A Visual Guide to USP Chapter <797>
Suggested Standard Operating Procedures

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Based on USP Chapter <797> effective June, 2008
**Personnel Related Suggested SOPs**

**SOP 9. Before entering buffer area, remove:**
- outer garments, makeup
- hand or wrist jewelry
- visible piercings

**Direct compounding area (DCA)**

**SOP 10.** Do not allow:
- gum, drinks, candy, food
- items from patient care/treatment in ante or buffer area

**SOP 10.* Don clean room garb**
- (Shoe covers, hair net, beard cover and mask)
- See note below

**SOP 11.* Wash hands and forearms with soap and warm water for 30 seconds.**
- Dry with hand dryer or non-shedding towel.

**SOP 12. When entering buffer area:**
- clean hands with waterless alcohol surgical scrub before
- don sterile gloves.

**SOP 13. Do not allow:**
- gum, drinks, candy, food
- items from patient care/treatment in ante or buffer area

**SOP 13.**
- before compounding:
  - clean PEC work surfaces with USP purified water;
  - disinfect with non-residue-generating agent and non lint wipe.

**SOP 14. Before compounding:**
- clean PEC work surfaces with USP purified water;
- disinfect with non-residue-generating agent and non lint wipe.

**SOP 15.**
- Keep primary engineering control (PEC) on at all times during compounding.
  - If PEC is off:
    - Allow only one person in buffer area to start and disinfect PEC.
    - Allow 30 minute start up period after PEC blower is started prior to compounding.

**SOP 16. Minimize traffic in the area of the DCA.**

**SOP 17. Wipe/spray outer surface with sterile 70% IPA or remove outer wrapper at edge of DCA before placing supplies into the DCA.**

**SOP 18. Arrange supplies efficiently to minimize clutter in DCA and maximize efficiency and workflow.**

**SOP 19. Arrange supplies in DCA to ensure first air at critical site.**

**SOP 20. All procedures performed to minimize touch contamination. Routinely disinfect gloves with approved disinfectant.**

**SOP 21. Disinfect all vial stoppers and ampoule necks with sterile 70% IPA for at least 10 seconds prior to use.**

**SOP 22. Ensure CSPs thoroughly mixed. Inspect all CSPs for particulate, incompatibility or other defects.**

**SOP 23. Remove supplies with minimum of entry/exit motion to reduce risk of contamination.**

**Note:** Actual garbing order in your facility may differ slightly, depending upon current ante-area layout and storage of garbing supplies (for example, you might don shoe covers before head covers). “Dirtiest to cleanest” as the general principal for garbing order.

**‡Placement of isolator within an ISO Class 7 area is dependent on the performance of the device.**
Product Related Suggested SOPs

SOP 1. Do not roll storeroom supply carts past ante area demarcation line without disinfection.

SOP 2. Place decartoned, decontaminated supplies onto disinfected cart for transfer to buffer area.

SOP 3. Store fast moving, decontaminated products on ante area shelving.

SOP 4. Do not roll storeroom supply carts past ante area demarcation line without disinfection.

SOP 5. Backup supplies may be stored on buffer area shelving.

SOP 6. Do not allow:
- cardboard
- pencils
- paper towels
- cotton or gauze in buffer area.

SOP 7. Wipe down and disinfect essential paper products before introduction to buffer area.

SOP 8. Avoid excessive supplies on buffer area shelving.

SOP 9. Do not allow:
- gum, drinks, candy, food
- Items from patient care/treatment in ante or buffer area.

SOP 10. Wipe down and place supplies used during compounding shift on rolling cart for introduction to buffer area.

SOP 11. Do not allow:
- gum, drinks, candy, food
- Items from patient care/treatment in ante or buffer area.

SOP 12. Do not allow:
- gum, drinks, candy, food
- Items from patient care/treatment in ante or buffer area.

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- gum, drinks, candy, food
- Items from patient care/treatment in ante or buffer area.

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