Sterile/Non-Sterile HD and Sterile NHD Compounding Pharmacy

- Sterile HD Buffer: (-0.01 – 0.03) 12 ACH
- HD Storage: (-0.01 – 0.03) 12 ACH
- Sterile HD Buffer: ISO 7 (-0.01 – 0.03) 30 ACH
- Ante Room: ISO 7 (+0.02 – 0.05) 30 ACH
- NHD Buffer: ISO 7 (+0.02 – 0.05) 30 ACH

- Monitor: Pressure, Temperature, Humidity, Air Changes

Pharmacy

LAFW or CAl

RM

BSC II or CACI

RM

RM

LAFW or CAl

CRC
CRITICAL ROOM CONTROL
The revisions to <795> and <797> published on June 1, 2019 and which make reference to <800>, have been postponed until further notice, pending resolution of appeals of those chapters. Although these revisions have been postponed, <800> will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP continues to encourage early adoption and implementation of <800> to help ensure a safe environment and protection of healthcare practitioners and others when handling hazardous drugs.

- usp.org updated 27-Sept-2019
USP Updates – 2019

• Removal of door sweeps in USP 800
  • Ability to clean and decontaminate
• Pass through between HD areas no longer allowed
  • No pressure relationship defined and leak rates
• Pressurization changed in Ante and non HD sterile, +0.02 to no max
Pharmacy USP<795><797><800>

- Synchronization of all local displays
- Temperature and Humidity
- Meet ventilation requirements
- Ensure pressure relationships
  - ANTE Positive
  - USP 800 Hazardous Drug – Negative
  - USP 797 Sterile Compounding - Positive
- Tracking Pairs in each space
- USP 800
  - 100% Exhaust, typically through BSC constant volume
- Direct Pressure or Volumetric Control?
USP 797 Pharmacy Lab – Case Study #1

Initially, all doors had sweeps and frame seals

**Code requires that rooms must remain properly pressurized when any single door is opened**

Problems:
- Pass-through window in Workroom caused Gowning to drop in pressure
- When opening up Chemo Compounding the Gowning-Ante door would go neutral
- Spaces were too tight, a change in 50 cfm was causing large swings in dP

Remove door sweeps
- Decreased offset to be more neutral
- Increased supply offset

Architecture – Engineering Coordination
- Beware of pass through windows and refrigerators – how are they sealed? Include room pressure monitors, and detail locations

Engineers – leave capacity on the terminal units for Cx fine tuning during the certification process
Equipment for Critical Environments

- Air terminal devices
  - Repeatable and reliable – Difficult to get above ceiling
  - Many pharmacies operate 24/7
  - Energy requirement
- Pressure Monitor
  - Repeatable and reliable – continuous monitoring required
  - Accuracy, cleaning, calibration
- Room Display
  - Local environmental controls display for user of space
- Sensors
  - Accuracy, 1%, 3%, 5%....
  - GMP?
Desired outcome

- Touchscreen monitors and controllers
  - Safe working environments with clear indication of lab status
  - Easy to use, setup, and modify
  - Automated sequencing and procedures

- Energy efficient low pressure drop closed loop air valves
  - Lower first cost installation
  - Lower life cycle cost
    - Energy usage
    - Reduce maintenance

- Simple integration with BAS allows for greater system metrics and access to critical information

- Comprehensive solution for pharmacy space

- Safe Working Environments
- Energy Efficient Sequencing
- Reduced Maintenance
- Improved User Experience
- Automate Pressure Control Sequences
Healthcare Design

PHARMACY

SURGICAL SUITE

MODE: OCCUPIED OR

AUTHORIZED PERSONNEL ONLY

ROOM: 70°F, ROOM HUMIDITY: 46%, ROOM PRESSURE: 0.025" WC, AGE: 21 AOI

CRITICAL ROOM CONTROL
Isolation Patient Room

- Meet ventilation requirements
- Ensure pressure relationships
- Airborne infectious isolation
  - Negative room
  - Negative pressure to adjacent spaces
- Protective environment
  - Positive Room
  - Positive/Negative Pressurization of Ante?

Direct Pressure or Volumetric Control?

Local, permanent continuous monitoring of room
Operating Room

- Ensure proper pressure relationships:
  - Operating Room to Main Corridor
  - Operating Room to Sterile Corridor

- Unoccupied ACH to save energy;
  - Number of air changes can be reduced; pressure relationship to adjoining spaces must be maintained.

- Synchronization of all local displays:
  - Outside Main Corridor and inside the suite
  - Coordinate where they are installed

- Direct Pressure or Volumetric Control?
Energy Savings – Occupied / Unoccupied

• Reduce air changes
  • Reduction up to 70%
• Adjustments to temperatures
• Scheduled, automatic or manual setback?
• Is an unoccupied room with reduced ACH unsafe?
  • Environmental controls?
  • Intended use?

Clear indication of room status when changing environmental controls

Continuously monitor pressure and ability to alarm
Occupant Comfort

• **Occupant Options**
  • Ability to adjust temperature?
  • Ability to adjust humidity?
  • Clear unambiguous indication of status
    • Mode
    • Pressurization
    • Temperature
    • Humidity
    • Air Changes
Questions?