Ask the Experts:

The Need for Field Certification of Biosafety Cabinets

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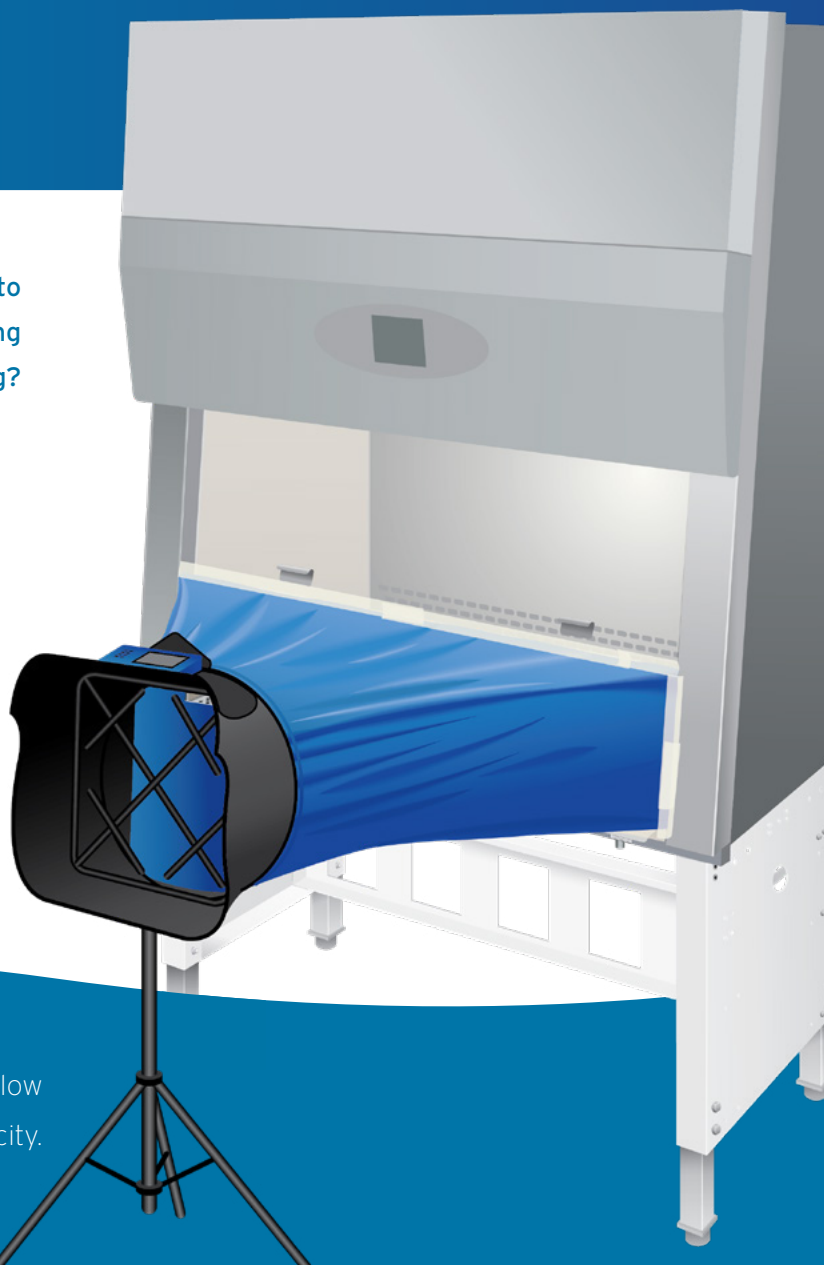
Have you ever wondered what the individual hired to certify your biosafety cabinet (BSC) is actually doing when they are in your lab? Or what they should be doing?

In this article, we will discuss:

1. How Class II BSCs are initially performance tested then validated and certified by NSF International
2. When, how, and why BSCs need to be certified while in your lab
3. What you should expect to see during BSC field certification
4. How to find a qualified BSC field certifier



Class II Type A2 Biosafety Cabinet with airflow capture hood used to measure the inflow velocity.

Biosafety Cabinet Performance Testing and Certification

In order to provide their three levels of protection (personnel, product, and environmental), Class II BSCs must be specifically designed and constructed to achieve and regularly demonstrate certain performance criteria as described in the NSF/ANSI Standard 49- 2022.[1,2] This formal standard describes the entire life cycle of a BSC from design to disposal.[1] For an overview of BSC class functionality, performance testing, field certification, and information about the NSF field certifier accreditation programs, consider reviewing NSF's webinar "Biosafety Cabinetry Testing, Certification, and Field Certifier Accreditation Overview" for more details.

At a high level, the performance validation part of this life cycle includes several steps that we will cover in more detail below. First, the cabinet manufacturer designs, manufactures, and tests the cabinet to meet NSF/ANSI Standard 49. Then they send the cabinet to NSF International for testing to validate it meets the specific performance criteria required in the NSF/ANSI Standard 49. If the BSC passes the testing, NSF places the cabinet model on a searchable list of certified biosafety cabinet models on its website. Lab users purchasing BSCs can use this list to determine if the cabinet models of interest for their laboratory have been tested and certified by NSF to meet these critical performance criteria. The manufacturer then mass produces and sells the identical model and size as an NSF/ANSI Standard 49 labeled and listed cabinet.[1] BSCs whose designs have been NSF/ANSI Standard 49 certified will also receive an "NSF" marking.[2] The BSC manufacturer will conduct specific factory testing on each cabinet manufactured to ensure it performs as expected, consistent with the NSF certified BSC cabinet model. Finally, the cabinet owner and lab user have the BSC installed and field certified in their laboratory to ensure the BSC is performing as designed and constructed by the manufacturer and certified by NSF International using a qualified, and preferably an NSF accredited, BSC field certifier.[1]

Biosafety Cabinet Certification Testing

The NSF/ANSI Standard 49 requires 13 physical tests be performed to be qualified for certification by NSF International. Often the manufacturer will pre-test the BSC cabinet model before sending it to NSF International to evaluate its performance and likelihood of passing NSF certification. These tests are described in the Standard Section 6: Performance with the test methods and acceptance criteria specified in Normative Annex N-1.[1] These

Airflow probes are used to calculate the downflow velocity of biosafety cabinets.

requirements include tests of pressure decay/tracer gas leak, HEPA/ULPA filter leak, noise level, lighting intensity, vibration, personnel, product, and cross-contamination protection, stability, downflow and inflow velocities, airflow patterns, drainage trough leak, motor/blower performance, and electric safety.[1] The most important NSF/ANSI Standard 49 Normative Annex N-1 tests for verifying biological containment are the microbiological challenge tests for personnel, product, and cross-contamination using *Bacillus subtilis* var. *niger (B. subtilis)* spores. These tests involve varying concentrations of the *B. subtilis* spores that are nebulized (aerosolized) in or around the BSC and the visualization of where the resulting spores are identified.[1] The *personnel protection* test demonstrates that particulates/aerosols are contained within the BSC.[1] The *product protection* test demonstrates that contaminants present outside of the BSC cannot enter the work zone.[1] The *cross-contamination* test demonstrates that there is a minimization of particulate/aerosol contamination of materials and equipment handled inside of the biosafety cabinet.[1] These protection tests along with the other physical tests specified in the Normative Annex N-1 must be conducted before the Class II BSC is certified by NSF International and available for listing on their website.

Biosafety Cabinet Factory Quality Control Testing

As the model is mass produced by the BSC manufacturer, NSF requires documented factory tests of pressure decay/tracer gas leak, HEPA/ULPA filter leak, downflow and inflow velocities, and airflow patterns on every cabinet made in addition to tests of noise level, lighting intensity, and vibration on one out of every ten cabinets made. Notably, however, they do *not* require microbiological testing on mass produced units.[1]

Biosafety Cabinet Field Certification

To ensure the Class II BSC is still performing as designed and then certified by NSF International, it must be tested at the time of installation (before being used for any lab work), after repairs or relocation, and at least annually after installation.[2,3,4] This "field certification" testing should be performed based on the NSF/ANSI Standard 49 Normative Annex N-5 testing methods and the acceptance criteria provided by the BSC manufacturer and NSF International.[4] This testing does not include all of the tests described in Normative Annex N-1 but consists of 5 required tests for containment (6 if the BSC has a positive pressure plenum) and 4 optional worker comfort and safety tests.[4]

The required tests evaluate the effectiveness of the biosafety cabinet's containment[3,4] and include:

1. The Downflow Velocity - this testing compares the actual flow of HEPA filtered air down over the work surface based on a specific grid pattern published by the BSC manufacturer using a probe (thermal anemometer) mounted on a stand.
2. The Inflow (Face) Velocity - this testing evaluates the flow of air into the BSC through the front sash opening using either a large, tented capture hood device (the "Direct Inflow Method" or "DIM" for short) or a manufacturer/NSF approved secondary method (often the use of a thermal anemometer probe held with a manufacturer supplied probe fixture while the front sash is closed to a designated, restricted height).
3. The Airflow Patterns - testing includes 4 airflow visualization tests that are often referred to as "smoke tests" since they must use a visible aerosol to evaluate the product/cross-contamination, personnel, and environmental protection of the BSC.
4. The Integrity of the HEPA/ULPA Filters - this testing involves the generation of particles (DOP/PAO) which are introduced into the BSC and then the HEPA/ULPA filters are scanned for leaks using a handheld photometer to evaluate the penetration percentage of particles and the location where they make it through the filters.
5. The Site Installation - this testing includes assessments of the function of alarms associated with the front sash height, the exhaust system (whether hard ducted or canopy/thimble connected), the interlocking of internal supply and exhaust fans, and the inflow velocity (if the alarm is present).

To visualize the downflow velocity, inflow velocity, HEPA filter leak, and smoke tests, NSF has created a set of videos. These videos are also available with Spanish and Chinese subtitles. BSC owners and lab users should be familiar with how these tests are performed so they can identify discrepancies, if any, between the method used by their field certifier and the NSF/ANSI Standard 49 Normative Annex N-5 that details how to conduct these field certification tests appropriately.[4]

The optional worker comfort and safety tests may be conducted if they are requested by the lab user or performed at the discretion of the certifier. These tests evaluate the intensity of light on the BSC work surface, the amount of noise the BSC makes, the level of vibration generated by a functioning cabinet, and the electrical leakage, ground circuit resistance, and polarity if the BSC was qualified prior to the 2009 edition of the NSF/ANSI Standard 49.[4] Additional testing may also be required based on the industry using the cabinet such as if it is used in pharmaceutical or electronics operations.[4] For instance, BSC use in hospital pharmacy drug compounding has additional testing requirements that are not covered in this article.

Selecting a Qualified Field Certifier

Ensuring the Class II BSC meets the cabinet manufacturer's and NSF/ANSI Standard 49 Normative Annex N-5's acceptance criteria in your laboratory application requires training and education, as well as specialized, properly maintained, and calibrated equipment.[2,3] Therefore, it is critically important to choose qualified, competent individuals to perform these BSC field certification tests[2,3] preferably those who are accredited.[2] Consider involving your organization's health and safety group in this selection effort[2] and searching for an accredited individual on the NSF's list of accredited BSC field certifiers from their Enhanced Accreditation Program. The BSC field certifier chosen should also be able to troubleshoot and repair your cabinet if issues are identified during testing. They should be able to assist you in performing a risk assessment if the cabinet requires gas decontamination before certification or maintenance activities and in selecting the appropriate PPE needed to handle the BSC while performing testing. More information on gas decontamination and selecting qualified professionals can be found in this article: Biosafety Cabinet Gas Decontamination Considerations.

As noted in the previous section, one way to identify if your BSC field certifier is qualified and competent is to familiarize yourself with the types of equipment required for testing and how the test methods that are required by the NSF/ANSI Standard 49 for field certification are performed. You should also expect to receive two forms of documentation after Class II BSC field certification testing is completed including a certification label and a certification report from qualified field certifiers. The contents of both of these records is described fully in the NSF/ANSI Standard 49 Normative Annex N-5.[4] In general, the certification label is attached to the front of the BSC in a visible location and must include the certification test date and retest due date, the certification test report number, the certifier information (company name, website or street address, and phone number), the BSC's serial number, and the certifier's printed name, signature, and accreditation number, if applicable.[4] The certification report is provided to the lab user for their records and if the BSC was certified in accordance with the NSF/ANSI Normative Annex N-5 must include at least the BSC model and serial number, the location of the cabinet, venting information (ducted or not ducted and type of connection- canopy, direct, or none), the type of BSC, the testing equipment used by the certifier (including manufacturer, model, serial number, and calibration date), reported values of the test data and their acceptance criteria, the certifier's printed name, and the certification test date and retest due date.

Conclusions

BSCs are the primary engineering control devices used to mitigate exposure risk to biohazardous materials, particulates, and aerosols in many different industries. To ensure that they are appropriately designed, constructed, and manufactured to protect the user and contain these potential hazards the NSF/ANSI Standard 49 details specific performance criteria and ongoing field certification testing that should be conducted. The BSC manufacturer and NSF International perform specific testing before listing the cabinet model as meeting the NSF/ANSI Standard 49 criteria. Qualified field certifiers (preferably those who have been NSF accredited) then conduct a subset of this testing in laboratory settings to ensure the BSC has been installed appropriately and that it is maintaining its personnel, product, and environmental protection on an ongoing basis. Understanding this biosafety cabinet performance and field certification life cycle will aid laboratory professionals in making informed decisions about the purchase, use, continued evaluation, maintenance, and care of these primary containment devices.

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Learn more at: www.nuaire.com

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