Joint Committee on Biosafety Cabinetry

July 18, 2024

## Proposed revision to NSF/ANSI: 49 – Biosafety Cabinetry: Design, Construction, Performance and Field Certification (49i198r2)

Revision 2 of NSF/ANSI 49, issue 198 is being forwarded to the Joint Committee on Biosafety Cabinetry for consideration. Please review the proposal and **submit your ballot by August 8, 2024** via the [NSF Online Workspace](#).

Please review all ballot materials. When adding comments, please include the section number for your comment and add all comments under one comment number whenever possible. If additional space is needed, you may upload a MS Word or .PDF version of your comments directly to the NSF Online Workspace.

## Purpose
The purpose of this ballot is to affirm new language related to replacement filters in section 5.22 of Standard 49.

## Background
The idea of Filter Equivalent Language was discussed during a breakout session of the BSC Joint Committee during the 2023 Face-to-Face meeting. At that time the group found the topic worthy of discourse and motioned to set up a TG called *Replacement Parts* and discuss this topic further

This group met once since that time agreeing on the concept and drafting some language during the meeting. A small ad hoc group cleaned up the language a bit, and submitted an issue paper with that language which yielded a straw ballot vote of **3 : 1 : 0 (Yes : No : Abstain)** and one comment. That comment was incorporated into this revision 2 ballot which is presented here now for your consideration.

If you have any questions about the technical content of the ballot, you may contact me in care of:

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**[Note – the recommended changes to the standard which include the current text of the relevant section(s) indicate deletions by use of ~~strikeout~~ and additions by grey highlighting. Rationale statements are in *red italics* and only used to add clarity; these statements will NOT be in the finished publication.]**

# NSF/ANSI International Standard
# for Biosafety Cabinetry —

## Biosafety Cabinetry: Design, Construction, Performance, and Field Certification

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### 5.22 Filters
— HEPA/ULPA filters shall be required for the downflow and exhaust air systems; and

— HEPA/ULPA filters for downflow and exhaust systems shall conform to the materials, construction, and aerosol efficiency requirements of IEST-RP-CC001.5[12] for Type C, Type J, Type K, or Type F filters. Filter media shall be tested in accordance with the methods of IEST-RP-CC021.3[12] with performance levels to meet the minimum efficiency requirements as specified above and the pressure drop requirements as required by the specific application. In addition, HEPA/ULPA filters shall be scan tested for a leakage not to exceed 0.01% when tested in accordance with Section N-1.2.

— HEPA/ULPA filters shall be specified (and considered equivalent) as to:
  ● Type or grade (i.e. per IEST-RP-CC001.5[12])
  ● External physical dimensions (width x depth x height)
  ● Location and description, including the material of the gasketing on the filter
  ● Presence and description of protective screens
  ● Other structures on or inside the filter, specifically structural elements and media separator type
  ● Material and construction of filter frame
  ● Internal physical dimensions of the media pack unobstructed by potting or sealing media
  ● Pressure drop across the filter +/- 0.05" w.g. (12.5 Pa) at the rated flow

The cabinet shall be designed to provide accessibility for filter installation, testing, and sealing.

— HEPA/ULPA filters shall be mounted to prevent air bypass of the filters. When required, one or more plugged penetrations shall be located in the plenum upstream of the HEPA/ULPA filters and accessible from under the work surface. In the case of a Type B2 cabinet where the downflow plenum is not contaminated, the sample port may terminate anywhere that is accessible from the front of the cabinet. If a Type B2 cabinet is equipped with an exhaust sample port, that sample

port shall be accessible from under the work surface. Sample ports shall be capped and labeled. The label shall include the purpose of the penetration (upstream aerosol sampling). Sample ports coming from the plenum to the area under the work surface shall have a minimum inside diameter of 1/4 in (6.4 mm). The tube shall be short enough that it cannot break the plane of the sash. These penetrations are used to measure the aerosol concentration upstream of the HEPA/ULPA filters during the HEPA/ULPA filter leak test (see Section 6.3). When the penetration enters a potentially contaminated space, it shall be labeled "Decontaminate Cabinet Before Opening";

— cabinets exhausting into the room shall be provided with a perforated exhaust filter guard (see Figure 9) to prevent damage to the filter and blockage of exhaust air; and

NOTE — An additional airflow sensor may be provided to indicate blockage of exhaust air.

— HEPA/ULPA filter patches shall not exceed 3% of the total face area of the side being patched. The maximum width of any one patch shall not exceed 1.5 in (38 mm).

*Rationale:  This language fully defines the characteristics and specifications of HEPA/ULPA filters used in biosafety cabinets to ensure consistency in performance between initial certification testing and production units produced during the listing period.  This language also allows biosafety cabinet manufacturers to source HEPA/ULPA filters from multiple filter manufacturers providing the filter meets every characteristic/specification and all requirements of NSF/ANSI 49.  This became an acute problem during COVID and resulted in delays/reduction in shipments of biosafety cabinets to those conducting critical public health work.*