Addressing Unique Challenges Influencing Contamination Control of Common Biocontainment Enclosures

by F. Grinstead and T. Grindrod
CURIS System

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Objectives

The wide variety of enclosures in use throughout biocontainment facilities present distinct design differences affecting implementation of gaseous biodecontamination systems. It is often assumed that high consequence, high concentration chemicals are necessary to ensure comprehensive contamination control processes. This study examines a compilation of studies performed at Pell Labs of Penn State University, Texas A&M, Virginia Tech, and Baker, which evaluated efficacy of low-level 7% gaseous cycles with a hybrid hydrogen peroxide biodecontamination system in treating common biocontainment enclosures, such as Class II A2 biological safety cabinets, Class III isolators, and filter banks.

Methods

The system chosen for these studies was an automated closed-loop device which connected up to the enclosures (Class II A2 BSCs, a Class III Isolator, and Filter Housings up to 270 feet long) via hoses with camlock couplings. Using the protocols already established within the closed-loop system, a total of thirty-two tests were completed across three different manufacturers and two sizes of Class II A2 BSCs (4 foot and 6 foot); three tests were completed on the Class III Isolator; and one test on each size of filter housing (10 foot, 12 foot, 32 foot, 50 foot, 72 foot, 110 foot, and 270 foot) was completed. The system's efficacy was examined by placing gaseous hydrogen peroxide chemical indicators (CIs) and biological indicators (BIs) (Geobacillus stearothermophilus, either 1.7 or 2.0 x 10^6) in various challenged locations throughout the enclosures including within the pleats on the upstream and downstream side of the HEPA filters when applicable. At the end of each treatment cycle, CIs were evaluated and recorded. BIs were aseptically processed and incubated at 59 degrees Celsius and observed according to manufacturer's instructions. Results were recorded.

Biological Safety Cabinets

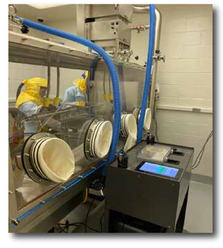
Manufacturer	BSC Sizes	Total # Tests	Total # BIs	# BIs Passed	#BIs Failed
NuAire	4' Class II A2	3 Taping	27	27	0
		3 Tenting	27	27	0
Germfree	4' cGMP Class II A2	3 Taping	27	27	0
		3 Tenting	27	27	0
Baker	4' Class II A2 SterilGARD (2 BSCs)	6 Taping	51	51	0
		10 Tenting	91	91	0
	6' Class II A2 SterilGARD	2 Taping	24	23	1*
		2 Tenting	24	24	0
Total Overall			277	277	1

Efficacy was tested throughout the various brands and sizes of BSCs noted in the table below. Biodecontamination of each BSC was tested via two different methods of sealing—tenting and taping. For each test, BIs and CIs were placed in the following locations:

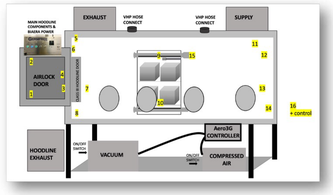
- On the Work Surface
- Under the Work Surface
- Filters and Plenum
- NSF Standard Locations

*BI was placed on Control Panel, which was not in the field of decontamination; therefore, a failure was to be expected.

Class III Isolator



BI Location	Location Description	Results by Test # 1	2	3
1	Front left bottom corner of airlock	P	P	P
2	Back left top corner of airlock	P	P	P
3	Front right mid/bottom corner of airlock	P	P	P
4	Back right middle corner of airlock	P	P	P
5	Back left top corner of cabinet	P	P	P
6	Front left top corner of cabinet	P	P	P
7	Back left bottom corner of cabinet	P	P	P
8	Front left bottom corner of cabinet	P	P	P
9	Inside collar pipe	P	P	P
10	Inside bottom of whole-body chamber	P	P	P
11	Back right top corner of cabinet	P	P	P
12	Front right top corner of cabinet	P	P	P
13	Back right bottom corner of cabinet	P	P	P
14	Front right bottom corner of cabinet	P	P	P
15	Inside detached mixing pipe	P	P	P
16	Positive Control—did not undergo HHP exposure	F	F	F



Filter Banks

Testing Location	Housing Size (cubic feet)	HEPA Filter Size (cubic feet)	BI Results Pass	Fail
CURIS R&D Facility AAF Flanders	12	1	(All)	0
Texas A&M Facility camfil	10	1	(All)	0
	32	4	(All)	0
	50	8	(All)	0
	70	8	(All)	0
	110	16	(All)	0
	270	24	(All)	0

No Blower BSC Decon

Occasionally, a BSC blower may be inoperable, necessitating service; however, the BSC and filters ideally should be decontaminated prior to maintenance to prevent contamination and health risks to staff. Three validation tests using BIs were performed with the addition of a simple desk fan, and results were recorded.

# of Tests	# of BIs	BI Results Pass	Fail
3	21	(All)	0

Results

All BI controls were positive for growth and all treated BIs were successfully inactivated, proving a 6-log or greater reduction of bacterial spores throughout the various enclosures, including a total of 277 BIs passing in the four Class II A2 BSCs and 45 BIs in the Class III Isolator. Filter housings demonstrated a pass of 35 BIs throughout the seven filter housings treated. No degradation of materials or surfaces was observed in any of the equipment tested.

Conclusion

Overall, the low-level gaseous hybrid hydrogen peroxide system proved successful at achieving reliable, repeatable 6-log reductions throughout a wide variety of biocontainment enclosures, including through challenging filters, regardless of size or configuration and without observable damage to materials.