October 2017 "USP 800 – Safe Handling of Hazardous Drugs - Are you ready?" Volume 39 #10

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"Update - Safe Handling of Hazardous Waste"

October 2017

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In this lesson, we will focus on the safe handling of hazardous drugs in the hospital and in the community pharmacy setting. The goal is to review the requirements of USP Chapter <800>, which will take effect July 1, 2018.

This lesson provides 1.25 (0.125 CEUs) contact hours of credit, and is intended for pharmacists & technicians in all practice settings. **The program ID # for this lesson is 707-000-17-010-H01-P for pharmacists, and 707-000-17-010-H01-T for technicians.**

Participants completing this lesson by September 30, 2020 may receive full credit. Release date for this lesson is October 1, 2017.

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call 1-847-945-8050. **Please write your name, NABP eProfile (CPE Monitor®) ID Number & birthdate (MM/DD) in the indicated space on the quiz page.**

The objectives of this lesson are such that upon completion participants will be able to:

For Pharmacists:

1. Review the historical, current & approved hazardous drug standards.
2. Summarize the existing hazardous drug handling standards.
3. Discuss the challenges in meeting the new & emerging regulatory requirements for safe handling of hazardous products.

For Technicians:

1. Review approved hazardous drug standards.
2. Summarize the existing hazardous drug handling standards.
3. Discuss the new requirements for safe handling of hazardous products.

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INTRODUCTION

The need to protect healthcare workers from hazardous drugs has been an issue for several decades. Approximately 8 million U.S. healthcare workers may be exposed to hazardous drugs in their workplace.1 This includes physicians, pharmacists, pharmacy technicians, nurses, veterinarians, environmental services employees, and shipping and receiving staff. There is significant evidence that exposure to hazardous drugs can result in acute and chronic effects to the healthcare worker, including skin rash, reproductive toxicity and cancers. The risk of toxicity depends on the level of exposure to hazardous drugs. Implementation of operational and administrative controls, as well as personal protective equipment (PPE) can reduce the risks of exposure to healthcare workers.

The National Institute for Occupational Safety and Health (NIOSH) has developed a list of antineoplastic and other hazardous drugs used in healthcare settings.[1] This list is updated regularly and can be found at https://www.cdc.gov/niosh/docs/2016-161/default.html. The NIOSH Working Group on Hazardous Drugs has defined hazardous drugs as any drug that includes one or more of the following six characteristics in humans or animals:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

USP Chapter <800> describes the requirements and standards that must be in place when handling hazardous drugs.[2] These requirements apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs. Although much of the handling of hazardous drugs occurs in a hospital setting, ambulatory pharmacies and physician/veterinary offices may also be exposed to these hazardous drugs and must comply with the regulations as well. Below shows all of the potential sites where pharmacy workers may come into contact with hazardous drugs. (Hospital or any type pharmacy).

Before Arriving at Pharmacy	**Pharmacy**	**After Leaving Pharmacy**
Drug Company	Pharmacy Receiving	Waste Handler
Delivery	Pharmacy	Waste Management
Wholesaler	Patient Unit Delivery	Linen Handling
Packaging	Administration	Linen Management
Delivery to Pharmacy	Housekeeping	

Adapted from and with permission of Massoomi August 2017.

The original draft of USP Chapter <800> was published in March, 2014, with the second draft released in December, 2014 after public comment.[2] The final version was approved on February 1, 2016; however, the official effective date is July 1, 2108. Compliance with USP <800> was delayed to allow healthcare facilities additional time to implement the standard. In this lesson, we review the requirements of USP <800> that must be in place by July 1, 2018. The mandate may be enforced by State Health Departments, Centers for Medicare and Medicaid Services (CMS), State Boards of Pharmacy and accrediting agencies like the Joint Commission. USP <800> contains specific language that indicates requirements and suggestions. When "must" is used, that is a requirement within USP <800>. When the word "should" is used, it is a recommendation.

USP CHAPTER <800>

The USP Chapter <800> describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety and environmental protection.[2] The chapter contains 18 sections that will be discussed:

1. Introduction and scope
2. List of hazardous drugs
3. Types of exposure
4. Responsibilities of personnel handling hazardous drugs
5. Facilities and engineering control
6. Environmental quality control
7. Personal protective equipment
8. Hazard communication program
9. Personnel training
10. Receiving
11. Labeling, packaging, transport and disposal
12. Dispensing final dosage forms
13. Compounding
14. Administering
15. Deactivating, decontaminating, cleaning and disinfecting
16. Spill control
17. Documentation and SOPs
18. Medical surveillance

Section 1 is an introduction and reiterates that these standards apply to all healthcare workers who handle hazardous drugs.[2] This includes ambulatory pharmacies, physician offices, veterinarians, home care workers and hospital staff. There are a number of drugs dispensed in ambulatory pharmacies that are considered hazardous drugs by NIOSH. Examples include cyclosporine, abacavir, carbamazepine, estrogen, phenytoin, progestins, and risperidone. Ambulatory pharmacies that dispense hazardous drugs must comply with USP<800>.

Section 2 requires that each facility have a list of hazardous drugs. This list must include all

drugs on the current NIOSH list that are handled in the facility. The list must be reviewed each year and updated if necessary. All new drugs that are used should be compared to the current list of hazardous drugs. The NIOSH list should be reviewed annually. New drugs are summarized as they are approved so the facility's list can be updated regularly using the link indicated earlier in the Introduction.

Certain dosage forms of hazardous drugs (tablets or capsules) may not pose a significant risk of exposure to the healthcare worker.[2] However, dust from tablets and capsules may result in skin or respiratory exposure. Each facility must complete an assessment of risk and document what work practices or containment strategies are being used to reduce the risk of exposure. This assessment must be reviewed every 12 months and updated when necessary.

Many ambulatory pharmacies that only handle oral tablets and capsules can develop a straight forward policy on handling hazardous drugs.[2] This policy should include proper unpacking of products, use of separate counting trays, use of special gloves when handling antineoplastic agents, and steps for proper decontamination of equipment. The table below provides examples of containment strategies.

Example containment strategies[2]

Drug Name	Type of Drug	Risk of exposure	Containment strategy	Review date and signature
Ocella, Yasmin, Yaz, Prempro	Non-antineoplastic drug Unit dosed tablet	None, tablets are unit dosed & employees not exposed directly to tablet & do not manipulate	Tablets will not be removed from unit dose packaging	MM/DD/YYYY by:_____
Topiramate suspension	Drug with reproductive risk	Crushing tablets to compound suspension	Only employees of non-reproductive age will compound Must use chemotherapy gloves and face shield Do not pre-crush topiramate tablets Wipe down all containers touched during compounding Discard gloves and face mask in the hazardous waste container	MM/DD/YYYY by:_____
Progesterone vaginal suppositories	Non-antineoplastic drug Use progesterone powder (API) (Active pharmaceutical ingredient)	Risk of exposure to API	Must follow all USP <800> Containment requirements Compound in negative pressure room with at least 12 ACPH (air changes per hour) Must use Containment-Primary Engineering Control Must use PPE (personal protective equipment)	MM/DD/YYYY by:_____

Section 3 describes the various types of potential exposure to hazardous drugs.[2] Exposure can be through the skin, mucosa, inhalation, injection and ingestion (spills, mouth contact

with contaminated hands). The following table shows examples of unintentional exposure to hazardous drugs.

Potential opportunities for healthcare workers to be exposed to hazardous drugs[2]

Activity	Opportunity for exposure
Unpacking shipment of hazardous drug	Outside of containers may be contaminated with hazardous drugs
Dispensing	Counting and repackaging tablets or capsules
Compounding	Crushing tablets, opening capsules; Reconstituting drug powder in a vial; Expelling air from a syringe of hazardous drug; Weighing or mixing hazardous drugs
Administration	Priming an intravenous set; Generating aerosols during administration
Patient care	Handling body fluids, linens
Hazardous drug spill	Cleaning spill, disposal of materials
Waste disposal	Collection and disposal of hazardous waste

Section 4 describes the responsibilities of staff who handle hazardous drugs.[2] This standard requires that each facility have one person designated for developing and implementing policies and procedures related to hazardous drugs. This individual is responsible for ensuring all policies are adhered to and that all staff are properly trained in handling hazardous drugs. In addition this person must maintain all reports and testing/sampling that is conducted for hazardous drug. Each ambulatory pharmacy should identify one person who is responsible for overseeing hazardous drugs. The table below describes these responsibilities in detail.

Responsibilities of personnel handling hazardous drugs[2]

People	Processes	Products
Designated Expert	Address all risk points	Safety
Aptitude of risk	Continuous education	Sterility
Training	Consistency	Labeling
Math skills	Documentation of processes	Ingredient standards
Environmental monitor	Documented training	Reduce contamination
Clean environment	Operator testing	Consistency
Trustworthy	Re-training process	Safe transport

Section 5 explains the facilities and engineering controls that must be in place when handling hazardous drugs.[2] This section describes all controls necessary from the time a hazardous drug is received to when it is ready to administer to the patient. There is no longer an exemption for low volume hazardous sterile compounding.

Receipt - All hazardous drugs must be unpacked from shipping containers in a negative pressure or neutral (normal) pressure area.[2] Individuals who are unpacking hazardous drugs must be trained in handling hazardous drugs. They must wear personal protective equipment (PPE), including chemotherapy gloves. Section 10 will describe how to handle damaged hazardous drugs received during shipment.

Storage - All hazardous drugs must be stored in a way to prevent the container from falling and breaking or spilling.[2] Antineoplastic drugs that require reconstitution or dilution must be stored separately from other inventory. These hazardous drugs must be stored in an externally

ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Antineoplastic hazardous drugs that require refrigeration must be kept in a separate refrigerator in a negative pressure room with at least 12 ACPH. Non-antineoplastic drugs with only reproductive risk, and final dosage forms of antineoplastic HDs (hazardous drugs) may be stored with other inventory if permitted by the facility's policy.

Compounding - USP <800> requires specific controls to be in place to minimize both worker exposure and environmental exposure to hazardous drugs.[2] In addition, these controls prevent cross-contamination of equipment used in compounding. There are primary, secondary and supplemental controls that must be used. The primary control is the use of a containment-primary engineering control (C-PEC). This is a ventilated device that protects the worker from exposure. The C-PEC must provide an ISO (International Standards Organization) Class 5 or better air quality, such as a Class II or III Biologic Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI). Class II BSC types A2, B1, or B2 are acceptable. The C-PEC must be located in a containment secondary engineering control (C-SEC). The C-SEC is the actual room where the ventilated device is located. Whether compounding sterile or non-sterile hazardous drugs, the pharmacist must use a C-PEC within a C-SEC. The C-SEC must:

- Be externally vented through HEPA filters
- Be physically separated (i.e., a different room from other preparation areas)
- Have an appropriate air exchange (e.g., 12 ACPH)
- Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas

In addition to these controls, there must be a handwashing sink available that will not interfere with the required ISO classifications.[2] An emergency eyewash station must be available and any other required safety precautions. USP <800> details additional specific requirements for both non-sterile and sterile compounding requirements.

Containment Supplemental Engineering Controls - Supplemental engineering controls provide an extra level of protection when compounding and administering intravenous hazardous drugs.[2] The primary example of a supplemental engineering control is a closed system transfer device (CSTD). A CSTD is a drug transfer device that prevents both microbial contamination and the escape of drug or vapors outside the system, minimizing individual and environmental exposure to drug vapor aerosols and spills. Unless a hazardous drug is incompatible with CSTD, pharmacists should use these supplemental controls when compounding hazardous drugs. A CSTD must be used when administering hazardous drugs unless there is a documented incompatibility.

Section 6 discusses the recommended environmental controls required in pharmacies handling hazardous drugs.[2] A wipe sample of hazardous drug compounding surfaces should be done at least every 6 months to verify that there is no surface contamination. Wipe sampling should be conducted in the C-PEC, work areas near the C-PEC and adjacent areas including the floor under the C-PEC, dispensing areas and any storage areas. If the tests are positive for surface contamination, the individual responsible for managing hazardous drugs must document the contamination and implement procedures to deactivate and decontaminate the work areas. Repeat sampling is recommended to ensure effectiveness of deactivation/decontamination procedures.

Section 7 details the requirement for personal protective equipment (PPE) when handling

hazardous drugs.[2] Pharmacies must have an established policy for the use of PPE when handling hazardous drugs. These policies should define requirements during receipt, transfer and storage, compounding and administration, cleaning, spill control and waste disposal. USP <800> has specific requirements for types of PPE that include:

Gloves

USP <800> requires chemotherapy gloves be used when handling all hazardous drugs.[2] These gloves must meet the American Society for Testing and Materials (ASTM) standard D6978, and must be so labelled. Gloves should be inspected before each use to ensure their integrity. When specifically handling chemotherapy hazardous drugs, individuals should use double gloves. Chemotherapy gloves should be changed every 30 minutes or sooner if they are damaged. Healthcare workers should wash their hands thoroughly with soap after gloves are removed. When compounding sterile hazardous drugs, the outer chemotherapy gloves must be sterile.

Gowns

Gowns should be disposable and should be made of material that resists permeability by hazardous drugs.[2] Gowns should be worn so that they close in back. Gowns should be long-sleeved and should have an elastic or knit cuff that closes. Use of scrubs or white cloth coats can result in hazardous drug contamination of the material which can then contaminate other healthcare workers and surfaces. Only disposable external gowns should be permitted when compounding hazardous drugs. Any potentially contaminated clothing must not be taken out of the facility. It should be washed according to the administrative policy.

Head, hair, shoe and sleeve covers

These items provide additional protection from contact with hazardous drugs.[2] Double shoe covers should be worn when compounding hazardous drugs. The outer shoe covers are then removed to prevent spreading the hazardous drug to other workers. Healthcare workers may choose to use disposal sleeve covers to provide greater coverage than disposable gown alone.

Eye and face protection

Eye and mucus membrane irritation can occur with hazardous drug exposure.[2] Face and eye protection must be worn when compounding hazardous drugs in case of spills. The use of a face shield and goggles provides protection against splashes or spills. The use of eyeglasses or a face shield alone does not provide adequate protection.

Respiratory equipment

There are several types of masks and respirators that should be used when working with hazardous drugs.[2] Individuals who are unpacking hazardous drugs should use a half-mask with multi-gas cartridge when determining if there was any breakage during shipment. A standard surgical mask is not adequate protection. For most procedures, healthcare workers can use a fit-tested NIOSH-certified N95 respirator to protect against airborne particles.

Section 8 provides information about the facility's requirement for a hazard communication program.[2] Each facility must have a set of policies and procedures in place to protect workers who are exposed to hazardous drugs. Procedures must be in place to ensure proper training of all personnel before they work with hazardous drugs. In addition, all staff who are of child-bearing age, must document in writing that they understand the risks associated with handling hazardous

drugs. Staff must undergo additional training if the hazard changes. Another component of the hazard communication plan is that all containers of hazardous drugs be labeled with the name of the hazardous drug and any warnings regarding exposure.

Section 9 describes the personnel training requirements associated with handling hazardous drugs.[2] All employees must undergo training based on their job function. For example, employees who unpack hazardous drugs when received from the manufacturer must receive specific training, while individuals who compound hazardous drugs will complete more comprehensive training because of their higher risk. All training of employees must occur before they handle hazardous drugs independently. Hazardous drug training must be reassessed every 12 months or when there is a change in process. Training must include an overview of the hazardous drugs used in the facility, proper use of equipment, personal protective equipment, spill management and proper disposal.

Section 10 states that each facility must have policies for receiving hazardous drugs.[2] The supplier must send hazardous drugs in impervious plastic to prevent contact with other drugs. The hazardous drugs must be sent directly to the hazardous drug storage area for unpacking. When employees are unpacking hazardous drugs they must wear chemotherapy gloves and a spill kit should be available in the immediate area. If a shipping container arrives and is damaged, seal the container immediately and contact the supplier. If the supplier will not accept this return, the product should be disposed as hazardous waste. If the container must be opened, place the material in the C-PEC on a plastic-backed preparation mat and remove any undamaged containers. Clean the undamaged containers with disposal wipes. Place damaged product in an impervious container and label as hazardous. Return damaged container to supplier. The C-PEC should be cleaned and decontaminated. The cleaning material and disposable mat should be placed in hazardous waste containers.

Section 11 describes the labeling, transport and packaging requirements.[2] Hazardous drugs that require special handling must be clearly labeled during any transport through the facility. Each facility must have specific policies for the type of containers that can be used for transport to reduce the risk of breakage. Hospitals must not use pneumatic tubes for transport of liquid hazardous drugs including antineoplastics. Any staff responsible for the disposal or cleaning of areas where hazardous drugs are used must be trained in procedures to protect themselves from exposure.

Section 12 If the pharmacy is dispensing oral hazardous drugs that do not require any special handling, no additional steps are required.2 This would apply to products such as oral hazardous drugs that need to be counted or repackaged only. Hazardous drugs should be counted using dedicated equipment. All equipment should be thoroughly cleaned after each use. Automated machines for counting or repackaging must not be used with hazardous drugs since powder contamination may occur.

Section 13 states that individuals responsible for compounding hazardous drugs must comply with all USP <797> and <795> standards.[2-4] Plastic-backed disposal mats should be used when compounding hazardous drugs and should be changed if a surface spill occurs. Staff should handle bulk containers of hazardous drugs carefully to avoid a spill.

Section 14 describes the specific need to use PPE when administering hazardous drugs.[2] Nurses and others who administer hazardous drugs must wear disposable PPE and use protective medical devices (closed system transfer device, needleless system). Hazardous waste containers must be available at the administration site to dispose of tubing, containers and garb.

Section 15 This section provides details regarding proper deactivation, decontamination and disinfecting of materials and equipment used for compounding hazardous drugs.[2] Policies and procedures must be established that also comply with USP <795> and <797>. [2-4] When cleaning or decontaminating areas, the individual must wear 2 pairs of chemotherapy gloves, impermeable disposable gown, face shield and eye protection in the event of a splash. Cleaning solutions should be applied using wipes and not a spray bottle, which may result in spreading of the hazardous drug. All cleaning solutions must be approved for use with the specific hazardous drug as well as the surface area that is being cleaned. Consult the product manufacturer for more information. All areas where hazardous drugs are handled must be deactivated, decontaminated and cleaned. Sterile compounding areas and equipment must also be disinfected. The table below provides additional information on deactivation, decontamination and cleaning.

USP <800> requirements for deactivating, cleaning and disinfecting [2]

Cleaning step	Purpose	Example
Deactivation	Render compound inert or inactive	EPA registered oxidizers (peroxide formulations, sodium hypochlorite)
Decontamination	Remove hazardous drug residue	Alcohol, water, peroxide, sodium hypochlorite
Cleaning	Remove organic and inorganic material	Germicidal detergent
Disinfection	Destroy microorganisms	EPA registered disinfectant, sterile alcohol

Section 16 explains the requirements for managing a hazardous drug spill. All staff who are responsible for cleaning up spills should receive training.[2] They must wear PPE and certified-NIOSH respirator when cleaning up a spill. Spill kits should be available to staff where hazardous drugs are handled (stored, compounded and administered). All spills should be documented, including circumstances of the spill. If staff have direct contact with hazardous drug during the spill (eye or skin contact), they must have immediate evaluation. All spill materials are considered hazardous waste.

Section 17 describes the need for each facility to develop standard operating procedures (SOPs) for handling of hazardous drugs.[2] These SOPs should cover all aspects of hazardous drug use in the facility including receipt of shipment, storage, compounding, administration and disposal. Individuals must receive additional training if a change in procedure or new hazardous drugs are compounded. All training must be documented and available for review. Training should be updated every 12 months to ensure continued knowledge of processes.

Section 18 discusses the requirement for medical surveillance.[2] All healthcare workers who handle hazardous drugs should be enrolled in a medical surveillance program. Baseline data should be collected and compared to data after there is hazardous drug exposure. Baseline laboratory testing, medical history, previous work history (exposure) and any symptoms should be documented. Implementing a medical surveillance program can help with early detection if a health problem occurs.

CONCLUSION

USP Chapter <800> is a major step forward in ensuring the safety of healthcare workers handling hazardous drugs. It will have a major impact on all areas of pharmacy practice. All pharmacists who handle hazardous drugs must be aware of the requirements of USP <800> and facilities must be compliant by July 1, 2018. Not only will pharmacy policies and procedures be impacted to achieve compliance, the physical building environment will require an evaluation to ensure compliance. An existing facility needs to begin evaluating current operating procedures and space/infrastructure needs to support the new USP 800 requirements and develop a plan to achieve compliance.

REFERENCES

1. National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. https://www.cdc.gov/niosh/docs/2016-161/default.html. Accessed August 15, 2017.
2. United States Pharmacopeial Convention. General chapter <800> hazardous drugs-Handling in healthcare settings. http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare. Accessed August 15, 2017.
3. United States Pharmacopeial Convention. First Supplement to USP 39-NF 34. General chapter <797> Pharmaceutical compounding- Sterile preparations. 2016:39-84.
4. United States Pharmacopeial Convention. First Supplement to USP 39-NF 34. General chapter <795> Pharmaceutical compounding- Nonsterile preparations. 2016:31-39.

ABBREVIATIONS USED IN THIS LESSON

PPE	Personal protective equipment
NIOSH	National Institute for Occupational Safety & Health
ACPH	Air changes per hour
API	Active pharmaceutical ingredient
HD	Hazardous drug
C-PEC	Containment – primary engineering control
BSC	Biologic safety cabinet
CASI	Compounding aseptic containment isolator
C-SEC	Containment secondary engineering control
ISO	International Standards Organization
CSTD	Closed system transfer device
ASTM	American Society for Testing & Materials
SOPs	Standard Operating Procedures

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LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?
   - Review hazardous drug standards — YES NO
   - Summarize existing HD handling standards — YES NO
   - Discuss the new HD handling standards — YES NO

2. Was the program independent & non-commercial? YES NO

3. Relevance of topic (Low Relevance 1 2 3 4 5 6 7 Very Relevant)

4. What did you like most about this lesson?_____

5. What did you like least about this lesson?_____

Please Mark the Correct Answer(s)

1. **USP <800> applies to:**
   A. Hospital pharmacies.
   B. Community pharmacies.
   C. Specialty pharmacies.
   D. All of these.

2. **A pharmacy compounds a cream using estrogen & progesterone powders. USP <800> requires the product be compounded within a containment device, in a separate room, with negative pressure & 12 ACPH.**
   A. True
   B. False

3. **A specialty pharmacy dispenses oral chemotherapy agents that appear in the 2016 NIOSH list. The pharmacy policy is that only original containers of oral chemotherapy be dispensed & no repackaging occurs. Is the pharmacy compliant with USP <800>?**
   A. Yes
   B. No

4. **The pharmacy must have a written standard operating procedure about what specific PPE is worn when unpacking hazardous drugs.**
   A. True
   B. False

5. **When cleaning a hazardous drug compounding area, all cleaners must have separate spray bottles for use.**
   A. True
   B. False

6. **An ambulatory pharmacy purchases several hazardous drug active pharmaceutical ingredients (API) & compounds IV chemotherapy. These products should be stored separately from other inventory in an externally vented negative pressure room that contains a designated refrigerator for hazardous drugs, if necessary.**
   A. True B. False

7. **PPE used in hazardous drug compounding can be placed in regular trash.**
   A. True
   B. False

8. **The newest version of the NIOSH list of Antineoplastic & Other Hazardous Drugs in Healthcare Setting was published in:**
   A. 2004
   B. 2010
   C. 2014
   D. 2016

9. **The role of CSTDs when the new hazardous drug handling requirements are in place will be required for HD administration when dosage forms allow.**
   A. True
   B. False

10. **When compounding hazardous chemotherapeutic drugs, PPE should be used.**
    A. True
    B. False