Joint Committee Issue Paper

NSF Standard(s) Impacted**: NSF/ANSI Standard 49**

Background:

Provide a brief background statement indicating the cause and nature of concern, the impacts identified relevant to public health, public understanding, etc, and any other reason why the issue should be considered by the Committee. Reference as appropriate any specific section(s) of the standard(s) that are related to the issue.

Based on discussion during the 4/10/23 Secondary Method Task Group call, new language is proposed for the standard. The ballot language proposed below attempts to capture the sentiment during the call.

Recommendation:

Clearly state what action is needed: e.g., recommended changes to the standard(s) including the current text of the relevant section(s) indicating deletions by use of ~~strike-out~~ and additions by highlighting or underlining; e.g., reference of the issue to a Task Group for detailed consideration; etc.

Ballot the following language within the task group:

3 Definitions

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3.xx Inflow velocity data set: An inflow velocity data set is generated when there is both a primary method measurement and secondary method measurement completed on the same day by the same test technician on the same biosafety cabinet.

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N-1.9.3.4 Alternate inflow measurement methods

These methods~~, approved by the testing organization, shall~~ may be ~~validated and~~ provided by the manufacturer ~~and shall be subject to review by the testing organization~~. ~~Manufacturer validation procedures shall contain no fewer than ten replicate tests. The testing organization's approval shall be based on review of data and successful reproduction of test results.~~ When an alternate inflow measurement method is provided, it shall be validated by the testing organization. The following methods have been found to be acceptable on some cabinets:

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N-1.9.3.5 Alternate inflow measurement method validation

When a manufacturer provides an alternate inflow measurement method, validation shall be completed by the testing organization. Validation is completed according to the requirements in this section.

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The manufacturer shall submit a minimum of 10 inflow velocity data sets. No more than 40 percent of the inflow velocity data sets shall be generated on a single BSC. In other words, there shall be at least 3 unique serial numbers for the different BSC's used to generate the data. A minimum of 3 different trained test technicians shall be used to generate the data and each test technician shall not be responsible for generating more than 40 percent of the data submitted. The BSC's shall be balanced within listed ranges for inflow (primary method) and downflow velocity. Each inflow velocity data set shall include the following information:

- Cabinet model number and serial number
- Name of test technician
- Date of testing
- Measured downflow velocity (this could be measured by a different technician on the same day)
- Primary method inflow velocity
- Uncorrected secondary method inflow velocity
- Fully corrected secondary method inflow velocity

A manufacturer's secondary method for measuring inflow velocity will be considered validated when the difference between the primary method inflow velocity and the fully corrected secondary method inflow velocity for each inflow velocity data set is 5 ft/min or less.

Correction factors may change over time as the manufacturer generates more data. When additional data justifies a change to the correction factor, a manufacturer may submit the data and propose a changed correction factor. The new correction factor shall be applied to qualification and requalification test results and cannot change the result of those tests from pass to fail for the new correction factor to be accepted. When a new correction factor is approved, cabinet data plates and service manuals are modified to include this going forward but there is no requirement to update data plates for cabinets already in the field.

The standard recognizes that when a biosafety cabinet is initially being developed, 3 unique cabinets may not be available until production starts. Therefore, validation of the secondary method may take place following initial qualification of the cabinet model.

N-1.9.4 Acceptance

Acceptance criteria shall be based on inflow determined by the direct measurement. Subsequent production cabinets of the initial model and size may also qualify as meeting Section N-1.6 when the directly measured inflow velocities are provided within ± 5 ft/min (± 0.025 m/s) of the nominal set point velocities.

The minimum inflow velocity of Type A1 cabinets shall be 75 ft/min (0.38 m/s). The minimum inflow volume shall be 45 ft^3/min (76 m^3/h) per 1 ft (0.3 m) of total work area width (see Sections N-1.6 and N-1.8).

The minimum inflow velocity of Type A2, B1, and B2 cabinets shall be 100 ft/min (0.51 m/s). The minimum inflow volume shall be 65 ft^3/min (110 m^3/h) per 1 ft (0.3 m) of total work area width (see Sections N-1.6 and N-1.8).

The fully corrected alternate inflow measurement shall be within ± 5 ft/min (± 0.025 m/s) of the primary inflow velocity measurement when both measurements are completed on the same day.

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N-5.3.3.1 General

When the testing organization has determined the nominal set point on a given model and size of cabinet using a DIM device, and an appropriate alternative method has been validated for that cabinet by the testing organization, this alternate method may be used to establish the set point on the same model and size of cabinet in the field, when the DIM cannot be used for one or more of the reasons in N-5.3.3.3.

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N-5.3.3.3 Alternate inflow measurement methods

If the DIM method cannot be used, one of the alternative methods below may be used to determine the inflow velocity, if provided by the manufacturer.

Alternate inflow measurement methods shall only be used for any or all of the following reasons:

— the space between the ~~face of the BSC~~ inlet of the DIM (after sealing the DIM into the BSC access opening) and permanent fixture directly opposite the access opening is less than ~~42~~ 6 in (~~1.1 m~~152 mm);

— the BSC was certified by the testing organization prior to NSF/ANSI 49-2002, when the DIM method for measuring inflow velocity was added to the standard; and

— testing is completed on a BSC not located in North America; ~~and~~

— ~~the owner / operator of the BSC requests use of a secondary method due to DIM instrument cleanability when the BSC is located in sterile area or clean room.~~

The DIM shall be used in all other circumstances.

Supplementary Materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

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**Type written name will suffice as signature*

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