

Danger, Will Robinson!
Overview of USP Chapter <800>

Patricia C. Kienle, RPh, MPA, FASHP
 Director, Accreditation and Medication Safety
 Cardinal Health Innovative Delivery Solutions

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Disclosure

- Patricia Kienle is an employee and stockholder of Cardinal Health
- She is an elected member of the USP Compounding Expert Committee, but is not speaking as a USP representative
- All conflicts resolved through peer review

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Objectives for Pharmacists and Pharmacy Technicians

- Cite the document that defines hazardous drugs (HDs)
- List the three categories of HDs
- Explain the containment strategies related to HDs.
- Identify elements that could be used for an Assessment of Risk
- List the types of PPE that need to be used with HDs

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Patti's Wish

- Identify three things that you can improve the next day you are at work



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

What's All the Fuss?



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Why <800>?

- To promote patient safety, worker safety, and environmental protection when handling hazardous drugs (HDs)
- Addresses, but is not limited to
 - Receipt
 - Storage
 - Compounding
 - Dispensing
 - Administration
 - Disposal
- Applies to all healthcare personnel who handle HDs
- Applies to all healthcare entities that store, prepare, transport, or administer HDs

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

What Regulations Exist?

- USP <795> Pharmaceutical Compounding – Nonsterile Preparations
- USP <797> Pharmaceutical Compounding – Sterile Preparations
- OSHA regulations
- State regulations



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Is your site compliant with the hazardous drug part of <797>?

- Yes
- Partially
- No



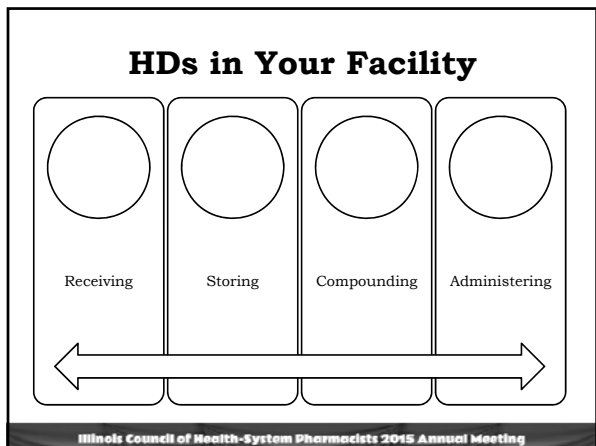
Illinois Council of Health-System Pharmacists 2015 Annual Meeting

What are the Upcoming Regulations?

- Proposed USP <800>
 - Federally-enforceable regulation
- Applies to both sterile and nonsterile compounding
- State regulations
 - Enforcement




Illinois Council of Health-System Pharmacists 2015 Annual Meeting



11

Hazardous Drug Definition

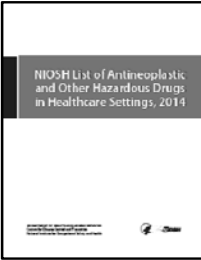
- Carcinogens
- Genotoxins
- Teratogens
- Reproductive toxins
- Organ toxicity at low doses
- Structure or toxicity similar to drugs classified as hazardous



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

12

NIOSH 2014 List of Hazardous Drugs



www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

13

NIOSH 2014 List of Hazardous Drugs


- Antineoplastic
- Non-antineoplastic
- Reproductive hazard only

- Drugs that are hazardous to personnel
 - Different from EPA-hazardous, which are hazardous to the environment

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

14

Show Me the Science




www.cdc.gov/niosh/topics/hazdrug/

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

15

Your HD List

- Review the NIOSH list
- Identify the meds you stock
- Determine the containment strategies



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Your Handling Options

Treat all HDs the same

- Use all the containment strategies in <800>

Assess risk and stratify

- Identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or are not API

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Assessment of Risk

- Drug
- Dosage form
- Risk of exposure
- Packaging
- Manipulation
- Documentation of alternative containment strategies and /or work practices
- Review annually and document

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Can you identify HD packages when they are delivered?

- Yes
- No




Illinois Council of Health-System Pharmacists 2015 Annual Meeting

19

HD Receipt

- Your supplier should mark containers
- Your receiving personnel need to be inserviced to assess the integrity of the container
- You must provide
 - Chemo gloves
 - Chemo spill kit



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

20

HD Storage


- Shall be stored separately from other inventory
- Shall be in
 - Negative pressure room
 - Vented to the outside
 - At least 12 air changes per hour
- Take the plastic-wrapped package into the negative pressure storage area to unwrap it

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

21

Where are your HDs mixed?

- BSC or CACI in negative pressure cleanroom
- BSC or CACI in positive pressure cleanroom
- BSC or CACI in normal pressure room
- Outside of BSC or CACI



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

22

HD Preparation

- Shall be in physically separate space
 - Negative pressure room
 - Vented to the outside
 - Appropriate number of air changes per hour

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

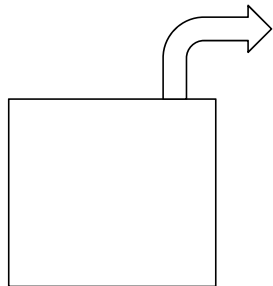
Engineering Controls

- Primary
 - Biological Safety Cabinet (BSC)
 - Compounding Aseptic Containment Isolator (CACI)
- Secondary
 - The room in which the PEC is placed
- Supplemental
 - Closed system drug-transfer devices

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Two Tenets of Safety

- Containment
- Dilution



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

25

Why Negative Pressure?

PEC

Positive Pressure

↓

✗

CPEC

Negative Pressure

↑

✓

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Nonsterile Compounding

C-PEC	C-SEC Requirements
<ul style="list-style-type: none"> Externally vented (preferred) OR redundant HEPA-filtered in series Examples: CVE, Class I or II BSC, CACI 	<ul style="list-style-type: none"> 12 ACPH Externally vented Negative pressure between 0.01 and 0.03" w.c.

CVE or BSC

Negative Pressure
12 ACPH

↑

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Sterile Compounding

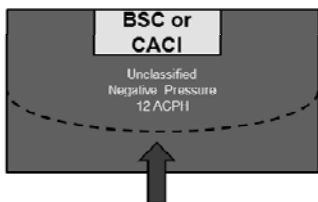
Elimination of "low use" exemption in <797>

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 Buffer Room	<ul style="list-style-type: none"> Externally Vented Examples: Class II BSC or CACI 	<ul style="list-style-type: none"> 30 ACPH Externally vented Negative pressure between 0.01 and 0.03" w.c. 	As described in <797>
C-SCA	<ul style="list-style-type: none"> Externally Vented Examples: Class II BSC or CACI 	<ul style="list-style-type: none"> 12 ACPH Externally vented Negative pressure between 0.01 and 0.03" w.c. 	12 hours

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Containment Segregated Compounding Area

- Not currently allowed in <797>
- Not acceptable for high-risk



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

CSTDs

- Closed system drug-transfer devices
- Mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system



Photo courtesy of BD

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

30

Administering HDs

- Requires Supplemental Engineering Controls
- Why?

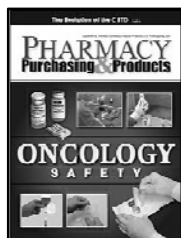


Illinois Council of Health-System Pharmacists 2015 Annual Meeting

CSTD Resources



PPN, June 2013



PPPMag Supplement, February 2015

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

USP <797> and <800> Requirements

- Didactic
- Overseen by experts
- Monitored
- Media fill test
 - Initial
 - Requalifying
- Gloved fingertip test
 - Initial
 - Requalifying
- Surface sampling



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Training Materials Available

- Policies and procedures
- Device manufacturers
- NIOSH
- ASHP
- Critical Point




Illinois Council of Health-System Pharmacists 2015 Annual Meeting

34

What gloves are worn to prepare hazardous drugs?


- Same as for non-hazardous compounding
- One pair of chemo gloves
- Two pairs of chemo gloves
- Compounder can decide which to wear



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

PPE Requirements in <800>

- Gloves
- Gowns
- Hair covers
- Shoe covers
- Face protection
- Respirators



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Gloves for Handling HDs

- Chemo gloves tested to ASTM D6978
- Non-powdered
- Two pairs
- Outer gloves must be sterile when compounding sterile preparations

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Gowns for Handling HDs

- Tested and shown to resist permeability by HDs
- Disposable
- Polyethylene-coated polypropylene or other laminate
- Close in back (no open front)
- Long-sleeved
- Elastic or knit closed cuffs
- No seams or closures that could allow HDs to pass through

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

PPPMag – January 2015



PPE

By Thomas H. Connor, PhD, and A. Peter, MS, BS, FELLOW, MASSPH, FHEA, FADP, and MARIA FURVIA, PhD, DR, ACCP

Are Gloves and Gowns Safe for Handling Chemotherapy?

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Other Garb Issues

- Eye protection
 - BSC/CACI provide eye protection
 - Use goggles when working outside a PEC
- Respirators
 - Use when outside a PEC
- All garb is required when using a CACI

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

40

Chemo hoods are cleaned with ...

- Sterile alcohol
- Germicidal detergent
- Bleach
- Commercial product for hazardous drugs



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Cleaning Process

- Deactivation and decontamination
- Use of detergent
- Disinfecting surfaces



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

PPPMag Articles



September 2013



October 2014

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Environmental Monitoring

- USP <797> requirements
- Wipe samples



Screenshot courtesy of ChemoGLO

Illinois Council of Health-System Pharmacists 2015 Annual Meeting

44

How close to <800> compliant is your site?

- Less than half-way there
- Between 50-90%
- Close to compliant



Illinois Council of Health-System Pharmacists 2015 Annual Meeting

Your Action Plan

-
-
-
-
-
-

Illinois Council of Health-System Pharmacists 2015 Annual Meeting



Playing Your Role:
Handling Hazardous Drugs: Protecting Patients and Practitioners
Illinois Council of Health-System Pharmacists
September 12, 2015
Patricia C. Kienle

OBJECTIVES

- Cite the document that defines hazardous drugs (HDs)
- List the three categories of HDs
- Explain the containment strategies related to HDs
- Identify elements that could be used for an Assessment of Risk
- List the types of PPE that need to be used with HDs

SELF-ASSESSMENT QUESTIONS

1. Pharmacy mixes IV chemo for the health-system's inpatients and attached oncology clinic. Vials of antineoplastic HDs may be stored:
 - a. Intermingled with regular stock since the vial is a final dosage form
 - b. Intermingled with regular stock since the health-system does not identify it as a HD
 - c. In the positive pressure anteroom
 - d. In the negative pressure buffer room
2. HDs are sorted into which three groups?
 - a. Oral antineoplastic, parenteral antineoplastic, reproductive hazards only
 - b. Antineoplastic, non-antineoplastic, reproductive hazards only
 - c. Antineoplastic, injectable reproductive hazards, other
 - d. Antineoplastics, other oral HDs, other injectable HDs
3. Which of the following documents is the basis for the HDs identified in USP <800>?
 - a. ASHP Drug Information
 - b. EPA list of hazardous materials
 - c. NIOSH list of hazardous drugs
 - d. The Joint Commission Medication Management standards
4. A supplier follows the shipping recommendations in <800>. A tote with a HD indicator is received from the supplier. Can the tote be opened in the general pharmacy area?
 - a. Yes, because it will have a sealed impervious wrapper around the HDs in the tote
 - b. Yes, because all HDs may be unwrapped as long as the outside packaging of the vial or box is not opened
 - c. No, because the tote must be taken into the positive pressure anteroom to open it
 - d. No, because the tote must be taken into the negative pressure chemo hood to open it

5. What does <800> say about the use of Closed System Drug-Transfer Devices (CSTDs)?
- a. Must be used when compounding and should be used when administering
 - b. Should be used when compounding and must be used when administering
 - c. Should be used for both compounding and administering
 - d. Must be used for both compounding and administering