Assessment of Containment and Product Protection In a Class II Type B3 Biological Safety Cabinet Under "As-used" Laboratory Conditions

Peter Harris and Dave Lupo
B & V Testing, Inc.
ABSA, 1999

Study Objective

To Investigate the Effect of

"As-used" Laboratory Environmental Conditions On the Performance of a Class II Type B3 Biological Safety Cabinet (BSC)

How Do The Following “As-used” Conditions Affect BSC Performance?

- Personnel traffic walking by the BSC access opening
- Partially blocked front air intake grille
- Incubator door opening and closing in close proximity to the BSC access opening
- Presence of ceiling supply air diffuser in front of the BSC
- Excess material stored in the BSC
- Use of BSC at improper sash height

Class II Biological Safety Cabinet (BSC) Performance Validation Overview

- ***Microbiological challenge test:*** National Sanitation Foundation (NSF) Standard No. 49 test of new BSCs performed under controlled environmental conditions in test laboratory at NSF or manufacturer which quantifies performance
- ***Field certification test:*** NSF Std. 49, Annex F test of in-field BSCs which confirms proper setting of inflow and downflow air velocities established by microbiological testing along w/filter integrity test
- ***Bio-analog test***: factory and field test developed by The Baker Company which correlates to the microbiological challenge[1] and quantifies containment and product protection performance of in-field ducted BSCs.

1. **Field Test Quantifying Biological Safety Cabinet Containment.** R.L. Jones, The Baker Company, Inc., Sanford, ME. Presented at annual conference 1994 of American Industrial Hygiene Association

B&V TESTING, INC.

Bio-Analog Test: Containment Testing

- ***Tracer Gas Challenge***: Sulfur hexafluoride (SF_6) introduced at 20psi through NSF Std. 49 6-jet collision nebulizer with water resulting in approx. 10,000 ppm of SF_6 challenging access opening for five minute period
- ***Challenge Location:*** 4" behind access opening and 14" above work surface along cabinet centerline
- ***Detection Instrumentation:*** iTi Qualitek 200 Ultra High Sensitivity Trace Gas Leak Detector with detection range of 0.01- 60.0 ppm. Sample probe located 1.5" in front of access opening and 6.5" above work surface along cabinet centerline

Bio-Analog Test: Containment Testing

Bio-Analog Test: Product Protection Test

- ***Mineral Oil Challenge:*** Mineral oil in NSF Std. 49 6-jet collision nebulizer pressurized to 20psi resulting in 6 X 10^9 particles per minute for five minute period[2]
- ***Challenge Location:*** 4" in front of access opening and 8" above work surface along cabinet centerline
- ***Detection Instrumentation:*** Lasair 510-8 particle counter @ 1 CFM sample rate set for .5 micron with sampler located 1.25" above work surface and 3" back from rear of front perforated air intake grille along cabinet centerline

2. **Estimating Mineral Oil Smoke Challenge From the 6-Jet Collison Nebulizer.**
1997. Stuart, D. G., Jones, R. L., Ghidoni, D. A., and Eagleson, D. The Baker
Company, Inc. Sanford, Maine 04073

Bio-Analog Test: Product Protection Test

Study Methodology: BSC Investigated

- Class II Type B3 Baker Model SG400, serial 32541 in BL3 at Whitehead Institute placed in lab consistent with manufacturer's recommendations

Study Methodology: BSC and BL3 Constant Conditions

- BSC at nominal inflow of 105 fpm and downflow of 75 fpm at sash consistent with results of original microbiological challenge testing. Ductwork .03” negative. NSF test arm in BSC.
- BL3 lab supply air 470 CFM, exhaust air 572 CFM, lab pressure .08” negative to exterior corridor

Study Methodology: Bio-Analog Testing

- Performed six repetitions of Bio-Analog Test for the following “as-used” scenarios:
  1. Baseline performance
  2. Personnel traffic walking by the BSC access opening
  3. Partially blocked front air intake grille
  4. Incubator door opening and closing in close proximity to the BSC access opening
  5. Presence of ceiling supply air diffuser in front of the BSC
  6. Excess material stored in the BSC
  7. Use of BSC at improper sash height

Scenario 1: Baseline Performance

- BSC operating at nominal airflow velocities
- NSF test arm present on cabinet work surface

Baseline Performance Results

Containment Testing

- Average concentration of SF_6 detected: 0.02 ppm
- Standard Deviation: 0.02 ppm*
- 2nd Standard Deviation: 0.04 ppm

Product Protection Testing

- Average number of particles measured: 84**
- Standard Deviation: 50
- 2nd Standard Deviation: 100

* Low limit of detection instrument is 0.01 ppm

** Corrected for background due to normal HEPA penetration

Scenario 2: Personnel Walk-by in Front of BSC Access Opening

- 6’ tall, 190 lb. man walking 2.5’ from cabinet face
- Pace = 169 feet/minute = 13 passes per minute

Personnel Walk-by Results

Containment Testing Results

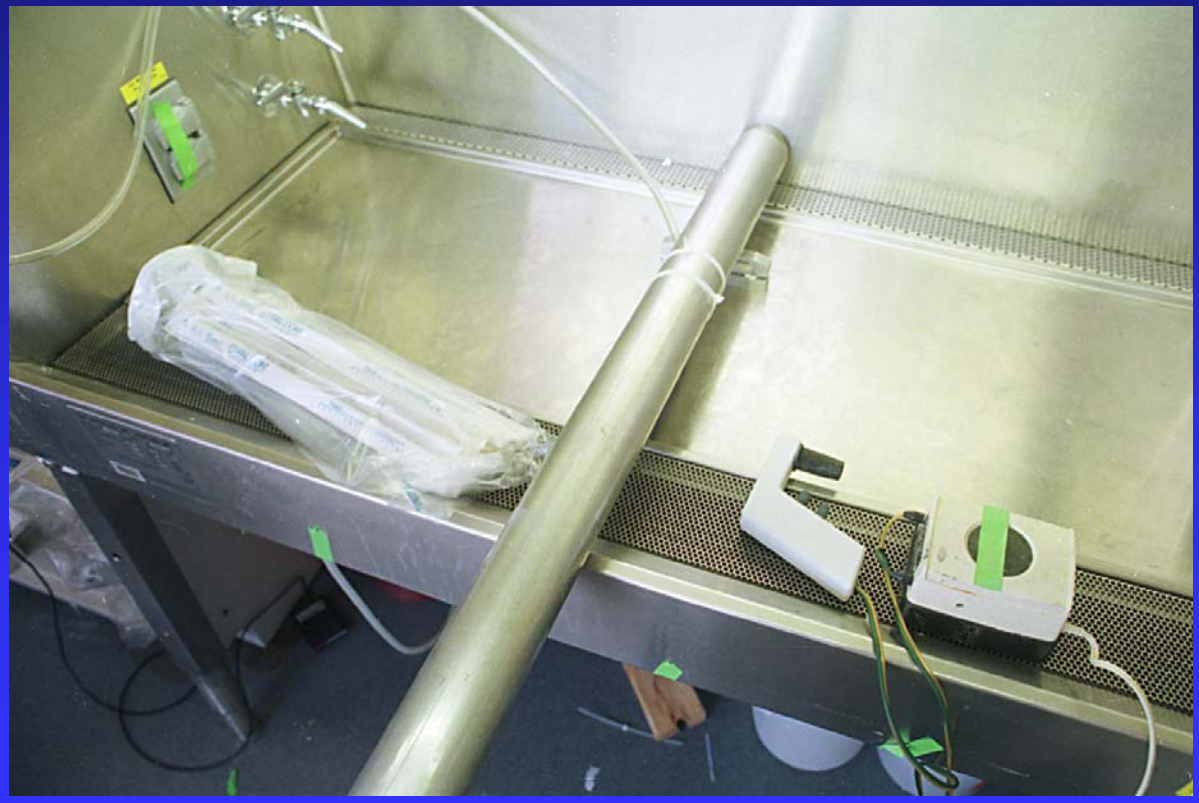
- Average concentration of SF_6 detected: 2.42 ppm
- Standard Deviation: 0.31 ppm
- 2nd Standard Deviation: 0.62 ppm
- 2 ORDERS MAGNITUDE CONTAINMENT LOSS VS. BASELINE (0.02 ppm)

Product Protection Testing Results

- Average number of particles measured: 93
- Standard Deviation: 73
- 2nd Standard Deviation: 146
- ✓ NO CHANGE VS. BASELINE (84 particles)

Scenario 3: Partially Blocked Front Air Intake Grille

- 24% of surface area of front perforated air intake grilled covered with supplies



Blocked Air Intake Grille Results

Containment Testing Results

- Average concentration of SF_6 detected: 0.01 ppm
- Standard Deviation: 0.01 ppm
- 2nd Standard Deviation: 0.02 ppm
- ✓ NO CHANGE VS. BASELINE (0.02 ppm)

Product Protection Testing Results

- Average number of particles measured: 116,000
- Standard Deviation: 12,000
- 2nd Standard Deviation: 25,000
- 3 ORDERS MAGNITUDE PRODUCT PROTECTION LOSS VS. BASELINE (84 part.)

Scenario 4: Incubator Door Opening Adjacent to BSC Access Opening

- 17” X 21” single door incubator door 4” from BSC
- Rate of opening and closing door = 6 X per minute

Incubator Door Opening Results

Containment Testing Results

- Average concentration of SF_6 detected: 1.99 ppm
- Standard Deviation: 0.46 ppm
- 2nd Standard Deviation: 0.91 ppm
- 2 ORDERS MAGNITUDE CONTAINMENT LOSS VS. BASELINE (0.02 ppm)

Product Protection Testing Results

- Average number of particles measured: 104
- Standard Deviation: 41
- 2nd Standard Deviation: 82
- ✓ NO CHANGE VS. BASELINE (84 particles)

Scenario 5: Ceiling Supply Diffuser in Front of BSC Access Opening

- Simulated downward airflow in front of BSC
- Average airflow of 79 fpm 4” from access opening 8” above work surface

Ceiling Supply Diffuser Results

Containment Testing Results

- Average concentration of SF_6 detected: 0.29 ppm
- Standard Deviation: 0.08 ppm
- 2nd Standard Deviation: 0.16 ppm
- 1 ORDER MAGNITUDE CONTAINMENT LOSS VS. BASELINE (0.02 ppm)

Product Protection Testing Results

- Average number of particles measured: 191
- Standard Deviation: 27
- 2nd Standard Deviation: 53
- ✓ NO CHANGE VS. BASELINE (84 particles)

Scenario 6: Excess Material Stored inside BSC

- 72% of work surface covered with supplies

Excess Material Results

Containment Testing Results

- Average concentration of SF_6 detected: 0.02 ppm
- Standard Deviation: 0.02 ppm
- 2nd Standard Deviation: 0.03 ppm
- ✓ NO CHANGE VS. BASELINE (0.02 ppm)

Product Protection Testing Results

- Average number of particles measured: 113
- Standard Deviation: 23
- 2nd Standard Deviation: 47
- ✓ NO CHANGE VS. BASELINE (84 particles)

Scenario 7: Improper Sash Height— Set at 12” (vs. 8”)

Containment Testing Results

- Average concentration of SF_6 detected: 0.02 ppm
- Standard Deviation: 0.02 ppm
- 2nd Standard Deviation: 0.03 ppm
- ✓ NO CHANGE VS. BASELINE (0.02 ppm)

Product Protection Testing Results

- Average number of particles measured: 117
- Standard Deviation: 31
- 2nd Standard Deviation: 61
- ✓ NO CHANGE VS. BASELINE (84 particles)

Summary of Key Results: "As-used" Environmental Conditions Resulting in Loss of Containment

- Personnel walk-by in front of BSC face:
  - 2 ORDERS MAGNITUDE LOSS
- Incubator door opening and closing in close proximity to BSC face:
  - 2 ORDERS MAGNITUDE LOSS
- Presence of ceiling supply diffuser in front of BSC face:
  - 1 ORDER MAGNITUDE LOSS

Summary of Key Results: "As-used" Environmental Conditions Resulting in Loss of Product Protection

- Partially blocked air intake grille
  - 3 ORDERS MAGNITUDE LOSS

Conclusions and Looking Ahead

- "As-used" laboratory environmental conditions do adversely affect containment and product protection of a Class II Type B3 Biological Safety Cabinet
- The Bio-analog test can be used in the field as a risk assessment tool to quantify in-field performance of biological safety cabinets and containment devices
- The Bio-analog test should be considered for inclusion in the field performance testing section of NSF Std. 49