

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 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 work flow order.
- SOP 19. Arrange supplies in DCA to ensure first air at critical site.
- SOP 23. Remove supplies with minimum of entry/exit motion to reduce risk of contamination.

Laminar Airflow Workbench (LAFW), Isolator[†] (CAI/CACI) or Biological Safety Cabinet (BSC)

LAFW, CAI/CACI[†] BSC

Direct compounding area (DCA)

Laminar Airflow Workbench (LAFW), Isolator[†] (CAI/CACI) or Biological Safety Cabinet (BSC)

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

- 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

Work Table

Work Table

- SOP 1. Allow only qualified personnel permitted in compounding area.

- SOP 8. Minimize traffic in and out of buffer area.

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

Note: Shown as physical wall. In the case of low/medium risk compounding, could be line of demarcation (depends on meeting displacement airflow requirements)

Observation window

Buffer Area Supply Shelf

Observation window

Pass Thru with Interlocked Doors

Buffer Area Door

Garbing Supply Cart

Gowning Bench

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

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

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

STOCKROOM

Stockroom Supply Shelf

- SOP 9. Before entering buffer area, remove:**
- Outer garments, makeup
 - Hand or wrist jewelry
 - Visible piercings

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

Line of demarcation

Lint free towel dispenser

Hand sink

Garbing Supply Cart

Supply Shelving

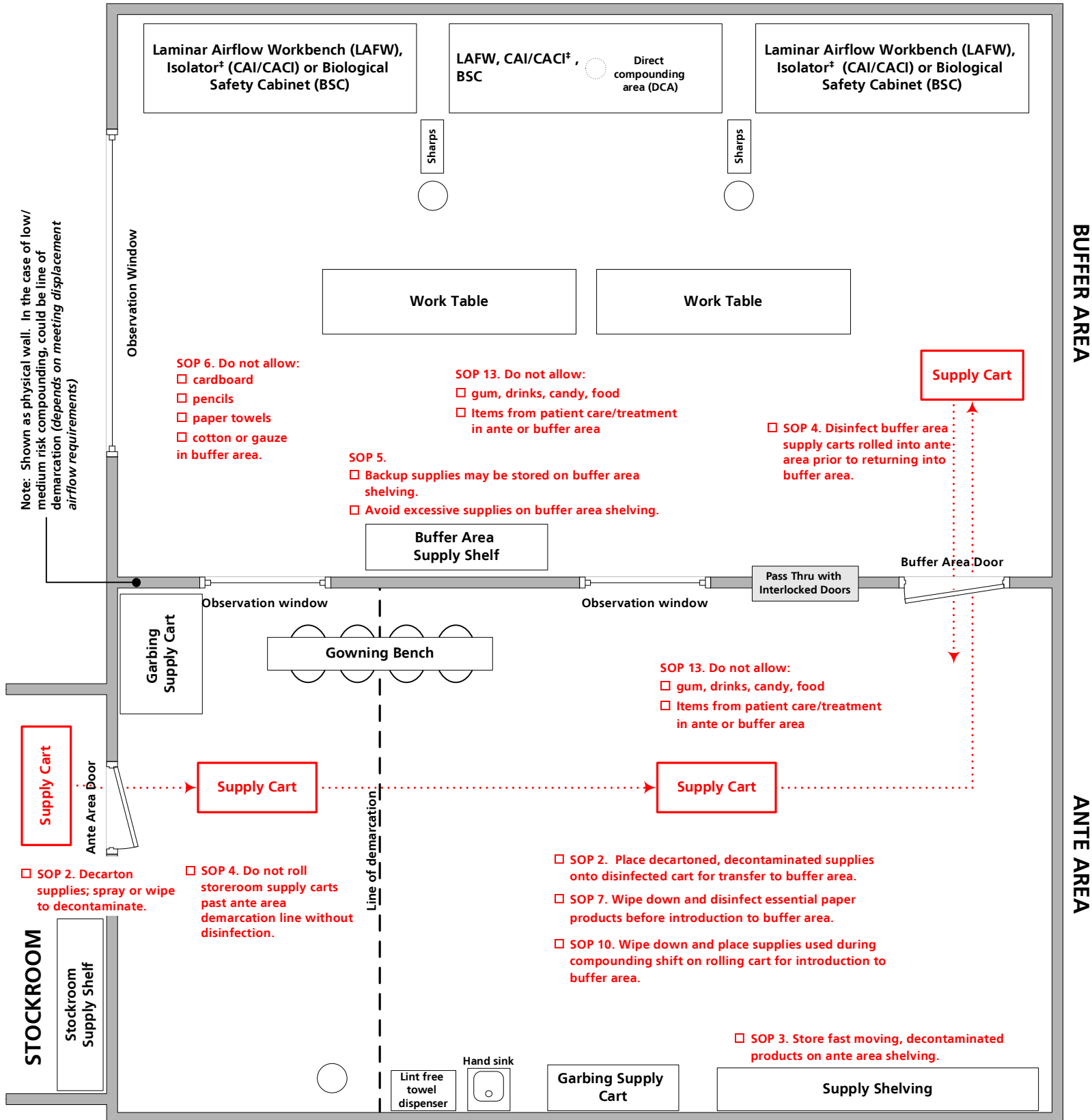
BUFFER AREA

ANTE AREA

*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



[†]Placement of isolator within an ISO Class 7 area is dependent on the performance of the device

Procedures described have been adapted from *Revision Bulletin: USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations*, © 2007 The United States Pharmacopeial Convention. Please refer to the full text of USP Chapter <797> for complete Suggested Standard Operating Procedures.

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