Hazardous Drugs 101: How to Protect Yourself

A presentation for HealthTrust Members

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Speaker Disclosures

- The presenter and their preceptor have no financial relationships with any commercial interests pertinent to this presentation.

- This program may contain the mention of drugs, brands or suppliers presented in a case study or comparative format using evidence-based research. Such examples are intended for educational and informational purposes and should not be perceived as an endorsement of any particular drug, brand or supplier.

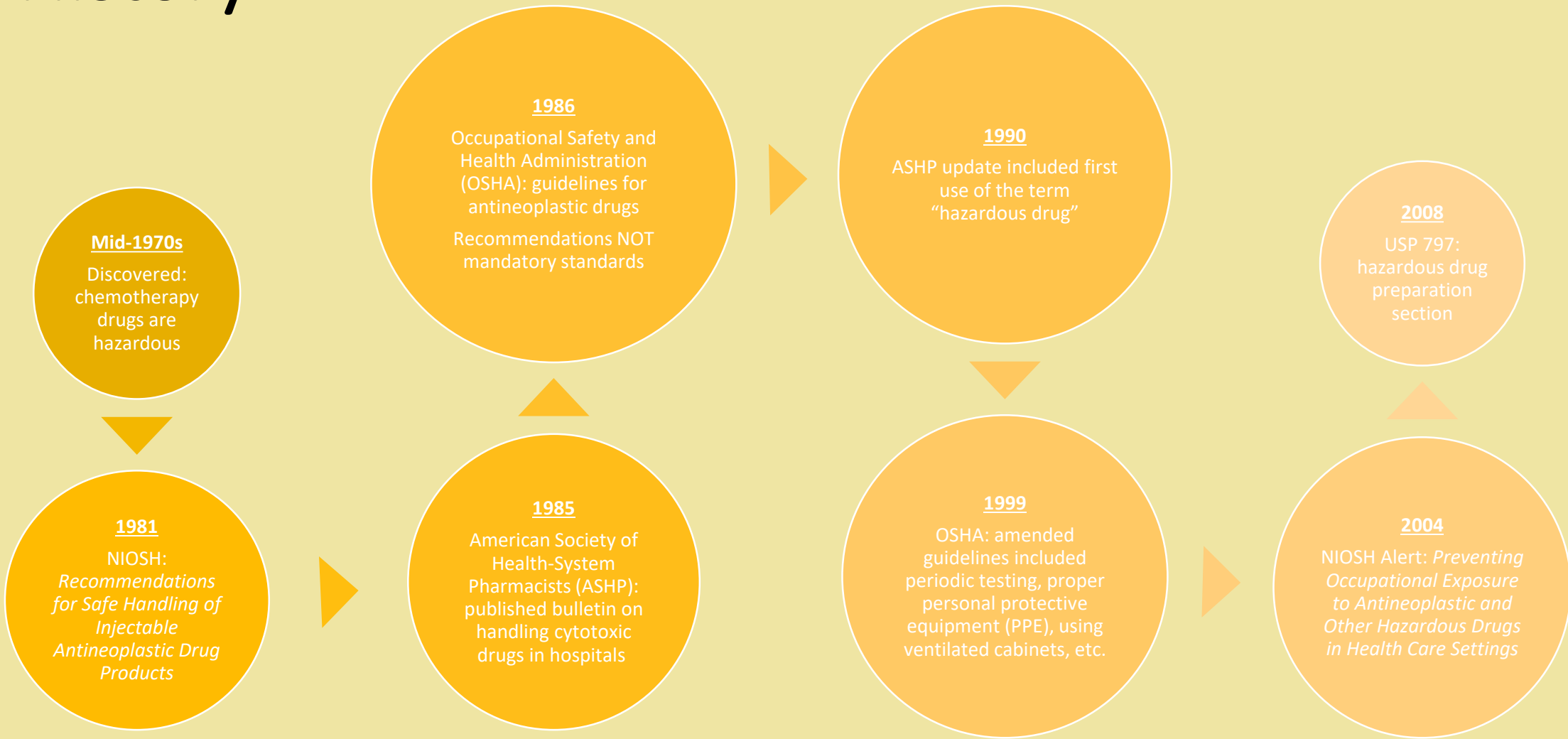
Learning Objectives for Pharmacists

- Identify the appropriate setting needed for sterile vs nonsterile hazardous compounding
- Recall the types of closed system drug-transfer devices that are available
- Recognize the purpose of assessment of risk and how it is performed

Learning Objectives for Pharmacy Technicians

- Recall the proper storage of hazardous drugs and the importance of decontamination and clean-up of hazardous drug spills
- Identify what types of personal protective equipment (PPE) are needed for the preparation of hazardous medications
- Recognize why a drug is hazardous and belongs to the NIOSH hazardous drug list

History



Source: Cathy Zhao and Allison Radwick. PDA Letter. Last Updated August 13, 2020.

History, cont.

2010: “Lifesaving Cancer Drug May Put Workers’ Lives at Risk”

- Sue Crump, 55-year old pharmacist died of pancreatic cancer
- Washington state passed two HD rules:
  - Requirements of for handling HDs
  - HD workers’ registry → track adverse experiences

USP Council of Experts to create a single guidance standard → USP 800

Source: Cathy Zhao and Allison Radwick. PDA Letter. Last Updated August 13, 2020.

NIOSH

- National Institute for Occupational Safety and Health (NIOSH)
  - Focuses on the study of worker safety and health
  - A part of Centers for Disease Control and Prevention (CDC) and US Department of Health and Human Services (HHS)
  - Established as a research agency as a result of the Occupational Safety and Health Act of 1970
    - Enforces standards for safe and healthful conditions for workers

Source: Centers for Disease Control. The National Institute for Occupational Safety and Health (NIOSH). Updated June 29, 2022

A Case Report

From NIOSH 2004 Alert

- 39-year old pharmacist
- Two episodes of blood in the urine → papillary transitional cell carcinoma
- 12 years prior to diagnosis → worked full time x20 months hospital IV room
  - Prepared cytotoxic agents: cyclophosphamide, fluorouracil, methotrexate, doxorubicin, cisplatin, etc.
- Used a horizontal laminar-flow hood → directed air towards her
- Non-smoker, no other environmental/occupational risk factors
  - Cause was attributed to antineoplastic exposure (not established in literature)

Source: Centers for Disease Control and Prevention. NIOSH Alert. Revised 2004.

Hazardous Drug (HD)

Source: https://adioma.com/icons/pregnancy

- NIOSH revised ASHP definition (per the 2016 update):
  - Drugs that exhibit ≥ 1 characteristic in humans or animals
    - Carcinogenicity
      - Tumors
    - Teratogenicity or developmental toxicity
      - In 2015, removed pregnancy categories A, B, C, D, and X → "Pregnancy", "Lactation", and "Females and Males of Reproductive Potential"
    - Reproductive toxicity
    - Organ toxicity at low doses
      - Low dose: 10 mg/day or 1 mg/kg/day
    - Genotoxicity
      - Mutagenicity or clastogenicity
    - New drugs with similar structure and toxicity profiles as drugs deemed hazardous by the above criteria

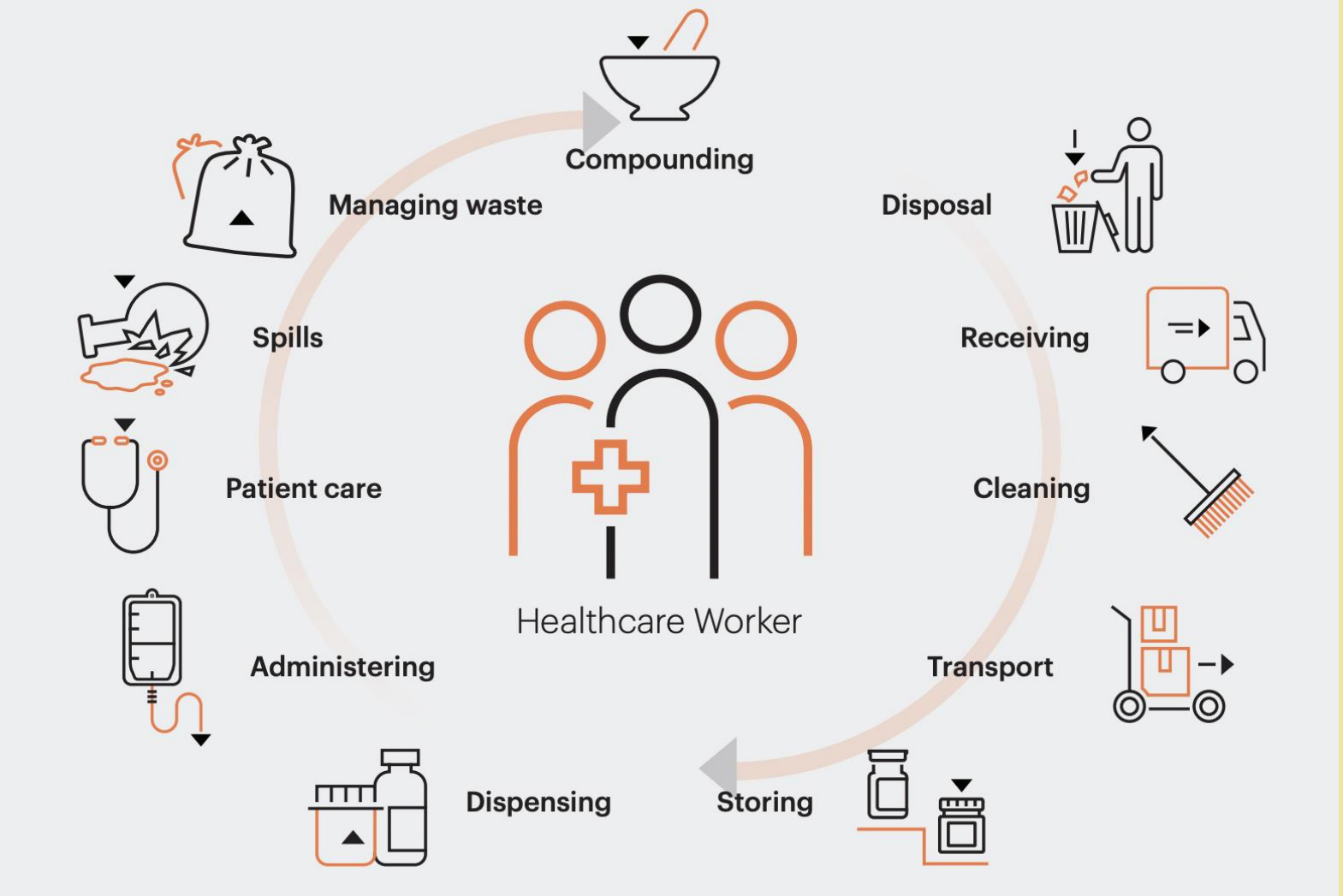
Source: Centers for Disease Control. The National Institute for Occupational Safety and Health (NIOSH). Updated June 29, 2022

Hazardous Drug List

- Each entity must maintain a list of hazardous drugs that it handles based on the most up to date NIOSH list
- With every new agent (including investigational drugs) and dosage form, use the HD criteria to determine if the drug is hazardous especially if the drug/dosage form entered the market after the NIOSH list was last updated
- List should be updated by entity every 12 months

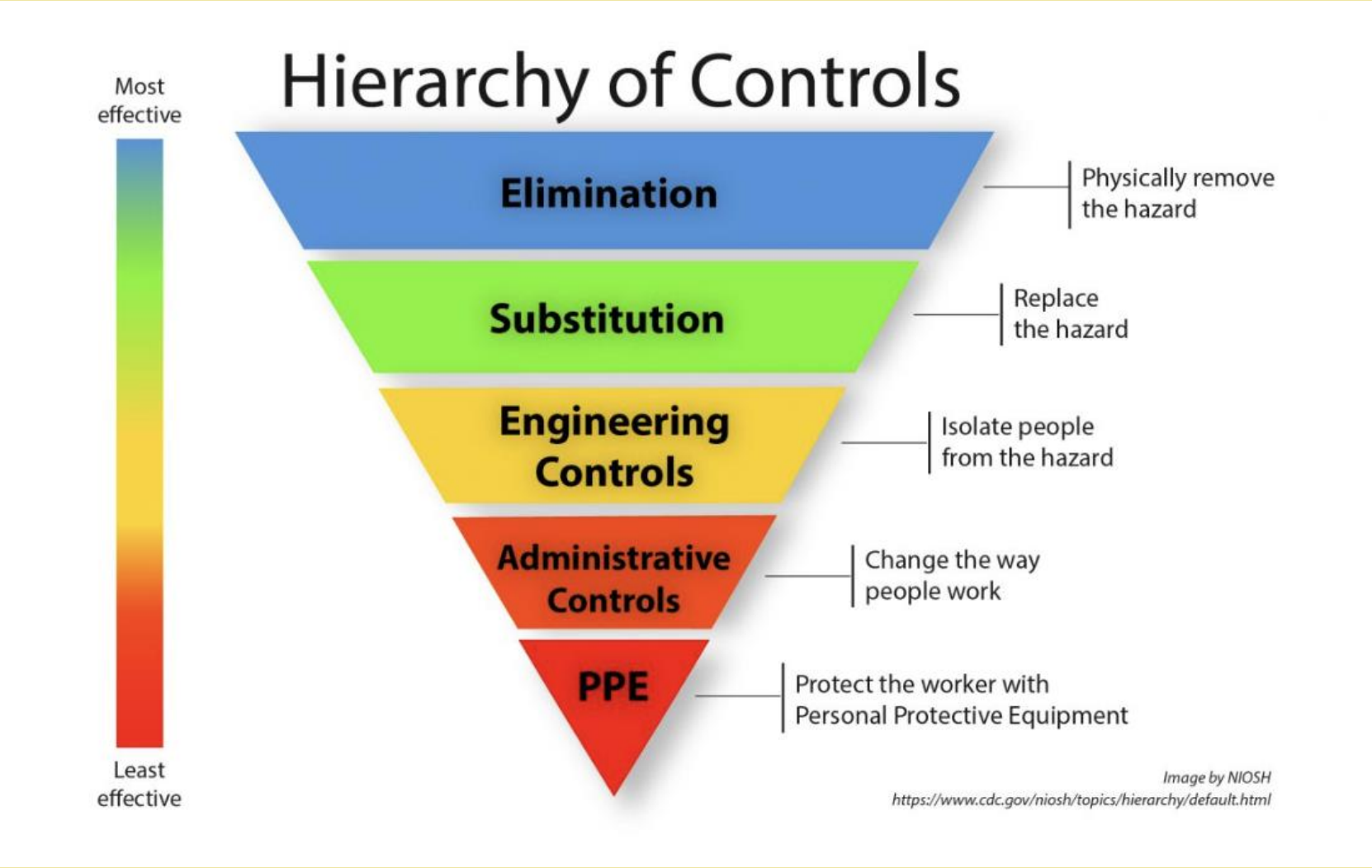
Sources: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020
Centers for Disease Control and Prevention. NIOSH List of Hazardous Drugs in Healthcare Settings, 2020. Official July 2020.

Exposure



Source: https://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/800-know-your-exposure-to-hazardous-drugs.pdf

Hierarchy on Controls



Source: Centers for Disease Control. The National Institute for Occupational Safety and Health (NIOSH). Updated June 29, 2022

United States Pharmacopeia (USP) 800

- Provides standards for safe handling of hazardous drugs to minimize its exposure to healthcare personnel, patients, and the environment
- Last updated in December 2019
- Since USP 797 (2023) references USP 800, USP 800 will become compendially applicable beginning November 1, 2023

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Engineering Controls

- Protect product from cross-contamination and microbial contamination during compounding
  - Containment primary engineering control (C-PEC)
    - Minimizes worker and environmental HD exposure when directly handling HD
  - Containment secondary engineering control (C-SEC)
    - The room which contains the C-PEC

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

C-PEC

Example	Properties	Environment	Notes
Laminar airflow workbench (LAFW)	Unidirectional, HEPA-filtered airflow (vertical or horizontal)	ISO Class 5 or better	Not to be used for HD preparation
Class II Biological Safety Cabinet (BSC)	Inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust	ISO Class 5 or better	Exhaust must be externally vented to use for HD compounding
Compounding Aseptic Isolator (CAI)	No air exchange into the CAI until it passes through HEPA filter	Maintains ISO Class 5 throughout compounding and material transfer	For non-HD compounding
Compounding Aseptic Containment Isolator (CACI)	Protects worker from airborne drug	Maintains ISO Class 5 throughout compounding and material transfer	For sterile HD compounding

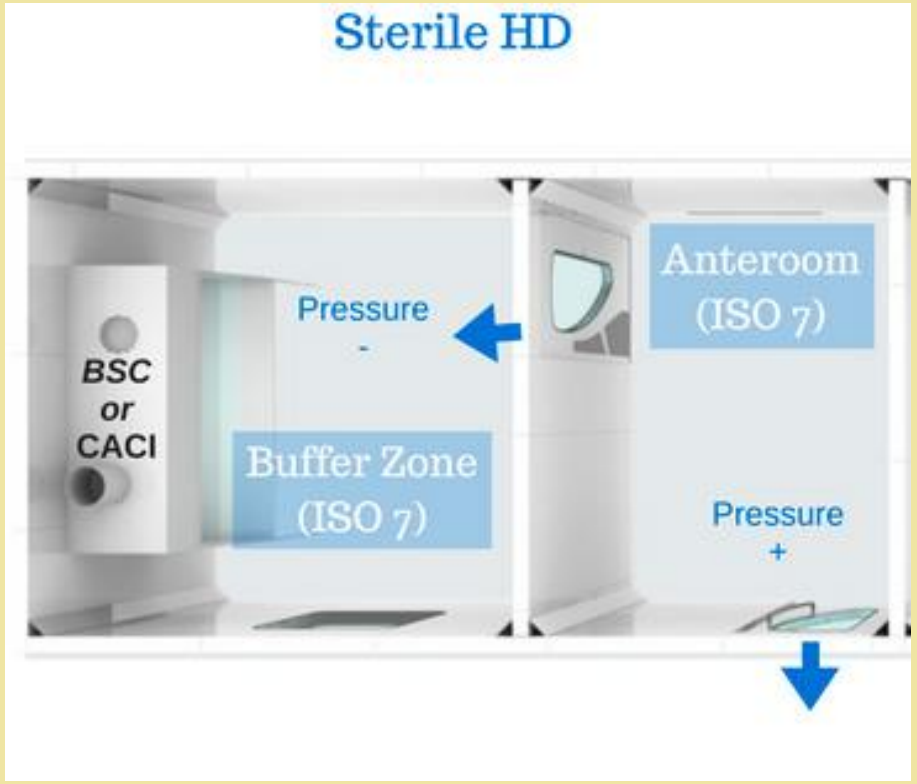
Source: The United States Pharmacopeial Convention. USP 797 Pharmaceutical Compounding - Sterile Preparations.

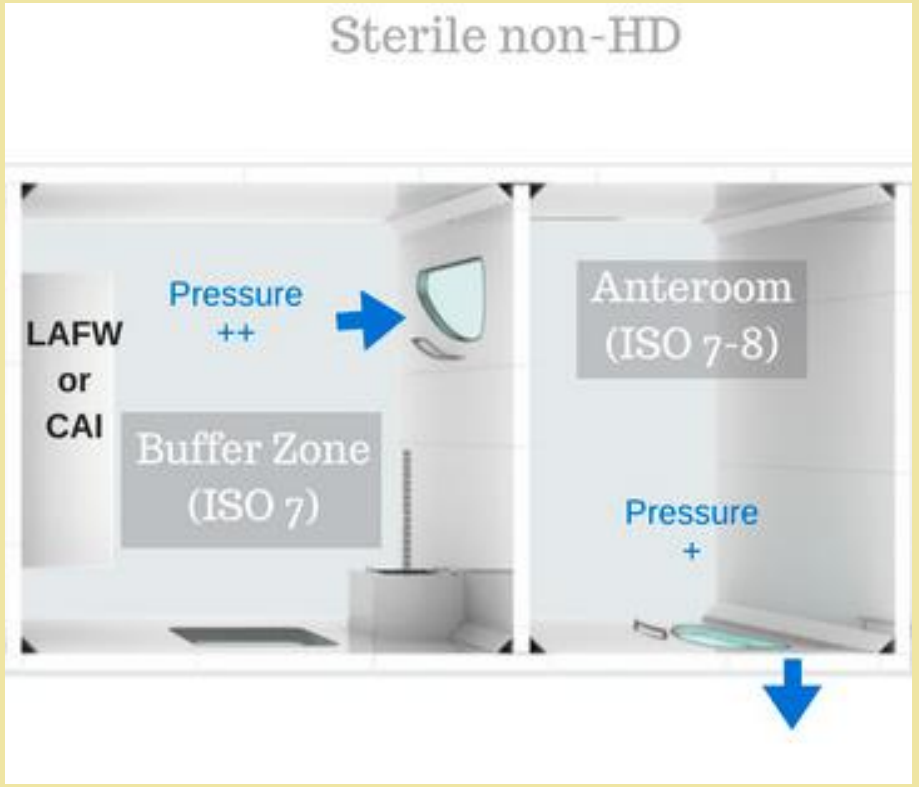
C-SEC

- Cleanroom suite: ISO-classified ante-room and buffer room
- Segregated compounding area (SCA): unclassified area (no ante-room or buffer room)

Source: The United States Pharmacopeial Convention. USP 797 Pharmaceutical Compounding - Sterile Preparations.

Compounding Environments





Source: https://www.mecart-cleanrooms.com/

Non-sterile Compounding of Hazardous Drugs

- C-PEC not required if:
  - Counting or repackaging tablet or capsule
    - Does not produce gas, aerosols, or particles
- Requirements for manipulation beyond the final dosage form:

Type of Engineering Control	Requirements

C-PEC	• Externally vented or redundant-HEPA filtered in series
	  • Containment Ventilated Enclosure (CVE)
	  • Class I or II Biological Safety Cabinet (BSC)
	  • Compounding aseptic containment isolator (CACI)

C-SEC	• Externally vented • 12 air changes per hour (ACPH) • Negative pressure (0.01 to 0.03 inches of water column) • Relative to adjacent rooms

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Sterile Compounding of Hazardous Drugs

- Do NOT use LAFW or CAI for HD preparation

Type of Engineering Control	**Requirements**
C-PEC	Externally vented • Class II BSC or CACI • ISO Class 5 or better
C-SEC	ISO Class 7 buffer room with an ISO Class 7 ante-room • Externally vented • 30 ACPH • Negative pressure (0.01 to 0.03 inches of water column) OR Containment segregated compounding area (C-SCA) with unclassified air • Externally vented • 12 ACPH • Negative pressure (0.01 to 0.03 inches of water column)

Beyond use dates (BUD) for each setting should be determined based on current USP 797

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

HD Decontamination and Cleaning

- During compounding and handling

Cleaning Step	Purpose	Example Agents	Non-sterile Compounding	Sterile Compounding
Deactivation	Make the compound inactive	EPA*-registered oxidizers: peroxide, sodium hypochlorite	Yes	Yes
Decontamination	Remove HD residue	Alcohol, water, peroxide, sodium hypochlorite	Yes	Yes
Cleaning	Remove organic and inorganic material	Germicidal detergent	Yes	Yes
Disinfection	Kill microorganisms	EPA*-registered disinfectant or sterile alcohol	No	Yes
Combination products available (include cleaner, disinfectant, and decontaminant)				

* Environmental Protection Agency

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Personal Protective Equipment (PPE)

- Purpose: to protect the worker from HD aerosols and residues
- Should be used when handling HD during:
  - Receipt, storage, transport, **compounding (sterile and nonsterile)**, administration, deactivation/decontamination or spills, waste disposal

Source: https://www.skillshare.com/en/projects/PPE-Icon-setclip-art/278211

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

PPE - Chemotherapy Gloves

- 2 pairs → change every 30 mins or when torn, punctured, or contaminated
- Must be American Society for Testing and Materials (ASTM) certified – tested with different chemotherapy drugs to assure they are impermeable

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

PPE - Impermeable Disposable Gowns

- Change every 2-3 hours or after spill/splash (if permeation information not available from manufacturer)
- Remove gown prior to entering other areas

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

PPE – Covers

- **Shoe covers**
  - 2 pairs – remove 2nd pair upon exiting C-SEC
- **Head, hair, and sleeve covers**
  - Protect from contact with HD residue

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

PPE – Face Protection

- **Goggles or face shield**
  - When working with HD with risk for spills/splashes and working at or above eye level
- **Respiratory protection – when required**
  - Surgical masks do not provide protection against HDs
  - Surgical N95 – no protection against gases and vapors
  - Use:
    - Full-facepiece, chemical cartridge-type respirator
    - Powered air-purifying respirator (PAPR)

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Doffing

- Doffing is just as important as donning → dispose PPE in appropriate waste container before leaving C-SEC
  - Prevent those who handle the disposed PPE from being exposed to the contaminated PPE

Line of demarcation

Source: https://www.google.com/url?sa=i&url=https%3A%2F%2Fwww.pppmag.com%2Farticle%2F1988&psig=AOvVaw1GzxZaHtV_l5AQFBQJ_Ymh&ust=1675480261385000&source=images&cd=vfe&ved=0CA8QjRxqFwoTCMDSkMCw-PwCFQAAAAAdAAAAABAE

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Closed System Drug-Transfer Devices (CSTD)

- Supplementary engineering control
  - offers additional level of protection
  - NOT to be used in place of C-PEC
- Definition: “a drug transfer device that mechanically prohibits the transfer or environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system”
- Prevents escape of hazardous drug into the environment
- Protects healthcare workers during compounding and administration

Source: Centers for Disease Control and Prevention. Hazardous Drug Exposures in Healthcare. Reviewed January 2019

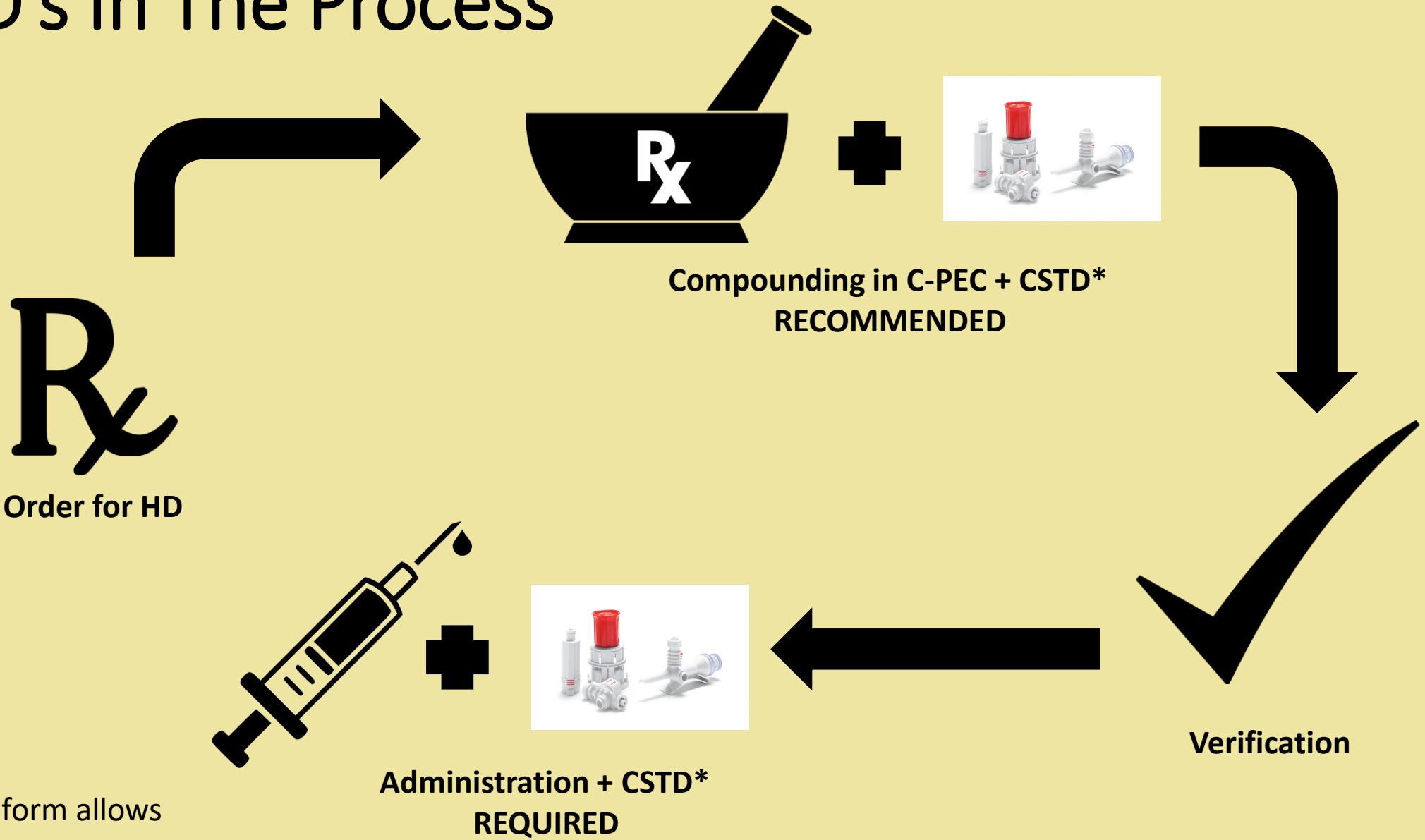
CSTDs, cont.

- Two design concepts:

Physical barrier	Air-cleaning technology
Arisure® CSTD	ChemoClave® Vented Vial Spike
ChemoClave® and ChemoLock™ Vial Spike with external balloon	ChemoLock™ Vented Vial Spike
Equashield® CSTD	OnGuard® 2 Chemfort™ ToxiGuard®
HALO® CSTD	OnGuard® Tevadaptor®
PhaSeal™ and PhaSeal™ Optima	Texium™ & SmartSite™ Vented Vial Access device
Texium™ & SmartSite™ VialShield	

Equashield®

CSTD's In The Process



*When dosage form allows

CSTDs In The Process, cont.

- Not all CSTDs are equally protective
- Should not be used as the only means of protection
  - Conjunction with other methods
- NIOSH recommendation: use CSTD throughout the hazardous drug-handling chain
- Studies show reduced contamination with the use of CSTD
- Currently, no standardized test available for testing the efficacy of CSTDs in containment of hazardous drug
  - Several methods have been used
    - Technical methods: smoke, titanium vapor, lactose, fluorescein, sulfur hexafluoride
    - Informal methods: coffee and lemon juice/litmus paper
  - NIOSH researchers are developing a test protocol

Source: Centers for Disease Control and Prevention. Hazardous Drug Exposures in Healthcare. Reviewed January 2019

CSTDs Approval Process

- 510K: application to the FDA to market a US Class I, II, or III device that is intended for human use
- Demonstrates to the FDA that the device is safe and effective
- FDA needs to clear the device as substantially equivalent (SE) to a legally marketed device
- FDA needs to state that the device can be marketed in the US

Source: U.S. Food and Drug. Premarket Notification 510(k). Updated October 3, 2022.

Assessment of Risk

- Purpose: to use an alternative containment strategies or work practices than those defined by USP 800 to minimize occupational exposure
- For dosage forms such as tablets or capsules
- Minimum considerations:
  - Type of HD (antineoplastic, non-antineoplastic, reproductive risk only)
  - Dosage form
  - Risk of exposure
  - Packaging
  - Manipulation
- When assessment of risk approach is used, it should be reviewed at least every 12 months

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Assessment of Risk, cont.

Assessment of Risk for USP <800> Compliant Alternative Containment Strategy	
Drug Name:	**Assessment of Risk Completed on (Date):**
Type of HD ☐ Antineoplastic ☐ Non-antineoplastic (may pose a reproductive risk) ☐ Reproductive risk primarily	
Dosage Form ☐ Tablet of conventionally manufactured product that requires only packaging or counting ☐ Capsule of conventionally manufactured product that requires only packaging or counting ☐ Oral liquids of conventionally manufactured product that requires only packaging or counting ☐ Injectables of conventionally manufactured product that requires only packaging or counting ☐ Other (explain):	
Packaging - *Include drug name, strength, and dosage form.*	

Source: NCPA. USP <800> assessment of risk templates available now. Updated July 25, 2019.

Assessment of Risk, cont.

Risk of Exposure

- ☐ **NIOSH Table 1:** The drug meets one or more of the NIOSH criteria for a hazardous drug. Many of these drugs are cytotoxic and may also be hazardous to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

  Supplemental Information:
  Route of exposure: Contact with skin (injectables, repackaged oral liquids)
  Ingestion of HD materials (capsules)
  Inhalation (powder)

- ☐ **NIOSH Table 2:** The drug meets one or more of the NIOSH criteria for a hazardous drug. Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.

  Supplemental Information:
  Route of exposure: Contact with skin (injectables, repackaged oral liquids)
  Ingestion of HD materials (capsules)
  Inhalation (powder)

- ☐ **NIOSH Table 3:** Potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk.

  Supplemental Information:
  Route of exposure: Contact with skin (injectables, repackaged oral liquids)
  Ingestion of HD materials (capsules)
  Inhalation (powder)

Source: NCPA. USP <800> assessment of risk templates available now. Updated July 25, 2019.

Assessment of Risk, cont.

Alternative Containment Strategies

- The receipt of any HD, except for an antineoplastic or API, will be handled and stored per the manufacturer.
- HD tablets and capsules will be cut, crushed, or otherwise manipulated ONLY in a C-PEC work station (double HEPA or vented to the outside) with a powder shield to protect the worker's face and eyes from exposure.
- Protection of face (with face shields), eyes (with goggles), and skin (with gloves) when manipulating HD liquids.
- The final compounded HD product will be placed in a sealed impervious plastic bag and labeled as per protocol.
- Non-disposable materials used to compound the HD will be cleaned in an empty sink with a specified lab grade detergent and suitable cleaning process as determined by protocol.
- The materials, sink, and designated compounding area will be decontaminated per protocol or material data sheet.
- Plastic wrap, PPE, and cleaning materials will be placed in hazardous waste disposal located near the compounding area, if necessary per HD disposal protocol.

Based on Assessment of Risk our pharmacy will proceed as follows:

- ☐ Follow alternative containment strategies documented above
- ☐ Follow all USP <800> requirements

Assessment of Risk written by:

_____ Date: _____

Source: NCPA. USP <800> assessment of risk templates available now. Updated July 25, 2019.

Assessment of Risk Examples

Assessment of Risk	Clonazepam	Cyclophosphamide
HD Category	Reproductive risk, primarily	Antineoplastic
Dosage Form	Tablet	Capsule
Packaging	Unit-dose, bulk bottle	Bulk bottle
Risk of Exposure	Dust from bulk bottle during repacking	Dust from bulk bottle during repacking
PPE	ASTM certified 2 chemotherapy gloves, N95 mask	ASTM certified 2 chemotherapy gloves, N95 mask
Plan	Intermixed with other non-HDs	Bulk bottle - segregated HD section; unit dose – intermixed with non-HDs

Prior to Preparing and Dispensing

- During receiving, unpacking, storing, and transporting:
  - Single pair of chemotherapy gloves
    - American Society for Testing and Materials (ASTM) certified

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

HD Storage

- Storage
  - Not on the floor
  - On secured shelves with raised front lips
    - Should prevent breakage or spillage if container falls
  - Antineoplastic that require manipulation
    - 12 ACPH, negative pressure, externally ventilated room
  - Non-antineoplastic, reproductive risk only, and final dosage form antineoplastic
    - May be stored with other drugs
  - HDs used for nonsterile compounding
    - Should not be stored in sterile compounding area
  - Refrigerated antineoplastic HDs
    - Dedicated refrigerator
    - Negative pressure, ≥ 12 ACPH

Source:
https://www.google.com/url?sa=i&url=https%3A%2F%2Fshop.gohcl.com%2Fdefault.aspx%3Fpage%3Ditem%2Bdetail%26itemcode%3D2290&psig=AOvVaw0NzYq4eB7J41vlK_IKkcWg&ust=1675475206539000&source=images&cd=vfe&ved=0CA8QjRxqFwoTCLje69Wd-PwCFQAAAAAdAAAAABAG

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

HD Spill Control

Source: https://www.google.com/url?sa=i&url=https%3A%2F%2Fstore.sharpsinc.com%2Fhazardous-drug-spill-control-kit&psig=AOvVaw3I__My-qo4f3-HqvlRFdWw&ust=1675475292900000&source=images&cd=vfe&ved=0CA8QjRxqFwoTCKjoo_-d-PwCFQAAAAAdAAAAABAG

- Proper PPE and NIOSH-certified respirator
  - Prevent physical or airborne exposure to HD
- Standard operating procedures (SOPs) for spill control
  - Size and scope of spill
  - Required PPE
  - Management of spill → decontamination, deactivation, cleaning
    - Decontamination: inactivate, neutralize, or physically remove HD residue from non-disposable surfaces
- Document management and circumstance of spill
- Signs for restricting access to spill area
- Spill materials → hazardous waste
- Spill skits available → each kit cleans up to a liter of a spill and has different components needed to control spills (appropriate PPE, clean up materials, etc)

Source: The United States Pharmacopeial Convention. USP 800 Hazardous Drugs - Handling in Healthcare Settings. Official July 2020

Assessment Questions

Pharmacist Question # 1

For the compounding of a non-sterile hazardous drug, all of these conditions are required except:

a) C-PEC that is externally vented
b) C-PEC with ISO Class 5
c) C-SEC that is externally vented
d) C-SEC with 12 ACPH and has negative pressure
e) All of the above are required

Pharmacist Question # 1 Correct Response

For the compounding of a non-sterile hazardous drug, all of these conditions are required except:

a) C-PEC that is externally vented

b) C-PEC with ISO Class 5

c) C-SEC that is externally vented

d) C-SEC with 12 ACPH and has negative pressure

e) All of the above are required

Pharmacist Question # 2

What types of CSTDs are available?

a) Physical barrier
b) Air-cleaning
c) Non-physical barrier
d) Both A and B
e) Both B and C

Pharmacist Question # 2 Correct Response

What types of CSTDs are available?

a) Physical barrier
b) Air-cleaning
c) Non-physical barrier
d) Both A and B
e) Both B and C

Pharmacist Question # 3

What needs to be considered for assessment of risk for determining the strategies of containment?

a) Who is receiving the drug
b) Who is preparing the drug
c) Dosage form of the drug
d) The adverse reaction profile of the drug
e) None of the above

Pharmacist Question # 3 Correct Response

What needs to be considered for assessment of risk for determining the strategies of containment?

a) Who is receiving the drug
b) Who is preparing the drug
c) Dosage form of the drug
d) The adverse reaction profile of the drug
e) None of the above

Pharmacy Technician Question # 4

Where should hazardous drugs be stored

a) On the floor
b) On shelves with raised front lips
c) In positive pressure room only
d) If refrigerated, with non-hazardous drugs
e) None of the above

Pharmacy Technician Question # 4 Correct Response

Where should hazardous drugs be stored

a) On the floor
b) On shelves with raised front lips
c) In positive pressure room only
d) If refrigerated, with non-hazardous drugs
e) None of the above

Pharmacy Technician Question # 5

Which of the following PPE are required for the preparation of hazardous drugs?

a) 2 pairs of shoe covers for sterile compounding
b) 2 pairs of chemotherapy gloves
c) Hair cover
d) Impermeable disposable gown
e) All of the above are required

Pharmacy Technician Question # 5 Correct Response

Which of the following PPE are required for the preparation of hazardous drugs?

a) 2 pairs of shoe covers for sterile compounding
b) 2 pairs of chemotherapy gloves
c) Hair cover
d) Impermeable disposable gown
e) All of the above are required

Pharmacy Technician Question # 6

A drug would receive a hazardous drug designation for all of the following reason except:

a) The drug is carcinogenic
b) The drug can pose a reproductive risk to the healthcare worker
c) The drug can cause organ toxicity at low doses
d) The drug can cause adverse drug reactions
e) All of the above

Pharmacy Technician Question # 6: Correct Response

A drug would receive a hazardous drug designation for all of the following reason except:

a) The drug is carcinogenic

b) The drug can pose a reproductive risk to the healthcare worker

c) The drug can cause organ toxicity at low doses

d) The drug can cause adverse drug reactions

e) All of the above

Pharmacy Technician Question # 7

It is important to decontaminate and clean up spills to avoid exposure to healthcare personnel

a) True

b) False

Pharmacy Technician Question # 7: Correct Response

It is important to decontaminate and clean up spills to avoid exposure to healthcare personnel

a) **True**

b) False

References

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Thank you!

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