IV ROOM PRINCIPLES

· Patient and employee safety
· Compounding sterile products
· Aseptic technique

An overview
for staff competency

0719

Target Zero Safety Practices

Prevent Sterile Compounding Errors

- Introduce yourself and your role
- Focus on the task

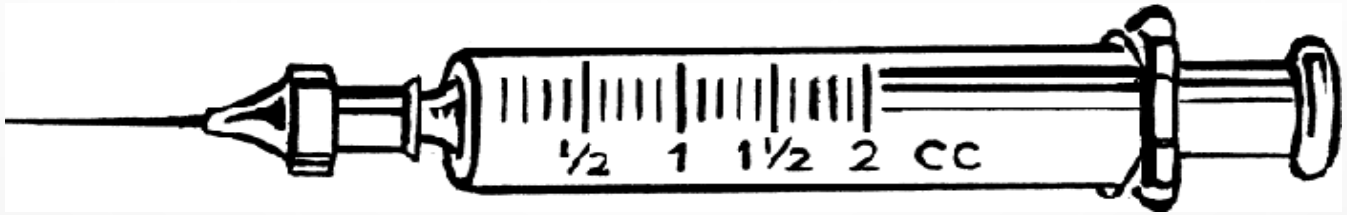
- Do not proceed in the face of uncertainty

- Strive for clear, complete, and respectful communication

PARENTERAL MEDICATIONS

The Risks

Parenteral Administration



Definition

Non-oral routes of medication administration that directly bypass many of the body's barrier defense systems (such as skin and mucous membranes).

Routes:

- intravenous
- intramuscular
- subcutaneous
- intrathecal
- epidural

Inherent risks

- Bypassing normal defense mechanisms
- Errors in preparation of compounded sterile products can have significant health consequences, including death.
  - Contamination
  - Wrong drug
  - Wrong patient
  - Wrong concentration

Morbidity & Mortality

1990 — **Pennsylvania**

Contaminated indomethacin eye drops à

2 patients go blind

2005 — **Maryland**

Gram negative rods in cardioplegia à

10 patients die

2006 — **Ohio**

Chemotherapy made with **23.4%** NaCl instead of **0.9%** NaCl à

1 child dies

2006 — **Nevada**

1000x overdose of zinc sulfate compounded in hospital à

1 baby dies

Newsweek

IN THE MAGAZINE U.S.

KILLER PHARMACY: INSIDE A MEDICAL MASS MURDER CASE

BY KURT EICHENWALD ON 4/16/15 AT 7:07 AM

Morbidity & Mortality, Continued

- 800 people infected with fungal meningitis
- 64 slow, painful deaths
- 14 NECC executives and pharmacists face charges of racketeering, fraud, conspiracy, violating drug laws, financial crimes and MURDER. Sentencing June 21, 2017

STERILE COMPOUNDING AREAS

Contamination

Gowning requirements

Primary engineering controls

CONTAMINATION

This is why we gown, clean, and practice aseptic technique

Contamination

- **Definition**
  - Presence of unwanted constituent(s) in a sterile product.
  - An unwanted constituent may be a particulate, microbe (bacterial, fungal, or viral), or chemical.
- **Sources of contamination**
  - Work environment, air, water, particulate matter, non-sterile equipment, gloved hands, dirty work surfaces, non-sterile critical sites, etc.
  - Everywhere!

GOAL:
Prevent contamination in the sterile compounding environment and in compounded sterile products.

Particulate:

A source of Bacterial, viral, fungal and pyrogen contamination

Each human generates a vast amount of particulates:

Skin cells, hair, clothing fibers/lint, flaking, facial makeup, pet hair, dirt, soil, dust etc….

The typical human sheds 1 billion dead skin cells per day. Each square centimeter of skin is colonized with 1 million bacteria

During compounding, sanitize gloves <u>OFTEN</u> with sterile Isopropyl Alcohol!

When compounding, gloved hands are likely the dirtiest things inside the hood.

Dirty Hood Surfaces

Spills and Dried Drug Residues on Hood Work Surface, A source of contamination.

GOWNING REQUIREMENTS

	Requirements for entering the IV room (the following should be performed in sequential order)
1	Do not bring outer clothing such as jackets, hats, etc. into the anteroom. Use your locker.
2	Don head cover. Cloth head covers may only be worn UNDER disposable bouffant cap.
3	Don beard cover if applicable. Men not clean-shaven must wear a beard cover.
4	Don facial mask.
5	Don shoe covers. Shoe covers may never be worn outside the IV room or Anteroom.
6	Step across line of demarcation.
7	Wash hands (including under fingernails) and arms up to the elbow with soap and warm water for a minimum of 30 seconds.
8	Don gown and fasten all closures up to the neck. Shirt collar must be covered.
9	Apply alcohol-based hand sanitizer with residual anti-microbial activity (Avagard) and allow hands to dry.
10	Don sterile gloves using proper donning technique.

Additional IV Room Requirements

In addition to the requirements listed on the previous slide…	
• After gowning, no skin showing below the neck. • All head and facial hair must be covered. • All makeup and cosmetics must be removed. • Remove all jewelry, watches and non-permanent piercings. • Sterile gloves are always required. Alternate sterile gloves will be provided for those with special requirements. • Don a new gown at the beginning of each shift and re-use for that shift only. • Change all other garb each time you enter the IV room (bonnet, booties, mask, beard cover, gloves). • Do not hang outer wear such as coats in the anteroom, use your locker. • Absolutely no cell phones allowed in the IV room.	• All skin must be completely covered below the hemline of the gown to the top of the shoes. • Skirts or capri pants may be worn with nylon stockings or leggings. • Colored fingernail polish must be removed. No artificial fingernails allowed. • No open toed or open matrix shoes allowed. • Sterile gloves must be re-sanitized with sterile alcohol often (i.e. when re-entering the hood, before preparing separate orders, etc.) during compounding. • Change gloves during compounding if they develop holes or tears. • Absolutely no food or drinks allowed in the IV room.


1 Head Cover
2 Mask and Beard Cover (if applicable)
3 Gown with Front Closure, buttoned up to neck
4 Sterile Gloves
5 Shoe Covers

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PRIMARY ENGINEERING CONTROLS

How to use the engineering controls correctly

How to clean the engineering controls correctly

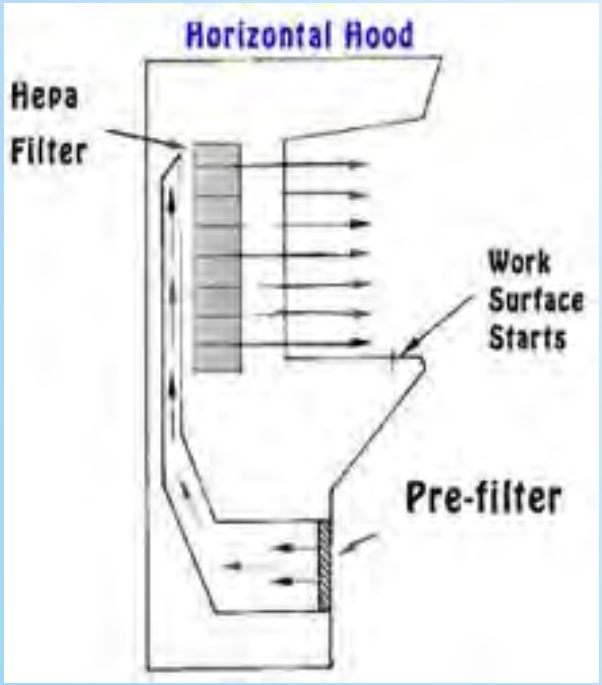
HORIZONTAL

HOODS

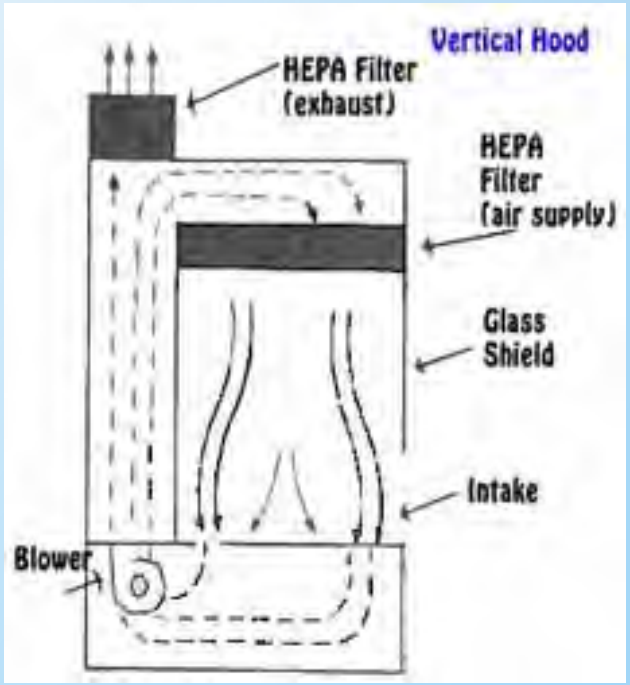
(PRIMARY ENGINEERING CONTROLS)

VERTICAL

The Hood

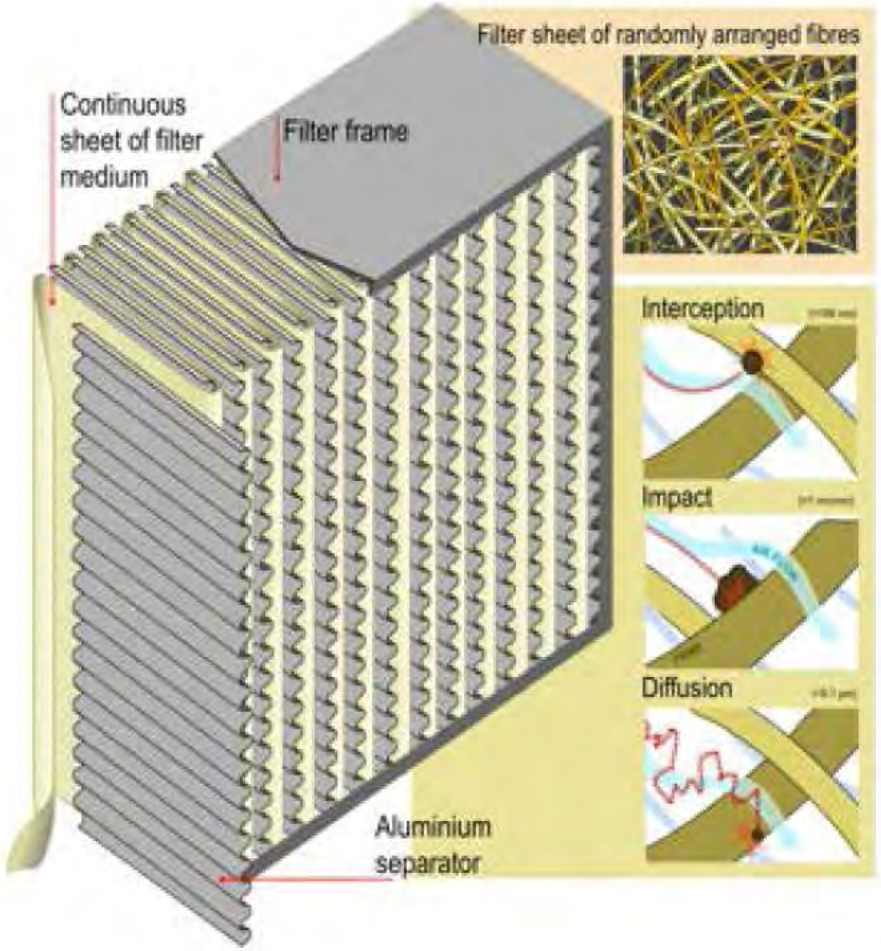


- **Other Names**
  - Laminar air-flow workbench (LAFW)
  - Primary engineering control (pec)
- **Definition**
  - Device that provides constant laminar flow of HEPA filtered, particulate free, high quality air in which compounding personnel perform aseptic manipulations of sterile products.
- **Laminar Flow**
  - Horizontal, or back to front (**left**)
  - Vertical, or top to bottom (**right**)



HEPA Filter

- Eliminates 99.97% of particles sized 0.3 microns
- NEVER spray a medication or cleaning product into HEPA filter!



Horizontal Laminar Airflow Workbench

- Pre-filter and HEPA filter provide filtered laminar layers of aseptic air, which flow in a straight line across the work surface
- LAFW design prevents entry of contaminated room air into compounding workspace
- Horizontal workbenches are most commonly used for preparation of non-hazardous sterile solutions
- Airflow moves from back to front of hood toward the user offering no protection from exposure to hazardous vapors, droplets or powders
- You will find these hoods in the central IV room and all satellite IV rooms

Vertical Laminar Airflow Workbench

- HEPA filter provides vertical filtered laminar layers of aseptic air
- Design prevents entry of contaminated room air into compounding workspace
- Airflow moves in a straight line from top toward bottom of hood
- Airflow does not exit the front of the hood towards the user, but instead is removed through a grill at the back of the hood and contaminated air is exhausted outside the building
- Glass shield at front offers face and eye protection to user
- Designed to protect the product being prepared from contamination ***and*** to protect the user from exposure to hazardous medications such as chemotherapy
- You will see this hood in compounding areas and the oncology satellite

Cleaning The Horizontal Laminar Flow Hood

- Ceiling of hood
- Back of hood
- The bar
- Sides of hood
- Deck/work surface of the hood
- Lastly, the sharps container(s)

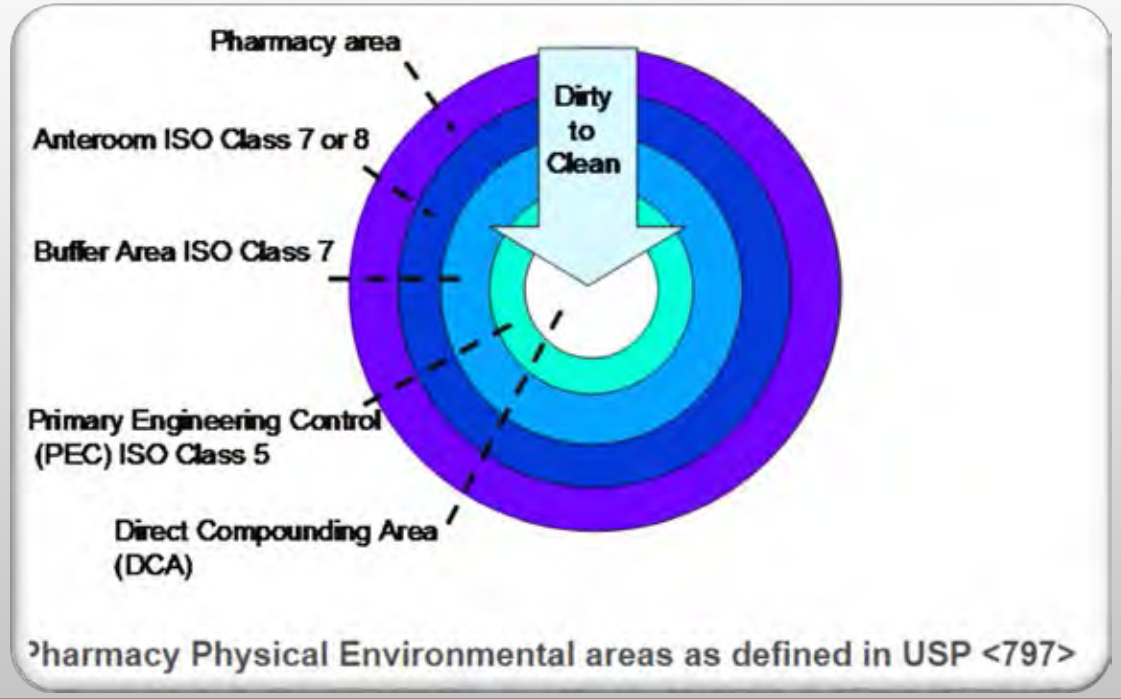
When Cleaning The Interior Of The Hood…

1. Remove dextrose, drug, or electrolyte residue from compounding workspace with a low-shedding wipe and sterile water
2. Clean the hood frequently throughout the shift with sterile isopropyl alcohol (sIPA)
3. Wipe up spills immediately during compounding using sterile, low-shedding wipes
4. Clean the hood with a sporicidal agent such as Oxivir at least once per shift (typically the beginning)
   - Use enough alcohol of Oxivir to wet surfaces for a minimum of 10 seconds (longer is better)

IV ROOM DESIGN

Secondary engineering controls

IV Room Design
(Secondary Engineering Controls)



Pharmacy Physical Environmental areas as defined in USP <797>

A decreasing pressure gradient continuously moves the air from the buffer-room toward the ante-room and then toward the line of demarcation, the gowning area and exit door.

Buffer-room

- Cleanest part of IV room
- Where hoods are located

Ante room

- Space where non-sterile activities related to sterile compounding are performed (storing sterile drug stock, garbing and handwashing)

HEPA filtered air and pressure gradient

- “Sweep” particulate and dust away from compounding area to outer pharmacy

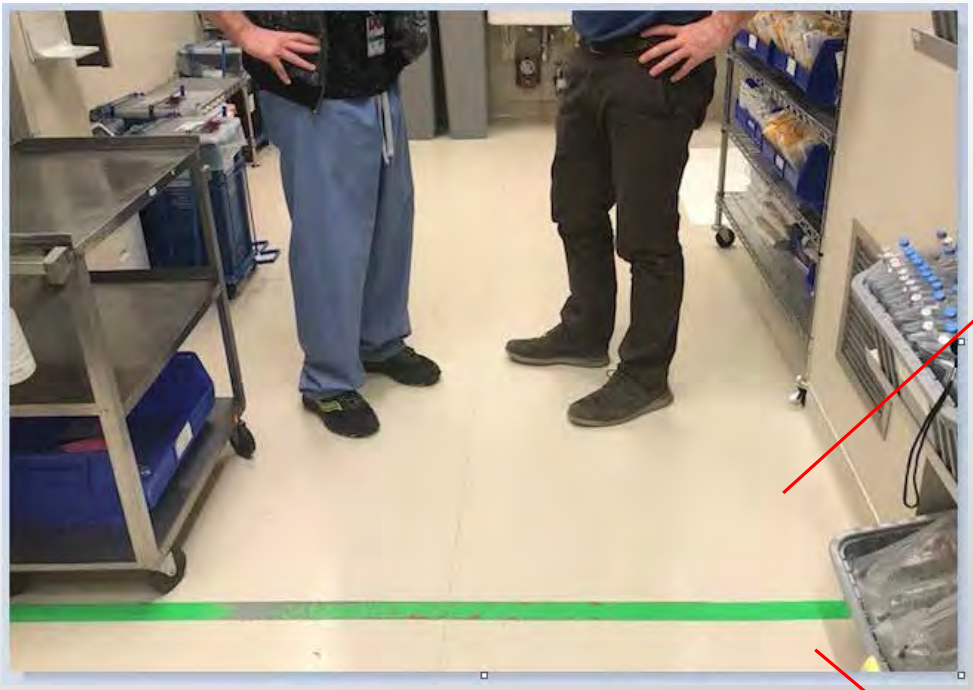
Line of Demarcation

("RED LINE") **SOMETIMES GREEN J**

Medication side

Gowning side

Clean Side



Gowning side

Dirty Side

Medication side

You must always be fully gowned to cross the line of demarcation to the clean side of the anteroom

ASEPTIC AND STERILE TECHNIQUES

Critical sites

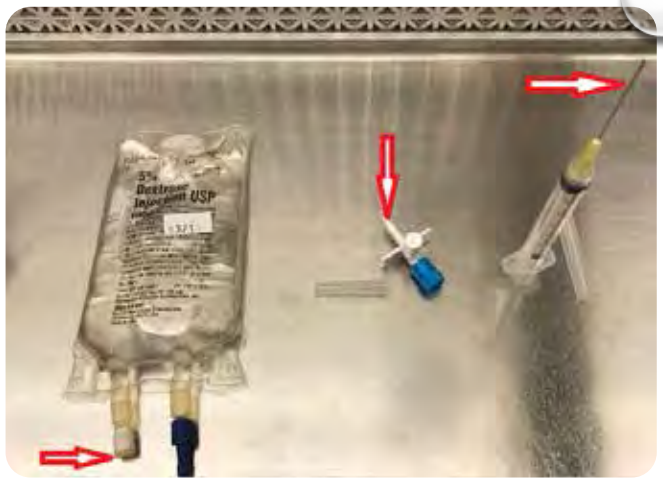
Correct iv room compounding techniques

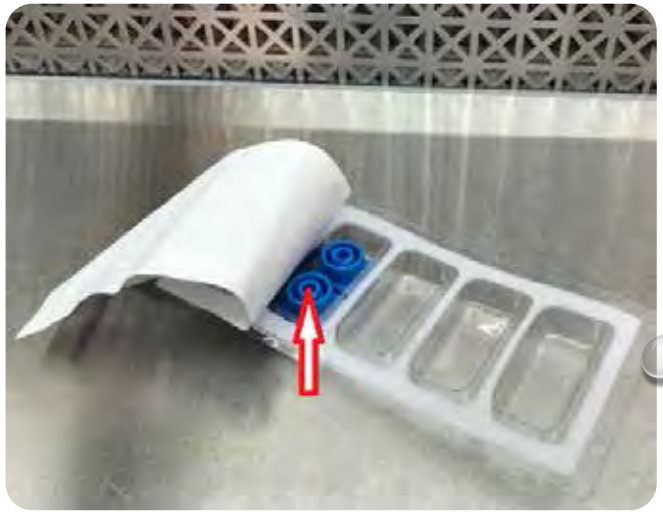
Critical Sites

- The sterility and cleanliness of critical sites must be maintained at all times during compounding. Any break in sterile technique must be corrected before continuing.

- A break in sterile technique could be accidentally touching a sterile critical site or blocking the “first air” flowing from the back of the hood over the critical site.

- First air it is the air exiting the HEPA filter in a unidirectional air stream that is essentially sterile and particle free. This unobstructed first-air should be flowing over all sterile critical sites during compounding.





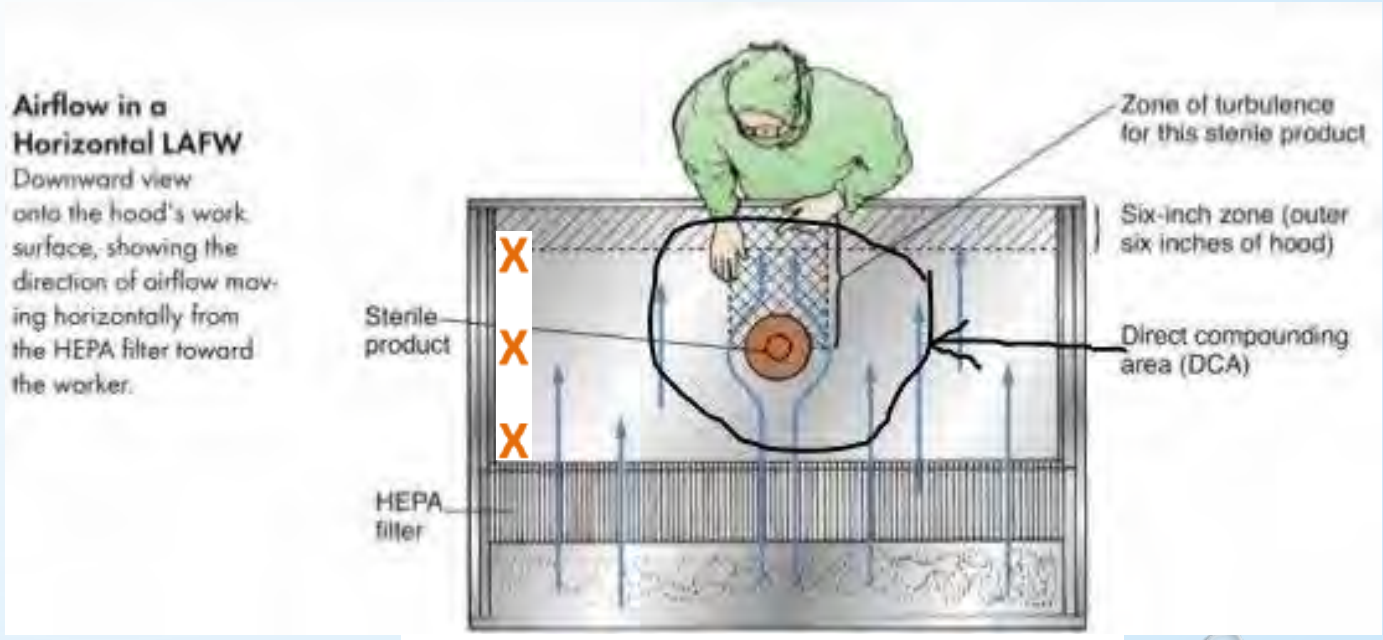
More Critical Sites

How To Correct A Break In Sterile Technique

- Discarding and replacing a contaminated needle
- Re-swabbing a contaminated part on a bag or vial stopper
- Discarding a vial of drug if contamination of the contents is suspected

Aseptic Technique In A Laminar Flow Workbench

- The direct compounding area (DCA) should be kept clean and un-cluttered
- Remember that clutter can disrupt the laminar flow of air in the hood and thus constitute a breakdown in aseptic compounding technique
- Only the product being prepared and the needed supplies should be in the DCA



Aseptic Technique In A Laminar Flow Workbench, Continued

- Perform aseptic manipulations within first-air flow, at least **6 inches inside** the hood and **3 inches above** the work surface if possible.
- Hands or objects **should not block first air** flowing over critical sites. **Air flows from back of hood toward user.** Do not block first air with diluent bags, hands, medication vials, equipment or supplies.
- Critical sites are exposed sterile surfaces of vial stoppers, needles, spikes, ports etc. (Examples circled in **red**). First air should flow **continuously** over these sites inside the hood.

Cleaning The Vials

- Use a sterile isopropyl alcohol swab
- Swab the stopper or port with friction (i.e. forcefully and purposefully)
- Wipe 3 times with the direction of airflow
- Use 1 wipe per vial

Take Home Points

1. Start with sterile gloves and sanitize gloves often (define) with sterile isopropyl alcohol. Replace torn or damaged gloves immediately.
2. Use first air correctly and maintain uninterrupted flow over all critical sites in the uncluttered DCA.
3. Be vigilant in maintaining sterility of critical sites by avoiding touch contamination. When a break in sterility occurs with stoppers, ports, needles, spikes, etc.; stop and replace the contaminated device or re-sterilize with alcohol.

Media Fill Test

All CHCO pharmacists, interns, and technicians must pass a didactic competency evaluation, a gloved fingertip test and observational media fill test once per year. These are a learning process and each person should feel comfortable asking questions during the process. Please read and understand the information in this PowerPoint, and take the competency evaluation quiz prior to performing your media fill test each year.

This powerpoint may be found on the “Y” drive; IV Room; Sterile Compounding Competency Powerpoint. Version 11/14/2019

IV Room Principles Competency Assessment

NAME:_____ DATE:_____

1. Which of the following PPE may be removed and re-donned throughout a single shift?

a. Hair Cover/Bonnet
b. Facial Mask
c. Gown
d. Shoe Covers
e. None of the Above

2. Non-Sterile Gloves may be donned for compounding as long as they are sanitized with sterile isopropyl alcohol (sIPA)?

a. True
b. False

3. Which of the following may help to reduce particulates in the buffer room?

a. Hair Cover/Bonnet
b. Facial Mask
c. Gown
d. Shoe Covers
e. All the Above
f. a, c and d only

4. When compounding sterile products only microbial contamination is of concern.

a. True
b. False

5. Contamination is defined as the presence of unwanted constituent(s) in a sterile product. Which of the following are examples of contaminants?

a. Particulate
b. Microbe
c. Chemical
d. All of the above

6. It is important for compounding staff to cover the maximum amount of skin surface while in the IV room. This is because the average human sheds the following number of dead skin cells per day.

a. 1 hundred
b. 1 thousand
c. 1 million
d. 1 billion

7. Which of the following indicates the proper order for donning garb?

a. Gloves, head cover, shoe covers, mask, gown
b. Shoe covers, head cover, mask, gown, gloves
c. Head cover, mask, shoe covers, gown, gloves
d. Gloves, head cover, mask, gown shoe covers

8. What is the minimum amount of time hands should be washed prior to entering the buffer room?

a. 20 seconds
b. 30 seconds
c. 45 seconds
d. 1 minute

9. Drugs spilled onto the work surface of the hood may potentially contaminate medications being compounded there.

a. True
b. False

10. The hood should be cleaned at least once per shift (typically in the beginning) with a sporicidal agent such as:

a. Sterile Isopropyl Alcohol (sIPA)
b. Sterile Water
c. Oxivir
d. Tap water and soap

11. When cleaning the interior of the hood in the middle of your shift it would be best to FIRST remove spilled & dried dextrose residue with _____ and then to clean with _____.

a. Sterile Isopropyl Alcohol (sIPA), Oxivir
b. Tap Water and soap, Sterile Isopropyl Alcohol (sIPA)
c. Sterile Water, Sterile Isopropyl Alcohol (sIPA)
d. Oxivir, Sterile Water

12. Patient Safety is a primary concern during sterile compounding.

a. True
b. False

13. An example of a critical site is:

a. The exterior of an IV Bag
b. The exterior barrel of an IV Syringe
c. A foil port cover
d. An uncapped needle

14. If your gloved finger accidentally touches an uncapped needle before piercing a vial of medication, you should:

a. Do nothing, you are working with gloved hands
b. Wipe the needle with alcohol
c. Throw the needle away and use a new needle
d. Clean the needle with Oxivir

15. You have just used a sterile alcohol pad to swab the port on a 100ml bag of 5% Dextrose hanging inside the hood before injecting a dose of medication. Just before adding the medication, your hand accidentally passes behind the port as it hangs. Is the port still sterile?

a. Yes
b. No

16. In general, the air in the Buffer Room is cleaner than the air in the ante-room.

a. True
b. False

17. The following hood is typically used to compound non-hazardous sterile products:

a. Horizontal Flow Hood
b. Vertical Flow Hood

18. Aseptic manipulations should not be compounded at the edge of the hood. When compounding sterile products, you should work at least _____ inches inside the hood:

a. 3”
b. 6”
c. 9”
d. 12”

19. Medications and supplies not immediately needed should be minimized within the hood or kept to the far side of the hood while making a preparation in the direct compounding area; this maintains an uncluttered workspace

a. True
b. False