

NVBOP – Primary Engineering Controls Reference Information

Test	LAFW	BSC
Placement of Primary Engineering Control	Placed in ISO Class 7 buffer room with 0.02" w.c. positive pressure or greater. May also be placed in SCA.	Placed in ISO 7 buffer room with 0.01" w.c. or greater negative to anteroom. May also be placed in SCA but must still be negative to adjacent space.
HEPA Filter Leak tests	HEPA filters must be leak tested during each certification period (every 6 months).	HEPA filters must be leak tested during each certification period (every 6 months).
Airflow Pattern Smoke Test	Smoke study must be performed during each certification period (every 6 months) and must be performed under dynamic conditions. It is recommended that smoke study video is provided to the facility.	Smoke study must be performed during each certification period (every 6 months) and must be performed under dynamic conditions. It is recommended that smoke study video is provided to the facility.
Non-Viable Particle Counts	Particle counters capable of detecting 0.5 micron size particles are used to verify ISO class 5 conditions during each certification period (every 6 months). Particle counts must be performed under dynamic conditions.	Particle counters capable of detecting 0.5 micron size particles are used to verify ISO class 5 conditions during each certification period (every 6 months). Particle counts must be performed under dynamic conditions.

Test	CAI	CACI
Placement of PEC	Preferably room or area devoted to compounding. Proposed USP 797 requires placement in ISO 7 area for full beyond use dating.	Placed in ISO Class 7 that is negative to ante room. May be placed in C-SCA with at least 12 ACPH and negative to adjacent space.
HEPA Filter Leak Test	Same as LAFW	Same as LAFW
Airflow Smoke Pattern Test	Same as LAFW	Same as LAFW
Non-Viable Particle Counts	Same as LAFW	Same as LAFW

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.