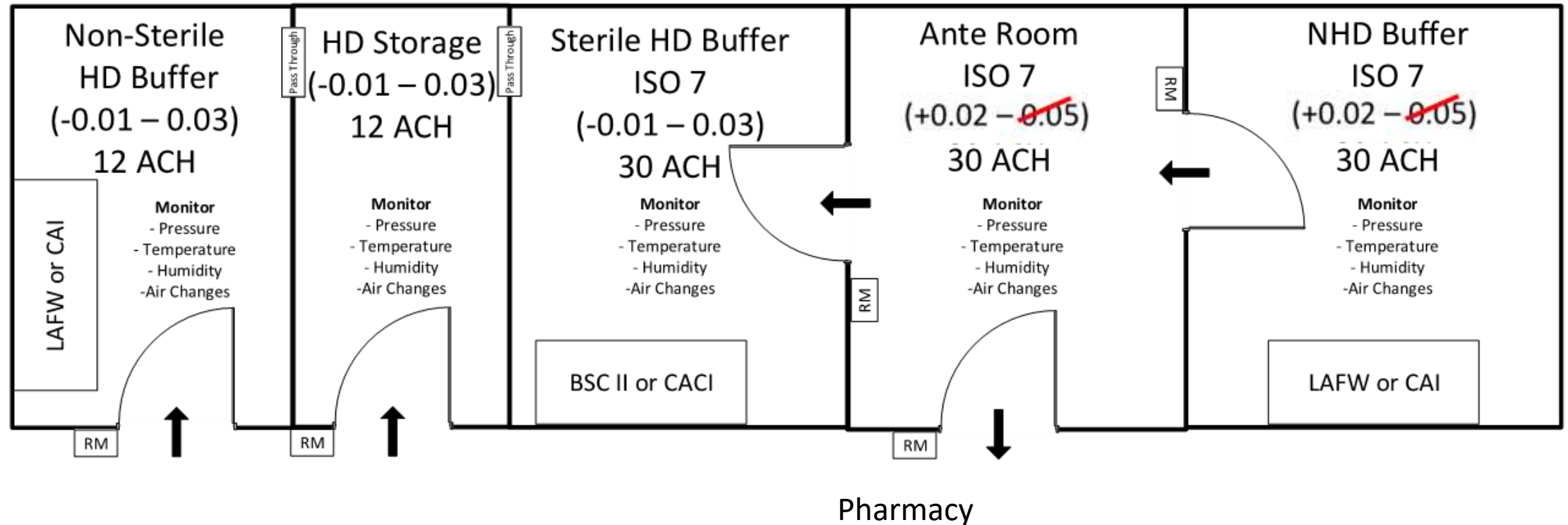


Sterile/Non-Sterile HD and Sterile NHD Compounding Pharmacy



USP Updates – 2019

*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.*

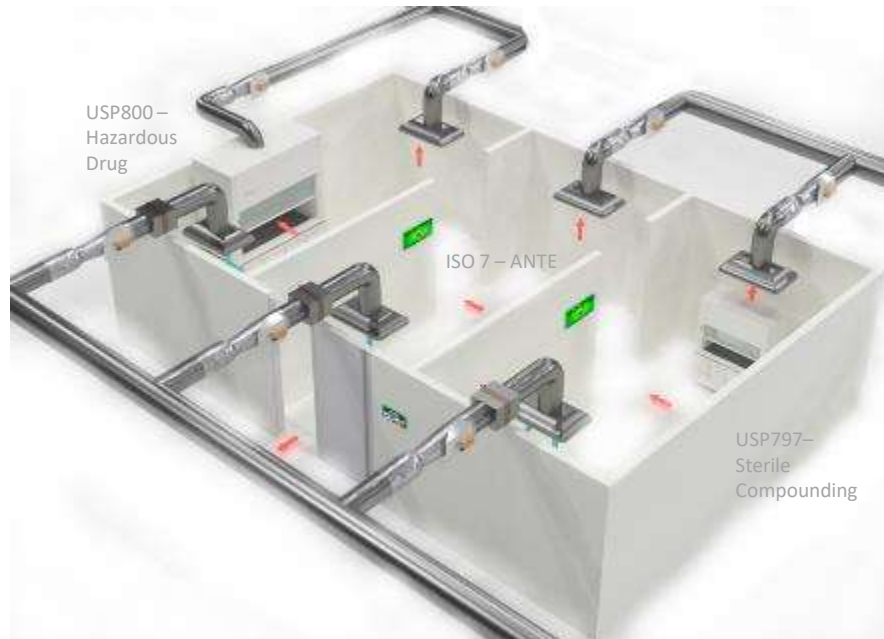
- usp.org updated 27-Sept-2019

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

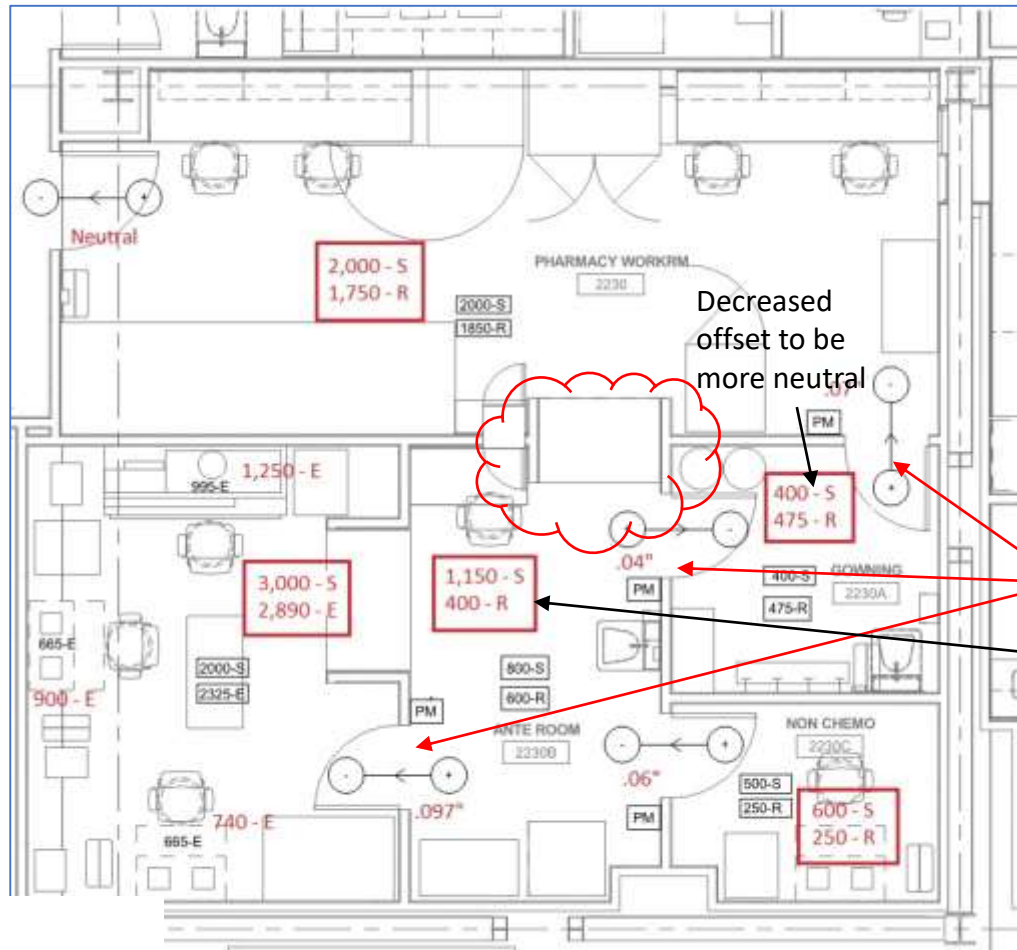


Pharmacy USP<795><797><800>



- 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

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

Remove door sweeps

Increased supply offset



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



Grumman/Butkus Associates
<http://grummanbutkus.com>
Energy Efficiency Consultants and Sustainable Design Engineers

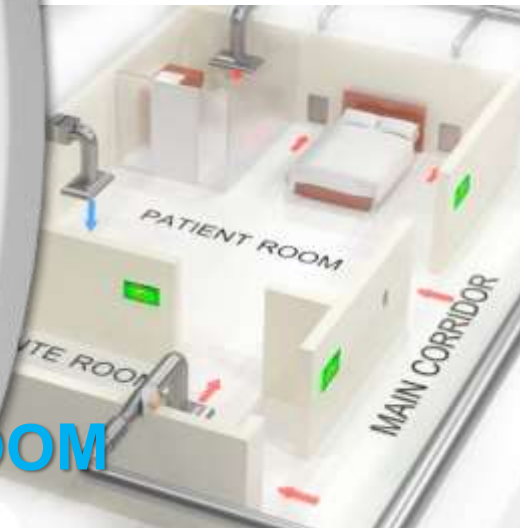
Equipment for Critical Environments

- 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?

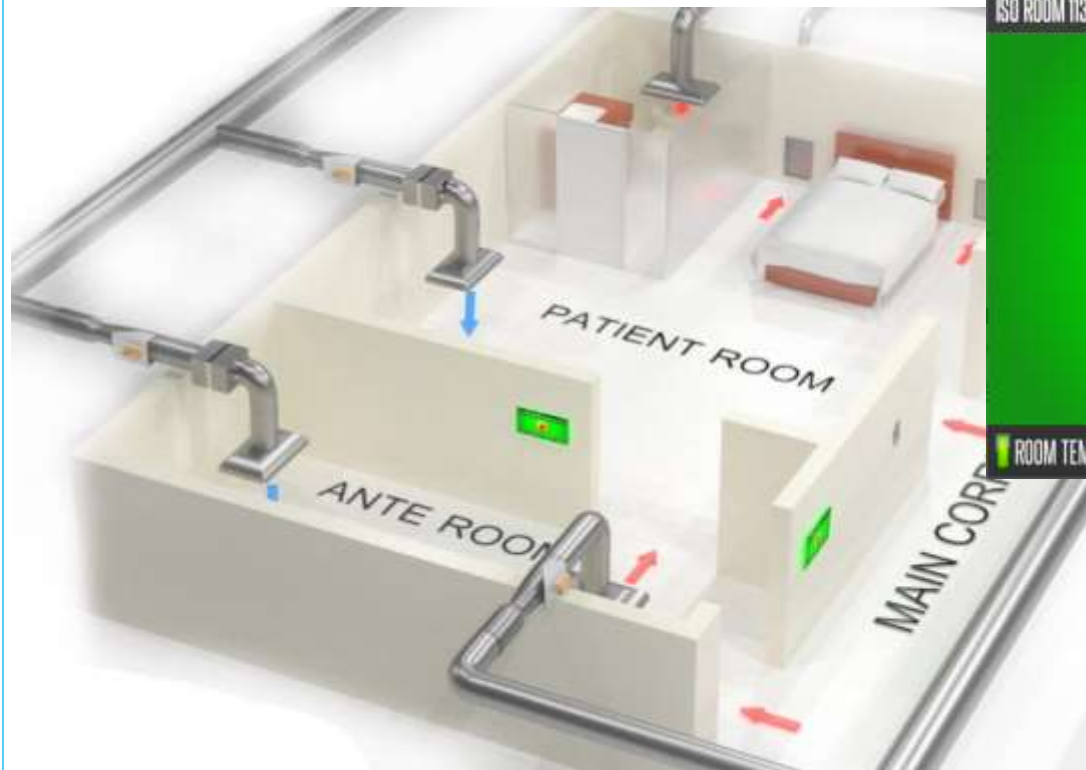
Desired outcome

- 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



Isolation Patient Room



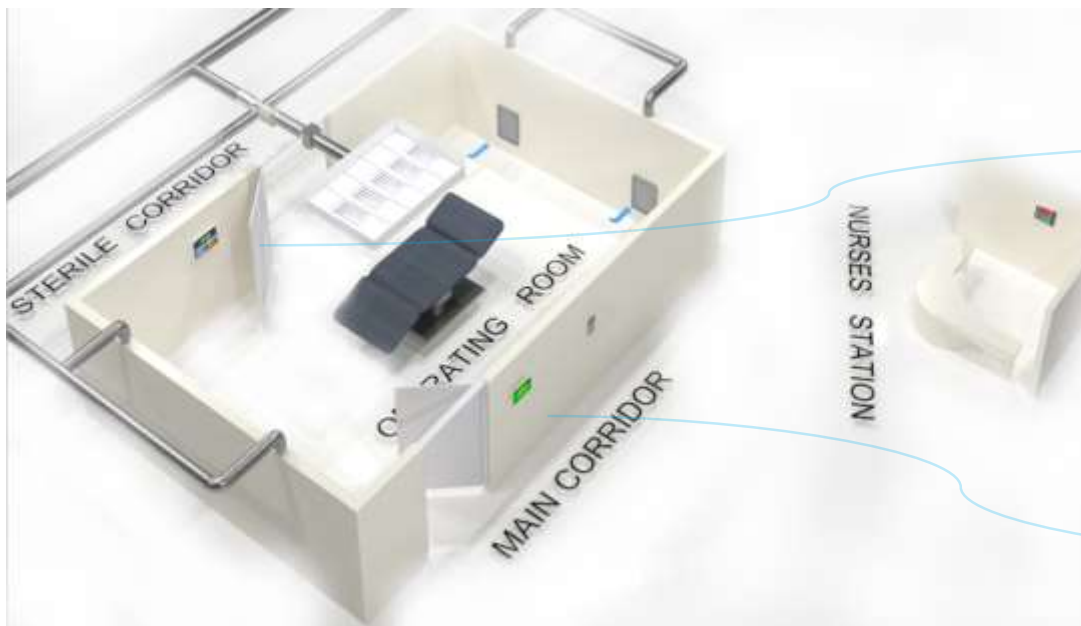
- Meet ventilation requirements



- Negative room
- Isolation spaces
- Isolation Room
- Positive/Negative
Control?

Local, permanent continuous
monitoring of room

Operating Room



- Ensure **proper**
 - Operate
 - Operate
- Unoccupied
 - Number of personnel; pressure relationship to adjoining spaces must be maintained
- Synchronizing
 - Outside
 - Coordination
- Direct Pre

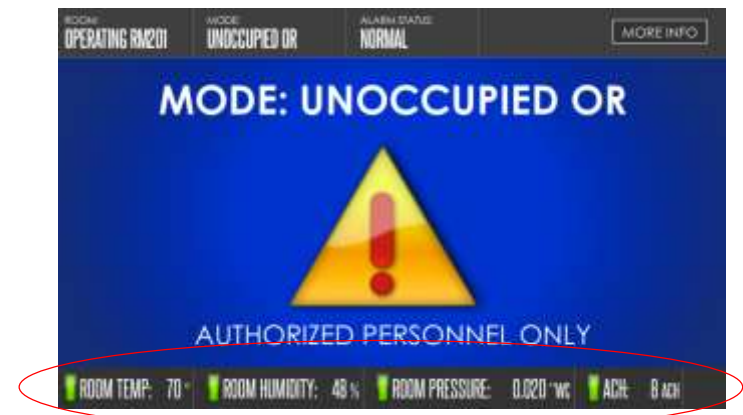


Energy Savings – Occupied / Unoccupied

- 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

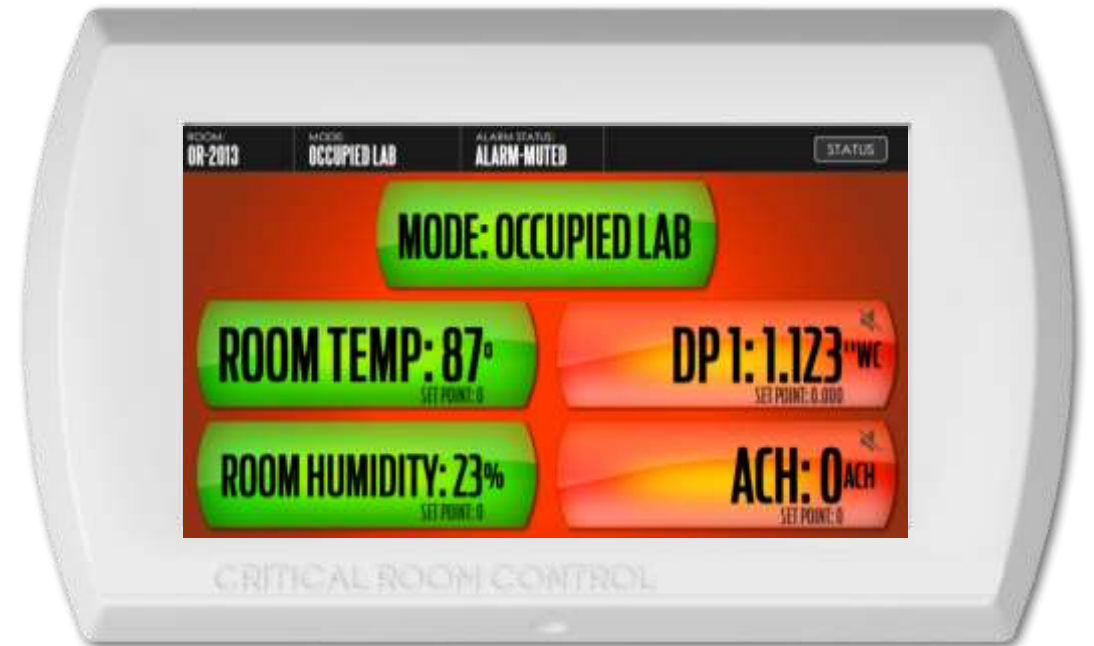


Continuously monitor pressure and ability to alarm

Occupant Comfort

- **Occupant Options**

- Ability to adjust temperature?
- Ability to adjust humidity?
- Clear unambiguous indication of status
 - Mode
 - Pressurization
 - Temperature
 - Humidity
 - Air Changes





Questions?