Attitude Matters
when compounding sterile preparations

If you always keep in mind that there is a patient that will be injected
with the compounded preparation you are mixing → Motivation

Why does a cleanroom have to be cleaner than an operating room?

Air directly from the HEPA filter in the hood is the cleanest; it has the lowest particle count of anywhere in the room. Sometimes referred to as FIRST AIR.

Bathe the critical site in FIRST AIR.

Avoid blocking FIRST AIR. Allow air flowing from the HEPA filter to remove contaminants introduced by personnel.

Poor technique can overcome the air flow direction and introduce reverse air currents that reintroduce contaminants into the hood.

Examples: quick movements, talking, coughing, sneezing, and leaning into the hood.

Poor placement of objects in the hood aseptic technique can also block the FIRST AIR.

Introducing Items into the PEC
Proposed USP <797>Section 8.2

• Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using low lint wipers and allowed to dry before use.

• When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA.

• The wiping procedure must not render the product label unreadable.

A direct path must be maintained between the HEPA filter and critical sites

Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to undirectional HEPA filtered air, also known as first air.

First air: The air exiting the HEPA filter in an undirectional air stream.

Figure 1: Diagram of HEPA filter and critical sites.
CRITICAL SITES require extra focus

Critical site:
- A location that includes
  - any component or fluid pathway surface (e.g., vial septa, injection ports, and beakers) or
  - openings (e.g., opened ampules and needle hubs)
- that are
  - exposed and
  - at risk of direct contact with
    - air (e.g., ambient room or HEPA filtered),
    - moisture (e.g., oral and mucosal secretions), or
    - touch-contamination.

Dispensing pins
Vial stoppers
IV bag ports
Ampule necks
Syringe tips
Needles
Transfer devices
Syringe connectors
Tubing connectors

Touch Contamination is the #1 Cause of CSP Contamination

Avoid touching any CRITICAL SITE including:
- Vial Stoppers
- Ampule necks
- IV bag ports
- Syringe tips
- Needles- all parts
- Transfer devices
- Dispensing pins
- Syringe connectors
- Tubing connectors

Best Practices
Do not lean into or on the hood during compounding
Keep arms up off surface including edge
Keep head and shoulders out of the hood
Check manufacturers recommendations for particular equipment

Syringe Selection and Use
- For best accuracy, use the smallest syringe that can hold the amount of solution needed
- However, use the 80% rule: When dispensing syringes, it is a good practice to only fill the syringe to approx. 80%, to avoid plunger drawbacks.
- Avoid using the same needle to draw up different medications
- Limit syringe and needle use to not more than ___ times
**Suggested needle size selection guidelines**

Limit needle use to not more than 3-5 times

<table>
<thead>
<tr>
<th>SYRINGE CAPACITY (ML)</th>
<th>NEEDLE GAUGE</th>
<th>NEEDLE LENGTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 3, 5</td>
<td>21-20 G</td>
<td>1 inch</td>
</tr>
<tr>
<td>10, 20, 30, 35</td>
<td>18 – 19 G</td>
<td>1 - 1 ½ inches</td>
</tr>
<tr>
<td>50, 60 (or viscous liquids)</td>
<td>16 G</td>
<td>1 ½ inches</td>
</tr>
</tbody>
</table>

**NEEDLE RISKS**

Avoid recapping needles

Use a one-handed scoop method if needed

Report to management, follow SOPs

**Needle Sticks**

To inject fluid into a vial

If you just add the fluid, pressure builds!

Allow air to leave as fluid enters the vial.

Maintain equal pressures, so you don’t have to fight the vial.

To withdraw fluid from a vial

Inject portions of air as you withdraw fluid to equalize pressure.

Make sure the needle remains in the fluid.
Check, check, and check again

- Mix until completion, one batch or one patient’s medication at a time
- Keep talking to a minimum, maintain focus
- Use a triple check method. Check BEFORE compounding, Recheck during compounding, and Check again upon completion.

Remember the 4 Ds:
- Do I have the right DRUG?
- Do I have the correct DILUENT?
- Did I make the correct DOSE?
- Does it have the proper DURATION?

Not in USP<797>
UConn Best Practices

Best Practices for aseptic manipulation

- Items should be wiped down with sterile 70% IPA in the before entering the clean side of the ante room or pass through. Use gloves (not sterile) initially.
- Gather all items needed for the compound; place only items needed to complete the task in the ISO 5 PEC.
- Wipe down supplies again when placing in ISO 5 PEC. Inspect supplies when wiping down to place in ISO 5 PEC.
- Proposed <797> requires re-inspection at some point; this is a good point to assure re-inspection.
- Maintain distance of _____ between objects.
- Swab critical sites with sterile 70% IPA and allow to dry ___.
- 3 times and away from the HEPA filter.
- Open packages toward HEPA filter.
- Avoid punching through paper packaging.
- Move trash to the side of the hood.
- Avoid moving in and out of hood.
- Disinfect gloves every time you leave the ISO 5 air.

On January 31, 2018, Pharmacy Technician (b) (6) was sterile processing TPN products in Hood (b) (6) when I observed that (b) (6) consistently put the top of her head (exposing the skin from her neck and face) into the hood (b) (6) with part of her shoulders. 1 also noted on February 1, 2018, an instance in which (b) (6) left the ISO 5 hood for supplies in the ISO 2 area and upon her return to the ISO 5 (b) (6) immediately changed out of sterile gear, gave prior to entry into the ISO 5 hood. (b) (6) had processed IVP tubes that day.