Class II biological safety cabinets (BSCs) are vital pieces of laboratory equipment in many life science applications requiring contamination control. In addition to providing a workstation with aseptic conditions for product protection, a BSC also helps protect laboratory personnel from exposure to aerosols of hazardous substances and prevents the release of such hazards into the environment. Field certification is the method by which proper BSC operation is verified over time, to be sure that product, personnel, and environmental protection are maintained.

Requirements for Class II biological safety cabinets in the United States are established by NSF International and published in NSF/ANSI Standard 49.1 Class I and Class III cabinets also exist and are generally used only for special applications. Class II cabinets are by far the most prevalent, and NSF 49 is specific to Class II BSCs. Therefore, this article will focus on Class II BSCs, and all subsequent uses of “BSC” are in respect to Class II BSCs.

NSF 49 includes definitions of the types and function, acceptable materials, design and construction requirements, and performance requirements for Class II BSCs. NSF International manages a program of type testing and product certification for Class II BSCs. Annex F of the standard includes specific requirements for field certification. To ensure that individuals performing certification are properly qualified, NSF International also administers a program for Biosafety Cabinet Field Certifier Accreditation.

This article will review the function and designs of Class II BSCs and describe the field tests that should be performed during certification. The relationship between certification and commissioning will then be discussed, and the process and requirements for accreditation of field certifiers will be reviewed.

Types of Class II biological safety cabinets
All Class II biological safety cabinets offer product, personnel, and environmental protection from biological and other aerosolized contaminants. Product protection is offered by unidirectional (commonly called “laminar”) downflow air in the work chamber, generated by the cabinet blower pushing air through the supply HEPA filter. Personnel protection comes from the intake air pulled into the front access opening of the cabinet. Environmental protection is provided by HEPA filters in the exhaust air stream of the cabinet. The airflow pattern in a generic Class II BSC is shown in Fig. 1.

Different types of Class II BSCs are utilized when protection from chemical vapor hazards is also a concern, as HEPA filters do not capture gases or vapors. Type B1 and B2 cabinets must be directly connected to the building’s exhaust system for venting to the outdoors via a hard connection (see Fig. 2). Type A1 and A2 cabinets usually return their filtered exhaust air to the room but may optionally be connected to the building exhaust system with a canopy.
Field tests for biological safety cabinets

BSC field tests should be performed by the certifier upon installation and relocation of cabinets, after major maintenance is conducted, changing of HEPA filters, and at regular intervals thereafter. NSF 49 recommends a maximum interval of 12 months between certification, though many organizations re-certify more frequently. For example, pharmacies certify their BSCs every 6 months as required by USP Chapter <797> on sterile compounding.

In order to verify proper operation of a biological safety cabinet, the following tests are performed. These tests are related to the containment and product protection provided by the cabinet, and results must correlate to the values obtained by NSF for type testing of that particular make, model, and size of cabinet.

- Downflow velocity profile test
- Inflow velocity test
- Airflow smoke pattern tests
- HEPA filter leak test
- Cabinet integrity test (for Type A1 cabinets with positive-pressure contaminated plenums only)
- Alarm function verification
- Blower interlock (for Type B1 and B2 cabinets)
- Exhaust system performance (for any cabinet connected to the building exhaust)

While not part of Class II BSC field certification to NSF Standard 49, for certain installations additional validation tests may be required. For example, most cGMP compliant facilities will verify air cleanliness with a particle counter to the required ISO class per IEST protocols. Any such validation tests should be performed in conjunction with field certification.

The following tests, related to worker comfort and safety, may optionally be performed. These tests verify functions of the cabinet not directly related to containment or product protection.

- Lighting intensity test
- Vibration test
- Noise level test
- Electrical tests (leakage, ground circuit resistance, and polarity)

Certification and commissioning

The goal of commissioning is to verify and document that the facility and its systems meet defined objectives and criteria for performance. Commissioning is performed prior to occupying new laboratory facilities to ensure that systems are operating as specified. Many organizations also repeat commissioning, or at least some portion thereof, at regular intervals to ensure continued proper operation of building systems. This “re-commissioning” is a good practice to guarantee that all building systems continue to function as required.

One of the most important systems considered in the commissioning process for laboratory facilities is the HVAC (heating, ventilation, and air conditioning) system. This is where commissioning and certification have a vital overlap and interdependency. Proper HVAC design and operation is crucial to the proper operation of BSCs. While the majority of BSCs
installations simply return cabinet exhaust to the room, the may still impact, or be impacted by, the function of the HVAC system.

From a heating and cooling standpoint, a typical 4-ft Class II, Type A2 cabinet may generate 2,000 to 3,000 BTU/hr. Air conditioning and heating systems should be verified to maintain desired environmental conditions when BSCs are in operation, as well as when cabinets are turned off.

More crucial to the safety of laboratory workers an the integrity of aseptic work processes is the possible impact of air currents in the room on the performance of the BS itself. Location of room air supplies and returns is critical as cross-drafts may negatively affect the performance of BSCs. This dependency should be taken into account when designing room air ventilation and should be verified during the commissioning process.

Another level of complexity is introduced when BSCs are vented to the outdoors via the building exhaust system. With such an installation, the BSC itself becomes the first piece of the system ductwork and needs to be designed for and tested as such. In addition to the possible impact of cross-drafts, the commissioning process for BSCs should also verify that the required exhaust and room supply air to operate the BSC are available and that HVAC controls are interfaced with the BSC controls.

1. Supply air
Supply air requirements for BSCs are often overlooked. However, they can be just as critical as exhaust air requirements to proper cabinet function. Whatever volume of air is exhausted by the BSC must also be supplied to the room in order to avoid "starving" the cabinet of air. The supply air available to the BSC should be verified as well as the supply air to maintain desired room pressurization and air exchange rates. A BSC cannot be certified if a lack of supply air causes a low or inconsistent inflow or downflow velocity.

2. Exhaust airflow and static pressure
Biological safety cabinets are constant volumetric airflow devices, and the fan energy to exhaust the cabinet must be provided by the building exhaust system. In addition to the exhaust airflow, the static pressure requirements for hard connected Type B cabinets are relatively high (up to ~2.5 in. of water column for a 6-ft B2 cabinet). This is due to the resistance added to pull air through the cabinet and its exhaust HEPA filters. For canopy connected Type A cabinets, the cabinet blower overcomes the resistance of the exhaust filter; however, sufficient exhaust flow is still important. Biological safety cabinets will not function properly and cannot be certified if the exhaust flow or static pressure is not sufficient (or potentially if either is too high).

3. HVAC and cabinet controls
Low exhaust flow can lead to a loss of containment at the front access opening of the BSC and pose a risk to workers. As indicated by NSF 49, exhausted BSCs should have airflow monitors that alarm when the exhaust flow is too low. This feature is required for hard connected Type B cabinets and should be considered as good practice for canopy connected Type A cabinets. The alarm function should be verified during commissioning, as well as for certification. It is often desirable, or even required, to control the BSC and HVAC systems in concert, and verification of any such interlocks should be included in the commissioning process. Interlocks in the controls allow the room to maintain required pressurization, air changes, and exhaust flow when the cabinet is in operation as well as when the cabinet is turned off.

In the author’s experience, a great majority of the problems encountered in field certification and proper operation of BSCs could be avoided if a thorough commissioning process were followed. The commissioning process should include documentation and verification of the requirements for BSCs as they relate to the building’s HVAC systems. Field certification can be successfully completed only after the HVAC requirements for BSCs have been verified through commissioning.

Accreditation for field certifiers
Because of the specialized knowledge required for proper and safe certification of BSCs, NSF International administers an accreditation program for field certifiers. To become accredited, a field certifier must pass a written and a practical test administered by NSF. Additionally, continuing education and periodic re-examination are required in order to maintain accreditation.

When selecting a service provider for certification, BSC owners should be sure that the vendor company’s technicians are accredited field certifiers. To help locate a certifier, NSF maintains a searchable listing on its website of accredited certifiers. Certification companies also provide service when problems with BSC function occur between regular certification intervals, or when maintenance tasks such as filter changes are necessary. If an organization performs certification using its own employees, such technicians should also obtain NSF accreditation to be sure that they possess the knowledge and experience required for field certification of BSCs.

Conclusion
Biological safety cabinets are critical pieces of contamination control equipment in the laboratory setting. In order to ensure proper functioning and maximum safety, it is imperative that the HVAC systems, BSCs, and field certifiers are properly maintained and certified.
control equipment in many settings. Field certification is essential to verify that BSCs continue to provide the product, personnel, and environmental protection that they were designed to offer. While commissioning and field certification technicians have distinct roles, it is vital to each that they collaborate to ensure that HVAC systems will support BSCs and that BSCs function as intended. Field certification of BSCs should occur at regular intervals and be conducted by field certifiers accredited by NSF International.

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Table 1: Definitions of Class II biological safety cabinet types

<table>
<thead>
<tr>
<th>Class II BSC Type</th>
<th>Minimum Intake Velocity (fpm)</th>
<th>Construction</th>
<th>Airflow Pattern</th>
<th>Volatile Toxic Chemicals (gases or vapors) Permitted</th>
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<tbody>
<tr>
<td>A1</td>
<td>75</td>
<td>May have biologically contaminated ducts and plenums under positive pressure to the room</td>
<td>Downflow and inflow air mix in a common plenum, approximately 70 percent recirculated as downflow, 30 percent exhausted</td>
<td>No</td>
</tr>
<tr>
<td>A2</td>
<td>100</td>
<td>Biologically contaminated ducts and plenums must be under negative pressure to the room, or surrounded by negative-pressure ducts and plenums</td>
<td>Downflow and inflow air mix in a common plenum, approximately 70 percent recirculated as downflow, 30 percent exhausted</td>
<td>No—when exhaust air is vented back into the room Yes—minute quantities allowed when canopy connected and exhausted to the outdoors</td>
</tr>
<tr>
<td>B1</td>
<td>100</td>
<td>Biologically contaminated ducts and plenums must be under negative pressure to the room, or surrounded by negative-pressure ducts and plenums</td>
<td>Approximately 60 percent of downflow air exhausted through a dedicated duct; the remainder of downflow air (approximately 40 percent) mixes with intake air and is recirculated</td>
<td>Yes—minute quantities allowed</td>
</tr>
<tr>
<td>B2</td>
<td>100</td>
<td>Contaminated ducts and plenums must be under negative pressure to the room, or surrounded by negative-pressure ducts and plenums</td>
<td>Downflow air drawn from laboratory; inflow and downflow air exhausted with no recirculation in the cabinet or return to the laboratory (100 percent exhausted)</td>
<td>Yes—as an adjunct to microbiological work</td>
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References