Welcome!
USP 800: Handling Hazardous Drugs in Healthcare Settings

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Disclosures

• I have no disclosures
Program Summary

• The U.S. Pharmacopeial Convention (USP) Chapter 800 “Hazardous Drugs – Handling in Healthcare Settings” was published in February 2016 and will become effective July 1, 2018

• USP Chapter 800 describes practice and quality standards for handling hazardous drugs in healthcare settings and is intended to promote patient safety, worker safety and environmental protection

• The chapter applies to all healthcare personnel and locations that handle Hazardous drug preparations

• This presentation will focus on identifying Hazardous Drugs in your practice setting and reviewing the facilities, systems, and policies and procedures necessary for the safe handling of Hazardous Drugs according to USP 800
Learning Objectives

1. Review the history of hazardous drug guidelines, recommendations and best practices

2. Define “Hazardous Drug”

3. Describe a process for creating a Hazardous Drugs list for your Pharmacy

4. Review the facility requirements of USP 800

5. Review the workflow, procedural and personnel requirements of USP 800
Pre-Test

1. USP 800 applies to
   A. Sterile compounders
   B. Non-sterile compounders
   C. Pharmacies
   D. Doctors offices that handle hazardous drugs
   E. All of the above

2. My pharmacy compounds hormone cream using estrogen and progesterone powders. According to USP 800 I should compound these creams
   1. On my countertop
   2. In a separate area
   3. Within a containment device, in a separate room with negative pressure and 12 air exchanges per hour
   4. Within a containment device, in an ISO Class 7 negative pressure clean room
3. My specialty pharmacy dispenses a lot of oral chemotherapy agents on the NIOSH list. However, our policy is that we only dispense full vials of oral chemotherapy agents and we do not repackage them. I am compliant with USP 800
   A. Yes
   B. Yes if I do a risk assessment on each oral chemotherapy agent
   C. No

4. Select all true statements about unpacking hazardous drug orders according to USP 800
   A. PPE must be worn when unpacking hazardous drugs only if the HDs are not packaged in plastic by the wholesaler
   B. Hazardous drugs can be unpacked in the general pharmacy area
   C. My entity should write an SOP about what PPE to wear when unpacking hazardous drugs
5. My pharmacy purchases several HD active pharmaceutical ingredients and also does compounding of intravenous chemotherapy. We should store these items
   A. With the rest of our inventory
   B. Separate from the rest of our inventory
   C. Separate from the rest of our inventory, in an externally vented negative pressure room that contains a designated refrigerator for hazardous drugs if necessary
# History of Hazardous Drug Guidelines / Recommendations

<table>
<thead>
<tr>
<th>1980s</th>
<th>National Institutes of Health (NIH)</th>
<th>American Society of Health System Pharmacists (ASHP)</th>
<th>Occupational Safety and Health Administration (OSHA)</th>
<th>National Institute of Occupational Safety and Health (NIOSH)</th>
<th>United States Pharmacopeia (USP)</th>
</tr>
</thead>
</table>

**Alert:** Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings (2004)
Recommendations for the safe handling of injectable antineoplastic drug products

PF Zimmerman, RK Larsen, EW Barkley and JF Gallelli

Abstract

Routes through which health-care workers may be exposed to injectable antineoplastic drug products are reviewed, and recommendations developed by the National Institutes of Health for the safe handling of such products are presented. Routes of exposure are primarily through inhalation of the aerosolized drug product and by direct skin contact. The potential risks from repeated contact with injectable antineoplastic drug products can be controlled by the use of specific containment equipment and certain work techniques. It is recommended that all procedure involved in the preparation of injectable antineoplastics be performed in a Class II laminar flow biological safety cabinet.

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1. INTRODUCTION AND SCOPE

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

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

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

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

USP: U.S. Pharmacopeial Convention

• Not a government entity
  – A scientific nonprofit organization
• Sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements
• USP Council of Experts and Expert Committees developing and revise standards
• Standards are enforceable by the FDA
• State Boards of Pharmacy may adopt USP compounding standards into their regulations

Exposure to Hazardous Drugs can Occur During...

- Receipt
- Dispensing / Transport
- Administration / Pt Care Activities
- Compounding / Manipulating
- Spills, Waste
# Hazardous Drug Definition

Drugs are considered hazardous if they meet one or more of the following criteria:

<table>
<thead>
<tr>
<th>ASHP 1990 Criteria</th>
<th>NIOSH 2004 Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity in animal models, in the patient population, or both as reported by the International Agency for Research on Cancer</td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td>Teratogenicity in animal studies or in treated patients</td>
<td>Teratogenicity or developmental toxicity</td>
</tr>
<tr>
<td>Fertility impairment in animal studies or in treated patients</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>Evidence of serious organ or other toxicity at low doses in animal models or treated patients</td>
<td>Organ toxicity at low doses</td>
</tr>
<tr>
<td>Genotoxicity (i.e., mutagenicity and clastogenicity in short-term test systems)</td>
<td>Genotoxicity</td>
</tr>
<tr>
<td></td>
<td>Structure and toxicity profile of new drugs that mimic existing drugs determined hazardous by the above criteria</td>
</tr>
</tbody>
</table>

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USP 800 Requirement: Create a Hazardous Drug List

• Each entity must maintain a list of hazardous drugs that the entity handles

• Drugs included on the entity’s list of hazardous drugs must be handled according to the requirements in USP Chapter 800

• Step 1 = identify your hazardous drugs! This will help you design appropriate facilities / workflows / policies to meet USP 800

Creating a USP 800 Compliant Hazardous Drug List

- Must use the NIOSH List of Antineoplastic and Other Hazardous Drugs as a basis for your Hazardous Drug List
  - All antineoplastics that require manipulation and are included on the NIOSH list must be on the entity’s list
  - All active pharmaceutical ingredients (APIs) included on the NIOSH list and handled by the entity must be on the entity’s list
    - i.e. hormone powders, antineoplastic powders
  - Other agents on the NIOSH list → perform risk assessment → document other containment strategies or work practices if necessary
    - If no risk assessment performed, must handle as hazardous and according to USP 800 requirements
    - Risk assessments must be documented and reviewed annually
Creating a USP 800 Compliant Hazardous Drug List

• Must use NIOSH definition of a hazardous drug to identify new drugs that enter the market after the most recent NIOSH list update
  – Assess whether new drug should be added to your hazardous drug list based on NIOSH criteria (see preface to list)
  – If the information available on a drug is deemed insufficient to make an informed decision, consider the drug hazardous until more information is available
    • i.e. Investigational medications

• Must review list at least every 12 months and document review
NIOSH List of Antineoplastic and Other Hazardous Drugs

• 2014 NIOSH List
  – Published September 2014
  – Warning: only contains FDA approved drugs through December 2011
  – Available at: http://www.cdc.gov/niosh/docs/2014-138/

• Proposed Additions to the 2016 NIOSH List
  – Reviewed drugs that were FDA approved between January 2012 – December 2013 (n = 60)
  – Reviewed drugs with new special warnings (including black box warnings) between January 2012 – December 2013 (n = 270)
  – Proposed addition of 33 new hazardous drugs
  – Comments were accepted through July 27, 2015
  – Available at: http://www.cdc.gov/niosh/docket/review/docket233a/default.html
  – 2016 list has been approved and will be “published soon”

• Entities should assess new drugs approved after December 2013 for addition to their hazardous drugs list because NIOSH has not assessed these
• **Table 1**: Antineoplastic Drugs
• **Table 2**: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug
• **Table 3**: Non-antineoplastic drugs that primarily have adverse reproductive effects

• Tables 1 & 2 also list whether the drug has Manufacturer Safe Handling Guidance (MSHG) listed in the prescribing information
  – Typically section 16 of the package insert

  **16 HOW SUPPLIED/_STORAGE AND HANDLING**

  Follow guidelines for handling and disposal for cytotoxic drugs, including the use of gloves and other protective clothing to prevent skin contact.

• All tables include both parenteral and oral medications (if available as both oral and parenteral, may only be listed once)
• Drugs are classified as antineoplastic agents by the American Hospital Formulary Service (AHFS) [http://ahfs.ashp.org/drug-assignments.aspx](http://ahfs.ashp.org/drug-assignments.aspx)
  – Can see new drug classifications on this website
Proposed Assessment of Drugs on Most Recent NIOSH List
Assess Drugs on Most Recent NIOSH List

ANY Hazardous Drug Active Pharmaceutical Ingredient (API)
(API - any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity)

Table 1 – Antineoplastic Agents (AHFS Classification)
*Note – not all AHFS classified antineoplastic agents are included in Table 1 of the NIOSH list
Example: Rituximab, Trastuzumab

Require manipulation (i.e. compounding) or MSHG?

Perform Risk Assessment... every 12 months
Risk Assessment must be documented
If no risk assessment performed, drug MUST follow USP 800 requirements
Risk Assessment must include
Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only), Dosage form, Risk of exposure, Packaging, Manipulation

Add to List of Medications with Other Safe Handling Requirements

Add to Facility Hazardous Drugs List & Follow USP 800

All Others (Tables 2-3)

Alternative containment strategies and/or work practices required to minimize occupational exposure?

Do not add to Facility Hazardous Drugs List or Safe Handling List

Yes

No
Proposed Assessment of New Drugs
New Drugs (after most recent NIOSH list) or Investigational Drugs

Assess the Following
- AHFS Classification (AHFS monograph or http://ahfs.ashp.org/drug-assignments.aspx)
- Prescribing Information
  - Black Box Warnings related to NIOSH hazardous drug criteria (i.e. rash)
  - Section 8 – pregnancy and lactation (Pregnancy Category)
  - Section 12 – Mechanism of action (DNA altering?)
  - Section 13 – non clinical toxicology (Carcinogenesis, Mutagenesis, Impairment of Fertility)
  - Section 16 – MSHG
- Other references as desired
- See pages 3-4 of 2014 NIOSH list introduction for additional assessment opportunities

Meets Hazardous Drug Criteria per NIOSH (Carcinogenicity, Teratogenicity or developmental toxicity, Reproductive toxicity, Organ toxicity at low doses, Genotoxicity, Structure and toxicity profile of new drugs that mimic existing drugs determined hazardous by the above criteria)

Insufficient info to determine if drug is Hazardous

API?
- Yes
- No

Does not meet Hazardous Drug Criteria per NIOSH

Do not add to Facility Hazardous Drugs List or Safe Handling List

Risk Assessment must be documented
- If no risk assessment performed, drug MUST follow USP 800 requirements

Risk Assessment must include
- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only), Dosage form, Risk of exposure, Packaging, Manipulation

Yes
- Add to Facility Hazardous Drugs List & Follow USP 800

No
- Add to List of Medications with Other Safe Handling Requirements

Yes
- Require manipulation (i.e. compounding) or MSHG?

- Yes
- No

Perform Risk Assessment... every 12 months

No
USP 800 Requirement: Risk Assessments

• Consider the following during an Assessment of Risk
  – Type of HD (e.g. antineoplastic, non-antineoplastic, reproductive risk only)
  – Dosage Form
  – Risk of Exposure
  – Packaging
  – Manipulation

• If an assessment of risk approach is taken, must document what alternative containment strategies and/or work practices are being employed to minimize occupational exposure

• Review risk assessments every 12 months and document review
### Example Assessments of Parenteral NIOSH List Medications

<table>
<thead>
<tr>
<th>Drug</th>
<th>Oral / Parenteral</th>
<th>NIOSH List Table</th>
<th>Require Manipulation?</th>
<th>At our institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleomycin</td>
<td>Parenteral</td>
<td>Table 1</td>
<td>Yes</td>
<td>On Hazardous Drug List</td>
</tr>
<tr>
<td>Pemetrexed (Alimta)</td>
<td>Parenteral</td>
<td>Table 1</td>
<td>Yes</td>
<td>On Hazardous Drug List</td>
</tr>
<tr>
<td>Rituximab (Rituxan)</td>
<td>Parenteral</td>
<td>Not on NIOSH list (note – classified as antineoplastic by AHFS)</td>
<td>Yes</td>
<td>Not on Hazardous Drug List</td>
</tr>
<tr>
<td>Panitumumab (Vectibix)</td>
<td>Parenteral</td>
<td>On proposed Table 1 2016 NIOH List</td>
<td>Yes</td>
<td>On Hazardous Drug List</td>
</tr>
</tbody>
</table>
## Common NIOSH Table 1 Oral Agents

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS Classification</th>
<th>MSHG?</th>
<th>Reason for Listing on NIOSH List</th>
<th>At Our Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastrazole (Arimidex)</td>
<td>10:00 antineoplastic agents</td>
<td>No</td>
<td>FDA Pregnancy Category X</td>
<td>Perform Risk Assessment</td>
</tr>
<tr>
<td>Capecitabine (Xeloda)</td>
<td>10:00 antineoplastic agents</td>
<td>Yes</td>
<td>Metabolized to 5-fluorouracil; FDA Pregnancy Category D</td>
<td>Add to HD List due to MSHG</td>
</tr>
<tr>
<td>Imatinib (Gleevec)</td>
<td>10:00 antineoplastic agents</td>
<td>Yes</td>
<td>FDA Pregnancy Category D</td>
<td>Add to HD List due to MSHG</td>
</tr>
<tr>
<td>Letrozole (Femara)</td>
<td>10:00 antineoplastic agents</td>
<td>No</td>
<td>FDA pregnancy Category</td>
<td>Perform Risk Assessment</td>
</tr>
<tr>
<td>Megestrol (Megace)</td>
<td>10:00 antineoplastic agents</td>
<td>No</td>
<td>Nursing should be discontinued if megestrol is required. Women at risk of pregnancy should avoid exposure; FDA Pregnancy Category X</td>
<td>Perform Risk Assessment</td>
</tr>
</tbody>
</table>

Many of the oral chemotherapy agents are included in table 1.
NIOSH Table 2 & 3
Oral Agents

• Table 2
  – Hormones
  – Immunosuppressants
  – Anticonvulsants

• Table 3
  – Reproductive risk only

• Perform Risk Assessment & Document!
Otherwise handle per USP 800 requirements.
## Proposed Risk Assessments

<table>
<thead>
<tr>
<th>Drug</th>
<th>Hazardous Risk</th>
<th>Dosage Form</th>
<th>Risk of Exposure</th>
<th>Packaging / Manipulation</th>
<th>Alternative Safe Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastrazole</td>
<td>Reproductive (pregnancy category X)</td>
<td>Film Coated Tablets</td>
<td>May occur during counting</td>
<td>30 or 90 count vials or unit dose</td>
<td>Dispense in original container and do not repackage</td>
</tr>
<tr>
<td>Megestrol</td>
<td>Reproductive (pregnancy category X)</td>
<td>Tablets / Suspension Tablets scored for splitting</td>
<td>May occur during counting and repackaging</td>
<td>Must count</td>
<td>Reproductive age staff do not handle</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Often must pour suspension</td>
<td>Separate counting tray cleaned before &amp; after</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>May split tablets</td>
<td>Wear gloves</td>
</tr>
</tbody>
</table>
USP 800 Requirement: Designated Person

- Each entity must designate a person responsible for overseeing compliance with USP 800
- Responsibilities would include
  - Implementing procedures
  - Assessing competency of personnel
  - Ensuring environmental control of storage and compounding areas
  - Monitoring facility reports of testing / sampling performed
## USP 800 Requirement: Facilities and Engineering Controls

<table>
<thead>
<tr>
<th>Hazardous Drug Activity</th>
<th>Sterile Compounding</th>
<th>Non-Sterile Compounding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt</td>
<td>Receipt and unpacking must occur in a neutral or negative pressure area</td>
<td></td>
</tr>
<tr>
<td>Storage</td>
<td>HDs and APIs requiring manipulation <strong>must be stored separately</strong> from non hazardous medications (separate refrigerator) in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH)</td>
<td>Non-antineoplastic, reproductive risk only drugs and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy</td>
</tr>
<tr>
<td>Compounding</td>
<td>In a C-PEC located in a C-SEC</td>
<td>In a C-PEC located in a C-SEC</td>
</tr>
<tr>
<td></td>
<td>• C-PEC must be</td>
<td>• C-PEC must</td>
</tr>
<tr>
<td></td>
<td>• Externally vented (preferred) or have a redundant HEPA filter</td>
<td>• Be externally vented</td>
</tr>
<tr>
<td></td>
<td>• C-SEC must</td>
<td>• Provide an ISO Class 5 or better environment</td>
</tr>
<tr>
<td></td>
<td>• Be externally vented</td>
<td>• C-SEC can be either an</td>
</tr>
<tr>
<td></td>
<td>• Be physically separate</td>
<td>• An externally vented, negative pressure ISO Class 7 buffer room/ante room with 30 ACPH or</td>
</tr>
<tr>
<td></td>
<td>• Have 12 ACPH</td>
<td>• A negative pressure containment segregated compounding area that is externally vented with 12 ACPH</td>
</tr>
<tr>
<td></td>
<td>• Have a negative pressure of 0.01 – 0.03 inches of water column relative to adjacent areas</td>
<td></td>
</tr>
</tbody>
</table>

**C-PEC =** containment primary engineering control  
**C-SEC =** containment secondary engineering control
USP 800 Requirement: Facilities and Engineering Controls

USP 800 Optimal Facility Design for Non-Sterile Compounding

Containment Primary Engineering Control (i.e. Biological Safety Cabinet)

Containment Secondary Engineering Control (Buffer Room)

Room Air: 12 Air Exchanges per Hour (ACPH)

Negative pressure 0.01 – 0.03”
USP 800 Requirement: Facilities and Engineering Controls

USP 800 Optimal Facility Design for Sterile Compounding

- **Negative Buffer Rm - ISO 7**
  - Hazardous Compounding
  - **BSC**
  - **Room Air:** 30 Air Exchanges per Hour (ACPH)
  - **Negative pressure:** 0.01 – 0.03”

- **Ante ISO 7**

- **Positive Buffer Rm - ISO 7**
  - Non-Hazardous Compounding
  - **LAFH**
  - **Positive pressure**
Layout Option with Negative Pressure Hazardous Drug Storage
Ante Room
Non Hazardous Clean Room
Hazardous Clean Room
USP 800 Requirement: Facilities and Engineering Controls

• Closed system transfer devices should be used for compounding HDs when the dosage form allows.
• Closed system transfer devices should be used when administering antineoplastic HDs.
• Environmental wipe sampling for HD surface residue:
  – Every 6 months
  – Include areas where contamination from HDs likely
  – If measurable contamination found → identify, document and contain contamination then repeat wipe test.
# USP 800 Requirement: Personal Protective Equipment (PPE)

<table>
<thead>
<tr>
<th>PPE</th>
<th>Sterile Compounding</th>
<th>Non-Sterile Compounding</th>
<th>Cleaning</th>
<th>Unpacking Orders</th>
<th>Administering</th>
<th>Cleaning up Spills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gowns</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>Per institutional SOPs</td>
</tr>
<tr>
<td>Head / Hair Covers</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>Per institutional SOPs</td>
</tr>
<tr>
<td>Shoe Covers</td>
<td>2 pairs</td>
<td>2 pairs</td>
<td></td>
<td></td>
<td></td>
<td>Per institutional SOPs</td>
</tr>
<tr>
<td>Chemotherapy gloves</td>
<td>2 pairs (outer must be sterile)</td>
<td>2 pairs</td>
<td>2 pairs</td>
<td>✓</td>
<td>2 pairs</td>
<td>Per institutional SOPs</td>
</tr>
<tr>
<td>Eye / Face Protection</td>
<td>Per institutional SOPs</td>
<td></td>
<td>If splashing likely</td>
<td>Per institutional SOPs</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Respiratory Protection</td>
<td>Per institutional SOPs</td>
<td></td>
<td>Yes when cleaning under surface of C-PEC</td>
<td>Yes if HDs not contained in plastic</td>
<td>Per institutional SOPs</td>
<td>Yes when spills to large for a spill kit</td>
</tr>
</tbody>
</table>

*Institutional SOPs for PPE must be designed based on risk of exposure, types of activities performed, and an assessment of risk.*
USP 800 Requirement: Personal Protective Equipment (PPE)

- Chemotherapy Gloves
  - When chemotherapy gloves are required they must meet American Society for Testing and Materials (ASTM) standard D6978
  - Chemotherapy gloves should be worn for handling all HDs including non-antineoplastics
  - Should be powder free
  - For sterile compounding, outer glove must be sterile
  - Change gloves every 30 minutes unless otherwise recommended by manufacturer’s documentation
USP 800 Requirement: Personal Protective Equipment (PPE)

• Gowns
  – Must be disposable
  – Must be shown to resist permeability by HDs
  – Must close at the back, be long sleeved and have closed cuffs that are elastic or knit
  – Change per manufacturer’s recommendations or every 2-3 hours & always after a spill / splash

• Head, Hair, Shoe & Sleeve Covers
  – When compounding, second pair of shoe covers must be donned before entering the C-SEC and taken off when exiting

• PPE worn when handling hazardous drugs should be disposed of as hazardous drug waste
**USP 800 Requirement:**

Deactivating, Decontaminating, Cleaning, Disinfecting

- **All areas** where hazardous drugs are handled and all reusable equipment must be deactivated, decontaminated, and cleaned

  – Sterile compounding areas and devices must be subsequently disinfected

<table>
<thead>
<tr>
<th>Cleaning Step</th>
<th>Purpose</th>
<th>Example Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deactivation</td>
<td>Render compound inert / inactive</td>
<td>EPA registered oxidizers (peroxide formulations, sodium hypochlorite)</td>
</tr>
<tr>
<td>Decontamination</td>
<td>Remove HD residue</td>
<td>Alcohol, water, peroxide, sodium hypochlorite</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Remove organic and inorganic material</td>
<td>Germicidal detergent</td>
</tr>
<tr>
<td>Disinfection</td>
<td>Destroy Microorganisms</td>
<td>EPA registered disinfectant, sterile alcohol</td>
</tr>
</tbody>
</table>
USP 800 Requirement: Personnel Training

• All personnel who handle hazardous drugs must be trained and pass competency before they handle HDs and every 12 months

• Training / competency assessment must be documented and must include
  – An overview of the entity’s HD list
  – Review of the entity’s HD SOPs
  – Proper use of PPE
  – Proper use of equipment and devices (engineering controls)
  – Response to known or suspected HD exposure
  – Spill management
  – Proper disposal of HDs and trace-contaminated materials
USP 800 Requirement: Dispensing Final Dosage Forms

• HDs that only require counting or repackaging of final dosage forms may be prepared for dispensing without any further requirements for containment
  – unless required by the manufacturer (MSHG)
  – or if visual indicators of HD exposure hazard are present (i.e. dust / leakage)

• Counting / repackaging of HDs should be done carefully
  – Use clean equipment dedicated for use with HDs
  – Decontaminate equipment after each use
  – Do not place HD tablets / capsules in automated counting machines

• Healthcare personnel should avoid crushing tablets or opening capsules of HDs
  – If manipulation is required, must wear PPE and use a plastic pouch to contain any dust or particles
USP 800 Requirement: Medical Surveillance

• Healthcare workers who handle HDs should be enrolled in a medical surveillance program
• Baseline and after HD exposure
• Assess
  – Labs
  – Medical history
  – Work history (previous hazardous drug exposure)
  – Estimated amount of HD handling
  – Symptoms that arise post handling of HDs
USP 800 Requirement: SOPs

- Entity must maintain SOPs for the safe handling of HDs for all situations
- Must be reviewed annually by the designated person

<table>
<thead>
<tr>
<th>USP 800 Required SOPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Communication Program</td>
</tr>
<tr>
<td>Designation of HD Areas</td>
</tr>
<tr>
<td>Storage</td>
</tr>
<tr>
<td>Use and Maintenance of Proper Engineering Controls</td>
</tr>
<tr>
<td>Deactivation, Decontamination, Cleaning and Disinfection</td>
</tr>
<tr>
<td>Transport</td>
</tr>
<tr>
<td>Environmental Monitoring (including wipe sampling)</td>
</tr>
<tr>
<td>Spill Control</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Occupational Safety Program</td>
</tr>
<tr>
<td>Receipt</td>
</tr>
<tr>
<td>Compounding</td>
</tr>
<tr>
<td>Hand Hygiene, use of PPE based on activity (receipt, transport, compounding, administration, spill, disposal etc.)</td>
</tr>
<tr>
<td>Dispensing</td>
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<tr>
<td>Administering</td>
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<td>Disposal</td>
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<td>Medical Surveillance</td>
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USP 800 Requirements… there are more!

This presentation was not an all inclusive summary of USP 800 Requirements
Kansas Board of Pharmacy

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

• The Board has been working on compounding regulations and recently completed a draft that does not yet include USP 800. However, they have every intention of including USP 800 when the time comes.

• I anticipate that the Board will likely adopt compounding regulations that address all current USP requirements next summer.
Post-Test

1. USP 800 applies to
   A. Sterile compounders
   B. Non-sterile compounders
   C. Pharmacies
   D. Doctors offices that handle hazardous drugs
   E. All of the above

2. My pharmacy compounds hormone cream using estrogen and progesterone powders. According to USP 800 I should compound these creams
   1. On my countertop
   2. In a separate area
   3. Within a containment device, in a separate room with negative pressure and 12 air exchanges per hour
   4. Within a containment device, in an ISO Class 7 negative pressure clean room
3. My specialty pharmacy dispenses a lot of oral chemotherapy agents on the NIOSH list. However, our policy is that we only dispense full vials of oral chemotherapy agents and we do not repackaging them. I am compliant with USP 800
   A. Yes
   B. Yes if I do a risk assessment on each oral chemotherapy agent
   C. No

4. Select all true statements about unpacking hazardous drug orders according to USP 800
   A. PPE must be worn when unpacking hazardous drugs only if the HDs are not packaged in plastic by the wholesaler
   B. Hazardous drugs can be unpacked in the general pharmacy area
   C. My entity should write an SOP about what PPE to wear when unpacking hazardous drugs
5. My pharmacy purchases several HD active pharmaceutical ingredients and also does compounding of intravenous chemotherapy. We should store these items
   A. With the rest of our inventory
   B. Separate from the rest of our inventory
   C. Separate from the rest of our inventory, in an externally vented negative pressure room that contains a designated refrigerator for hazardous drugs if necessary
Questions?
References