

# Implications of USP 797 for Pharmacy Facilities Design



# USP 797 Guidelines

- USP 797 — Proposed Revisions (est. 2007), ISO 7 with ISO 5 Zone/work benches and anteroom
- Anteroom must be ISO 8 (**ISO 7 for Chemo**).
- Current Status — ISO 8 with ISO 5 work bench and anteroom

**Conclusion Build for Proposed Revisions**

# A “Cleanroom” is a Cleanroom if..

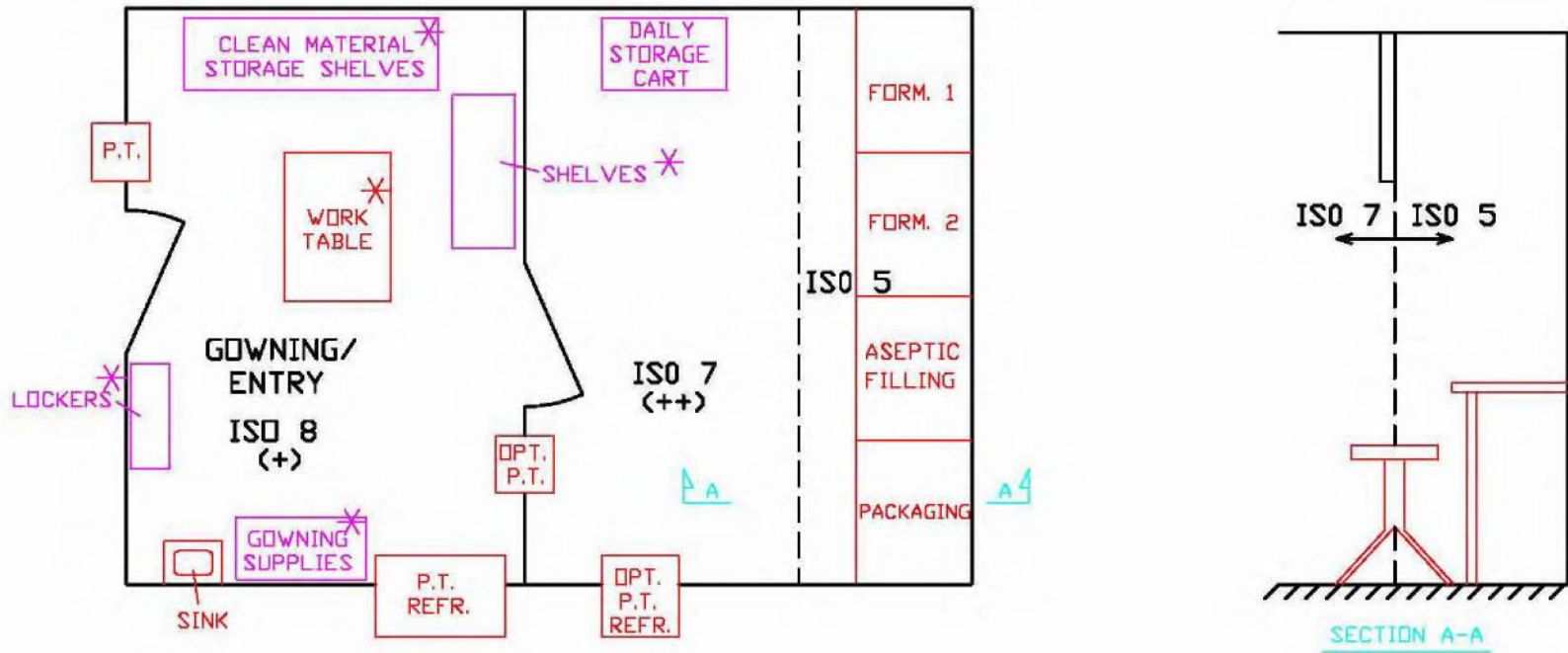
- Particle, Bio Burden, Temperature, Humidity and Pressure are **controlled and monitored**.
- Typically at least 0.05”WC pressure differentials are required.
- The Air Handling System is critical to the success of the clean room.
- It is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room. The main sources of particles are:
  - Make-up air supply
  - infiltration air
  - internal generation

# Why a Dedicated AH System is a “*MUST*”

**A Shared system can not meet the requirements because:**

- Typically not enough air changes available to control temp/RH/pressure
- You will disperse Pharmacy air throughout the building
- Filters will be filtering more dirty air, reducing HEPA life.

# TYPICAL IV PHARMACY



TYPICAL IV PHARMACY LAYOUT

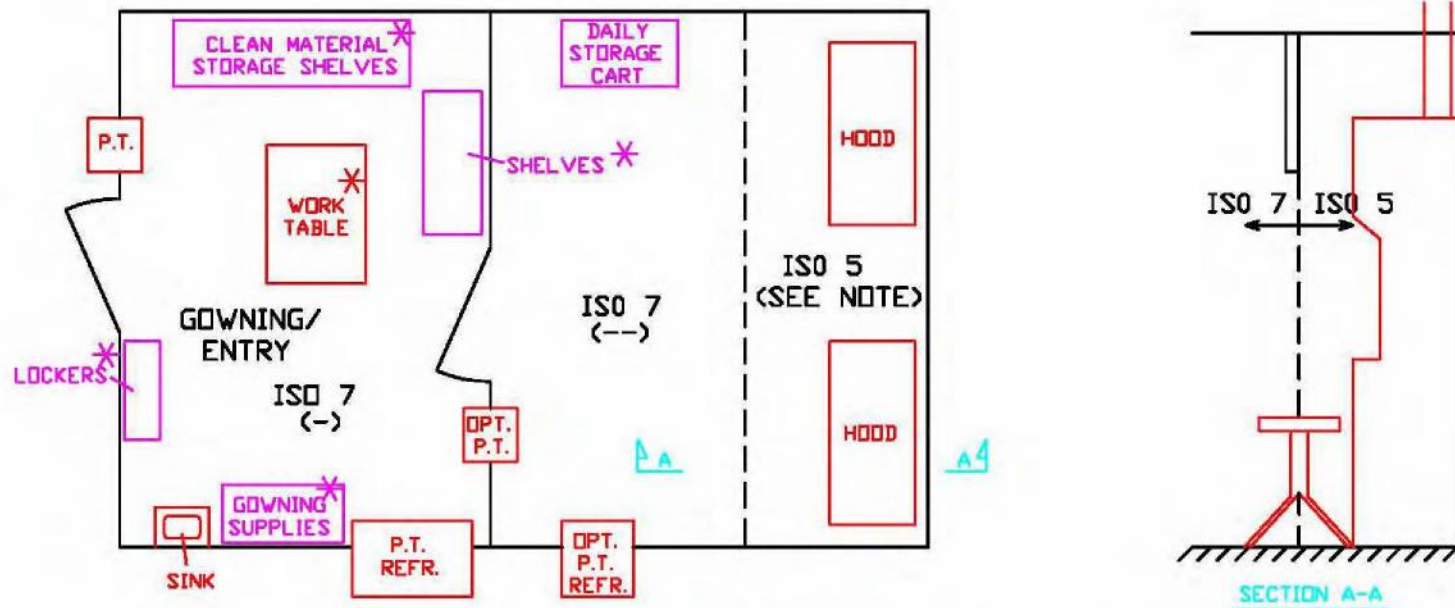
**ABBREVIATIONS:**

- P.T. PASS THROUGH
- P.T. REFR. PASS THROUGH REFRIGERATOR
- OPT. OPTIONAL
- SS STAINLESS STEEL
- FORM. FORMULATION

**SYMBOLS:**

- \* REMOVABLE W/CASTERS - SS

# TYPICAL NUCLEAR/ONCOLOGY/ CHEMO PHARMACY LAYOUT



TYPICAL NUCLEAR/ONCOLOGY PHARMACY LAYOUT

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**SYMBOLS:**

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**NOTE:**

ISO 5 ZONE IS OPTIONAL (NOT CURRENTLY REQUIRED BY USP 797).