



Revisions to the National Sanitation Foundation International/American National Standards Institute Requirements

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Abstract

Recent revisions in the National Sanitation Foundation International/American National Standards Institute Requirements (49-2002) for field certification of Class II biosafety cabinets are described, along with recommendations for end-users as to how to meet these modified standards.

Introduction

In March 2002, the National Sanitation Foundation International (NSF) completed an extensive revision of its Standard 49, which addresses the design, construction, and performance of Class II biosafety cabinets (BSC). The modified Standard contains significant changes in the test procedures and acceptance criteria for Field Certification. These revisions are retroactive in nature, applying to old and new Class II BSCs.

The following six containment tests are required for a cabinet to earn "Field Certified in Accordance with NSF 49":

1. Downflow velocity profile
2. Inflow velocity
3. Airflow smoke patterns
4. HEPA filter leak
5. Cabinet integrity (type A1 only)
6. Site installation assessment

The revisions in the HEPA filter leak, the cabinet integrity, and the site installation assessment tests are the ones most likely to have an impact on current users and are the subject of this brief report. The minor changes in the other three tests are relatively transparent. For example, the uniformity requirement for downflow velocities has been expanded from 20% to 25% using the same test method. Therefore, the only changes in this test concern data analysis and a less restrictive acceptance criterion.

HEPA Filter Leak Test

Although the test itself remains unchanged, the maximum allowable patch restriction has been reduced. While the previous Standard allowed up to 5% of the HEPA filter area to be obstructed by patching, the revised NSF/American National Standards Institute (ANSI) 49-2002 Standard permits only a 3% maximum filter obstruction. The replacement of the HEPA filter is the only available remedy for units in which the extent of patching exceeds this new standard.

Cabinet Integrity Test

Class II, Type A1 BSCs (formerly Class II, Type A) is one of the least common Class II BSCs and the only one requiring an integrity test when it is installed or moved, and/or when the containment

panels are removed or replaced (e.g., upon replacement of filters or if repaired in a contaminated space).

The test, which requires no more than an hour to complete, involves sealing the cabinet with tape, plastic, and blank off panels. It is then pressurized to 2 inches w.g. and a soap solution applied to all welds, gaskets, penetrations, and seals. Leaks will be audible or indicated by bubbles and may be easily repaired by tightening panels.

Site Installation Tests

The assessment of the BSC's installation represents an entirely new category of containment test and is designed to evaluate its operation when in actual use. The following are the four site installation tests which must be performed:

Sash Alarm Function

When the sash is raised 1 inch above the manufacturer's recommended height, an audible alarm must sound.

Exhaust Alarm Function

There are two types of cabinet exhausts—direct connection and exhaust canopy. The former represents a solid connection between the BSC exhaust opening and the building's dedicated BSC exhaust system. It is recommended that this dedicated system have constant flow rates, local flow adjustments (i.e., damper adjustments in the rooms), test ports for exhaust velocity measurements, and filter leak testing, as well as flexible connections or gas-tight dampers to facilitate an airtight seal for gas decontamination.

An exhaust canopy is a flared canopy, usually about 1 inch above the BSC exhaust opening. The canopy captures all of the exhaust flow coming from the biosafety cabinet and is recommended for all

Type A1 and A2 (formerly A and B3, respectively) BSCs when external exhaust is desired. Many manufacturers can provide exhaust canopies and transitions designed to work with their biosafety cabinets.

The NSF/ANSI 49-2002 Standard requires that externally exhausted Class II BSCs have audible and visual alarms which are initiated within 15 seconds of a 20% decrease in exhaust air volume.

Blower Interlock Function

Class II, Type B2 BSCs (commonly referred to as "Total Exhaust" units) are required to have an alarm interlock that shuts off power to the supply blowers when the exhaust alarm is activated.

Exhaust System Performance

The revised Standard requires that no smoke escape the exhaust canopy once drawn in through the gap from the cabinet. Alternatively, the exhaust duct for BSCs that are exhausted through a direct connection must be negatively pressurized relative to the room.

Conclusion

The revisions contained in the NSF/ANSI 49-2002 Standard enhance the criteria for field certification of NSF listed Class II BSCs. As a result, cabinets certified under the old Standard may be required to undergo repair or, at an extreme, to be discarded as being incapable of meeting the new requirements. If the BSC is not NSF listed, then the issues relative to the new Standard would appear not to apply, as the cabinet was not designed to meet NSF criteria.

Copies of NSF/ANSI 49-2002 are available by contacting NSF International, 789 North Dixboro Road, P.O. Box 130140, Ann Arbor, MI 48113-0140, phone: 734-769-8010, fax: 734-769-0109, web site: www.nsf.org.