APPENDIX – Compounding Hazardous Drugs

LEARNING OBJECTIVES

- Recognize hazardous drugs.
- Discuss the precautions required when working with hazardous drugs.
- Describe the key elements for decontaminating and cleaning areas used for compounding hazardous drugs.
- Discuss the components of a recommended medical surveillance program for those who compound hazardous drugs.

Note: This chapter includes the provisions required by USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, which will become official on December 1, 2019. ASHP is updating the *Guidelines on Handling Hazardous Drugs*, which are expected to be published by early 2018. Recommendations in the revised ASHP guidelines will supersede the requirements in the current recommendations.

Overview

Compounding hazardous drugs requires skill in preparation, as well as protection of the compounding personnel. Injectable oncology agents comprise the majority of hazardous drugs compounded, but agents for other routes of administration and other conditions are also prepared. Competence for compounding hazardous drugs includes written and verbal instruction and review of practices for both sterile and nonsterile compounding. An overview of nonsterile compounding can be found in Chapter 48: Compounding Nonsterile Preparations and an overview of sterile compounding can be found in Chapter 46: Compounding Sterile Preparations (Murdaugh LB, *Competence Assessment Tools for Health-System Pharmacies*, 5th ed., ASHP, 2015).

In addition to the ASHP videos and publications listed in Chapter 46, the video and workbook *Compounding Hazardous Drugs* provides a bridge between didactic instruction and practical skills.[1] Three other resources are critical to knowledge concerning hazardous drugs:

- Guidelines on Handling Hazardous Drugs[2] (https://www.ashp.org/search?q=Guidelines%20on%20Handling%20Hazardous%20Drugs)
- NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings[3] (www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf)
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016[4] (www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf)

Completion of written materials is not sufficient to demonstrate competence to compound hazardous drugs. Manipulation of safe and accurate preparations must be demonstrated to a skilled compounder. Competence must be reassessed on a regular basis.

Individuals who compound hazardous drugs must be mentally and physically able to perform accurate calculations and precise and repetitive manipulations; maintain aseptic technique for those preparations intended to be sterile; gown and glove appropriately; clean and decontaminate the compounding areas; and recognize breaks in processes that could result in a hazardous drug preparation, which does not meet quality standards or result in unacceptable risks to patients or personnel.

Definition of a Hazardous Drug

A *hazardous drug* is any drug identified by at least one of the following six characteristics:

1. Carcinogenicity
2. Teratogenicity or developmental toxicity
3. Reproductive toxicity in humans
4. Organ toxicity at low doses in humans or animals
5. Genotoxicity
6. New drugs that mimic existing hazardous drugs in structure or toxicity

Note that the hazardous drugs discussed in this chapter meet the above definition and are hazardous to personnel. However, they are in a different designation than the Environmental Protection Agency (EPA) hazardous materials, which are a hazard to the environment. (See Chapter 18: Hazardous Materials in Murdaugh LB, *Competence Assessment Tools for Health-System Pharmacies*, 5th ed., ASHP, 2015.) There is some overlap between the lists, but the reg-

Source: Updated and reprinted with permission from Kienle, PK. Compounding hazardous drugs. In: Murdaugh LB. *Competence Assessment Tools for Health-System Pharmacies*, 5th ed. Bethesda, MD: ASHP; 2015.

ulations stem from different organizations and are directed at different issues.

Each organization must establish its own list of hazardous drugs based on the NIOSH list.[4] The list should be reviewed and revised as formulary changes are made or as nonformulary agents are used for patients, and documentation of the updated list must be done at least annually.

Precautions

When hazardous drugs are manipulated, compounding personnel must be protected from exposure in addition to the requirements for safe and effective preparations for the patient.

The Occupational Safety and Health Administration (OSHA) Hazard Communication Standard requires employers to transmit information concerning workplace hazards to employees.[5] Information must include a safety program, proper labeling, use of safety data sheets (SDS, which were formerly known as material safety data sheets [MSDS]), and employee training.

USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations[6] and USP Chapter <800>[7] provide requirements and recommendations for patient and personnel protection.

Precautions with hazardous drugs are not limited to compounding personnel. Employees who receive, transport, administer, or dispose of the agents must also be aware of the necessary precautions. Inhalation or skin contact and absorption is the most likely way for personnel to be exposed to hazardous drugs. Because manufacturer's vials can be contaminated with trace amounts of hazardous substances, those personnel who receive supplies must follow precautions. All suppliers should provide hazardous drugs in marked and wrapped containers. Personnel who receive and transport hazardous drugs should wear chemotherapy gloves meeting American Society for Testing and Materials (ASTM) standard D6978 when unpacking and transporting hazardous drugs and when wiping supplies and equipment removed from shipping cartons prior to placement in storage bins.

Facility Design

Facilities for Storing and Compounding Hazardous Drugs

The hazardous drug storage or compounding area must have four characteristics[3,7]:

1. It must be a room with fixed walls that is separate from nonhazardous drug storage and preparation.
2. It must be a negative pressure room, which would contain any breakage or spill. USP Chapter <800> requires the pressure to be between 0.01–0.03" wc negative to adjacent areas.
3. It must be vented to the outside of the building.
4. It must have sufficient general exhaust ventilation to dilute potential particles and vapors. Rooms for storage of hazardous drugs, for compounding nonsterile hazardous drugs, or a containment segregated compounding area must have at least 12 air changes per hour (ACPH). Anterooms and buffer rooms for compounding sterile hazardous drugs must have at least 30 ACPH.

Many organizations build their negative pressure sterile buffer area, which requires 30 ACPH, with enough space to also use the area for storage of hazardous drugs. If this is done, care must be taken to ensure that only smooth, impervious containers and shelving (such as cleanable plastic and stainless steel) are used for the storage and that no corrugated cardboard or outer shipping containers are brought into the ante or buffer area. If storage of products is kept in the ante or buffer area, the area must be able to meet the International Organization for Standardization (ISO) 7 air quality standards required of an area for sterile compounding.

Other Attributes of Facilities for Compounding Hazardous Drugs

OSHA recommends an eye wash station in areas where hazardous drugs are manipulated.[8] The American National Standards Institute provides details for the device and its maintenance.[9]

General issues include the following:

- Availability in close proximity to compounding areas used for hazardous drugs
- Plumbed eyewash units connected to cool (not hot) water
- Weekly activation of the station to verify proper operation

Requirements for Compounding Nonsterile Hazardous Drugs

Manipulation of hazardous drugs for oral or other nonsterile routes must be performed in an area separate from the general compounding area. Use of a containment ventilated enclosure such as a Class I

biological safety cabinet (BSC) or a ventilated safety enclosure (called a containment ventilated enclosure [CVE] in USP <800> and often informally referred to as a *powder hood*) is recommended. The cabinet or enclosure should be vented to the outside to prevent the hazardous drug particles or vapors from contaminating the area. If it is not externally vented, it must have redundant high-efficiency particulate air (HEPA) filters in series.

Figure 1 provides recommendations for compounding and handling noninjectable hazardous drug dosage forms.

Requirements for Compounding Sterile Hazardous Drugs

See Chapter 46: Compounding Sterile Preparations (Murdaugh LB, *Competence Assessment Tools for Health-System Pharmacies*, 5th ed., ASHP, 2015) for a discussion of components of a sterile compounding area. Hazardous drugs that are intended to be sterile must comply with USP Chapter <797> and USP Chapter <800>.

USP Chapter <800> describes the requirements for preparation areas, which must contain a primary engineering control (PEC), often informally called the *chemo hood,* a secondary engineering control (often called the *IV room*) that is either an IV compounding suite (containing a positive pressure anteroom that serves as a transition area between the general pharmacy area and the site where the hazardous drugs are compounded and a negative pressure buffer room in which the PEC is placed) or a containment segregated compounding area (a negative pressure room in which the PEC is placed).

PECs for compounding hazardous drugs can be a traditional BSC, a compounding aseptic containment isolator (CACI), or a robotic device designed for the preparation of hazardous drugs that meets the definition of a BSC or CACI. PECs used for the preparation of hazardous drugs must not be placed in a positive pressure buffer area used for preparation of nonhazardous drugs.

The National Institute for Occupational Safety and Health (NIOSH) defines a closed system transfer device (CSTD) as one that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system. USP Chapter <800> requires use of a CSTD for administration of antineoplastic hazardous drugs when the dosage form allows. Many organizations use a CSTD for administration of all antineoplastic hazardous drugs. See **Figure 2** for information on use of a Class II BSC and **Figure 3** for information on use of Class III BSCs and CACIs.[2]

Aseptic Technique

Facilities alone cannot prevent exposure to personnel or the environment. Rather, it is dependent on use of proper technique by compounding personnel. *Aseptic technique* refers to a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens (microbial or fungal contamination). When preparing compounded sterile preparations (CSPs), the compounder must be aware of proper procedures including workflow in the compounding area, placement of products and devices in the PEC, and infection prevention practices including hand hygiene and proper garbing procedures.

Different techniques are used with BSCs, CACIs, and robotic devices. Compounding personnel must have sufficient didactic and practical instruction in the devices and procedures used to be competent to prepare CSPs.

Personal Protective Equipment

Protective clothing, known as *garb*, helps contain the particles and microorganisms produced by compounding personnel. Personal protective equipment (PPE) includes gowns, masks, gloves, hair covers, eye protection, respiratory protection, and shoe covers. **Figure 4** provides recommendations for the use of gloves when handling hazardous drugs.

Key points include the following:

- Use powder-free gloves that meet the ASTM standard D6978 for chemotherapy gloves.
- Follow USP Chapter <797> requirement for use of sterile gloves for the preparation of CSPs.
- Wear gloves that meet ASTM D6978 standard for handling of hazardous drugs. Two pairs must be worn for compounding and administering injectable antineoplastics.
- Change gloves every 30 minutes or as recommended by the manufacturer during compounding or immediately if damaged or contaminated.

When using a CACI, place a sterile glove on the outside of the fixed glove assembly. Follow the manufacturer's recommendations for inspecting and changing the fixed glove assembly and gauntlets. The outer ASTM-tested chemotherapy glove (the glove that touches the CSP) must be sterile. The inner glove needs to be an ASTM-tested chemotherapy glove and should be sterile.

Figure 5 provides recommendations for the use of gowns when handling hazardous drugs.[2] Key points include the following:

- Use coated chemotherapy gowns to protect against contamination.
- Change gowns every 3 hours or as recommended by the manufacturer during compounding and immediately when damaged or contaminated.

Two pairs of shoe covers must be donned prior to entering the negative pressure buffer room. Remove the outer pair when leaving the negative pressure buffer room to avoid tracking potential hazardous drug contamination into adjacent areas.

Eye Protection and Respirators

Eye protection is required when working with hazardous drugs. Proper use of BSCs and CACIs provides eye and respiratory protection. Respirators must be worn when handling spills, decontaminating a PEC, and as required by hospital policy. N-95 respirators are effective protection against particles but not gases.

Work Practices

Compounding Procedures

Procedures for CSPs can be found in Chapter 46: Compounding Sterile Preparations (Murdaugh LB, *Competence Assessment Tools for Health-System Pharmacies*, 5th ed., ASHP, 2015). **Figure 6** provides recommendations for working in PECs designed for hazardous drugs.[2] Figure 1 provides recommendations for compounding and handling noninjectable hazardous drug dosage forms.[2]

Decontaminating, Deactivating Substances, and Cleaning the Work Area

In addition to cleaning and disinfecting required for all compounding, working with hazardous drugs also requires deactivation and decontamination of the agents used. There is no single process recommended to deactivate all hazardous drugs. The SDS for each drug used should be reviewed to determine the appropriate agent to use to deactivate and decontaminate an area used for compounding hazardous drugs. Many SDSs recommend decontamination with sodium hypochlorite (bleach). Other commercial products are also available, including those designed for decontaminating hazardous drugs. Alcohol does not deactivate hazardous drugs and can spread contamination if used prior to deactivation.

BSCs and CACIs should be cleaned as detailed in the manufacturers' recommendations. Full PPE must be worn while performing this process. Decontaminating, deactivating, cleaning, and disinfecting include the following steps:

- Decontaminate the PEC and deactivate the hazardous drug using an agent recommended in the SDS (such as 2% sodium hypochlorite or other EPA-approved oxidizer intended for use with hazardous drugs). If sodium hypochlorite is used, deactivate the sodium hypochlorite (and some hazardous drugs) with 1% sodium thiosulfate, rinse with sufficient amount of sterile water, or immediately follow with the next step to remove the sodium hypochlorite.
- Clean the area with a germicidal detergent.
- Disinfect the area with sterile 70% isopropyl alcohol.

The decontamination process should be used prior to starting the day's operation, at regular intervals during compounding, in the case of a spill or suspected contamination, and when the shift's work is completed.

Spills

All personnel who receive, transport, compound, or administer hazardous drugs must be trained in actions to take in case of a spill or breakage. **Figure 7** lists the recommended contents of a spill kit.[2] The kit must be available in all areas where hazardous drugs are received, stored, compounded, or administered. **Figure 8** lists recommendations for spill cleanup procedures.[2] Your organization should have a detailed procedure, including specific departments to contact if a spill or breakage occurs.

Direct Skin or Eye Contact

Figure 9 provides recommendations for immediate treatment of personnel with direct skin or eye contact with hazardous drugs, including flushing the affected eye with water or isotonic eyewash in a continuous stream for at least 15 minutes.[2]

Disposal

The federal Resource Conservation and Recovery Act (RCRA) was enacted in 1976 to provide a means for tracking hazardous waste. RCRA defines hazardous waste as substances that are considered detrimental to the environment and must be segregated for special waste management. RCRA states hazardous waste cannot be discarded into waste water systems (e.g., sewers, drains) or landfills. Some hazardous

drugs are defined as hazardous waste under this act. Follow your health-system's policy concerning disposal and segregation of all hazardous drugs.

Medical Surveillance Program

NIOSH has defined a medical surveillance program for healthcare workers who are exposed to hazardous drugs.[10] Healthcare organizations are expected to have in place a comprehensive approach to worker safety and health, including the following:

- Engineering controls
- Good work practices
- Availability of PPE
- Follow-up for workers who had health changes or had a significant exposure

Elements of the medical surveillance program include the following, performed at hire and periodically:

- Reproductive and general health questionnaire
- Laboratory studies, including complete blood counts, urinalysis, and other appropriate tests
- Physical examination

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Resources

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Competence Checklist

Name: _____ **Date:** _____

Knowledge and Skills	Yes	No
Recognizes that cytotoxic and other hazardous medications must not be prepared in a PEC designed for use with nonhazardous drugs. *Note:* The organization may entity-exempt some dosage forms of nonantineoplastic and reproductive-only hazards from this requirement.		
Demonstrates knowledge of preparation of nonsterile hazardous medications including packaging activities		
Recognizes that hazardous medications must be prepared only in a BSC or CACI or robotic device designed for compounding sterile hazardous drugs		
Recognizes that the BSC or CACI is dedicated only to preparing hazardous medications		
Recognizes that if the exhaust fan on a BSC or CACI is turned off, the cabinet must be decontaminated, cleaned, and disinfected before reuse		
Recognizes that a BSC or CACI must be serviced and certified by a qualified technician every 6 months and when it is moved, repaired, or if the HEPA filter is contaminated by a spill		
Demonstrates proper infection control (removes jewelry, ties long hair back, washes hands with approved cleaning agents, etc.)		
States the organization's requirements for PPE.		
Wears appropriate protective equipment properly (e.g., ASTM-tested chemotherapy gloves, impervious gown, mask, hair and shoe covers)		
Cleans and disinfects the BSC or CACI at the beginning of the work shift, as appropriate during compounding, and at the end of each shift		
Decontaminates, deactivates, cleans, and disinfects the BSC or CACI with appropriate agents and in the proper order, working from the top to the bottom or as according to manufacturer's recommendations		
Correctly performs all required calculations prior to compounding preparation		
Uses appropriate safeguards that may reduce the potential for medication errors involving chemotherapy agents (e.g., independent double checks)		
Collects correct medications, solutions, and supplies; inspects all components, including vials, ampules, IV bags for damage/contamination and expiration date before compounding		
Places appropriate medications and supplies in the BSC or CACI prior to compounding; demonstrates proper placement of items to prevent blocking air flow; keeps nonessential items outside PEC		
Checks labels both prior to and after compounding to ensure medications and solutions being used agree		
Maintains BSC glass safety shield at appropriate opening height (based on manufacturer recommendations and confirmation by certifier) during admixture operations		

Demonstrates understanding of air flow in C-PEC, maintains flow of clean air over objects in C-PEC, does not interrupt air flow; places only hands and arms in BSC		
Does not utilize outer area of BSC opening (based on manufacturer's recommendations and confirmation by certifier), work too close to sides of C-PEC, or block air intake grills during admixture preparation		
Does not take hands out of C-PEC or leave the C-PEC during admixture preparation		
Does not compromise air flow in the ante or buffer area		
Does not touch or contaminate any component that must remain sterile during aseptic admixture preparation		
Reviews Master Formulation Record prior to mixing		
Performs all work on plastic-backed paper mat placed on the work surface		
Demonstrates proper swabbing and entering of vials, ampules, and bags		
Correctly uses appropriate transfer devices (CSTDs, Luer-Lok syringes, filter needles, vented needles, dispensing pins, etc.)		
Reconstitutes powders using proper technique		
Uses negative pressure technique during reconstitution and withdrawal of medication; does not aspirate at any time		
After preparation, inspects solution for cores, precipitates, particulate matter, etc.		
Wipes admixture container with approved decontamination agent before labeling the container		
Removes outer gloves, then affixes appropriate labels to admixture container including auxiliary and chemotherapy hazard labels; places container in a sealable plastic bag prior to removal from the PEC		
Disposes of all used equipment and waste in appropriate hazardous waste disposal containers; seals and wipes waste containers prior to removal from the PEC		
After completion of operations in the PEC, removes PPE (e.g., hair cover, gown, shoe covers, gloves) and places in appropriate waste container; performs hand hygiene after completion of compounding activities		
Documents preparation in appropriate records (e.g., patients' medication profiles, compounding records)		
Demonstrates knowledge of proper procedure for reporting and cleaning up hazardous medication spills both within and outside the PEC; correctly verbalizes location of materials used to clean up spills (e.g., spill kit)		
NOTES		

Competence certified by:_____ Date:_____

Competency Assessment Exam

Name: _____ **Date:** _____

___ 1. When reconstituting and withdrawing chemotherapy medications from vials, aerosol droplets may be generated. This can be minimized or eliminated by using _____.

a. Negative pressure technique
b. Luer-Lok syringes
c. Closed-system transfer devices (CSTDs)
d. a and c

___ 2. All of the following statements is true *except* _____.

a. Personnel preparing hazardous medications should wear protective apparel.
b. Personnel should wash hands after preparing chemotherapy medications.
c. Syringes or admixtures containing chemotherapy agents should have distinctive chemotherapy cautionary labeling.
d. Gowns and gloves worn in preparing chemotherapy medications can be used for several days.

___ 3. Gloves used in the preparation of chemotherapy must be _____.

a. Disposable
b. Powdered to facilitate removal
c. Specified as ASTM-tested chemotherapy gloves
d. a and c

___ 4. Gowns and gloves worn while working in the chemotherapy preparation area can be worn while working in other medication preparation areas.

a. True
b. False

___ 5. When wearing double gloves, _____.

a. The gown cuffs should be tucked over both gloves
b. The gown cuffs should be tucked under both gloves
c. The inner glove should be worn under the gown cuff and the outer glove should be worn over the gown cuff
d. It makes no difference if gown cuffs are worn over or under the gloves

___ 6. Hazardous medication warning labels are required on _____.

a. Shelves and bins where hazardous medications are stored
b. Syringes, vials, IV bottles, and IV bags containing chemotherapy preparations
c. Waste containers for disposal of hazardous drugs
d. All of the above

___ 7. When reconstituting a hazardous powder, the needle should be removed and the vial shaken before withdrawing the liquid.

a. True
b. False

___ 8. After preparing a chemotherapy medication, the product should be wiped and placed in a sealable plastic bag before removal from the BSC.

a. True
b. False

___ 9. Excess amounts of hazardous medications drawn into a syringe should be _____.

a. Squirted down the sink drain
b. Squirted into the chemotherapy waste container
c. Injected back into the vial before removing the needle
d. Any of the above techniques are acceptable

___ 10. Which of the following types of PECs can be used for preparing sterile hazardous medications?

a. Ventilated safety enclosure
b. Biological safety cabinet (BSC)
c. Horizontal laminar air flow workbench
d. Compounding aseptic isolator (CAI)

___ 11. When decontaminating a BSC, _____.

a. Protective apparel must be worn
b. Media fill testing should be performed
c. Rinse water can be poured down the sink
d. a and c

___ 12. BSCs and CACIs must be serviced and certified _____.

a. Every month
b. Every 6 months
c. Every year
d. Prior to accreditation surveys

___ 13. If a BSC is turned off, it must be decontaminated before reuse.

a. True
b. False

___ 14. BSCs must be decontaminated _____.

a. Regularly as specified by facility policy
b. When the cabinet is moved or serviced
c. When a spill occurs
d. All of the above

___ 15. A BSC is cleaned from the top to bottom.

a. True
b. False

___ 16. When preparing hazardous medications in a BSC, the glass shield must be raised _____.

a. All the way
b. As recommended by the manufacturer and confirmed by the certifier
c. No more than 6 inches
d. Depending on the height of the operator

___ 17. Spill kits _____.

a. Should be available only from the facility's central supply room
b. Should be kept wherever chemotherapy agents are handled
c. Contain supplies needed to clean a hazardous drug spill
d. b and c

___ 18. During hazardous drug compounding, gloves should be _____.

a. Used for one shift
b. Changed every batch
c. Changed every 30 minutes or as recommended by the manufacturer
d. Changed every 3 hours or as recommended by the manufacturer

___ 19. During hazardous drug compounding, gowns should be _____.

a. Used for one shift
b. Changed every batch
c. Changed every 30 minutes or as recommended by the manufacturer
d. Changed every 3 hours or as recommended by the manufacturer

___ 20. Cleaning hazardous drug preparation areas requires decontamination and deactivation prior to cleaning and disinfecting.

a. True
b. False

_____ _____

Competence certified by Date

Answer Key

1. d. CSTDs provide a supplemental engineering control to reduce risk of contamination. Negative pressure technique must be used if CSTDs are not used.
2. d. Work practices including hand hygiene and appropriate PPE must be followed. Distinctive cautionary labeling should be used. Garb used when mixing chemotherapy must be discarded when leaving the hazardous drug compounding area.
3. d. Disposable chemotherapy gloves that meet ASTM standard D6978 are required. Powdered gloves are not permitted.
4. False. PPE used when mixing chemotherapy must be removed and discarded when leaving the hazardous drug compounding area.
5. c. Placing the inner glove under the gown cuff and the outer glove over the gown cuff provides the best protection, and this allows removal of the outer glove without compromising the protection provided by the gown and inner glove.
6. d. All areas where hazardous medications are stored or disposed require warning labels.
7. False. Technique that minimizes the potential for droplets of hazardous medications to escape from a closed container must be used.
8. True. Hazardous drug preparations must be contained in a sealable plastic bag prior to removal from the PEC to minimize the possibility of contamination outside the BSC or CACI.
9. c. Unused hazardous drugs must be contained, such as in the vial. Never expel unused hazardous drugs down a drain or into an open waste container.
10. b. Sterile hazardous drugs can be compounded only in either a BSC or a CACI.
11. a. PPE must be worn when decontaminating a BSC.
12. b. All PECs must be certified every 6 months.
13. True. BSCs and CACIs should be powered on continuously. If the power has been off, the PEC must be decontaminated, cleaned, and disinfected prior to use.
14. d. The PEC must be decontaminated whenever there is a risk that it might have been contaminated. This would include anytime a spill occurs or if the cabinet was moved. Additionally, the facility policy requirements must be followed.
15. True. The BSC or CACI should be cleaned from top to bottom and from back to front.
16. b. The manufacturer's information and the results of the certification of the particular BSC will determine the height of the glass shield.
17. d. Spill kits must be available wherever hazardous drugs are located and must include all the equipment that would be required to clean a spill.
18. c. Outer gloves should be changed every 30 minutes or as recommended by manufacturer or when contaminated or suspected of being contaminated.
19. d. Gowns should be changed following manufacturer's recommendations or every 3 hours if no manufacturer's information is available.
20. True. Cleaning hazardous drug preparation areas requires decontamination and deactivation prior to cleaning and disinfecting.

FIGURE 1. *Recommendations for Compounding and Handling Noninjectable Hazardous Drug Dosage Forms*

- Hazardous drugs should be labeled or otherwise identified as such to prevent improper handling.
- Tablet and capsule forms of hazardous drugs should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area.
- During routine handling of noninjectable hazardous drugs and contaminated equipment, workers should wear two pairs of gloves that meet the ASTM standard for chemotherapy gloves.
- Counting and pouring of hazardous drugs should be done carefully, and clean equipment should be dedicated for use with these drugs.
- Contaminated equipment should be cleaned initially with wipes saturated with sterile water; decontaminated, then further cleaned with detergent, sodium hypochlorite solution, and neutralizer; and then rinsed. The wipes and rinse should be contained and disposed of as contaminated waste.
- Crushing tablets or opening capsules should be avoided when possible; liquid formulations should be used whenever possible.
- During the compounding of hazardous drugs (e.g., crushing, dissolving, or preparing a solution or an ointment), workers should wear nonpermeable gowns and double chemotherapy gloves. Compounding must take place in a ventilated cabinet.
- Compounding nonsterile forms of hazardous drugs in equipment designated for sterile products must be undertaken with care. Appropriate containment, deactivation, cleaning, and disinfection techniques must be utilized.
- Hazardous drugs should be dispensed in the final dose and form whenever possible. Most unit-of-use containers exhibit some spillage during preparation or use. Caution must be exercised when using these devices.
- Bulk containers of liquid hazardous drugs, as well as specially packaged commercial hazardous drugs (e.g., Neoral [manufactured by Novartis]), must be handled carefully to avoid spills. These containers should be dispensed and maintained in sealable plastic bags to contain any inadvertent contamination.
- Disposal of unused or unusable noninjectable dosage forms of hazardous drugs should be performed in the same manner as for hazardous injectable dosage forms and waste.

ASTM = American Society for Testing and Materials.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 2. *Recommendations for Use of Class II Biological Safety Cabinets (BSCs)*

- The use of a Class II BSC must be accompanied by a stringent program of work practices, including training, demonstrated competence, contamination reduction, and decontamination.
- Only a Class II BSC with outside exhaust should be used for compounding hazardous drugs. Total exhaust is required if the hazardous drug is known to be volatile.
- Consider using closed system transfer devices while compounding hazardous drugs in a Class II BSC; evidence documents a decrease in drug contaminants inside a Class II BSC when such devices are used.
- Reduce the hazardous drug contamination burden in the Class II BSC by wiping down hazardous drug vials before placing them in the BSC.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 3. *Recommendations for Use of Class III BSCs and Compounding Isolators*

- Only a ventilated cabinet designed to protect workers and adjacent personnel from exposure and to provide an aseptic environment may be used to compound sterile hazardous drugs.
- Only ventilated cabinets that are designed to contain aerosolized drug product within the cabinet should be used to compound hazardous drugs.
- The use of a Class III BSC or compounding isolator must be accompanied by a stringent program of work practices, including operator training and demonstrated competence, contamination reduction, and decontamination.
- Decontamination of the Class III BSC or compounding isolator must be done in a way that contains any hazardous drug surface contamination during the cleaning process.
- Appropriate decontamination within the cabinet must be completed before the cabinet is accessed via pass-throughs or removable front panels.
- Gloves or gauntlets must not be replaced before completion of appropriate decontamination within the cabinet.
- Surface decontamination of final preparations must be done before labeling and placing into the pass-through.
- Final preparations must be placed into a transport bag while in the pass-through for removal from the cabinet.

BSC = biological safety cabinet.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 4. *Recommendations for Use of Gloves*

- Wear chemotherapy gloves for all activities involving hazardous drugs. Gloves must be worn during any handling of hazardous drug shipping cartons or drug vials, compounding and administration of hazardous drugs, handling of hazardous drug waste or waste from patients recently treated with hazardous drugs, and cleanup of hazardous drug spills.
- Select powder-free, high-quality gloves made of latex, nitrile, polyurethane, neoprene, or other materials that meet the ASTM standard for chemotherapy gloves (D6978).
- Inspect gloves for visible defects.
- Disinfect gloves with sterile 70% alcohol or other appropriate disinfectant before performing any aseptic compounding activity.
- Change gloves every 30 minutes during compounding or as recommended by the manufacturer, and immediately when damaged or contaminated.
- Remove outer gloves after wiping down final preparation but before labeling or removing the preparation from the BSC.
- Outer gloves must be placed in a containment bag while in the C-PEC.
- In a compounding isolator, a sterile glove must be worn over the fixed-glove assembly.
- In a compounding isolator, fixed gloves or gauntlets must be surface cleaned after compounding is completed to avoid spreading hazardous drug contamination to other surfaces.
- Clean gloves (e.g., the clean inner gloves worn by compounding personnel) should be used to surface decontaminate the final preparation, place the label onto the final preparation, and place it into the pass-through.
- Don fresh gloves to complete the final check, place preparation into a clean transport bag, and remove the bag from the pass-through.
- Wash hands before donning and after removing gloves.
- Remove gloves with care to avoid contamination. Specific procedures for removal must be established and followed.
- Change gloves after administering a dose of hazardous drugs or when leaving the immediate administration area.
- Dispose of contaminated gloves as contaminated waste.

ASTM = American Society for Testing and Materials; C-PEC = containment primary engineering control.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 5. *Recommendations for Use of Gowns*

- Gowns should be worn during compounding, during administration, when handling waste from patients recently treated with hazardous drugs, and when cleaning up spills of hazardous drugs.
- Select disposable gowns of material tested to be protective against the hazardous drugs to be used.
- Coated gowns must be worn no longer than 3 hours or as required by the manufacturer during compounding and changed immediately when damaged or contaminated.
- Remove gowns with care to avoid spreading contamination. Specific procedures for removal must be established and followed.
- Dispose of gowns immediately upon removal.
- Contain and dispose of contaminated gowns as contaminated waste.
- Wash hands after removing and disposing of gowns.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 6. *Recommendations for Working in BSCs and Compounding Isolators*

- The use of a C-PEC or isolator must be accompanied by a stringent program of work practices, including operator training and demonstrated competence, contamination reduction, and decontamination.
- Do not place unnecessary items in the work area of the cabinet or compounding isolator where hazardous drug contamination from compounding may settle on them.
- Do not overcrowd the BSC or CACI.
- Gather all needed supplies before beginning compounding. Avoid exiting and reentering the work area of the BSC or compounding isolator (CACI).
- Appropriate handling of the preparation in the BSC or pass-through of the isolator, including wiping with sterile 70% alcohol, is necessary for aseptic compounding.
- Reduce the hazardous drug contamination burden in the BSC or CACI by wiping down hazardous drug vials before placing them in the BSC or CACI.
- Do not place transport bags in the BSC or the CACI work chamber during compounding to avoid inadvertent contamination of the outside surface of the bag.
- Final preparations should be surface decontaminated within the BSC or CACI and placed into the transport bags in the BSC or in the CACI pass-through, taking care not to contaminate the outside of the transport bag.
- Decontaminate the work surface of the BSC or CACI before and after compounding per the manufacturer's recommendations.
- Decontaminate all surfaces of the BSC or CACI at the end of the batch, day, or shift, as appropriate to the workflow. Typically, a BSC or CACI in use 24 hours a day would require decontamination two or three times daily. Disinfect the BSC or CACI before compounding a dose or batch of sterile hazardous drugs.
- Wipe down the outside of the C-PEC front opening and the floor in front of it with detergent, sodium hypochlorite solution, and neutralizer at least daily.
- Seal and then decontaminate surfaces of waste and sharps containers before removing from the BSC or CACI.
- Decontamination is required after any spill in the BSC or CACI during compounding.
- Seal all contaminated materials (e.g., wipes, towels, wash or rinse water) in bags or plastic containers and discard as contaminated waste.
- Decontamination of the C-PEC must be done in a way that contains any hazardous drug surface contamination during the cleaning process.
- Appropriate decontamination within the C-PEC must be completed before the cabinet is accessed via the pass-throughs or removable front panels.

- Gloves or gauntlets must not be replaced before completion of appropriate decontamination within the CACI.
- Surface decontamination of final preparations must be done before labeling and placing into the pass-through of the CACI.
- Final preparations must be placed into a transport bag while in the pass-through for removal from the cabinet.

BSC = biological safety cabinet; CACI = compounding aseptic containment isolator; C-PEC = containment primary engineering control.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 7. *Recommended Contents of Hazardous Drug Spill Kit*

- Sufficient supplies to absorb a spill of about 1,000 mL (volume of one IV bag or bottle)
- Appropriate PPE to protect the worker during cleanup, including two pairs of disposable chemotherapy gloves (one outer pair of heavy utility gloves and one pair of inner gloves); nonpermeable, disposable protective garments (coveralls or gown and shoe covers); and face shield
- Absorbent, plastic-backed sheets or spill pads
- Disposable toweling
- At least two sealable, thick plastic hazardous waste disposal bags (prelabeled with an appropriate warning label)
- One disposable scoop for collecting glass fragments
- One puncture-resistant container for glass fragments

IV = intravenous; PPE = personal protective equipment.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 8. *Recommendations for Spill Cleanup Procedure*

General

- Assess the size and scope of the spill. Call for trained help, if necessary.
- Spills that cannot be contained by two spill kits may require outside assistance.
- Post signs to limit access to spill area.
- Obtain spill kit and respirator.
- Don PPE, including inner and outer gloves and respirator.
- Once fully garbed, contain spill using spill kit.
- Carefully remove any broken glass fragments and place them in a puncture-resistant container.
- Absorb liquids with spill pads.
- Absorb powder with damp disposable pads or soft toweling.
- Spill cleanup should proceed progressively from areas of lesser to greater contamination.
- Completely remove and place all contaminated material in the disposal bags.
- Rinse the area with water and then clean with detergent, sodium hypochlorite solution (or other appropriate decontamination agent), and neutralizer.
- Rinse the area several times and place all materials used for containment and cleanup in disposal bags. Seal bags and place them in the appropriate final container for disposal as hazardous waste.
- Carefully remove all PPE using the inner gloves. Place all disposable PPE into disposal bags. Seal bags and place them into the appropriate final container.

Continued on next page

- Remove inner gloves; contain in a small, sealable bag; and then place into the appropriate final container for disposal as hazardous waste.
- Wash hands thoroughly with soap and water.
- Once a spill has been initially cleaned, have the area recleaned by environmental services.

Spills in a BSC or Compounding Isolator

- Spills occurring in a BSC or isolator should be cleaned up immediately.
- Obtain a spill kit if the volume of the spill exceeds 30 mL or the contents of one drug vial or ampul.
- Utility gloves (from spill kit) should be worn to remove broken glass in a BSC or CACI. Care must be taken not to damage the fixed-glove assembly in the CACI.
- Place glass fragments in the puncture-resistant hazardous drug waste container located in the C-PEC or discard into the appropriate waste receptacle of the isolator.
- Thoroughly clean and decontaminate the C-PEC.
- Clean and decontaminate the drain spillage trough located under the C-PEC.
- If the spill results in liquid being introduced onto the HEPA filter or if powdered aerosol contaminates the "clean side" of the HEPA filter, use of the BSC or CACI should be suspended until the equipment has been decontaminated and the HEPA filter replaced.

BSC = biological safety cabinet; CACI = compounding aseptic containment isolator; C-PEC = containment primary engineering control; HEPA = high-efficiency particulate air; PPE = personal protective equipment.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.

FIGURE 9. *OSHA-Recommended Steps for Immediate Treatment of Workers with Direct Skin or Eye Contact with Hazardous Drugs*

- Call for help, if needed.
- Immediately remove contaminated clothing.
- Flood affected eye with water or isotonic eyewash for at least 15 minutes.
- Clean affected skin with soap and water; rinse thoroughly.
- Obtain medical attention.
- Document exposure in employee's medical record and medical surveillance log.
- Supplies for emergency treatment (e.g., soap, eyewash, sterile saline for irrigation) should be immediately located in any area where hazardous drugs are compounded or administered.

OSHA = Occupational Safety and Health Administration.

Source: Adapted from and originally published in American Society of Health-System Pharmacists (ASHP). ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63(Jun 15):1172-1193.