Sterile Compounding of Hazardous Drugs

Session II

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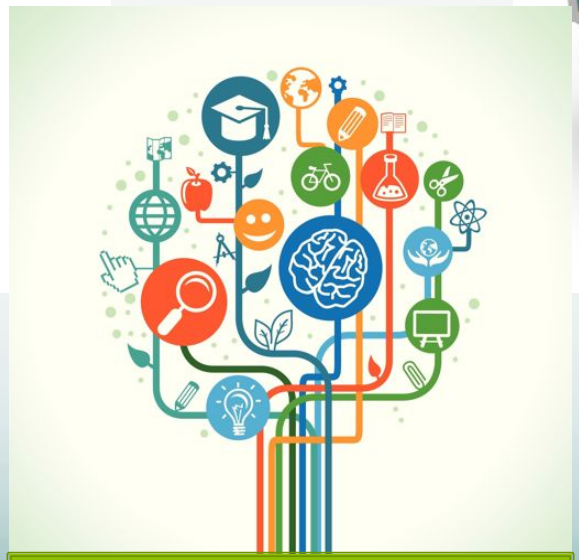
Objectives

- List requirements of secondary engineering controls for hazardous compounding
- Explain requirements for environmental and personnel monitoring as it relates to hazardous drug handling and compounding
- Demonstrate use of a chemo spill kit
- State personnel qualifications and responsibilities for hazardous compounding
- Describe techniques and manipulations for hazardous compounding
- Summarize patient safety considerations for chemotherapy orders
- Explain the role and requirements of USP <800> for hazardous drug handling and compounding

Interactive Activities

POLLS



INTEGRATED LEARNING

ASSESSMENT

Agenda

- Part 2 (2 hour CE)
  - Secondary Engineering Controls
  - Handling Waste
  - Handling Chemo Spills 
  - Patient Safety Considerations
  - Documentation and Standard Operating Procedures
  - Personnel Training and Competency 
  - Aseptic Techniques and Manipulations 

Secondary Engineering Controls

Design and Monitoring

Buffer Room[1]

- ISO Class 7
- Negative pressure room
  - 0.01-0.03 inches of water column
- Minimum 30 air changes per hour (ACPH)
- If entry is through positive pressure buffer room not used for hazardous compounding, then:
  - Line of demarcation for garbing/degarbing within negative pressure room
  - Method of transport in/out
    - Pass-through
    - Sealed containers
      - Must demonstrate effective containment

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

Ante-Area[1]

- Positive pressure
  - 0.02 inches of water column relative to adjacent unclassified spaces
- ISO Class 7 or better

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

Unclassified Segregated Compounding Area

- May contain PEC
- Negative pressure
  - 0.01-0.03 inches of water column
  - 12 ACPH of HEPA filtered air

If PEC placed in segregated compounding area, then beyond-use date (BUD) of all compounded preparations must be limited per USP <797>

Compounding Areas - Design[1]

- Areas where hazardous drugs are handled must:
  - Be restricted to authorized personnel
  - Located away from break rooms/highly populated areas
  - Have prominent sign outside of entrance designating hazard
- Dedicated area for unpacking
  - Negative pressure or neutral/normal
  - NOT in sterile compounding areas
  - NOT in positive pressure areas

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

Additional Design[1]

- Storage
  - Hazardous drugs for sterile compounding need to be stored in negative pressure buffer room
    - At least 12 ACPH
  - Dedicated refrigerator
- External ventilation through HEPA filtration
- Physical separation
- Sink must be available
  - At least one meter from entrance of buffer room
- Eye wash station

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

Cleaning

- All chemotherapy vials must be decontaminated with sodium hypochlorite wipes before shelving
  - Wear PPE when unpacking/decontaminating
  - Wash hands after removal of PPE
- When decontaminating/cleaning/disinfecting, full PPE must be worn
  - Double chemotherapy gloves
  - Impermeable gown

Quality Assurance

- Environmental wipe sampling
  - ChemoGLO™
    - Quantify trace amounts of contaminants from the use of 7 antineoplastic agents
    - 6 wipes to test sites in compounding areas
  - Testing areas should include:[1]
    - Inside PEC and any equipment inside of it
    - Staging/work areas near PEC
    - Areas adjacent to PECs
    - Patient administration areas
- Initially (baseline) and at least every 6 months[1]

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

Handling Waste

Proper Disposal and PPE

Compounding Waste

- Dispose waste inside PEC
  - Hazardous waste bag
- Seal bag completely
- Dispose of bag in hazardous waste container

Images from: http://extww02a.cardinal.com/us/en/distributedproducts/ASP/8985-S.asp?cat=surgerycenter (sharps container) and http://medimart.com/product/chemotherapy-waste-handling-bag-yellow-12x15/ (waste bag)

Disposal

- Compliance
  - Institutional policies and procedures
  - State regulations
- Use licensed medical waste contractor
- Wear FULL PPE when handling waste
- Keep containers closed

Image from: http://img.ehowcdn.com/640/ehow/images/a05/7e/ug/medical-waste-disposed-of_-800x800.jpg

PPE

- All PPE used for compounding must be removed and placed in an appropriate waste bin prior to exiting the buffer area
- PPE used for transport, administration, shelving, etc. must be disposed of in an appropriate waste bin

Chemotherapy Spills

Spill Kits and Handling Spills

POLL

Have you ever cleaned up a chemotherapy spill using a spill kit?

True: Yes
False: No

Spill Kits

- Used for containment and cleanup of spills involving hazardous drugs
  - Supplies for absorption of up to 1000 mL
- Must be available in all areas in which hazardous drugs are:
  1. Received[1]
  2. Prepared
  3. Transported
  4. Administered
- Must be available to personnel involved in hazardous compounding
- Circumstances and management of spills must be documented

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

Contents

- Appropriate PPE
- Spill pads
- Disposable towels
- At least 2 hazardous waste bags
- One disposable scoop
- One puncture resistant container
- Supplies for decontamination

Handling Chemo Spills

< 5 mL

- Responsible personnel

> 5 mL

- Environmental services

CONTAIN FIRST!

INTEGRATED LEARNING

Chemotherapy Spill Kit

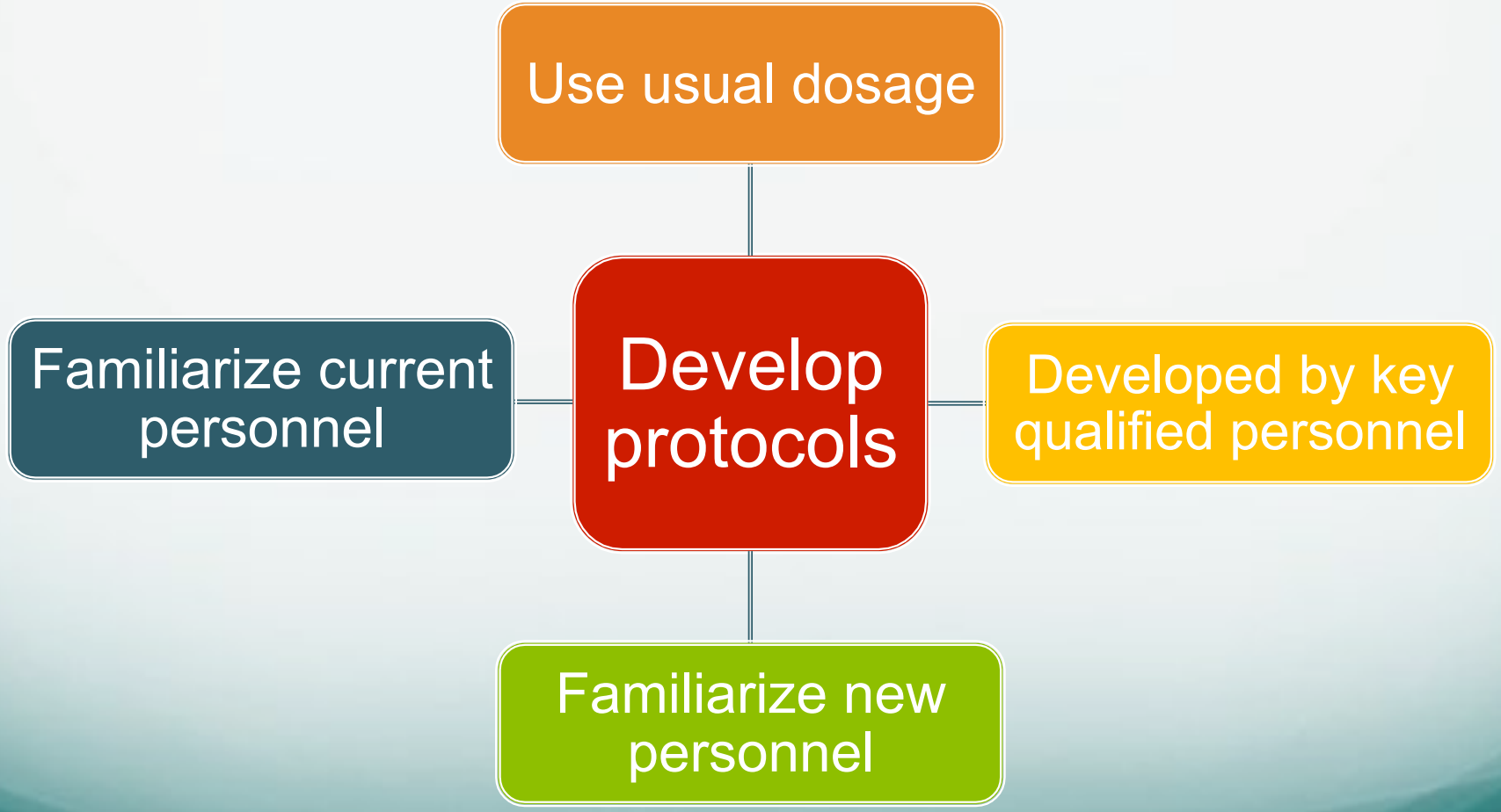
Sterile Compounding Resources

Patient Safety

Considerations for Chemotherapy Orders

Preventing Errors in Orders

Preventing Errors in Orders



Components of a Chemotherapy Order

Components of an Order
1. Patient name
2. Height
3. Weight
4. Diagnosis
5. Cycle number
6. Patient specific chemotherapy protocol
7. Drug amount in mg/m^2
8. Total daily dose
9. Total number of days for dose to be administered

STANDARDIZE

Image from: http://www.rollingwavesoftware.com/StandardizedEntries.aspx

Standardization

- Use standardization for the following:
  - Administration times
  - Protocols
  - Procedures
  - Drug concentrations
  - Packaging
  - Labeling
  - Delivery times
  - Verification
  - Order entry data and process

Double Check Method

- Implement a “double check” method
  - A person not involved in the process or preparation
  - Verifies all aspects of order
  - Must be documented in log

Verify With Original Order

- *Diagnosis/contraindications*
- *Number of doses*
- *Number of days*
- *Number of cycles*
- *Which cycle patient is currently receiving*
- *Dose and volume of drug*
- *Concentration and volume of final preparation*
- *Expiration dates of components*
- *Adjunctive therapies*

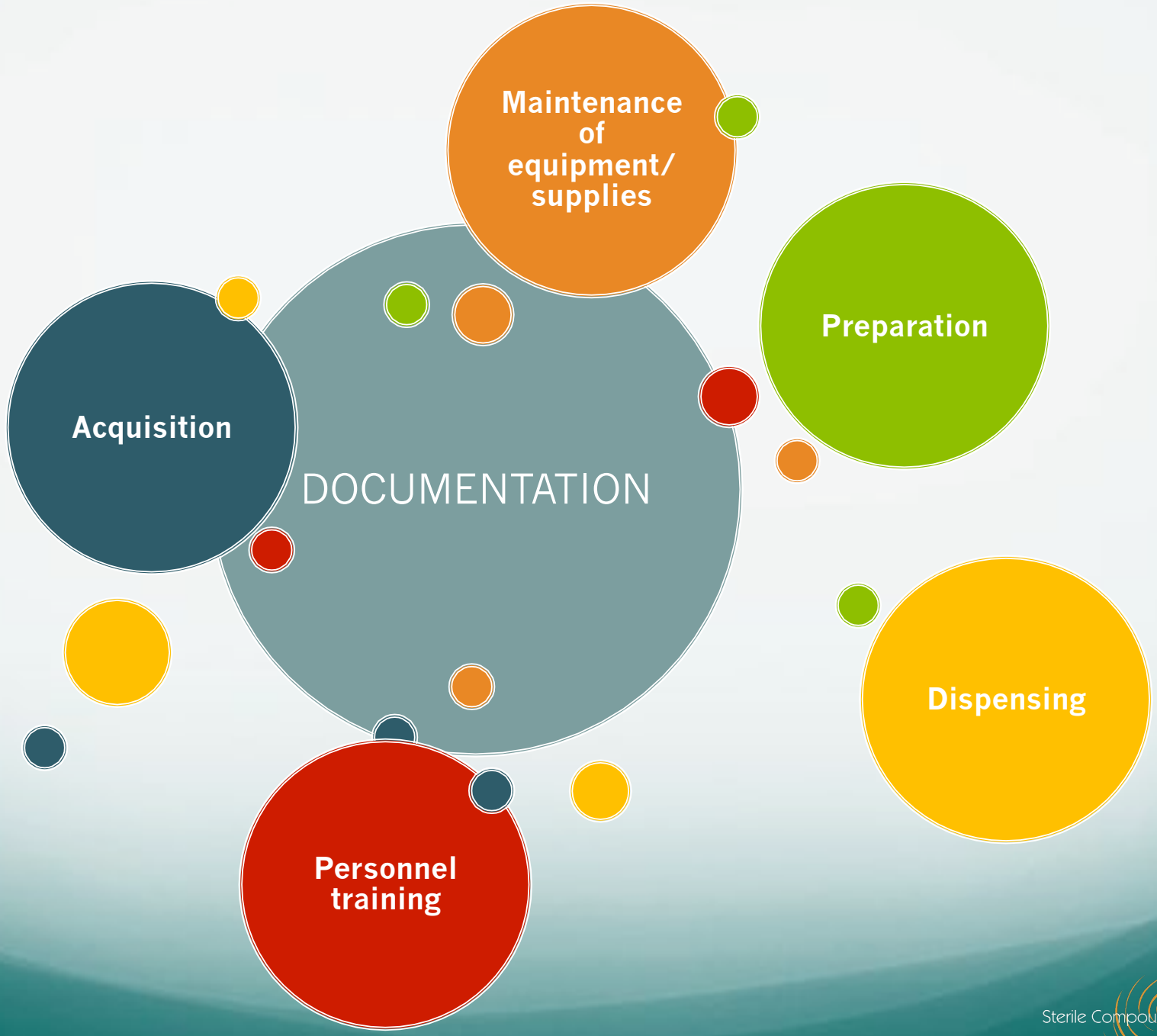
ASSESSMENT

Which of the following labs should be checked prior to dispensing a chemotherapy order?

A: Serum creatinine
B: Liver function tests
C: Complete blood count
D: All of the above

Documentation and Standard Operating Procedures

Inclusions and Requirements



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

Standard Operating Procedures (SOP)

- Must be maintained for safe handling of hazardous drugs for all situations for use throughout facility
- Reviewed at least annually
  - Document review
  - Revisions must be communicated to personnel

SOP Inclusions[1]

- Hazardous communication program
- Occupational safety program
- Labeling
- Procurement
- Use of PECs
- Use of PPE based on activity and exposure risk
- Decontamination/deactivation, cleaning, disinfection
- Transport
- Environmental monitoring
- Spill control
- Medical surveillance

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

Standard Operating Procedures[1]

- Must be developed for PPE based on:
  - Risk of exposure
  - Activities performed
- Must be developed for hazardous drug:
  - Receiving
  - Labeling
  - Handling
  - Packaging
  - Transport
  - Storage
  - Use of Safety Data Sheets (SDS)
  - Cleaning
- Must address:
  - Prevention of accidental exposures/spills
  - Personnel training on response to exposure
  - Use of a spill kit

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

Hazardous Communication Program[1]

- Elements must include:
  - Written plan for implementation of standard
  - All containers of hazardous chemicals must be labeled, tagged, or marked with identity
    - Appropriate hazard warnings
  - SDS for each hazardous chemical
  - SDS are readily accessible to personnel
  - Personnel who may be exposed to hazardous chemicals must be provided information and training
    - Before initial assignment to work
    - Whenever hazard changes

Best Practice: Document that info and training has been provided

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

Medical Surveillance[1]

- Personnel involved in hazardous compounding as regular part of job
- Includes assessment and documentation of:
  - Symptom complaint
  - Physical findings
  - Laboratory values (blood count)
- Follow-up plan should be completed for workers with potential toxicity/acute exposure
- Exit examination

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

POLL

Do you think medical surveillance is needed?

True: 

False: 

Personnel

Qualifications, Training, and Monitoring

General Requirements

- Qualifications must be specified
  - Ordering hazardous drugs
  - Handling hazardous drugs
- Responsibilities include:[1]
  - Understanding fundamental practices and precautions
  - Continuous evaluation of procedures
  - Continuous evaluation of quality of final hazardous drug preparations

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

Designee

- Designated person qualified and trained to:[1]
  - Developing and implementing appropriate procedures
  - Overseeing compliance
  - Ensuring environmental control
  - Ensuring competency of personnel
- Designated person must conduct continuous monitoring of facility and maintaining reports of testing/sampling[1]
  - Must contain cause of contamination if applicable

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

Competency

- Specific for hazardous compounding
- Different competencies for pharmacists and pharmacy technicians
- Frequency:
  - All new personnel involved in hazardous compounding
  - At least annually for current personnel
- Components:
  - Written evaluation
    - Including handling of hazardous drugs
  - Media fill test
  - Observation of simulated chemotherapy preparation
    - Using fluorescein dye

Fluorescein Dye Surrogate

- Evaluates for contamination
  - Handling
  - Compounding
- QI Medical
  - ChemoTest

    http://www.qimedical.com/wp-content/uploads/2014/04/DFU022-D-8-10.pdf
- Covidien
  - ChemoPlus

    http://products.covidien.com/pages.aspx?page=ProductDetail&id=147640&cat=Chemo&cat2=Default

Image accessed from: http://www.patientcare.edu.com/imageServer.aspx?contentID=28339&contenttype=application/pdf

Personnel Training

- Didactic training
- Skills training

Topics (minimum)[1]
List of hazardous drugs and their risks
Review of institution standard operating procedures related to handling of hazardous drugs
Proper use of PPE
Proper use of equipment and devices
Spill management
Response to known or suspected hazardous drug exposure

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

INTEGRATED LEARNING

Fluorescein Dye for Personnel Monitoring

Aseptic Technique and Manipulations

For Hazardous Compounding

ASSESSMENT

The manner in which a syringe is held when compounding in a BSC is the same for both hazardous and non-hazardous drugs?

True or False

BSC Work Zone

- Must adapt compounding techniques to account for directional differences of first air
- Recommended area for compounding in BSC is:
  - Between front and rear air intake grilles
  - At least 4 inches from the front grille
  - Six inches from each side of the BSC

Work Zone


Rear Intake Grille
WORK ZONE
6 inches
6 inches
4 inches
Front Intake Grille

Compounding Considerations

- **"Three-fourths rule"**
  - Syringe should be large enough that it will never be more than ¾ full after prescribed volume is drawn up

Compounding Considerations

- Avoid **positive** pressure to prevent spraying or dripping of drug
- Use negative pressure
  - Too much negative pressure can cause leakage from the needle when withdrawing the needle from vial
- Use **slight** negative pressure to draw **large** volume of fluid
- Use **closed** system drug transfer device
  - Mechanically prevents escape of drug during transfer
    - PhaSeal™
    - OnGuard™
    - LifeShield™ ChemoClave™

INTEGRATED LEARNING

Compounding Techniques & Manipulations

Sterile Compounding Resources

Updates in Sterile Compounding

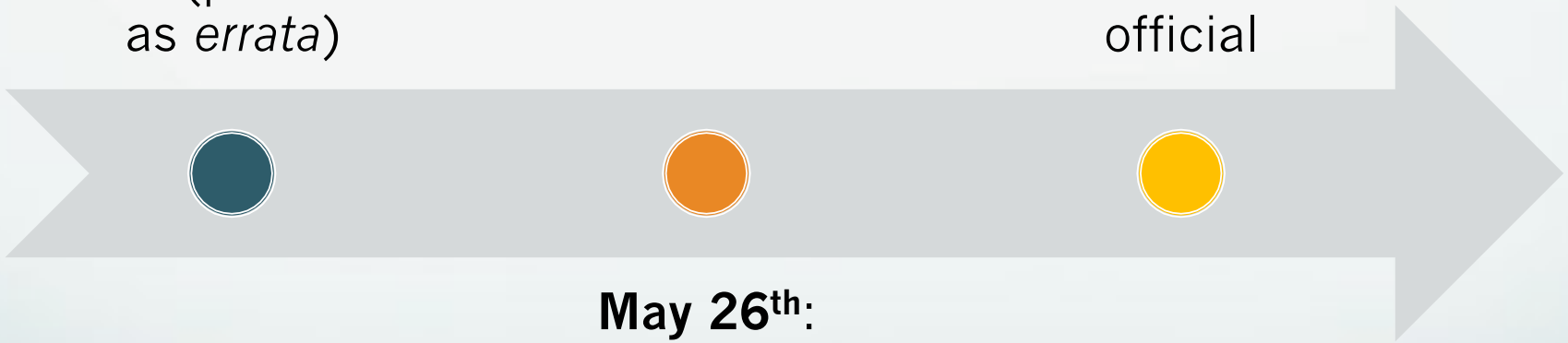
Key Updates

USP Chapter <800>

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

May 26th: *Errata* published

June 1st: USP Chapter <800> becomes official



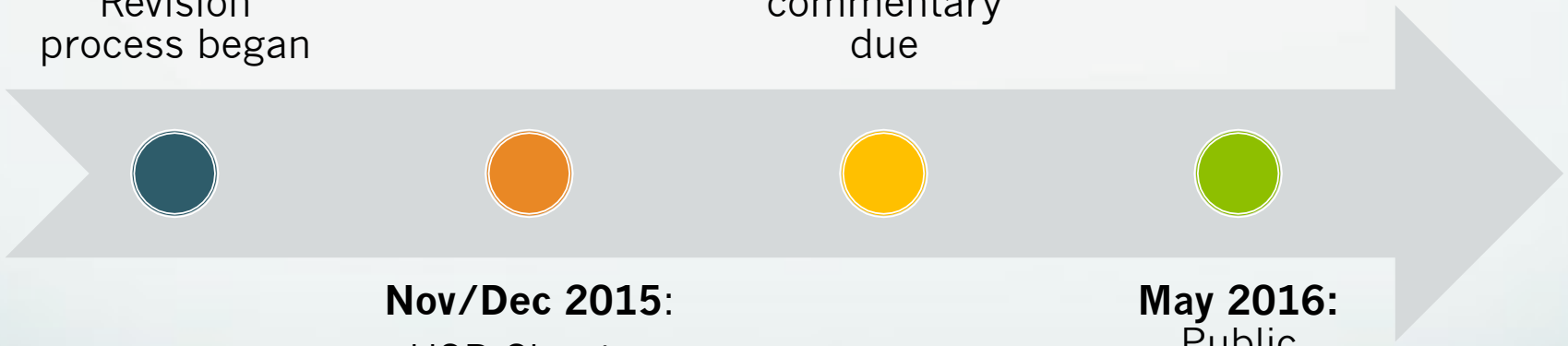
USP Chapter <797>

July 2010: Revision process began

Nov/Dec 2015: USP Chapter <797> published for public comment

January 2016: Public commentary due

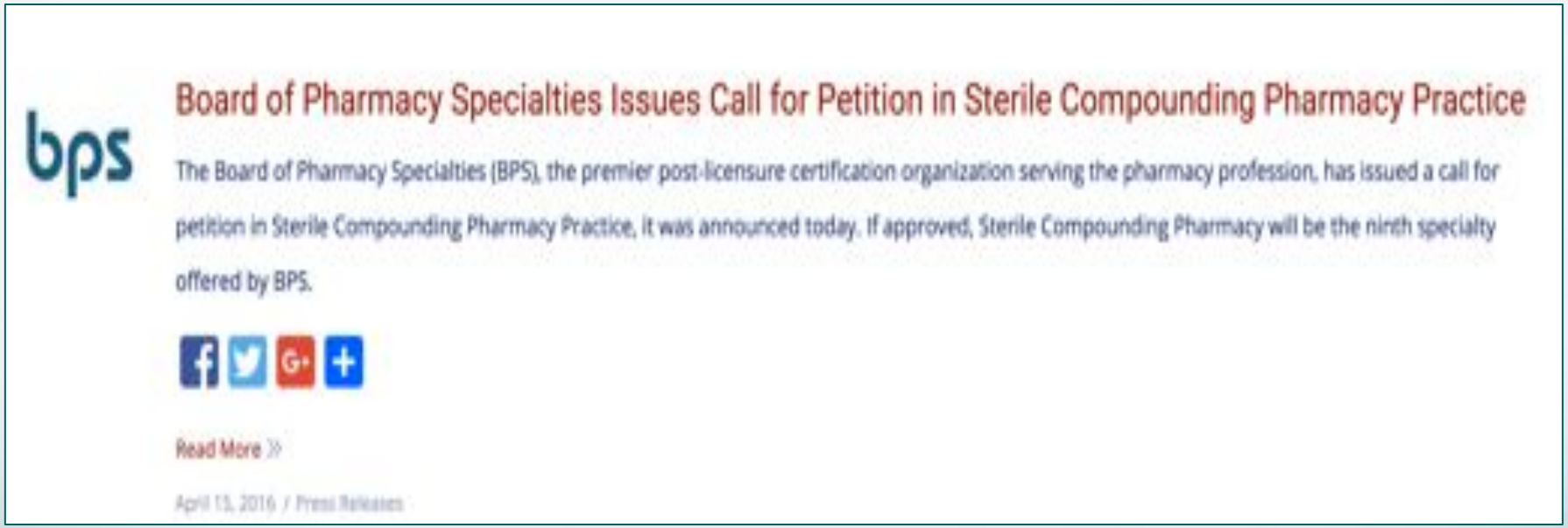
May 2016: Public comments under review



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, 2014http://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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THANK YOU!

We enjoyed the opportunity.

Sterile Compounding Resources