



Biosafety Cabinet Certification Guide

Biosafety Cabinet Certification Report

Why do I need a Biosafety Cabinet Certification Report?

If you will be using a Class II Biosafety Cabinet (BSC) for study agent preparation, you will need to provide Sabai IBC Services with a BSC Certification Report.

BSC operations, as specified by NSF/ANSI 49, need to be verified at the time of installation and, at a minimum, annually thereafter. **A cabinet should be recertified whenever a HEPA or ULPA filter is replaced, maintenance repairs are made to internal parts, or a cabinet is relocated.**

"These field certification procedures are intended to confirm that an installed cabinet evaluated under the current version of the standard has met all design criteria contained in NSF/ANSI 49 and currently meets all criteria contained in this annex(N-5.1)"

For a certification to be considered Field Certified in accordance with NSF/ANSI 49, the following physical tests shall be conducted on site.

Minimum Testing Requirements

Site installation assessment tests (as applicable)

- Alarm functions
- Blower Interlocks
- Exhaust system performance (proper exhaust duct negative pressure and canopy performance)

- Down flow Velocity Profile
- Inflow Velocity
- Airflow Patterns
- HEPA/ULPA Filter Leak
- Cabinet Integrity (positive pressure plenum cabinets only)

For Type A cabinets with exposed biologically contaminated positive pressure plenums, either a pressure decay or soap bubble leak test is mandatory. The tests shall be performed at the time of installation, when positive pressure containment panels are removed, and after relocation of the BSC.



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Tests Related to Worker Comfort and Safety*

*By customer request or at the discretion of the field certification provider

- Lighting Intensity
- Noise Level
- Vibration
- Electrical leakage, ground circuit resistance, and polarity tests

Tests Related to Industry-specific Use

- When field testing any Class II BSC, the certifier should take into consideration any industry-specific testing. Examples include but are not limited to pharmaceuticals and electronics.
- Any additional testing completed is an adjunct to, and not a substitute for, the minimum testing required to consider a BSC field tested in accordance with NSF/ANSI 49.

Field certification of a cabinet is not intended to provide complete verification that the cabinet conforms to all of the requirements of NSF/ANSI 49.

Steps to Request the BSC Certification Report

- **Verify Accreditation:** Confirm the technician holds active **NSF-49** accreditation, preferably from the Enhanced Accreditation Program.
- **Specify the Standard:** Explicitly request that testing and the final report comply with the current **NSF/ANSI Standard 49, Annex F.**
- **Define Scope of Work:** Ensure the report includes comprehensive tests: [airflow velocity \(inflow/downflow\)](#), [HEPA filter leak integrity](#), [cabinet integrity](#), and [site installation assessment \(smoke patterns\)](#).
- **Request Documentation:** The final report should include a signed certification label, calibration records for testing equipment, and detailed test results.

Post-Certification

Once certified, the BSC is usually tagged with a sticker/certificate of satisfactory performance (see examples below).

A BSC Certification Report is provided thereafter.

BSC sticker examples (from internal Sabai IBC files).



Example of BSC Certification Report

Biological Safety Cabinet Certification Report

Date: June 5, 2023
 Report #: J12345-1
 Technician: Donald D.
 Customer: Research Site name
 Address:
 City/State:
 Contact: Site Contact /
 Telephone: (714) 948-0443 / (714) 948-5372
 PO Number:

Overall Status: Pass Fail
 Requires Attention

Device ID#: XXXXXX
 Manufacturer: Consalmyr
 Model: XXXXXX
 Serial Number: 12345
 Device Location: Suite 101

Notes:

ACCEPTANCE CRITERIA

Inflow / Face Velocity Tests: 100 - 110 fpm
 Downflow / Supply Velocity: 60 - 70 fpm

Individual point readings should be within +/- 25% of 18 fpm whichever is greater.
 Individual Readings: 52 Low 84 High
 65 Low 72 High

HEPA Filter Leak Test
 Maximum challenge of 10 micrograms per liter. No was should exceed 0.01% when scanned or 0.05% when sealed.

Upstream Concentration: 2% µg/l
 Number of leaks Detected: 0
 Number of leaks Sealed: 0

Particulate Matter Profile
 Maximum number of 5 micron size particles and above allowed for ISO Class 5 is 350 particles per cubic meter.
 ISO Class Achieved: N/A

Static Pressure Readings: 0.18 "WG Duct Pressure: N/A "WG Measured Downstream

Air Flow Smoke Pattern Test
 Downflow Test, View Screen Retention Test, Sash Seal Containment Test and Work Access Opening Retention Test.

Site Assessment Test
 Window Sash Alarm: Pass Fail N/A
 Negative Pressure visualization at exhaust canopy: N/A "WG
 Air Flow Alarms and Interlocks: Pass Fail N/A

Minimum Testing Requirements Included

FINAL RESULTS

Inflow / Face Velocity Tests
 Pass Fail N/A

Downflow /Supply Velocity Tests
 Pass Fail N/A

HEPA Filter Integrity Test
 Pass Fail N/A

Particulate Matter Profile
 Pass Fail N/A

Air Flow Smoke Pattern Test
 Pass Fail N/A

Site Assessment Test
 Pass Fail N/A
 Pass Fail N/A
 Pass Fail N/A

Report Number: J12345-1
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INSPECTION DATA

Equipment Data
 Type of Cabinet: A1 (75 fpm inflow) A2 B1 B2 Class I / Powder Hood

Exhaust Configuration: Room No Blower Thimble Hard Connect Aux Blower Total Exhaust

Supply HEPA Filter: (1) 18 X 72 X 6
 Exhaust Filter: (1) 18 X 24 X 12

Supply / Exhaust Area: 11.58 sq.ft. / 2.44 sq.ft.
 Supply / Exhaust Velocity: 65 fpm. / 210 fpm.
 Volume: 755 cfm. / 513 cfm. Total Volume: 1268 cfm.

Work Access Opening Dimensions: 10 Height / 70.00 Width / Work Access Opening Area: 4.86 sq.ft.

Exhaust Method Range: 199 - 219 IDV Range: 486 - 535 Restricted Access Range: N/A - N/A

Notes:

Downflow/Supply Velocity Readings: 6 inch grid
 Exhaust, Traverse or Dim Readings: DM inch grid

72	71	69	67	67	63	61	63	61	63	68	218	228	239	257	234
75	78	71	72	73	72	70	66	69	76	77	178	196	212	234	187
73	71	68	66	62	57	55	57	60	84	70	175	194	180	217	263

Average: 98
 Average: 213

HEPA Filter Integrity Test: Zero Leaks
 Particulate Matter Profile: N/A

SUMMARY

MTA warrants that this air system was tested under the requirements as set forth in the following applicable standard(s):
 IES-PP-002.2: Hepa Filters NSF-49: Class I LAF Biosafety Cabinet Annex F Owners Specifications
 Manufacturer's Specifications ISO 14644-1: 1999 (E); Class at 0.5 µm size particle, Status: _____

Status of System after Inspection:
 Certified to the Above Applicable Standard(s). Undergoing Corrective Action by MTA.
 Not Certified to the Above Applicable Standard(s). It is Recommended that this System be Corrected by the Owner Prior to any Additional Testing.

CERTIFICATE OF INSPECTION expires 12 months from date of issue.

*Indicates duct area

BMBL 6th edition, p388
Performance Testing BSCs in the Field (references NSF/ANSI 49). NSF/ANSI 49, N-5.1 Field certification preconditions and intervals p83