TO: Joint Committee on Biosafety Cabinetry

FROM: Robert W. Powitz, Chairperson of the Joint Committee

DATE: September 12, 2023

SUBJECT: Proposed revision to NSF/ANSI 49 – *Biosafety Cabinetry: Design, Construction, Performance and Field Certification* (49i188r2)

Revision 2 of NSF/ANSI 49 issue 188 is being forwarded to the Joint Committee for balloting. Please review the changes proposed to this standard and **submit your ballot by October 3, 2023** via the NSF Online Workspace <www.standards.nsf.org>.

When adding comments, please identify the section number/name for your comment and add all comments under one comment number where possible. If you need additional space, please upload a word or pdf version of your comments online via the browse function.

Purpose

The purpose of this ballot is to affirm revised language related to the personal and product protection test in section N-1 of Standard 49.

Background

Issue paper **BSC-2023-14 – Personal and Product Protection Test** highlighted the redundant language in section N-1.6.3 and N-1.6.4. This issue was presented during the June 2023 Face-to-Face meeting of the JC at which time the group motioned this proposal be sent directly to the JC as an approval ballot without further discussion.

The issue paper language was in fact sent as Revision 1 ballot, however a voting member noticed some of the newly proposed language was not highlighted as such in the ballot so Revision 1 ballot was withdrawn and corrected. This corrected and highlighted language is now presented here as Revision 2 ballot for your consideration.

Public Health Impact

The proposed changes have no negative impact on public health.

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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Normative Annex 1
(formerly Annex A)

Performance tests

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N-1.6.3 Personnel protection test (system challenged with 1×10^8 to 8×10^8 B. subtilis spores in 5 min).

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N-1.6.3.1 Method

g) For new and major modification redesign cabinet models, repeat the above steps ~~after setting the cabinet airflow velocities at the manufacturer's recommended nominal set points ± 2 ft/min (0.01 m/s) - 10 ft/min (-0.051) inflow using a direct airflow reading instrument and + 10 ft/min downflow:~~
once more under the following conditions:

— If the manufacturer-specified inflow velocity alarm set point is no more than 10 ft/min (0.051 m/s) less than the nominal inflow velocity or there is no low inflow alarm, adjust the inflow velocity to 10 +/- 2 ft/min (0.01 m/s) less than the nominal inflow, using a direct airflow reading instrument.
— If the manufacturer-specified inflow velocity alarm set point is more than 10 ft/min (0.051 m/s) less than the manufacturer's recommended nominal inflow velocity, adjust the inflow velocity to the manufacturer's recommended alarm set point ± 2 ft/min (0.01 m/s)
— Adjust the downflow to 10 +/- 2 ft/min (0.01 m/s) greater than the nominal downflow.
— airflow velocity readjustments shall be made per the manufacturer's procedure;
— the overall average downflow velocity shall be used in making downflow adjustments; and
— removable equipment not essential to cabinet operation shall be removed to set the downflow velocity.

Rationale: In addition to clarifying the balance point by putting it into bullet format, this addresses language missing to account for a low inflow alarm with this test. During discussion of the requirement to reduce the inflow velocity to the low inflow alarm point during the envelope tests, it was clear the intent of the JC was for this to apply to both low inflow tests. However, the current language in the standard only requires this for the -10 inflow/-10 downflow test. This addition makes it clear that it also applies to the -10 inflow/+10 downflow test.

h) For new and major modification redesign cabinet models, repeat the above steps ~~setting the airflow velocities at the manufacturer's recommended nominal set points ± 2 ft/min (0.01 m/s) - 10 ft/min~~

~~(- 0.051) for both downflow and inflow, except as noted below~~ once more under the following conditions:

— If the manufacturer-specified inflow velocity alarm set point is no more than 10 ft/min (0.051 m/s) less than the nominal inflow velocity or there is no low inflow alarm, adjust the inflow velocity to 10 +/- 2 ft/min (0.01 m/s) less than the nominal inflow, using a direct airflow reading instrument.
— If the manufacturer-specified inflow velocity alarm set point is more than 10 ft/min (0.051 m/s) less than the manufacturer's recommended nominal inflow velocity, adjust the inflow velocity to the manufacturer's recommended alarm set point ± 2 ft/min (0.01 m/s)
— Adjust the downflow to 10 +/- 2 ft/min (0.01 m/s) greater than the nominal downflow.
— airflow velocity readjustments shall be made per the manufacturer's procedure;
— the overall average downflow velocity shall be used in making downflow adjustments; and
— removable equipment not essential to cabinet operation shall be removed to set the downflow velocity.

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~~When an inflow alarm is present on a Type A1, A2, or C1 BSC, the appropriate cabinet blower(s) speed shall be reduced (from nominal set point) without damper adjustment (if one is present), until the inflow alarm is activated:~~

~~— if the manufacturer-specified inflow velocity alarm set point is more than 10 ft/min (0.051 m/s) less than the manufacturer's recommended nominal inflow velocity, the test as specified in this section will be performed with the inflow velocity at the manufacturer's recommended alarm set point ± 2 ft/min (0.01 m/s); or~~

~~— if the manufacturer-specified inflow velocity alarm set point is no more than 10 ft/min (0.051 m/s) less than the nominal inflow velocity, the inflow alarm point shall be tested as specified in in this section.~~

Rationale: Reformats this section to read the same as g), clarifying the requirements into bullet points.

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N-1.6.4 Product protection test (system challenged by 1 10^6 to 8×10^6 B. subtilis spores in 5 min.)

N-1.6.4.1 Method

h) For new and major modification redesign cabinet models, ~~the above steps shall be repeated after the cabinet airflow velocities are set at the manufacturer's recommended nominal set points ± 2 ft/min (0.01 m/s) + 10 ft/min (- 0.051) inflow using a direct airflow reading instrument and - 10 ft/min (- 0.051) downflow: — airflow velocity readjustments shall be made per the manufacturer's procedure; — the overall average downflow velocity shall be used in making downflow adjustments; and — removable equipment not essential to cabinet operation shall be removed to set the downflow velocity~~.
repeat the above steps once more under the following conditions:

— Adjust the inflow to 10 +/- 2 ft/min (0.01 m/s) greater than the nominal inflow, using a direct airflow reading instrument.
— Adjust the downflow to 10 +/- 2 ft/min (0.01 m/s) less than the nominal downflow.
— airflow velocity readjustments shall be made per the manufacturer's procedure;

— the overall average downflow velocity shall be used in making downflow adjustments; and
— removable equipment not essential to cabinet operation shall be removed to set the downflow velocity.