

SECs

Test	Present?	Significant Issues?	Comments
A - Airflow Measurements (ACPH)	Yes	Yes	<i>Calibration dates are acceptable, but "Nov. 2022" is ambiguous: Nov 1 or Nov 30? If the former, it is only five days after this certification: also, is it likely that all these dates are the same?</i>
			<i>Conflicting reporting of ceiling heights. Diagram and Anteroom reported as 9', but the two buffer rooms are reported as 10' and 11'. Significant effect on calculations, but assuming actually 9', this only increases ACPH. Suggest that pharmacy provide actual room measurements to allow resolution of this concern.</i>
B - HEPA Integrity (Leak) Testing	Yes	Partial	<i>Equations shown, but not actual calculations as required.</i>
			<i>Method of aerosol introduction, e.g. ceiling or wall ports, can be inferred from diagram, but should be reported.</i>
			<i>Method of upstream concentration determination is not reported.</i>
C - Total Particle Counts	Yes	No	<i>Calculations based upon the average, not the maximum particle counts. However, when correct calculation performed, ISO classification is still met.</i>
			<i>Number of workers not stated as required, simply "Operational (dynamic) testing performed in conditions outlined by the client."</i>
			<i>Number of samples taken in each room are slightly below suggested numbers.</i>
D - Pressure Differentials	Yes	Partial	<i>Readings are >15% different than those recorded for pharmacy manometer. This should have been noted and discussed with leadership.</i>
E - Temperature and humidity*	No	No	<i>Not reported, but this is an optional service.</i>
F - Viable Air Sampling - Testing	Yes	Partial	<i>Number of samples per room (one) is lower than a best practice recommendation of approximately four per room.</i>
G- Viable Air Sampling - Results	Yes	No	
H - Smoke Study (initial and as needed)	N/A	N/A	
I - Surface Sampling (if performed)	Yes	Partial	<i>Number of samples per room (one) is lower than a best practice recommendation of approximately four per room.</i>
J - Surface Sampling - Results (if performed)	Yes	No	

* *Optional but often done*

PECs

Laminar Airflow Workstations (LAFWs)

Test	Present?	Significant Issues?	
A - Dynamic Airflow Smoke Pattern Tests	Yes	Partial	<i>Direct compounding area not specifically identified as required.</i>
			<i>Simulated compounding not stated as occurring</i>
B - Airflow Velocities	Yes	No	
C - HEPA Filter Integrity Test	Yes	No	
D - Induction Leak / Backstream Tests	Yes		
E - Dynamic Total Particle Count Test	Yes		
F - Viable Air Sampling - Testing	Yes	Yes	<i>Report does not verify that conducted under dynamic conditions</i>
			<i>Number of samples per PEC (one) is lower than a best practice recommendation of approximately three.</i>
G - Viable Air Sampling - Results	Yes	No	
I - Surface Sampling (if performed)	Yes	Partial	<i>Number of samples per PEC (one) is lower than a best practice recommendation of approximately three.</i>
J - Surface Sampling - Results (if performed)	Yes	No	

Biological Safety Cabinets (BSCs)

Test	Present?	Significant Issues?	
A - Dynamic Airflow Smoke Pattern Tests	Yes	Partial	<i>Direct compounding area not specifically identified as required.</i>
			<i>Simulated compounding not stated as occurring</i>
B - Downflow Velocities	Yes		
C - Inflow Velocities	Yes		
D - Airflow Smoke Pattern Tests	Yes		
	1 - Downflow Test	Yes	
	2 - View Screen Retention Test	Yes	
	3 - Work Opening Edge Retention Test	Yes	
	4 - Sash Seal Test	Yes	
E - HEPA Filter Integrity Test	Yes		
F - Site Installation Assessment Test	Yes		
G - Dynamic Total Particle Count Test	Yes	Partial	<i>Simulated compounding not stated as occurring</i>
H - Viable Air Sampling - Testing	Yes	Partial	<i>Number of samples per PEC (one) is lower than a best practice recommendation of approximately three.</i>
I - Viable Air Sampling - Results	Yes	No	
I - Surface Sampling (if performed)	Yes	Partial	<i>Number of samples per PEC (one) is lower than a best practice recommendation of approximately three.</i>
J - Surface Sampling - Results (if performed)	Yes	No	