Operational Impacts of Adhering to NIOSH and USP 800 Standards

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Sutter Health

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Kaiser Permanente
Disclosure

The speakers have nothing to disclose and report no financial relationships relevant to this activity.
Learning Objectives

Learners will be able to explain relevant sections of USP Chapter 800, NIOSH, and CA BOP regulations related to hazardous drugs.

Learners will compare the differences between USP 800 standards and CA BOP regulations in relation to HDs.

Learners will be able to describe an organizational strategy for the handling, storage and disposal of hazardous drugs.
Definitions

**USP** - The U.S. Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets *standards* for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.

USP 800 is a federal *standard* that *can be* adopted as a state or federal *regulation*. 
Definitions

OSHA – Occupational Safety and Health Administration
  ◦ Mission: To assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance.

NIOSH – The National Institute for Occupational Safety and Health
  ◦ Mission: To develop new knowledge in the field of occupational safety and health and to transfer that knowledge into practice.
  ◦ A department of the Centers for Disease Control and Prevention (CDC)

https://www.osha.gov/about.html (accessed 8/1/16)
https://www.cdc.gov/niosh/about/default.html (accessed 8/1/16)
History of Hazardous Drug Guidelines, Standards & Regulations

- OSHA 1986
- ASHP 1990
- HOPA 2009
- USP <800> 2016-2018
- Centers for Disease Control and Prevention: Lack of Adherence
- CA BOP ???

- ONS 1988
- USP <797> 2004
- ISMP 2012
USP <800> - Overview

Protect patients, personnel and the environment from exposure to hazardous drugs.

Applies to *all* healthcare settings

Applies to *all* personnel
Complying with USP <800>

Planning
- Determine HD List
- Risk Assessment
- Personnel Training
- Facilities

Monitoring
- Facilities
- Decontamination
- Medical Surveillance
- Monitor Compliance
Sections in USP <800>

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling HDs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport and Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning and Disinfecting
16. Spill Control
17. Documentation and SOPs
18. Medical Surveillance
19. Glossary
20. Appendices
Team for Implementation

- Nursing
- CEO
- Pharmacy
- Human Resources
- Quality
- Health & Safety
Visual Mapping Tool

Hazardous Drug Process

Pre-Hospital

- RX Company
- Delivery
- Wholesaler
- Packaging
- Delivery

Hospital

- Pharmacy Receiving
- Pharmacy Compounding
- Patient Unit Delivery
- Nurse Administration Patient
- Housekeeping

Post-Hospital

- Waste Hauler
- Waste Management
- Linen Haulers

Hazardous Drugs products should always be considered contaminated on the packaging and vials until properly decontaminated.


Without a total hazardous drug safety program in place the drug products, the patient, the linen from patients, the pharmaceutical wastes provides multi-sourced contaminated risk to healthcare providers.

NIOSH Safety Alert 2004

Hazardous Drug

NOTE: Red Indicates Contamination points
Implementing USP <800>

Determine HD List
Hazardous Risk Assessment
Training Personnel
Facilities
Decontamination / Cleaning
Monitoring Compliance
Implementing USP <800>
2. LIST OF HAZARDOUS DRUGS

The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity’s list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity’s list.

The NIOSH list of antineoplastic and other HDs provides the criteria used to identify HDs. These criteria must be used to identify HDs that enter the market after the most recent version of the NIOSH list, or that the entity handles as an investigational drug. If the information available on a drug is deemed insufficient to make an informed decision, consider the drug hazardous until more information is available.
NIOSH* Definition of Hazardous Drug

Drugs considered hazardous if exhibit one or more of the following 6 characteristics in humans or animals:

1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing drugs determine hazardous by the above criteria.
# NIOSH Groups of Hazardous Drugs

<table>
<thead>
<tr>
<th>Group Type</th>
<th>2014 Total Drugs</th>
<th>2016 Proposed Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1: Antineoplastic drugs</strong></td>
<td>106</td>
<td>17</td>
</tr>
<tr>
<td><strong>Group 2: Non-antineoplastic drugs</strong></td>
<td>58</td>
<td>5</td>
</tr>
<tr>
<td><strong>Group 3: Drugs that primarily pose a reproductive risk</strong></td>
<td>47</td>
<td>14</td>
</tr>
<tr>
<td><strong>Total Drugs</strong></td>
<td>211</td>
<td>36</td>
</tr>
</tbody>
</table>

- Group 1: Antineoplastic drugs (AHFS Classification 10:00) [ASHP/AHFS DI 2013]. Note that many of these drugs may also pose a reproductive risk for susceptible populations (Table 1).
- Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug. Note that some of these drugs may also pose a reproductive risk for susceptible populations (Table 2).
- Group 3: Drugs that primarily pose a reproductive risk to men and women who are actively trying to conceive and women who are pregnant or breast feeding, because some of these drugs may be present in breast milk (Table 3).
New drugs highlighted in red

Drug insert contains safe-handling warnings (section 16)

Drug groupings

Table 1. Antineoplastic drugs including those with manufacturers’ safe handling guidance (MSHG)

<table>
<thead>
<tr>
<th>Drug</th>
<th>AHFS classification</th>
<th>MSHG</th>
<th>Reason for listing</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>abiraterone</td>
<td>100:00 antineoplastic agents</td>
<td>FDA Pregnancy Category X</td>
<td></td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>ado-trastuzumab emtansine</td>
<td>100:00 antineoplastic agents</td>
<td>yes</td>
<td>Conjugated monoclonal antibody; FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>altretamine</td>
<td>100:00 antineoplastic agents</td>
<td>yes</td>
<td>FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>amsozole</td>
<td>NA antineoplastic agents</td>
<td>IARC Group 2B</td>
<td></td>
<td>DrugBank</td>
</tr>
<tr>
<td>arsenic trioxide</td>
<td>100:00 antineoplastic agents</td>
<td>yes</td>
<td>IARC Group 1 carcinogen**; FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>azacitidine</td>
<td>100:00 antineoplastic agents</td>
<td>yes</td>
<td>IARC Group 2A carcinogen; FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>bacillus calmette Guerin (BEG)***</td>
<td>80:12 vaccines</td>
<td>yes</td>
<td>See special handling requirements**; FDA Pregnancy Category C</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>bendaamustine</td>
<td>100:00 antineoplastic agents</td>
<td>yes</td>
<td>FDA Pregnancy Category D</td>
<td>DailyMed; DrugBank</td>
</tr>
<tr>
<td>bexarotene</td>
<td>100:00 antineoplastic agents</td>
<td>FDA Pregnancy Category X</td>
<td></td>
<td>DailyMed; DrugBank</td>
</tr>
</tbody>
</table>

Obtain drug inserts, toxicology data, etc.

NIOSH HD criteria
Live Biological Agents

- Bacillus Calmette-Guerin (BCG) is listed as a NIOSH Table 1 antineoplastic HD.
  - New agent: talimogene laherparepvec

- NIOSH
  - Parenteral drugs should not be prepared where BCG has been prepared.
  - If preparation cannot be done in a containment device, respiratory protection, gloves and gown should be worn

- USP <800> requires compounding in the Primary Engineering Control (C-PEC) located in either a negative pressure room or Segregated Compounding Area (C-SCA)

- Facilities can address with more rigorous cleaning standards
Monoclonal Antibodies (mAbs)

- Decisions Facility Specific
  - What does your facility currently do?
  - Will there be confusion for staff if they are classified in different classes?
    - Consider labeling, Closed system safety devices (CSTDs), RN administration
  - Possible solutions
    - Non-antineoplastic HD
    - Pharmacy special handling/RN different handling
  - Monoclonal antibodies conjugated to antineoplastic HD are NISOH Group 1 antineoplastic
    - ado-trastuzumab emtansine
Determine HD List

**Kaiser Permanente**
- Adopt NIOSH list
- Use assessment tool to identify additional HDs
- Use labeling and medication administration record for communication to employees

**Sutter Health**
- Adopt NIOSH list
- Use assessment tool to identify additional HDs
- Use labeling, medication administration record and IV pump drug library for communication to employees
HD Assessment Tool

Legend
Solid, black line = no
Dashed, red line = yes

Start

On NIOSH HD List? *

Classified as antineoplastic by American Hospital Formulary Service (AHFS)?

PI or SDS indicate MSHG?

HD

* If reviewed by NIOSH and deemed non-HD, not an HD
HD Assessment Tool

Legend
Solid, black line = no
Dashed, red line = yes

Active ingredient as carcinogen classified by IARC 1, 2A, 2B?

Organ toxicity at low dose in humans (<10 mg/day) or in animals (<1 mg/kg/day)?

International Agency for Research on Cancer (IARC)
http://monographs.iarc.fr/ENG/Classification/

Group 1: Carcinogenic to humans
Group 2A: Probably carcinogenic to humans
Group 2B: Possibly carcinogenic to humans
Group 3: Not classifiable as to its carcinogenicity to humans
Group 4: Probably not carcinogenic to humans

*not updated frequently with new drugs
HD Assessment Tool

Legend
Solid, black line = no
Dashed, red line = yes

Structure similar to known HD?

Mutagenic in animals or humans and there is sufficient Occupational Risk?

Sufficient reproductive/teratogenic data and Occupational Risk?
- FDA pregnancy category C, D or X
- PI lists “pregnancy”, “lactation” or “females & males of reproductive potential”

Not a HD

HD
## NIOSH Reviewed – Non-Hazardous

**Drugs Reviewed for the NIOSH Hazardous Drugs List but NOT included 2010-2016**

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Established Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>abatacept</td>
<td>Orencia</td>
</tr>
<tr>
<td>amifostine</td>
<td>Ethyl</td>
</tr>
<tr>
<td>asparaginase Erwinia chrysanthemi</td>
<td>Erwinaze</td>
</tr>
<tr>
<td>bevacizumab</td>
<td>Avastin</td>
</tr>
<tr>
<td>bimatoprost</td>
<td>Lumigan</td>
</tr>
<tr>
<td>canakinumab</td>
<td>Ilaris</td>
</tr>
<tr>
<td>cetuximab</td>
<td>Erbitux</td>
</tr>
<tr>
<td>darbepoetin alfa</td>
<td>Aranesp</td>
</tr>
<tr>
<td>efalizumab</td>
<td>Raptiva</td>
</tr>
<tr>
<td>golimumab</td>
<td>Simponi</td>
</tr>
<tr>
<td>iloprost</td>
<td>Ventavis</td>
</tr>
<tr>
<td>infliximab</td>
<td>Remicade</td>
</tr>
<tr>
<td>interferon beta 1a</td>
<td>Avonex</td>
</tr>
<tr>
<td>interferon beta 1b</td>
<td>Betaseron</td>
</tr>
<tr>
<td>natalizumab</td>
<td>Tysabri</td>
</tr>
<tr>
<td>porfimer</td>
<td>Photofrin</td>
</tr>
<tr>
<td>ranibizumab</td>
<td>Lucentis</td>
</tr>
<tr>
<td>rituximab</td>
<td>Rituxan</td>
</tr>
<tr>
<td>trastuzumab</td>
<td>Herceptin</td>
</tr>
</tbody>
</table>
KP - Communication Strategy

Leverage technology
◦ Labeling
Sutter - Communication Strategy

Leverage technology
◦ Labeling
◦ Alert on drug library

Use Chemotherapy Precautions with this medication.
Communication Strategy

Leverage technology
- Epic Medication Administration Record (MAR)
Implementing USP <800>

- Determine HD List
- Hazardous Risk Assessment
- Training Personnel
- Facilities
- Decontamination / Cleaning
- Monitoring Compliance
Hazardous Risk Assessment

Some dosage forms of drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (e.g., tablets or capsules—solid, intact medications that are administered to patients without modifying the formulation). However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation. An assessment of risk may be performed for these dosage forms to determine alternative containment strategies and/or work practices. If an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in this chapter.

The assessment of risk must, at a minimum, consider the following:

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

<table>
<thead>
<tr>
<th>Kaiser Permanente</th>
<th>Sutter Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed Risk Assessment Algorithm</td>
<td></td>
</tr>
<tr>
<td>Reviewing each NIOSH Table 2 &amp; Table 3 medication – assigning appropriate containment strategies</td>
<td>Review of compounding and dosage forms used by all affiliates.</td>
</tr>
<tr>
<td>Use Epic labeling and MAR as communication vehicle (Specific PPE requirements)</td>
<td>System-wide decision on handling, PPE, personnel at risk for each class.</td>
</tr>
<tr>
<td></td>
<td>Affiliate specific HD lists and system-wide review of new medications.</td>
</tr>
</tbody>
</table>
## Sutter - Possible Risk Assessment by Group

<table>
<thead>
<tr>
<th></th>
<th>Antineoplastic HDs</th>
<th>Non-antineoplastic</th>
<th>Reproductive Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PPE</strong></td>
<td>Full PPE</td>
<td>Modified PPE for administration</td>
<td>Modified PPE for administration</td>
</tr>
<tr>
<td><strong>Administration</strong></td>
<td>- Double RN check</td>
<td>One RN</td>
<td>One RN</td>
</tr>
<tr>
<td></td>
<td>- ONS certified</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oral Doses</strong></td>
<td>Do not crush*</td>
<td></td>
<td>Staff may crush except for reproductive risk</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Labeled in EMR; pharmacy may crush under antineoplastic engineering controls (e.g., BSC, CACI, full PPE, labeled as antineoplastic); suspensions dispensed as unit dose by pharmacy not in bulk bottles.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medications</strong></td>
<td>NIOSH list Group 1 APIs</td>
<td>NIOSH list Group 2</td>
<td>NIOSH list Group 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Different risks for certain agents (ex: finasteride vs. clonazepam)</td>
</tr>
</tbody>
</table>
### Sutter - Example of Facility Specific Assessment

**Group 1: Antineoplastics**

List drugs, dosage forms, allowable manipulation: to include any cytotoxic, immunosuppressive and antiviral agents that qualify.

Handle with required PPE and dispose of properly or per policy. Labeled do not crush in EMR. Labeled as Cytotoxic Agent. *Do not tube or load in pyxis.*

<table>
<thead>
<tr>
<th></th>
<th>Pharmacy</th>
<th>Nursing (who can administer)</th>
<th>Nursing Body Fluids</th>
<th>EVS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IM, SubQ, Intradermal</strong></td>
<td>BSC, sterile double chemo gloves, chemo gown, face shield, double booties*</td>
<td>Double chemo gloves, chemo gown, face shield (oncology RN)</td>
<td>Double chemo gloves, chemo gown, add face shield if splashing possible</td>
<td>Double chemo gloves, chemo gown, chemotherapy labeled bag</td>
</tr>
<tr>
<td><strong>IV Push, IVPB, CIVI</strong></td>
<td>BSC, sterile double chemo gloves, chemo gown, face shield, double booties</td>
<td>Double chemo gloves, chemo gown, face shield (oncology RN)</td>
<td>Double chemo gloves, chemo gown, add face shield if splashing possible</td>
<td>Double chemo gloves, chemo gown, chemotherapy labeled bag</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td>BSC, sterile double chemo gloves, chemo gown, double booties</td>
<td>Double chemo gloves, chemo gown (oncology RN)</td>
<td>Double chemo gloves, chemo gown, add face shield if splashing possible</td>
<td>Double chemo gloves, chemo gown, chemotherapy labeled bag</td>
</tr>
</tbody>
</table>

* only when not in final dosage form
# Hazardous Risk Assessment - KP

<table>
<thead>
<tr>
<th>Risk of Exposure (highlight)</th>
<th>Likelihood of Exposure (Based upon occupational risk)</th>
<th>Severity of Exposure (based upon toxicity)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low (reproductive only)</td>
<td>Moderate (Organ or genotoxicant)</td>
</tr>
<tr>
<td></td>
<td>High (antineoplastic or carcinogen)</td>
<td></td>
</tr>
<tr>
<td>Unlikely: Intact Pills/Capsules, Cutting Table 2,3</td>
<td>Low Risk</td>
<td>Low Risk</td>
</tr>
<tr>
<td>Likely (non-sterile): Cutting Table 1, Crushing, suspensions, creams</td>
<td>Moderate Risk</td>
<td>Moderate Risk</td>
</tr>
<tr>
<td>Very Likely (sterile): IV, aerosolized procedure, injections, ampoules, irrigation, powders</td>
<td>High Risk</td>
<td>High Risk</td>
</tr>
</tbody>
</table>

**PROPOSED**
Hazardous Risk Assessment - KP

**Low risk:** single pair of gloves only, use pill cutter

**Moderate risk:** Crushing pills, opening capsules, suspensions and creams utilize ‘alternate containment strategy’: prepare in pharmacy using C-PEC with 12 ACPH and negative pressure. If using same C-PEC for sterile and non-sterile compounding, decontaminate, clean and disinfect C-PEC before resuming sterile compounding. Handle with double chemo gloves and impermeable gown when administering. Use eye protection if patient may resist (infant, unruly patient, veterinary patient) or if administered by feeding tube.

**High Risk:** prepare in ISO certified C-PEC, C-SEC, negative air pressure, appropriate ACPH. CSTD required for all antineoplastics (NIOSH Table 1). CSTD optional for all other HDs (NIOSH Table 2 and 3). Handle with gloves, gown, eye protection.

Waiting for NIOSH 2016....
Implementing USP <800>

- Determine HD List
- Hazardous Risk Assessment
- Training Personnel
- Decontamination / Cleaning
- Facilities
- Monitoring Compliance
9. PERSONNEL TRAINING

All personnel who handle HDs must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP. All training and competency assessment must be documented.

The training must include at least the following:

- Overview of entity’s list of HDs and their risks
- Review of the entity’s SOPs related to handling of HDs
- Proper use of PPE
- Proper use of equipment and devices (e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials
Training Personnel

Kaiser Permanente
- Implementation of National Pharmacy Onboarding Document (Orientation Checklist)
- Implementation of National Pharmacy Compounding Competency
- Implementation of National EVS Training
- Collaboration with ASHP Library
  - Sterile Compounding Training
  - USP 800 (to be released)

Sutter Health
- Didactic system presentation
- Department specific orientation training
- Annual training in system wide compliance training
- Demonstrative training tools
<table>
<thead>
<tr>
<th>Change every <strong>30 min</strong></th>
<th>Pharmacy change every <strong>2-3 hours</strong></th>
<th><strong>Second pair booties</strong> donned before entering buffer room</th>
<th>Use <strong>face shields</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Double glove</strong> when compounding, administering and disposing of hazardous drugs</td>
<td><strong>Polyethylene-coated polypropylene</strong></td>
<td>• Outer pair removed before exiting buffer room</td>
<td><strong>N95</strong> or equivalent respirator whenever there is risk of inhalation exposure in spills</td>
</tr>
<tr>
<td>• Outer glove shall be <strong>sterile</strong></td>
<td>• Disposal after administration of HD</td>
<td></td>
<td><strong>When manipulating HDs outside of C-PEC</strong>, splashing potential, or possible broken container</td>
</tr>
<tr>
<td></td>
<td>• Do not wear gowns outside of administration area to prevent contamination</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Closed System Transfer Devices

**Safety**
- ONB Product Code
- Passes all 3 safety tests*

**Recommendations**
- *Required* for administration
- *Recommended* for admixture

**Standardization**
- Employees must demonstrate
- Facility onerous to demonstrate CSTD

*Devices: Equashield, Phaseal, ChemoLock, Spiros, Texium, Halo, On Guard*

- NIOSH ALCOHOL PROTOCOL, FLUORESCENCE, LITMUS
Signs for Hazardous Areas

Signs designating hazardous areas must be prominently displayed before entrance to HD handling areas.

Signs identifying patients that may be contaminated with HDs
## Environmental Health & Safety (EH&S) Review

<table>
<thead>
<tr>
<th>Item</th>
<th>Complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Health &amp; Safety Website</td>
<td></td>
</tr>
<tr>
<td>Trace Chemo/Bulk Chemo</td>
<td></td>
</tr>
<tr>
<td>Bulk Non-Hazardous Waste Container</td>
<td></td>
</tr>
<tr>
<td>Trash and Patient Health Information (PHI) Receptacles</td>
<td></td>
</tr>
<tr>
<td>Sharps Container</td>
<td></td>
</tr>
<tr>
<td>Safety Data Sheet (SDS) Location</td>
<td></td>
</tr>
<tr>
<td>Eyewash Location</td>
<td></td>
</tr>
<tr>
<td>Spill Kit Location</td>
<td></td>
</tr>
<tr>
<td>Department Of Transportation (DOT) Training (KP Learn)</td>
<td></td>
</tr>
</tbody>
</table>
Training Personnel – KP
National Pharmacy Competency

G

Exposure/Spills

User understands procedure in the event of drug exposure on skin, eye, needle stick, etc.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

User is able to describe the steps to take after exposure:
- Wash off affected area for a minimum of 10-15 minutes.
- Notify manager/supervisor/PIC
- Proceed to Employee Health Department (if applicable)

User is aware of location of eye wash station

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

User understands and can demonstrate appropriate use of the chemotherapy drug spill kit

User demonstrates SDS retrieval either online or hard copy of a hazardous medication.

User demonstrates and understands the reporting process for spills

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
# Training Personnel – KP

## National EVS Training

### Infusion Pharmacy EVS Personnel Training/Competency Attestation

<table>
<thead>
<tr>
<th>EVS Employee Name:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Competency</th>
<th>EVS Personnel Initial</th>
<th>EVS Manager Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Knowledge of all necessary cleaning/disinfecting equipment and Personal Protective Equipment (PPE).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. All reusable equipment used for ante and buffer rooms are dedicated to that area only. Equipment and supplies include but are not limited to mops, mop pads, mop buckets, etc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Demonstrates proper infection control (remove jewelry, no cosmetics or artificial fingernails, too long hair back, etc.).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Proper Hand Washing and proper sequence of getting and removing of Personal Protective Equipment (PPE) and gloves.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 5. Proper cleaning/disinfecting sequence:  
  - Cleaning/disinfecting shall occur from the cleanest to dirtiest areas  
  - Buffer rooms first, then ante room, start in the chemo prep room, then the non-chemo buffer room, followed by the ante room.  
  - Clean from "top to bottom" and "back to front" - front the farthest point in the buffer area towards the doorframe. |  |  |  |
| 6. Knowledge of daily, weekly, and monthly (if applicable) duties. |  |  |  |
| 7. Do not clean inside the IV hoods, chemo hoods, and refrigerators. |  |  |  |
| 8. EVS staff aware that if they need to exit & re-enter the IV room, the gown shall be removed & hung by the door for re-use. Hair cover, face mask, shoe covers and gloves shall be discarded & replaced with new ones upon re-entry. |  |  |  |
| 9. Proper documentation in QA logs. |  |  |  |

### Signature of EVS Employee:  
Signature: __________________  
Date: __________

### Signature of EVS Manager:  
Signature: __________________  
Date: __________

### Infusion Pharmacy EVS Personnel Observational Review

<table>
<thead>
<tr>
<th>EVS Employee Name:</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Observational Review Requirements</th>
<th>Compliant</th>
<th>Non-Compliant</th>
<th>Observer’s Initial</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Knowledge of all necessary cleaning/disinfecting equipment and Personal Protective Equipment (PPE).</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. All reusable equipment used for ante and buffer rooms are dedicated to that area only. Equipment and supplies include but are not limited to mops, mop pads, mop buckets, etc.</td>
<td></td>
<td></td>
<td></td>
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  - Cleaning/disinfecting shall occur from the cleanest to dirtiest areas  
  - Buffer rooms first, then ante room, start in the chemo prep room, then the non-chemo buffer room, followed by the ante room.  
  - Clean from "top to bottom" and "back to front" - front the farthest point in the buffer area towards the doorframe. |  |  |  |  |
| 6. Knowledge of daily, weekly, and monthly (if applicable) duties. |  |  |  |  |
| 7. Do not clean inside the IV hoods, chemo hoods, and refrigerators. |  |  |  |  |
| 8. EVS staff aware that if they need to exit & re-enter the IV room, the gown shall be removed & hung by the door for re-use. Hair cover, face mask, shoe covers and gloves shall be discarded & replaced with new ones upon re-entry. |  |  |  |  |
| 9. Proper documentation in QA logs. |  |  |  |  |

### Overall Assessment:

|  
|  
| Notes: |  |

### Signature of Observer (EVS Manager/Pharmacy Supervisor/Pharmacist/designee):  
Signature: __________________  
Date: __________
Training Personnel – KP
ASHP Library
Implementing USP <800>

1. Determine HD List
2. Hazardous Risk Assessment
3. Training Personnel
4. Decontamination / Cleaning
5. Monitoring Compliance
6. Facilities

Flow:
- Determine HD List
- Hazardous Risk Assessment
- Training Personnel
- Decontamination / Cleaning
- Monitoring Compliance
- Facilities
Facilities

5. FACILITIES AND ENGINEERING CONTROLS

HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. Access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling. HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure.

Designated areas must be available for:
- Receipt and unpacking
- Storage of HDs
- Nonsterile HD compounding (if performed by the entity)
- Sterile HD compounding (if performed by the entity)

Certain areas are required to have negative pressure from surrounding areas to contain HDs and minimize risk of exposure. Consideration should be given to uninterrupted power sources (UPS) for the ventilation systems to maintain negative pressure in the event of power loss.
Facilities

**Kaiser Permanente**
- Remodeling strategy – Consolidate when possible
- Internal National Templates Committee
- Collaboration with Strategic and Capital Planning Department and National Facilities Services for scoping, design, and construction

**Sutter Health**
- Independent contract gap analysis of every site.
- System wide plan for development of sites incl. construction plan, timelines, mobile unit coordination and California BOP waivers.
- Segregated compounding and clean rooms.
Facilities – KP & Sutter
Remodeling - Strategy

Consolidate sterile compounding when possible based on:
- Volume of chemotherapy
- Distance to nearest compliant pharmacy
- Future plans for additional services
- Future growth
- Consolidate sub-specialties into one area.

**Consolidate** hazardous drug / antineoplastic compounding when possible based on factors above.

Remodel only if **consolidation** not feasible
Two Types of Compounding Areas

Containment Segregated Compounding Area (C-SCA)
- Fixed walls separate from non hazardous drugs
- Vented to outside
- Negative pressure: at least 12 air changes/hr
- Does NOT need to be in ISO classified buffer
Negative Pressure Room

Refrigerator

Receiving Area (Neutral/Negative)

KP National Template for Oncology Pharmacy
Implementing USP <800>

1. Determine HD List
2. Hazardous Risk Assessment
3. Training Personnel
4. Facilities
5. Decontamination / Cleaning
6. Monitoring Compliance

This diagram outlines the steps involved in implementing USP <800>, emphasizing the importance of each stage in ensuring compliance with hazardous materials regulations.
<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 or inactive</td>
<td>As listed in the HD labeling or other agents which may incorporate Environmental Protection Agency (EPA)-registered oxidizers (e.g., peroxide formulations, sodium hypochlorite, etc.).</td>
</tr>
<tr>
<td>Decontamination</td>
<td>Remove HD residue</td>
<td>Materials that have been validated to be effective for HD decontamination, or through other materials proven to be effective through testing, which may include alcohol, water, peroxide, or sodium hypochlorite</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Remove organic and inorganic material</td>
<td>Germicidal detergent</td>
</tr>
<tr>
<td>Disinfection (for sterile manipulations)</td>
<td>Destroy microorganisms</td>
<td>EPA-registered disinfectant and/or sterile alcohol as appropriate for use</td>
</tr>
</tbody>
</table>
Decontamination / Cleaning

Kaiser Permanente
- Collaboration with Environmental Health & Safety to develop National Cleaning Guidelines
- Standardized policies
- Focus on identifying ideal sporicidal

Sutter Health
- Standardize solutions throughout all facilities and rotation schedule.
- Work with vendors for commercially available dilutions and ready made products.
Decontamination / Cleaning – KP
National Cleaning Guidelines

Table 4: Decontamination

<table>
<thead>
<tr>
<th>Surface</th>
<th>Responsibility</th>
<th>Frequency</th>
<th>Agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEC, interior surfaces, including under work tray</td>
<td>Pharmacy</td>
<td>At least weekly, in addition to: • Following clean-up of a hazardous drug spill</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Before and after certification, voluntary interruption, or if the BSC or CACI is moved</td>
<td>Bleach solution followed by sodium thiosulfate Note: ensure area is completely dry before application of disinfection agent following clean-up of a hazardous drug spill to prevent an adverse reaction.</td>
</tr>
<tr>
<td>Any surface contaminated with a hazardous drug spill</td>
<td>Pharmacy</td>
<td>Following clean-up of a hazardous drug spill</td>
<td></td>
</tr>
</tbody>
</table>

Definitions

1. Cleaning is the removal of soil (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically using water with detergents.

2. Deactivation is the treatment of a HHD with another chemical, heat, ultraviolet light, or other agent to create a less hazardous agent in order to lessen the severity of unintended absorption, ingestion or inhalation of the HHD by a health care worker.

3. Decontamination is the inactivation, neutralization, or removal of HHDs on environmental surfaces, usually by chemical means, in order to prevent cross-contamination of drug preparations.

4. Disinfectant is an agent that hinders infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects. Disinfectant must be an EPA registered hospital-grade agent: http://www.epa.gov/ceppo/501antimicrobial-testing-program.html

5. Disinfecting is the removal of visible organisms from surfaces using 70% alcohol or other appropriate disinfectant prior to compounding sterile hazardous drugs.

6. Hazardous Drug is defined as a drug that exhibits one or more of the following six characteristics in humans or animals:
   - Carcinogenicity
   - Teratogenicity or other developmental toxicity
   - Reproductive toxicity
   - Organ toxicity at low doses
   - Genotoxicity

*Open review of industry definitions, it appears that terms associated with the cleaning, disinfection, and decontamination of surfaces are either not defined, inconsistently defined and/or are used interchangeably, which may lead to confusion regarding the interpretation of these definitions and the recommendations contained within these guidelines. Foremost is the difference between Adverse Drug Events (ADEs) and the terms “cleaning” and “disinfection” can be confusing. The National Center for Infectious Diseases and the Centers for Disease Control and Prevention’s Technical Guidelines for Adverse Drug Events: definitions are consistent with the definitions used in the current guidelines. However, the term “disinfection” is not defined. The term “disinfection” has been used in the context of USP 797 and the Center for Devices and Radiological Health guidelines, however, this term is not officially defined. Adverse Drug Events (ADEs) are included in the definition of “disinfection” and are related to the use of an ADEs and the term “disinfection” should be avoided. The term “disinfection” has been used to describe the use of a disinfectant when a patient is not at risk of infection. This document attempts to balance the various organizational recommendations for these management practices.
<table>
<thead>
<tr>
<th></th>
<th>Decontaminate</th>
<th>Deactivate</th>
<th>Cleaning= Germicidal</th>
<th>Disinfect</th>
</tr>
</thead>
</table>
| **Agents**     | 2% Sodium hypochlorite (bleach)                                                                                                                                                                                                                                                                                                             | • Sodium thiosulfate  
  • Wiping up decontamination agent with sterile water                                                                                                                                                              | • 3% hydrogen peroxide  
  • Lysol IC  
  • Virex  
  • Bleach                                                                                                                                                                                                                           | • UV light  
  • 70% sterile isopropyl alcohol                                                                                                                                                                                                                                                   |
| **Frequency**  | **Daily** or after spill occurs                                                                                                                                                                                                                                                                                                           | **Weekly** or after spill occurs                                                                                                                                                                                | Exterior surfaces, walls, floors, ceilings, shelves, tables **monthly***, work surfaces, floors **daily**                                                                 | Work surfaces/ante areas, floors **daily**                                                                                                                                                                                                                                             |

*What is chosen should be discussed in detail in policies and procedures*
Sporicidal – help or harm?

Occupational exposure limits:

Bleach:
- 8-hr Cal/OSHA 8-hr Time Weighted Average (TWA) Permissible Exposure Limit (PEL) of 0.5 part per million (ppm)
- Short Term Exposure Limit (STEL) of 1 ppm

Hydrogen peroxide
- Cal/OSHA 8-hr TWA PEL of 1 ppm

Peroxyacetic acid (peracetic acid)
- ACGIH STEL Threshold Limit Value (TLV) of 0.4 ppm
Decontamination / Cleaning – KP Sporicidals – help or harm?

- Pharmacy staff using bleach to decontaminate the inside of the BSC located in the hazardous drug compounding room
  - Minimal exposure risk

- Conduct air monitoring to determine exposure risk for:
  - Staff using sporicidal agent to disinfect floors, walls, ceilings and shelving of the ante, buffer and laminar flow rooms in pharmacies
  - Pharmacy staff using sporicidal agent to disinfect surfaces of the laminar flow hood located in the non-hazardous compounding room
Implementing USP <800>

- Determine HD List
- Hazardous Risk Assessment
- Training Personnel
- Facilities
- Decontamination / Cleaning
- Monitoring Compliance
Monitoring Compliance

- Environmental Sampling
- Medical Surveillance
6. ENVIRONMENTAL QUALITY AND CONTROL

Environmental wipe sampling for HD surface residue should be performed routinely (e.g., initially as a benchmark and at least every 6 months, or more often as needed, to verify containment). Surface wipe sampling should include:

- Interior of the C-PEC and equipment contained in it
- Pass-through chambers
- Surfaces in staging or work areas near the C-PEC
- Areas adjacent to C-PECs (e.g., floors directly under C-PEC, staging, and dispensing area)
- Areas immediately outside the HD buffer room or the C-SCA
- Patient administration areas
Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. Healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program. The general purpose of surveillance is to minimize adverse health effects in personnel potentially exposed to HDs. Medical surveillance programs involve assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood count) to determine whether there is a deviation from the expected norms.
Monitoring Compliance

**Kaiser Permanente**
- Environmental
  - Wipe sampling guidelines
- Employee Health
  - Yearly baseline questionnaire at risk personnel
  - Labs, physical based on questionnaire

**Sutter Health**
- Environmental
  - Every 6 month wipe testing by independent vendor
- Employee Health
  - Baseline questionnaire at risk personnel
  - Annual lab review
  - Exit questionnaire
Environmental Sampling - HDs

- Common HDs assayed
  - Cyclophosphamide, methotrexate, fluorouracil and platinum drugs.

- Any contamination should be followed up with remediation and decontamination plan

- Companies performing testing
  - TSS Hood certification ~$2400
  - Chemoglo ~$2300
  - Good to perform these at same time hood is being certified.
Environmental Sampling - HDs

- There are currently no studies demonstrating the effectiveness of a specific number or size of wipe samples in determining levels of HD contamination.

- There are currently no certifying agencies for vendors of wipe sample kits.

- There is currently no standard for acceptable limits for HD surface contamination.
Conclusion

Establish the following prior to conducting surface wipe sampling for hazardous drugs:

1. Establish a clear purpose for conducting surface wipe sampling.

2. Identify which hazardous drugs are used most often.

3. Observe work practices to aid in the selection of appropriate locations to sample.

4. Designate a single person to conduct surface wipe sampling to ensure consistency of results.

5. Select a vendor that is preferably AIHA-LAP accredited (GLP is also available), has experience conducting wipe sampling for hazardous drugs and has a validated method to analyze the drugs most commonly used in your department.

6. Determine an acceptable surface level to aid in the interpretation of results (i.e., 0.1 ng/cm², 1 ng/cm² or ALARA).
Baseline Employee Assessment

Exposure History:

Most commonly handled drugs/chemical? 1. ________________________ 2. ________________________

Frequency: _______ times per day/week _______ times per day/week

Duration (min/hrs handling each): ________________________

Reproductive History:

1. Have you or your partner ever had a problem conceiving a child?
   □ Yes  If yes, please specify: □ present partner □ previous partner
   □ No

2. Have you or your partner consulted a physician for a fertility or other reproductive problem?
   □ Yes  If yes, please specify:
   □ No
   If yes, please specify the diagnosis: _______________________________

3. Have you or your partner ever conceived a child resulting in a miscarriage, still birth or deformity?
   □ Yes
   □ No

4. If yes to question 3, please specify the type of outcome: □ Miscarriage □ stillbirth □ deformity
Designated Person?

Nursing:
- Education
- Nurse Managers
- Audit/compliance

CEO

Pharmacy:
- IV Room Supervisor
- Lead Technician
- Training Subject Matter EXPERT

Human Resources:
- Employee Health
- Employee Training

Quality

Health & Safety:
- Compliance Officer
- Safety
- Auditing
- Coordination
- Maintain Files
Implementing USP <800>

1. Determine HD List
2. Hazardous Risk Assessment
3. Training Personnel
4. Facilities
5. Decontamination / Cleaning
6. Monitoring Compliance
Instructions for Using the CHA/CSHP Compounding Grids 2016

WHAT

The California Hospital Association (CHA)/California Society of Health-System Pharmacists (CSHP) Compounding Grids identify the proposed Board of Pharmacy requirements that will take effect Jan. 1, 2017, as well as describe the upcoming USP 797 and USP 800 requirements that will likely be effective July 1, 2018. There are six compounding grids: Physical Plant Requirements for Non-Hazardous Compounding, Physical Plant Requirements for Hazardous Compounding, Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous and Hazardous Garbing.

These tools are intended for hospital and health care pharmacists in charge (PICs) and other hospital staff as they evaluate their current sterile compounding practices. The grids are based on the Board of Pharmacy’s Feb. 24, 2016, “Order of Adoption-Sterile Compounding Regulations” and interpreted by CHA’s and CSHP’s Medication Safety senior pharmacy leaders. The grids are not a fixed compliance assessment that must be followed, and they should not be construed as legal advice or used to resolve legal problems.
## Physical Plant Requirements - Hazardous

<table>
<thead>
<tr>
<th>PRIMARY ENGINEERING CONTROL</th>
<th>Beyond Use Dates</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Temp 20-24°C (68-75°F)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>- Externally vented</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>- Negative pressure</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>- Physically separate room</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

### ISO Class 7 or better
- Sink in ante area
- At least 0.01"-0.03" w.c. negative relative to all adjacent space (rooms, above ceiling and corridors)
- Minimum 30 ACPH
- Ante-area ISO 7 or better

### Biological Safety Cabinet, Class II Type A2
- Biological Safety Cabinet, Class II Type B2
- Compounding Aseptic Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent.

#### Beyond Use Dates
- 48 hours at Room Temp*
- 14 days at Cold Temp**
- 45 days Solid Frozen State***

#### Comments
- Document daily Pressure Differential or air velocity, or use continuous recording device, between adjoining ISO rooms. 1751.1(a)(8)
- Requires negative pressure ISO 5 PEC 1751.4(g)
- Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f)
- Externally vented 1751.4(g), 1735.6(e); each hood must have a separate vent
- All surfaces with the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)
- No requirements for negative pressure drug storage

### Segregated Compounding Area
- Sterile to sterile compounding only
- Sink at least 3 ft from PEC
- Emergency eye wash station acceptable
- At least 0.01"-0.03" w.c. negative relative to all adjacent space (rooms, above ceiling and corridors)
- Minimum 12 ACPH

#### Beyond Use Dates
- 12 hours

#### Comments
- Requires negative pressure ISO 5 PEC 1751.4(g)
- Each ISO environment requires certification at least q 6 months CCR §1751(b)(1), 1751.4(f)
- Externally vented 1751.4(g), 1735.6(e)
- All surfaces with the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)
- Sink can be within 3 ft of CACI if CACI meets requirements in 1751.4(f)(1-3)
- No requirements for negative pressure drug storage

---

All drugs prepared in a Hazardous Drug Primary Engineering Control (PEC) must be labeled with HD Cautions

**Controlled Cold Temp (Refrigerator): 2 to 8 degrees C, 35.6 to 46.4 degrees F**

***Controlled Freezer Temp: (-25) to (-10) degrees C, (-13) to 14 degrees F**
### California vs. USP <800>

<table>
<thead>
<tr>
<th><strong>California BOP (1735.6)</strong></th>
<th><strong>USP &lt;800&gt;</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(d)</strong> Any pharmacy engaged in hazardous drug compounding shall maintain written documentation regarding cleaning, including equipment, cleaning agents as well as documentation of cleaning.</td>
<td></td>
</tr>
</tbody>
</table>
| **(e)** HD compounding completed in :  
  - Min of 30 ACPH except that 12 air ACPH acceptable for segregated compounding area with its BUD of 12 hrs or when non-sterile products are compounded.  
  - Negative pressure of 0.01-0.03” of water column relative to all adjacent spaces  
  - each PEC shall be externally vented  
  - all surfaces shall be smooth, seamless, impervious, non-shedding (**only California BOP**)  
  
  **May include modular structure housing an internal separate room** | |
<p>| <strong>(f)</strong> Jan 1, 2017 : included waiver provision to allow pharmacies who require time to modify facilities additional time to complete process. Plan must be submitted with waiver | July 1, 2018 |</p>
<table>
<thead>
<tr>
<th>California BOP</th>
<th>USP &lt;800&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sterile Compounding Policy and Procedures 1751.3</strong></td>
<td></td>
</tr>
<tr>
<td>(a)(16) Procedures for handling, compounding and disposal of hazardous agents. Written P&amp;Ps shall describe protocols for cleanups and spill. Include details about acquisition, storage and reference all equipment, facilities and cleaning solutions.</td>
<td></td>
</tr>
<tr>
<td><strong>Facility and Equipment Standards for Sterile Compounding 1751.4</strong></td>
<td></td>
</tr>
</tbody>
</table>
| (g) Negative-pressure PEC must be certified every six months  
• garbing shall include hair cover, facemask, beard cover, polypropylene or low shedding gown closes in back, shoe covers and two pairs of ASTM D6978 standard gloves: prepared in hazardous PEC, must be labeled as hazardous | Garbing: same as Ca BOP except, N95 certified respirator if not in PEC, face shield if not in PEC, 2 pairs of shoe covers, one removed before leaving compounding hazardous area, and second pair of gloves shall be sterile. |
<table>
<thead>
<tr>
<th>California BOP</th>
<th>USP &lt;800&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Training of Sterile Compounding Staff</strong></td>
<td></td>
</tr>
<tr>
<td>(b) PIC pharmacy personnel have training and demonstrated competence.</td>
<td>Training should include reading the pharmacy SOPs pertaining to transport, manipulation, labeling, documentation, cleaning and disinfecting, spill cleanup and disposal of hazardous drugs. Personnel should also be able to determine which drugs should be treated as hazardous.</td>
</tr>
<tr>
<td><strong>Labeling 1735.4</strong></td>
<td></td>
</tr>
<tr>
<td>(e) All hazardous agents shall bear a special label which states “Chemotherapy – Dispose of Properly” or “Hazardous – Dispose of Properly”</td>
<td></td>
</tr>
</tbody>
</table>
**Enforcement: California BOP**

- **Board of Pharmacy: January 1, 2017**
  
  ***Waiver application due by December 2016 for a plan to obtain plans***

  - Includes only **Antineoplastic** agents
  
  - Includes deactivation, policies, training
  
  - Compounding must be externally vented, negative pressure *dedicated* to one BSC or CACI
  
  - Does not deal with storage requirements
  
  - Only refers to *compounding* only, not packaging and dispensing
Questions?

Thank you for your time and consideration,
Corbin and Jennifer
References


The NIOSH list of hazardous drugs sorts the medications into which three categories?

a. Antineoplastic,
b. Non-antineoplastic
c. Reproductive-only
d. All of the above
e. None of the above
The NIOSH list of hazardous drugs sorts the medications into which three categories?

a. Antineoplastic,
b. Non-antineoplastic
c. Reproductive-only
d. All of the above
e. None of the above
Products prepared in containment segregated compounding area (C-SCA)?

a. Should be prepared in ISO 7 environment
b. Assigned beyond-use-date (BUD) of 12 hours
c. Do not have to be contained in negative pressure room
d. None of the above
Products prepared in containment segregated compounding area (C-SCA)?

a. Should be prepared in ISO 7 environment
b. Assigned beyond-use-date (BUD) of 12 hours
c. Do not have to be contained in negative pressure room
d. None of the above
All statements about personal protective equipment (PPE) are true except.

a. Second pair of shoe covers should be removed before exiting buffer room.
b. Gloves must be ASTM standard D6978
c. A NIOSH certified N95 respirator should be worn when compounding in BSC
d. Gowns should be coated with polyethylene polypropylene
e. All statements are true
All statements about personal protective equipment (PPE) are true except.

a. Second pair of shoe covers should be removed before exiting buffer room.

b. Gloves must be ASTM standard D6978

c. A NIOSH certified N95 respirator should be worn when compounding inside BSC

d. Gowns should be coated with polyethylene polypropylene

e. All statements are true
Session Code:

1. Write down the course code. Space has been provided in the daily program-at-a-glance sections of your program book.

2. To claim credit: Go to www.cshp.org/cpe before December 1, 2016.