

## Compounding Area type:

- Cleanroom Suite: Sterile HDs and non-HDs
- Cleanroom Suite: Sterile HD only
- Cleanroom Suite: Sterile HDs only
- Segregated Compounding Area
- Containment-Segregated Compounding Area

Item	YES	NO	Notes
<b>1. Room Identification</b>			
Each room type for sterile compounding is identified (HD buffer, non-HD buffer, ante-room, etc.)			
Room square footage for rooms associated with sterile compounding is calculated and documented			
PEC types and locations documented			
Room occupancy is determined and maintained			
<b>2. Air Change Rates</b>			
Meets or exceeds ASHRAE 170 minimum ACH for cleanrooms (USP has ACPH)*			
Supply airflow measured and documented			
Total ACPH (supply + infiltration) validated			
Return air &/or exhaust airflow matches design requirements			

\*ACH = Air Changes per Hour or as in USP ACPH

Item	YES	NO	Notes
<b>3. Pressure Relationships</b>			
Non-HD sterile buffer is positive to ante-room by at least 0.02”W.C			
HD sterile buffer is negative to ante-room within the range of -0.01 to -0.03”W.C.			
Pressure gradient is in place from buffer rooms to the anteroom			
Continuous pressure monitoring installed			
Pressure alarms tested and functioning			
<b>4. Filtration Requirements</b>			
Upstream filtration meets ASHRAE 170 (MERV 14+)			
Terminal HEPA filters installed In the ceiling terminal - ISO-class rooms			
HEPA integrity testing performed at least every 6 months on certification (per IEST RP-12/USP)			
Pre-filters to room HEPA filters are accessible and changed on a maintenance schedule			
<b>5. Exhaust System (HD Rooms Only)</b>			
Exhaust is 100% to outdoors			
Ducts for exhaust are sealed or welded and negative pressure			
Exhaust fan meets ANSI/AIHA Z9. 5-2003 for stack height and Location to building air intake			
A failure detection system is in place for the HD exhaust			
The HD exhaust system has a redundancy system in place			

Item	YES	NO	Notes
<b>6. Temperature &amp; Humidity Control</b>			
Temperature maintained per design (often < 20°C for HD)			
Humidity < 60% RH (typical) is maintained per design			
Temperature and humidity sensors are calibrated at least annually or per manufacturer specifications			
<b>7. Airflow Patterns &amp; Distribution</b>			
Supply diffusers positioned for uniform airflow			
No turbulence-generating obstructions			
Returns low on the wall in HD rooms			
PECs not blowing against diffuser streams or blocking			
<b>8. Monitoring &amp; Controls</b>			
Building Monitoring System or standalone environmental monitoring			
Alarm thresholds are set to USP defined specifications for sterile compounding			
Trend logs available and demonstrate documentation of the compounding environment and out of specification events.			
Calibration logs maintained and documentation demonstrates calibration of all environmental monitoring equipment annually or to manufacturer specifications.			

Item	YES	NO	Notes
<b>9. Commissioning &amp; Ongoing Verification</b>			
HVAC system commissioned to ASHRAE 170 parameters			
Semi-annual cleanroom certification is performed by a CETA certified third party certification technician.			
Deviations to defined compounding environment specifications corrective actions are documented.			
SOPs updated when the HVAC unit is updated or changed to reflect changes in the defined specifications.			