

# Implications of USP 797 for Pharmacy Facilities Design



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# USP 797 - Guidelines

- Current Status – ISO 8 with ISO 5 work bench and anteroom
- 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**).

Ref: Dr. Christina Lee, USP

**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 cleanroom
- 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*”

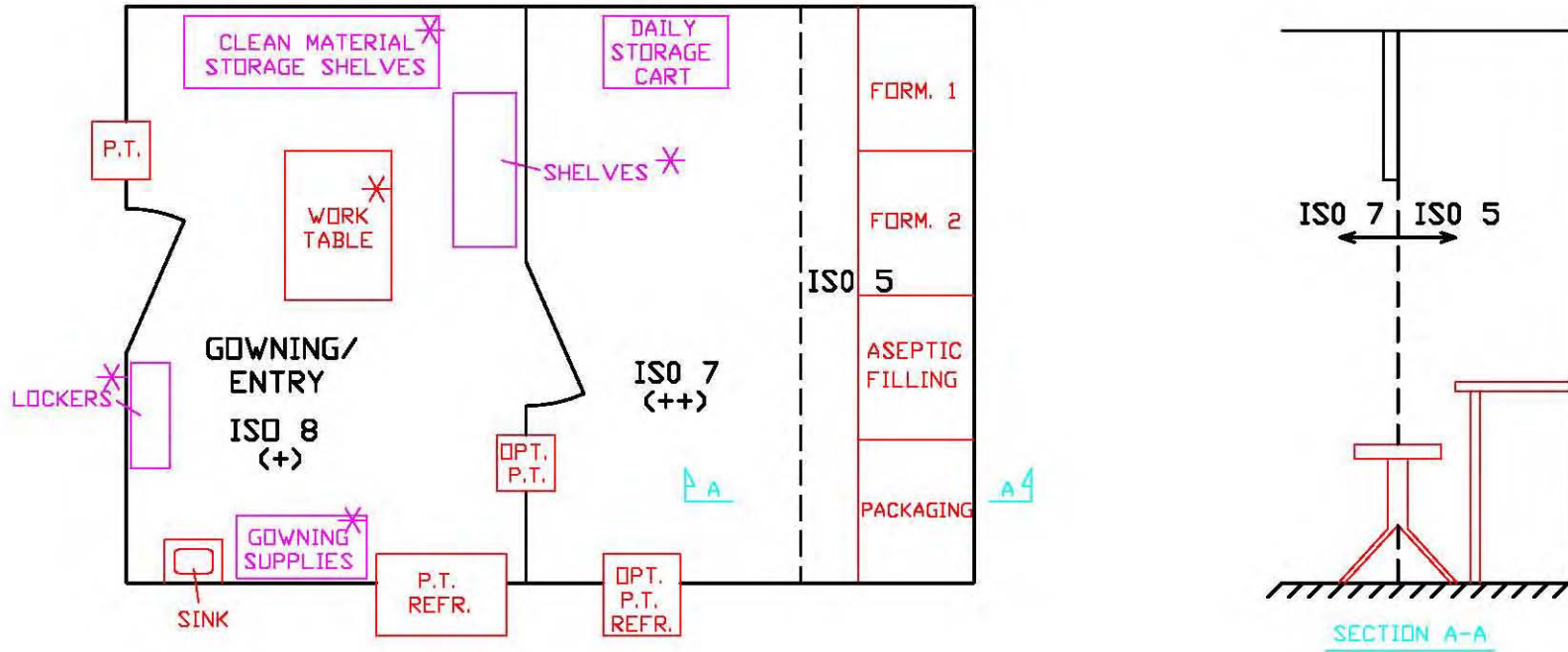
A Shared system can not meet the requirements because:

- Typically not enough air changes available
- Lose control of the T, H, P
- You will disperse Pharmacy chemicals/air throughout the building
- Filters will be filtering more dirty air, less useful life of HEPA's

# Technovation's Design Advantage

- Contiguous Class 5 Environmental Zones created in Class 7 Room for **improved productivity**.
- **No restrictive Flow Benches or Isolators** are required.
- Bactericidal BioPlus® HEPA's **ensure low bio burden**.
- **Energy Efficient Design** – save about \$25,000 per year for every 500 ft<sup>2</sup> of cleanroom space – **without incurring initial cost penalty**.
- Technovation is a Design/Build firm specializing in Cleanroom – i.e. has **specialized knowledge regarding cleanroom design and construction**. General architects and construction companies do not have this knowledge – see our **Design/Build Application Notes**.

# TYPICAL IV PHARMACY



TYPICAL IV PHARMACY LAYOUT

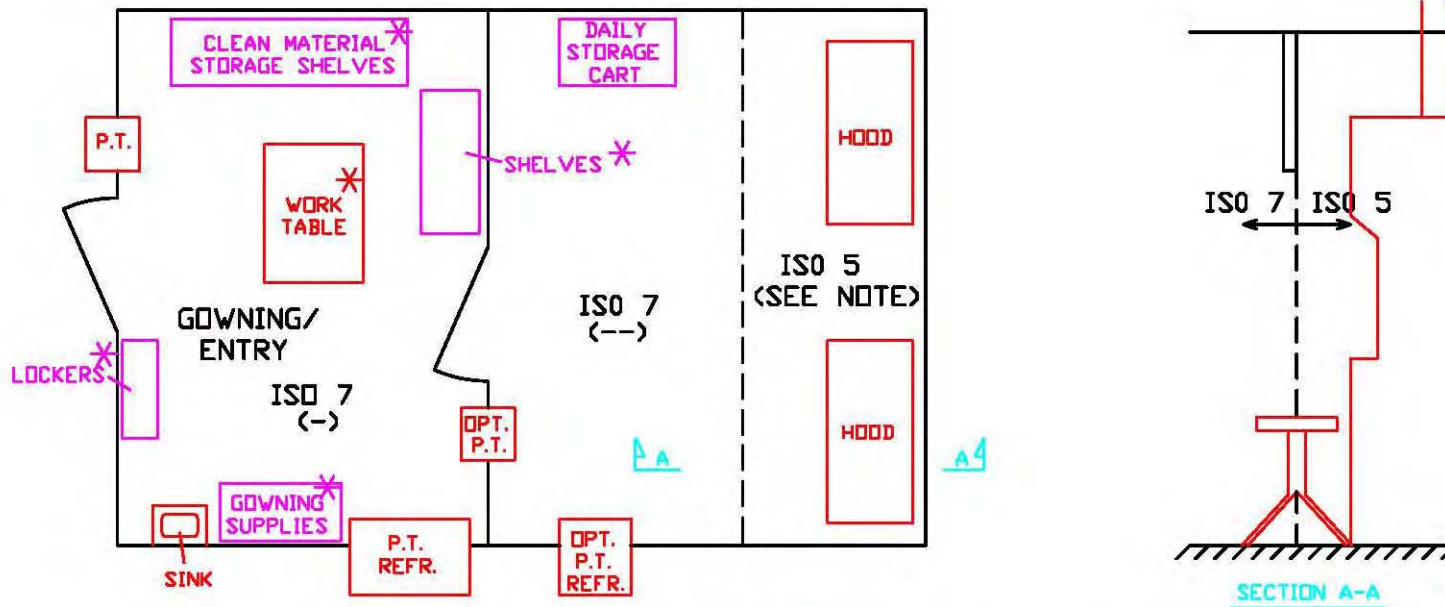
**ABBREVIATIONS:**

- 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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**NOTE:**

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

# Technovation Systems, Inc.

- A design/build engineering firm specializing in cleanrooms for Life Sciences, Biotech, Pharmaceutical and Hospital applications. ~ 100 Cleanroom projects completed
- Experienced in USP 797 facility requirements
- Currently designing USP 797 projects for **Walter Reed, MCV and all Bon Secours hospitals in VA.**
- A manufacturer of advanced energy efficient filtration/air handling equipment.
- Expertise in contamination control, particles science, fluid mechanics and engineering.



# Next Step – Phase I Design

- Technovation will assist your Hospital in the assessment of your pharmacies USP 797 compliance and potential cost.
- Coordinate meeting with Pharmacists to develop design specifications.
- Conduct field survey.
- Develop architectural and equipment layout.
- Define utility requirements.
- Develop budget cost.

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