FOR PROVIDERS. BY PROVIDERS.

PHARMACY

USP<800> UPDATE

Jon Pritchett, Pharm.D., RPh.
Associate Director, Pharmacy

OBJECTIVES

- Identify what drugs are considered hazardous
- Recognize engineering controls discussed in USP<800>
- Recognize USP's implementation timeline for Chapter <800> and revisions to <795> and <797>

HISTORY

- Concern over exposure to hazardous drugs (HDs) is not new!
  - 1986 – first OSHA guidelines for cytotoxic drugs
  - 1990 – ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs
  - 2004 - NIOSH Alert - Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
  - 2008 – USP Chapter <797> included sterile hazardous drug guidance
  - March 2014 – USP Chapter <800> draft released
  - February 2016 – final version of Chapter <800> released
  - December 1, 2019 - "Effective Date" for *<800> Hazardous Drugs – Handling in Healthcare Settings*

WHY SHOULD I CARE? - INDUSTRY EVIDENCE

- 1999: Pharmacists, techs, & nurses handling HDs
  - 40% higher risk of stillbirths and spontaneous abortions
- 2010: Healthcare Worker Study (including pharmacy)
  - Chromosome 5&7 abnormalities
  - Breast and prostate cancer both linked to C-5
- 2014: Pharmacy student dies of fentanyl overdose at a compounding pharmacy
  - After only four days on the job
- 2014: Evaluation of manufacturing practices finds drug residue on external packaging of containers of 5-FU and cisplatin

WHY SHOULD I CARE? – EXTERNAL FACTORS

- HD protection is growing as a regulatory requirement
  - State Boards of Pharmacy
  - FDA
  - OSHA – *Controlling Occupational Exposure to Hazardous Drugs*
- Growing interest in waste-streams
- Liability?

Hartford News

OSHA cites New Haven pharmacy for multiple violations

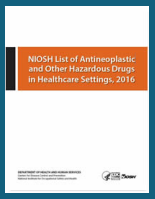
Posted: 10/23/2014, 03:00pm | WTNH

New Haven, Conn. (WTNH) — The Occupational Safety and Health Administration (OSHA) has cited a New Haven pharmacy for multiple violations during their most recent inspections following a July chemical spill that sent four employees to the hospital.

In all, OSHA's proposed fines total $77,220.

WHAT IS A "HAZARDOUS" DRUG???

- NIOSH HDs are:
  - Carcinogenic
  - Teratogenic
  - Reproductive toxicity
- NIOSH Classification:
  - Group 1 (Table 1) - Antineoplastics
  - Group 2 (Table 2) - Other drugs that nonetheless meet NIOSH criteria
  - Group 3 (Table 3) - Substances mainly posing reproductive risk



CHAPTER <800> COVERS:

- List of HDs
- Areas where exposure may occur
- Personnel responsibilities
- Facility and engineering controls
- Environmental quality and control
- Personal Protective Equipment (PPE)
- Hazard Communication Program
- Personnel training
- Receiving HDs
- Labeling, packaging, transport, disposal
- Dispensing final dosage forms
- Compounding
- Administering
- Deactivation, decontamination, cleaning, disinfecting
- Spill control
- Documentation and SOPs
- Medical Surveillance

CONTAINMENT REQUIREMENTS

- What qualifies?
- What are environmental requirements?
- Engineering controls?
- Additional equipment?

WHAT REQUIRES CONTAINMENT?

- NIOSH-list drugs that must follow <800>'s containment requirements:
  - HD API
  - Antineoplastics requiring *further manipulation*
- NIOSH-list drugs that do not have to follow containment requirements *if an assessment of risk is performed and implemented:*
  - Final dosage forms of compounded HD preparations
  - Conventionally manufactured HD products that require no further manipulation other than counting or repackaging (caution – automated devices that generate dust, manufacturer exceptions)
  - Non-antineoplastic HD dosage forms on the NIOSH list

ASSESSMENT OF RISK

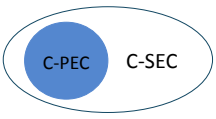
- Assessment of Risk must include the following:
  - Type of HD
  - Dosage form
  - Risk of exposure
  - Packaging
  - Manipulation

ASSESSMENT OF RISK

- Must list each drug and dosage form individually:
  - May have same information for multiple drugs or dosage forms
- Must document **what** alternative containment strategies or work practices are being employed
- Must be reviewed every 12 months:
  - Review must be **documented**!

CONTAINMENT IN USP<800>

- C-PEC – *Containment Primary Engineering Control*
- C-SEC – *Containment Secondary Engineering Control*
- Remember – requirements are different for sterile and non-sterile!



NON-STERILE HD COMPOUNDING

Containment Secondary Engineering Control (C-SEC):

- Dedicated room for HD compounding
- Negative pressure -0.01 to 0.03 inches water
- 12 ACPH
- Unclassified air
- Externally vented

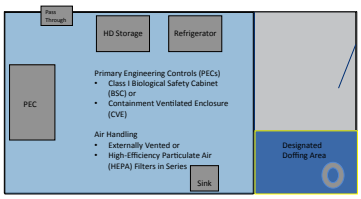
NON-STERILE HD COMPOUNDING

Smooth, seamless, and impervious surfaces:

- **Avoid particle board**
- **Floor laid seamlessly**
- **Epoxy drywall or other wall material**
- **Coved moldings**
- **Impervious ceiling tiles and lighting fixtures**

Must be able to stand decontamination with sodium hypochlorite solution

NON-STERILE HD COMPOUNDING



CLASS I BSCS FOR NON-STERILE COMPOUNDING

- Protect the operator from exposure to HDs
- Do not protect HDs from exposure to the compounder

Image used with permission of AirClean Systems

Class I BSC – Externally Vented

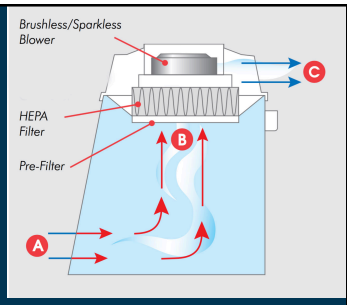


Image courtesy AirClean Systems

Class I BSC – Redundant HEPA Filter

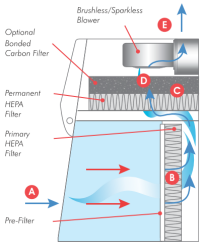
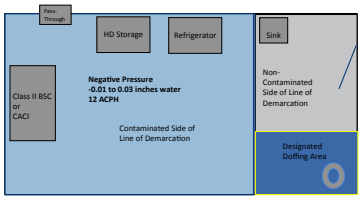


Image courtesy AirClean Systems

KEY POINTS ABOUT C-PECS – NS

- C-PEC may be either externally vented or go through redundant HEPA filters in series
- These devices can include:
  - Class I or II BSCs
  - Vented balance safety enclosures
  - Compounding Aseptic Containment Isolators (CACIs)
- The C-PEC must operate continuously if it supplies some or all of the negative pressure for the C-SEC

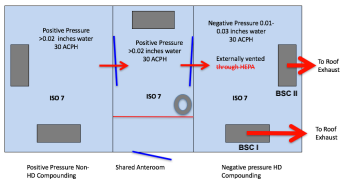
STERILE HD COMPOUNDING – CATEGORY 1



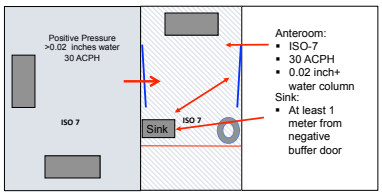
CONTAINMENT SEGREGATED COMPOUNDING AREA (C-SCA)

- Surfaces: Smooth, seamless, and impervious
- Pressure: 0.01-0.03 inches negative water column
- Air changes: 12 per hour
- Unclassified air
- May be used for storage (sterile HDs) and compounding
- Only for Category 1 CSPs
  - ≤12h room temperature
  - ≤24h refrigerated

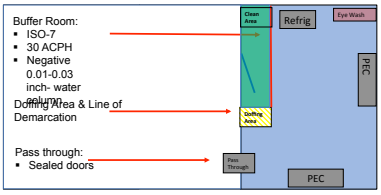
DESIGNS FOR BOTH CATEGORY 1 & 2 COMPOUNDING



THE SHARED ANTEROOM



THE BUFFER ROOM



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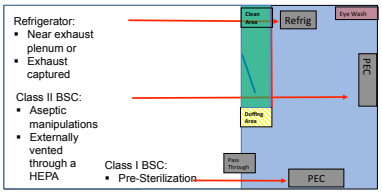


STERILE HD COMPOUNDING

- Smooth, seamless, and impervious surfaces
- Avoid particle board
- Floor laid seamlessly
- Epoxy drywall or other wall material
- Coved moldings
- Impervious ceiling tiles and lighting fixtures
- Must be able to stand decontamination with sodium hypochlorite solution
- Can ruin stainless steel if not inactivated

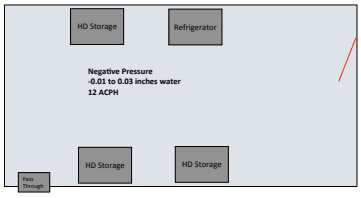
CLASS II BSC TYPES

- Type A1:
  - 75 ft./min. inflow velocity
  - Exhaust into lab or canopy:
    - Into lab would be non-compliant
  - 70% of the air recirculated/30% exhausted
  - Have positive-pressure exhaust ducts - NOT SUITABLE FOR HDs
- Type A2:
  - 100 ft./min. inflow velocity
  - Exhaust into lab or through canopy:
    - Into lab would be non-compliant

CLASS II BSC TYPES

- Type B1:
  - 100 ft./min. inflow velocity
  - Exhaust to outside via direct duct connection
  - 30% of the air recirculated/70% exhausted
  - Suitable for minute quantities of volatile drugs
- Type B2:
  - 100 ft./min. inflow velocity
  - Exhaust to outside via direct duct connection
  - 100% of the air is exhausted
  - Suitable for volatile drugs

A SEPARATE HD STOREROOM



To HD buffer room or non-sterile HD compounding

OTHER EQUIPMENT

- Spill kits
- Eye washes:
  - OSHA requirement: Handling materials that are "corrosive"
  - ANSI: Eye wash where employees are exposed to HDs
- Closed system transfer devices should be used:
  - MUST be used for administration if the dosage form allows
- Plastic-backed prep mat on surface of PEC
- Dedicated equipment is required:
  - Mortars
  - Pestles
  - Spatulas

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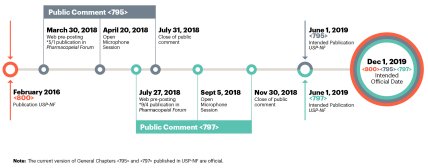
USP <795> AND <797> UPDATE TIMELINE

www.usp.org/compounding/updates-on-standards, accessed 3/9/2018



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

STAY ABREAST OF USP CHANGES

- Expected date of final publication is June 1, 2019; becomes official December 1, 2019:
  - Harmonizes with USP<800> official date
- Sign up for updates at www.usp.org/hqs-signup-form
- Follow FAQs on USP website

QUIZ TIME!

Per USP<800>, what is the 'starting point' for defining a drug as hazardous?

1. OSHA Technical Manual
2. NIOSH List
3. Safety Data Sheets
4. Pharmacist's judgment

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Which hazardous drugs **CANNOT** be exempted from the containment requirements of USP <800> by performing an assessment of risk?

1. HD APIs
2. Final dosage forms of compounded HD preparations
3. Antineoplastics requiring further manipulation
4. 2 & 3

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4. 1 & 3

QUIZ TIME!

Per USP<800>, external venting of the C-PEC is required for **nonsterile** compounding.

1. True
2. False

QUIZ TIME!

Per USP<800>, external venting of the C-PEC is required for **nonsterile** compounding.

1. True
2. False

QUIZ TIME!

Per USP<800>, external venting of the C-PEC is required for **sterile** compounding.

1. True
2. False

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1. True
2. False

QUIZ TIME!

The implementation date of USP<800> and revised <795> and <797> is:

1. June 1, 2018
2. June 1, 2019
3. December 1, 2019
4. If I close my eyes it will go away….

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THANK YOU

- Accreditation Commission for Health Care
- 139 Weston Oaks Ct., Cary, NC 27513
- (855) 937-2242 | achc.org