



**PHARMACY**  
**VIS/ON**  
**20/20**

CSHP SEMINAR 20 • OCTOBER 21-25  
**Disneyland**  
RESORT

# IV ROOM 101

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# DISCLOSURE

- I have no potential conflict of interest regarding the content of this presentation

# LEARNING OBJECTIVES

- 1. EXPLAIN THE RATIONALE OF CLEANROOM DESIGN AND AIRFLOW**
- 2. DEFINE ASEPTIC TECHNIQUE**
- 3. DESCRIBE THE ROLE OF THE PHARMACIST IN MONITORING PERSONNEL WORKING IN THE CLEANROOM**
- 4. DEFINE BEYOND USE DATE**
- 5. DISCUSS STRATEGIES FOR CHECKING ORDERS TO ENSURE ACCURATE PRESCRIPTION PREPARATION**

# EXPLAIN THE RATIONALE OF CLEANROOM DESIGN AND AIRFLOW

- Sterile compounding and compounded sterile preparations (CSPs)
- USP, USP 797, and USP 800
- The IV Room by Definition
- Main IV room components and airflow
- Movement of personnel and supplies

USP = United States Pharmacopeial Convention

# QUESTION #1

What is the IV Room?

- A. A room in the pharmacy where any medication with any route can be prepared.
- B. A room that contains secondary engineering controls, but no primary engineering controls.
- C. A location where personal protective equipment (PPE) is not required
- D. The location where compounded sterile preparations (CSPs) are made

# WHAT IS STERILE COMPOUNDING?

- “Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.”
- Sterile compounding involves manipulating a sterile or nonsterile product to produce a sterile final product (per USP)
- Involves compounded sterile preparations (CSPs)

U.S. Food and Drug Administration. FDA’s human drug compounding progress report. 12.19.2019 Accessed July 4, 2020

# COMPOUNDED STERILE PREPARATIONS (CSPS)

- A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

Pharmaceutical compounding – sterile preparations (general information chapter 797). In: The United States pharmacopeia, 39th rev., and The national formulary, 34th ed. Rockville, MD: United States Pharmacopeial Convention. Revised 1 May 2018. Accessed June 4, 2020.

# EXAMPLES OF COMPOUNDED STERILE PREPARATIONS

## Injections (Parenteral Orders):

- Intravenous (IV)
- Subcutaneous (SC)
- Intramuscular (IM)
- Intrathecal (IT)
- Intradermal (ID)
- Epidural
- Ophthalmic injectable orders:  
Subconjunctival, Intravitreal,  
Intraocular
- Aqueous bronchial and nasal inhalations
- Bath soaks for live organs and tissues
- Irrigations for wounds and body cavities
- Ophthalmic drops or ointments
- Tissue implants

Pharmaceutical compounding – sterile preparations (general information chapter 797). In: The United States pharmacopeia, 39th rev., and The national formulary, 34th ed. Rockville, MD: United States Pharmacopeial Convention. Revised 1 May 2018. Accessed June 4, 2020.

# A BRIEF HISTORY

## 1950s:

RNs add KCl and Vitamins B and C to IV orders

## 1950s:

Prescribing of IV medications increased

## 1960s:

Preparations were mainly prepared by nurses in patient care areas

## 1963:

Pharmacy-based IV services at Clinical Center of the NIH

## 1964:

*Mirror to Hospital Pharmacy* Published

Meyers, C. History of sterile compounding in U.S. hospitals: Learning from the tragic lessons of the past. Am J Health-Syst Pharm. Vol 70: 1414-1427. Aug 15, 2013. Accessed July 21, 2020.

# WHY IS PHARMACY INVOLVED WITH STERILE COMPOUNDING?

- Majority of parenteral medications were previously compounded by nursing staff
- *Mirror to Hospital Pharmacy* (1964)
  - Issues identified included lack of sterile environment for compounding and lack of safeguards in place for accurate prescription preparation

Francke DE, et al. Washington, DC: *Mirror to Hospital Pharmacy*. American Society of Hospital Pharmacists; 1964. Accessed May 20, 2020

# WHY ARE COMPOUNDING STANDARDS IMPORTANT TO FOLLOW?

1. Patient Safety
2. Prevent patient harm, infections, outbreaks, and death
3. Required by law

# HISTORY OF STERILE COMPOUNDING TRAGEDIES

## 1970s

- Contaminated Large Volume Parenterals (9 deaths)

## 1980s

- Contaminated Cardioplegia solutions (5 deaths)

## 1990s

- Contaminated hospital syringes (11 deaths)
- 4 deaths due to non-sterile cardioplegia solutions
- 2 patients blinded after contaminated ophthalmic drops contained *P. aeruginosa*

# HISTORY OF STERILE COMPOUNDING TRAGEDIES

## 2000s

- 16 eye infections
- 33 fungal infections
- 9 deaths from contaminated TPN
- Multiple deaths from contaminated steroid injections

## USP Publications

- USP Publishes General Chapter <797> Pharmaceutical Compounding-Sterile Preparations in 2004
- USP Publishes 1<sup>st</sup> revision to <797> in 2008

## 2010s

- Multiple patients blinded due to bevacizumab intravitreal injections
- **Fungal Meningitis Outbreak in 2012- NECC\*** (64 deaths)
- 2 deaths from fungal bloodstream infections
- 2019: USP <797> Second revision and USP <800> Official

Staes C et al. Am J Health-Syst Pharm.2013; 70 (15)1307-12. Access May 1, 2020

# UNITED STATES PHARMACOPEIAL CONVENTION (USP)

- Non-profit scientific organization
- Mission statement: “To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods”

USP.org. FAQs: USP and its standards. Accessed July 4<sup>th</sup>, 2020

# USP AND THE LAW

- A medication with a name recognized by USP must comply with USP compendial standards
- USP is a standard source and resource for compounding

United States Pharmacopeial Convention. <http://www.usp.org>. Accessed July 4<sup>th</sup>, 2020

# USP 797

- Provides minimum practice and quality standards for CSPs
- Includes practices to prevent harm as a result from:
  1. Microbial contamination
  2. Excessive bacterial endotoxins
  3. Variability in the intended strength of correct ingredients
  4. Chemical and physical contaminants
  5. Ingredients of inappropriate quality

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# USP 797

Specific information provided:

1. ISO-classified air environments
2. Personnel garbing and gloving
3. Personnel training and testing
4. Practices of aseptic manipulations and sterilization
5. Environmental quality specifications and monitoring\*
6. Disinfection of gloves and surfaces of the ISO Class 5 environment

ISO = International Organization for Standardization

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# USP 800

- Provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment
- Specifics for handling hazardous drugs including:
  1. Receipt
  2. Storage
  3. Compounding
  4. Dispensing
  5. Administration
  6. Disposal of sterile and nonsterile products and preparations

USP <800>: Hazardous drugs- handling in healthcare settings (general information chapter 800). Rockville, MD: The United States Pharmacopeial Convention; 2016. United States Pharmacopeial Convention. Updates on compounding standards. . Accessed June 1, 2020.

# USP 800 – HAZARDOUS DRUGS

- Special procedures for labeling, storage, transport
- Special clothing and PPE
- Specific PECs are required (Ex: Biological Safety Cabinet)
- Special handling of spills & waste

PEC = Primary Engineering Control

USP <800>: Hazardous drugs- handling in healthcare settings (general information chapter 800). Rockville, MD: The United States Pharmacopeial Convention; 2016. United States Pharmacopeial Convention. Updates on compounding standards. . Access June 1, 2020

# WHAT IS A AN IV ROOM?

The IV Room, or cleanroom, is the area where compounded sterile preparations are prepared

- Limited access
- Contains multiple rooms each with a specific purpose
- Includes special equipment and engineering controls

# THE IV ROOM PER USP <797>

Clean Room:

*“A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class.”*

*“Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.”*

# PRIMARY ENGINEERING CONTROL (PEC)

- The apparatus in which CSPS are actually prepared using strict aseptic technique
- Has many essential functions including:
  1. Filter particles, microbes, and contaminants from the air
  2. Generates unidirectional airflow out of the apparatus
  3. Maintains an ISO 5 environment

# SECONDARY ENGINEERING CONTROLS (SECs)

Secondary engineering controls, i.e., the rooms that contain(s) the following:

- Buffer Area (contains the PEC)
- Ante Area (garbing, hand hygiene)
- Filtration systems to maintain air quality

# SECONDARY ENGINEERING CONTROLS (SECs)

Buffer Area = An ISO Class 7 area where the primary engineering control (PEC) is physically located

Ante Area = An ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high particulate generating activities are performed

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# MAIN IV ROOM COMPONENTS & AIR QUALITY

- The ISO environment involves various standards for air quality
- As the ISO number decreases, air quality increases:
  - ISO 5: PEC used within the Buffer Room
  - ISO 7: Buffer Room where the PEC is held
  - ISO 8: Anteroom

# ISO CLASSIFICATIONS AND THE IV ROOM

ISO Class	Particle Count* (m <sup>3</sup> )	Area
5	3,520	Primary Engineering Control (PEC)
7	352,000	Buffer Area
8	3,520,000	Ante Area

\*Limits are in particles of 0.5 µm and larger per cubic meter

ISO Classification of Particulate Matter in Room Air. USP 797 May 1, 2018. Adapted from Table 1. Accessed May 3, 2020.

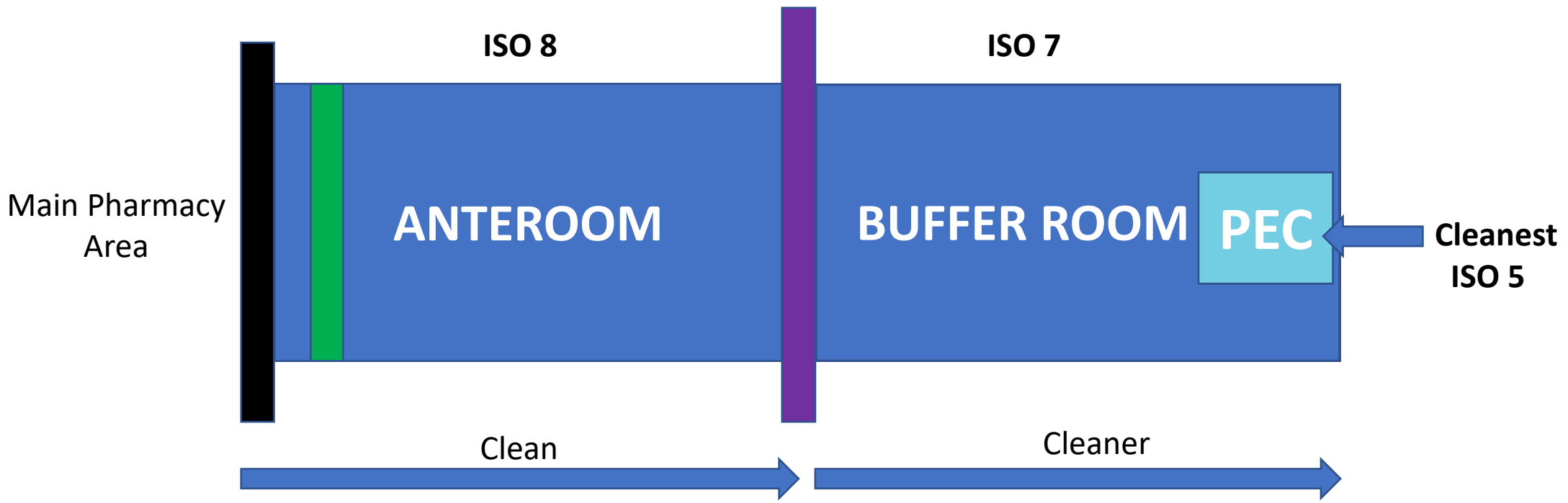
# SEGREGATED COMPOUNDING AREA VS. THE IV ROOM

Segregated Compounding Area (SCA): A designated space where low-risk level CSPs with 12-hour or less beyond use dates are prepared

- Still utilizes a device that provides ISO Class 5 air quality for the preparation of CSPs

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# MAIN IV ROOM COMPONENTS



*Presenter data on file.*

# MOVEMENT OF AIR WITHIN THE IV ROOM

- Dirtiest to cleanest
- Engineering controls are a constant
- Positive pressure vs. Negative Pressure

# POSITIVE AND NEGATIVE PRESSURE BUFFER ROOMS

- Positive pressure room: Non-hazardous compounding: A room at a higher pressure than the adjacent spaces where the net airflow is out of the room
- Negative pressure room: Hazardous medication compounding: A room that is at a lower pressure than the adjacent spaces where the net flow of air is into the room

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Controlled Environment Testing Association. CETA CAG-005-2007 servicing hazardous drug compounding primary engineering controls. Raleigh, NC: CETA; 2007. Accessed Jun 4, 2020.

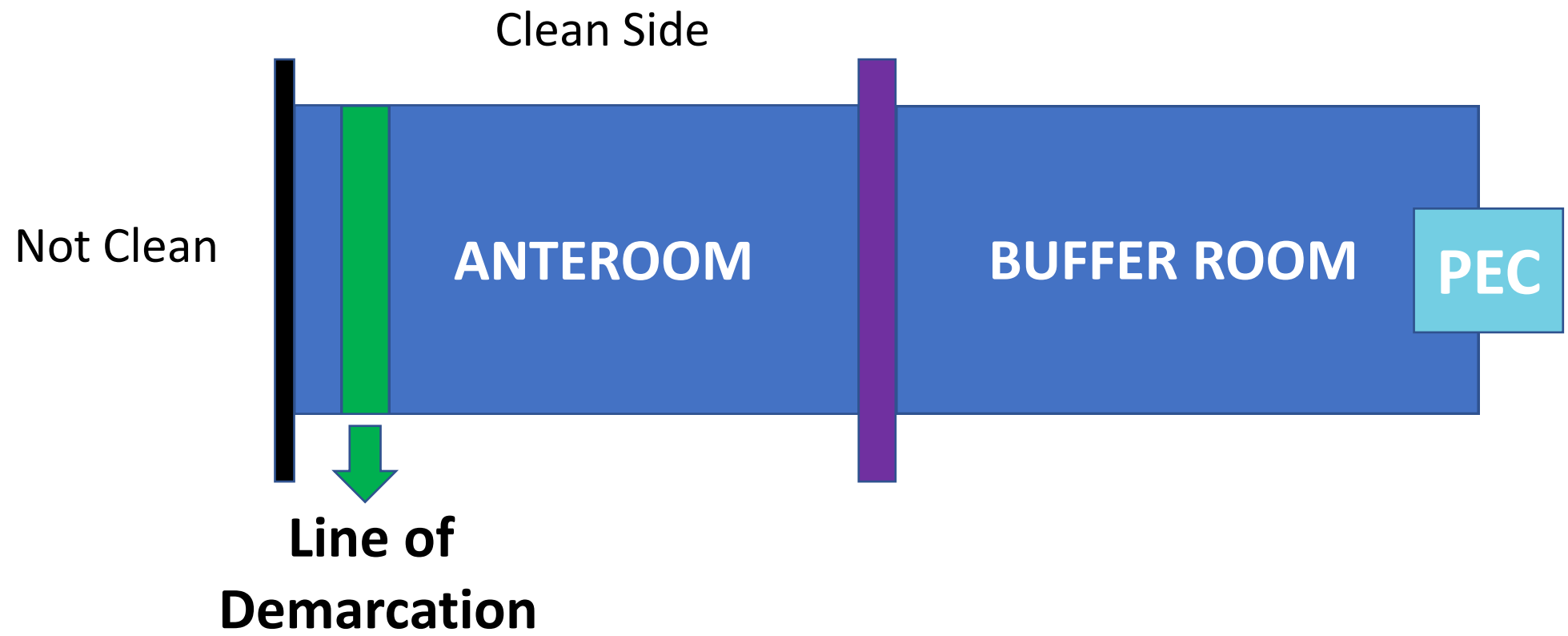
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Answer: D

# MOVEMENT OF PERSONNEL AND SUPPLIES

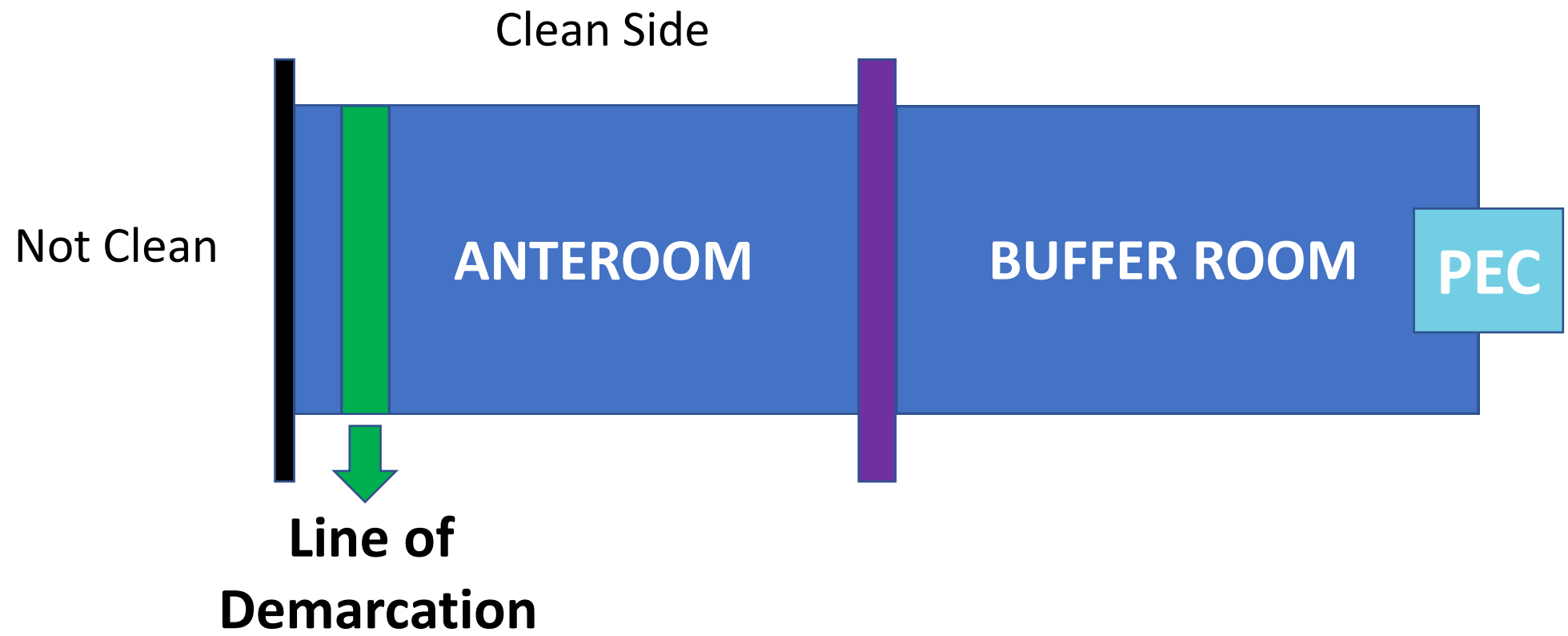


## QUESTION #2

The IV room refrigerator needs to be calibrated and a facilities staff member tells you that he needs to enter the IV room to perform the work. He immediately walks over the line of demarcation to access the refrigerator. What are the appropriate actions to take as the pharmacist?

- A. No action needed. Non-pharmacy personnel do not need to follow strict garbing procedures like pharmacy personnel because they are not involved with sterile compounding.
- B. Immediately stop the person, have them move back to the "dirty side" of the line, and instruct the person on proper donning of PPE before they start working.
- C. Have your technician colleague notice this person eventually because you usually take your break at this time and do not have time to assist the facilities person.
- D. Immediately stop the person, have them stay on the "clean side" of the line with you, and instruct them to don PPE appropriately.

# MOVEMENT OF PERSONNEL AND SUPPLIES



# HOW DO WE MOVE ACROSS THE LINE OF DEMARCATION?

- Per USP 797, the ante-room must have a line of demarcation to separate the “clean side” from the “dirty side”
- Garbing and Personal protective equipment (PPE)
- All supplies are disinfected before being moved over the line

## BEFORE ENTERING THE ANTEROOM

- Remove outer garments (ex: jacket, hat)
- No makeup, jewelry, artificial nails, or nail polish
- Be mindful of the following situations: sunburns, rashes, weeping sores, conjunctivitis, active respiratory infections

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# GARBING STEPS

1. Shoe covers
2. Head cover (**ALL** hair must be covered)
3. Face mask
4. Hand hygiene (including using a nail pick, vigorous hand washing where hands and forearms are washed up to the elbows for at least 30 seconds with soap and water)
5. Don Gown with sleeves
6. Antiseptic hand cleansing
7. Don sterile gloves
8. Disinfection of gloves with 70% Sterile Isopropyl Alcohol (before compounding starts)

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# BEFORE AND AFTER THE LINE OF DEMARCATION



# THE ASEPTIC ENVIRONMENT

- Personal Attire and PPE
- Hand washing
- Touch is most common source of contamination
- Gloves
- Only sterile until they touch something not sterile

# ASEPTIC TECHNIQUE

- By definition
- Critical site, first air, and the zone of turbulence
- Equipment and supplies
- Drawing up additives
- Cleaning and disinfecting

# ASEPTIC TECHNIQUE KEY CONCEPTS

Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient.

- Achieved by using practices that maintain the microbe count at an “irreducible minimum”
- Involves manipulating sterile products without compromising their sterility

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# ASEPTIC TECHNIQUE KEY CONCEPTS

**Critical Site:** A location that includes any component or fluid pathway surfaces or openings exposed and at risk of direct contact with air, moisture, or touch contamination.

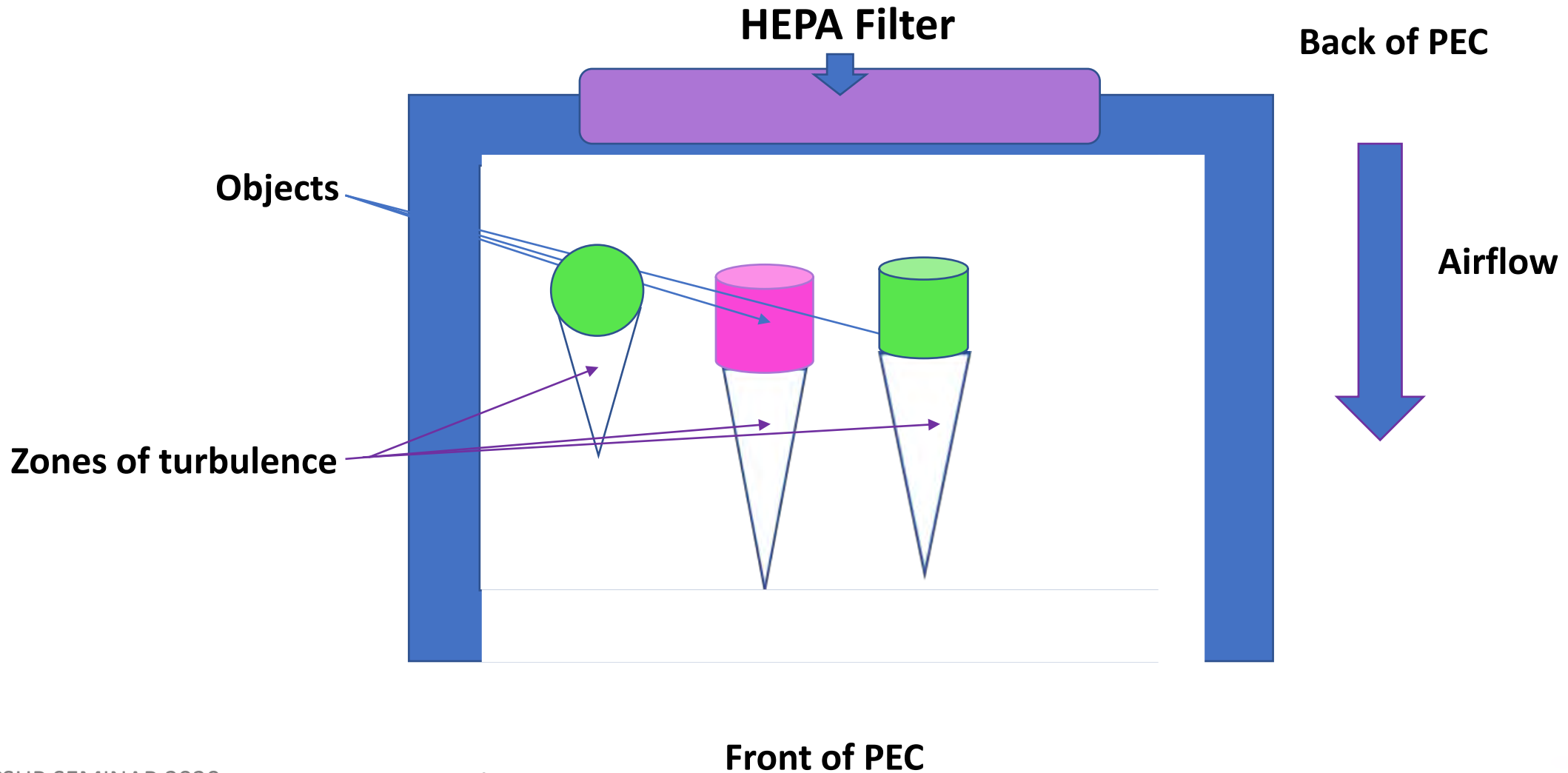
**First Air:** The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

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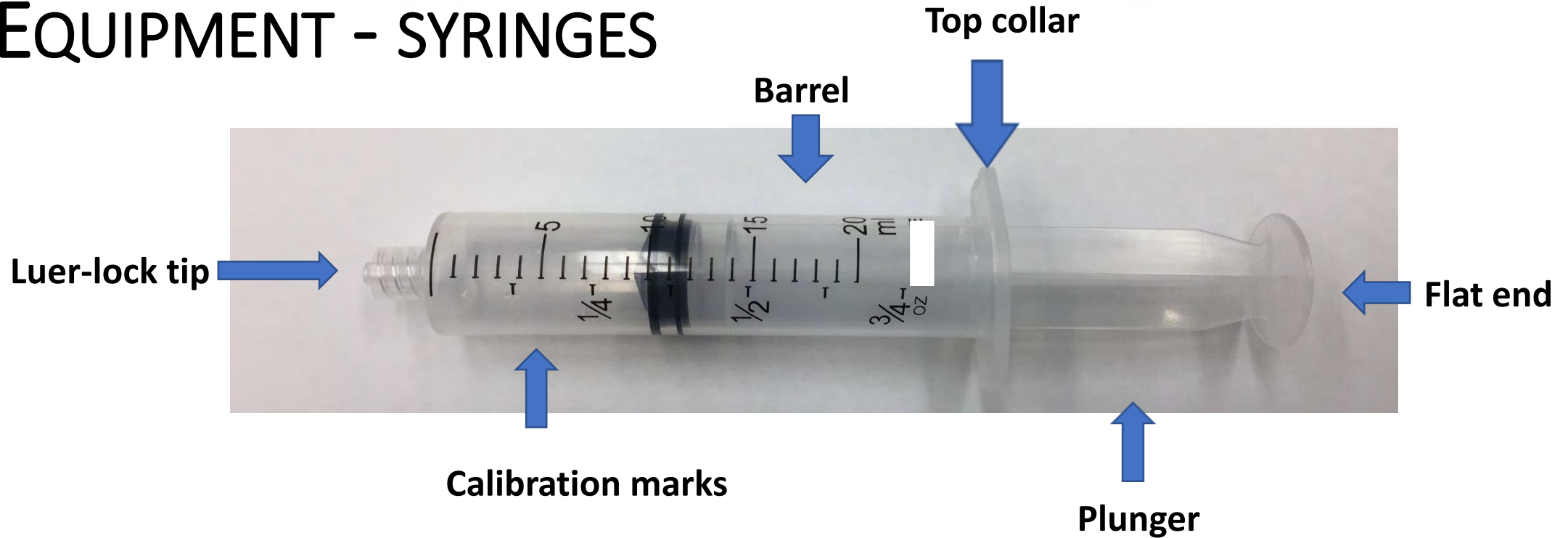
## BEFORE WORKING IN THE PEC

- Disinfect hands before placing them in the PEC
- Disinfect products as they are moved into the PEC
- Manipulations to take place at least 6 inches within the PEC called the direct compounding area
- Only essential items should be placed inside the PEC
- No talking or coughing into the PEC
- No eating, drinking, or smoking
- Strict aseptic technique must be used at all times

# ZONE OF TURBULENCE

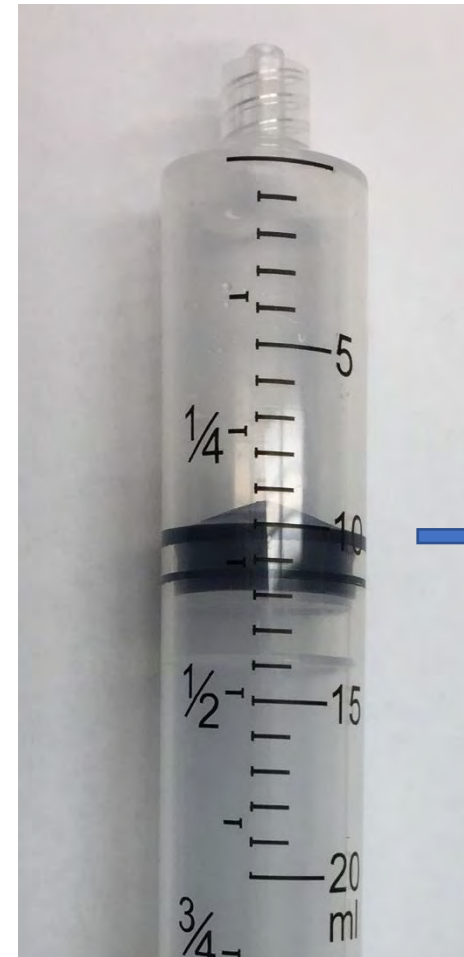


# EQUIPMENT - SYRINGES



# SYRINGES

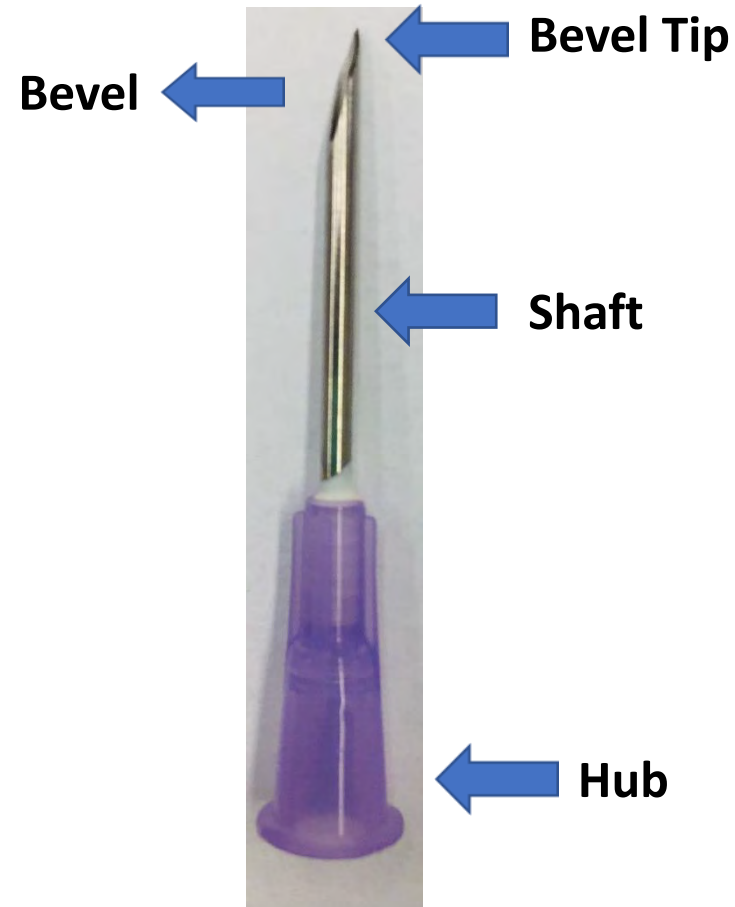
- Volume of solution- 1/2 to 2/3 of syringe capacity
- Open syringe package in PEC to maintain sterility
- Peel wrapper & discard
- Leave syringe tip protector in place until time to attach needle
- To attach needle to Luer-lock-type syringe:  
“Righty tighty/Lefty loosy”



Final edge of  
plunger piston

# NEEDLES

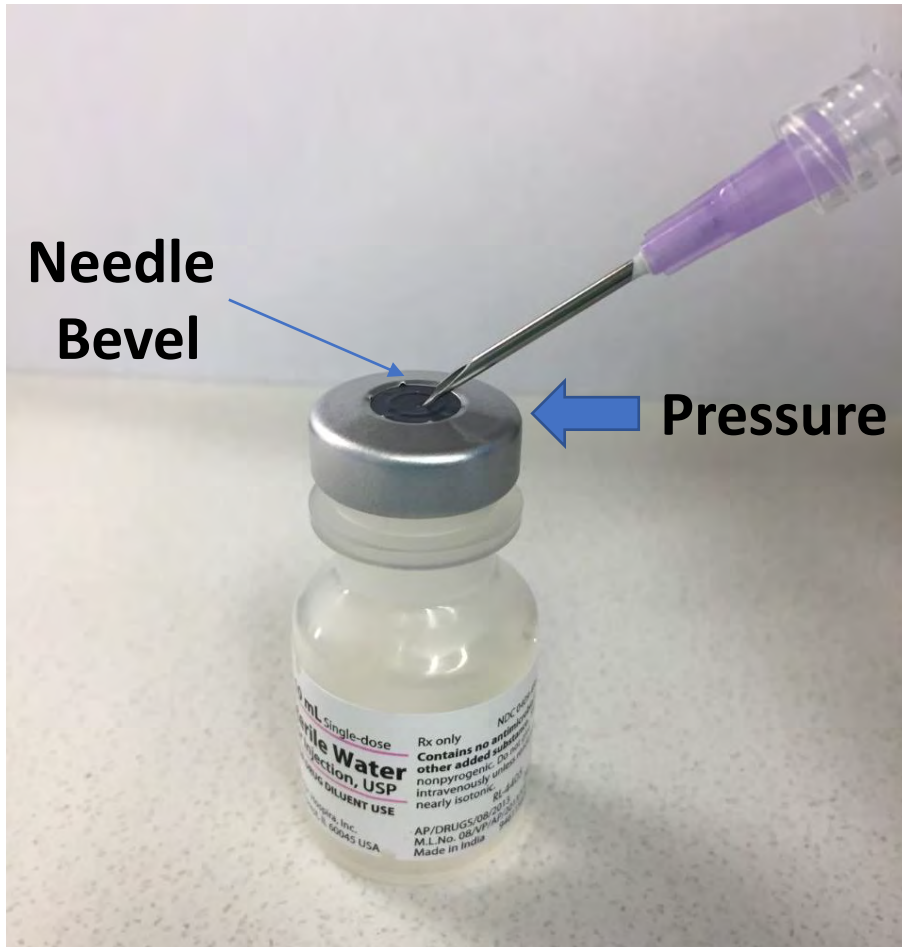
- Note components
- Often color-coded=gauge
- Vented needles
- Filter needles



# DRAWING UP ADDITIVES

- Gather supplies
- Needles, syringes, alcohol swabs, medication, diluent
- Are medications correct, have no precipitation/discoloration, and within date?
- Flip off cap and swab top of vial with alcohol
- Determine amount of volume you will need and pull back syringe plunger to that line
- Invert setup and inject air \*slowly\* into vial
- Draw up medication volume needed and remove any air bubbles
- Swab injection port of diluent with alcohol and inject medication into port

# NON-CORING TECHNIQUE

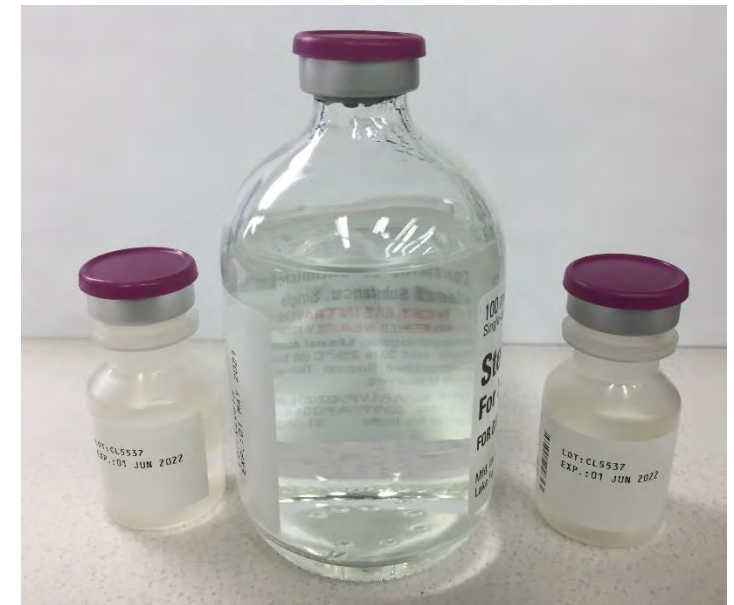


# DRAWING UP ADDITIVES



# VIALS

- Powders or liquids
- Avoid coring
- Normalize pressure
- Single or Multi-Dose Vials
- Preservative considerations



# AMPULES

- A glass container that houses various medications
- Move fluid to body of ampule
- Swab neck with alcohol pad
- Break at neck
- Tilt ampule, needle bevel down
- Use filter needle



← Head

← Neck

← Body

# TIPS

- Bevel up!
- Wait for alcohol to dry before inserting needle into vial or port
- Inspect medication vial and bag for coring and particulates
- Vial is under pressure, so go slow at first
- Make sure there is no air in the syringe
- Never re-use a needle



Cored piece of rubber in vial from stopper



Air and air bubble in syringe

# PREFILLED SYRINGES

- Manufactured ready-to-inject syringes
- Commonly given IM, IV, or subcutaneously
- Convenient for emergency situations
- Most likely to be kept in patient care areas



# IV CONTAINERS

- Large Volume Parenterals (LVPs)
- Small Volume Parenterals or “Piggyback” Systems
- Vial Spike Systems
- Flexible Plastic Bags
- Glass Containers
- Pre-mixed Bag

# PRE-MADE ADMIXTURES

- Manufactured LVPs with additives
- Stable in solution for longer periods of time
- Reduced handling by pharmacy
- Reduce potential for contamination
- Useful in emergencies - stocked in patient care areas
- Standard concentrations of parenteral medications
- Decrease potential medication errors in compounding & administration

# ASEPTIC TECHNIQUE PRACTICAL CONSIDERATIONS

- Workflow and airflow in the IV room
- Placement of supplies
- Placement of hands and hand hygiene
- Donning and doffing of PPE, ie, garbing procedures
- Note: Techniques and attachments differ based on the medication being prepared (i.e., negative pressure technique while working in the negative pressure room when compounding hazardous medications)

# CONSIDERATIONS FOR PREPARING HAZARDOUS DRUGS

Same as non-hazardous medications EXCEPT:

- Additional PPE required
- PEC is specific for compounding hazardous drugs
- Attach & prime IV sets before adding hazardous drug
- Maintain slight negative pressure inside vial
- Use syringes & IV sets with locked fittings
- Apply specific hazardous sticker on order
- Place in a special, sealable bag to contain any leakage and to designate that it is hazardous



# CLEANING AND DISINFECTING

Cleaning = The process of removing soil from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products

Disinfectant = “An agent that frees from infection and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores” (ex: 70% Isopropyl alcohol)

USP <800>: Hazardous drugs- handling in healthcare settings (general information chapter 800). Rockville, MD: The United States Pharmacopeial Convention; 2016. United States Pharmacopeial Convention. Updates on compounding standards. . Accessed June 1, 2020.

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# CLEANING AND DISINFECTING FREQUENCY

Workspace:	Frequency:
Counters, work surfaces, and floors	Daily
Walls, ceilings, and storage shelves	Monthly
ISO 5 PEC	Beginning of each work shift, before each batch, every 30 minutes, when there is a spill, and when surface contamination is known or suspected

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# DESCRIBE THE ROLE OF THE PHARMACIST IN MONITORING PERSONNEL WORKING IN THE CLEANROOM

# QUESTION #3

You are a new pharmacy resident staffing in the IV room. On the first day of work, you notice the following taking place:

1. Your IV room technician colleague (with a full beard) has a mask on, but no beard cover and visible hair exposed in the buffer room.
2. A new intern has just picked up a patient label notating "Doxorubicin HCl injection. Hazardous: Antineoplastic," and starts preparing the order in the positive pressure room PEC.
3. Another IV room technician has a visible sunburn and is sweating profusely while compounding an order in the PEC.

What are the appropriate actions to take as the pharmacist?

- A. Stop the intern because they about to expose themselves to a hazardous medication.
- B. No action needed. These are all acceptable situations.
- C. Wait for a more senior pharmacist to tell the technician with a beard that they are not properly gowned up.
- D. Inform the technician that is sweating with a sunburn that they actually are not allowed to work in the IV room today and have them switch out with a technician that can.
- E. Both A and D.

# MONITORING PERSONNEL

- ALL staff (including non-pharmacy departments)
- Proper gowning procedures
- Aseptic technique, first air, zone of turbulence
- Proper fitting PPE
- Cleaning and disinfecting with the correct frequency
- Temperature and humidity
- A constant and continuous process throughout the shift

# LET'S TALK ABOUT HAIR



Photo courtesy of Thaine Ross, CPhT, MPA



# MONITORING PERSONNEL

- Hair
- Staff who do not feel or look well
- Be mindful of what you can and cannot see

# PRACTICAL CONSIDERATIONS AND QUESTIONS

- What if the order is STAT?
- Can I cross over the line without gowning up correctly if it is an emergency?

# THE ROLE OF THE PHARMACIST PER USP 797

- Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments
- Review all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded
- Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling

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**E. Both A and D.**

# BEYOND USE DATE (BUD)

# BEYOND USE DATE

- By Definition
- Beyond Use Date (BUD) vs. Expiration Dates
- Stability and Sterility
- USP 797 Beyond Use Dates (current vs. revised)
- Multifactorial including :
  1. Ingredients (Sterile vs. Nonsterile)
  2. Risk levels (Low, Medium, High, Immediate Use)
  3. The environment where the CSP is prepared

# BEYOND USE DATE

- Beyond use date (BUD) = The date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored
- The BUD is *not* the same as an expiration date
- The BUD is assigned by the staff member compounding the CSP
- The expiration date is determined by the manufacturer of the medication, diluent, and/or container system

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# BEYOND USE DATE

- Substantiated by
  - Stability
  - Sterility
  - Published literature and professional judgment
- Label on the CSP must have the BUD

# CATEGORIES OF CSPPS AND THE BEYOND USE DATE

1. Low-risk level
2. Medium-risk level
3. High-risk level
4. Immediate Use

# LOW RISK

- Prepared entirely within an ISO Class 5 with only sterile ingredients
- Not to exceed more than 3 sterile products
- Not to exceed more than 2 entries into a sterile container

Pharmaceutical compounding – sterile preparations (general information chapter 797). In: The United States pharmacopeia, 39th rev., and The national formulary, 34th ed. Rockville, MD: United States Pharmacopeial Convention; 2016. Accessed May 1, 2020.

# MEDIUM RISK

- Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP
- Complex aseptic manipulations (Ex: TPN with 40 medications!)
- Preparation requires an unusually long duration for compounding

TPN= Total Parenteral Nutrition

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# HIGH RISK

- **Non sterile** ingredients
- Specific products are exposed to air quality worse than an ISO Class 5 for more than 1 hour
- **Compounding personnel are improperly garbed and gloved**
- Nonsterile water containing preparations are stored for more than 6 hours before being sterilized
- It is **assumed** that the chemical purity and content strength of ingredients must meet their original or compendial specifications in unopened or in opened packages of bulk ingredients

# IMMEDIATE USE

- A simple transfer of not more than three commercially manufactured packages of sterile **non-hazardous** products and not more than two entries into any one container or package of sterile infusion solutions or administration container/device
- Compounding does not to exceed 1 hour to prepare
- Aseptic technique is followed and the finished CSP is under continuous supervision
- Administration begins not later than 1 hour following the start of the preparation of the CSP\*

\* 4 hours in the Revised Version of USP 797

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# IMMEDIATE USE

- Unless immediately and completely administered, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1 hour BUD and time.
- Discard the CSP if administration has not started within 1 hour

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# CATEGORIES OF CSPPS AND THE BUD

	Low Risk	Medium Risk	High Risk	SCA	Immediate Use
Room Temperature	48 hours	30 hours	24 hours	12 hours	1 hour
Refrigerated	14 days	9 days	3 days	12 hours	N/A
Freezer	45 days	45 days	45 days	N/A	N/A

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# CATEGORY 1 AND CATEGORY 2 CSPs

- Category 1 CSPs:
  - ISO Class 5 PEC may be located in an unclassified SCA
- Category 2 CSPs:
  - PEC must be located within a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better ante room
  - A dynamic airflow smoke pattern test must be performed in the PEC initially and at least every 6 months

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# CSPS AND THE *REVISED* USP 797: CATEGORY 1

Room Temperature	Refrigerated	Freezer
≤ 12 hours	≤ 24 hours	N/A

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# CSPS AND THE *REVISED* USP 797: CATEGORY 2

Sterilization Method	Sterility Testing	Starting Ingredients	Room Temperature	Refrigerator	Freezer
Aseptically Prepared CSP	No	Some Nonsterile	1 day	4 days	45 days
	No	All Sterile	4 days	9 days	45 days
	Yes	Sterile/Nonsterile	30 days	45 days	60 days
Terminally Sterilized CSP	No	Sterile/Nonsterile	14 days	28 days	45 days
	Yes	Sterile/Nonsterile	45 days	60 days	90 days

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# SINGLE DOSE AND MULTIPLE DOSE VIAL BUDS

Type of Vial or Container	Beyond Use Date
Single dose containers if opened in <i>worse</i> than ISO Class 5 air quality	1 hour
Single dose vials exposed to ISO Class 5 or cleaner air	6 hours
Multi-dose vials	28 days

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# STRATEGIES FOR CHECKING ORDERS TO ENSURE ACCURATE PRESCRIPTION PREPARATION

# STRATEGIES FOR CHECKING ORDERS

- Correct medication, dose, route, concentration, and patient
- Correct label components:
  1. Patient name, identification #
  2. Name & amount of medication(s) added
  3. Name & volume of admixture solution
  4. Final total volume of admixture
  5. Prescribed flow rate (in milliliters per hour) if applicable
  6. Date & time of scheduled administration
  7. Date & time of preparation
  8. Beyond use date of the admixture
  9. Initials of person who prepared and checked IV admixture
  10. Auxiliary labeling (if applicable)

# STRATEGIES FOR CHECKING ORDERS

- Ensure the vials and diluent used for compounding are not expired
- Ensure technician withdraws appropriate volume from vials to ensure the correct dose was made by showing all work involved with compounding
- Should it be protected from light?
- Any auxiliary labels or specific containers?
- Product integrity check (visual inspection)

# STRATEGIES FOR CHECKING ORDERS

- Utilizing published references vs. memorizing
- Master formula
- Calculations and using a calculator
- Use of barcode technology (if available)
- Look alike/sound alike medications (ex: Doxorubicin HCl)

# PRACTICAL CONSIDERATIONS: LOOK ALIKE/SOUND ALIKE DOXORUBICIN HCL



DOXOrubicin HCl  
Powder  
50 mg/vial



DOXOrubicin HCl  
Liquid  
2 mg/mL



DOXOrubicin HCl Liposome  
(Doxil®)  
2 mg/mL

# STRATEGIES FOR CHECKING ORDERS

- Adult vs. Pediatric vs. Neonatal medication and storage
- High risk orders and hazardous medications
- Technician and Nursing colleagues' experience

# CONCLUDING REMARKS

- The IV room can get complicated quickly, but a solid foundation for best practice and the law is key to building your skill set.
- When in doubt, ask!
- Never assume anything, even if the order looks easy!

# QUESTION #1

What is the IV Room?

- A. A room in the pharmacy where any medication with any route of administration can be prepared.
- B. A room that contains secondary engineering controls, but no primary engineering controls.
- C. A location where personal protective equipment (PPE) is not required
- D. The location where compounded sterile preparations (CSPs) are made

Answer: D

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Answer: D

## QUESTION #2

The IV room refrigerator needs to be calibrated and a facilities staff member tells you that he needs to enter the IV room to perform the work. He immediately walks over the line of demarcation to access the refrigerator. What are the appropriate actions to take as the pharmacist?

- A. No action needed. Non-pharmacy personnel do not need to follow strict garbing procedures like pharmacy personnel because they are not involved with sterile compounding.
- B. Immediately stop the person, have them move back to the "dirty side" of the line, and instruct the person on proper donning of PPE before they start working.
- C. Have your technician colleague notice this person eventually because you usually take your break at this time and do not have time to assist the facilities person.
- D. Immediately stop the person, have them stay on the "clean side" of the line with you, and instruct them to don PPE appropriately.

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# QUESTION #3

You are a new pharmacy resident staffing in the IV room. On the first day of work, you notice the following taking place:

1. Your IV room technician colleague (with a full beard) has a mask on, but no beard cover and visible hair exposed in the buffer room.
2. A new intern has just picked up a patient label notating "Doxorubicin HCl injection. Hazardous: Antineoplastic" and starts preparing the order in the positive pressure room PEC.
3. Another IV room technician has a visible sunburn and is sweating profusely while compounding an order in the PEC.

What are the appropriate actions to take as the pharmacist?

- A. Stop the intern because they about to expose themselves to a hazardous medication.
- B. No action needed. These are all acceptable situations.
- C. Wait for a more senior pharmacist to tell the technician with a beard that they are not properly gowned up.
- D. Inform the technician that is sweating with a sunburn that they actually are not allowed to work in the IV room today and have them switch out with a technician that can.
- E. Both A and D.

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**E. Both A and D.**

# REFERENCE LIST

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# SPECIAL ACKNOWLEDGMENTS

- Cynthia Lieu, Pharm.D., BCNSP
- Nancy Yam, Pharm.D., MHA, BCPS
- Kendria McCrary, CPhT
- Michele Gardiner, CPhT, CSPT

# Thank You!

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