

Sterile Compounding of Hazardous Drugs

Session I

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Sterile Compounding Resources



Objectives

- Define a hazardous drug
- List chronic and acute effects of exposure to chemotherapy drugs
- List personal protective equipment for compounding of hazardous preparations
- Summarize requirements of primary engineering controls for hazardous compounding
- Sequence cleaning and decontamination steps for a biologic safety cabinet
- Describe proper process for priming intravenous (IV) tubing
- Explain the use of closed system drug transfer devices for hazardous compounding

Interactive Activities

POLLS





ASSESSMENT



**INTEGRATED
LEARNING**

Agenda

- Session I (2 hour CE)
 - Chemotherapeutic Risks and Effects
 - Personal Protective Equipment
 - Primary Engineering Controls
 - Cleaning Biological Safety Cabinets
 - Priming IV Tubing 
 - Closed System Transfer Devices 

Hazardous Drugs

Definition and Characteristics

Defining Hazardous Drugs

- Hazardous drugs pose potential health risks to workers exposed to them
- May include:¹
 - Chemotherapy
 - Antiviral drugs
 - Hormone therapy
 - Some bioengineered drugs
 - Miscellaneous
- National Institute for Occupational Safety and Health (NIOSH)
 - Maintains list of antineoplastics and other hazardous drugs
 - USP <800> recognizes this list

¹ “Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings”. Available at: http://www.cdc.gov/niosh/docs/2014_138/niosh/2014_138_v3.pdf.

Characteristics of Hazardous Drugs

- Hazardous drugs exhibit one or more of the following characteristics in humans and/or animals:

Carcinogenicity

**Teratogenicity/
Developmental
Toxicity**

**Reproductive
Toxicity/Fertility
Impairment**

Genotoxicity

**Organ Toxicity at
Low Doses**

**New drugs
resembling
existing hazardous
drugs**



Institutions need to develop and maintain a list of hazardous drugs...

- ✓ May include drugs on NIOSH list
- ✓ Any additional drugs not on NIOSH list
- ✓ Must be reviewed at least annually
- ✓ Must be reviewed when a new agent or dosage form is used

POLL

How many are involved in hazardous compounding on a:

- A: Daily basis
- B: Weekly basis
- C: Monthly basis
- D: Not at all

Chemotherapy & Exposure

Agents & Risks of Exposure

Types of Chemotherapy

- Chemotherapy encompasses chemical treatments used for conditions such as cancer

Chemotherapy Class	Drug Name
Alkylating Agent (+ platinum drugs)	cisplatin, carboplatin, cyclophosphamide (Cytoxan), ifosfamide
Anti-tumor Antibiotic	doxorubicin (Adriamycin), bleomycin
Mitotic Inhibitor	paclitaxel (Taxol), docetaxel (Taxotere), vinblastine (Velban), vincristine (Oncovin)
Antimetabolite	cytarabine (Ara-C), 5-fluorouracil (5-FU), capecitabine (Xeloda), gemcitabine (Gemzar)
Topoisomerase Inhibitor	topotecan, irinotecan, etoposide

ASSESSMENT

Which of the following are effects of exposure to chemotherapy?

- A: Cancer
- B: Fertility
- C: Hair loss
- D: Kidney damage
- E: All of the above

Acute Effects of Exposure to Chemotherapy



Chronic Effects of Exposure to Chemotherapy



Exposure Routes

Inhalation

- Inhaling air contaminated with hazardous drug

Ingestion

- Transferring from hands into the mouth
- Transferring from hands onto food/drink

Accidental Injection

- Needle stick
- Glass/ampule cut

Dermal/Mucosal Absorption

- Touching contaminated surfaces bare skin
- Direct contact

Chemotherapy Spill



Personal Protective Equipment

For Compounding Hazardous Preparations

Personal Protective Equipment (PPE)

- PPE has two functionalities:
 - Protect preparation from US
 - Protect US from the compounded sterile preparation (CSP)
 - Unique to hazardous compounding
- PPE must be removed prior to exiting direct compounding area
- Hands must be washed thoroughly after compounding and removing PPE

PPE Required for Sterile Compounding

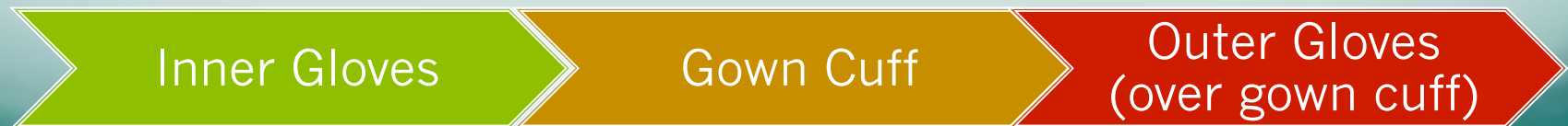


*When risk for spills or splashes per USP <800> 40(3)

PPE for Hazardous Drug Preparation

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- DOUBLE GLOVE
 - Always don double gloves for compounding
 - Both must be “chemotherapy gloves”
 - Meet American Society of Testing and Materials (ASTM) standard
 - Powder-free gloves
 - Outer pair for compounding
 - Remove in hood
 - Inner pair for affixing label and placing preparation in designated bag for chemotherapy



PPE for Hazardous Drug Preparation

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- Gloves
 - Worn at ALL times when:
 - Compounding
 - Handling preparation
 - Handling vials
 - Handling packaging cartons
 - Unpacking shipments
 - Cleaning “hood”
 - Cleaning surface

PPE for Hazardous Drug Preparation

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- Gown

Lint-Free

Low
Permeability

No Seams/
Closures

Closures in
Back

Long Sleeves

Knitted,
Tight Fitting
Elastic Cuffs

Special Considerations¹

- Gloves
 - Change every 30 minutes
 - Change when torn, punctured, or contaminated
- Shoe covers
 - Don two pairs and remove outer pair prior to exiting buffer area
- Gowns
 - Change per manufacturer recommendations (permeability info)
 - Change every 2-3 hours if recommendations not available
 - Change immediately after splash or spill

¹ USP <800> Hazardous Drugs—Handling in Healthcare Settings, PF 40(3) [May–Jun.2013].

Handling Hazardous Drugs

– When to Wear PPE

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Receiving hazardous medications from supplier



Storage



Transport



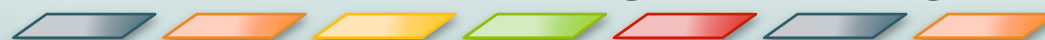
Compounding (sterile and nonsterile)



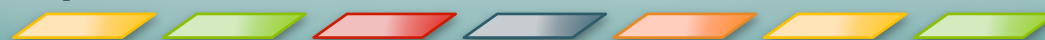
Administration



Decontamination, cleaning, disinfecting



Spill control



Primary Engineering Controls (PECs)

For Hazardous Compounding

Purpose of PEC

- Two main purposes for hazardous compounding:
 1. Protect the operator from exposure to hazardous drugs (fumes, splashes, sprays, etc.)
 2. Protect the CSP by providing quality air supply and environment

Must be a dedicated PEC!
No non-hazardous compounding in
hazardous compounding PEC
(and vice versa)

PECs for Hazardous Compounding

- ISO Class 5 environment in PEC
 - Not to exceed 3,520 particles per square meter

- PECs:

- Laminar ~~Flow Workbench~~ (LAFW)

- Biologic Safety Cabinet (BSC)

- Compounding ~~Aseptic Isolator~~ (CAI)

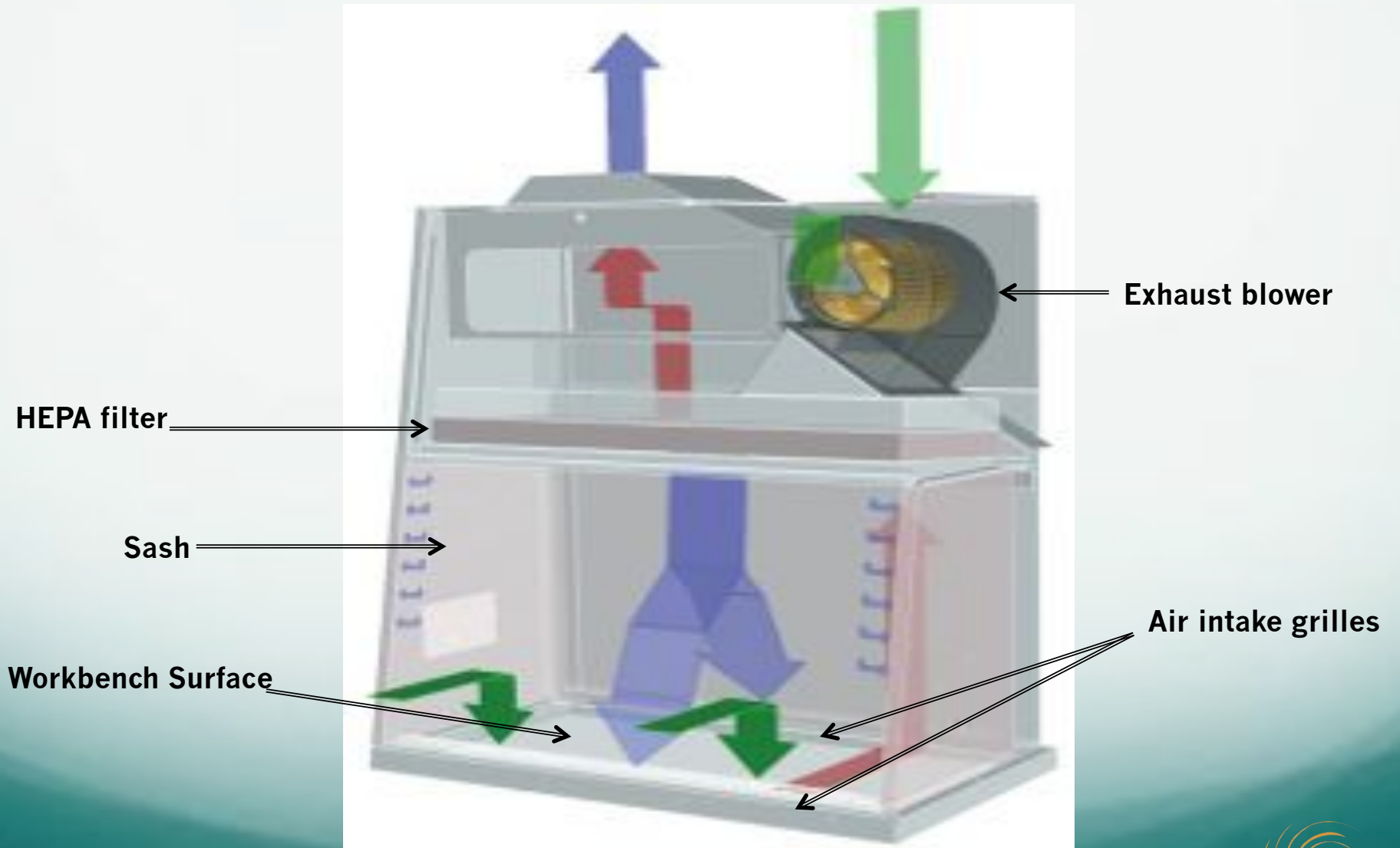
- Compounding Aseptic Containment Isolator (CACI)

CACI



Image from: J Oncol Pharm Pract. July 29, 2014. [epub].

BSCs



BSCs

	Characteristics	Protects operator?	Protects CSP?
Class I	“Fume hood”	✓	
Class II	Types A1, A2, B1, B2	✓	✓
Class III	Attached gloves; air-tight construction	✓	✓

POLL



Which is used for hazardous compounding at your facility?

A: BSC

B: CACI

C: Horizontal laminar airflow workbench

Ideal Characteristics of PEC for Hazardous Compounding

- Unidirectional airflow
- Air intake grilles
- Sash
- Completely vented to outside air
- ISO Class 5

Ideal Choices for PECs

For compounding of hazardous preparations, the following are ideal choices:

1. Class II BSC, type B2 that is 100% vented to outside
2. CACI with unidirectional airflow that is 100% vented to outside

Cleaning the BSC

Deactivation/Decontamination, Cleaning, and Disinfecting

Operation¹

- Must be left “on” continuously
 - Loss of power => suspension of activities + covering
 - Restored => decontaminate + clean + disinfect + wait
- Must use a “chemo mat”
 - Inside PEC
 - Replace:
 - If spill occurs
 - Regularly during use
 - Discard at end of day



Image from: http://www.healthmark.ca/DATA/PRODUIT/61_1_1.jpg

¹ USP <800> Hazardous Drugs—Handling in Healthcare Settings, PF 40(3) [May–Jun.2013].

Decontamination

- Must decontaminate dedicated workbenches used for hazardous drug preparations
 - Must occur prior to disinfection
 - Alcohol will NOT deactivate hazardous contamination
 - Follow manufacturers' recommendations for cleaning
 - Sodium hypochlorite
- Neutralization should follow
 - Sodium thiosulfate

Disinfection

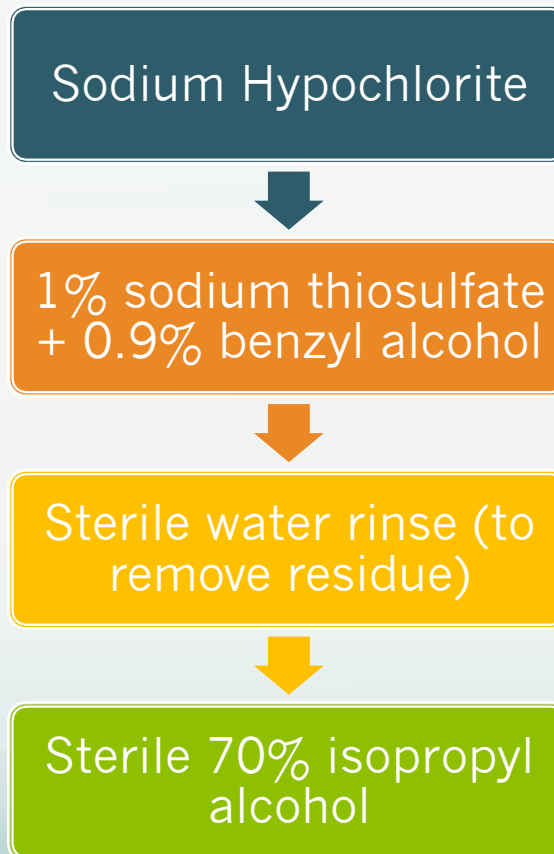
- Use sterile 70% isopropyl alcohol
- Always start near HEPA filter
- Depends on direction of laminar flow
 - Sides – Streaks should be perpendicular to airflow direction
 - Horizontal laminar flow – up and down (vertical)
 - Vertical – side to side (horizontal)

ASSESSMENT

Alcohol used for compounding must be:

- A: Sterile
- B: 70% or greater
- C: Any kind of alcohol
- D: Ethyl alcohol

Example



Disposable Cleaning Wipes

- 2-step process in a pair of wipes
 - 2% sodium hypochlorite
 - 1% sodium thiosulfate with 0.9% benzyl alcohol



Image from: <http://www.chemoglo.com/whatis.aspx>



Image from: <http://www.cleanroomconnection.com/chemo-safety-apparel-products/>

Disinfecting the BSC

- STEP 1 • Hood is running and has been ON for at least 5 min
- STEP 2 • Use sterile, lint-free wipes with sterile water to remove visible debris then dry
- STEP 3 • Place sterile, lint-free wipes in a pile and saturate with sterile 70% isopropyl alcohol by pouring alcohol onto wipes and removing one from the top of pile to clean
- STEP 4 • Clean hooks. Then wrap a sterile, lint-free wipe around IV pole and clean from one side of the hood to the other (not back and forth)
- STEP 5 • Clean the back wall of the hood beginning at the top corner and working downward using horizontal overlapping strokes side to side
- STEP 6 • Clean each side, starting in upper corner near HEPA filter using overlapping strokes side-to-side horizontally
- STEP 7 • Clean the glass sash, beginning in the upper corner near HEPA filter using overlapping strokes side-to-side horizontally
- Step 8 • Clean the workbench last beginning from back corner and working toward the front of the hood using overlapping strokes side to side

Cleaning Tips

Wash hands and
sanitize gloves
BEFORE cleaning
workbench

Do **NOT** bring
hands out of
workbench during
cleaning

Sanitize gloves
AFTER cleaning
workbench

Clean all the way to
the very edge

Do **NOT** place dirty
wipes on clean
surfaces

Take unused gauze
from the pile each
time a new surface
is cleaned

Work Tray¹

- Some PEC's have work tray
 - Contamination can build up
 - Access may be difficult
- Clean monthly
 - Wear respiratory protection
 - NIOSH approved and fitted is recommended

¹ USP <800> Hazardous Drugs—Handling in Healthcare Settings, PF 40(3) [May–Jun.2013].

Preparing Chemotherapy

Priming Tubing & Closed System Transfer Devices

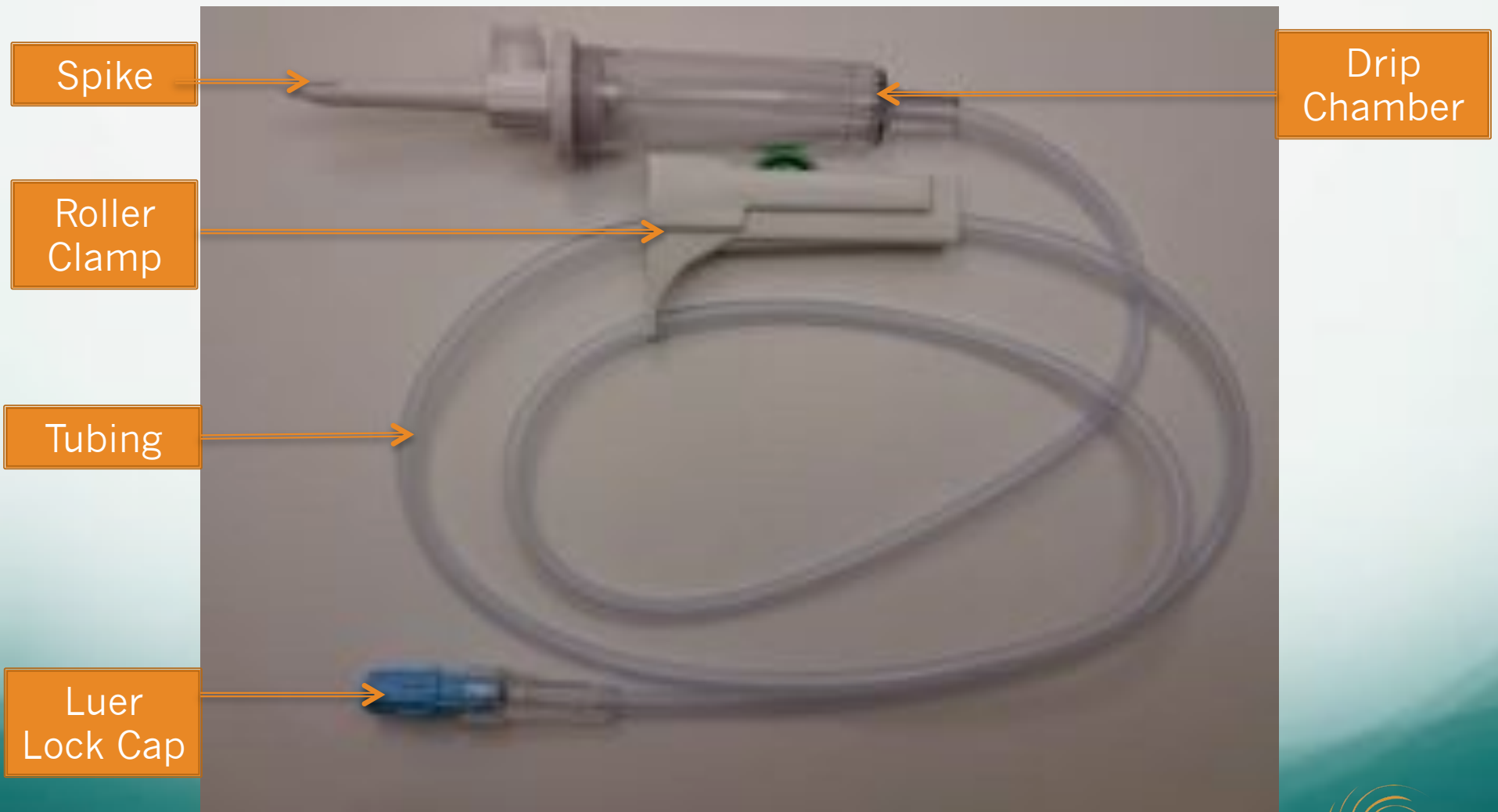
Priming Line

- Solutions from chemotherapy preparations will be directly administered to patient
- Nurse needs to attach line from bag to patient
- “Priming” bag is needed for hazardous compounds
 - Attaching an administration set and filling it with diluent
 - Prevents nurse from having to prime line with hazardous compound

Priming Line

Priming of an infusion set should be done before chemotherapy or other hazardous drug is added.

Parts of Infusion Set



Priming Procedure

1

- Close slide clamp
- Close roller clamp

2

- Insert spike from infusion set into spike port of bag (also known as set port)

3

- Hang bag from hook inside PEC

4

- Squeeze drip chamber on infusion set a few times to fill chamber half-way

5

- Release slide clamp

6

- Slowly release roller clamp while watching drug-free solution fill line

7

- When solution reaches 2 inches before end of tubing, close roller clamp

After Attaching Set



Primed Line



LEAVE 2 INCH SPACE AT
END OF TUBING
(stop flow 2 inches before it
reaches the end)

Prepare for Transport

- Affix patient label
- Affix auxiliary labels
- Place preparation in dedicated transport bag
 - Bag must be for hazardous drugs



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Priming IV Tubing

Closed Systems

- Closed System
 - “A device that does not exchange unfiltered air or contaminants with the adjacent environment” (*NIOSH, 2004*)
- Closed System Drug-Transfer Device
 - “A drug transfer device that mechanically inhibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system” (*NIOSH, 2004*)
 - Decrease operator exposure and surface contamination

POLL



Does your facility use
Closed System Drug-
Transfer Device for
hazardous
compounding?

True: Yes
False: No

Systems

- ChemoLock (icumedical)
- OnGuard with Tevadaptor (B.Braun/Teva Medical)
- PhaSeal (BD)
- LifeShield ChemoClave (Hospira)
- Halo (Corvida Medical)
- Equashield (Equashield)
- Texium (CareFusion)
- Chemoprotect (Codan)

Equal?

Time &
Efficiency

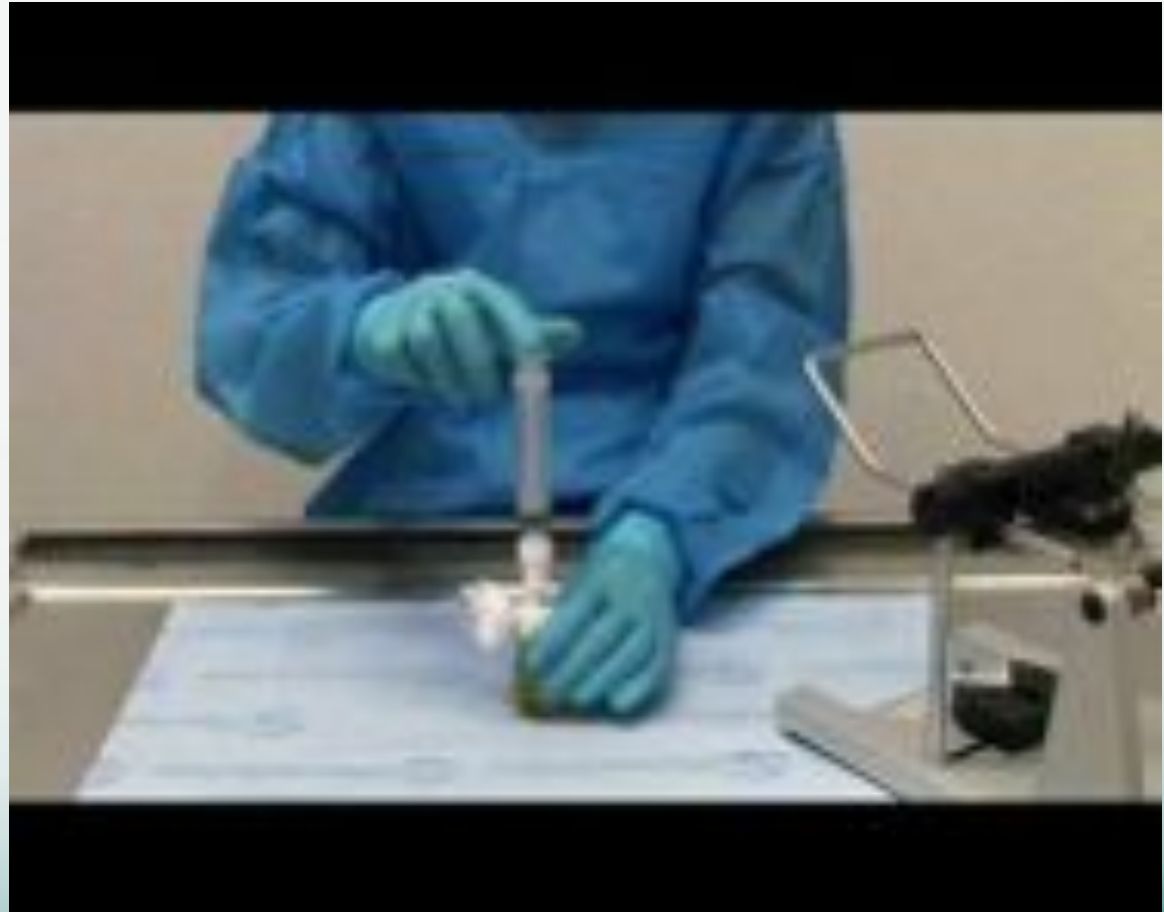
Cost!!

Effective??

Ease of
Use
(Eou)

J Oncol Pharm Pract. 2013 Dec;19(4):338-47. (PhaSeal)
J Oncol Pharm Pract. 2014 Dec;20(6):426-32. (PhaSeal)
Hosp Pharm. 2013 Mar; 48(3): 204-212. (PhaSeal)
J Oncol Pharm Pract. July 29, 2014. [epub]. (Tevadaptor)
J Oncol Pharm Pract. 2013 Jun;19(2):99-104. (Equashield)

PhaSeal[®] System



Instructional Video: <https://www.youtube.com/watch?v=whKZWkCPbc8>

Tevadaptor™



Instructional Video: <http://www.tevadaptor.com/demo.html>

Equashield®



Instructional Video: <https://www.youtube.com/channel/UCPknyhfzHF2f3fApTVR5c0w>

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Closed System Transfer Devices

Updates in Sterile Compounding

Key Updates

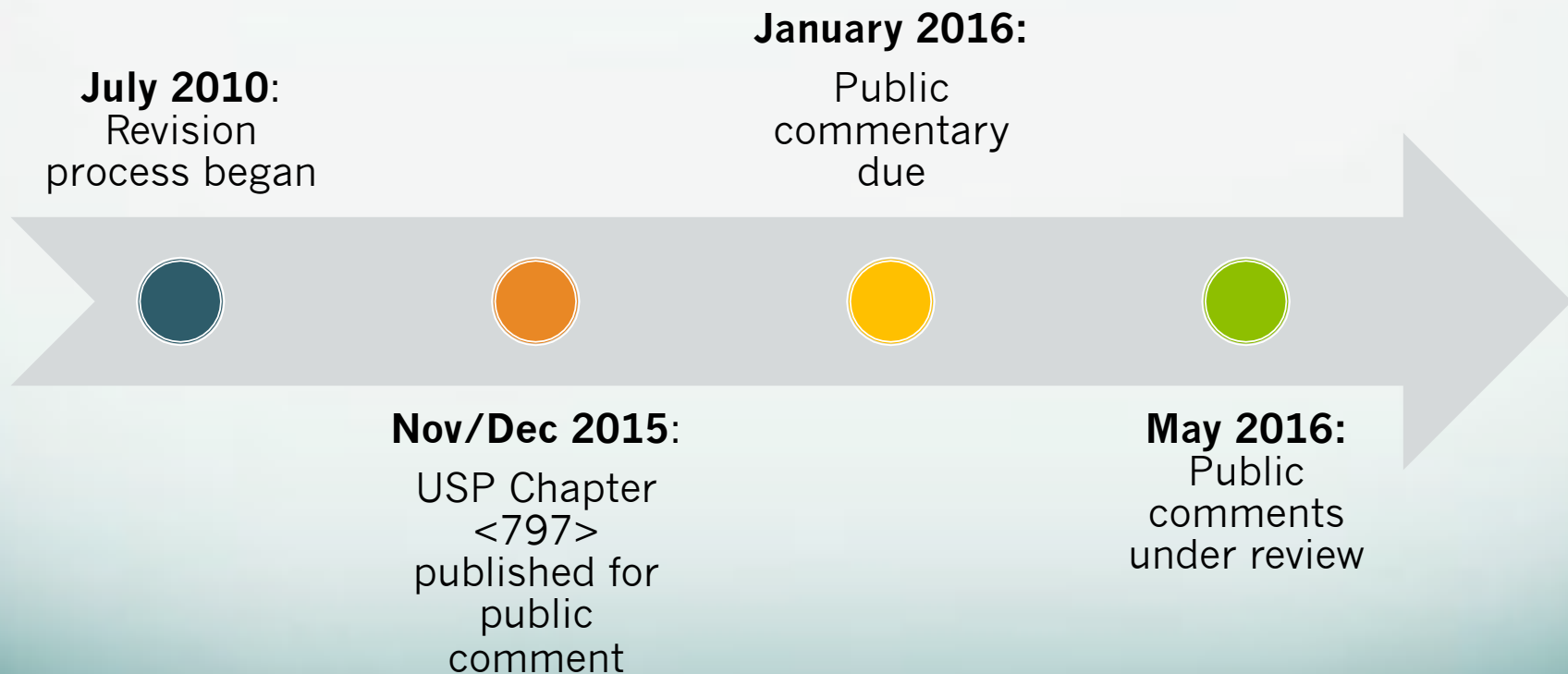
USP Chapter <800>

April 29th:
Updated notice
of intent to
revise (published
as *errata*)

June 1st:
USP Chapter
<800> becomes
official

May 26th:
Errata published

USP Chapter <797>



TSBP

- Met February 2016
 - Discussion and passing of amendments to §291.133
 - Update requirements for sterility testing
 - Clarify requirements for temperature and humidity
 - Clarify requirements for blood labeling procedures
 - Compounding Stakeholders Meeting
 - March 1st

Board of Pharmacy Specialties

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Board of Pharmacy Specialties Issues Call for Petition in Sterile Compounding Pharmacy Practice

The Board of Pharmacy Specialties (BPS), the premier post-licensure certification organization serving the pharmacy profession, has issued a call for petition in Sterile Compounding Pharmacy Practice, it was announced today. If approved, Sterile Compounding Pharmacy will be the ninth specialty offered by BPS.



[Read More >>](#)

April 13, 2016 / Press Releases

Additional Resources

For Hazardous Drug Handling and Compounding

Additional Resources

- American Society of Hospital Pharmacists. ASHP guidelines on handling hazardous drugs. *Am J Health Sys Pharm*. 2006; 63: 1172-93.
http://www.ashp.org/s_ashp/docs/files/bp07/prep_gdl_hazdrugs.pdf.
- National Institute for Occupational Safety and Health (NIOSH)
 - NIOSH alert: preventing occupational exposure to anti-neoplastic and other hazardous drugs in health care settings.
<http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf>
 - List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014
<http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf>.
- American Society of Clinical Oncology/Oncology Nursing Society.
 - Chemotherapy Administration Safety Standards, 2013.
<https://www.ons.org/practice-resources/standards-reports/chemotherapy>
- Eisenberg S. Safe handling and administration of antineoplastic chemotherapy. *J Infus Nurs*. 2009 Jan-Feb;32(1):23-32.



QUESTIONS?

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