



Asepsis = the Absence of microorganisms, such as bacteria, fungus, and viruses.

1 in 31 hospital patients will develop a Healthcare-Associated Infection(HAI).

HAIs are potentially life threatening and kill thousands of people every year.

The five most common HAIs cost the US approx. \$9.8 Billion per year

These are not all from injectable compounded preparations.

CDC Data Portal 2017 HAI Progress Report, published 2019

Attitude Matters

Always keep in mind that there is a patient that will be injected with the compounded preparation you are mixing.

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

Allow air flowing from the HEPA filter to remove contaminants introduced by personnel

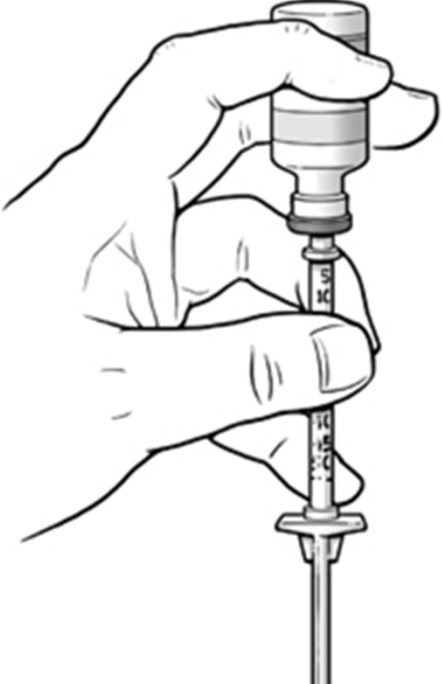
Limitations: Poor technique can overcome the air flow direction and introduce reverse air currents that reintroduce contaminants into the hood.

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

Poor aseptic technique can also block the FIRST AIR, by poor placement of objects in the hood and poor hand placement.



What happens if you DO sneeze in the buffer room?



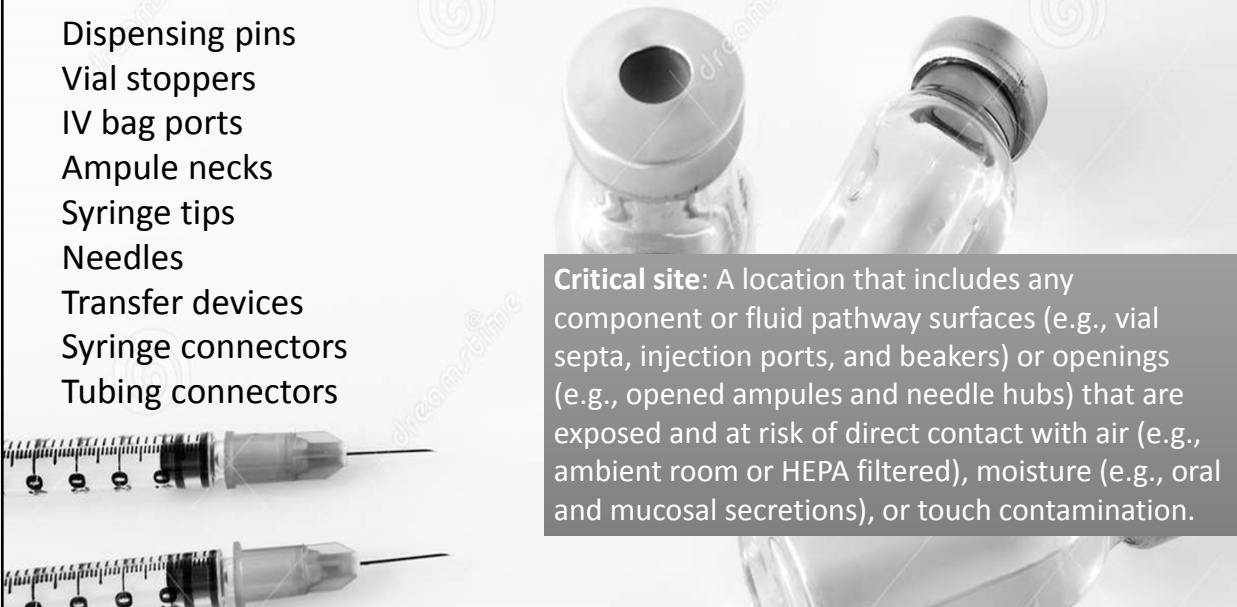
A direct path must be maintained between the HEPA filter and critical sites

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

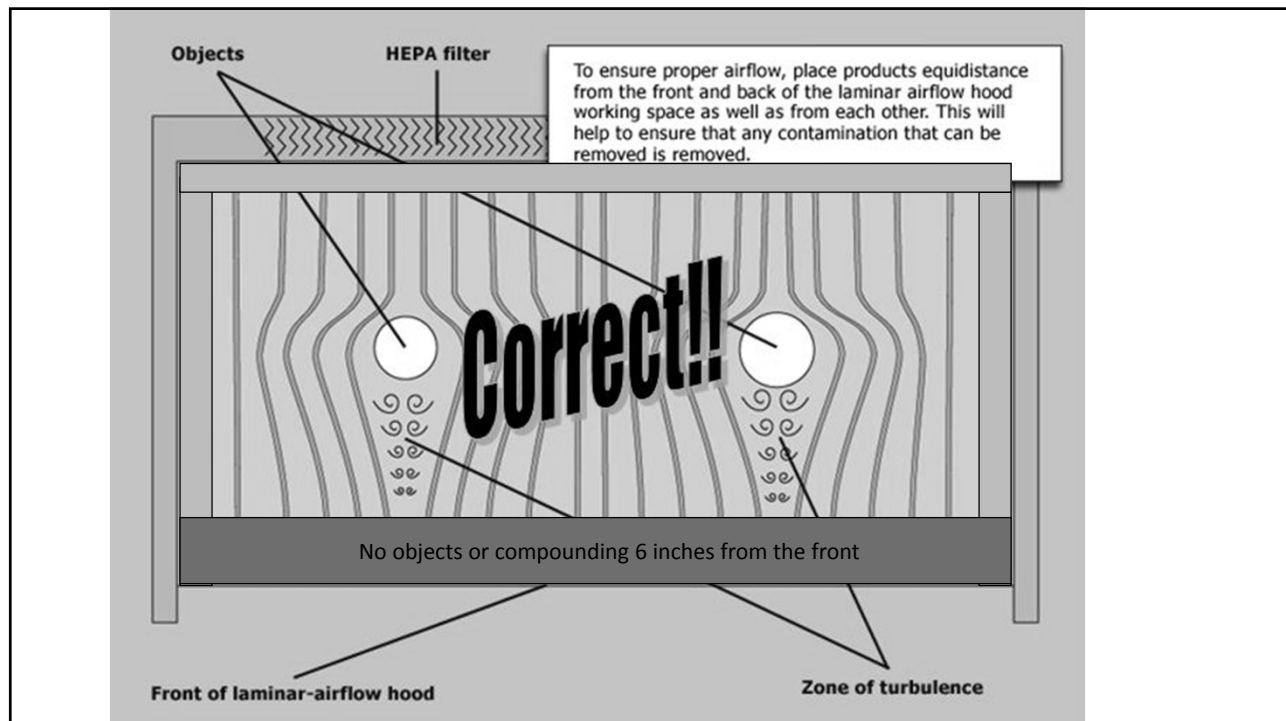
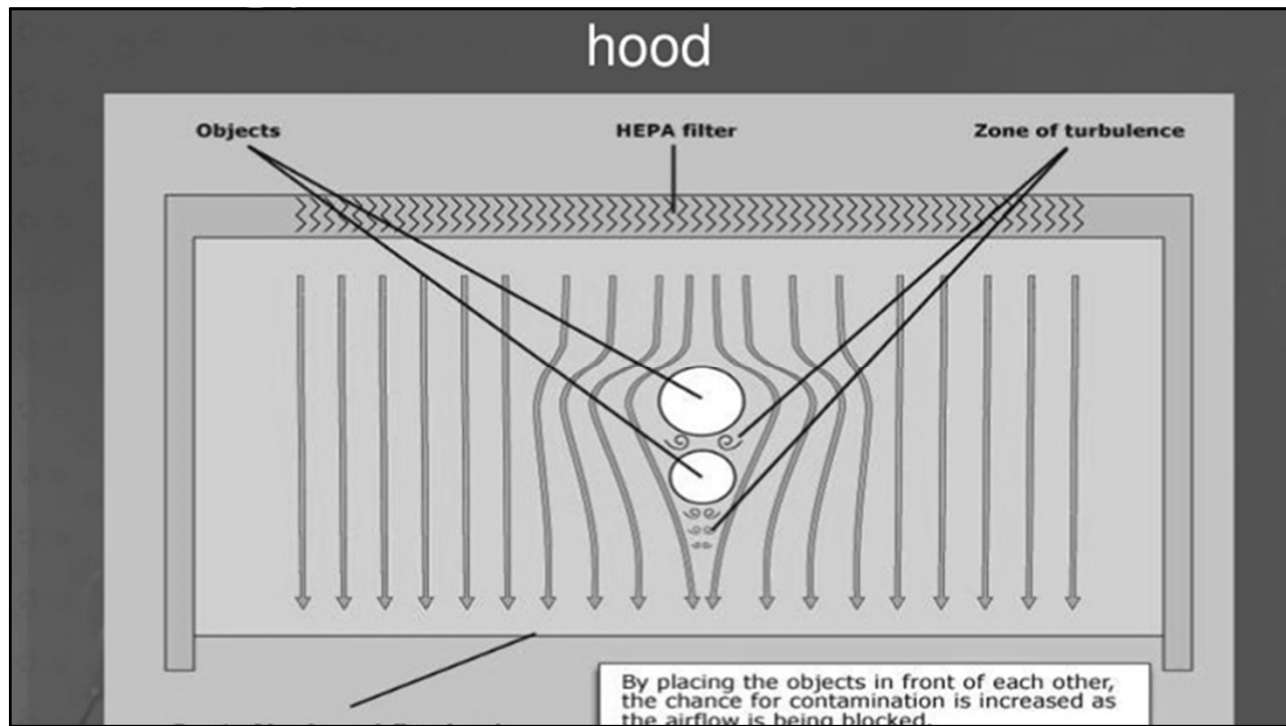
First air: The air exiting the HEPA filter in a unidirectional air stream.

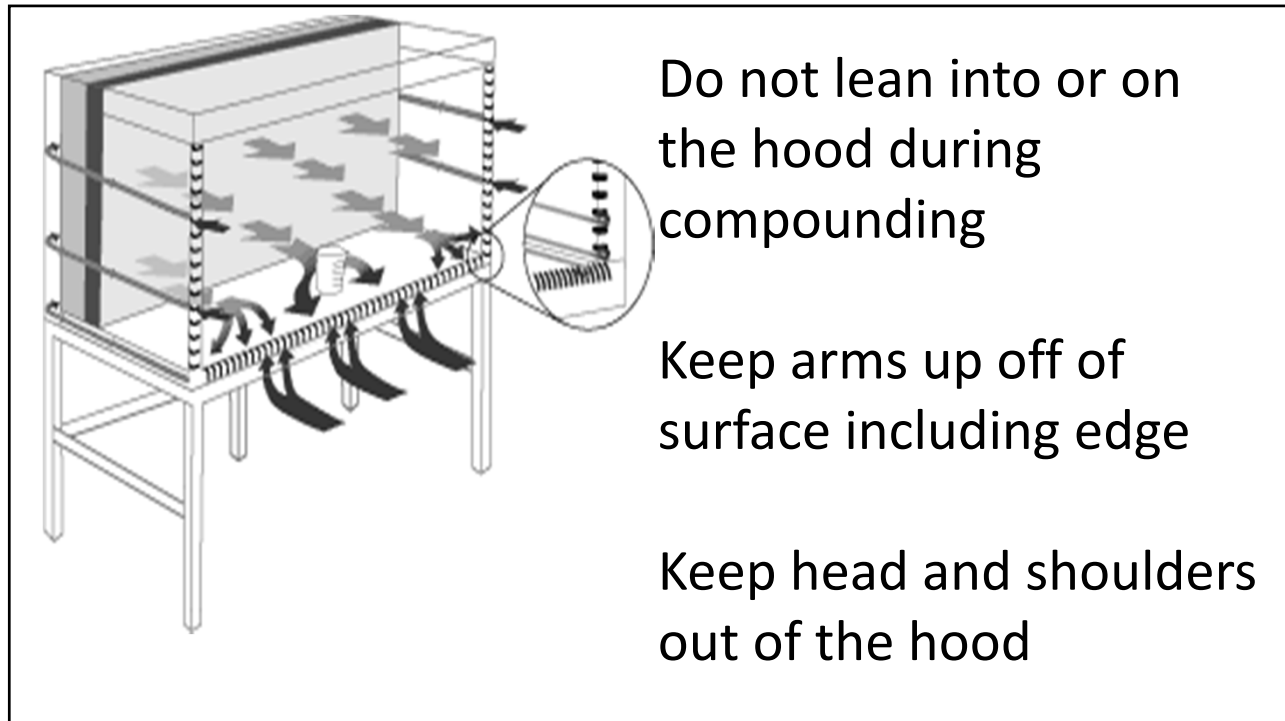
Be aware of CRITICAL SITES

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



Critical site: A location that includes any component or fluid pathway surfaces (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.





Touch Contamination is the #1 Cause of Contamination

Avoid touching all critical points including:

- Vial Stoppers
- Ampule necks
- IV bag ports
- Syringe tips
- Needles- all parts
- Transfer devices
- Dispensing pins
- Syringe connectors
- Tubing connectors



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.

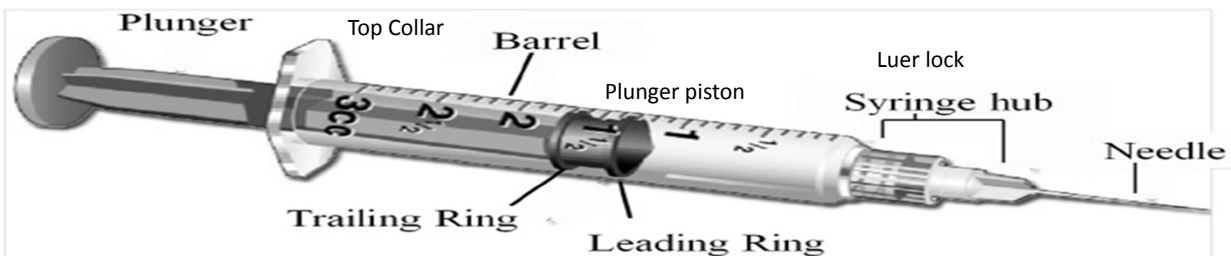
Remember the 4 D's :

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



Proper Syringe Selection

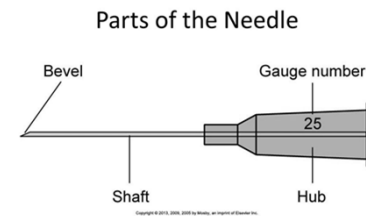
- To maximize accuracy, use the smallest syringe that can hold the amount of solution needed
- The measured dose is at the leading ring on the plunger piston
- Do not use the same syringe more than 5 times for a single compounded dose
- Use the 80% rule: When dispensing syringes, it is a good practice to only fill the syringe to approx. 80%, to avoid plunger drawbacks.



Selecting the proper needle

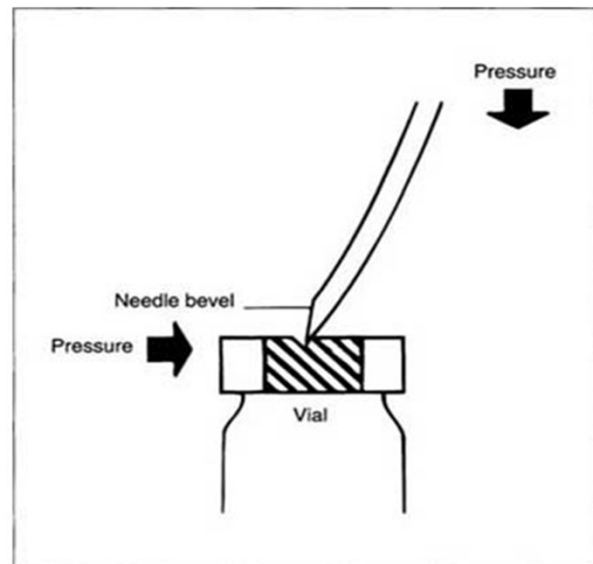
- Do not use the same needle more than 3-5 times

SYRINGE	NEEDLE GAUGE	NEEDLE LENGTH
1ml, 3 ml, 5 ml	21 -20 G	1 inch
10ml, 20ml, 30ml,35ml,	18 – 19 G	1- 1 ½ inches
60 ml or viscous	16 G	1 ½ inches



Coring RISKS

- The development of a core or hole in the rubber of a vial
- To prevent coring insert needle as shown
- Insert the bevel tip first, then pressing downward and toward the bevel so the bevel tip and heel enter at the same point



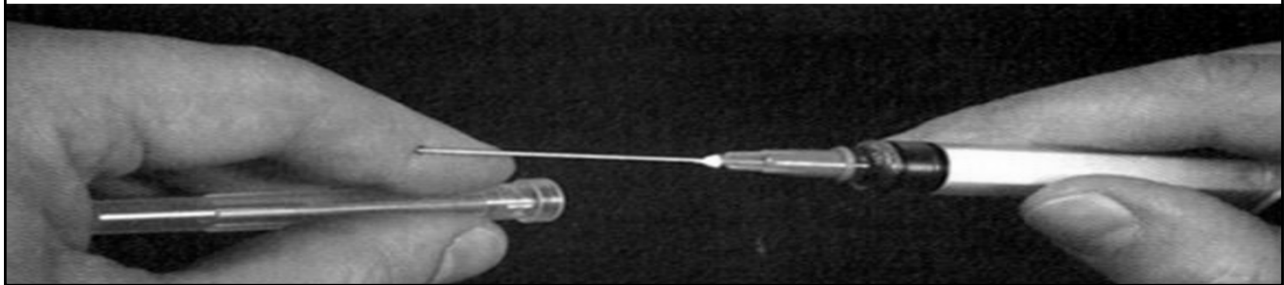
Risks

Needle Sticks

Avoid recapping needles

Use a one-handed scoop method if needed

Report to management, follow SOPs

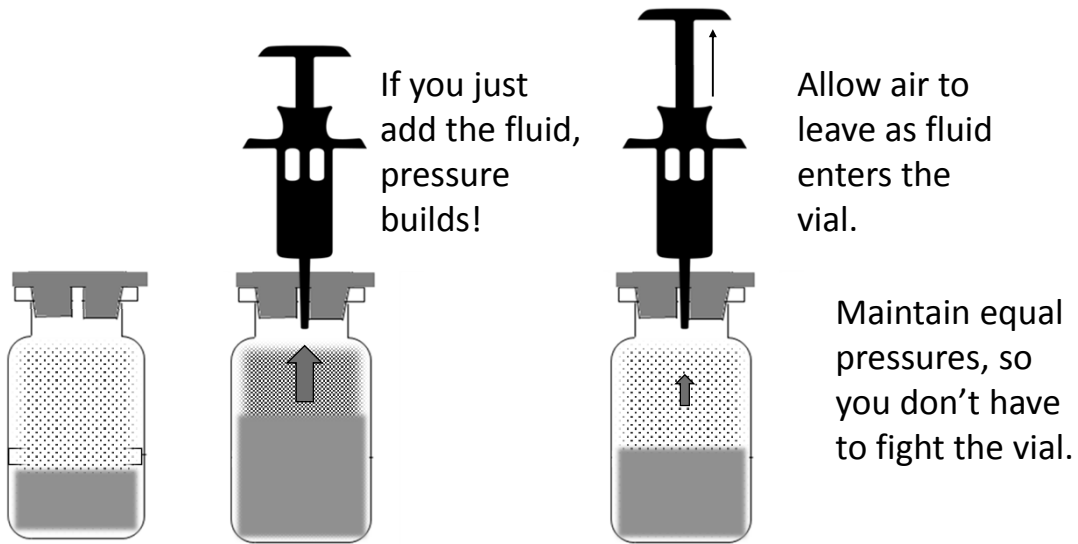


Vials and Ampules

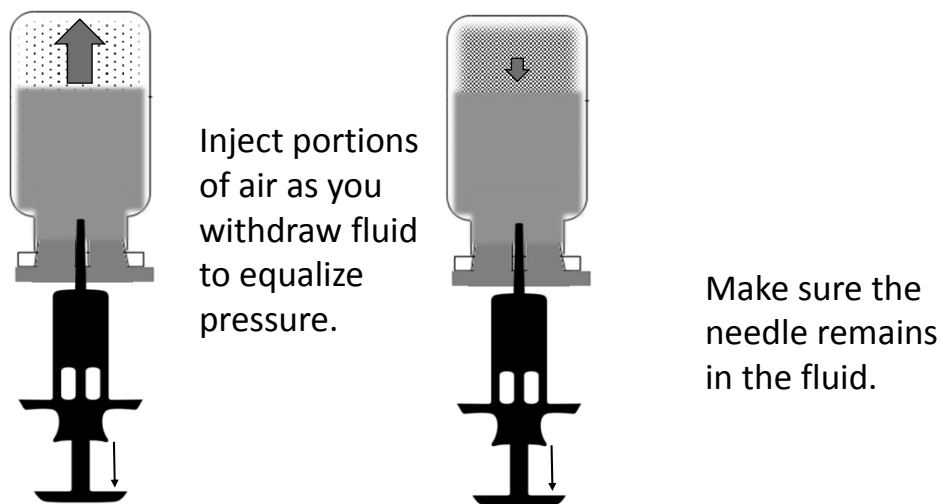
- Vials are closed system containers
- For easier injection and withdrawal of fluids from the vial, equalize the pressure in the vial to the pressure outside the vial
- Equalize the air pressure:
 - Inject air into the vial first before fluid withdrawal
 - For powdered drugs, inject the diluent, then withdraw an equal volume of air
- Ampules are usually made of glass
- Have a dot or stripe on the neck to indicate the weak spot for opening. Swab the neck, open to the side of the hood, away from HEPA filter. Use a filter needle



To inject fluid into a vial



To withdraw fluid from a vial



Best Practices for aseptic compounding

- 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). USP<797>
- Gather all items needed for the compound; place only items needed to complete the task in the ISO 5 PEC
- Inspect and wipe down supplies again when placing in ISO 5 PEC
- Keep distance ? between objects
- Swab vial stoppers with sterile 70% IPA swabs – 3 times away from the HEPA filter
- Open packages with the sterile supply facing the HEPA filter
- Avoid punching through paper packaging.
- Move trash to the side of the hood
- Avoid moving in and out of hood
- Sanitize gloves every time you leave the ISO 5 air

Section 8.2 Introducing Items into the PEC

USP <797> June 1, 2019

- 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.

FDA 483 – Pharmacy in Massachusetts

- On January 31, 2018, Pharmacy Technician (b) (6) was sterile processing TPN products in Hood (b) (4) RX# (b) (6). I observed that (b) (6) consistently put the top of her head (exposing the skin from her neck and face) into the hood along with parts of her shoulders. I also noted on February 1, 2018, an instance in which (b) (6) left the ISO 5 hood for supplies in the ISO 8 area and upon her return to the ISO 5 (b) (6) neglected to change and/or sanitize her gloves prior to entry into the ISO 5 Hood. (b) (6) had processed RX#'s (b) (6) (b) (6) that day.