California Institute of Technology

BIOSAFETY CABINET CERTIFICATION QUALITY CONTROL PROGRAM

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Table of Contents

OVERVIEW

Biosafety cabinets (BSCs) are the primary means of containment developed for working safely with infectious microorganisms and other biohazardous material. When functioning correctly and used in conjunction with good microbiological techniques, BSCs are very effective at controlling infectious aerosols. BSCs control airborne contaminants during work with infectious material through the use of laminar airflow and High Efficiency Particulate Air (HEPA) filtration.

Consistent performance testing for Biosafety cabinets is necessary to ensure that all Caltech's cabinets are operating properly and able to protect both the investigators and their experiments from exposures or potential contaminations.

Per Caltech's Institutional Biosafety Committee (IBC), performance testing of BSCs is required to be conducted according to ANSI/NSF -2018 edition. Personnel conducting the testing will be specifically trained and accredited to accomplish the task. This Biosafety Cabinet Certification Quality Control Program verifies and documents relevant aspects of the BSCs' certification processes.

INTRODUCTION

Biosafety Cabinets Introduction

BSCs are designed to provide personnel, environmental and product protection when appropriate practices and procedures are followed. Selecting the correct type of BSC, installing it, using it properly and annually certifying its operation are complex processes.

Two kinds of biological safety cabinets, designated as Class II and III, are currently meeting varying biological research and clinical needs on Caltech's campus.

The most widely utilized class of BSCs are Class II Cabinets.

CLASS II TYPE A1, A2—recirculates 70% of the internal air and exhausts 30% of filtered air into the laboratory.

CLASS II TYPE B1, B2—either recirculates 30% of internal air and exhausts 70% of filtered air through a dedicated exhaust duct to the outside atmosphere or has a hard-duct installation directing 100% total exhaust of the cabinets.

Regulations/Standards

Regulations and Standards increase safety and are used to rationalize operations. They provide requirements, specifications, guidelines and/or characteristics that can be used consistently to make certain that materials, products, processes, and services are fit for their purpose. IBC oversight of this Program helps to ensure that all research protocols involving biohazardous materials and the facilities and equipment used to the conduct the research are in compliance with government regulations and applicable Caltech policies.

- **NSF/ANSI-49 2018 - Biosafety Cabinetry: Design, construction, Performance, and Field Certification.**

- **Cal-OSHA 8 CCR § 5154.2 – Ventilation requirements for Biological Safety Cabinets.**
- **BMBL 5th Edition**

According to the BMBL 5th edition:

NSF/ANSI Standard 49—2007 pertains to all models of Class II cabinets (Type A1, A2, B1, B2) and provides a series of specifications regarding:

- Design/construction
- Performance
- Installation
- Microbiological decontamination procedures

The functional operation and integrity of a BSC must be validated before it is placed into service and after it has been repaired or relocated. Relocation may compromise the HEPA filter seals or otherwise damage the filters and/or the cabinet. **Each BSC requires annual testing and certification to ensure continued, proper operation.**

On-site field-testing (NSF/ANSI Standard 49—2007 Annex F plus Addendum #1) must be performed by experienced, qualified personnel. Some basic information is included in the Standard to assist in understanding the frequency and kinds of tests to be performed. NSF's biosafety cabinetry program was initiated at the request of the regulatory community including the Centers for Disease Control, the National Institutes of Health and the National Cancer Institute. NSF certifies the design, construction and performance of biosafety cabinets to NSF/ANSI-49 and provide biosafety cabinet field certifier accreditation.

Caltech requires use of accredited field certifiers to test and certify BSCs.

CERTIFICATION REQUIREMENTS

Accreditation of Field Technician

Technicians sent to Caltech for certifying and/or recertifying Caltech BSCs are to be current in their **NSF accreditation** and the service company will provide copies of current accreditations for each technician performing maintenance and repair on BSCs.

QC process:

- *NSF Accreditation documents should be provided for each technician working on Caltech Campus (Those are individual accreditations).*

Equipment Calibration and Certification

Required equipment

- Calibrated hot-wire anemometer or calibrated direct airflow reading instrument
- Airflow visualization smoke tubes or smoke generator
- Calibrated aerosol photometer
- Calibrated aerosol generator

- Air flow capture hood if using Direct Method for inflow velocity test.

Additional equipment for recommended tests

- Calibrated light meter
- Calibrated manometer capable of measuring 2 inches of water column
- Vibration meter
- Sound Meter

All instruments used to certify BSCs should undergo **yearly calibration** and certification. This process is usually documented by NSF accredited personnel of services companies.

QC process:

- *Calibration/certification documents should be provided for each instruments used to certify and/or recertify Caltech BSCs.*

Preparation of BSCs and communication with the laboratories prior to performance testing

It is the responsibility of each laboratory to properly prepare their BSCs for performance testing.

- BSC should be emptied of biological material and supplies (pipettes, boxes, waste containers).
- Work surfaces should be decontaminated with the appropriate disinfectant, this includes the countertop, side and back wall as well as the interior of the sash.
- If small or large equipment is designed to be operated in the BSC, then the BSC should be able to pass certification with the equipment in place inside the unit. Laboratory is responsible for making sure the equipment is also properly decontaminated and does not contained biological material prior to performance testing.

Most BSC are located in laboratories operating at BSL2 and which operate with increased access control. Proper certification of BSCs takes approximately one to one-half hours, therefore it is recommended that the laboratory and the field technician(s) schedule the most appropriate time for the performance testing to allow ample time for the lab to prepare the BSC and minimize impact on the research activities.

Field technicians should always seek the Lab Safety Coordinators, lab managers or someone in the laboratory and verify that the BSCs are ready for performance testing prior to proceeding.

QC process:

- *Survey Lab personnel on preparation of BSC, quality of scheduling and quality of interaction with field technician(s).*

Performance testing for BSCs

From the BMBL 5th Edition:

Table 3. Field Performance Tests Applied to the Three Classes of Biological Safety Cabinets

Test Performed for	Biosafety Cabinet Class I	Class II	Class III
Primary Containment			
Cabinet Integrity	N/A	A (A1 Only)	A
HEPA Filter Leak	Required	Required	Required
Down flow Velocity	N/A	Required	N/A
Face Velocity	Required	Required	N/A
Negative Pressure / Ventilation Rate	B	N/A	Required
Airflow Smoke Patterns	Required	Required	E, F
Alarms and Interlocks	C, D	C, D	Required
Electrical Safety			
Electrical Leakage, etc.	E, D	E, D	E, D
Ground Fault Interrupter	D	D	D

Required Required during certification.
A Required for proper certification if the cabinet is new, has been moved or panels have been removed for maintenance.
B If used with gloves.
C If present.
D Encouraged for electrical safety.
E Optional, at the discretion of the user.
F Used to determine air distribution within cabinet for clean to dirty procedures.
N/A Not applicable.

Cal-OSHA requirement: Where biological safety cabinets are attached to external duct systems with a blower and the cabinet system also contains a blower, or where the cabinet uses an external blower (Only applicable for B cabinets), an **audible and visual alarm system to alert the user indicating the loss of exhaust flow in the external duct shall be used**. Biological safety cabinets which are served with a canopy or thimble connected exhaust system shall have a ribbon streamer or like device attached to the edge of the canopy or thimble to indicate the direction of flow and are exempt from the requirement for flow alarms.

Performance tests description – Required tests

The following is a brief description of the steps necessary for BSC performance testing according to the ANSI/NSF Standard.

Each certifying company should have internal SOPs for the detailed description of these tests.

QC process:

- *Companies testing SOP(s) should be provided to and reviewed by the Institute Biosafety Officer*

Down flow Velocity Profile Test: This test is performed to measure the velocity of air moving through the cabinet workspace, and is to be performed on all Class II BSCs.

Procedures:

- Adjust the sash to its design-use position.
- Using the anemometer holder, place the probe in an equidistant grid-spacing of ≤~6x6 inches, and a distance of 6 inches from the sidewalls, measuring the downward air at the center point of each grid cell, recording the values in the corresponding cells of the "Downflow'' grid on the form.
- Calculate and record the average down flow velocity.

Inflow Velocity Test: This test is performed to determine the calculated or directly measured velocity through the work access opening (front of the BSC), to verify the nominal set point average inflow velocity and to calculate the exhaust airflow volume rate – and set the alarm point for some units.

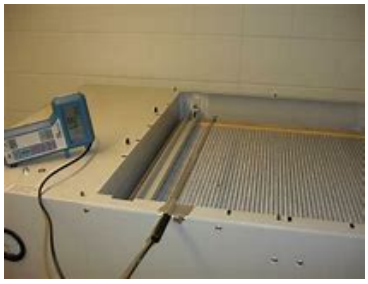
Procedures (choose one):

<u>Direct Inflow Method</u>

- Use a **Seal capture hood** placed to the face of the BSC and record 5 airflow volume readings.
- If the unit is a B2 cabinet then turn off the down flow and cover the supply air intake and record the 5 airflow readings.
- Calculate and record the average of these readings (extra calculations are needed for B cabinets).

<u>Readings above Exhaust HEPA</u>

- With the **thermal anemometer** ~4 inches above the HEPA secured in a stand with clamp, measure and record the individual air flow velocity readings above the HEPA filter, sampling in a grid with spacing not greater than 4 inches between points and 4 inches from the inside edge of the filter frame. There should be at least 12 inches of clearance above the filter per NSF/ANSI 49 Standard.
- Average the readings and calculate the inflow velocity.



Constricted/Reduced Access Method:

This method is usually accompanied with explicit specifications and probe holder from the manufacturer.

- Lower the front window to a height of 3 in.
- Insert the thermal anemometer probe into the probe holder.
- Place the probe holder at the window opening work surface, ensuring it is seated properly.
- See *Figure 8-1. Constricted Window Method*. Adjust the probe so the air passing through probe is centered in the window opening (1.5 in.)

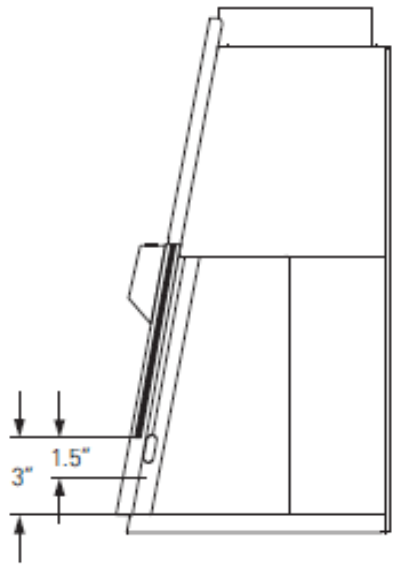


Figure 8-1. Constricted Window Method

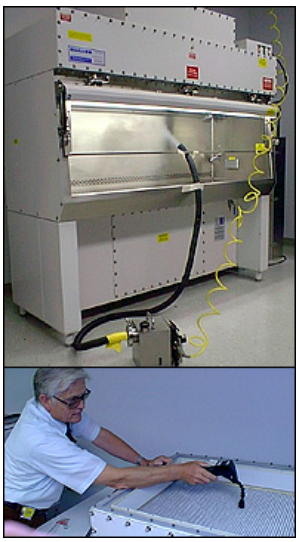
Note: The thermal anemometer probe must be positioned at a 10° angle from front vertical and located on the same plane as the inside of the window glass.

- Beginning 5.9 inches in from the left inside wall, record successive readings every 5.9 inches (5 readings for 3 ft, 7 readings for 4 ft, 9 readings for 5 ft, and 11 readings for 6 ft models).
- Average those readings and correct result for true velocity.
- Calculate the inflow velocity

Airflow Smoke Patterns Test: This test is performed to determine if: 1) the airflow along the entire perimeter of the work access opening is inward; 2) if airflow within the work area is downward with no dead spots or refluxing; 3) if ambient air passes onto or over the work surface; and 4) if there is no escape to the outside of the cabinet at the sides and top of the window. **The smoke test is an indicator of airflow direction, not velocity. See the video: Airflow Smoke Pattern Test:** https://www.youtube.com/watch?v=a7GBk1vSIsU

HEPA Filter Leak Test: This test is performed to determine the integrity of **supply** and **exhaust** HEPA filters, filter housing and filter mounting frames while the cabinet is operated at the nominal set point velocities. An aerosol in the form of generated particulates of dioctylphthalate (DOP) or an accepted alternative (e.g., poly alpha olefin (PAO), di(2-ethylhexyl) sebecate, polyethylene glycol and medical grade light mineral oil) is required for leak-testing HEPA filters and their seals. The aerosol is generated on the intake side of the filter and particles passing through the filter or around the seal are measured with a photometer on the discharge side. This test is suitable for ascertaining the integrity of all HEPA filters.

Procedures



Introduce the aerosol from the generator in the center rear of the work area, using a tee fitting to evenly distribute the aerosol.

- Testing the **Supply** HEPA filter:

Scan with aerosol photometer the downstream side and perimeter of the filter and record data.

- Testing the **Exhaust** HEPA filter:

Scan with aerosol photometer the upstream side and perimeter of the filter (on top of the unit) and record data.

Cabinet Integrity Test (A1 Cabinets only): This pressure holding test is performed to determine if exterior surfaces of all plenums, welds, gaskets and plenum penetrations or seals are free of leaks. In the field, it need only be performed on Type A1 cabinets at the time of initial installation when the BSC is in a free-standing position (all four sides are easily accessible) in the room in which it will be used, after a cabinet has been relocated to a new location, and again after removal of access panels to plenums for repairs or a filter change.

Performance tests description – Recommended tests

Electrical Leakage and Ground Circuit Resistance and Polarity Tests: Electrical testing has been taken out of NSF/ANSI 49 Standard—2007 for new cabinets certified under this Standard. This responsibility has been turned over to UL. All new cabinets must meet UL 61010A-1 in order to be certified by NSF. These safety tests are performed to determine if a potential shock hazard exists by measuring the electrical leakage, polarity, ground fault interrupter function and ground circuit resistance to the cabinet connection. An electrical technician other than the field certification personnel may perform the tests at the same time the other field certification tests are conducted.

Lighting Intensity Test: This test is performed to measure the light intensity on the work surface of the cabinet as an aid in minimizing cabinet operator fatigue.

Vibration Test: This test is performed to determine the amount of vibration in an operating cabinet as a guide to satisfactory mechanical performance, as an aid in minimizing cabinet operator fatigue, and to prevent damage to delicate tissue culture specimens.

Noise Level Test: This test is performed to measure the noise levels produced by the cabinets, as a guide to satisfactory mechanical performance, and an aid in minimizing cabinet operator fatigue.

QC process:

- *Performance testing to be observed by Caltech personnel (Lab, division, EHS) who are knowledgeable of the SOPs, testing standards and Institute expectations on a regular basis and observations shall be documented.*

Performance testing documentations

BSC performance testing should always be documented using two methods:

Performance Testing Report:
A testing report will be issued by the testing company for each BSC, including general information about the BSC (type, location, serial number, etc.) and each of the tests that have been performed. Report to include raw data (measurement from instruments) and final calculated results. Pass/Fail test should be documented as Pass or Fail, or N/A if the test was not performed. The Report will also record the date of testing, and the name and accreditation number of the field technician(s) in a visible manner (initials are not sufficient).

Reports shall be sent to Caltech personnel (Division, Lab, etc.) in a timely manner and kept for at least a year.

QC process:

- *Report to be verified for accuracy of information and for congruency with field observations of performance testing.*
  Example: if the inflow velocity was testing using the "reading above the Exhaust HEPA" technique, this should be congruent in the report.

BSC Certification Stickers:
Companies that certify BSCs will place a company sticker on each BSC that passed certification. Sticker will contain Company contact information, BSC information, date of certification, next due date, and field technician name or initials.

The Sticker should be placed on the Cabinet AFTER all performance tests are performed and final calculations made and ONLY if the Cabinet passes each of the performance test.

If a BSC does not pass one or more performance tests the unit should not be certified and the lab should be notified.

QC process:

- *Stickers to be verified for accuracy of information and observations during performance testing, and record the timing in which stickers are filled by the technician(s).*

SUMMARY OF INSITUTE MINIMUM EXPECTATIONS FOR BSC CERTIFICATIONS:

All field technicians certifying BSCs at Caltech are to be NSF accredited and accreditation documentation must be made available upon request.

All Caltech Biosafety Cabinets, regardless of type, brand, and model or manufacturer specification are to be tested on an annual basis for the following performance tests:

- Down flow velocity
- Inflow velocity (chosen method to be documented)
- HEPA filter leak test for Supply filter
- HEPA filter leak test for Exhaust filter
- 4 directions smoke pattern

All Type B cabinets with audible and visual alarm systems to alert the user(s) of the loss of exhaust flow in the external duct are to be tested.

For Class II A1 Cabinets: Integrity Tests should be performed at time of initial installation when the BSC is in a free-standing position (all four sides are easily accessible) in the room in which it will be used, after a cabinet has been relocated to a new location, or again after removal of access panels to plenums for repairs or a filter change.

SUMMARY QUALILTY CONTROL POINTS

All QC processes below should be performed on a regular basis and properly documented:

- *Institute expectations, administrative and technical, to be communicated to BSC service companies before entering into a commercial agreement with the Institute.*
    - *Scope of work to match the requirements set by the Institute.*
    - *Contracted prices to be compared to invoices received at the time of service.*
- *NSF Accreditation documents to be provided for each technician working on Caltech Campus (Those are individual accreditations).*
- *Calibration/certification documents to be provided for each instrument(s) used to certify and/or recertify Caltech BSCs.*
- *Survey Lab personnel on preparation of BSC, quality of scheduling and quality of interaction with field technician(s).*
- *Companies testing SOP(s) should be provided and reviewed.*
- *Performance testing to be observed by Caltech personnel (Lab, division, EHS) who are knowledge of the SOPs, testing standards, and Institute expectations on a regular basis and observations to be documented.*
- *Certification Reports shall be verified for accuracy of information and for congruency with field observations of performance testing when applicable*
- *Certification Stickers to be verified for accuracy of information and observations of performance testing will record the timing in which stickers are filled by the technician(s) when applicable.*

Roles and Responsibilities – TBD