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# USP <800> What You Need to Know

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## Objectives

- 1 Define "Hazardous Drugs"
- 2 Discuss the dangers of hazardous drug exposure
- 3 Discuss the USP <800> standards for handling hazardous drugs
- 4 Define steps to implement USP <800> compliance

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**OSHA and NIOSH** define Hazardous Drugs as having **1 or more** of the following characteristics:

1. **Carcinogenicity:** causes cancer
2. **Teratogenicity:** causes birth defects
3. **Reproductive Toxicity:** affects fertility
4. **Organ Toxicity** in low doses
5. **New drugs** that **mimic existing drugs** that have been deemed hazardous by the above criteria



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There is **NO**  
minimum  
**acceptable level**  
of exposure to  
**Hazardous**  
**Drugs!**



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## Hazardous Drug Examples

- Cancer Chemotherapy
  - ✓ MMC-only FDA-approved is Mitosol-Fluorouracil (5-FU)- off-label
- Antiviral Medications
- Hormones
- Some bioengineered drugs
  - ✓ Avastin (reproductive risk only)
- Other miscellaneous drugs
  - ✓ Drugs with safe handling guidelines from manufacturer

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The **National Institute for Occupational Safety and Health (NIOSH)** maintains a list of antineoplastic and other hazardous drugs used in healthcare.

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## Potential for Exposure

### ○ Receipt of HDs

- ✓ e.g., HD residue found on external containers

### ○ Administering/Manipulations

- ✓ Administration: generating aerosols while squirting HD into a cup or stirring
- ✓ Reconstitution
- ✓ Expelling air from syringes
- ✓ Cleaning/deactivating items contaminated with HDs

### ○ Spills

### ○ Transport

### ○ Waste/Disposal

### ○ Patient Care Activities

- ✓ e.g., Handling body fluids of patient receiving HDs (IV or urology, not ophthalmic surgery)



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## Types of Exposure: Unintentional Entry of HDs

Skin &  
Mucosal  
Absorption



Inhalation



Injection



Ingestion



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## Environmental Contamination



### ○ Surveillance Studies:

- ✓ HDs found on: chairs, pens, keyboards, printers, telephones
- ✓ Staff who were not involved in administering HDs
  - i.e., unit clerks, volunteers, etc., were exposed.

## Guidelines vs. Standards

**GUIDELINES**  
*recommendations*  
from NIOSH, ASHP, etc.


**NOT**  
**Enforceable**

**STANDARDS**  
*requirements*  
from DOH, CMS, TJC


**Enforceable**



“This chapter applies to all healthcare professionals who handle HD preparations and all entities that store, prepare, transport or administer HDs, e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics physician’s practice facilities...”



## USP <800>

○ Includes, but **NOT LIMITED TO**:

- ✓ Pharmacists
- ✓ Pharmacy technicians
- ✓ Nurses/OR technologists
- ✓ Physicians
- ✓ Physician Assistants

○ Does **NOT** provide exemptions for HD use outside of the pharmacy

- ✓ e.g. Operating Rooms, Physician Offices

A legally recognized compendium of standards for drugs, published by the United States Pharmacopeial Convention, Inc.

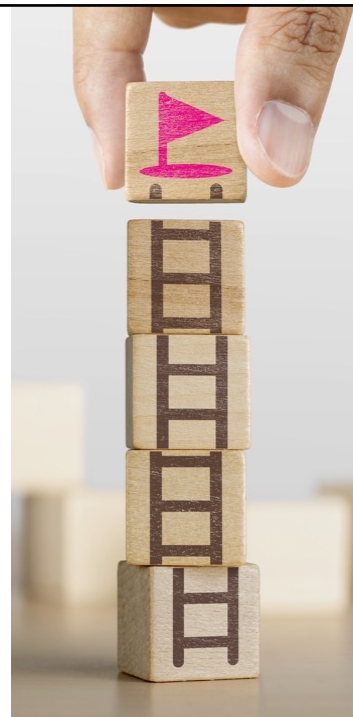


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## Requirements

### 1. Designated Person

- Each facility must have a **designated person** who is **qualified and trained** to be responsible for:
  - ✓ Developing and implementing appropriate standard operating procedures
  - ✓ Overseeing facility compliance with USP <800> and other regulations / standards
  - ✓ Ensuring competency of personnel: oversees training and documentation
  - ✓ Ensuring environmental controls: storage, disposal, etc.)



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## Designated Person Must Understand...

- Rationale for risk-prevention policies
- Risk to themselves and others
- Risks of non-compliance that may compromise safety
- Must report potentially hazardous situations to management team
- Must oversee monitoring of facility maintenance reports



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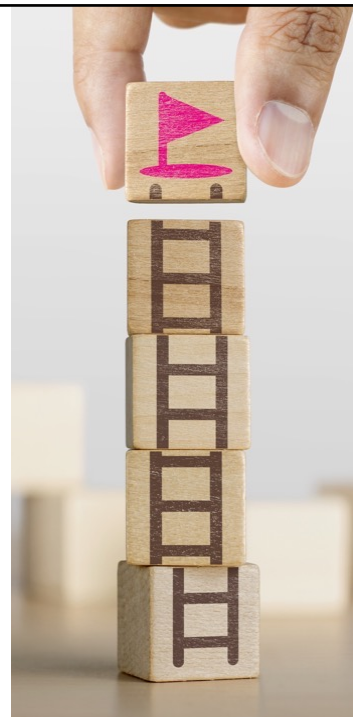


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## Requirements

### 2. Create a List of Hazardous Drugs

- Create a facility-specific list of all HDs accessible by staff: NIOSH list
  - ✓ Review every 12 months and update accordingly
  - ✓ Post for viewing by staff



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# Requirements

## 3. Staff Training

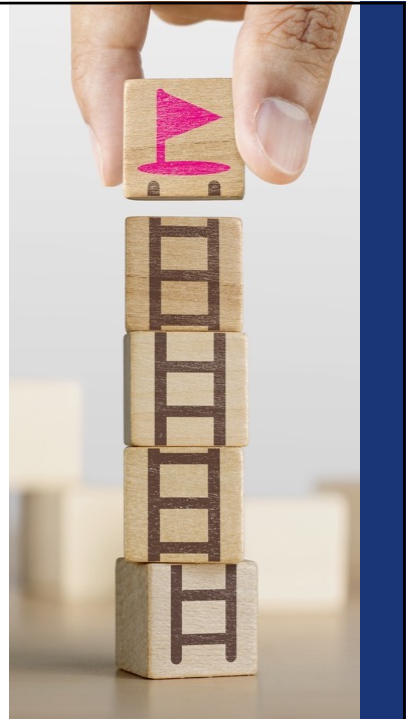
- Policies and Standard Operating Procedures
- Proper use of PPE
- Proper Exposure Response
- Spill Management
- Proper disposal of HDs and trace-contaminated materials
- Proper use of CSTDs



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# Requirements

## 4. Hazard Communication Program

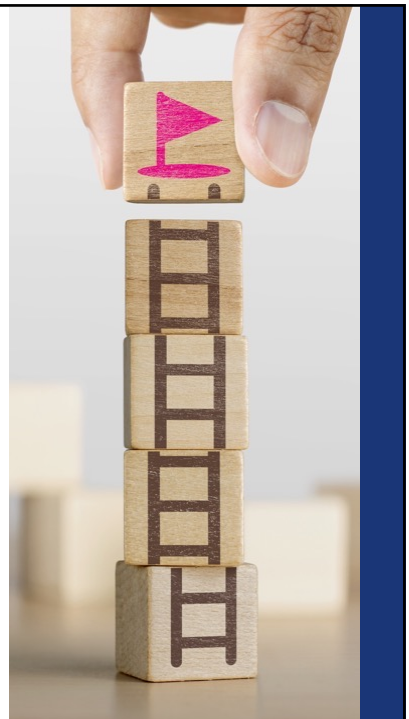
- Policies and standard operating procedures to ensure worker safety
- Standards must be written
- Staff training must be documented
- Obtain written attestation from all personnel of reproductive capability of HD risks



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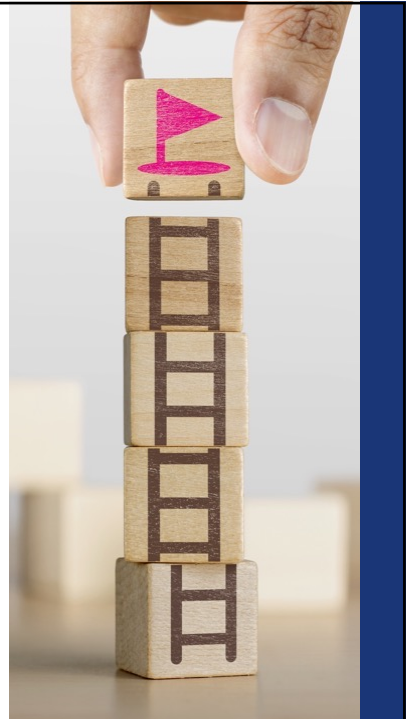
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# Requirements

## 5. Administration

- Requires use of a Closed System Transfer Device (CSTD) “when dosage form allows” of the HD
- No distinction between OR and other areas of the facility

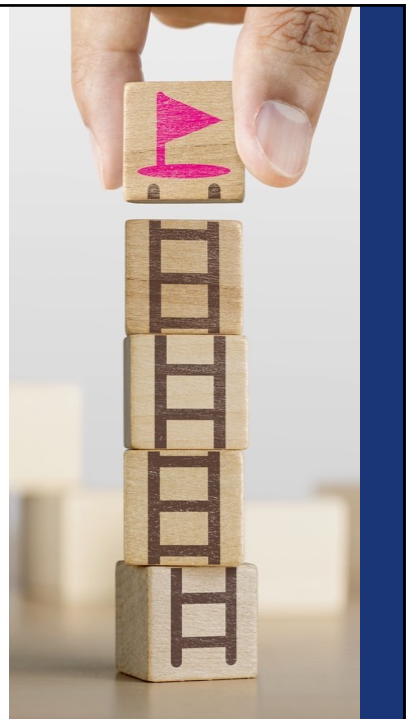


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# Requirements

## 6. PPE: Single Use Only

- Gloves
  - ✓ Double-glove with 2 pairs of ASTM 6978 tested chemotherapy gloves
  - ✓ Glove must cover cuff of gown
  - ✓ Must be changed after 30 minutes – risk assessment?
- Gowns
  - ✓ Solid front; closable back, elastic or knit cuffs
  - ✓ Impermeable to HDs
  - ✓ Sterile ASTM chemo-tested gowns are not presently available for OR



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# Requirements

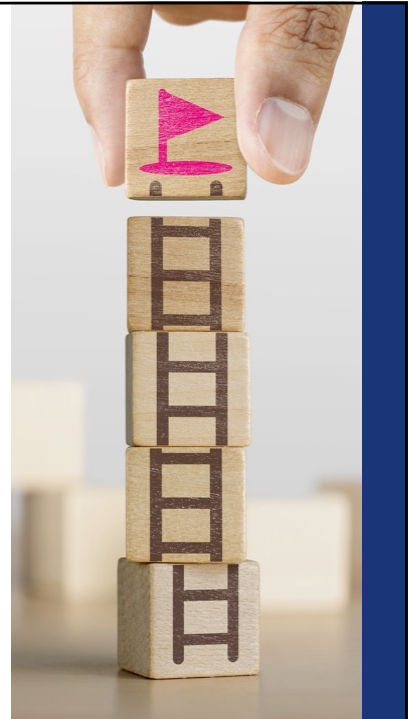
## 6. PPE: Single Use Only

### ○ Other

- ✓ Eye goggles or face shield required if splashing is possible
- ✓ Shoe covers need to be removed before leaving area and disposed of in a designated chemo waste bag or bin
- ✓ Masks: typical OR mask is **not sufficient** to protect against splashes, N95 respirator provides more protection.
  - Face shield most protective



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# Standards of Practice



- Hazard communication and occupational safety programs
- Designation of HD areas
- Receipt and storage documentation
- Use of proper engineering controls - CSTDs
- Hand hygiene and proper use of PPE
- Deactivation, decontamination, cleaning and disinfection
- Transport
- Administration
- Environmental monitoring
- Disposal
- Spill management

**Must be reviewed every 12 months by designated person.**

**Review must be documented.**



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## What's Next?

### ○ USP <800> covers all aspects of HD Exposure:

- ✓ Receipt
- ✓ Transport
- ✓ Storage
- ✓ Containment Handling / Administration
- ✓ Disposal



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## GAP Analysis

- Performing a gap analysis helps identify areas in need of improvement for compliance
- Assess process of HD handling from receipt to disposal to determine compliance gaps



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## Risk Assessment (Optional)

- Some drugs defined as hazardous **may not pose a significant risk** of occupational exposure due to their dosage formulations
- If a risk assessment approach is taken, the facility **must document what alternative containment strategies and/or work practices** are being employed for specific dosage forms to minimize risk of occupational exposure.
- Criteria for consideration, **at a minimum, should include:**
  - ✓ Type of HD: Antineoplastic, non-neoplastic, reproductive risk only
  - ✓ Dosage Form
  - ✓ Risk or Exposure
  - ✓ Packaging
  - ✓ Manipulation

**Risk Assessment must be reviewed every 12 months**



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## Receipt



- HDs must be unpacked in an area that is neutral/normal or negative pressure
- At least one pair of ASTM D6978 chemotherapy-tested gloves

### RISK ASSESSMENT

*If using the Mitosol kit, exposure is eliminated due to the dosage form (the kit itself); how the drug is packaged.*



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## Transport

- Appropriate PPE must be worn when handling HDs, including during transport, i.e., chemo-tested gloves
- HDs must be transported in containers that minimize the risk of leakage or breakage

### RISK ASSESSMENT

*If using the Mitosol kit, due to the dosage form, the risk of leakage or breakage is eliminated. Chemo-tested gloves, therefore, are not required for transport.*

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## Storage

- HDs must be stored in a manner that prevents environmental contamination or exposure
- **CANNOT** combine HDs with other medications
- **DO NOT** store any medications with food
- **Dedicated Refrigerator in negative pressure room with 12 air changes per hour**

### RISK ASSESSMENT

*If using the Mitosol kit, due to the dosage form, there are no special storage requirements. Does not require refrigeration. Can be stored with other drugs.*

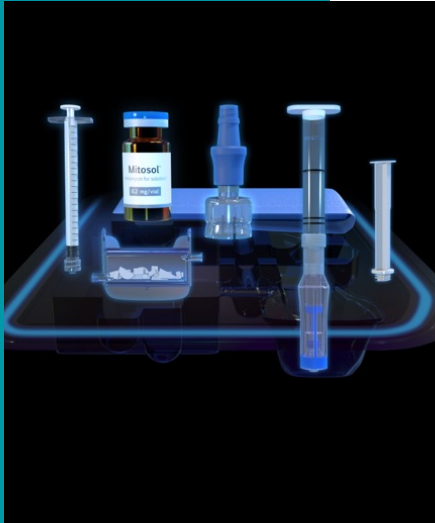
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## Containment / Administration



- Needleless / Closed System Transfer Devices required when administering antineoplastic HDs.
- Isolate instruments and items in direct contact with Mitomycin-C (MMC)

*The Mitosol kit* provides the Closed System Transfer Device (CSTD) required for administration.



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## Disposal



- Hazardous waste disposal: Federal law requires that chemotherapy be disposed of in appropriate yellow or black bins designated for chemo waste.

*The Mitosol kit* contains a yellow disposal bag in the kit to dispose of contaminated items on the field immediately after use.



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## Cleaning Instruments Contaminated with HDs

- Instruments that **come into contact with a hazardous drug** including, but not limited to, the forceps used to apply and remove a sponge soaked with the HD **must be isolated from the other instruments** on the surgical field.
- The tips of these instruments should be wiped with an **instrument wipe designed for ophthalmic instruments** to remove the HD residue prior to leaving the OR for processing. The instrument wipe must be disposed of as contaminated waste.
- These instruments must be **pre-washed with water and a fresh instrument wipe designed for use with ophthalmic instruments** prior to being put with other instruments for final cleaning. The instrument wipe must be disposed of as contaminated waste.



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## Hazardous Drug Spill Management



- Cleaning a HD spill **ON** the sterile field
- Cleaning a HD spill **OFF** the sterile field
- **Documentation** of HD Spills



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## Cleaning a HD Spill **ON** the Sterile Field

1. While double-gloved with ASTM6978 chemotherapy-tested gloves, place a stack of 4x4 gauze pads onto the spill. **HOLD AND BLOT**
2. Immediately dispose of contaminated 4x4 gauze pads into appropriate chemotherapy bag or bin.
3. Change gloves.
4. Cover area where spill occurred with a folded disposable towel to contain the drug residue.
5. Contaminated drape and disposable towel must be disposed of into chemotherapy bag or bin.



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## Cleaning a HD Spill **OFF** the Sterile Field

- Circulating nurse or other designated individual should **utilize a chemotherapy spill kit** to clean the spill.
  - ✓ Kits contain proper items, including: PPE, and instructions to clean spill.
- All contaminated items must be **disposed of into chemotherapy bag or bin**.
- Hands must be washed after removing PPE.



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## Documentation of HD Spills:

- All HD spills must be documented
- Document the circumstances:
  - ✓ How the spill occurred
  - ✓ Details of spill clean up and disposal
  - ✓ Action plan to prevent this type of spill from occurring again.
- Utilize your facility's existing document forms that are used for unusual occurrences
  - ✓ eg; incident report



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## What's Next?



- USP <800> will greatly impact facilities and patient care areas where HDs are used
- Compliance will require planning and preparation.



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## References

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- United States Pharmacopeial Convention(2019). USP General Chapter <800> Hazardous Drugs –Handling in Healthcare Settings



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## Questions?

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### USP <800> HANDLING OF HAZARDOUS DRUGS

#### COURSE DESCRIPTION

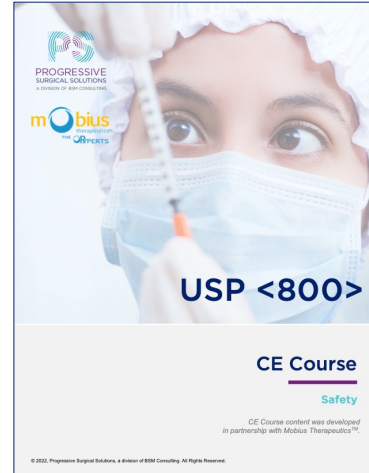
USP <800> provides standards for the safe handling of hazardous drugs from the ordering process to use in the clinical space. This course will review the standards in detail and provide specific guidance on how to implement these standards in your facility.

#### LEARNING OBJECTIVES

- Describe what USP <800> is and who it applies to.
- List 3 safety protocols for the handling of hazardous drugs.
- Identify what must be included in facility policies related to the handling of hazardous drug.

[CLICK TO DOWNLOAD COURSE PDF](#)

Once you have read and assimilated the course material, come back here to take the quiz and process your certificate.



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APR 29	60	RN, CASC	The Great Resignation: Recruiting, Hiring, and Retention in a Tight Labor Market	Abtin Mehdizadegan
MAY 23	20		Benchmarking Made Simple	Vanessa Sindell
JUN 24	60	RN, CASC	What's Your Pulse? Connecting With and Understanding Your Staff	Elizabeth Monroe Kellie Wynne
JUL 25	20		Allied Health Workers in the ASC	Debra Stinchcomb
AUG 26	60	RN, CASC	Meaningful Hand Hygiene Surveillance	Crissy Beze
SEP 26	20		Excel for Nurse Leaders	Nancy Stephens
OCT 28	60	RN, CASC	Revenue Cycle Management: Improving the Bottom Line	Kylie Kaczor
NOV 28	20		Annual Survey Watch Report 2022	Cyndi Krause
DEC 16	60	RN, CASC	Life Safety Risk Assessment: What is it and what is Required?	John Crowder, Jr.



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