USP Chapter <800> - Part 1: Deciphering Requirements

L. R. Dillon, RPh, ASQ CMQ/OE, ASQ CQA, ACHC/PCAB CAC

Patricia C. Kienle, RPh, MPA, FASHP
Disclosures

- Patricia Kienle is a member of the USP Compounding Expert Committee, but this presentation is not endorsed by or affiliated with USP.
- L. Rad Dillon is a surveyor and consultant for ACHC / PCAB Accreditation University.
CPE Information

• Target Audience: Pharmacists and Pharmacy Technicians
• ACPE#: 0202-0000-19-063-L07-P/T
• Activity Type: Knowledge-based
Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

• Discuss the purpose of the United States Pharmacopeia Chapter <800>, to whom the chapter applies, and what setting it impacts.

• List the resources that can be used to identify hazardous drugs (HDs).

• Define the process for establishing an assessment of risk (AOR).

• Identify types of hazardous drug exposures and explain the responsibilities of staff handling hazardous drugs.
1. What is USP’s role concerning USP <800>?

A. Standard-setting
B. Federal enforcement of the Chapter
C. State enforcement of the Chapter
D. Required for accreditation organizational standards
2. What organization establishes the list of drugs that are hazardous to healthcare personnel?

A. Centers for Medicare and Medicaid Services
B. Environmental Protection Agency
C. The Joint Commission
D. National Institute for Occupational Safety and Health
3. Which of the following requires all containment strategies and work practices defined in <800> and is not eligible for inclusion in your Assessment of Risk?

A. Methotrexate tablets
B. Megestrol suspension
C. Cyclophosphamide IV
D. Oxytocin IV
4. What type of solution deactivates hazardous drugs?

   A. Isopropyl alcohol
   B. Oxidizer
   C. Germicidal detergent
   D. Surfactant
Why USP <800>?

• USP is a standard-setting organization
• <800> Hazardous Drugs – Handling in Healthcare Settings protects
  • Patients
  • Personnel
  • Environment
• First enforceable standard that protects healthcare personnel from risk of hazardous drugs
Evidence: Health Effects

1970s: Secondary malignancies identified in patients following treatment

1980s: Association between exposure to antineoplastics and adverse reproductive effects

1990s: Link of cancer occurrence to healthcare workers exposed to antineoplastics

NIOSH Hazard Drug Information

NIOSH Hazardous Drug Exposures in Healthcare

Hazards of Hazardous Drug Exposures in Healthcare

Overview

Healthcare workers who prepare or administer hazardous drugs (e.g., those used for cancer therapy, and some antiviral drugs, hormone agents, and biologically engineered drugs) or who work in areas where these drugs are used may be exposed to these agents in the workplace. About 8 million U.S. healthcare workers are potentially exposed to hazardous drugs, including pharmacy and nursing personnel, physicians, operating room personnel, environmental services workers, workers in research laboratories, veterinary care workers, and shipping and receiving personnel.

Exposure to hazardous drugs can result in adverse health effects in healthcare workers. In fact, published studies have shown that workplace exposure to hazardous drugs increases both acute and chronic health

www.cdc.gov/niosh/topics/hazdrug/default.html
Genesis of USP <800>

NIOSH Approach to Risk Reduction

Hierarchy of Controls

- Elimination: Physically remove the hazard
- Substitution: Replace the hazard
- Engineering Controls: Isolate people from the hazard
- Administrative Controls: Change the way people work
- PPE: Protect the worker with Personal Protective Equipment

www.cdc.gov/niosh/topics/hierarchy/
Preparing for <800>: The Requirements

1. Responsible person
2. Training
3. Acknowledgement of Risk
4. Facility Design
5. Personal Protective Equipment
6. Work Practices
Each facility where hazardous drugs are handled needs to assign a person to oversee the hazardous drug requirements

- Personnel awareness, training, and monitoring
- Facility requirements, such as hood certification and results
Training and Competency Documentation

- Receiving and transporting
  - Competency concerning personal protective equipment (PPE)
  - Spill awareness
- Competency for mixing
  - Didactic test
  - Media fill
  - Gloved fingertip test
- Competency for administering
  - Documentation

With permission © ASHP (www.ashp.org)
Acknowledgement of Risk

• OSHA: Hazard Communication Standard (HCS) is based on a simple concept: that employees have both a need and a right to know the hazards and identities of the chemicals they are exposed to when working.

• USP <800:8>: “Personnel of reproductive capability must confirm in writing that they understand the risks of handling hazardous drugs” (HDs).

• Applies to all personnel who handle HDs.
What Drugs are Hazardous to Us?

- Carcinogen
- Genotoxin
- Teratogen
- Reproductive Toxin
- Organ Toxicity at Low Doses

Reference: NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 II. Defining Hazardous Drugs

New agent that mimics known HD in structure or toxicity
What Drugs are Hazardous to Us?

GHS*
Symbols of Concern:

* Globally Harmonized System of Classification and Labelling of Chemicals
What Drugs are Hazardous to Us?

Fentanyl Safety Data Sheet (SDS)

<table>
<thead>
<tr>
<th>Classification of Substance or Mixture</th>
<th>Acute toxicity, oral Category 2, Acute toxicity, dermal Category 2, Acute toxicity, inhalation Category 2, Specific target organ toxicity, single exposure Category 3 narcotic effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Word</td>
<td>Danger</td>
</tr>
<tr>
<td>Hazard Statement(s)</td>
<td>H300 Fatal if swallowed, H310 Fatal in contact with skin, H330 Fatal if inhaled, H336 May cause drowsiness or dizziness</td>
</tr>
<tr>
<td>Pictogram(s)</td>
<td><img src="image" alt="Warning and Poison Symbols" /></td>
</tr>
<tr>
<td>Precautionary Statement(s)</td>
<td>P260 Do not breathe dust/inhalable particles, P262 Do not get in eyes, on skin, or on clothing, P264 Wash hands thoroughly after handling, P270 Do not eat, drink or smoke when using this product, P271 Use only outdoors or in a well-ventilated area, P280 Wear protective gloves/protective clothing/eye protection/face protection, P301+P310 In case of contact, wash with plenty of soap and water, P305+P362 If exposed: Immediately call a POISON CENTER or doctor/physician, P304+P340 If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing, P310 Immediately call a POISON CENTER or doctor/physician, P311 Immediately call a POISON CENTER or doctor/physician, P312 Call a POISON CENTER or doctor/physician if you feel unwell, P330 Rinse mouth, P361 Remove/Take off immediately all contaminated clothing, P363 Wash contaminated clothing before reuse, P403+P233 Store in a well ventilated place, keep container tightly closed, P405 Store locked up, P401 Dispose of contents/container to an approved waste disposal plant</td>
</tr>
</tbody>
</table>

*SDS sheet compliments of Letco Medical.*
What Drugs are Hazardous to Us?

<table>
<thead>
<tr>
<th>Section 4: First Aid Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General Advice</strong></td>
</tr>
<tr>
<td><strong>If Inhaled</strong></td>
</tr>
<tr>
<td><strong>In Case of Skin Contact</strong></td>
</tr>
<tr>
<td><strong>In Case of Eye Contact</strong></td>
</tr>
<tr>
<td><strong>If Swallowed</strong></td>
</tr>
<tr>
<td><strong>Most Important Symptoms and Effects</strong></td>
</tr>
</tbody>
</table>

* SDS sheet compliments of Letco Medical.*
What Drugs are Hazardous to Us?

Section 6: Accidental Release Measures

| Personal Precautions, Protective Equipment and Emergency Procedures | See protective measures under point 7 and 8. |
| Methods and Materials Used for Containment | Avoid generation of dust. Remove all sources of ignition. Ensure that the equipment is adequately grounded. Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Cleanup Procedures | Avoid generation of dust. Remove all sources of ignition. Ensure that the equipment is adequately grounded. Dispose of contents/container in accordance with local/regional/national/international regulations. |

Section 7: Handling and Storage

| Precautions for Safe Handling | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take care for general good hygiene and housekeeping. |

* SDS sheet compliments of Letco Medical.*
What Drugs are Hazardous to Us?

Anhydrous Dextrose!

<table>
<thead>
<tr>
<th>Section 4: First Aid Measures</th>
</tr>
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<tr>
<td>General Advice</td>
</tr>
<tr>
<td>If Inhaled</td>
</tr>
<tr>
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</tr>
<tr>
<td>In Case of Eye Contact</td>
</tr>
<tr>
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What Drugs are Hazardous to Us?

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Personal Precautions, Protective Equipment and Emergency Procedures</strong></td>
</tr>
<tr>
<td><strong>Methods and Materials Used for Containment</strong></td>
</tr>
<tr>
<td><strong>Cleanup Procedures</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section 7: Handling and Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Precautions for Safe Handling</strong></td>
</tr>
<tr>
<td><strong>Conditions for Safe Storage</strong></td>
</tr>
</tbody>
</table>

* SDS sheet compliments of Letco Medical.*
NIOSH List of Hazardous Drugs

• Drugs that must conform with all containment strategies and work practices included in <800>
  • Active pharmaceutical ingredient (API) of any hazardous drugs on the NIOSH list
  • Antineoplastics in Table 1 that must be manipulated

• Drugs that you can consider for your Assessment of Risk
  • Antineoplastics in Table 1 that only need to be counted or packaged
  • Other drugs on Tables 2 and 3
AOR Flowchart

Provided courtesy of Hazardous Drug Consensus Group AOR Subcommittee
Your Hazardous Drug List

1. Review the NIOSH list of hazardous drugs
2. Identify the drugs and dosage forms you handle
3. Perform an Assessment of Risk
   - Risk of exposure
   - Packaging
   - Manipulation
4. Implement alternative containment strategies and work practices
5. Review and document the list annually
Assessment of Risk

Drug: Chemotrexate® (lethamycin)

1. Type of HD:
   □ NIOSH Group 1 - antiepileptic
   □ NIOSH Group 2 - non-antiepileptic
   □ NIOSH Group 3 - reproductive risk only
   □ Other

2. Other Information (e.g. relevant toxicology):
   SDS contains teratogenic potential

3. Dosage form:
   □ Capsule
   □ Tablet
   □ Other

4. Packaging:
   □ Unit dose
   □ Glass vial
   □ Other

5. Manipulation:
   □ Reconstituting dissolved manufacturer container
   □ Other

6. Handling Frequency: Daily

7. Worker Restrictions:
   □ None
   □ As follows: Workers known to be or possibly pregnant are not allowed to handle this drug

8. Handling Details

<table>
<thead>
<tr>
<th>Details</th>
<th>Exposure Risk</th>
<th>Containment</th>
<th>Work Practices &amp; PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt &amp; Storage</td>
<td>1 800</td>
<td>Armored or enclosed reverse pressure storage</td>
<td>800 Lab safety glasses, face mask</td>
</tr>
<tr>
<td>Compounding / Preparing</td>
<td>1 800</td>
<td>Magnetized funnel</td>
<td>800 NA</td>
</tr>
<tr>
<td>Counting / Packaging / Labelling</td>
<td>1</td>
<td>Armored air</td>
<td>Face mask, lab safety glasses</td>
</tr>
<tr>
<td>Transport / Dispensing</td>
<td>1 800</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Administering</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Deactivating and Cleaning</td>
<td>1 800</td>
<td>Counting tray and associated equipment after each exposure</td>
<td>800 Chem gloves</td>
</tr>
<tr>
<td>Disposal</td>
<td>1 800</td>
<td>流程 hazardous waste container</td>
<td>800 Chem gloves, mask</td>
</tr>
<tr>
<td>Spills / Broken Upon Receipt</td>
<td>2 800</td>
<td>As per spill kit instruction</td>
<td>800 Chem gloves, gown, shoe covers, apron</td>
</tr>
<tr>
<td>Other</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NA = not applicable to this drug product; 1 = minimal danger; 2 = moderate danger; 3 = significant danger

9. Details Concerning Alternative Containment / Work Practices & PPE:
   - One pair of "thick" grade gloves and face mask are donned prior to handling
   - Source container opened in designated HD area
   - Drug counted using designated spatula and counting tray
   - Spatula and counting tray cleaned with hypochlorite solution followed by detergent
   - Worker dons gloves and mask into trace hazardous waste container
   - Worker washes hands thoroughly

Provided courtesy of Hazardous Drug Consensus Group AOR Subcommittee
Assessment of Risk

1. Type of HD:
   - NIOSH Group 1 - antineoplastic
   - NIOSH Group 2 - non-antineoplastic
   - NIOSH 3 - reproductive risk only
   - Other:

2. Other Information [e.g. relevant toxicology]:
   SDS confirms teratogenic potential

3. Dosage Form:
   - Capsule
   - Tablet
   - Powder for Reconstitution
   - Other:

4. Packaging:
   - multicontact vial
   - unit dose
   - glass vial
   - Other:

Drug: Chemotrexate® (lethamycin)

Provided courtesy of Hazardous Drug Consensus Group AOR Subcommittee
Assessment of Risk

5. Manipulation:
   - Counting and final packaging
   - Reconstituting closed manufacturer container
   - Other:

6. Handling Frequency: Daily

7. Worker Restrictions:
   - None
   - As Follows: Workers known to be or possibly pregnant are not allowed to handle this drug.

Provided courtesy of Hazardous Drug Consensus Group AOR Subcommittee
### Assessment of Risk

<table>
<thead>
<tr>
<th>8. Handling Details</th>
<th>Exposure Risk</th>
<th>Containment</th>
<th>Work Practices &amp; PPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receipt &amp; Storage</td>
<td>1</td>
<td>Ambient air receipt; negative pressure storage;</td>
<td>800</td>
</tr>
<tr>
<td>Compounding / Preparing</td>
<td>1</td>
<td>Designated HiD area</td>
<td>800</td>
</tr>
<tr>
<td>Counting / Packaging / Labeling</td>
<td>1</td>
<td>Ambient air</td>
<td>Face mask; chemo gloves;</td>
</tr>
<tr>
<td>Transport / Dispensing</td>
<td>1</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Administering</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Deactivating and Cleaning</td>
<td>1</td>
<td>Counting tray and spatula deactivated after each use</td>
<td>800</td>
</tr>
<tr>
<td>Disposal</td>
<td>1</td>
<td>Trace hazardous waste container</td>
<td>Chemo gloves, mask</td>
</tr>
<tr>
<td>Spills / Broken Upon Receipt</td>
<td>2</td>
<td>As per spill kit instructions</td>
<td>Chemo gloves, gown, shoe covers, eye cover</td>
</tr>
<tr>
<td>Other:</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

N/A = not applicable to this drug product  
1 = minimal danger  
2 = moderate danger  
3 = significant danger

Provided courtesy of Hazardous Drug Consensus Group AOR Subcommittee
Assessment of Risk

9. Details Concerning Alternative Containment / Work Practices & PPE:
   • One pair of "chemo" grade gloves and face mask are donned prior to handling
   • Source container opened in designated HD area
   • Drug counted using designated spatula and counting tray
   • Spatula and counting tray cleaned with hypochlorite solution followed by detergent
   • Worker discards gloves and mask into trace hazardous waste container
   • Worker washes hands thoroughly

Provided courtesy of Hazardous Drug Consensus Group AOR Subcommittee

HD = hazardous drug
PPE = personal protective equipment
Hazardous Drug Processes

- Select
- Receive
- Store
- Mix
- Give
- Monitor
Receiving: Visible Warnings

With permission from PCCA
Containment Primary Engineering Control (C-PEC)

• Three types
  • Containment Ventilated Enclosure (CVE, powder containment hood)
  • Biological Safety Cabinet (BSC)
    • Class II required
    • Type A2 preferred
  • Compounding Aseptic Containment Isolator (CACI)

• Must be placed in a room that meets the four characteristics we just discussed

• Must be certified by an independent qualified certifier every six months
  • CVE – every 12 months (proposed revised <795>)
  • BSC and CACI – every 6 months

Reference: USP <800:5.3>
Containment Secondary Engineering Control (C-SEC)

Room with fixed walls separate from non-hazardous storage and compounding

Vented outside the building

Negative pressure of 0.01 to 0.03 inches to adjacent space

At least 12 air changes per hour (ACPH) (30 if buffer room)

Contains hazard

Removes hazard

Must be used for storage and compounding, unless eligible for entity exemption

Reference: USP <800:5.3>
Personal Protective Equipment (PPE)

• Gloves
  • Must meet American Society for Testing and Materials (ASTM) standard D6978
  • Review the minimum breakthrough detection time for the gloves you use
    • Most will be 240 minutes
    • Some will be short or indicate that they should not be used with certain drugs

• Gowns
  • Impervious, intended for use with chemo

• <800> standards and Oncology Nursing Society (ONS) guidance agrees
  • Two pairs of gloves when administering injectable chemo
  • Gowns when administering chemo
  • Goggles if potential of splashing
  • Respiratory protection when appropriate

Reference: USP <800:7>
## Personal Protective Equipment (PPE)

<table>
<thead>
<tr>
<th></th>
<th>Gloves</th>
<th>Gowns</th>
<th>Hair Cover</th>
<th>Shoe Covers</th>
<th>Eye / Face</th>
<th>Respiratory Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Receipt &amp; Storage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>1 pair</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not in plastic</td>
<td>1 pair</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspected breakage</td>
<td>1 pair</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Simple Dispensing</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BPR *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>BPR *</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N95</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>N95 - BPR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **2** - American Society for Testing and Materials (ASTM) standard D6978 "chemo" gloves; unpowdered; change at least every 30 minutes; after puncture or significant exposure to HD; inner glove under gown cuff, outer glove over gown cuff; remove outer layer for labeling, other handling of final product; wash hands when removed.

12 - In general whenever splashes likely.

17 - A powered air purifying respirator (PAPR) is an acceptable substitute for any respiratory protection shown below, including a FFR.

*BPR = best practice recommendation*

Provided courtesy of Hazardous Drug Consensus Group PPE Subcommittee
# Personal Protective Equipment (PPE)

## PPE: Where and When: Nonsterile Hazardous Drug Compounding

<table>
<thead>
<tr>
<th>PPE</th>
<th>Inner Shoe Cover</th>
<th>Outer Shoe Cover</th>
<th>Hair Cover</th>
<th>Hand Hygiene</th>
<th>Face Mask</th>
<th>Gown</th>
<th>Inner Gloves</th>
<th>Outer Gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Outer</td>
<td>+ BPR</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td></td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

1. If entering from a carpeted or general office area, don outer shoe covers within C-SEC.

Provided courtesy of Hazardous Drug Consensus Group PPE Subcommittee
## Personal Protective Equipment (PPE)

### PPE: Where and When: Nonsterile Hazardous Drug Compounding

<table>
<thead>
<tr>
<th></th>
<th>Inner Shoe Cover</th>
<th>Outer Shoe Cover</th>
<th>Hair Cover</th>
<th>(Hand Hygiene)</th>
<th>Face Mask</th>
<th>Gown</th>
<th>Inner Gloves</th>
<th>Outer Gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>After Compounding</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dispose of Sealed HD Waste in Proper Container</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Before Exiting C-SEC</strong></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>After Exiting C-SEC</strong></td>
<td>-</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
<td>-</td>
</tr>
</tbody>
</table>

*2 - while still within C-PEC, remove and place in sealed container with other HD waste*

---

Provided courtesy of Hazardous Drug Consensus Group PPE Subcommittee
# Personal Protective Equipment (PPE)

<table>
<thead>
<tr>
<th></th>
<th>Gloves</th>
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<th>Shoe Covers</th>
<th>Eye / Face</th>
<th>Respiratory Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deactivation / Decontamination / Cleaning / Disinfection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>2 pair</td>
<td>Yes</td>
<td></td>
<td>BPR</td>
<td>BPR</td>
<td>1, 9</td>
</tr>
<tr>
<td>Underneath C-PEC work surface</td>
<td>2 pair</td>
<td>Yes</td>
<td></td>
<td>BPR</td>
<td>BPR</td>
<td><strong>FFR - BPR</strong></td>
</tr>
<tr>
<td>Above eye level</td>
<td>2 pair</td>
<td>Yes</td>
<td></td>
<td>BPR</td>
<td>BPR</td>
<td><strong>FFR - BPR</strong></td>
</tr>
<tr>
<td><strong>Spills</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>BPR</td>
<td>BPR</td>
<td></td>
<td>BPR</td>
<td>Yes</td>
<td>N95</td>
</tr>
<tr>
<td>Spill too large for kit</td>
<td>BPR</td>
<td>BPR</td>
<td></td>
<td>BPR</td>
<td>Yes</td>
<td>FFR</td>
</tr>
<tr>
<td>Other suspected exposure to powder, vapor</td>
<td>BPR</td>
<td>BPR</td>
<td></td>
<td>BPR</td>
<td>Yes</td>
<td>N95</td>
</tr>
<tr>
<td><strong>Disposal</strong></td>
<td>BPR</td>
<td>BPR</td>
<td></td>
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</tr>
</tbody>
</table>

1 - can be provided by a full-face respirator (FFR); otherwise, must be goggles

7 - impermeable; disposable; back-closing; closed cuffs; change as per manufacturer recommendations or every 2-3 hrs and after spill / splash

9 - if splashes likely

12 - in general whenever splashes likely

Provided courtesy of Hazardous Drug Consensus Group PPE Subcommittee
Work Practices

• Technique (aseptic if required, including negative pressure technique)

• Use of Closed System Drug-Transfer Devices (CSTDs)
  • Required by <800> when administering injectable antineoplastics
  • Utility for compounding, including some nonsterile components

• Decontamination and cleaning surfaces

• Handling spills

Photo courtesy of BD
Cleaning Processes for Hazardous Drugs

1. Decontaminate with an oxidizer
2. Clean with a detergent
3. Disinfect with sterile isopropyl alcohol
Spill Management

• Have a clear policy and checklist
• Document competence
• Contain the spill
• Safe clean-up
• Review process
Hazardous Materials Waste

• Follow state and municipal requirements
• Get clear direction from waste hauler concerning type of bins and how to control them prior to pick-up
• Be aware of the difference between bulk RCRA* waste and trace RCRA waste

* Resource Conservation and Recovery Act
Recommendations – Not Requirements

• Environmental monitoring
  • Requires microbial monitoring mandated by USP <797> for sterile preparations
  • Recommends wipe sampling

• Medical surveillance
  • Recommended
How the USP Chapters Fit Together

Graphic courtesy of USP

Note: The current version of General Chapters <795> and <797> published in USP-NF are official.
To Do List

• Subscribe to the USP *Compounding Compendium*

• Perform a gap analysis:
  • [www.797gaptool.com](http://www.797gaptool.com)
  • [http://compoundingtoday.com/Compliance/USPGap.cfm](http://compoundingtoday.com/Compliance/USPGap.cfm)
  • [www.800gaptool.com](http://www.800gaptool.com)

• Certification:
  • [https://www.accreditationuniversity.com/hdhdp](https://www.accreditationuniversity.com/hdhdp)

• Provide comments for proposed <797>

• Watch for final versions of <795>, <797>, and <825>

• Get ready for December 1, 2019
Resources ... 

  - USP <800>
  - USP <800> FAQs
- State laws and regulations
- NIOSH, [www.cdc.gov/niosh](http://www.cdc.gov/niosh) → hazardous drugs
  - Alert
  - Current HD list
  - Medical Surveillance document
... Resources ...

• Pharmacy Today, [www.pharmacytoday.org](http://www.pharmacytoday.org)
  • *Compounding nonsterile preparations: USP <795> and <800>, 2017, v 23, no 10, 56-72*

• ASHP, [www.ashp.org](http://www.ashp.org)
  • Compounding Resource Center
  • Guidelines on Compounded Sterile Preparations
  • Guidelines on Hazardous Drugs
  • *Compounding Sterile Preparations, 3rd edition*
  • *The Chapter <800> Answer Book*

• American Journal of Health-System Pharmacy, [www.ajhp.org](http://www.ajhp.org)
  • *Pharmacy Quick Reference Guide: Hazardous Drug Safety and Compliance with USP Chapter <800> in the Health System*
... Resources ...

• Critical Point, [www.criticalpoint.info](http://www.criticalpoint.info)
  • Sterile Compounding Pearls

• Oncology Nursing Society, [www.ons.org](http://www.ons.org)
  • *Handling Hazardous Drugs*, 3rd edition

• Joint Commission, [www.jointcommission.org](http://www.jointcommission.org)
  • Standards Interpretation FAQs

• Joint Commission Resources, [www.hazmedsafety.com](http://www.hazmedsafety.com)
  • *Improving Safe Handling Practices for Hazardous Drugs*
... Resources

- Pharmacy Purchasing and Products, [www.pppmag.com](http://www.pppmag.com)
  - February 2015, Evolution of the CSTDs (Massoomi)
  - March 2017, Performing an Assessment of Risk for USP <800> Compliance (Kienle and Douglass)
  - May 2018, Wipe Sampling (Kastango, Kienle, and Fortier)
- Pharmacy Practice News, [www.pharmacypracticenews.com](http://www.pharmacypracticenews.com)
  - July 2018, Kienle’s 10 Building Blocks of Compounding Safety
Assessment Questions

1. What is USP’s role concerning USP <800>?

   A. **Standard-setting**
   B. Federal enforcement of the Chapter
   C. State enforcement of the Chapter
   D. Required for accreditation organizational standards
2. What organization establishes the list of drugs that are hazardous to healthcare personnel?

A. Centers for Medicare and Medicaid Services
B. Environmental Protection Agency
C. The Joint Commission
D. National Institute for Occupational Safety and Health
3. Which of the following requires all containment strategies and work practices defined in <800> and is not eligible for inclusion in your Assessment of Risk?

A. Methotrexate tablets
B. Megestrol suspension
C. Cyclophosphamide IV
D. Oxytocin IV
4. What type of solution deactivates hazardous drugs?

A. Isopropyl alcohol  
B. Oxidizer  
C. Germicidal detergent  
D. Surfactant
Questions? Comments?