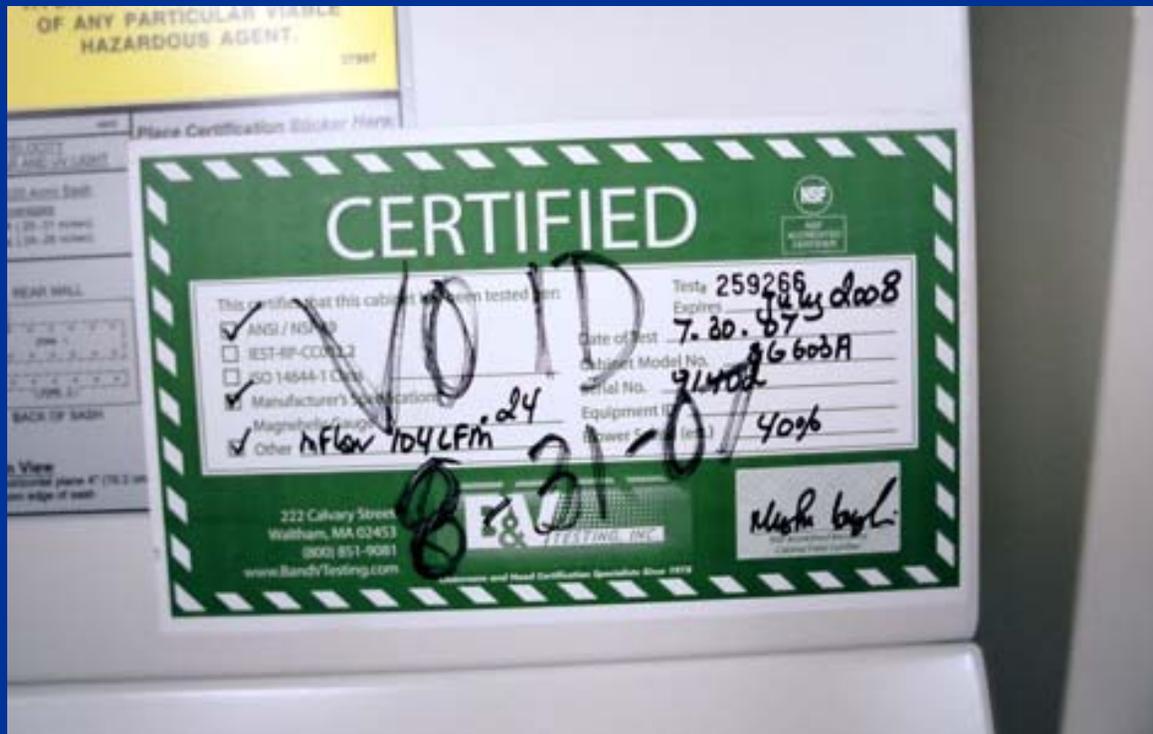


Loss of Class II Type A2 Biological Safety Cabinet Containment in a BSL-3 Laboratory Due to Supply Air Outlet Temperature



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Study Background

- B & V Testing contracted by Broad Institute, Cambridge, MA to perform in-situ containment testing of Class II type A2 biological safety cabinet (BSC) with liquid reagent handler and spectrophotometer installed in new BSL-3 lab during commissioning process



Study Background (contd)

- For comparative performance data evaluated containment performance of adjacent empty Class II Type A2 BSC
- Baker SG403A with canopy connection to building exhaust certified to NSF/ANSI 49 and manufacturer's specifications



Class II BSC Performance Testing Overview

- **Microbiological challenge test:** National Sanitation Foundation (NSF) 49 test of new BSCs performed under controlled environmental conditions in test laboratory at NSF or manufacturer site which quantifies performance
- **Field testing and certification:** NSF/ANSI 49 Annex F, to ensure proper inflow and downflow air velocity set points at which microbiological test performance data was established; also includes HEPA filter integrity testing, airflow smoke patterns testing and site installation assessment testing where applicable



Class II BSC Performance Testing Overview (contd)

- **Bio-Analog Test¹**: factory and field test developed by the Baker Company which quantifies containment and product protection performance of BSCs
- For containment test utilizes sulfur hexafluoride (SF_6) as tracer gas (ducted BSCs only)

1. **Field Test Quantifying Biological Safety Cabinet Containment Performance**, R.L. Jones, The Baker Company, Presented at 1994 Annual Conference of American Industrial Hygiene Association

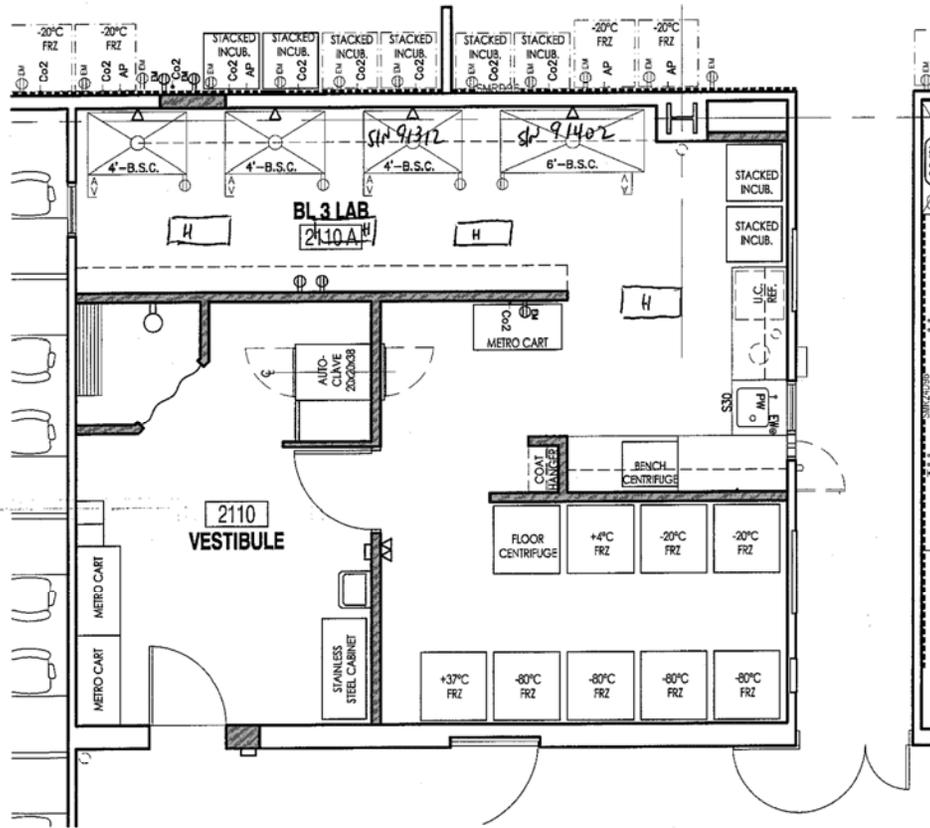


Study Methodology: Bio-Analog Containment Test



- **Tracer Gas:**
SF₆ ~ 10,000 ppm @ 20 psi through NSF 6-jet collision nebulizer w/H₂O
- **Challenge Location:**
14" above work surface centerline, 4" back from viewscreen
- **Detection Instrument:**
iTi Qualitek Leak Detector range .01-60 ppm, probe 1.5" from access opening, 6.5" above work surface

BROAD, BSL-3, 7 CAMBRIDGE CENTER, 2ND FLOOR

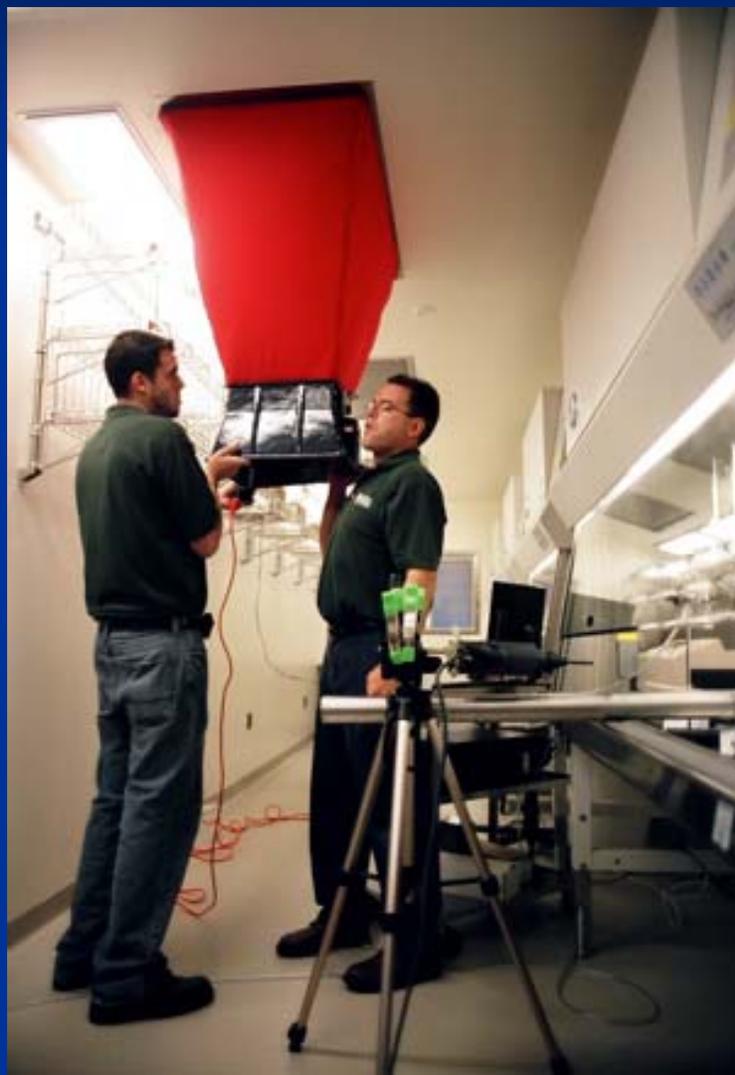


H = HEPA FILTER

BSL-3 Lab Layout



BSL-3 Lab Constant Conditions



- **Lab Pressure:** - .06" w.g. (-15 pascals)
- **Lab Supply Air:** 1320 CFM Via Four 2' X 4' Terminal Ceiling HEPA Filters and Two Diffusers (~ 250 CFM/HEPA following re-direction of supply air to rear of lab)
- **Lab Exhaust Air:** 1500 CFM Via Four BSCs, One Exhaust Register and Autoclave Exhaust
- **Cooling Mode Supply Air Outlet Temperature:** 58 - 63 degrees F (14 -17 C) Note: outside air ~ 24 C

BSC Model SG403A Constant Conditions

- Passed microbiological challenge testing performed at manufacturer's test site
- Following field installation and air balancing, tested and certified to NSF/ANSI 49 – 2007 Annex F and manufacturer's specifications by NSF-accredited biosafety cabinet field certifier
- Inflow velocity: 107 feet per minute (.54 m/s)
- Downflow velocity: 54 feet per minute (.27 m/s)
- Canopy duct connection: - .05" w.g. (-12 pascal)



BSC Model SG403A Conditions (contd)

- As component of NSF/ANSI 49 Annex F certification, passed Airflow Smoke Patterns Test
- **F.4.1 Purpose**

This test...determines that there is no escape to the outside of the cabinet at the sides and top of the window.
- **F.4.3.2 View screen retention test**

Smoke shall be passed from one end of the cabinet to the other, 1.0 in (2.5 cm) behind the view screen at a height 6.0 in (15 cm) above the top of the access opening.



SG403A Containment Test Scenarios

- **Two Scenarios, Ten 5-Min Runs Each Scenario**
 - 1) **Warming Mode:** HEPA filter supply outlet temperature 64 – 70 degrees F (18-21 C)
 - 2) **Cooling Mode:** HEPA filter supply outlet temperature 58 – 63 degrees F (14-17 C)

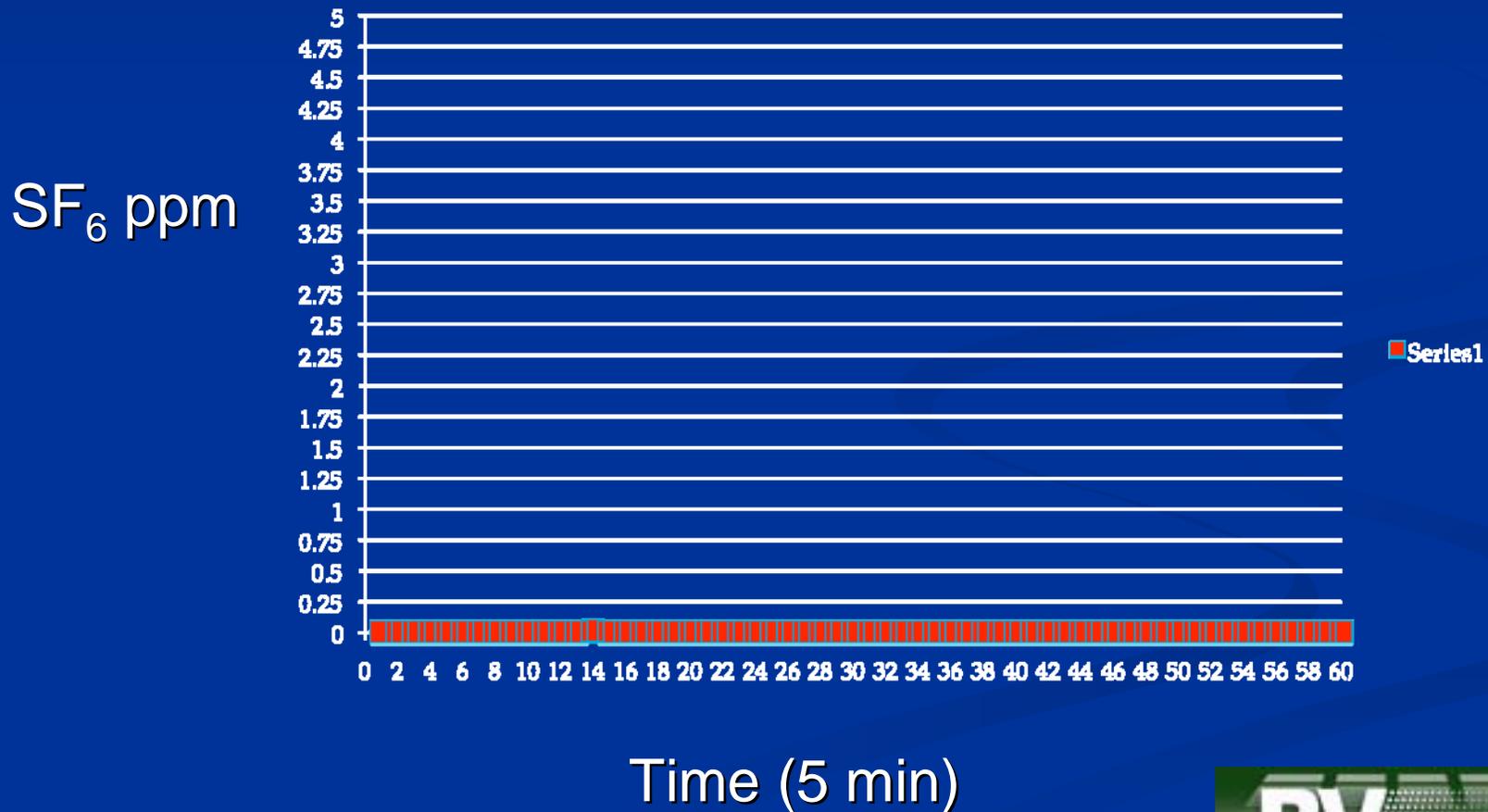


SG403A Containment Test Results

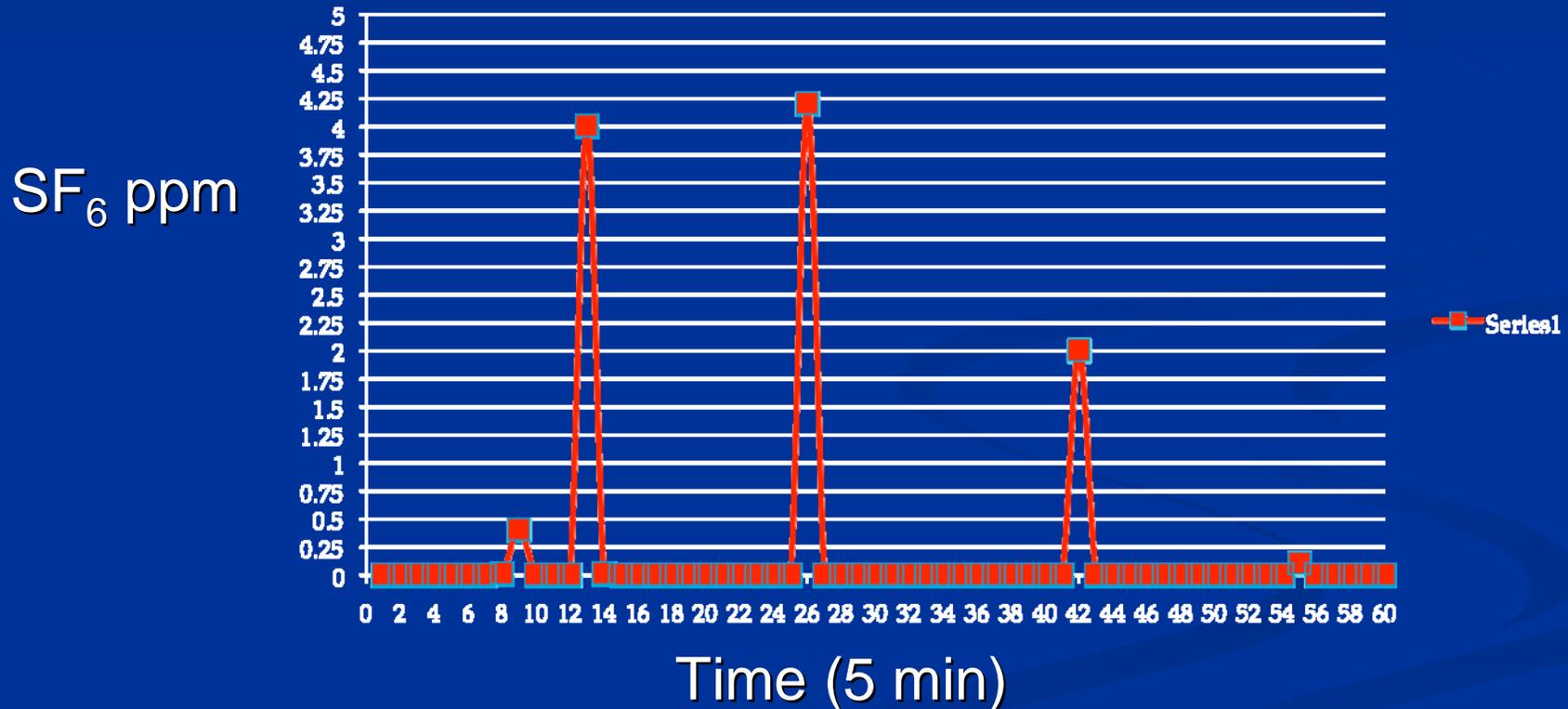
- Average SF₆ release concentration per 5 min test runs
- Containment protection factor/run (interior SF₆ concentration 10,000 ppm/average SF₆ release concentration)
- Number of peak releases SF₆/run due to periodic loss of containment (peak release defined as SF₆ release of ≥ 0.10 ppm which results in loss of \geq one log protection factor)
- Average SF₆ peak release concentration/run
- Peak release containment protection factor/run (interior SF₆ concentration 10,000 ppm/average SF₆ peak release concentration)



SG403A Containment Results: Typical 5 Min. Test Run Warm Supply Outlet Temperature Scenario (18-21 C)



SG403A Containment Results: Typical 5 Min. Test Run Cold Supply Outlet Temperature Scenario (14-17 C)



Note: periodic SF₆ release verified with modified smoke test.



Efforts to Mitigate Periodic Containment Loss in Cold

Temperature Scenario

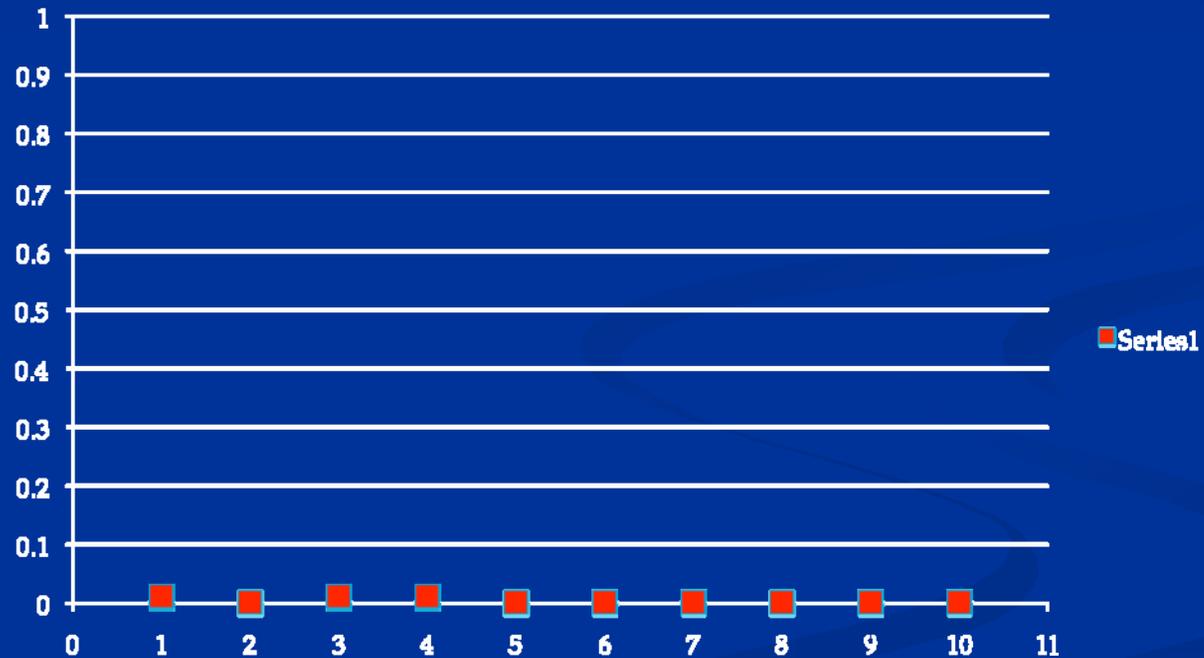
- Reduction of supply airflow in proximity to BSC access opening from ~ 60 fpm to ~ 30 fpm—no change
- Re-direction of supply airflow away from BSC access opening with 2' deep panel hanging down from HEPA filter at 90 degrees—no change
- Re-direction of supply airflow away from BSC access opening with 2' deep panel hanging down from HEPA filter at 45 degrees angled away from BSC face—minor improvement, still periodic containment loss

SG403A Containment Summary

Results: Average SF₆ Release Concentration, Warm Supply Outlet Temperature Scenario (18-21 C)

SF₆ ppm

Mean:
< 0.01 ppm



5-Min. Test Runs

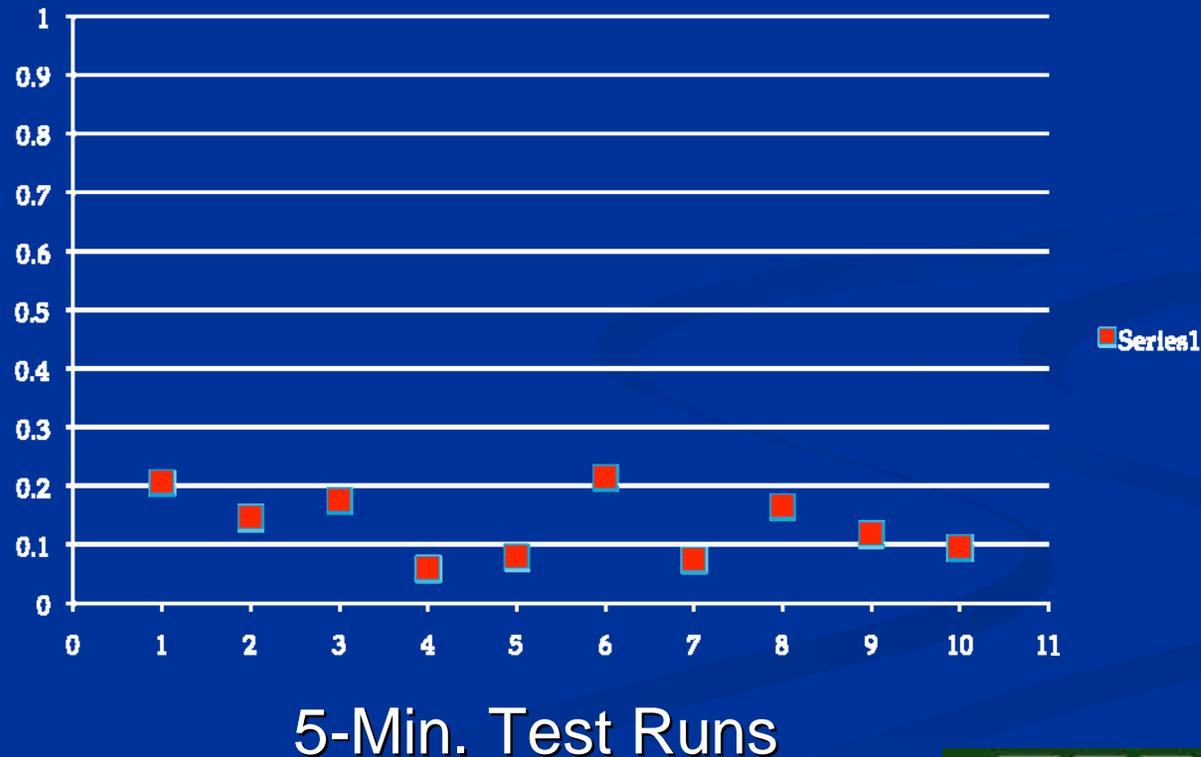


SG403A Containment Summary

Results: Average SF₆ Release Concentration, Cold Supply Outlet Temperature Scenario (14-17 C)

SF₆ ppm

Mean:
0.13 ppm



SG403A Containment Summary

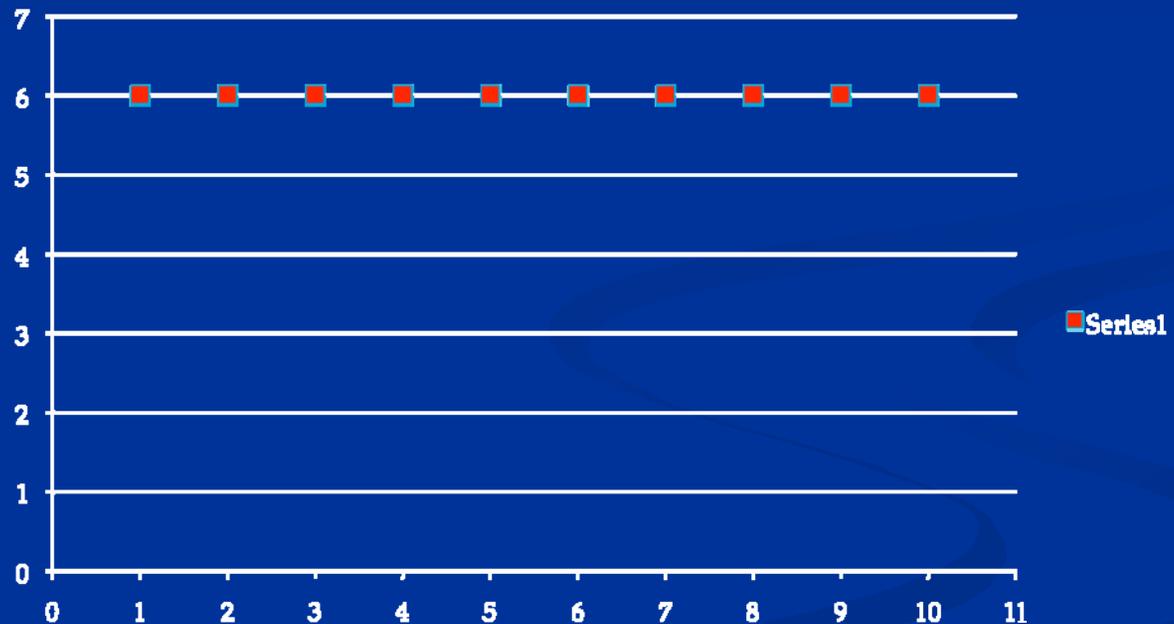
Results: Containment Protection

Factor per Test Run, Warm Supply

Outlet Temperature Scenario (18-21 C)

Log Protection
Factor

Mean:
6 logs



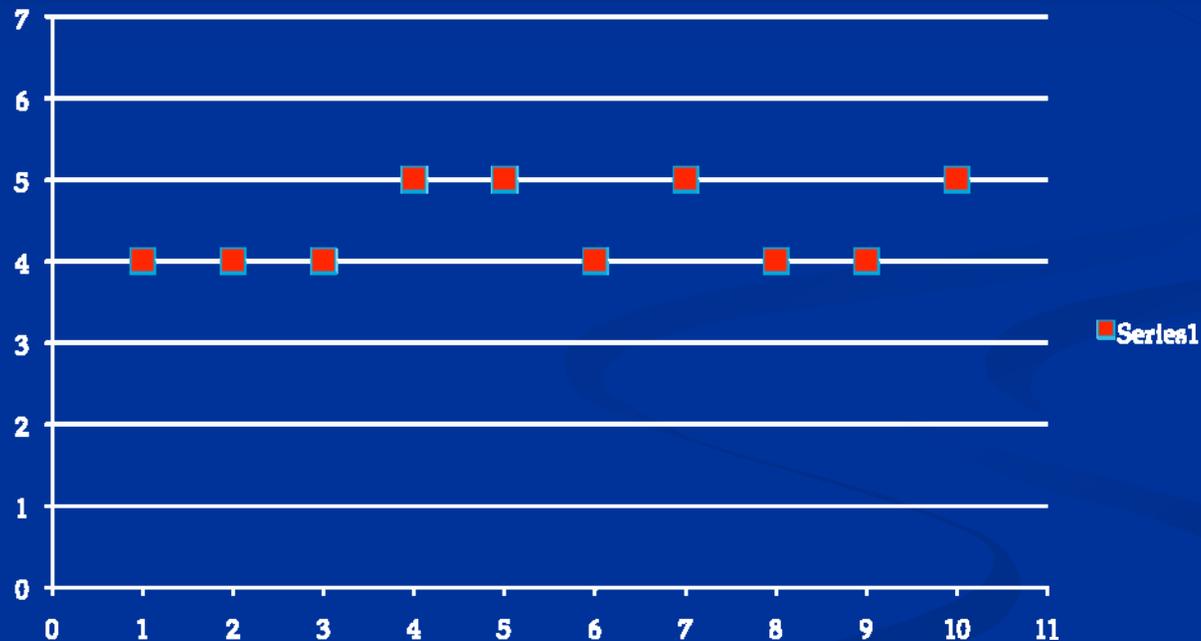
5-Min. Test Runs



SG403A Containment Summary Results: Containment Protection Factor per Test Run, Cold Supply Outlet Temperature Scenario (14-17 C)

Log Protection
Factor

Mean:
4.4 logs



5-Min. Test Runs

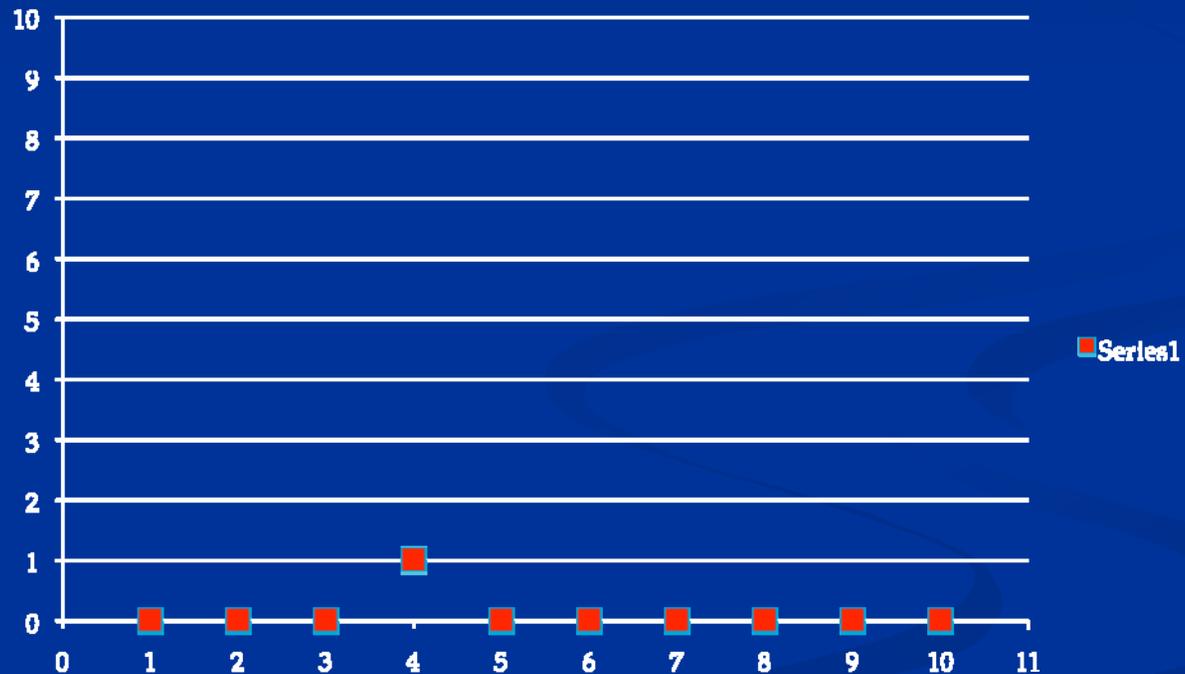


SG403A Containment Summary

Results: Number of Periodic Peak Releases Per Test Run, Warm Supply Outlet Temperature Scenario (18-21 C)

Number Peak Releases*

Mean:
< 1 Peak Releases



* ≥ 0.10 ppm release

5-Min. Test Runs

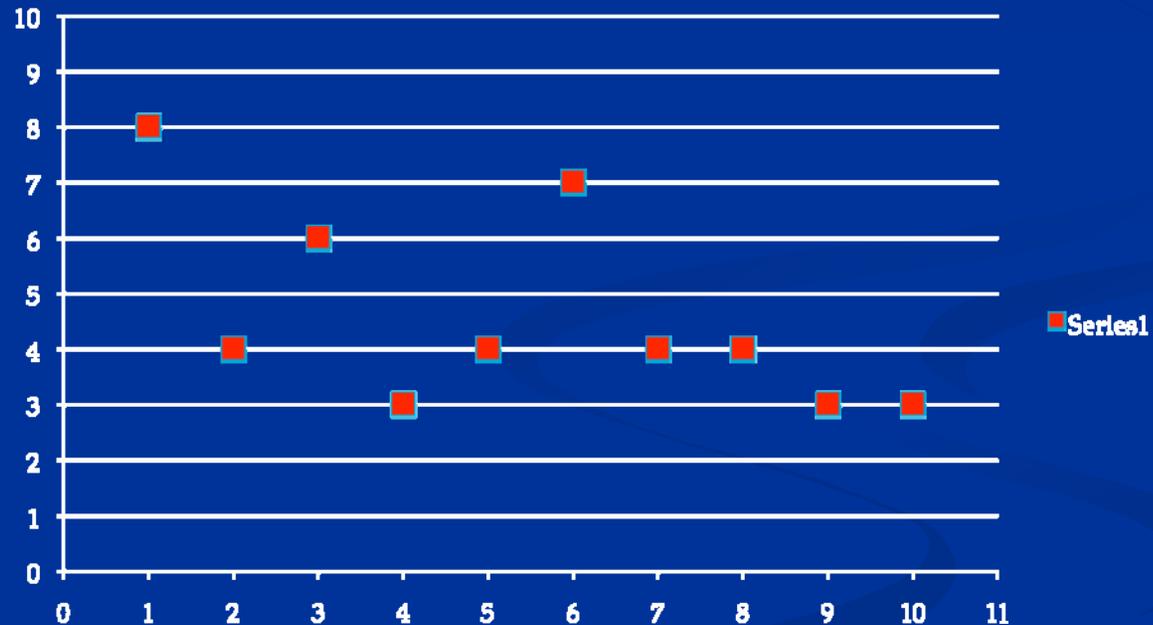


SG403A Containment Summary

Results: Number of Periodic Peak Releases Per Test Run, Cold Supply Outlet Temperature Scenario (14-17 C)

Number Peak Releases*

Mean:
4.6 Peak Releases



* ≥ 0.10 ppm release

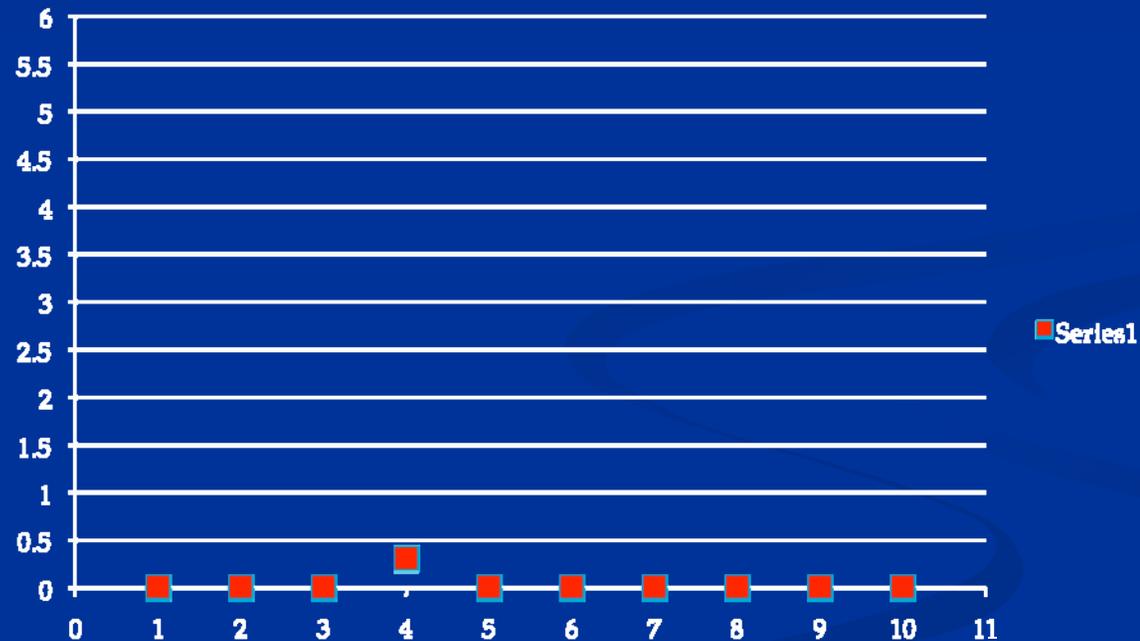
5-Min. Test Runs



SG403A Containment Summary Results: Average Peak Release Concentration Per Test Run, Warm Supply Outlet Temperature Scenario (18-21 C)

SF₆ ppm

Mean:
0.3 ppm



5-Min. Test Runs



SG403A Containment Summary Results: Average Peak Release Concentration Per Test Run, Cold Supply Outlet Temperature Scenario (14-17 C)

SF₆ ppm

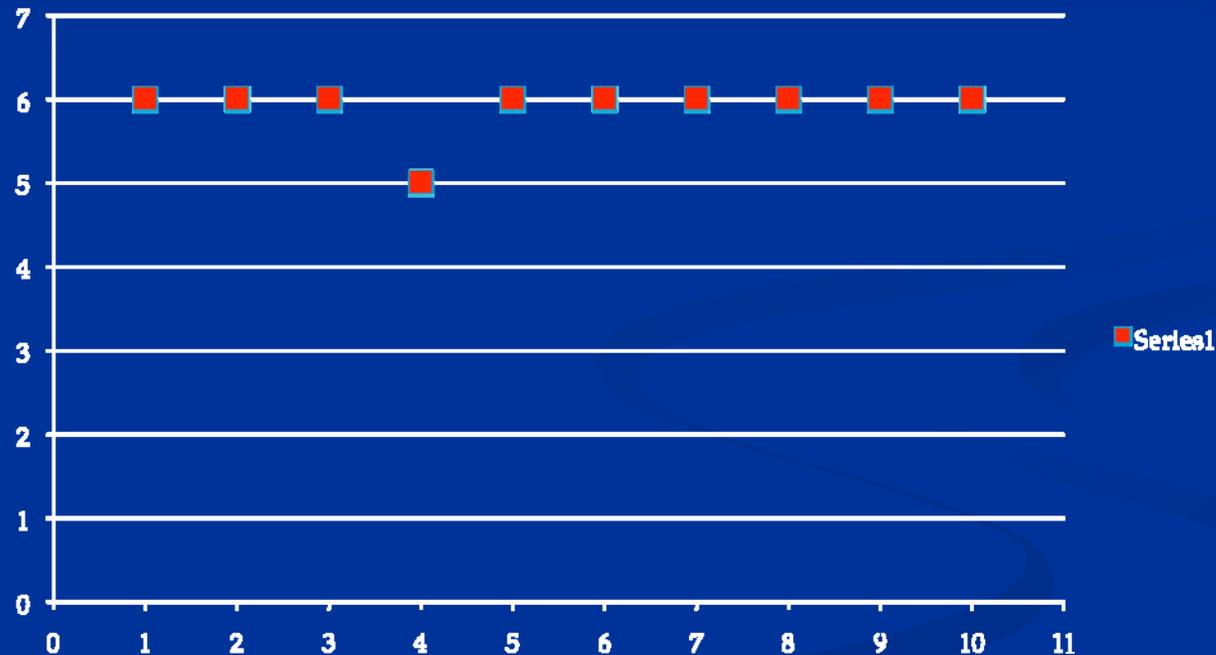
Mean:
1.73 ppm



SG403A Containment Summary Results: Peak Release Containment Protection Factor per Test Run, Warm Supply Outlet Temperature Scenario (18-21 C)

Log Protection
Factor

Mean:
5.9 logs



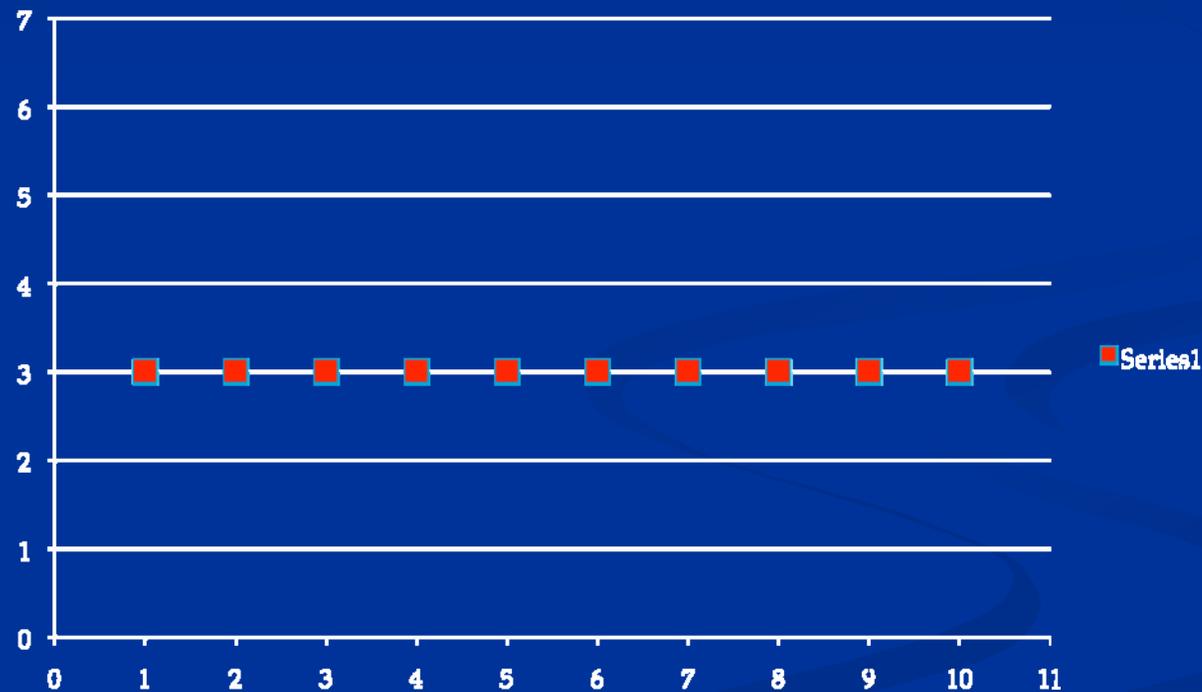
5-Min. Test Runs



SG403A Containment Summary Results: Peak Release Containment Protection Factor per Test Run, Cold Supply Outlet Temperature Scenario (14-17 C)

Log Protection
Factor

Mean:
3 logs



5-Min. Test Runs



Outcomes

- Certification of SG403A was voided until supply outlet temperature controls were modified to maintain specification $> 17\text{ C}$
- Other BSCs in BSL-3 were evaluated utilizing Bio-Analog test and demonstrated adequate containment performance when supply air outlet temperature was $> 17\text{ C}$ (including SG603A with installed equipment)

Conclusions/Recommendations

- Supply air outlet temperature of air sources in close proximity to Class II, Type A2 biological safety cabinets under certain laboratory conditions may adversely impact BSC containment performance
- Airflow smoke patterns testing as described in NSF/ANSI 49 2007 may be inadequate to accurately assess BSC containment performance under certain laboratory conditions. Consideration should be given to amend Annex F to describe rate of smoke scanning during view screen retention test to facilitate identification of potential periodic containment failures
- For critical and/or questionable BSC installations, field certification should be performed with supply air systems operating in “worse-case” scenarios (at coldest/max set-points)



Acknowledgements

- Dr. James Gomez, Ph.D., Broad Institute
- Dan Ghidoni, PE, CIH, Northeast Scientific Associates
- Aaron Johnson, The Baker Company

