
515 administration. Equipment (such as tubing and needles) and packaging materials must  
516 be disposed of properly, such as in HD waste containers after administration.

517 CSTDs must be used for administration when the dosage form allows. Techniques and  
518 ancillary devices that minimize the risk posed by open systems must be used when  
519 administering HDs through certain routes. Administration into certain organs or body  
520 cavities (e.g., the bladder, eye, peritoneal cavity, or chest cavity) often requires  
521 equipment for which locking connections may not be readily available or possible.

522 Healthcare personnel should avoid manipulating HDs such as crushing tablets or  
523 opening capsules if possible. Liquid formulations are preferred if solid oral dosage forms  
524 are not appropriate for the patient. If HD dosage forms do require manipulation such as  
525 crushing tablet(s) or opening capsule(s) for a single dose, personnel must don  
526 appropriate PPE and use a plastic sleeve to contain any dust or particles generated.

527 The Oncology Nursing Society (ONS) Safe Handling of Hazardous Drugs publication  
528 contains additional information on handling HDs for administration.

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#### 15. DEACTIVATION/DECONTAMINATION, CLEANING, AND DISINFECTION

531 All areas where HDs are handled (e.g., such as during receiving, compounding,  
532 transport, administering, and disposal) and all reusable equipment and devices (e.g., C-  
533 PEC, carts, and trays) must be routinely deactivated/decontaminated and cleaned.  
534 Additionally, sterile compounding areas and devices must be subsequently disinfected.

535 All healthcare personnel who perform deactivation/decontamination, cleaning, and  
536 disinfection activities in HD handling areas must be trained in appropriate procedures to  
537 protect themselves and the environment from contamination. All personnel performing

538 these activities must wear appropriate PPE resistant to the cleaning agents used,  
539 including two pairs of ASTM-tested chemotherapy gloves and impermeable disposable  
540 gowns. Consult manufacturer or supplier information for compatibility with cleaning  
541 agents used. Additionally, eye protection and face shields must be used if splashing is  
542 possible. Respiratory protection must be used if warranted by the activity.

543 The entity must establish written procedures for decontamination, deactivation,  
544 cleaning, and disinfection (for sterile compounding areas). Cleaning of nonsterile and  
545 sterile compounding areas must also comply with < 795 > and < 797 >. Written  
546 procedures for cleaning must include procedures, agents used, dilutions used,  
547 frequency, and documentation requirements. [Table 5](#) summarizes the purpose and  
548 example agents for each step.

549 The deactivating, decontaminating, cleaning, and disinfecting agents selected must be  
550 appropriate for the type of HD contaminant(s), location, and surface materials. The  
551 products used must not contaminate the surfaces with substances that are toxic,  
552 volatile, corrosive, or otherwise harmful to the surface material. Perform cleaning in  
553 areas that are sufficiently ventilated to prevent accumulation of hazardous airborne drug  
554 concentrations and decontamination agents.

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**Table 5. Summary of Cleaning Steps**

<b>Cleaning Step</b>	<b>Purpose</b>	<b>Agents</b>
Deactivation	Render compound inert or inactive	As listed in the HD labeling or if no specific information available, sodium hypochlorite or other Environmental Protection Agency (EPA)-registered oxidizer
Decontamination	Remove inactivated residue	Sterile alcohol, sterile water, peroxide, or sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent and sterile water
Disinfection	Destroy microorganisms	Sterile alcohol or other EPA-registered disinfectant appropriate for use

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### **15.1 Deactivation/Decontamination**

557 Deactivation renders a compound inert or inactive. Decontamination occurs by  
558 physically removing HD residue from non-disposable surfaces and transferring it to  
559 absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area  
560 being cleaned. All disposable materials must be discarded as contaminated HD waste.

561 Chemical deactivation of HD residue is preferred, but no single process has been  
562 found to deactivate all currently available HDs. Studies have examined oxidizing agents  
563 such as potassium permanganate, hydrogen peroxide, and sodium hypochlorite;  
564 vaporized hydrogen peroxide and detergents; and high- and low-pH solutions, all with  
565 varying results. Some potential deactivators have produced byproducts that are as  
566 hazardous as the original drug. Other deactivators have respiratory effects or result in  
567 caustic damage to surfaces. Note that sodium hypochlorite is corrosive to stainless steel  
568 surfaces if left untreated; therefore, sodium hypochlorite must be neutralized with  
569 sodium thiosulfate or followed by use of a germicidal detergent.

570 A multi-component deactivation system is theoretically more efficient than a single-  
571 agent system because of the diverse nature of HDs. One commercially available  
572 product provides a system for decontamination and deactivation using sodium  
573 hypochlorite, surfactant, and thiosulfate neutralizer. This combination product, followed  
574 by rinsing, has been shown to be effective for cleaning HD-contaminated surfaces.  
575 Other products use combinations of deactivating agents and/or cleaning agents,  
576 followed by rinsing and disinfecting. Because of the growing number of assays available  
577 for HDs, additional surface wipe sampling is now possible and should be done to  
578 document the effectiveness of any agent used for decontamination of HD residue from  
579 work surfaces (see *Environmental Quality and Control*).

## 580 **15.2 Cleaning and Disinfection**

581 Cleaning is a process that results in the removal of contaminants (e.g., soil, microbial  
582 contamination, HD residue) from objects and surfaces using water, detergents,  
583 surfactants, solvents, and/or other chemicals. Disinfection is a process of destroying  
584 microorganisms. Disinfection must be done for areas intended to be sterile including the  
585 sterile compounding areas.

## 586 **15.3 Cleaning the Compounding Area**

587 The [Cleaning and Disinfecting the Compounding Area](#) section in ( 797 ) applies to both  
588 sterile and nonsterile HD compounding areas. Cleaning agents used on compounding  
589 equipment should not introduce microbial contamination.

590 All C-PEC used for either nonsterile or sterile compounding must be decontaminated  
591 between compounding of different HDs, any time a spill occurs, before and after  
592 certification, any time voluntary interruption occurs, and if the ventilation tool is moved.  
593 No cleaning step may be performed when compounding activities are occurring.

594 The amount of HD contamination introduced into the C-PEC may be reduced by  
595 surface decontamination (i.e., wiping down) of HD containers. Although no wipe-down  
596 procedures have been studied, the use of disposable material moistened with alcohol,  
597 sterile water, peroxide, or sodium hypochlorite solutions may be effective. To avoid  
598 spreading HD residue, spray the wiper, not the HD container. The solution used for  
599 wiping HD packaging must not alter the product label.

600 C-PECs may have areas under the work tray where contamination can build up. These  
601 areas must be cleaned at least monthly to reduce the contamination level in the C-PEC.  
602 Accessing this area may be difficult. Clean as much as possible of the C-PEC surfaces  
603 before accessing the area under the work tray. When cleaning the area under the work  
604 tray of a C-PEC, the containment airflows are compromised by opening the cabinets. To  
605 provide protection to the worker performing this task, respiratory protection may be  
606 required. An NIOSH-approved respirator worn by a worker who has been fit tested and  
607 cleared to use a respirator would be appropriate.

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## **16. SPILL CONTROL**

610 All personnel who may be required to clean-up a spill of HDs must receive proper  
611 training in spill management and the use of PPE and NIOSH-certified respirators (see  
612 *Personal Protective Equipment*). Spills must be contained and cleaned immediately only  
613 by qualified personnel with appropriate PPE. Qualified personnel must be available at

614 all times in entities handling HDs. Signs must be available for restricting access to the  
615 spill area. Spill kits containing all of the materials needed to clean HD spills must be  
616 readily available in all areas where HDs are routinely handled. If HDs are being  
617 prepared or administered in a non-routine healthcare area, a spill kit and respirator must  
618 be available. All spill materials must be disposed of as hazardous waste.

619 The circumstances and management of spills must be documented. Personnel who  
620 are potentially exposed during the spill or spill clean-up or who have direct skin or eye  
621 contact with HDs require immediate evaluation. Non-employees exposed to an HD spill  
622 should report to the designated emergency service for initial evaluation and also  
623 complete an incident report or exposure form.

624 SOPs must be developed to prevent spills and to direct the clean-up of HD spills.  
625 SOPs must address the size and scope of the spill and specify who is responsible for  
626 spill management and the type of PPE required. The management of the spill (e.g.,  
627 decontamination, deactivation, and cleaning) may be dependent on the size and type of  
628 spill. The SOP must address the location of spill kits and clean-up materials as well as  
629 the capacity of the spill kit. Written procedures should address use of appropriate full-  
630 facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded  
631 or if there is known or suspected airborne exposure to vapors or gases.

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## 17. DISPOSAL

634 Disposal of all HD waste (including unused and unusable HDs) must comply with all  
635 applicable federal, state, and local regulations. All personnel who perform routine  
636 custodial waste removal and cleaning activities in HD handling areas must be trained in  
637 appropriate procedures to protect themselves and the environment to prevent HD  
638 contamination.

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## 18. DOCUMENTATION AND STANDARD OPERATING PROCEDURES

641 Activities that must be documented include, but are not limited to, the acquisition,  
642 preparation, and dispensing of an HD; personnel training; and the use and maintenance  
643 of equipment and supplies. These records must be available for review. Personnel who  
644 transport, compound, or administer HDs must document their training according to  
645 OSHA standards (see OSHA Standard 1910.120 Hazardous Waste Operations and  
646 Emergency Response) and other applicable laws and regulations.

647 The entity must maintain SOPs for the safe handling of HDs for all situations in which  
648 these HDs are used throughout a facility. The SOPs must be reviewed at least annually  
649 by the designated responsible individual, and the review must be documented.

650 Revisions in forms or records must be made as needed and communicated to all  
651 personnel handling HDs.

652 The SOPs for handling of HDs should include:

- 653 • Hazard communication program
- 654 • Occupational safety program
- 655 • Labeling of HDs
- 656 • Procurement of HDs
- 657 • Use of proper engineering controls (e.g., C-PECs, C-SECs)

- 658 • Use of PPE based on activity (e.g., receipt, transport, compounding,  
659 administration, spill, and disposal)
- 660 • Decontamination/deactivation, cleaning, and disinfection
- 661 • Transport
- 662 • Environmental monitoring
- 663 • Spill control
- 664 • Medical surveillance

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## 19. MEDICAL SURVEILLANCE

667 Medical surveillance is part of a comprehensive exposure control program  
668 complementing engineering controls, safe work processes, and use of PPE. Entities  
669 should ensure that healthcare workers who handle HDs as a regular part of their job  
670 assignment are enrolled in a medical surveillance program. The general purpose of  
671 surveillance is to minimize adverse health effects in personnel potentially exposed to  
672 HDs. Medical surveillance programs involve assessment and documentation of  
673 symptom complaints, physical findings, and laboratory values (such as a blood count) to  
674 determine whether there is a deviation from the expected norms.

675 Medical surveillance can also be viewed as a secondary prevention tool that may  
676 provide a means of early detection if a health problem develops. Tracking personnel  
677 through medical surveillance allows the comparison of health variables over time in  
678 individual workers, which may facilitate early detection of a change in a laboratory value  
679 or health condition. Medical surveillance programs also look for trends in populations of  
680 workers. Examining grouped data compared with data from unexposed workers may  
681 reveal a small alteration or increase in the frequency of a health effect that would be  
682 obscured if individual workers' results alone were considered.

683 Medical surveillance evaluates the protection afforded by engineering controls, other  
684 administrative controls, safe work processes, PPE, and worker education about the  
685 hazards of the materials they work with in the course of their duties. The data-gathering  
686 elements of a medical surveillance program are used to establish a baseline of workers'  
687 health and then to monitor their future health for any changes that may result from  
688 exposure to HDs.

689 Elements of a medical surveillance program should be consistent with the entity's  
690 Human Resource policies and should include:

- 691 • Development of an organized approach to identify workers who are potentially  
692 exposed to HDs on the basis of their job duties
- 693 • Use of an 'entity-based' or contracted employee health service to perform the  
694 medical surveillance while protecting the confidentiality of the employees'  
695 personal medical information
- 696 • Initial baseline assessment (pre-placement) of a worker's health status and  
697 medical history. Data elements collected include a medical (including  
698 reproductive) history and work history to assess exposure to HDs, physical  
699 examination, and laboratory testing. Methods used to assess exposure history  
700 include a review of:

- 701 - Records of HDs handled, with quantities and dosage forms
- 702 - Number of HD preparations/administrations per week
- 703 - Estimates of hours spent handling HDs per week and/or per month
- 704 - Performance of a physical assessment and laboratory studies linked to target  
705 organs of commonly used HDs, such as a baseline complete blood count.  
706 Note that biological monitoring to determine blood or urine levels of specific  
707 HDs is not currently recommended in surveillance protocols, but may have a  
708 role in the follow-up of acute spills with a specific agent.
- 709 • Medical records of surveillance should be maintained according to OSHA  
710 regulation concerning access to employee exposure and medical records
  - 711 • Monitoring workers' health prospectively through periodic surveillance using the  
712 elements of data gathering described above (updated health and exposure  
713 history, physical assessment, and laboratory measures, if appropriate)
  - 714 • Monitoring of the data to identify prevention failure leading to health effects; this  
715 monitoring may occur in collaboration with the employee health service
  - 716 • Development of a follow-up plan for workers who have shown health changes  
717 suggesting toxicity or who have experienced an acute exposure. This follow-up  
718 should include evaluation of current engineering and administrative controls and  
719 equipment to ensure that all systems are appropriately and accurately  
720 implemented (see *Follow-Up Plan* below).
  - 721 • Completion of an exit examination when a worker's employment at the entity  
722 ends, to document the information on the employee's medical, reproductive,  
723 and exposure histories. Examination and laboratory evaluation should be  
724 guided by the individual's history of exposures and follow the outline of the  
725 periodic evaluation.

## 726 **19.1 Follow-Up Plan**

727 The occurrence of exposure-related health changes should prompt immediate re-  
728 evaluation of primary preventive measures (e.g., administrative and engineering  
729 controls, PPE, and others). In this manner, medical surveillance acts as a check on the  
730 effectiveness of controls already in use.

731 The entity should take the following actions:

- 732 • Perform a post-exposure examination tailored to the type of exposure (e.g., spills  
733 or needle sticks from syringes containing HDs). An assessment of the extent of  
734 exposure should be conducted and included in a confidential database and in  
735 an incident report. The physical examination should focus on the involved area  
736 as well as other organ systems commonly affected (i.e., the skin and mucous  
737 membranes for direct contact or inhalation; the pulmonary system for  
738 aerosolized HDs). Treatment and laboratory studies will follow as indicated and  
739 be guided by emergency protocols.

- 740 • Compare performance of controls with recommended standards; conduct  
741 environmental sampling when analytical methods are available.
- 742 • Verify and document that all controls are in proper operating condition.
- 743 • Verify and document that the worker complied with existing policies. Review  
744 policies for the use of PPE and employee compliance with PPE use and  
745 policies. Review availability of appropriate PPE (see *Personal Protective*  
746 *Equipment*).
- 747 • Develop and document a plan of action that will prevent additional exposure of  
748 workers.
- 749 • Ensure confidential, two-way communication between the worker and the  
750 employee health unit(s) regarding notification, discussions about a change in  
751 health condition, or detection of an adverse health effect.
- 752 • Provide and document a follow-up medical survey to demonstrate that the plan  
753 implemented is effective.
- 754 • Ensure that any exposed worker receives confidential notification of any adverse  
755 health effect. Offer alternative duty or temporary reassignment.
- 756 • Provide ongoing medical surveillance of all workers at risk for exposure to HDs to  
757 determine whether the plan implemented is effective.

758 **APPENDIX A: ACRONYMS AND DEFINITIONS**

759 **Acronyms**

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ACPH	Air changes per hour
API	Active pharmaceutical ingredient
ASTM	American Society for Testing and Materials
BSC	Biological safety cabinet
BUD	Beyond-use date
CACI	Compounding aseptic containment isolator
CAI	Compounding aseptic isolator
CDC	Centers for Disease Control and Prevention
C-PEC	Containment primary engineering control
C-SCA	Containment segregated compounding area
C-SEC	Containment secondary engineering control
CSP	Compounded sterile preparation
CSTD	Closed-system drug-transfer device
CVE	Containment ventilated enclosure
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
HD	Hazardous drug

HEPA	High-efficiency particulate air
IV	Intravenous
LAFW	Laminar airflow workbench
NIOSH	National Institute for Occupational Safety and Health
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
PPE	Personal protective equipment
SDS	Safety Data Sheet
SOP	Standard operating procedure
ULPA	Ultra-low particulate air

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### Definitions

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**Active pharmaceutical ingredient (API):** Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

**Alternative duty:** Performance of other tasks that do not include the direct handling of HDs.

**Assessment of risk:** Evaluation of risk to determine alternative containment strategies and/or work practices.

**Beyond-use date (BUD):** The date or time after which a compounded preparation must not be used, stored, or transported (see [795](#) and [797](#)).

**Biological safety cabinet (BSC):** A ventilated cabinet often used for preparation of hazardous drugs. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2). See *Appendix C* for details.

**Buffer room:** A type of C-SEC under negative pressure where the C-PEC is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.

**Chemotherapy glove:** A medical glove that meets the ASTM Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs (D6978) or its successor.

**Cleaning:** The removal of soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.

**Closed-system drug-transfer device (CSTD):** A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.

**Compounded preparation:** A nonsterile or sterile drug or nutrient preparation that is compounded in a licensed pharmacy or other healthcare-related facility in response to or anticipation of a prescription or a medication order from a licensed prescriber.

794 **Compounding aseptic containment isolator (CACI):** A specific type of CAI that is  
795 designed for the compounding of sterile HDs. The CACI is designed to provide worker  
796 protection from exposure to undesirable levels of airborne drugs throughout the  
797 compounding and material transfer processes and to provide an aseptic environment  
798 with unidirectional airflow for compounding sterile preparations.

799 **Compounding aseptic isolator (CAI):** An isolator specifically designed for  
800 compounding sterile, non-hazardous pharmaceutical ingredients or preparations. The  
801 CAI is designed to maintain an aseptic compounding environment throughout the  
802 compounding and material transfer processes.

803 **Compounding personnel:** Individuals who participate in the compounding process.

804 **Compounding supervisor:** Individual(s) responsible for developing and implementing  
805 appropriate procedures; overseeing facility compliance with this chapter and other  
806 applicable laws, regulations, and standards; ensuring the competency of personnel;  
807 and maintaining environmental control of the compounding areas.

808 **Containment primary engineering control (C-PEC):** A ventilated device designed  
809 and operated to minimize worker and environmental exposures to HDs by controlling  
810 emissions of airborne contaminants through the following:

- 811 • The full or partial enclosure of a potential contaminant source
- 812 • The use of airflow capture velocities to trap and remove airborne contaminants  
813 near their point of generation
- 814 • The use of air pressure relationships that define the direction of airflow into the  
815 cabinet
- 816 • The use of HEPA filtration on all potentially contaminated exhaust streams

817 Examples of C-PECs include Class I, II, or III BSCs, CACIs, and CVE (e.g., powder  
818 hood). C-PECs used for nonsterile compounding do not need to have ISO Class 5 air  
819 quality, whereas C-PECs used for sterile compounding must have ISO Class 5 air  
820 quality (see [Table 2](#) and [3](#)).

821 **Containment secondary engineering control (C-SEC):** The C-SEC is the room in  
822 which the C-PEC is placed. It incorporates specific design and operational parameters  
823 required to contain the potential hazard within the compounding room.

824 **Containment segregated compounding area (C-SCA):** A type of C-SEC with  
825 nominal requirements for airflow and room pressurization as they pertain to HD  
826 compounding.

827 **Containment ventilated enclosure (CVE):** A full or partial enclosure that uses  
828 ventilation principles to capture, contain, and remove airborne contaminants through  
829 HEPA filtration and prevent their release into the work environment.

830 **Deactivation:** Treatment of an HD contaminant on surfaces with a chemical, heat,  
831 ultraviolet light, or another agent to transform the HD into a less hazardous agent.

832 **Decontamination:** Inactivation, neutralization, or removal of HD contaminants on  
833 surfaces, usually by chemical means.

834 **Disinfectant:** A chemical agent that destroys or inhibits the growth of microorganisms.

835 **Engineering control:** Primary, secondary, and supplemental devices designed to  
836 eliminate or reduce worker exposure to a chemical, biological, radiological, ergonomic,  
837 or physical hazard, and in the case of CSPs, to protect the compounded preparation

838 from environmental contamination.  
839 **Entity:** Pharmacy, hospital, physician's office, clinic, veterinary office, or other location  
840 where HDs are received, stored, prepared, dispensed, administered, and/or  
841 distributed.

842 **EPA-registered disinfectant:** Antimicrobial products registered with the  
843 Environmental Protection Agency (EPA) for healthcare use against pathogens  
844 specified in the product labeling.

845 **Externally vented:** Exhausted to the outside

846 **Globally Harmonized System of Classification and Labeling of Chemicals (GHS):**  
847 A system for standardizing and harmonizing the classification and labeling of  
848 chemicals.

849 **Goggles:** Tight-fitting eye protection that completely covers the eyes, eye sockets,  
850 and facial area that immediately surrounds the eyes. Goggles provide protection from  
851 impact, dust, and splashes. Some goggles fit over corrective lenses.

852 **Hazardous drug (HD):** Any drug identified as hazardous or potentially hazardous on  
853 the basis of at least one of the following six criteria:

- 854 • Carcinogenicity
- 855 • Teratogenicity or developmental toxicity
- 856 • Reproductive toxicity in humans
- 857 • Organ toxicity at low doses in humans or animals
- 858 • Genotoxicity
- 859 • New drugs that mimic existing HDs in structure or toxicity

860  
861 **High-efficiency particulate air (HEPA) filtration:** An extended-medium, dry-type  
862 filter in a rigid frame, having a minimum particle collection efficiency of 99.97% for  
863 particles with a mass median diameter of 0.3 µm when tested at a rated airflow in  
864 accordance with MIL STD 282 using IEST Recommended Standard RP-CC001.5.

865 **Negative-pressure room:** A room that is maintained at a lower pressure than the  
866 adjacent spaces; therefore the net flow of air is into the room.

867 **Pass-through:** An enclosure with interlocking doors that is positioned between two  
868 spaces for the purpose of reducing particulate transfer while moving materials from  
869 one space to another. A pass-through serving negative-pressure rooms needs to be  
870 equipped with sealed doors.

871 **Personal protective equipment (PPE):** Items such as gloves, gowns, respirators,  
872 goggles, faceshields, and others that protect individual workers from hazardous  
873 physical or chemical exposures.

874 **Positive-pressure room:** A room that is maintained at a higher pressure than the  
875 adjacent spaces; therefore, the net flow of air is out of the room.

876 **Safety data sheet (SDS):** An informational document that provides written or printed  
877 material concerning a hazardous chemical. The SDS is prepared in accordance with  
878 the HCS [previously known as a Material Safety Data Sheet (MSDS)].

879 **Spill kit:** A container of supplies, warning signage, and related materials used to  
880 contain the spill of an HD.

881 **Standard operating procedure (SOP):** Written procedures describing operations,

882 testing, sampling, interpretation of results, and corrective actions that relate to the  
883 operations that are taking place.

884 **Supplemental engineering control:** An adjunct control (e.g., CSTD) that may be  
885 used concurrently with primary and secondary engineering controls. Supplemental  
886 engineering controls offer additional levels of protection and may facilitate enhanced  
887 occupational protection, especially when handling HDs outside of primary and  
888 secondary engineering controls (e.g., during administering).

889 **Trace contaminated waste:** Items used in the handling, compounding, dispensing,  
890 administration, or disposal of antineoplastic agents that are not overtly contaminated  
891 (e.g., gowns, gloves, goggles, wipes).

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## APPENDIX B: EXAMPLES OF DESIGNS FOR HAZARDOUS DRUGS COMPOUNDING AREAS<sup>A</sup>

894

895

Use	Optimal Primary and Secondary Control	Minimum ACPH	Limitations Primary and Secondary Control	Minimum ACPH	Notes for limitations		
Nonsterile HD compounding		12					
Sterile HD compounding		30		12	Maximum BUD as described in <797> for segregated compounding area.		
	OR			OR		30	If this design is in place, measures must be taken to avoid contamination of the positive-pressure buffer room.
				<p>This design is not recommended</p>	30	Maximum BUD as described in <797>.	
Both sterile HD and nonsterile HD compounding	A separate room for sterile and nonsterile compounding is recommended			30	For rooms used for both sterile and nonsterile compounding, particle-generating activity must not be performed when sterile compounding is in process. C-PECs must be at least 1 meter apart.		
			OR	12	Maximum BUD as described in <797> for segregated compounding area.		
				OR	12	Maximum BUD as described in <797> for segregated compounding area.	

\* The arrows indicate direction of airflow.

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## APPENDIX C: TYPES OF BIOLOGICAL SAFETY CABINETS

900 **Class I:** A BSC that protects personnel and the environment but does not protect the  
901 product/preparation. A minimum velocity of 75 linear feet/min of unfiltered room air is  
902 drawn through the front opening and across the work surface, providing personnel  
903 protection. The air is then passed through a HEPA/ULPA (ultra-low particulate air)  
904 filter, either into the room or to the outside in the exhaust plenum, providing  
905 environmental protection.

906 **Class II:** Class II (Types A1, A2, B1, and B2) BSCs are partial barrier systems that  
907 rely on the movement of air to provide personnel, environmental, and  
908 product/preparation protection. Personnel and product/preparation protection are  
909 provided by the combination of inward and downward airflow captured by the front  
910 grille of the cabinet. Side-to-side cross-contamination of products/preparations is  
911 minimized by the internal downward flow of HEPA/ULPA filtered air moving toward the  
912 work surface and then drawn into the front and rear intake grilles. Environmental  
913 protection is provided when the cabinet exhaust air is passed through a HEPA/ULPA  
914 filter.

915 **Type A1 (formerly, Type A):** These Class II BSCs maintain a minimum inflow  
916 velocity of 75 feet/min; have HEPA-filtered, down-flow air that is a portion of the  
917 mixed down-flow and inflow air from a common plenum; may exhaust HEPA-filtered  
918 air back into the laboratory or to the environment through an exhaust canopy; and  
919 may have positive-pressure contaminated ducts and plenums that are not  
920 surrounded by negative-pressure plenums. Type A1 BSCs are not suitable for use  
921 with volatile toxic chemicals and volatile radionucleotides.

922 **Type A2 (formerly, Type B3):** These Class II BSCs maintain a minimum inflow  
923 velocity of 100 feet/min; have HEPA-filtered, down-flow air that is a portion of the  
924 mixed down-flow and inflow air from a common exhaust plenum; may exhaust HEPA-  
925 filtered air back into the laboratory or to the environment through an exhaust canopy;  
926 and have all contaminated ducts and plenums under negative pressure or  
927 surrounded by negative-pressure ducts and plenums. If these cabinets are used for  
928 minute quantities of volatile toxic chemicals and trace amounts of radionucleotides,  
929 they must be exhausted through properly functioning exhaust canopies.

930 **Type B1:** These Class II BSCs maintain a minimum inflow velocity of 100 feet/min;  
931 have HEPA-filtered, down-flow air composed largely of uncontaminated, recirculated  
932 inflow air; exhaust most of the contaminated down-flow air through a dedicated duct  
933 exhausted to the atmosphere after passing it through a HEPA filter; and have all  
934 contaminated ducts and plenums under negative pressure or surrounded by  
935 negative-pressure ducts and plenums. If these cabinets are used for work involving  
936 minute quantities of volatile toxic chemicals and trace amounts of radionucleotides,  
937 the work must be done in the directly exhausted portion of the cabinet.

938 **Type B2 (total exhaust):** These Class II BSCs maintain a minimum inflow velocity of  
939 100 feet/min; have HEPA-filtered, down-flow air drawn from the laboratory or the  
940 outside; exhaust all inflow and down-flow air to the atmosphere after filtration through  
941 a HEPA filter without recirculation inside the cabinet or return to the laboratory; and  
942 have all contaminated ducts and plenums under negative pressure or surrounded by  
943 directly exhausted negative-pressure ducts and plenums. These cabinets may be  
944 used with volatile toxic chemicals and radionucleotides.

945  
946 **Class III:** The Class III BSC is designed for work with highly infectious microbiological  
947 agents and other hazardous operations. It provides maximum protection for the  
948 environment and the worker. It is a gas-tight enclosure with a viewing window that is  
949 secured with locks and/or requires the use of tools to open. Both supply and exhaust  
950 air are HEPA/ULPA filtered. Exhaust air must pass through two HEPA/ULPA filters in  
951 series before discharge to the outdoors.

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