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Joint Committee Meeting on Biosafety Cabinetry

June 19, 2025

8:00 am – 1:45 pm

(Eastern)

Microsoft Teams meeting

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505 #

Joint Committee on Biosafety Cabinetry
2025 Annual In Person Meeting – AGENDA

Wednesday and Thursday, June 18 and 19
NSF, 789 N Dixboro Road, Ann Arbor, Michigan 48105

June 18	Lunch 12:00 – 1:00 p.m. Eastern
Snyder	

Public Agency / User / Certifier Breakout Meeting June 18	1:00 – 4:00 p.m. Eastern
Innovation Room	
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Industry Forum June 18	1:00 – 4:00 p.m. Eastern
Vaughn	
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June 19 8:00 a.m. – 2:00 p.m. Microsoft Teams Meeting	
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Vaughn Room

	Time	Item	Speaker	Action / Info
Meeting Open	June 20 – 8:00 a.m.	Welcome & Introductions	B.Powitz	Action / Info
		Best practices for teleconferencing	A.Rose	
		Antitrust Statement		
		Attendance – Roll Call and Quorum Determination		
		Membership Updates		
		Review of and acceptance of agenda	B.Powitz	
		Review and acceptance of 2024 Joint Committee Meeting Summary		

	Time	Item	Speaker	Action / Info
Open Issue Updates	8:15 - 8:25 a.m.	Filter Integrity Testing	D.Phillips	Info
	8:25 - 8:40 a.m.	Class II, Type B Language	D.Phillips	Info
	8:40 – 8:55 a.m.	Canopy Connection Set Point	B.Sage	Info
	8:55 - 9:05 a.m.	Design and Construction Requirements	S.Williams	Info
	9:05 - 9:20 a.m.	Vibration Testing	K.Mulder	Info
	9:20 - 9:35 a.m.	Biological Measurements	S.Williams	Info
	9:35 – 9:50 a.m.	Chemical Resistance Testing	B.Gray	Info
	9:50 – 10:00 a.m.	Scanning through the Diffuser	K.Mulder	Info
10:00 – 10:15 a.m. Eastern		**BREAK**		

	Time	Item	Speaker	Action / Info
New Issues	10:15 – 10:30 a.m.	Product Protection and Cross Contamination	S.Williams	Info / Action
	10:30 – 10:45 a.m.	HEPA Gross Leak	B.Peters	Info / Action
	10:45 – 11:00 a.m.	Corrected Cabinet Types in N-5.3	B.Peters	Info / Action
	11:00 – 11:15 a.m.	DIM Clearance	J.Wagner	Info / Action
	11:15 – 11:30 a.m.	Personnel Protection Updates	S.Williams	Info / Action
11:30 – 12:30 p.m. Eastern LUNCH				
Open Topics	12:30 – 1:00 p.m.	EN 12469 – update on publication	B.Peters S.Schneider	Info
	1:00 – 1:30 p.m.	ATP Method – discussion of use in biological measurements	B.Powitz	Info

	Time	Item	Speaker	Action / Info
Meeting Wrap up	1:30 – 1:45 p.m.	Review of Action Items	B.Powitz	Info
		Planning of next in-person meeting in Ann Arbor June 17 and 18, 2026		

1:45 p.m. Eastern ADJOURN

NSF Meeting Process Guideline

1. Presentation of an issue

2. Discussion (questions & answers) on the issue

   - **In person attendees**: Please raise your hand to make a comment
   - **Phone and online attendees**: Please use the raise hand and/or chat features

3. Motion on the issue (only voting members may make a motion)

4. Second to the motion (only voting members may second a motion)

5. Discussion on the motion

   - **In person attendees**: Please raise your hand to make a comment
   - **Phone and online attendees**: Please use the raise hand and/or chat features

6. Vote on the motion (voting members only)

To ensure voting members clearly understand the motion, the motion shall be restated by the secretariate immediately prior to the vote.

- Yes, Aye, Affirmative
- No, Nay, Negative
- Abstain, Abstention

If a voice vote seems to be close, a show of hands or a roll call vote is used to confirm the vote on the motion. A "friendly amendment" to the motion may be offered by voting members if the person making the original motion and the person seconding the motion agree.

A motion may be withdrawn by the person making the motion at any time.
A second to the motion may be withdrawn by the person seconding the motion at any time.

During the discussion of an issue or motion, the chair will recognize each person in turn so that everyone has an opportunity to comment in an orderly manner.

The above guideline is roughly based on Robert's Rules of Order and may be modified as necessary at any time.

NSF Antitrust Statement

Because this meeting may involve representatives of competing businesses or otherwise implicate antitrust laws, it is important that I get everyone's agreement before we begin that the meeting will be conducted in full compliance with the antitrust laws. We must avoid any comment or action that encourages joint action by participating organizations or persons to restrict their competition or to violate the antitrust law. If you have any questions, I refer you to the NSF Antitrust policy. All committee work will be conducted in full compliance with the NSF Code of Conduct for standards development.

Is there anyone participating who is not in full agreement with the NSF Antitrust statement?

Joint Committee on Biosafety Cabinetry
Meeting Summary
June 20, 2024

I OPENING REMARKS

Tab Set A – Meeting Open

B.Powitz welcomed the group and thanked everyone for the participation. A.Rose read off the Antitrust Statement, and recorded voting member attendance as the group went around the room introducing themselves. Fifteen of the 22 voting members (68%) were present representing a quorum.

B.Powitz then reviewed the agenda briefly, and asked for comments and a motion to accept:

Motion by K.Mulder:	Accept the agenda
Second:	J.Wagner
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Review of June 22, 2023 Meeting Summary

B.Powitz then asked if there were any updates, additions, deletions, or any other changes suggested to the 2023 meeting summary. There were none and so asked for a motion to accept the summary.

Motion by D.Phillips:	Accept the 2023 BSC meeting summary
Second:	A.Atmadi
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

JC Membership

B.Powitz presented a table of the current JC membership structure. He named the 2 new members seated since the previous JC meeting, T.Fincham and A.Atmadi, as well as departed members R.Gilpin and X.Lin and Emeritus Member J.Hunter.

He then requested the group share contact information to potential new members and A.Rose conducted the official call for membership stating the Joint Committee on Biosafety Cabinetry was seeking members in the PUBLIC HEALTH and USER categories. Those interested parties should send in a completed application and resume to him for consideration by the chair.

B.Powitz asked if there were any other questions; there were none.

2024 Publication

A.Rose indicated the next publication of NSF/ANSI 49 is due by the end of August and that there are currently 9 approved issues with at least 6 more in process. He then thanked everyone for the great efforts over the last 12 months and presented the 9 approved issues:

Issue 172
This revision confirms revised language regarding the pressure decay test.

Issue 176
This revision affirms revised language related to the verification of the Secondary Inflow Method in Normative Annex 1 and 5.

Issue 179
This revision affirms new language related to the requirements for canopy connections in Section 5.

Issue 186
This revision affirms revised language related to drop testing in Sections 6 and Section N-1.

Issue 187
This revision affirms revised language related to power failure stability testing in Section 6 and Section N-1.

Issue 190
This revision affirms revised language related to the personal protection test in Section N-1.

Issue 192
This revision affirms revised language related to the resistance to overturning test in Section 6 and Annex N-1.

Issue 194
This revision affirms revised language related to the noise level acceptance criteria in Annex N-5.

Issue 195
This revision affirms revised language related to the installation and lifespan of BSCs in Annex N-1.

B.Powitz asked if there were any other questions; there were none.

Tab Set B – Open Issue Updates

49i128 – Filter Integrity Testing

D.Phillips is the Task Group Chair, and recapped the background of the project and progress update:

- This issue was presented to the JC during the 2018 Face to Face meeting where it was sent to the filter integrity testing Task Group for discussion. Suggested revisions were then presented to the JC during the 2022 teleconference where it was motioned to be sent to JC approval ballot.
- R1 ballot resulted in a vote of **15 : 5 : 0 (Affirmative : Negative : Abstain)**, and 6 total comments which were discussed and voted on by this task group prior to sending to the JC as R3 approval ballot.
- That ballot just ended and yielded a vote of **11 : 2 : 2 (Affirmative : Negative : Abstain)**, and 3 total comments.
- These ballot results were discussed during the November 13 meeting where S.Williams and J.Wagner agreed to write language for lab testing. As yet this is not complete.
- Next meeting scheduled for July 8, 2024

He confirmed the group was making great progress on this issue and the next ballot would be presented in the near future.

B.Powitz opened the floor for comments and questions; there were none

49i145 – Class II, Type B Language

D.Phillips is the Task Group Chair, and recapped the background of the project and progress update:

- Issue paper presented and discussed during the 2019 JC Face-to-Face meeting. JC motioned to create this TG for discussion.
- Action item from January meeting was for S.Williams and D.Phillips to develop some first pass language for the TG to discuss during the next meeting.
- The next meeting is scheduled for July 29, 2024.

B.Powitz opened the floor for comments and questions

As happened in the past, there was a discussion concerning the challenges with connecting multiple cabinets to a single exhaust, versus the ideal (but unrealistic) scenario of having one cabinet connected to one exhaust. In the end the TG has decided to work on language that accounts for reality rather than perfection. D.Phillips confirmed this language will be written and shared with the task group prior to the next meeting at the end of July.

B.Powitz asked if there were any other questions; there were none.

49i164 – Wireless Communication Devices

C.Binder was the Task Group Chair, but as explained below the issue paper has been withdrawn.

- Issue paper presented and discussed during the 2021 JC Teleconference; JC motioned to create this TG for discussion
- Action item from March 4, 2024 was for issue proponent to finalize some language for straw ballot.
- This ballot completed in April with a vote of **0 : 4 : 0 (Yes : No : Abstain).**
- After the vote, the issue proponent decided to withdraw the issue paper because the discussion had strayed far away from the intent of the issue, namely into the area of cyber security and no longer his concept for RF personnel safety.

B.Powitz opened the floor for comments and questions

B.Peters said he wouldn't mind picking up the issue as this is something that is going to happen and we should continue to discuss. He volunteered to work on this starting with a new issue paper and A.Rose indicated he would keep the Task Group active to support these efforts.

B.Powitz asked if there were any other questions; there were none.

49i173 – Design and Construction Requirements

S.Williams is the Task Group Chair, and recapped the background of the project and progress update:

- Issue paper presented and discussed during the 2022 JC Teleconference, at which time the JC motioned to create a TG for further discussion.
- This TG met three times into September 2022, and able to make several language proposals for much of Section 5.
- With the understood discussion points from the meetings, 2 action items included the issue proponent rewriting the remainder of Section 5 and the whole of Section 4 in the spirit of the discussion, and then for the language to be circulated to the TG via Straw Ballot. That straw ballot completed Friday November 24, 2023 with a vote of **0 : 2 : 3 (No : Yes : Abstain)**.
- The group met shortly after on November 27, 2023 and continued to discuss this rather large body of revisions, continuing further during the April 22, 2024 meeting.
- Action from the April meeting was for the issue proponent to complete the revisions and break each section out into 19 separate small straw ballots, the process for which is complete as of June 13, 2024.

B.Powitz opened the floor for comments and questions

S.Williams explained that these 19 separate small straw ballots would be combined into 4 or 5 JC Ballots and sent to out as approval ballots in the near future.

He added that during the industry forum meeting yesterday there was discussion regarding sharp edges and two new proposals put forth. The first proposal was to use a specific instrument and a reference standard to test for sharp edges on biosafety cabinets, instead of relying on subjective judgment. The instrument is based on UL 1439 standard and uses a tape test to determine if an edge is too sharp. The task group agreed to write the instrument and the reference standard into Standard 49 as a requirement for sharp edges testing.

The second proposal was to change the requirement for the work surface edges to be rounded or chamfered to minimize potential injury to users. It was postulated that the current requirement is too vague and subjective and should be replaced by a more objective and measurable criterion, such as a minimum radius of curvature or a maximum angle of the edge. It was also proposed to add a note that the work surface edges should be free of burrs, cracks, or other defects that could cause injury.

B.Powitz asked if there were any other questions; there were none.

49i174 – Preventative Maintenance

D.Phillips is the Task Group Chair, and recapped the background of the project, a progress update and presented current proposed language:

- Issue paper presented and discussed during the 2022 JC Teleconference. JC motioned to create this new task group and send this issue here for discussion.
- This group met once in October 2022 with some language developed after and shared, but during 2023 JC Face to Face meeting it was decided to meet once more prior to sending any type of ballot.

- JC ballot sent in January 2024 yielding a **vote of 15 : 0 : 1** and 2 comments. Although this passed and is ready for the PHC (Public Health Council) vote, the comments are worth considering.

B.Powitz opened the floor for comments and questions

K.Mulder suggested the language should not get too prescriptive. A.Atmadi brought up the topic of UV lamps and K.Mulder suggested the group consider a list of items. D.Phillips reminded the group of past work that never went anywhere because we went down a path of creating a long list of specific items. In the end manufacturers should deal with this within the manual rather than specificity within the standard.

D.Phillips asked the group if additional rewrite was necessary. S.Williams asked for clarification on whether this would be the responsibility of the field certifiers, or cabinet owner. D.Phillips suggested this could be either, but the intent is field certification is not preventative maintenance. These are separate issues. In the end the manufacturers are the experts of their own cabinets and should share best practices with the users. The group agreed this was ready to be approved as is.

B.Powitz asked if there were any other questions; there were none.

49i191 – Personal Protection Test Method

A.Atmadi is the issue proponent, and recapped the background of the project and progress.

This issue paper was presented during the 2023 JC Face-to-Face meeting in June 2023, including a part A and B.

Part A has passed both the JC and the PHC, is approved and will appear in the next publication.

Part B has gone through 2 revision ballots, the latest of which yielded a vote of 0 : 5 : 6 (Affirmative : Negative : Abstain) and 8 **comments**. Due to the feedback, A.Atmadi agreed to withdraw part B of this issue paper.

B.Powitz opened the floor for comments and questions by presenting the idea of the group looking into using ATP testing (adenosine triphosphate) to measure contamination. The use of this type of testing has progressed much over the last decade and he explained it's use in other areas of determining contamination. A.Atmadi described another test being used in Europe and D.Phillips suggested that any new test that could reduce costs even 1/3 would be valuable to consider.

B.Powitz asked if there were any other questions; there were none.

49i177 – Noise Max Change

S.Williams is the Issue Proponent, and he and the TG Chair (B.Sage) recapped the background of the project and progress update:

- Issue paper submitted and the JC Chair decided to reconvene this TG for discussing this topic prior to the 2023 JC F2F.
- The TG met January 29, 2024 with the following action items:

    1. S.Williams to rewrite language based on today's discussion
    2. Gather and share more data based on revised language by mid-March in preparation for next scheduled meeting April 29.

- The TG met April 29, 2024 with the following action item:

S.Williams volunteered to clean up the language discussed here and send to this group as straw ballot, including a corresponding change to N-5.

That straw ballot closed last night with a vote of 8 : 0 : 1, but with some comments. The group decided to discuss these comments during this meeting here today and send to JC Ballot.

Motion by S.Williams:	Update ballot language from today's discussion and send to JC Approval Ballot
Second:	B.Peters
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above

49i181 – Motor Blower Update

B.Peters is the issue proponent, and recapped the Task Group progress thus far:

- Issue paper presented and discussed during the 2023 JC F2F. This TG met first in January 2024 to discuss and decided to work out revised language for testing procedures and gather data to discuss further during the next meeting.
- The next meeting was June 3 with the following Action items:

    — B.Peters to draft proposed language to revise the test procedure and share with S.Williams for feedback.
    — A.Rose to send to ballot once complete.

B.Powitz asked if there were any other questions; there were none.

Tab C – New Issues

49i197 – Chemical Resistance

B.Gray is the issue proponent, and recapped the background of the issue:

Biosafety cabinets contain components which are protected by powder coat (or other coating) paint. As a result, the current standard version requires Chemical Resistance testing of each coating paint color (and each manufacturer of each color). Additional coating testing is required, but that is outside the scope of this Issue Paper.

The Chemical Resistance test is defined in Normative Annex 4 (N-4.1), which includes eight (8) specific chemicals and concentrations to be tested by a specific method. There is a second reference to these specific chemicals in 4.5.2.1.

*Biosafety cabinet manufacturers have noticed that the 5% Phenol chemical is resulting in an unusually high number of failures compared to the other seven (7) chemicals. The definition of a passing result is defined in N-4.1.3, which is: "no visible effect on the finish, other than a slight change of gloss, slight discoloration, or temporary slight softening of the finish, with no loss of adhesion and film protection.". Quantifying "slight" may present a challenge, but that is outside the scope of this Issue Paper. NSF International has confirmed that phenol is the most significant chemical causing a failure when all other seven (7) chemicals provide a passing result on the coating sample under test (see "**Coating Failure Statistics from NSF International (provided 4/19/2024)**" under "Supplementary Materials" section.*

The test method for Chemical Resistance (N-4.1.2) requires each chemical to be placed onto the test coupon, covered, and left in contact for 4 hours. The 4 hour time is more than 8 times the longest recommended contact time of any of the eight (8) chemicals in the Chemical Resistance Test to achieve a bactericidal / fungicidal result on most target microorganisms (microorganisms other than: cryptosporidium, some spores and prions). See "Supplementary Materials" section for supporting documentation from: Universities, a Public Health government organization, and a disinfectant manufacturer.

*The concentration of Phenol at 5% is enough to kill anthrax spores if contact time is 48 hours; however, 1-2% Phenol is sufficient to achieve bactericidal / fungicidal results (see "**Phenol Data Point #2**" in "Supplementary Materials" section). 3% Phenol can achieve inactivation of M. Tuberculosis in 60 minutes (see "**Phenol Data Point #1**" in "Supplementary Materials" section). These data points suggest that 2% Phenol is recognized as sufficient for bactericidal / fungicidal results as a high-level disinfectant.*

*Further, how does 5% Phenol compare to the other seven (7) chemicals used in the Chemical Resistance Test? Fortunately, a study was performed in 1990 (see "**Disinfectant Comparison**" in Supplementary Materials" section) that compared multiple disinfectants for their CFU reduction on M. tuberculosis. Five (5) of the eight (8) chemicals from N-4.1 were tested in this study. This study shows that 5% Phenol reduces CFUs 28 times more than the next best disinfectant (2%*

Glutaraldehyde – which is closest to 5% formaldehyde). If efficacy is proportional to concentration, it could be inferred that 5% Phenol is still 11 times more biocidal than 5% formaldehyde; and 2% Phenol is 4 times more biocidal than 5% formaldehyde.

The unusually high number of failures with 5% Phenol is likely due to the unnecessarily high (4 hour) contact time and an unnecessarily high concentration compared to the other seven (7) chemicals when the comparison is made based upon efficacy of the chemical as a disinfectant.

Consequently, manufacturers of biosafety cabinets, and their coating suppliers are becoming increasingly frustrated and, in some cases, unable to produce biosafety cabinets for a period of time (when a supply disruption occurs with one or more primary coating suppliers and a new coating from a new supplier must be qualified) due to the unusually high failure rate of these coatings with 5% Phenol at a 4 hour contact time.

It would be in the best interest of public health to modify the Chemical Resistance test method to a concentration / contact time of Phenol in line with cellular inactivation provided by the other seven (7) chemicals, yet still ensure that coatings are durable and robust enough to perform in the field against the majority of common disinfectants at typical (but not extreme) concentrations. This change reduces risk to the scientific, medical, pharmaceutical, research and educational market's ability to procure biological safety cabinets in a timely fashion by avoiding shortages due to coating failures arising from an unnecessarily difficult Chemical Resistance Test.

B.Powitz opened the floor for comments and questions

The question arose whether there was much phenol even used in the field anymore and the general agreement was there was not, with the understanding that the EPA has great dislike for the compound. Some discussion about other chemicals as well with B.Gray confirming his issue paper was written simply to elevate understanding about the current chemical on the list, however there is a bigger consideration about the list itself.

Two motions were subsequently posed:

Motion by S.Williams:	Create a new TG to discuss the list of chemicals
Second:	K.Mulder
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above
B.Gray Chair, list of members: T.Fincham, K.Mulder, D.Phillips, A.Atmadi, S.Williams, B.Peters, J.Lambon, B.Powitz

Motion by S.Williams:	Send language from issue paper to JC Approval Ballot
Second:	T.Fincham
Discussion:	B.Sage suggested that someone online said phenol is used around BSCs even not as a disinfectant. S.Williams explained the surface requirements adding that B.Gray did his homework and language good to be sent to ballot.
Vote:	Fourteen in favor, zero opposed, K.Mulder abstained
Motion:	Carries

Action item: as described in motion above

B.Powitz asked if there were any other questions; there were none.

49i199 – Canopy Connection Set Point

B.Sage is the issue proponent, and recapped the background of the issue:

> *Some canopy connections are sent to NSF with minimal setup instructions. We cannot test every possible airflow, damper, and blower speed configuration. Since field certifiers are not required to check the inflow reduction during a failed external exhaust for listed canopy connections, there is the potential for it to not function properly in the field. Requiring some sort of set point would help ensure the canopy connection will function the same in the field as it was tested in the lab.*

B.Powitz opened the floor for comments and questions. S.Williams provided explanation and examples for this subject.

Two motions were subsequently posed:

Motion by D.Phillips:	Send language from issue paper to JC Approval Ballot
Second:	J.Wagner
Discussion:	J.Wagner asked if we are referring to a set point, what would be more helpful is a published range. D.Phillips indicated we don't want to add a bunch of other new tests, and how about adding the word '*single'* prior to the words '*set point*'. This is only for NSF testing not field testing.
Vote:	J.Wagner in favor, twelve opposed, A.Atmadi and J.Balsamo abstained
Motion:	Fails

Action item: nothing

Motion by S.Williams:	Create a new TG to discuss this topic
Second:	B.Peters
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above
B.Sage Chair, list of members: S.Williams, B.Peters, M.Lenart, J.Wagner, J.Miller, A.Atmadi, D.Phillips, T.Fincham

B.Powitz asked if there were any other questions; there were none.

New Business

The group broke into 3 smaller groups each with the task of taking a step back and discussing what would be good improvements to Standard 49. The full JC then reconvened with the following discussion

Idea #!
Specifications for vibration meters. The main points of the discussion were:

- The current criteria for vibration in Annex N5 is based on a unit of measure that is not readily available on most meters, and it is not sensitive enough to detect the complaints from some clients who have sensitive equipment or liquid samples in the biosafety cabinet.
- There was a suggestion to change the unit of measure and the specs for the vibration meters to reflect the market availability and the needs of the clients.
- There was also a suggestion to use a qualitative method, such as a Petri dish with water, to assess the vibration level, instead of a quantitative meter.
- There was some debate about whether vibration is a relevant criterion for biosafety cabinets, and whether it should be mandatory or optional in the field testing.

A motion was passed to form a task group to evaluate vibration in both Annex N1 and Annex N5, starting with instrumentation and considering other aspects such as units of measure, criteria, and methods.

Motion, **B.Peters**:	create TG to evaluate the value of vibration testing in both Annex N1 and N5, starting with instrumentation and considering other aspects such as units of measure, criteria and methods.
Second:	S.Williams
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above
K.Mulder Chair, list of members: M.Squire, T.Fincham, A.Atmadi, J.Miller, M.Lenart, S.Williams, B.Peters, B.Sage

S.Williams reminded the group of his issue paper from several years ago (BSC-2019-03).

B.Powitz asked if there were any other questions; there were none.

Idea #2

Biological measurements. The main points of the discussion were:

- The current method of using impingers is problematic because it involves many steps and people, and there is a high risk of contamination and retesting.
- There was a suggestion to look at alternative methods, such as impaction samplers, that are simpler, faster, and more reliable.
- There was also a suggestion to look at ATP as a possible measurement mode, instead of relying on viable organisms.
- There was some debate about what level of decontamination is required for biosafety cabinets, and whether the current criteria and methods are appropriate or need to be updated.
- A motion was passed to form a task group to

Motion, **K.Mulder**:	Create TG to reevaluate the biological tests and to consider different aspects such as instruments, units of measure, criteria, and methods.
Second:	S.Williams
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above
S.Williams Chair, list of members: B.Sage, B.Peters, K.Held, A.Atmadi, D.Phillips, B.Powitz, K.Mulder, M.Squire

B.Powitz asked if there were any other questions; there were none.

Idea #3

Scanning with the diffuser in place. The main points of the discussion were:

- The current method of scanning the filters without the diffuser is problematic because it increases the risk of damaging the filters or the diffusers, and it requires scanning the filters twice, once without and once with the diffuser.
- There was a suggestion to look at alternative methods, such as scanning the filters with the diffuser on, and using a more sensitive number to determine if the filter is intact or not.
- There was also a suggestion to collaborate with CETA, which is doing a grant to find out if scanning with the diffuser on is appropriate, and to draft a procedure for evaluating the

filter scanning with the diffuser on, based on the concerns and scenarios of the Joint Committee.

- A motion was passed to form a task group to

Motion, **K.Mulder**:	Create TG outline a process for filter scanning with the diffuser on, and to communicate with CETA about the possible testing methods.
Second:	J.Wagner
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above
K.Mulder Chair, list of members: J.Wagner, K.McKowen A.Atmadi B.Sage D.Phillips S.Pizzolato

B.Powitz asked if there were any other questions; there were none.

The discussion regarding decon took place in the last part of the meeting, when the informative annex on decontamination was brought up as a topic that needs some work. The main points of the discussion were:

- The annex should clarify the difference between decontamination, disinfection, and sterilization, and what level of decon is required for biosafety cabinets.
- The annex should consider the new methodologies and technologies that have emerged since COVID, such as chlorine dioxide, hydrogen peroxide, and ATP.
- The annex should address the issues of EPA registration, dwell times, temperature and humidity requirements, and validation methods for different decon agents.
- The annex should avoid making assumptions or judgments about the participants' roles, responsibilities, feelings, conduct, or performance in relation to decon.
- The annex should be based on solid evidence and reliable sources, and not make up facts or cite incorrectly.

There was no motion put to the floor on the subject

B.Powitz asked if there were any other commens; there were none and he opened the floor for a motion to adjourn.

Motion by J.Balsamo:	Adjourn
Second:	S.Williams
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

B.Powitz thanked everyone for participation and closed the meeting.

Joint Committee on Biosafety Cabinetry
Meeting Summary
June 20, 2024

ATTENDANCE:

Joint Committee Voting Members in Attendance

Company	Name	Interest Category	Role
R.W. Powitz & Assoc.	Robert Powitz, PhD, MPH, RS, DLAAS	Public Health / Regulatory	JC Chair
Consultant	James Balsamo, Jr.	User	Member
Labconco Corp.	Tori Fincham	Industry	Member
The Baker Company, Inc.	Aaron Johnson	Industry	Member
USDA - Animal Production and Protection	Joseph Kozlovac	Public Health / Regulatory	Member
USPHS	Justice Lambon	Public Health / Regulatory	Member
Clean Air Testing, Inc.	Mark Lenart	Product Certifier / Testing Lab	Member
ESCO	Alex Atmadi	Industry	Member
University of Michigan	Keith McKowen	User	Member
Kewaunee Scientific	Jeremy Miller	Industry	Member
Technical Safety Services	Kyle Mulder	Product Certifier / Testing Lab	Member
Public Health Agency of Canada	Tony Oliveira	Public Health / Regulatory	Member
NuAire, Inc.	William Peters	Industry	Member
Thermo Fisher Scientific	David Phillips	Industry	Member
Controlled Environment Consulting	Jim Wagner	User	Member
NSF	Steve Williams	Product Certifier / Testing Lab	Member
NSF	Allan Rose	General Interest	Secretariat

Joint Committee Members NOT in attendance

Company	Name	Interest Category	Role
Frederick National Laboratory for Cancer Research	Theresa Bell	Public Health / Regulatory	Member
Certified Air Solutions	James Flannery	Industry	Member
USDA Agricultural Research Service (ARS)	Nick Chaplinski	Public Health / Regulatory	Member
National Institutes of Health	Joshua Greenberg	Public Health / Regulatory	Member
Atlantic Technical Systems	Brian Flynn	Product Certifier / Testing Lab	Member
ENV Services, Inc.	Alberto Lopez	Product Certifier / Testing Lab	Member
Midwest Associations	Nicholas Rose	Product Certifier / Testing Lab	Member

Other Attendees

Company	Name	Interest Category	Role
NSF	Erin Bagosy	General Interest	Observer
NSF	Justin Brown	General Interest	Observer
Labconco	Brandon Gray	Industry	Observer
Kara Held	The Baker Company	Industry	Observer
Matt Squire	NuAire, Inc.	Industry	Observer
Shane Pizzolato	Gulf Coast Metrics	Product Certifier / Testing Lab	Observer
NSF	Emily Richardson	General Interest	Observer
NSF	Eliza Nejad	General Interest	Observer
TUV-Nord	Jan Ott	Product Certifier / Testing Lab	Observer
NSF	Leah Pollard	General Interest	Observer
NSF	William Sage	General Interest	Observer

[1] Proxy voter

Standard 49 was published in December 2024
Issues approved and published at that time

Issue 172
This revision updates language regarding the pressure decay test in Section 6.2 and Sections N-1.1.1.3 through N-1.1.1.5.

Issue 173
This revision adds definitions for cleanable, easily cleanable, and tubing restraint and affirms revised and new language related to design and construction requirements throughout Section 5. It also removes former Sections 5.7.1.3, 5.11, 5.12, 5.18.

Issue 174
This revision affirms revised language related to recommended preventative maintenance procedures in Section N-5.1.

Issue 176
This revision affirms revised language related to the verification of the Secondary Inflow Method throughout Section N-1.8.3 and N-5.3.3.

Issue 177
This revision affirms revised and new language related to noise level tests in Sections 6.4.2, N-1.3.3.c, N-1.3.4, N-5.11.3.c, N-5.11.3.g, and N-5.11.4.

Issue 179
This revision affirms new language related to the requirements for canopy connections as new Section 5.29.3.

Issue 180
This revision corrects language regarding motor blower performance procedure Section N-1.11.3.c.

Issue 181
This revision updates and adds language regarding motor blower performance procedure Sections N-1.11.2 and N-1.11.3.b.

Issue 182
This revision updates language related to the requirements canopy connection acceptance criteria in Section N-1.13.5.

Issue 186
This revision removes former Sections 6.17.1 and N-1.13.3.1 related to drop testing.

Issue 187
This revision updates power failure disconnection time from 1 h to 5 min in Section 6.17.2 and Section N-1.12.3.2.

Issue 190
This revision updates language related to the personal protection test in Section N-1.6.3.1.

Issue 191
This revision affirms revised language related to control plate placement in Sections N-1.6.3.1.c and N-1.6.4.1.e.

Issue 192
This revision updates a reference in Section 6.8.1 and removes previous Sections N-1.7 through N-1.7.2 relating to the resistance to overturning test.

Issue 194
This revision updates language related to the noise level acceptance criteria in Section N-5.11.4 and adds Table N-5.1.

Issue 195
This revision updates language related to the installation and lifespan of BSCs throughout Sections I-1.3, I-1.8, and I-1.9.

Issue 197
This revision updates and adds new language related to chemical resistance testing in Sections 4.5.2.1, N-4.1.1, and N-4.1.2.

Issue 198
This revision adds new language related to replacement filters in Section 5.19.

Open Issue Updates

TAB B1

Filter Integrity Testing

Joint Committee on Biosafety Cabinetry
Task Group on Filter Integrity Testing

Chair: Dave Phillips, Thermo Fisher Scientific

Task Group Roster:

Members	
Steve Williams	NSF
Eugen Bryan	QVA Test Solutions
Jim Wagner	Controlled Environment Consulting
Tori Fincham	Labconco
Cary Binder	NSF
Aaron Johnson	The Baker Company
Shane Pizzolato	Gulf Coast Metrics
Brian Flynn	Atlantic Technical Systems

Meetings held since last JC meeting:

The task group held 2 meetings since: August 28 and November 13, 2023
The next scheduled meeting is set for July 8, 2024

Summary of Task Group work:

- This issue was presented to the JC during the 2018 Face to Face meeting where it was sent to the filter integrity testing Task Group for discussion. Suggested revisions were then presented to the JC during the 2022 teleconference where it was motioned to be sent to JC approval ballot.
- R1 ballot resulted in a vote of **15 : 5 : 0 (Affirmative : Negative : Abstain)**, and 6 total comments which were discussed and voted on by this task group prior to sending to the JC as R3 approval ballot.
- That ballot just ended and yielded a vote of **11 : 2 : 2 (Affirmative : Negative : Abstain)**, and 3 total comments.
- These ballot results were discussed during the November 13 meeting where S.Williams and J.Wagner agreed to write language for lab testing. As yet this is not complete.

Support documents:

- BSC-2018-11 - HEPA Filter Integrity Testing.pdf
- Meeting Summary - Filter Integrity Testing – Meeting Summary – 11-13-23
- Meeting Summary - Filter Integrity Testing – TG – 08-28-23
- 49i128r3 - Filter Integrity Testing - JC Memo and Ballot
- 49i128r3 - Filter Integrity Testing - Ballot comments

Joint Committee Issue Paper

NSF Standard(s) Impacted: NSF-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.

The following factors are two of many critical components to performing a controlled and repeatable HEPA filter integrity test

1. An artificially generated particle challenge
2. A uniform (spatial) upstream particle challenge

The importance of upstream challenge uniformity has been grossly overlooked in many fields and areas involving HEPA filter integrity testing. Various HEPA filter housings and cabinet designs do a poor job at providing a means of achieving adequate aerosol distribution for testing purposes. The challenge uniformity is directly proportional to the measured leak size in the filter. As an example, a leak can easily be sized 4x larger or 4xsmaller than its true size simply due to poor aerosol challenge conditions. Current recommended practices or manufacturer's instructions (single point injection ports or a t-connection) for injecting an aerosol into a cabinet in many cases does not produce an adequate aerosol distribution and challenge. This situation can describe observed discrepancies between calculated challenges and measured challenges. Non-uniform challenges can also be identified by observing drifting leak sizes when the aerosol injection location is moved.

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.

A.2.3.1 Filters that can be scanned

a) Turn on the cabinet blower and lights (types A1/A2 and B2 – downflow filter test). Remove filter diffusers and protective covers if they are present. Place the generator so the aerosol is introduced into the cabinet, as specified by the manufacturer, to provide uniform distribution upstream of the HEPA/ULPA filter.

COMMENT: A manufacturer should be able to provide aerosol introduction instructions with validation data to the end user or be required to provide the information to NSF if this statement is to hold any weight.

~~When the manufacturer has not identified the aerosol introduction point(s), introduce the aerosol in such a manner as to ensure thorough mixing in the cabinet airflow. For example, a T-connection can be fitted to the aerosol generator output to enable distribution of challenge into both entrances of a~~

~~single blower, or entrances of multiple blowers~~. The manufacturer shall determine the aerosol introduction point that provides the most uniform distribution (reference IEST-RP-CC-034[24]). The location of the aerosol introduction point shall be clearly described or indicated in a manner readily available to the certifier. The location should be described either on the cabinet data plate or with the electrical schematic if the schematic is affixed to the cabinet.

COMMENT: This should become part of the NSF-49 new cabinet validation criteria

When the manufacturer has not identified the aerosol introduction point(s), introduce the aerosol in such a manner as to ensure thorough mixing in the cabinet airflow.

COMMENT: A multi point injection manifold such as a PVC pipe with multiple holes drilled in the side and placed at the cabinet opening will do much better than a T-connection. This has been observed and implemented in current the NSF-49 filter integrity test lab setup. The recommendation would be to move towards understanding how this could be written into the standard and applied to current BSC designs where additional methods may be required to produce a uniform aerosol particle challenge.

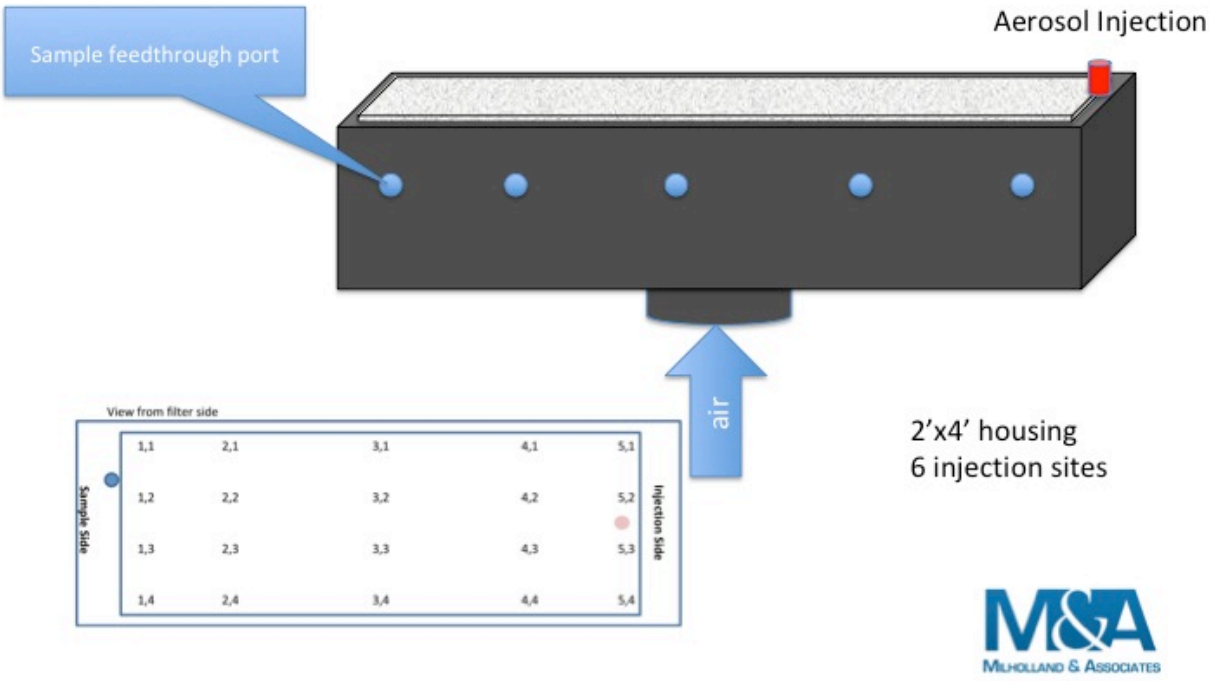
Supplementary Materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

The following aerosol distribution data was obtained from a filter housing with a room side injectable port by applying criteria outlined in IEST RP-CC-034. Although this is not a BSC component, it demonstrates the difficulty in achieving a uniform test challenge. In the example and reported data, an identical leak located at the two locations marked with an X can be under or oversized 4x simply based on its location in the filter. The housing utilizes a distribution manifold with 6 injection sites.

Joint Committee Issue Paper

Cleanroom Consulting & Test Equipment

Challenge Uniformity Measurements

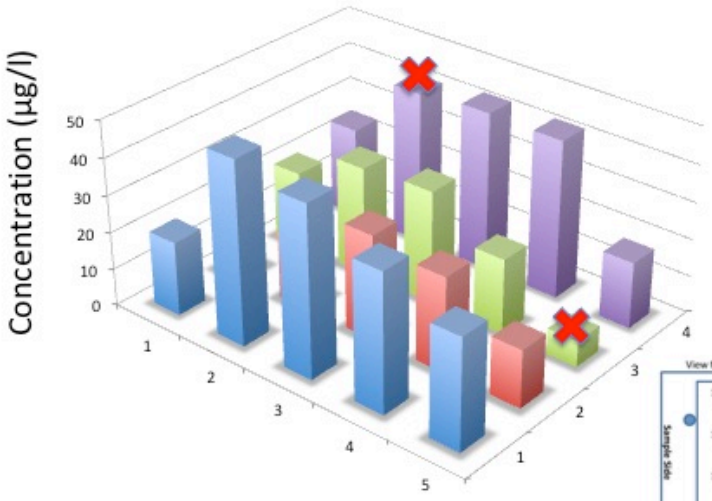


Item No. BSC-2018-11
(For NSF International internal use)
03/2013

Joint Committee Issue Paper

Cleanroom Consulting & Test Equipment

Room Side Injectable Housing



If two identical sized (physical) defects were located in different locations in the filter media marked by the X, one defect would size 4 times larger than the other.

Note: chart is inverted

Plot is based on 20 measurement locations

M&A
Milholland & Associates

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Signature*: Eugene Bryan

Company: Milholland & Associates

Telephone Number: 919 567-3208 E-mail: eugene@dmilholland.com

Submission Date: 22 May 2018

Please submit to: Al Rose, arose@nsf.org

**Type written name will suffice as signature*

Item No. BSC-2018-11
(For NSF International internal use)
03/2013

Task Group on Filter Integrity Testing
Teleconference Meeting Summary
July 8, 2024

Participating Members:
Dave Phillips (Thermo Fisher Scientific)
Eugene Bryan (QVA Test Solutions)
Jim Wagner (Controlled Environment Consulting)
Steve Williams (NSF)
Cary Binder (NSF)

Absent Members:
Aaron Johnson (The Baker Company, Inc.)
Shane Pizzolato (Gulf Coast Metrics)
Brian Flynn (Atlantic Technical Systems)
Tori Fincham (Labconco)

Participating observers:
Al Rose (NSF)
Bill Sage (NSF)

Supplemental Materials Referenced

- HEPA filter leak proposed ballot language 062724
- BSC-2018-11 - HEPA Filter Integrity Testing.pdf
- Meeting Summary - Filter Integrity Testing – TG – 08-28-23
- 49i128r3 - Filter Integrity Testing - JC Memo and Ballot
- 49i128r3 - Filter Integrity Testing - Ballot comments

Discussion

D.Phillips is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Five of the 9 voting members were present (56%) representing a quorum. D.Phillips presented the agenda indicating there was one item, specifically issue paper BSC-2018-11, and he recapped the work thus far including the discussion during the recent F2F.

S.Williams confirmed that that he and J.Wagner were charged with developing language not immediately for balloting but rather for discussion here and possible lab testing based on the discussion. He reminded the group that it was decided through discussions many years ago that spreading out the aerosol as much as possible was generally desired, specifically to make certain leaks do not bypass the filter.

The meeting focused specific attention to aerosol introduction points and the potential adoption of a manifold system for aerosol distribution. Below is the summary:

Aerosol Introduction Point Discussion:

- The meeting focused on the method of introducing aerosol for filter integrity testing, with a proposal to use a manifold for distribution to ensure coverage of potential leak points, especially in Type B cabinets. S.Williams and J.Wagner were tasked with researching and proposing language for this method. The importance of spreading out the aerosol to catch leaks not detected by the manufacturer's specified introduction point was emphasized.

Documentation and Accessibility:

- The need for manufacturers to clearly specify the aerosol introduction point was discussed. Suggestions were made to ensure this information is readily available to field certifiers, potentially near the electrical schematics or in a menu accessible from the front of the cabinet. The group discussed defining "readily available" more clearly.

Next Steps:

- S.Williams will conduct research to determine if a manifold provides significantly different results compared to a T connection for aerosol introduction. This research aims to inform whether a change in the testing protocol is even necessary in the first place.
- The group discussed working on language that clearly defines "readily available" for the accessibility of aerosol introduction point information. This involves ensuring that the information is accessible without extensive searching or the need for internet access.

Action Items:

- **Aerosol Introduction Point Research** - S.Williams to conduct research on the effectiveness of using a manifold for aerosol distribution.
- **Defining 'Readily Available'** – D.Phillips to work on language that clearly defines "readily available" for the accessibility of aerosol introduction point information.

Manufacturer's Guidance on Aerosol Introduction Point:

- The discussion highlighted the importance of manufacturers providing clear guidance on the aerosol introduction point for filter integrity testing. This may involve specifying the introduction point in a location that is easily accessible to field certifiers.

D.Phillips asked if there were any other questions; there were none and the meeting adjourned.

Task Group on Filter Integrity Testing
Teleconference Meeting Summary
January 13, 2025

Participating Members:
Dave Phillips (Thermo Fisher Scientific)
Eugene Bryan (QVA Test Solutions)
Jim Wagner (Controlled Environment Consulting)
Steve Williams (NSF)
Tori Fincham (Labconco)
Aaron Johnson (The Baker Company, Inc.)

Absent Members:
Brian Flynn (Atlantic Technical Systems)
Shane Pizzolato (Gulf Coast Metrics)
Cary Binder (NSF)

Participating observers:
Al Rose (NSF)
Erin Bagosy (NSF)
Bill Sage (NSF)
Cassandra Leone (NSF)

Supplemental Materials Referenced

- Agenda - Filter Integrity Testing - TG – 2025-01-13
- Discussion Points for the 2025-01-13 meeting

Discussion

D.Phillips is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Six of the 9 voting members were present (67%) representing a quorum. D.Phillips presented the agenda indicating there was one item, specifically issue paper BSC-2018-11, and he recapped the work thus far, including the discussion during the 2024 JC F2F and the Task Group meeting last July.

Meeting notes:

- **Aerosol Introduction Point:** D.Phillips and the team discussed the language change regarding the aerosol introduction point. They aimed to provide more guidance to certifiers and clarify where the information should be described.
    - **Language Change:** D.Phillips proposed modifying the language in the standard to provide more guidance to certifiers regarding the aerosol introduction point. The team discussed the importance of clearly describing the location on the cabinet data plate or with the electrical schematic.
    - **Manufacturer's Role:** J.Wagner suggested making the process easier for manufacturers by assuming the standard location unless specified otherwise. A.Johnson mentioned that Baker would continue labeling the aerosol introduction point regardless of the decision.
    - **Discussion Points:** The team discussed various points, including the importance of specifying the aerosol introduction point, the impact of different introduction methods, and the need for clear communication from manufacturers to certifiers.

- **Testing and Data Collection:**
    - **Testing Methods:** S.Williams and E.Bryan discussed various testing methods to determine the best aerosol introduction point. S.Williams planned to conduct tests using different introduction points and compare the results to identify the most effective method.

  - **Technical Insights:** E.Bryan suggested using a probe on a stand to measure the impact of different introduction points on a known leak. S.Williams considered this approach and planned to test multiple introduction points across the rear and front grills.
  - **Data Collection:** S.Williams aimed to collect data on the effectiveness of different introduction methods, including using a T-connector and a manifold. The goal was to determine if one method resulted in missing leaks or provided better quantification of leaks.

- **Reference to IEST RP34:**
  - **Debate on Reference:** The team debated the relevance of referencing IEST RP34 in the standard. J.Wagner highlighted that the current practices did not align with RP34, and the team considered removing the reference.
  - **Decision to Replace:** The team decided to replace the reference to IEST RP34 with language to be developed after S.Williams's testing. They agreed to revisit the language based on the results of S.Williams's tests and future discussions.
  - **Straw Vote:** D.Phillips proposed a straw vote to remove the reference to IEST RP34, pending confirmation of S.Williams's tests. The team unanimously agreed to replace the reference with language to be developed upon reviewing the test results.

- **Future Meetings and Testing:** The team discussed scheduling future meetings and conducting additional tests on various cabinets. S.Williams and B.Sage planned to collaborate on the testing.

Action Items

- **Testing Introduction Points:** Conduct tests on various aerosol introduction points using a T and manifold setup to determine the most effective method. (S.Williams)
- **Meeting Scheduling:** Coordinate with A.Rose to schedule the next meeting after completing the tests on aerosol introduction points. (S.Williams)
- **Reference Removal:** Remove the reference to IEST RP34 from the document and replace it with language to be developed after S.Williams's testing. (A.Rose)

TAB B2

Class II, Type B Language

Joint Committee on Biosafety Cabinetry
Task Group on Class II, Type B Language

Chair: Dave Phillips, Thermo Fisher Scientific

Task Group Roster:

Members	
Steve Williams	NSF
Bill Peters	NuAire, Inc.
Jim Wagner	Controlled Environment Consulting
Bill Sage	NSF
Cary Binder	NSF
Alex Atmadi	ESCO

Meetings held since last JC meeting:

The task group held 3 meetings since: July 29, 2024, February 10, 2025 and May 19, 2025
The next scheduled meeting TBD

Summary of Task Group work:
Follow-up tasks from May 19, 2025 meeting:
Meeting Summary - Class II Type B - TG - 2025-05-19 - Final.pdf

- **Valve Specification Language:** Find and provide language that specifies laboratory control valves with at least 5% tolerance and can control within 2% for B2 systems. (J.Garner)
- **Data Sheet Creation:** Create and distribute a data sheet for the group to fill in the blanks regarding the impact of different percentages on NSF testing criteria. (B.Peters)
- **Valve Manufacturer Feedback:** Talk to valve manufacturers to gather their input on language for specifying laboratory control valves and bring back their feedback to the group. (J.Garner)
- **Draft Language for Dedication Shift:** Draft language to change the current restrictive dedication to B2's on their own exhaust system with guidance on the precision of valves needed. (D.Phillips)
- **Data Collection for 2% Justification:** Collect and submit data from each manufacturer on operational setpoints, NSF range of acceptability, and low alarm points to justify the 2% requirement. (A.Atmadi, D.Phillips, B.Peters)
- **ASHRAE TC910 Communication:** Communicate with ASHRAE TC910 to explain the rationale behind the 2% requirement and provide supporting data. (J.Garner)
- **Seminar Preparation:** Prepare a seminar or PowerPoint presentation explaining the decisions and data supporting the new recommendations for B2 systems. (D.Phillips)

Follow-up tasks from February 10, 2025 meeting:

- **Data Compilation:** Clean up and compile the feedback and data received from manufacturers into a coherent document for the team. (J.Garner)
- **Outline Preparation:** Prepare and distribute an outline for the document that will include an introductory section explaining the importance of control for B2 cabinets and guidelines for dedicated and shared systems. (D.Phillips)
- **Information Sharing:** Send the compiled feedback and data document to AI for distribution to the team. (J.Garner)
- **Background Information:** Provide background information and testing data on why the 2% inflow velocity requirement is necessary for B2 cabinets. (B.Peters)
- **Guideline Development:** Draft additional guidelines to help ensure the successful implementation of B cabinets in the field, including do's and don'ts for system design. (B.Peters, D.Phillips)
- **Seminar Preparation:** Incorporate the additional guidance and information into the seminar presentation for the I2SL conference. (J.Garner)

Support Documents

- RE_ TC 9.10 - Discussion on proposed changes to NSF 49
- ETR-025 AccuValve Control Stability for 2 Percent Control
- Manufacturers Comments on NSF 49 Proposed Changes

Previous Progress Update

Key points from the July 29, 2024 meeting included:

• The current guidance emphasizes dedicated systems, meaning one fan, one duct, and one cabinet, to ensure safety and performance.
• There was consideration of allowing non-dedicated systems under specific conditions, such as having only B2 cabinets on the system, not varying the flow, and controlling within a 2% accuracy.
• Concerns were raised about the practicality of achieving the desired accuracy with non-dedicated systems and the potential need for a risk assessment when deviating from the dedicated system recommendation.

Action items included:
Valve Accuracy Specification: J.Garner to reach out to valve manufacturers for feedback on specifying a 2% accuracy requirement for valves in B2 cabinet applications.
Single Phase vs. Three Phase Exhaust Blower: A.Atmadi to investigate the impact of single phase vs. three phase exhaust blowers on B2 cabinet airflow stability and prepare findings.
Night Setback Mode for B2 Cabinets: D.Phillips to potentially draft guidance on the inapplicability of night setback modes for B2 cabinets.

Additionally, there have been a handful of emails since discussing the possibility of getting ASHRAE reps involved.

Support documents:

- Current text on dedicated for B2s - 01-2024.pdf

Action:

- Discuss issue and develop next steps

NSF Standard(s) Impacted: NSF/ANSI 49 - 2018

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.

The current standard limits Class II Type B biosafety cabinets (BSC) to dedicated exhaust fan systems. Multiple Type B BSCs could be manifolded on a common exhaust system if pressure independent airflow control devices, that instantly respond to duct pressure fluctuations, were applied to each cabinet. In such systems, the differential static pressure across the airflow control device changes inversely to that across the BSC's HEPA/ULPA filters, keeping the total differential pressure across both constant.

- With newly installed filter: Low static across BSC, high across airflow control device.
- With filter just prior to replacement: High static across BSC, low across the airflow control device.

Pressure independent airflow control devices that instantaneously compensate for pressure fluctuations provide consistent and accurate flow even as static pressure conditions within their design range change. BSCs with such consistent exhaust system flows eliminate problems that may arise in slower responding or pressure dependent systems, such as:

- Too little system exhaust can reduce inflow (while downflow remains the same) which reduces personnel protection.
- Too much system exhaust can increase inflow (while downflow remains the same) which reduces product protection.

A similar instantaneously compensating pressure independent airflow control device manifold approach could be used when Types A and C BSCs require connection to the external exhaust system to provide consistent, accurate exhaust flow to their canopies.

This proposal affects multiple sections of the Standard as detailed in the Recommendation section below. In addition to the manifold proposal above, it proposes use of a pressure independent, inlet insensitive airflow control device in Section E.4.2.3 text corrections/clarifications for Section E.4.2.6, Figure 37, and Figure 42.

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.

Recommend the following changes to the 2018 standard. Note:

- ~~Strikeout~~ for proposed removal of existing text.
- Grey hi-lite for proposed text addition.
- Rationale statements are in *RED italic* and are used to add clarity but are NOT intended to be part of the finished publication (should these proposals be accepted).

Page 97, Section E.3.1.4, “Question four: If the BSC requires an exhaust system, is there an appropriate location for the cabinet and its ductwork?”, last paragraph:

- canopy-connected Types A and C1 BSCs require a consistent, low static pressure. While a dedicated exhaust system is preferred, they may share a common exhaust system with other ~~exhausted~~ laboratory devices, if each is properly balanced and served by a pressure independent airflow control device that instantaneously compensates for duct pressure fluctuations to maintain flow setpoint;

Page 98, Section E.3.1.4, “Question four: If the BSC requires an exhaust system, is there an appropriate location for the cabinet and its ductwork?”, first paragraph:

- Type B BSCs require a higher static pressure that ~~must~~ increases as their exhaust filters load. They ~~must~~ shall either be connected to ~~on~~ a dedicated exhaust system or share a common exhaust system where each cabinet is served by a pressure independent airflow control device that instantaneously compensates for duct pressure fluctuations to maintain flow setpoint.~~, and not be ganged with other Type B BSCs, or other exhausted laboratory devices requiring a lower static pressure (e.g. fume hoods, canopy-connected BSCs)~~;

When served by pressure independent airflow control devices it should be acceptable to manifold Type B BSCs with other laboratory exhaust devices, even those operating at lower static pressures.

Page 100, Table E.1 “Characteristics of Type A1 and Type A2 BSCs”, row “exhaust system type”, columns for both Types A1 and A2:

Canopy-connected Type A BSCs may share a common exhaust system ~~be ganged into a multiple-cabinet exhaust system~~, if all laboratory devices ~~BSCs~~ are balanced properly and served by a pressure independent airflow control device that instantaneously compensates for duct pressure fluctuations to maintain flow setpoint.

Page 101, Table E.2 “Characteristics of Type B1 and Type B2 BSCs”, row “exhaust system type”, columns for both Types B1 and B2:

~~Must~~ Shall either have dedicated ductwork and exhaust fan ~~blower~~ for each BSC or share a common exhaust system where each cabinet is served by a pressure independent airflow control device that instantaneously compensates for duct pressure fluctuations to maintain flow setpoint.

When served by pressure independent airflow control devices it should be acceptable to manifold Type B BSCs with other laboratory exhaust devices, even those operating at lower static pressures.

Page 101, Table E.2 “Characteristics of Type B1 and Type B2 BSCs”, row “installation cost”, column for Type B1:

More expensive than a canopy-connected Type A and requires a dedicated exhaust fan or a manifolded exhaust system where each cabinet is served by a pressure independent airflow control device.

Page 101, Table E.2 “Characteristics of Type B1 and Type B2 BSCs”, row “installation cost”, column for Type B2:

> Most expensive. Higher exhaust volumes require larger ductwork and higher capacity ~~dedicated~~ exhaust fan, either dedicated to each BSC or on a manifold where each cabinet is served by a pressure independent airflow control device.

Page 102, Table E.3 “Characteristics of Type C1 BSCs”, row “exhaust system type”:

> Canopy-connected Type C1 BSCs may share a common exhaust system ~~be ganged into a multiple-cabinet exhaust system~~, if all laboratory devices ~~BSCs~~ are balanced properly and are served by a pressure independent airflow control device that instantaneously compensates for duct pressure fluctuations to maintain flow setpoint.

Page 105, Section E.4.2.3 “Exhaust requirements”, last sentence:

> Avoid cabinet locations that require either an elbow directly on top of the cabinet's exhaust connection or an excessive number of elbows to clear other items unless served by a pressure independent, inlet insensitive airflow control device which is unaffected by duct elbows.

Page 106, Section E.4.2.6 “Roof exhaust systems”, last sentence:

> A diagram illustrating a recommended roof exhaust facility is shown in Figure 40 - High velocity exhaust stack and fan~~s~~.[44]
>
> *Although the text above doesn’t show the strikeout, the footnote indication “44” should be struck out/removed, since it has no actual footnote associated with it.*

Page 126, Figure 37, description:

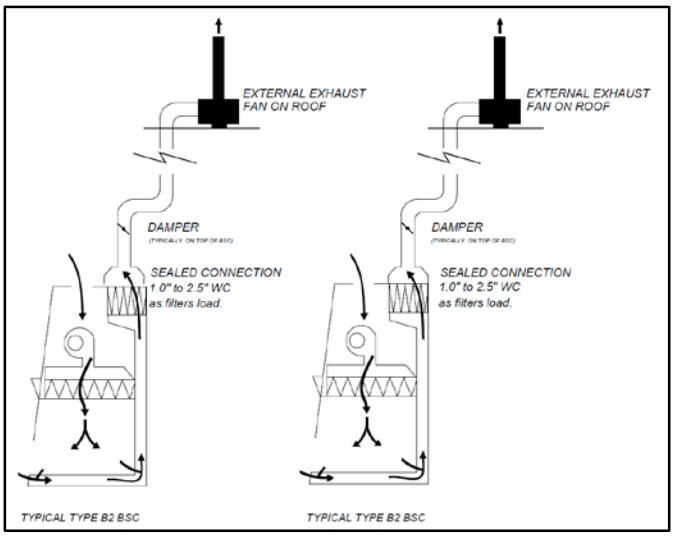
> Airflow patterns for Class ~~III~~ II Type B1 BSCs
>
> *Correct the typo of Class III to Class II.*

Page 131, Figure 42, description:

> High velocity ~~E~~exhaust stack and fan ~~blower~~
>
> *Make this description agree with the revised title used in Section E.4.2.6.*

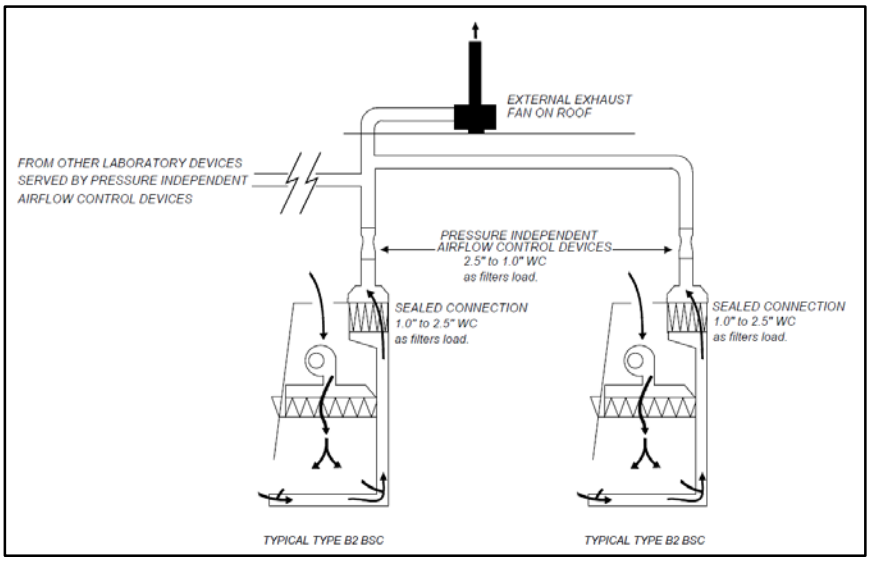
Supplementary Materials (photographs, diagrams, reports, etc.):
If not provided electronically, the submitter will be responsible to have sufficient copies to distribute to committee members.

Currently, each Class II Type B biosafety cabinet requires a dedicated exhaust fan system. As the HEPA/ULPA filters in each BSC load its static pressure increases. In the example drawn below, static pressure changes from 1.0” WC to 2.5” WC.



With pressure independent airflow control devices serving each BSC, the total static across both devices remains constant. In the example drawn below, total static remains 3.5” WC.

- With newly installed filter: 1.0” WC (BSC) + 2.5” WC (airflow control device) = 3.5” WC
- With loaded filter: 2.5” WC (BSC) + 1.0” WC (airflow control device) = 3.5” WC



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Submission Date: 5/29/2019

Please submit to: Al Rose, arose@nsf.org

**Type written name will suffice as signature*

Task Group on Class II, Type B Language
Teleconference Meeting Summary
July 29, 2024

Participating Members:

Dave Phillips (Thermo Fisher Scientific)
Bill Sage (NSF International)
Jim Wagner (Controlled Environment Consulting)
Steve Williams (NSF)
Cary Binder (NSF)
Alex Atmadi (ESCO)

Absent Members:

Bill Peters (NuAire, Inc.)

Participating observers:

Al Rose (NSF)
DJ Acker (Controlled Environment Consulting)
Erin Bagosy (NSF)
Justin Garner (Engineered Air Balance)

Supplemental Materials Referenced

- Meeting Summary - Class II Type B - TG – 2024-01-08
- Current text on dedicated for B2s - 01-2024.pdf

Discussion

D.Phillips is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Six of the 7 voting members were present (86%) representing a quorum. A.Rose presented the agenda indicating there was one item, specifically issue paper BSC-2019-10.

Motion, **S.Williams**:	Accept the previous meeting summary
Second:	C.Binder
Discussion:	None
Vote:	Six in favor, zero opposed, zero abstentions
Motion:	Carries

D.Phillips opened the floor asking J.Garner if he would share findings and feedback from the control manufacturers

J.Garner provided detailed insights on the performance of Venturi valves and other airflow control technologies, including:

- The performance of purely mechanical Venturi valves, highlighting their variability under different static pressures and airflow rates. He emphasized that while some valves perform better than others, all types of Venturi valves can experience shifts in accuracy due to system changes or static pressure variations.
- He also discussed the limitations of Venturi valves, noting that they do not measure airflow directly and can have accuracy issues at the low and high ends of their operating ranges.
- He suggested that for applications requiring tight airflow control, technologies that measure airflow directly, such as valves with airflow sensors or dampers, might offer better accuracy than purely mechanical Venturi valves.

A brief discussion ensued about the term "dedicated" revolved around the context of exhaust systems for B2 cabinets. The participants debated the feasibility and safety of using dedicated versus non-dedicated (or ganged) exhaust systems. Key points included:

- The current guidance emphasizes dedicated systems, meaning one fan, one duct, and one cabinet, to ensure safety and performance.
- There was consideration of allowing non-dedicated systems under specific conditions, such as having only B2 cabinets on the system, not varying the flow, and controlling within a 2% accuracy.
- Concerns were raised about the practicality of achieving the desired accuracy with non-dedicated systems and the potential need for a risk assessment when deviating from the dedicated system recommendation.

The discussion also touched on the technical capabilities of venturi valves and other airflow control technologies to maintain the required accuracy in airflow.

D.Acker presented a suggestion from one of the manufactures of Venturi style valves regarding trimming some of the static pressure when it gets high by putting a damper in front of the valve. They acknowledged this as a potential problem and a limitation of the valve, suggesting it should be considered during system design. He agreed on valve controllability and accuracy, emphasizing the challenges at the low and high ends of valve operation and suggesting that using lower pressure valves could help keep overall system static pressure lower for better controllability.

J.Wagner made several points during the meeting, including:

- Expressing concern about the practicality of achieving a 2% accuracy with airflow control valves and the feasibility of testing for this accuracy in the field.
- Highlighting the potential difficulty of enforcing a 2% accuracy requirement for airflow control devices without a practical test method.
- Discussing the risk assessment language and its potential to become a default position for engineers when specifications are not met.
- Mentioning the precedent of ASHRAE supporting research projects related to laboratory systems, suggesting collaboration with ASHRAE for further guidance on airflow control.

D.Phillips recapped the meeting and discussed the various options moving forward. One option he mentioned was adding a note to the language for dedicated systems that would indicate that it is risky to use non-dedicated systems, but it may be possible if certain conditions are met. Another option he mentioned was adding a description of a non-dedicated system that would include requirements such as having only B2s on the system, not attempting to vary the flow, and requiring the cabinet to behave safely by not varying more than 2% once the flow is set and certified. He also mentioned the possibility of adding a risk assessment to determine if it is safe to use a non-dedicated system.

The following action items were presented in preparation for the next meeting (not yet scheduled):

Valve Accuracy Specification: J.Garner to reach out to valve manufacturers for feedback on specifying a 2% accuracy requirement for valves in B2 cabinet applications.

Single Phase vs. Three Phase Exhaust Blower: A.Atmadi to investigate the impact of single phase vs. three phase exhaust blowers on B2 cabinet airflow stability and prepare findings.

Night Setback Mode for B2 Cabinets: D.Phillips to potentially draft guidance on the inapplicability of night setback modes for B2 cabinets.

D.Phillips asked if there were any other questions; there were none and the meeting adjourned

Task Group on Class II, Type B Language
Teleconference Meeting Summary
February 10, 2025

Participating Members:

Dave Phillips (Thermo Fisher Scientific)
Bill Sage (NSF)
Steve Williams (NSF)
Bill Peters (NuAire, Inc)

Absent Members:

Cary Binder (NSF)
Jim Wagner (Controlled Environment Consulting)
Alex Atmadi (ESCO)

Participating observers:

Al Rose (NSF)
DJ Acker (Controlled Environment Consulting)
Cassandra Leone (NSF)
Justin Garner (Engineered Air Balance)

Supplemental Materials Referenced

- Agenda - Class II, Type B - TG - 2025-02-10.pdf
- Meeting Summary - Class II Type B - TG – 2024-07-29

Discussion

D.Phillips is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Four of the 7 voting members were present (57%) representing a quorum.

Meeting notes:

- **Meeting Agenda:**
  - **Action Items:** D.Phillips mentioned three action items from the previous meeting: valve specifications, night setback language, and single-phase vs. three-phase exhaust blower. A.Rose confirmed these items and added that the night setback mode was for B2 cabinets and the valve accuracy specification was also included.

- **Valve Specifications:**
  - **Information Gathering:** J.Garner reported that he had spent a significant amount of time over the past six months gathering information from major lab control manufacturers. He had talked to all the major players in the industry to gather comprehensive data.
  - **Feedback from TC910:** Justin took the feedback he gathered to the Laboratory Technical Committee (TC910) and received additional feedback from select members who represent the design community. This feedback was crucial for understanding the design community's perspective.
  - **Test Reports:** He mentioned that two manufacturers agreed to conduct testing. He received an official test report from one manufacturer and the results from the other. This provided concrete data to support their discussions on valve specifications.

- **Valve Manufacturers' Feedback:**
  - **Manufacturers' Concerns:** J.Garner reported that many valve manufacturers acknowledged the possibility of achieving 2% accuracy under controlled conditions. However, they expressed

concerns about the engineering community misunderstanding the application of 2% versus 5% accuracy and the challenges of verifying 2% accuracy in the field.
  - **Testing Data:** Two manufacturers provided testing data proving the feasibility of 2% accuracy under controlled conditions. Another manufacturer confirmed similar testing results, although not conducted specifically for this project.
  - **Field Verification:** Manufacturers raised concerns about how the 2% accuracy would be verified in the field, highlighting the difficulty of maintaining such precision outside controlled environments.
  - **Engineering Misunderstanding:** Manufacturers emphasized the risk of the engineering community misapplying the 2% accuracy standard in inappropriate contexts, potentially leading to issues in practical applications.

- **Concerns About 2% Accuracy:**
  - **Verification Challenges:** J.Garner highlighted concerns from valve manufacturers about verifying the 2% accuracy in the field and the potential issues when cabinets are turned off or go into night setback mode.
  - **Night Setback Issues:** J.Garner noted that manufacturers were particularly concerned about the impact on accuracy when cabinets are turned off or enter night setback mode, as these conditions could disrupt the precise airflow control required to maintain 2% accuracy.

- **Scenarios for Achieving 2% Accuracy:**
  - **Ideal Conditions:** B.Peters emphasized the importance of identifying specific scenarios where 2% accuracy can be reliably achieved, such as systems with limited BSCs on a dedicated line and controlled exhaust conditions.
  - **System Limitations:** B.Peters and J.Garner discussed the limitations of achieving 2% accuracy, including the need for dedicated exhaust systems and the challenges posed by varying static pressures and airflow conditions.
  - **Manufacturer Feedback:** J.Garner reviewed the feedback from manufacturers, who generally agreed that 2% accuracy is achievable under specific conditions but highlighted the need for precise control of static pressure and airflow to maintain this accuracy.

- **Dedicated Exhaust Systems:**
  - **Dedicated Systems:** J.Garner explained that Type 2B cabinets should be installed on dedicated exhaust systems with fixed static pressure set points to achieve 2% accuracy. This approach ensures consistent airflow and minimizes external variables that could affect accuracy.
  - **Manufacturer Agreement:** Manufacturers unanimously agreed that dedicated exhaust systems are essential for achieving 2% accuracy, as they provide the necessary control over static pressure and airflow conditions.
  - **System Specifications:** J.Garner detailed the specifications for dedicated exhaust systems, including continuous operation at a fixed static pressure set point and the use of constant volume air valves for each BSC.

- **Engineering Community's Concerns:**
  - **Necessity of 2%:** The engineering community questioned the necessity of maintaining 2% accuracy, asking for evidence that this level of precision is required for safety. J.Garner explained the correlation between exhaust airflow and inflow, emphasizing the safety implications.
  - **Dedicated Systems:** B.Peters explained the importance of dedicated exhaust systems for chemical safety, highlighting that B cabinets often handle hazardous chemicals that require strict control over exhaust conditions to ensure safety.
  - **Alternative Solutions:** The engineering community also inquired about the possibility of using booster fans or other solutions instead of fully dedicated systems. B.Peters and J.Garner discussed the limitations and potential risks of such alternatives.

- **Room Pressurization and Environmental Factors:** J.Garner mentioned that room pressures and environmental factors can affect the accuracy of the valves and cabinets, especially in highly pressurized labs like BSL-3.

- **Night Setback Considerations:**
  - **Pressurization Challenges:** D.Phillips and D.Acker discussed the difficulty of maintaining room pressurization during night setback, as reducing exhaust flow can disrupt the balance of airflows in the room, leading to potential safety and performance issues.
  - **Control Accuracy:** They also highlighted the challenge of ensuring that the system can accurately return to the exact airflow settings after night setback, which is critical for maintaining the performance and safety of B2 cabinets.
  - **Application Specificity:** They agreed that night setback might not be suitable for all applications, particularly in environments where maintaining strict pressurization and airflow control is essential, such as pharmaceutical facilities.

- **Energy Savings and Risk:**
  - **Energy Savings:** J.Garner highlighted the significant energy savings that can be achieved through night setback, particularly by reducing the static pressure on exhaust systems during off-hours.
  - **Risk Assessment:** He also emphasized the importance of carefully assessing the risks associated with night setback, especially in pharmaceutical facilities where maintaining strict environmental controls is critical for safety and product integrity.

Follow-up tasks:

- **Data Compilation:** Clean up and compile the feedback and data received from manufacturers into a coherent document for the team. (J.Garner)
- **Outline Preparation:** Prepare and distribute an outline for the document that will include an introductory section explaining the importance of control for B2 cabinets and guidelines for dedicated and shared systems. (D.Phillips)
- **Information Sharing:** Send the compiled feedback and data document to Al for distribution to the team. (J.Garner)

- **Background Information:** Provide background information and testing data on why the 2% inflow velocity requirement is necessary for B2 cabinets. (B.Peters)
- **Guideline Development:** Draft additional guidelines to help ensure the successful implementation of B cabinets in the field, including do's and don'ts for system design. (B.Peters, D.Phillips)
- **Seminar Preparation:** Incorporate the additional guidance and information into the seminar presentation for the I2SL conference. (J.Garner)

D.Phillips asked if there were any other questions; there were none and the meeting adjourned

Task Group on Class II, Type B Language
Teleconference Meeting Summary
May 19, 2025

Participating Members:

Dave Phillips (Thermo Fisher Scientific)
Cary Binder (NSF)
Alex Atmadi (ESCO)
Bill Peters (NuAire, Inc)
Bill Sage (NSF)

Absent Members:

Jim Wagner (Controlled Environment Consulting)
Steve Williams (NSF)

Participating observers:

Al Rose (NSF)
DJ Acker (Controlled Environment Consulting)
Shawn Donaldson (ENV Services)
Justin Garner (Engineered Air Balance)

Supplemental Materials Referenced

- Agenda - Class II, Type B - TG - 2025-05-19.pdf
- RE_ TC 9.10 - Discussion on proposed changes to NSF 49
- ETR-025 AccuValve Control Stability for 2 Percent Control
- Manufacturers' Comments on NSF 49 Proposed Changes

Discussion

D.Phillips is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Five of the 7 voting members were present (71%) representing a quorum. D.Phillips recapped the work thus far, pointing out that the group has been drifting toward the requirement of the language to state that B2 systems need a static pressure through an area of a certain range. In other words, the stance of the current standard is not acceptable.

Meeting notes:

- **Valve Manufacturers Feedback:**
  - **Feedback Summary:** J.Garner shared that valve manufacturers expressed concerns about the 2% requirement for B2 systems. They questioned the necessity of such a tight tolerance and whether there was sufficient data to support it. The valve manufacturers were particularly concerned about the safety implications and the practical challenges of maintaining this tolerance. The group discussed this feedback in detail, confirming that the manufacturers could achieve the 2% tolerance but were worried about how it would be clarified and enforced. There is an ultimate concern about the potential for misinterpretation and the need for clear guidelines to ensure safety and compliance.
  - **ASHRAE Concerns:** J.Garner mentioned that the ASHRAE TC910 group, primarily composed of designers, also questioned the 2% requirement. They asked for data to justify this tight tolerance and whether it was necessary for safety. J.Garner conveyed that his team had explained the rationale behind the 2% requirement, but the ASHRAE group remained concerned about its necessity and application.

- **Data Collection Exercise:**
  - **Data Proposal:** B.Peters proposed that manufacturers collect and provide data on operational setpoints, NSF range of acceptability, and low alarm points for B2 cabinets. This data would help justify the 2% requirement and provide a basis for discussions with ASHRAE and other stakeholders.
  - **Expected Outcomes:** when asked, he expressed confidence that the collected data would justify the 2% requirement.
- **System Stability:**
  - **Valve Stability:** J.Garner explained that laboratory control valves, particularly mechanical venturi valves, are designed to maintain stable airflow and respond to minute pressure fluctuations. These valves can ensure the stability of B2 systems by adjusting to changes in static pressure and maintaining consistent airflow.
  - **Valve Performance:** He highlighted that mechanical venturi valves do not actively measure and control airflow but respond instantaneously to static pressure fluctuations. This design allows them to maintain stable airflow in B2 systems, even with minor changes in pressure.
  - **System Design:** he further emphasized the importance of using high-quality laboratory control valves in B2 systems.

- **Dedicated Exhaust System:**
  - **Recommendation Change:** The group reached consensus about changing the recommendation to state that for best performance, B2 cabinets should be on a dedicated exhaust system. This adjustment aims to ensure that B2 systems operate within the required tolerances and maintain stability. Secondarily, if the B2 Cabinets are not on a dedicated system, then there should be guidance for operational performance.
  - **Valve Tolerance:** The group had further discussion about laboratory control valves maintaining a 5% tolerance instead.
  - **Implementation Plan:** The group outlined a plan to implement the new recommendation, including updating the NSF standard and providing guidance to manufacturers and designers. The goal is to ensure that B2 systems are designed and operated in a way that maintains stability and meets the required tolerances.

- **Next Steps:**
  - **Standard Changes:** D.Phillips outlined the need to finalize changes to the NSF standard, including the new recommendation for B2 cabinets to be on their own exhaust system and the requirement for laboratory control valves to maintain a 5% tolerance.
  - **Data Sheets:** He noted that B.Peters would provide data sheets to support the 2% requirement. These data sheets will include information on operational setpoints, NSF range of acceptability, and low alarm points for B2 cabinets.
  - **Drafting Language:** D.Phillips emphasized the importance of drafting clear and precise language for the dedication shift and valve precision requirements. This language will be included in the updated NSF standard to ensure that all stakeholders understand the new requirements and their implications.

Follow-up tasks:

- **Valve Specification Language:** Find and provide language that specifies laboratory control valves with at least 5% tolerance and can control within 2% for B2 systems. (J.Garner)
- **Data Sheet Creation:** Create and distribute a data sheet for the group to fill in the blanks regarding the impact of different percentages on NSF testing criteria. (B.Peters)
- **Valve Manufacturer Feedback:** Talk to valve manufacturers to gather their input on language for specifying laboratory control valves and bring back their feedback to the group. (J.Garner)
- **Draft Language for Dedication Shift:** Draft language to change the current restrictive dedication to B2's on their own exhaust system with guidance on the precision of valves needed. (D.Phillips)
- **Data Collection for 2% Justification:** Collect and submit data from each manufacturer on operational setpoints, NSF range of acceptability, and low alarm points to justify the 2% requirement. (A.Atmadi, D.Phillips, B.Peters)
- **ASHRAE TC910 Communication:** Communicate with ASHRAE TC910 to explain the rationale behind the 2% requirement and provide supporting data. (J.Garner)
- **Seminar Preparation:** Prepare a seminar or PowerPoint presentation explaining the decisions and data supporting the new recommendations for B2 systems. (D.Phillips)

D.Phillips asked if there were any other questions; there were none and the meeting adjourned

TAB B3

Canopy Connection Set Point

Joint Committee Issue Paper

NSF Standard(s) Impacted: NSF/ANSI 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.

Some canopy connections are sent to NSF with minimal setup instructions. We cannot test every possible airflow, damper, and blower speed configuration. Since field certifiers are not required to check the inflow reduction during a failed external exhaust for listed canopy connections, there is the potential for it to not function properly in the field. Requiring some sort of set point would help ensure the canopy connection will function the same in the field as it was tested in the lab.

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.

5.4 Canopy exhaust connection

If Type A1, A2, and C1 cabinets are connected to an exhaust system, it shall only be done so via a canopy connection; direct connections are not acceptable. They are exhausted with the assistance of a remote fan to the atmosphere. In normal operation, the volume of room air drawn into the canopy connection's openings or gaps shall be sufficient to ensure the capture of all of the BSC's HEPA filtered exhaust, as verified by a visible medium. The flow of room air into the canopy connection through openings, or gaps, or both, provides assurance of consistent BSC performance during fluctuations in exhaust system flow rate, or room pressure, or both. Canopy connections listed as acceptable options for a BSC shall have a manufacturer specified set point (i.e. gap velocity, duct pressure, etc.), separate from the BSC's inflow and downflow set points, to ensure proper setup and function in the field.

For Types A1, A2, and C1 with a canopy connection, during an exhaust system failure:

— the canopy shall provide properly sized openings or gaps to allow for recirculation of HEPA filtered exhaust into the room;

— the BSC shall maintain an inflow velocity above the lowest value verified by the NSF/ANSI 49 biological challenge testing; and

Alternatively, the Type C1 canopy can direct the HEPA filtered exhaust into the exhaust duct during an exhaust system failure provided:

— the BSC shall maintain an inflow velocity above the lowest value verified by the NSF/ANSI 49 biological challenge testing if the unit is programmed to operate longer than 15 s after an exhaust system failure.

Joint Committee Issue Paper

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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Signature*: Bill Sage
Company: NSF
Telephone Number: 947-282-2867 E-mail: wsage@nsf.org

Submission Date: 6/2/24

Please submit to: Al Rose, arose@nsf.org

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Joint Committee on Biosafety Cabinetry

April 21, 2025

Proposed revision to NSF/ANSI: 49 – Biosafety Cabinetry: Design, Construction, Performance and Field Certification (49i199r1)

Revision 1 of NSF/ANSI 49, issue 199 is being forwarded to the Joint Committee on Biosafety Cabinetry for consideration. Please review the proposal and **submit your ballot by May 12, 2025** 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 proposed revised regarding the canopy connection set up instructions in Standard 49.

Background

Issue paper **BSC-2024-05 – Canopy Connection Set Point** highlighted that some canopy connections are sent to NSF with minimal setup instructions and it's not feasible to test every possible airflow, damper, and blower speed configuration. Since field certifiers are not required to check the inflow reduction during a failed external exhaust for listed canopy connections, there is the potential for it to not function properly in the field. The proponent suggested language requiring a set point to help ensure the canopy connection will function the same in the field as tested in the lab.

This issue was presented to the JC during the 2024 Face-to-Face meeting. At that time the proposed language was not motioned to go to ballot, but rather this TG was motioned into existence for discussing this issue.

The TG met twice since the 2024 Face-to-Face meeting and the group sorted out the language which is now presented here to the JC as revision 1 approval ballot.
The language submitted by the proponent is presented here for your consideration as revision 1 approval ballot.

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

Robert W. Powitz, PhD, MPH, RS, DLAAS
Chairperson, Joint Committee
c/o Allan Rose, Joint Committee Secretariat, NSF
Phone: (734) 827-3817
E-mail: arose@nsf.org

[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

•

5 Design and construction

•

5.22.4 Types A1 or A2 canopy exhaust alarm

Types A1 or A2 cabinets may be connected to an exhaust system via a canopy connection and exhausted by a remote fan. Once the cabinet and canopy is set or certified in its acceptable airflow range, audible and visual alarms shall be required to indicate within 15 s a loss of capture of room air using a visible medium to verify at the canopy air intake(s). The cabinet fan(s) ~~must~~ shall remain in operation when the alarm is activated. Canopy connections listed as acceptable options for a BSC shall have a manufacturer specified set up instructions separate from the BSC's inflow and downflow set points, to ensure proper setup and function in the field.

•

Normative Annex 1

Performance tests

•

N-1.13 Canopy connection test

N-1.13.1 Purpose

This test demonstrates the ability of a Types A1, A2, or C1 BSC to maintain inflow velocity during a facility exhaust system failure.

N-1.13.2 Method

a) Connect the BSC to a facility exhaust system via the BSC manufacturer's canopy connection.

b) ~~Adjust facility exhaust flow according to the BSC manufacturer's instructions~~ Setup the canopy connection and airflows according to the manufactuer's instructions using the provided canopy connection set up instructions and balance the cabinet inflow and downflow velocities at the manufacturer's recommended nominal set points ± 2 ft/min (0.01 m/s).

c) Follow the BSC / canopy connection manufacturer's instructions to calibrate the canopy alarm if needed.

d) Reduce facility exhaust flow until a loss of capture of room air at the canopy intake slots is verified using a visible medium.

e) Measure the amount of time from loss of capture to canopy alarm activation.

f) Restore facility exhaust flow to the previous setting.

g) Measure the inflow velocity using a DIM.

h) Turn off the facility exhaust fan. Do not close any valves in the facility exhaust ductwork.

i) Wait 15 s after the canopy exhaust alarm is activated and then measure the inflow velocity again, using a DIM instrument.

N-1.13.3 Acceptance

N-1.13.4 The canopy alarm shall activate within 15 s of loss of capture of the visible medium.

-

***Rationale**: this language is intended to establish a set point to help ensure the canopy connection will function the same in the field as tested in the lab.*

49i199r1 - Canopy Connection Set Point – Ballot

Comments
May 13, 2025

Vote – 17 : 1 : 0 (Yes : No : Abstain)

Submitter	Vote	Comment
Williams, Steve - NSF	Negative	Summary: The ballot doesn't go as far as I'd like in Annex N-1. I can live with this and move on as it was the clear consensus of the rest of the TG. I'm voting no because the ballot does not include updated instructions for balancing a canopy connected cabinet in Annex N-5. TG discussion demonstrated field certifiers do not look for canopy instructions but instead just look to insure there is capture at the canopy inlet openings. As we have decided it is important for the manufacturer to provide set up instructions, those instructions should be followed in the field. Proposed Solution: Add the following language to N-5, preferably in a new section, N-5.1.4: **When a cabinet is first set up with a canopy connection listed as an acceptable option, balance cabinet airflows following manufacturer instructions for canopy connection set up.**
Sage, Bill - NSF	Observer Comment	Summary: This language adds little value if field certifiers are not required to follow the manufacturer's setup instructions for canopy connections included as acceptable options in the listing. Testing only the canopy exhaust alarm at loss of smoke capture is not sufficient to ensure the canopy will maintain inflow during exhaust failure if the manufacturer's setup instructions are not followed. NSF has tested several canopy connections that have passed the exhaust alarm test but failed the inflow reduction test. Manufacturers have changed their setup instructions, not the physical design, in order to pass both tests. Due to that, listed canopy connections are potentially less safe than non-listed canopies since field certifiers aren't required to follow the manufacturer's instructions or complete the inflow reduction test (N-5.7.3.2.2.1.b). Proposed Solution: I suggest adding language requiring field certifiers to follow the manufacturer's setup instructions for listed canopy connections.

TAB B4

Design and Construction Requirements

Joint Committee Issue Paper

NSF Standard(s) Impacted: _____

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.

The standard should clarify recommendations on cleaning the drain trough.

Current guidance on cleaning and accessing the drain trough in the standard (emphasis added).

5.26 Drain spillage trough

A drain spillage trough shall be provided below the work surface to retain spillage from the total work area; the trough shall be easily cleanable. A drainpipe shall be connected to the drain spillage trough and fitted with a 3/8 in NPT (DN 10 or equivalent) or larger ball valve. The drainpipe and valve shall conform to the material requirements of the drain pan or trough. The drain spillage trough shall accommodate at least 1 gal (4 L). The drain valve shall be identified with a label and operating instructions placed in close proximity to, or on, the valve.

I-1.6.1 Dos and don'ts of disinfectant efficacy

- do evaluate the cleaning processes and frequencies for ability to control organisms separately from the disinfectant efficacy study;
- do design a meaningful study that represents use in the facility;
- do consider additional studies if quality metrics indicate current agents are no longer controlling microorganisms in the area using prescribed disinfection methods;
- don't expect the disinfectant study to replace routine cleaning, disinfection and monitoring programs;
- don't rely on disinfectant studies to establish that cleaning frequencies and processes to control organisms are sufficient and acceptable; and
- don't wait until there is a problem to evaluate the disinfectants being used in the facility.

I-1.7.8 Paper catch prefilter

Some BSCs have a paper catch filter installed behind the rear divider panel of the work zone. This area forms the return air path to the motor / blower. If the airflow is blocked, performance of the BSC can be compromised. Therefore, the paper catch should be checked and cleaned no less than weekly or daily if paper products are used for procedures. Removed paper must be properly discarded as contaminated hazardous waste.

I-2.1.1.3 Cabinet decontamination for spills and splashes

BSCs shall be appropriately decontaminated (surface) after spills and splashes of research agents. Contaminated surfaces should be suitably decontaminated. This also is to include all exposed interior surfaces, sashes, grilles, the drain spillage trough and drain valve, and any exposed exterior work surfaces such as arm rests.

Other guidance on cleaning and accessing the drain trough.

On page 384 of the 2020 "Biosafety in Microbiological and Biomedical Laboratories, 6th Edition" by CDC/NIH it states "Periodic removal of the cabinet work surface and/or grilles after the completion of drain pan decontamination is recommended because of dirty drain pan surfaces and grilles, which ultimately could occlude the drain valve or block airflow. However, extreme caution should be observed while wiping these

surfaces to avoid injury from sharp metal edges and other items (e.g., broken glass, pipette tips) that may be present. Always use disposable paper toweling and avoid applying harsh force. Wipe dirty surfaces gently. Never leave toweling on the drain pan because the paper could block the drain valve or the air passages in the cabinet."

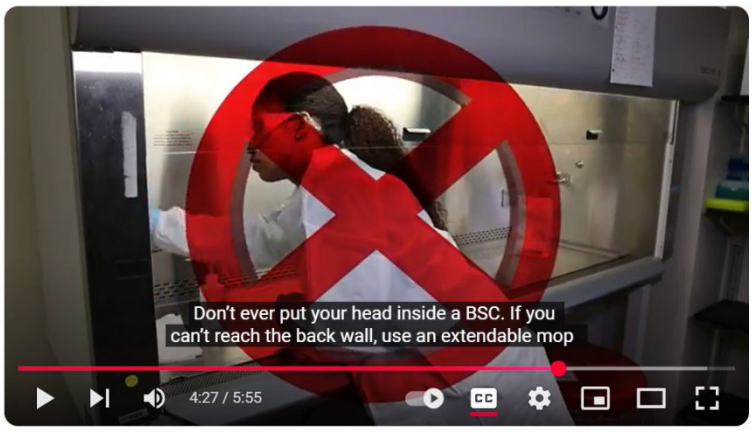
On page 143, Section 11.4.3 "completion of Work in the BSC" of the Government of Canada's *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2016, the fifth bullet states "Routinely remove the work surface and disinfect the tray beneath it."

There are a number of references addressing personal safety while surface decontaminating interior work surfaces in a Class II BSC

For example, note the screenshot below of a YouTube video posted by the US CDC at https://youtu.be/3vF5ZJi462Q?si=90Lm-IiTZg7chf3R

In addition, the following websites have similar guidance (emphasis added)

— The EHS department of Cornell University states "To avoid sticking your head in the BSC or possibly injuring yourself, use a Swiffer-style mop handle to clean those areas. Occasionally clean and decontaminate the space below the work surface, accumulating broken glass, spilled materials, and general gunk. Use tongs to remove broken glass. Establish a regular schedule to perform this activity, perhaps once or twice a year and as needed." https://ehs.cornell.edu/research-safety/biosafety-biosecurity/biological-safety-manuals-and-other-documents/biological/biological-safety-cabinets



— Environmental Health & Safety at UC Santa Barbara says the same thing (emphasis added) "Never place your head inside of a biosafety cabinet to reach surfaces; use a "Swiffer" or small mop to wipe down surfaces" and "Clean and disinfect the trough and grill if a spill breaches the area" at https://www.ehs.ucsb.edu/programs-services/biological-safety/biosafety-cabinets

— The University of Kentucky provides a document "Biological Safety Cabinet Operations, rev. 2017.0601 where they state, "Never lean into a BSC or place head into a BSC." https://ehs.uky.edu/docs/pdf/bio_le_biological_safety_cabinet_operations_0001.pdf.

Conclusions

— The frequency and processes of surface decontamination in a BSC should be determined based on evaluations of the cabinet as used in some say may be as infrequent as annually.

— As the potential contamination from contaminants on the surfaces of the drain trough is less likely to reach the user or cell cultures than contaminants in the work area, it is likely the drain trough will require less frequent surface decontamination that the work surface and working area.

- Care must be taken to safely clean and surface decontaminate the drain trough. It is more challenging to safely surface decontaminate the drain trough than it is to safety surface decontaminate the BSC work area. The work surface can be heavy, is often awkward to move. While one person, working alone can access interior surfaces of the cabinet work area relatively easy. In addition to managing the work surface, the drain trough extends back farther than the interior rear wall of the cabinet and out of reach for most people (based on standard lengths of shoulder to elbow and elbow to grip for adult workers in ISO 7250-3).
- The addressing potential obstruction in the paper catch from captured debris is a different issue than surface decontamination within the drain trough. For example, an application may specify a daily inspection of the paper catch for debris, but a less frequent surface decontamination of the paper catch and/or the drain trough.

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.

(Highlighting provides alternative language)

I propose moving “Paper Catch Prefilter” into “Terminal purging and wipedown” with added guidance on safe cleaning/decontamination of the drain trough. To add with context the section below starts with the unchanged sections on terminal purging and wipe down.

I-1.7.6 Terminal purging and wipedown

a) Following completion of work, allow the BSC to run for a 5-min period without personnel activity to purge air in the total work area;
b) Decontamination of the interior surfaces should be repeated after removal of all materials, cultures, apparatus, etc. Check grills and diffuser grids for spilled or splashed materials that may support fungus growth in the workspace; and
c) The interior surfaces of the workspace should next be disinfected with an appropriate disinfectant for an appropriate contact time. Use of chlorine bleach in the BSC will damage the BSC stainless steel work surface. Most surface disinfectants require a specific contact time, depending upon the microbiological agents used within the BSC. Consult appropriate disinfectant documents for proper application and suitability against the material used in the BSC.

I-1.7.7 Use the following procedure to effectively clean or surface disinfect the BSC work zone surfaces:

a) Raise the sliding sash window to a full-open position.
b) Silence the audible alarm during the cleaning process.
c) Wipe all surfaces in parallel strokes from clean to dirty.

I-1.7.8 ~~Paper catch prefilter~~

~~Some BSCs have a paper catch filter installed behind the rear divider panel of the work zone. This area forms the return air path to the motor / blower. If the airflow is blocked, performance of the BSC can be compromised. Therefore, the paper catch should be checked and cleaned no less than weekly or daily if paper products are used for procedures. Removed paper must be properly discarded as contaminated hazardous waste.~~ Consider the following elements to effectively clean or surface disinfect below the BSC work surface containing the drain trough and sometimes the paper catch screen behind the interior rear wall of the BSC work area:

As with the BSC work area, the frequency of surface decontamination under the work surface should be determined based on evaluations of the cabinet as used. Given the lack of exposure to splashes and other

materials used in the BSC work area, the appropriate frequency of cleaning and surface decontamination under the work surface may be much less including as infrequent as annually. One approach is to start with a frequency of monthly but inspect the area before cleaning and surface decontamination and note the condition. After the first quarter or year, if appropriate extend or reduce the intervals between cleaning and decontamination.

Additional care may be necessary to safely clean and surface decontaminate under the work surface. In order to access the area, the work surface must be raised. The work surface may be heavy and awkward to move. In addition to managing the work surface, the drain trough extends back farther than the interior rear wall of the cabinet and out of easy reach for many people. It may be necessary to identify cleaning tools to extend to the rear or a risk evaluation to assess cleaning and decontamination process.

Use the following procedure to effectively clean or surface disinfect the area under the BSC work zone:

a) Don appropriate PPE.
b) Raise the sliding sash window to a full-open position.
c) Silence the audible alarm during the cleaning process.
d) After cleaning or surface disinfecting the BSC work zone surfaces, raise the front of the work surface so it is at an angle with the rear edge still supported by the cabinet. For larger cabinets it may be necessary to have assistance or add a temporary support to hold the work surface at the angle needed for access.
e) Liberally spray or douse the area under the work surface with an appropriate surface decontaminant and let it sit for the required contact time for effectiveness.
f) Inspect the area for hazardous debris including broken glass, needles and other sharps. Take appropriate steps to safety remove this contaminated material.
g) After removal of hazardous debris and the contact time required for the decontaminant has elapsed, gently wipe the drain trough area. This gentle clean is intended to discover any hazardous debris that was not visible or was missed. After appropriate removal of any debris, continue to clean and disinfect the area under the work surface.
h) Inspect the drain valve. Over time debris and material may collect and block the drain valve. Inspect it to assure it is not blocked and will be functional if needed to manage and drain a spill.
i) Some BSCs have a paper catch screen installed to the rear of the area under the work surface in the return air path to the motor / blower. If the airflow is obstructed, performance of the BSC can be compromised. Therefore, the paper catch screen should be checked and obstructing material removed as appropriate. If paper products are used for procedures, the paper catch screen may require more frequent inspection. Removed paper must be properly discarded as contaminated hazardous waste.

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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Signature*: David S. Phillips
Company: Thermo Fisher Scientific
Telephone Number: 484-753-3665 E-mail: david.phillips@thermofisher.com
Submission Date: January 10, 2025

Item No. BSC-2025-01
(For NSF International internal use)
03/2013

Joint Committee Issue Paper

Please submit to: Al Rose, arose@nsf.org

**Type written name will suffice as signature*

Item No. BSC-2025-01
(For NSF International internal use)
03/2013

TAB B5

Vibration Testing

Joint Committee on Biosafety Cabinetry
Task Group on Vibration Testing

Chair: Kyle Mulder, Technical Safety Services

Task Group Roster:

Members	
Alex Atmadi	ESCO
Tori Fincham	Labconco
Mark Lenart	Clean Air Testing, Inc.
Bill Peters	NuAire, Inc.
Bill Sage	NSF
Steve Williams	NSF
Matt Squire	NuAire, Inc.

Meetings held since last JC meeting:

The task group held 1 meeting since: November 18, 2024
There is no further meeting scheduled at this time

Summary of Task Group work:

This topic was discussed and presented in detail during one of the breakout sessions of the 2024 JC Face-to-Face meeting.

The main points of the discussion were:

- The current criteria for vibration in Annex N5 is based on a unit of measure that is not readily available on most meters, and it is not sensitive enough to detect the complaints from some clients who have sensitive equipment or liquid samples in the biosafety cabinet.
- It was suggested that the vibration meters' units of measure and specs be changed to reflect market availability and client needs.
- There was also a suggestion to use a qualitative method, such as a Petri dish with water, to assess the vibration level, instead of a quantitative meter.
- There was some debate about whether vibration is a relevant criterion for biosafety cabinets, and whether it should be mandatory or optional in the field testing.
- A motion was passed to form a task group to evaluate vibration in both Annex N1 and Annex N5, starting with instrumentation and considering other aspects such as units of measure, criteria, and methods.

Action Items from meeting

- **Testing Plan:** Create and distribute a testing plan for vibration measurement to the group. (S.Williams)
- **Contact TUV Nord:** Contact TUV Nord to involve them in the vibration testing. (B.Peters)
- **Data Collection:** Collect vibration data from 10 units by NuAire, ESCO, and NSF and 5 units by Mark and Kyle. (M.Lenart, K.Mulder)
- **Instrument Information:** Share the make and model of the vibration meter used by the team for standardization purposes. (S.Williams)
- **Data Submission:** Submit collected vibration data to the group for analysis. (All participants)
- **Review Draft Plan:** Review and provide feedback on the draft testing plan once it is distributed. (All participants)

Support documents:

- BSC JC Meeting Summary - 2024-06-20 – Vibration Testing Excerpt
- NSF Vibration Task Group - TÜV NORD – 2025-01-20 Results
- NSF Vibration Task Group - TÜV NORD – 2025-01-20
- Nuaire.zip
- Vibration readings.xlsx
- Mark Lenart_Vibration method validation and data sheet 111824
- Vibration method validation and data sheet 111824

Joint Committee on Biosafety Cabinetry
Meeting Summary
June 20, 2024

New Business

The group broke into 3 smaller groups each with the task of taking a step back and discussing what would be good improvements to Standard 49. The full JC then reconvened with the following discussion

Idea #1

Specifications for vibration meters. The main points of the discussion were:

- The current criteria for vibration in Annex N5 is based on a unit of measure that is not readily available on most meters, and it is not sensitive enough to detect the complaints from some clients who have sensitive equipment or liquid samples in the biosafety cabinet.
- There was a suggestion to change the unit of measure and the specs for the vibration meters to reflect the market availability and the needs of the clients.
- There was also a suggestion to use a qualitative method, such as a Petri dish with water, to assess the vibration level, instead of a quantitative meter.
- There was some debate about whether vibration is a relevant criterion for biosafety cabinets, and whether it should be mandatory or optional in the field testing.

A motion was passed to form a task group to evaluate vibration in both Annex N1 and Annex N5, starting with instrumentation and considering other aspects such as units of measure, criteria, and methods.

Motion, **B.Peters**:	create TG to evaluate the value of vibration testing in both Annex N1 and N5, starting with instrumentation and considering other aspects such as units of measure, criteria and methods.
Second:	S.Williams
Discussion:	None
Vote:	Fifteen in favor, zero opposed, zero abstentions
Motion:	Carries

Action item: as described in motion above
K.Mulder Chair, list of members: M.Squire, T.Fincham, A.Atmadi, J.Miller, M.Lenart, S.Williams, B.Peters, B.Sage

S.Williams reminded the group of his issue paper from several years ago (BSC-2019-03).

B.Powitz asked if there were any other questions; there were none.

Task Group on Vibration Testing
Teleconference Meeting Summary
November 18, 2024

Participating Members:

Kyle Mulder (Technical Safety Services)
Mark Lenart (Clean Air Testing)
Alex Atmadi (ESCO)
Bill Peters (NuAire, Inc.)
Steve Williams (NSF)
Bill Sage (NSF)
Matt Squire (NuAire Inc.)

Absent Members:

Tori Fincham (Labconco)

Participating observers:

Al Rose (NSF)
Meg Wegmueller (NSF)

Supplemental Materials Referenced

- Agenda - Vibration Testing - TG - 2024-11-18.pdf
- BSC JC Meeting Summary - 2024-06-20 – Vibration Testing Excerpt

K.Mulder is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Seven of the 8 voting members were present (88%) representing a quorum. A.Rose presented the agenda indicating there was one item originating from the JC face-to-face meeting in June, however this item came from a breakout session and not an issue paper. He added that the group should consider whether this is still a topic of interest and if so set a general course of action before writing issue papers to support the project.

Key topics discussed:

- **Vibration Testing Concerns:** the group discussed challenges of vibration equipment specifically:
  - **Equipment Challenges:** difficulty finding affordable equipment that meets the requirements outlined in NXN 5 and NX 1 for vibration testing.
  - **Criteria for Meters:** including the tolerances allowed and the readout requirements. They noted that many vibration meters do not read directly in inches RMS, and questioned whether the 0.02 inches RMS requirement is sufficient in the field.
  - **Shift to Velocity:** S.Williams suggested shifting from measuring displacement to measuring velocity for vibration testing. He believes this would be a positive change based on his research, as velocity is a more appropriate mode for motor and fan-caused vibration. However, he acknowledged that this shift would require significant method development.

- **Test Plan Development:**
  - **Test Plan Proposal:** B.Peters proposed creating a test plan to gather data on vibration testing. He suggested that each member of the group should participate in the testing process to collect comprehensive data.
  - **Comparison of Measurements:** S.Williams and K.Mulder agreed on the need to compare displacement and velocity measurements. The group further discussed the importance of gathering data on both types of measurements to determine the effectiveness of velocity measurements compared to displacement.

- **Field and Lab Testing:**
  - **Field vs. Lab Testing:** S.Williams and B.Peters discussed the differences in vibration testing results between field and lab environments. S.Williams noted that lab testing has stricter requirements compared to field testing, which often results in more failures observed in the lab.
  - **Field Testing Challenges:** K.Mulder mentioned that in the field, it is challenging to find units that fail the vibration test, even when they exhibit significant vibration. This discrepancy between field and lab results highlights the need for a consistent testing methodology.

- **Equipment and Methodology:**
  - **Consistent Methodology:** B.Peters emphasized the importance of establishing a consistent methodology for vibration testing. He suggested starting with the current standards in Annex N1 and gathering data that matches those standards.
  - **Use of Different Meters:** B.Peters and Steve discussed the use of different meters for vibration testing. They noted that various meters are currently in use, and it is important to document the make and model of each meter used in the testing process to ensure consistency.
  - **International Involvement:** B.Peters proposed involving international counterparts, such as TUV Nord in Germany, in the testing process. He suggested recruiting experts from these organizations to contribute their data and expertise to the task group.

- **Data Collection and Analysis:**
  - **Data Collection Plan:** The group agreed on a plan to collect data from various units. B.Peters suggested targeting 10 units for a more comprehensive analysis, ensuring a diverse set of data points for comparison.
  - **Comprehensive Analysis:** B.Peters emphasized the importance of collecting data from different units to perform a comprehensive analysis. This approach will help the group identify trends and variations in vibration measurements across different units.

- **Potential Changes to Field Testing:** B.Sage and K.Mulder raised the possibility of removing the vibration test from field certification, considering the challenges and limited failures observed in the field.

- **Comparative Analysis:**
  - **Comparative Analysis Plan:** K.Mulder and S.Williams outlined a plan for comparative analysis. They proposed measuring both displacement and velocity on the same units to determine the effectiveness of velocity measurements compared to displacement.
  - **Measurement Process:** S.Williams explained the measurement process, suggesting that the accelerometer should be secured to the work surface, and the test should be run in both displacement and velocity modes to gather comparative data.

- **Instrumentation and Calibration:**
  - **Types of Meters:** The group discussed the types of vibration meters used for testing. They mentioned various models, including the S tech 407860 and the PCEV M3D, noting their features and capabilities.

  - **Calibration Needs:** S.Williams and B.Sage highlighted the importance of calibration for vibration meters. They noted that calibration is not cheap and requires sending the meters to the manufacturer, which can be a challenge for some organizations.
  - **Affordable Equipment:** K.Mulder expressed concerns about the cost of vibration meters, mentioning that some affordable options are available on platforms like Amazon. The group discussed the need to find accurate yet affordable equipment for both field and lab testing.

- **Testing Plan and Data Sharing:**
  - **Drafting Testing Plan:** S.Williams agreed to draft a testing plan and send it to A.Rose for distribution to the group. The plan will outline the process for collecting and comparing vibration data.
  - **International Coordination:** B.Peters and A.Atmadi will coordinate with international counterparts, such as TUV Nord, to involve them in the testing process. This will help ensure a comprehensive and consistent approach to data collection.
  - **Data Sharing:** The group planned to share data and meter specifications to ensure consistency in the testing process. This includes documenting the make and model of the meters used and providing calibration sheets where applicable.

- **Timeline and Next Steps:**
  - **Data Collection Timeline:** The group set a timeline for data collection, aiming to have results by Christmas. This will allow sufficient time for gathering and analyzing data from various units.
  - **Follow-Up Meeting:** The group planned a follow-up meeting to review the collected data and propose any necessary changes. This meeting will be scheduled after the data collection is complete, with the goal of discussing the findings and next steps.

Action Items:

- **Testing Plan:** Create and distribute a testing plan for vibration measurement to the group. (S.Williams)
- **Contact TUV Nord:** Contact TUV Nord to involve them in the vibration testing. (B.Peters)
- **Data Collection:** Collect vibration data from 10 units by NuAire, ESCO, and NSF and 5 units by Mark and Kyle. (M.Lenart, K.Mulder)
- **Instrument Information:** Share the make and model of the vibration meter used by the team for standardization purposes. (S.Williams)
- **Data Submission:** Submit collected vibration data to the group for analysis. (All participants)
- **Review Draft Plan:** Review and provide feedback on the draft testing plan once it is distributed. (All participants)

Motion, K.Mulder: Adjourn
Second: M.Lenart
All in favor

From:	Bill Peters
To:	Allan Rose
Cc:	Williams, Steve
Subject:	NSF Vibration Task Group
Date:	Monday, January 20, 2025 8:53:52 AM
Attachments:	image002.png image003.png Warning MS Excel attachment may contain malicious macrosAW NSF Vibration Test Review.msg

Good Morning Al,
Can you post this email I received from TUV Nord regarding vibration testing.
BTW, when is the next meeting scheduled for this task group?
Bill
PS. Has the revised NSF/ANSI 49 been published yet??

From: Ott, Jan <jott@tuev-nord.de>
Sent: Monday, January 20, 2025 7:08 AM
To: Bill Peters <bpeters@nuaire.com>
Cc: Schneider, Svenja <svschneider@tuev-nord.de>; Dieckhoff, Maike <mdieckhoff@tuev-nord.de>; Matt Squire <msquire@nuaire.com>
Subject: WG: NSF Vibration Test Review

Dear Bill,

please excuse the delay of my part of the feedback.

Svenja's calculation seems fine for me

There are some points I noticed when reading the results and doing some research:

Instrumentation

- Different level of precision/quality of measurement
  - For type testing/certification we need precise and reliable measurements; usually the intended target signal shall be clearly away from the background noise/interfering artefacts. The rule of thumb is 10 times. For a limit value of 5µm this would mean, that a value of 1/10 of that should still be detectable (0,5µm)
  - The sound analyzer (Norsonic 140) we use complies to class I according to IEC 61672. We use a "vibro-kit" including an acceleration sensor type 1270. The spectral reading (hertz bands) in dB is then calculated in an EXCEL-sheet provided by Norsonic. The final result is displacement RMS in µm. The advantage of this way of measuring is the additional information from the spectral results in hertz bands. It is thus easy to identify peaks/resonances. However it is a "batch" measurement and you can't see real-time effects (only in the display in dB). The measurements are cross-checked by our vibration calibrator (before and after measurement in order to prove correct setup).
- Instruments directly displaying displacement
  - There are/were instruments available, which could directly display displacement. They use analog integration circuits (e.g. Bruel&Kjaer measuring amplifier 2525 (old)), or digital signal processing (B&K 2250-W, 2270-W)
  - There are a lot of other brands on the market, I only know Norsonic and B&K from own experience. At the time of my last experience with the B&K (I think it was an early 2250-model) we had some issues with the precision of the digital (hertz band) filters. The final results did not completely match the reference calibrator.
- Different types of sensors – as far as I fount out there are available two different types of sensors:

Acceleration sensors
- Velocity sensors

General

Vibration measurements can be performed/expressed in different ways
- Acceleration [mm/s²]
- Velocity [mm/s]
- Displacement [mm]

Depending on the signal content/frequency the readings can differ. We found an interesting article about that fact:
IMI Sensors Displacement Sensor for Ultra Low Frequency Applications | PCB Piezotronics

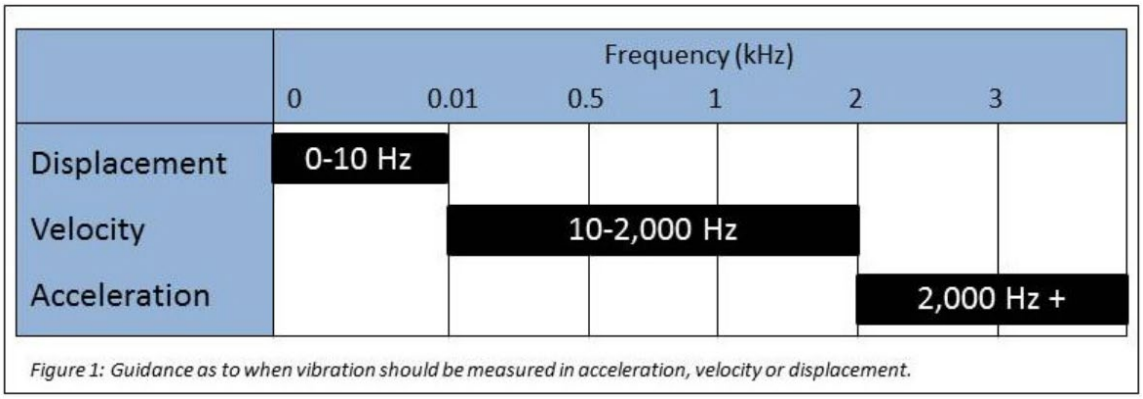

Figure 1: Guidance as to when vibration should be measured in acceleration, velocity or displacement.

To me it was never clear, why the MSC-standards chose displacement as reference, as the established labor-protection standards (e.g. ISO 5349) use acceleration (referring to a 8 hours workday).
Following the article and the figure 1 above, it would possibly make sense to use velocity as unit.

Comparing the results of the calibration measurement, we found that Displacement and Acceleration show a very close correlation.

The measurements you sent us show some interesting characteristic:

- Often the background signal is in the same range as the operating signal, in many cases even twice as high
- The variance within one set of tests is quite high in many cases
- The single value (displacement or velocity) does not say a lot about possible interferences from the environment
- It seems as if environmental artefacts occur randomly and interfere with the measurements
- In some cases the background is zero or the same value occurs for the whole series
- Only in a very few cases the background was below the limit value of 5µm

I hope this helps a bit and does not increase confusion…
…discussion welcome

…and of course, you can pass on all information to the NSF committee members

Take care, best regards from Hamburg,

Jan

Jan Ott

TÜV NORD CERT GmbH

Konsumgüter / Consumer Products
Biotechnologische Sicherheit / Biotechnological Safety

Große Bahnstraße 31
22525 Hamburg
Deutschland

Von: Bill Peters <bpeters@nuaire.com>
Gesendet: Montag, 13. Januar 2025 21:15
An: Schneider, Svenja <svschneider@tuev-nord.de>
Cc: Ott, Jan <jott@tuev-nord.de>; Dieckhoff, Maike <mdieckhoff@tuev-nord.de>; Matt Squire <msquire@nuaire.com>
Betreff: NSF Vibration Test Review

Hi Svenja,
Interesting note about your instrument. And this entire exercise from the NSF task group aspect is all about instrumentation. To my knowledge, I have never seen
an instrument that directly measures displacement. So our task group asked the question, why are using displacement instead of velocity or acceleration?
Why don't we research using a direct read instrument, so we decided to look at velocity first. I did attach our data of using a base line of calculated displacement
in comparison to direct read velocity. You can look at our data as attached, but at the first take. The instrument we are using doesn't seem to have the
resolution needed to at least 3 decimal places that I think we need. I believe we need a bit more research to see if there is an instrument available
that can do what we think we need?

Anyway, I had a hunch that might be the case on resolution and that is why I asked you to measure as I thought your instrument was more sensitive than ours,
but I didn't remember that you're required to calculate the for each mode. If OK, once you review your data with Jan, can I provide to the NSF task group?
Let me know and really appreciate your willingness to collect the data!
Best Regards,
Bill

From: Schneider, Svenja <svschneider@tuev-nord.de>
Sent: Thursday, January 9, 2025 9:19 AM
To: Bill Peters <bpeters@nuaire.com>; Ott, Jan <jott@tuev-nord.de>
Cc: Dieckhoff, Maike <mdieckhoff@tuev-nord.de>; Matt Squire <msquire@nuaire.com>
Subject: [Warning: MS Excel attachment may contain malicious macros]AW: NSF Vibration Test Review

Hi Bill

Attached you will find the first attempt of my measurement. Please note, it has not yet been checked by Jan

and I don't think the calculation is quite right. I just wanted to say briefly that we are measuring something. I have also attached all the raw data, that's all we would get.

The problem is that our device does not have a built-in displacement mode. We add up all the third octave bands to get a result with a single value (i.e. RMS displacement in µm).

So we can't make the desired measurements ("displacement mode") because we always have the level in dB as the primary unit and we only calculate the acceleration, velocity and displacement amplitude (integration) using our Excel sheet

So I tried to calculate the velocity (I hope this is the right value) in the same way as the displacement. (root of the sum of the squares) But since the values don't correlate, I don't think it's quite right. Jan is still away on business this week, but maybe we'll manage to look over the data again next week.

Tab 4 in the Excel you sent us and the "Cal." folder are measurements from our calibrator, which should have an amplitude of 10µm, which is about right. (In measurement no. 3 it failed in between. Unfortunately, I only saw this during the evaluation.)

We'll be in touch. What does your data look like? Did you also measure something?

Regards

Svenja

Von: Bill Peters <bpeters@nuaire.com>
Gesendet: Montag, 2. Dezember 2024 14:59
An: Ott, Jan <jott@tuev-nord.de>; Schneider, Svenja <svschneider@tuev-nord.de>
Cc: Dieckhoff, Maike <mdieckhoff@tuev-nord.de>; Matt Squire <msquire@nuaire.com>
Betreff: NSF Vibration Test Review

Hi Jan, Svenja,
Hope you both are well as we head into the Christmas season!
Say, we have a task group we started at NSF that is reviewing the vibration test. The test is being reviewed mostly for instrument compatibility with the test.

As you know today, we both measure vibration evaluating net displacement. However, most all instruments today (let's say instruments under a price point of $5K) do not directly measure net displacement (it can be calculated), but only measure acceleration and velocity directly. Our group has done some work on this and we think velocity maybe a better measure to use that is directly measured on most instruments. So we are gathering data using the method as attached to see what the actual measured relationship is.

I suggested we ask you to do the same as we know you use a more accurate and sensitive instrument than most of us use. We know 10 replicates maybe a bit much for you, but

even if you can provide a few, it would be interesting data to see your correlation. Any data you can send by mid-January would be greatly appreciated!

Thanks in advance for your consideration and wishing you both a Merry Christmas and happy New Year!!
Bill

William Peters
President/CEO

Phone: 763.551.2223
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CERT Newsletter: jetzt abonnieren und rund um das Thema Zertifizierung informiert bleiben

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Geschäftsführer: Dipl.-Ing. Wolfgang Wielpütz * Dipl.-Oec. Sandra Gerhartz

TÜV NORD GROUP
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From: Schneider, Svenja
To: Bill Peters; Ott, Jan
Cc: Dieckhoff, Maike; Matt Squire
Subject: [Warning: MS Excel attachment may contain malicious macros]AW: NSF Vibration Test Review
Date: Thursday, January 9, 2025 10:31:59 AM
Attachments: image001.png
Nuaire.zip

Hi Bill

Attached you will find the first attempt of my measurement. Please note, it has not yet been checked by Jan and I don't think the calculation is quite right. I just wanted to say briefly that we are measuring something. I have also attached all the raw data, that's all we would get.

The problem is that our device does not have a built-in displacement mode. We add up all the third octave bands to get a result with a single value (i.e. RMS displacement in µm).

So we can't make the desired measurements ("displacement mode") because we always have the level in dB as the primary unit and we only calculate the acceleration, velocity and displacement amplitude (integration) using our Excel sheet

So I tried to calculate the velocity (I hope this is the right value) in the same way as the displacement. (root of the sum of the squares) But since the values don't correlate, I don't think it's quite right. Jan is still away on business this week, but maybe we'll manage to look over the data again next week.

Tab 4 in the Excel you sent us and the "Cal." folder are measurements from our calibrator, which should have an amplitude of 10µm, which is about right. (In measurement no. 3 it failed in between. Unfortunately, I only saw this during the evaluation.)

We'll be in touch. What does your data look like? Did you also measure something?

Regards

Svenja

Von: Bill Peters <bpeters@nuaire.com>
Gesendet: Montag, 2. Dezember 2024 14:59
An: Ott, Jan <jott@tuev-nord.de>; Schneider, Svenja <svschneider@tuev-nord.de>
Cc: Dieckhoff, Maike <mdieckhoff@tuev-nord.de>; Matt Squire <msquire@nuaire.com>
Betreff: NSF Vibration Test Review

Hi Jan, Svenja,
Hope you both are well as we head into the Christmas season!
Say, we have a task group we started at NSF that is reviewing the vibration test. The test is being reviewed mostly for instrument

compatibility with the test.

As you know today, we both measure vibration evaluating net displacement. However, most all instruments today (let's say instruments under a price point of $5K) do not directly measure net displacement (it can be calculated), but only measure acceleration and velocity directly. Our group has done some work on this and we think velocity maybe a better measure to use that is directly measured on most instruments. So we are gathering data using the method as attached to see what the actual measured relationship is.

I suggested we ask you to do the same as we know you use a more accurate and sensitive instrument than most of us use. We know 10 replicates maybe a bit much for you, but even if you can provide a few, it would be interesting data to see your correlation. Any data you can send by mid-January would be greatly appreciated!

Thanks in advance for your consideration and wishing you both a Merry Christmas and happy New Year!!
Bill

William Peters
President/CEO

Phone: 763.551.2223
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Fax/Cell: 763.553.0459
Email: bpeters@nuaire.com
2100 Fernbrook Lane
Plymouth, MN 55447 U.S.A

TAB B6

Biological Measurements

Joint Committee on Biosafety Cabinetry

Task Group on Biological Measurements
Chair: Steve Williams, NSF

Task Group Roster:

Members	
Alex Atmadi	ESCO
Kara Held	The Baker Company
Kyle Mulder	Technical Safety Services
Bill Peters	NuAire, Inc.
Dave Phillips	Thermo Fisher Scientific
Bill Sage	NSF
Matt Squire	NuAire, Inc.

Meetings held since last JC meeting:

The task group held 1 meeting since: October 21, 2024
Next meeting scheduled for July 14, 2025

Summary of Task Group work:

This topic was discussed and presented in detail during one of the breakout sessions of the 2024 JC Face-to-Face meeting.

The main points of the discussion were:

- The current method of using impingers is problematic because it involves many steps and people, and there is a high risk of contamination and retesting.
- There was a suggestion to look at alternative methods, such as impaction samplers, that are simpler, faster, and more reliable.
- There was also a suggestion to look at ATP as a possible measurement mode, instead of relying on viable organisms.
- There was some debate about what level of decontamination is required for biosafety cabinets, and whether the current criteria and methods are appropriate or need to be updated.
- A motion was passed to form this task group and this is the first meeting of this TG.

Action Item from this meeting was for S.Williams to write 2 issue papers, one focusing on product and cross-contamination testing, and the other on personnel protection testing.

The first item is complete, and BSC-2025-03 – Product Protection and Cross Contamination will be discussed during the New Issues portion of this meeting

Support documents:

- BSC JC Meeting Summary - 2024-06-20 – Biological Measurements Excerpt

TAB B7

Chemical Resistance Testing

Joint Committee on Biosafety Cabinetry
Task Group on Chemical Resistance Testing

Chair: Brandon Gray, Labconco

Task Group Roster:

Members	
Alex Atmadi	ESCO
Tori Fincham	Labconco
Justice Lambon	USPHS
Kyle Mulder	Technical Safety Services
Bill Peters	NuAire
David Phillips	Thermo Fisher Scientific
Steve Williams	NSF

Meetings held since last JC meeting:

The task group held 1 meeting since: August 19, 2024
There is no further meeting scheduled at this time

Summary of Task Group work:

Issue paper **BSC-2024-03 – Chemical Resistance Test** highlighted that the chemical resistance test has not been evaluated for a long period of time, and the compounds and contact time information is outdated and should be considered. Moreover, the concentration of phenol specifically is creating unnecessary complications for BSC Manufacturers and the paint supply companies creating the paint to resist chemical exposure.

This issue was presented to the JC during the 2024 Face-to-Face meeting at which time a TG was motioned into existence. A second motion was passed to send the issue paper language directly to the JC as an approval ballot. This ballot passed the JC and was included in the 2024 publication of 49.

Support documents:

- BSC-2024-03 - Chemical Resistance Test
- BSC JC Meeting Summary - 2024-06-20 – Chemical Resistance Excerpt
- 49i197r1 - Chemical Resistance Test - JC Memo and Ballot
- 49i197r1 - Chemical Resistance Test – Ballot Comments

TAB B8

Scanning Through the Diffuser

Tab C

New Issues

TAB C2

HEPA Gross Leak

Joint Committee Information Paper

News of events or activities related to the field of interest of the Joint Committee

Subject:

Using the following reference from ANSI/ASSP Z9.14 - 2020 regarding testing of HEPA filters;

8.4.7 Testing of High-Efficiency Particulate Air (HEPA) Filters

	Test Purpose and Methodology
8.4.7.1	**Purpose of Test:** To verify HEPA filter leakage in situ.

15. If the HEPA-filter housing is not equipped with a scanning section, a downstream sampling port should be installed for gross probing the duct. This port should be placed where adequate air mixing can occur (approximately 8 duct diameters).

The above reference would add more guidance to the standard with regard to HEPA filters that cannot be scanned. The standard today reads “in the duct at a downstream location that will produce well mixed aerosol” that leaves both the duct design information and actual location subjective. By adding (approximately 8 duct diameters) as referenced, would provide more guidance for both duct design and certifiers.

Brief statement of information provided:

Changes and/or additions in various sections of the standard for clarification for gross leak of HEPA filters:

5.19 Filters

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

— 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% or if filters that cannot be scan tested for a leakage not to exceed 0.005% when tested in accordance with Section N-1.2;

6.3 HEPA/ULPA filter leak

6.3.1 HEPA/ULPA filters, filter housings, and mounting frames shall be tested with dioctyl phthalate (DOP) or equivalent and determined to be leak tight when cabinet is operating at the nominal set point velocities.

6.3.2 Polydisperse DOP or equivalent sustained penetration when filters are scanned tested shall not exceed 0.01% of the upstream concentration at any point when measured on a linear or logarithmic scale photometer (see high efficiency air filters).

6.3.3 Polydisperse DOP or equivalent sustained penetration when filters cannot be scan tested shall not exceed 0.005% of the upstream concentration at any point when measured on a linear or logarithmic scale photometer (approximately 8 duct diameters downstream) (see high efficiency air filters).

N-1.2 HEPA/ULPA filter leak test

N-1.2.3.2 Filters that cannot be scanned

When a cabinet is ducted so that the exhaust filter cannot be scanned, it may be leak tested by drilling a hole approximately 0.3 in (8 mm) in diameter in the duct at a downstream location that will produce a well- mixed aerosol (approximately 8 duct diameters), and inserting the photometer sampling probe with rigid extension tubing through the hole.

N-5.5 HEPA/ULPA filter leak test

N-5.5.3.2 Filters that cannot be scanned

a) When a cabinet is ducted so that the exhaust filter cannot be scanned, it may be leak tested by drilling a hole approximately 0.3 in (8 mm) in diameter in the duct at a downstream location that will produce a well-mixed aerosol (approximately 8 duct diameters) and inserting the photometer sampling probe with rigid extension tubing through the hole.

I-1.3.1.4 Question four: If the BSC requires an exhaust system, is there an appropriate location for the cabinet and its ductwork?

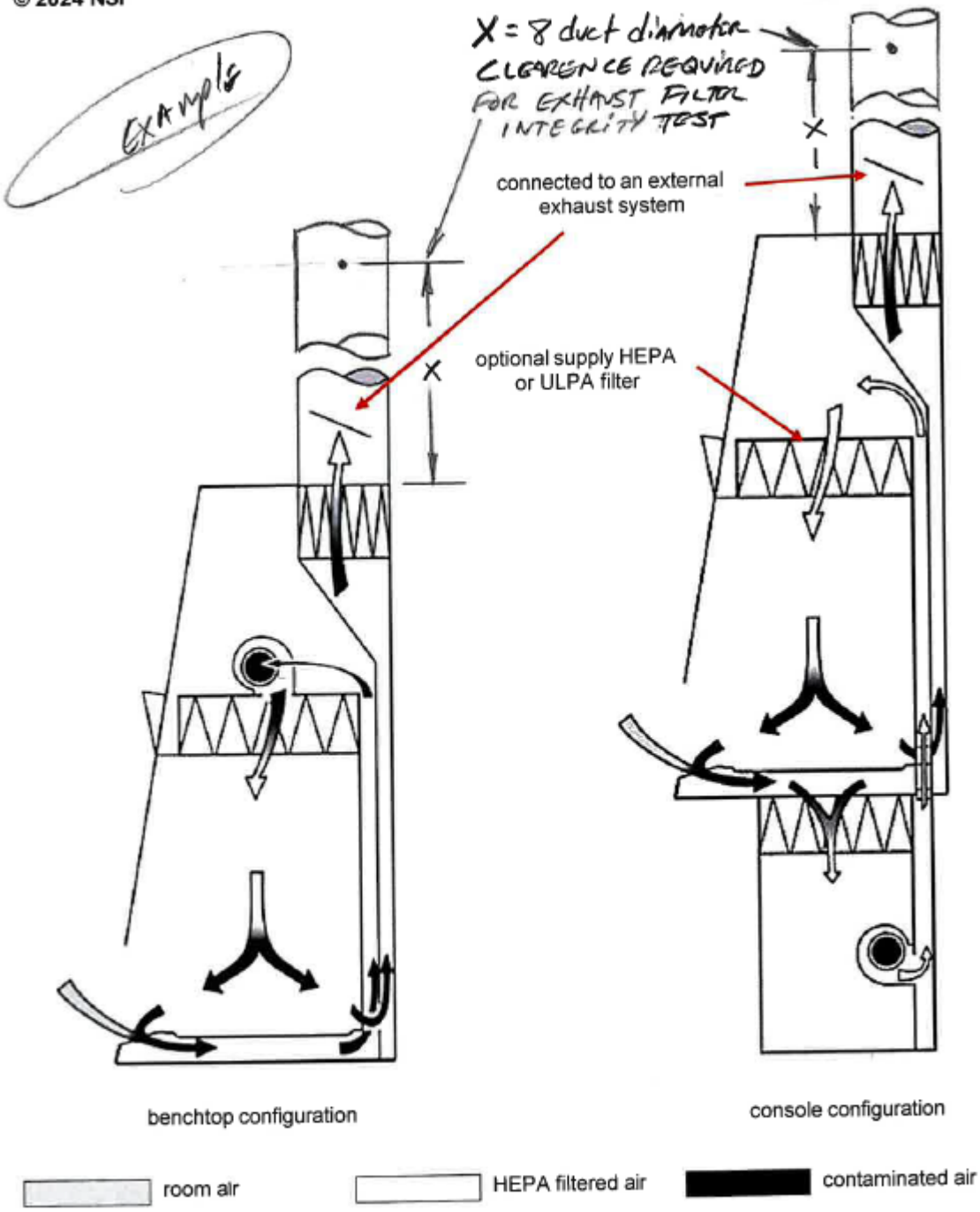
— Type B BSCs require a higher static pressure that must increase as their exhaust filters load. They must be direct hard connected ~~on an~~ exhaust duct and fan dedicated to that individual cabinet, and not be ganged with other Type B BSCs, or other exhausted laboratory devices requiring a lower static pressure (e.g., fume hoods, canopy-connected BSCs) and should have duct access approximately 8 duct diameters downstream of the cabinet for exhaust filter integrity testing;

I-1.4 Site review before BSC purchase

I-1.4.2.3 Exhaust requirements

If the BSC is to be connected to an external mechanical exhaust system, first examine the location to ensure that it is compatible with the cabinet's exhaust outlet. The area directly above the cabinet's exhaust outlet should be clear of structural elements, water and utility lines, or other fixed obstructions. There should be enough clearance to allow for the passage of a 10-in (250-mm) or 12-in (300-mm) diameter duct and for type B cabinets, access of approximately 8 duct diameters above the cabinet for downstream exhaust filter integrity testing. Avoid cabinet locations that require either an elbow directly on top of the cabinet's exhaust connection or an excessive number of elbows to clear other items.

Update Figures 33 as shown along with figures 34 and 35



NOTE — The simplified diagram illustrates airflow patterns only. All areas of the BSC containing contaminated air under positive pressure must be jacketed by negative pressure.

Figure 33
Airflow patterns for Class II Type B1 BSCs

Joint Committee Information Paper

Name: Bill Peters
Company: Nuaire Inc.
Telephone Number: 763-551-2223 E-mail:bpeters@nuaire.com

Please submit to: Al Rose, arose@nsf.org

TAB C3

Corrected Cabinet Types in N-5.3

Joint Committee Information Paper

News of events or activities related to the field of interest of the Joint Committee

Subject: Update/correct missing cabinet type in sections N-5.3.3.2.2 and N-5.3.3.2.4

Brief statement of information provided:

Add all applicable cabinet types for the constricted inflow method.

N-5.3.3.2.2 Method for Types A1, A2, B1, B2 and C1 ~~and B2~~ cabinets using a thermal anemometer to measure velocity through a constricted access opening to determine average inflow velocity:

Added type C1 to last sentence in section

N-5.3.3.2.4 Calculated method for Type B2 cabinets using an anemometer and pitot tube if applicable:

a) Turn on the cabinet downflow blower and exhaust system blower.

b) Set the sash at the height specified by the testing organization.

c) Measure and calculate the exhaust volume in accordance with the testing organization's verified methodology, or with ASHRAE standards for air velocity measurements in round or rectangular ducts, or with the *Industrial Ventilation Manual*.[3]

d) Measure the supply air velocity on a grid as specified on the data plate. The air measurement probe shall be held rigidly in a freestanding fixture (ring-stand and clamp) that permits accurate positioning and does not distort the airflow pattern (see Figure 26). The anemometer probe shall not be hand held. Average the velocity readings and multiply by the area in ft^2 (m^2) of the plane in which the velocities were measured to determine the total filtered supply air volume flow rate in ft^3/min (m^3/s).

e) Subtract the supply air volume rate in ft^3/min (m^3/s) from the total exhaust volume rate in ft^3/min (m^3/s); the difference represents the calculated inflow volume rate in ft^3/min (m^3/s).

f) Divide the calculated inflow volume rate by the area of the access opening in ft^2 (m^2) to determine the average inflow velocity in ft/min (m/s).

g) Include the following in reported data: individual exhaust velocity readings, calculated average exhaust velocity, exhaust duct area, calculated exhaust volume, individual supply velocity readings, average supply velocity, effective supply area, calculated supply air volume, area of the work access opening, calculated inflow air volume, calculated average inflow velocity, and methods used to determine them.

h) Reported values shall be:

- individual duct velocity readings;
- overall average of the duct velocity readings;
- calculated exhaust volume;
- duct size, shape and area;
- work access opening dimensions and area;
- dimensions and area of the supply velocity measurement location (used to determine supply volume);
- individual supply velocity readings (not to be confused with downflow velocities);
- calculated supply air velocity and volume;
- calculated inflow velocity and method used for calculations;
- correction factor used (if applicable);
- acceptance criteria for average inflow velocity;
- inflow velocity test method; and
- name of test (inflow velocity test).

Canopy-connected A1, A2 and C1 ~~and A2~~ cabinets shall be tested with a method that measures the inflow volume at the work access opening.

Name: Bill Peters
Company: Nuaire Inc.
Telephone Number: 763-551-2223 E-mail: bpeters@nuaire.com

Please submit to: Al Rose, arose@nsf.org

TAB C4

DIM Clearance

Joint Committee Issue Paper

NSF Standard(s) Impacted: NSF/ANSI std. 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.

The required clearance of 42 inches for use of a DIM might be more than is actually required. If a small skirt made specifically for measuring BSC inflow volumetric airflow is used, less than 42 inches would still allow for accurate measurement. See the paper published in CETA Performance Review.

Section N-5.3.3.2
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 and permanent fixture directly opposite the access opening is less than 42 in (1.1 m);

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.

Change the required clearance from 42" between the face of the BSC and permanent fixture opposite the access opening to " a minimum of 6" between the based of the DIM and a permanent fixture". See Below

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~~ base of the DIM and permanent fixture directly opposite the access opening is less than 6 in (1.1 m);

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

I hereby grant NSF International the non-exclusive, royalty free rights, including non-exclusive, royalty free rights in copyright; in this item and I understand that I acquire no rights in any

publication of NSF International in which this item in this or another similar or analogous form is used.

JAMES T WAGNER

Signature*: _____

Company: Controlled Environment Consulting

Telephone Number:610/428-0371 E-mail:jimwagner@cenvironment.com

Submission Date: 23APR2025

Please submit to: Al Rose, arose@nsf.org

**Type written name will suffice as signature*

Item No. BSC-2025-06

(For NSF International internal use)

03/2013

CETA Controlled Environment Testing Association

PERFORMANCE REVIEW

THE JOURNAL OF THE CONTROLLED ENVIRONMENT TESTING ASSOCIATION

SUMMER 2024

CETA Controlled Environment Testing Association

In This Issue

President's Message

Lewis Exner, Controlled Environment Consulting, LLC

I would like to start out by saying that time seems to speed up each year that passes by. It is hard to believe that the Annual Conference was 2 months ago. **I want to thank all the attendees at the Annual Conference along with all the sponsors and exhibitors.** Without each one of you, we would not be able to have the educational experiences at the conference.

I am glad this year was a lot less smoky than the 2021 conference in Reno. The weather was great and allowed for some awesome sightseeing for those that wandered outside the resort. The Conference started off on Friday, April 19, 2024, with the CNBT Practical Exam for those who either needed to retake their exam or take it for the very first time. The CETA Series was held on Friday afternoon, and this was the very first time that we have had several paths to follow, depending on your level and industry knowledge. The following was offered on Friday afternoon: Garbing and Glove Fingertip Testing, EM Sample Plan Creation, Micro/Facility Excursion Investigations, Primary versus Secondary BSC Testing, Certification Testing Order, Measuring Airflow/K Factor, Troubleshooting, Injection Ports, CETA Application Guides, and Fume Hood and CVE Testing.

Saturday morning started with the CNBT Written Multiple Choice Exam. Those not taking the exam could attend the Platinum Sponsor Updates by NuAire and Esco followed by numerous manufacturing updates by ClorDiSys Solutions, Thermo Fisher Scientific, LabConco, Lighthouse Worldwide Solutions, and TEC Services. Again, I want to thank all the sponsors and manufacturers for supporting CETA and contributing to the Annual Conference.

Saturday afternoon was the second day of the CETA Series presentations which included some of the same presentations from Friday and the infamous peanut butter & jelly sandwich SOP presentation! For the individuals that wanted to learn about geothermal technology, the resort gave a tour of their geothermal system right within the resort. This tour was also offered on Monday afternoon.

On Saturday evening, we held CETA's first New Member Reception for all our newly joined members. Others could attend the NSF Steering Committee Meeting. The evening concluded with the opening reception showcasing all of our awesome exhibitors.

The official Conference opened on Sunday morning with Leslie Mackay's President's Address. Thank you, Leslie, for all you have done for CETA during this past year. It is truly appreciated. The first

CONTINUED ON NEXT PAGE

PRESIDENT'S MESSAGE CONT.

presentation was on Annex 1 by Gordon Farquharson. He gave some great insight into the thoughts behind the Annex.

This was followed by Rolinda Bailey with a presentation on risk assessment. This turned out to be a great interactive presentation keeping the audience alert and attentive. Mike Turnure presented on IQ/OQ/PQ. He discussed the requirements for performing the qualifications which are above and beyond typical certification tests. Chris Rowe gave an update on the CNBT program, showing that it is thriving and has become a great program for CETA. Upon conclusion of the presentations, individuals were offered different opportunities to relax and unwind, including: The Annual Wally Whitt Memorial Golf Tournament, the Wild Burro & Horse Center Tour and the Reno Brewery Tour.

Monday began with a presentation by Gordon Farquharson discussing ISO TR 14644-21:2023. Todd Urton discussed the Tag Committee which helped us understand his role with this seat representing CETA. He was also able to help us understand acronyms within our industry. David Phillips described the new CETA Research Grant Program that I am extremely excited about and look forward to seeing through its initial implementation. Shawn Windley gave a great presentation regarding how HEPA filters are made and had some fantastic videos within the presentation. Following lunch, Neil DiSpirito discussed issues within the pharmaceutical industry regarding pharma law. With USP being a big part of most certifiers' business, the presentation on EM Sampling Competency, by Josh Erickson was very enlightening and put my mind at ease knowing that certifiers are competent in performing the EM sampling. The Annual Conference presentations were concluded with Natalie Miranda-Bachman discussing EM sampling challenges that certifiers face while serving their customers.

There were four CAG committees that met after the meeting concluded (CAG-002, CAG-005, CAG-012, and CAG-015), all having different agendas.

Monday evening wrapped up with the Annual Banquet which included some great food, drinks and CETA's first ever cornhole tournament. Four sets of custom boards were awarded to the first and second place teams. I want to thank the sponsors of the cornhole boards, and also Wag-N-Bag for making the custom boards and running the tournament.

There were many members that signed up for the different committees that will be started up in the very near future. The CETA Board is in the process of selecting the individuals for each of these committees and will be in touch shortly.

I would like to thank membership, exhibitors, and sponsors for all of their support and contributions. CETA would not exist without all of you, and I look forward, and am very excited, to move the organization forward during the next year. ■

CETA
Controlled Environment Testing Association

UPCOMING 2024 EXAM DATES

Raleigh, NC
Testing Date:
Friday, August 9

Registration closes Friday, July 19th

Webster, TX
Testing Date:
Saturday, September 14

Registration closes Friday, August 23

This is a private but open exam administration.
Anyone may register, but additional fees will apply.

St. Louis, MO
Testing Date:
Friday, October 18

Registration closes Friday, Sept. 27

No registrations will be granted following the registration cutoff date.
We apologize for any inconvenience.

A MESSAGE FROM THE PAST PRESIDENT

Dear CETA Members,

As I transition into the role of CETA's Past President, I want to take a moment to express my gratitude to each of you. Serving as President was both an honor and a privilege, and our collective achievements over the past year have been incredibly rewarding.

During the Annual Conference, elections for the CETA board were completed, with openings for two certifiers. I would like to thank everyone who ran for these positions. If you were not elected, please don't let that discourage you from running again or joining one of our new committees. By getting involved, you will have the opportunity to:

- Influence the direction of CETA
- Connect with industry professionals who share your enthusiasm for certification and this association
- Benefit from continuous learning and staying up to date with industry standards
- Gain recognition for your contributions and become a trusted voice in the CETA community

CETA is a strong organization because of the distinct individuals who volunteer their time and expertise. Your involvement is crucial to our continued success and growth.

Additionally, I would like to extend my thanks to Kim Coughlin for her years of dedicated service. Kim served as CETA President, CNBT Board Chair, and as a member of the CNBT committee. Her contributions have been invaluable.

I am also pleased to welcome Dan Valesquez to the board. Dan will be serving as the board liaison to CETA's new grant committee. Additionally, Jeremy Mahurin was re-elected to the board and will once again collaborate with Abby Roth on next year's CETA Series.

Lew Exner is now CETA's President, and judging by the outstanding Annual Conference he organized, I am confident he will excel in this role. David Phillips has moved into the position of President Elect and Annual Conference Chair, while David Wasescha is our new Secretary/Treasurer.

Thank you all for your continued support and dedication to CETA. I look forward to seeing you all in Orlando for the 2025 Annual Conference. ■

Leslie MacKay
CETA Past President

CETA has several committees dedicated to the improvement and maintenance of organizational programs, documents, and products. Please click through the links below to learn more about each committee.

Education & Training Committee

Internal Infrastructure Committee

Industry Impact Committee

Membership Committee

Research Grant Committee

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Purpose

The primary method of determining the face velocity of a Class II Biosafety Cabinet (BSC) has been the Direct Inflow Measurement (DIM) device since 1992. This method was confirmed to be the most repeatable method available in 2002. Since 1992, general practice has been to only use this method when there is at least 18 inches of clearance at the leading edge of the DIM. There is no consensus between practitioners as to where that required distance came from; therefore, we aim to determine whether the 18-inch distance from a DIM intake to obstruction is truly integral to accurate measurement of Class II BSC air intake velocity. An additional goal is to determine whether alternative DIM mounting methods, which would decrease the overall DIM length, result in reproducible and comparable intake volume measurements when compared to the traditional mounting method.

Questions:

- How does the distance between an obstruction and the front intake area of a BSC affect the flow rate of air through the front intake area with a DIM installed?
- Does the skirt used with the DIM device affect its accuracy relevant to the method of DIM installation used by NSF when the listed intake velocities are established? Will the same readings be measured when using a variety of skirts: "biobag" skirt, no skirt, or a 12" x 48" skirt?
- Does the distance between the obstruction and front intake area affect the differential pressure between the interior and exterior of the biosafety cabinet?

Hypotheses:

If the distance between a wall and the front intake area of a BSC decreases to below 18 inches, then airflow rate through the front intake area would decrease due to the obstruction. If that 18-inch clearance can be reduced, the use of a DIM device, which is the primary and most repeatable testing method, would be feasible for more field applications.

If the DIM device were to be assembled with a variety of skirts which help funnel air into the meter, there should be little to no observed difference in the readings in a scenario where all other independent variables are the same. If no difference is observed, this would make the DIM device more feasible and accessible in field applications.

If the distance between an obstruction and the front intake area of a BSC decreases to below 18 inches, and the velocity is affected, then the change in differential pressure across the biosafety cabinet is expected to be directly proportional through some square-rooted functional form to the change in velocity, that is $\frac{V_f}{V_i} \sim \sqrt{\frac{P_f}{P_i}}$ which is derived from the relationship between linear velocity and velocity pressure of air at standard conditions.

Experimental Design:

The experiment was conducted using a NUAIRE NU-540-400 Class II Type A2 BSC with a Shortridge Instruments flow hood kit attached to the front intake area. A voltmeter was connected to the main blower as a means of measuring the voltage at every reading to be able to determine if voltage variation is present and has any effect on reading variation. Additionally, a hydraulic lift fitted with two 96" x 48" sheets of 1/4" pine plywood fastened together with three pine boards running across the back and drywall screws was used to create a 96" x 96" artificial wall capable of moving varying distances from the leading edge of the flow hood. The method outlined above was used at CEC to eliminate any potential of perturbing the flow hood or biosafety cabinet, while maintaining a large flush face to avoid air moving from around the back of the obstruction. A series of readings were taken with the artificial wall placed at each of the varying distances from the DIM. The DIM was set to "Auto-Read" mode to allow a smooth collection of data without possible perturbations to the meter setup itself. In addition to the mode, we ran a short process to determine when balanced readings can be obtained through the Auto-Read mode. In addition to airflow measurements, we recorded voltages and the differential of pressure from the inside to outside of the biosafety cabinet at each stage of the data collection.

As a means of process qualification, we recorded a series of readings through the DIM in Auto-Read mode to determine the number of bad reads, or a measurement taken before proper stabilization of the DIM. This process was done five times, and the number of bad reads was averaged and rounded up to be conservative with the meter. Through five of these tests, we found that only the first readings are to be discarded at each stage due to DIM reading stabilization.

The independent variables for the experiment were the distance of the artificial wall from the leading edge of the

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

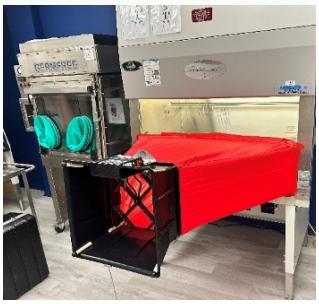
Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

flow hood, blower voltage, cabinet mode (run/calibration), and which, if any, skirt is attached. The two dependent variables were the volumetric rate at which air enters the BSC front access opening and the differential in pressure between the workspace of the cabinet and the room. Additionally, all sets of testing were done in both calibration mode and run mode to determine if any difference is observed.

Pictures documenting the data collection set-up and process are shown here.

Front side of the (wall) artificial obstruction, side facing the cabinet.

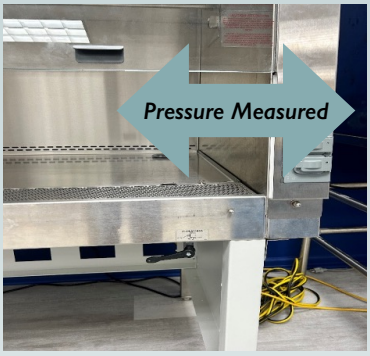
Back side of the (wall) artificial obstruction, side facing away from the cabinet.



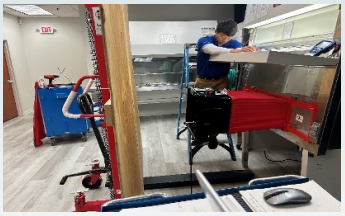
12" x 48" Capture Skirt Configuration

10" x 24" (Biobag) Capture Skirt Configuration

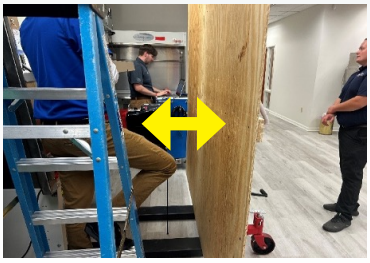
The three flow hood configurations used in this experiment, as well as the method they were connected to the biosafety cabinet.

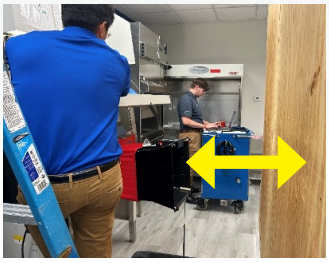


The set-up used for measuring the differential of pressure between the interior and exterior of the biosafety cabinet. Arrow indicates across the interface at which the pressure differential was measured.



DC Voltages of the blower were measured and recorded alongside the volumetric flow rate and pressure differential at each step in the procedure.





How the obstruction was used to simulate various distances between the front intake opening and a wall. The yellow arrow represents where the corresponding distance was measured.

Materials:

- 1 – Artificial wall made from the following materials:
  - 2 –1/4" x 48" x 96" Construction grade pine plywood sheets
  - 3 – Eight foot long 1" x 4" Pine boards
  - 12 – GripRite #6 x 1-5/8" Drywall Screws
  - 2 – National Hardware N100-362 - 5/16" x 1-1/8" Stainless steel rope loop
  - 4 - Generic Plastic Zip Ties

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

- 1 – Dayton: 2000lb capacity hydraulic forklift
- 1 – Fluke: 323 True RMS Clamp DC Voltage Meter
- 1 – Air Intake Measurement Flow Hood:
    - o 1 – Shortridge Instruments: Airdata multimeter ADM-870C | Electronic micromanometer | Model: ADM-870C | Serial No.: M19140 | Calibrated on: 02 MAR 2023 | Calibration due: 02 MAR 2024
    - o 1 – Shortridge Instruments: Bio Hood Series 8400 Frame
    - o 1 – Shortridge Instruments: Bio Hood Support Kit
    - o 1 – Shortridge Instruments: 10" x 24" Capture Skirt | Commonly referred to as "Biobag".
    - o 1 – Shortridge Instruments: 12" x 48" Capture Skirt
- 1 – TSI Manometer | Model: 9565P| Serial No.: 9565P1729024 | Calibrated on: 16 JUN 2023 | Calibration Due: 16 JUN 2024
- 1 – NUAIRE: Class II Type A2 BSC | Model: NU-540-400 | Series: 5 | Serial No.: 194499101519
- 4 – 9" x 12" Acrylic panels
- Stucco Tape
- Rubber Tube

Procedure:

1. A 1/4" x 96" x 96" artificial wall was assembled by putting two sheets of plywood together and securing from behind with planks using the following materials:
    a. Two sheets of 48" x 96" x ¼" pine plywood.
    b. Three boards of eight foot long 1" x 4" pine wood.
    c. Drywall Screws
    d. National Hardware N100-362 Stainless Steel Rope Loops (5/16" x 1-1/8")
2. The wall is then fastened upright to a hydraulic lift using plastic zip ties and set aside for later.
3. Assemble DIM device in desired configuration for current test on biosafety cabinet.
    a. "Biobag" Skirt: The Shortridge Instruments flow hood with "biobag" skirt and micromanometer were assembled and secured to the front intake area of the NUAIRE BSC. BSC is then further sealed using acrylic panels and stucco tape around the perimeter where the flow hood meets the biosafety cabinet and cabinet sash.
    b. 12" x 48" Skirt: The Shortridge Instruments flow hood with the 12" x 48" skirt and micromanometer were assembled and secured to the front intake area of the NUAIRE BSC. BSC is then further sealed using stucco tape around the perimeter where the flow hood meets the biosafety cabinet and cabinet sash.
    c. No Skirt: The Shortridge Instruments meter frame was propped within the sash opening and further sealed using acrylic panels and stucco tape around the perimeter where the frame meets the biosafety cabinet and cabinet sash.
4. The BSC is then turned on and allowed to complete its warmup cycle.
5. Set up the required independent variables as desired for current testing set on the biosafety cabinet.
    a. Make sure biosafety cabinet is in the proper mode for the desired test (Run/Calibration)
    b. Set blower voltage to desired value (Low blower speed ≈ 6.0 Volts; High Blower Speed ≈ 8.0 Volts)
6. After powering up the micromanometer, the hydraulic lift is first placed 48 inches from the top legs of the capture hood frame.
7. The first reading is discarded as a bad reading due to adjustments and stabilization in the micromanometer.
8. Five readings are recorded at each distance.
9. Average the five readings taken then round the answer to the nearest integer. This is the final value used for each distance.
10. The hydraulic lift is then brought closer to the opening of the capture hood at varying distances (48", 36", 24", 18", 12", 6", 2"). Repeat from step 8 until at 2" from the biosafety cabinet. After collecting data for 2" from the biosafety cabinet, move to step 11.
11. Upon completion of the testing set with given independent variables, continue by starting from step 4 as needed.

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Presenting of Data:

The data was recorded and organized into the tables on the next several pages, grouped by a variety of parameters for clarity. Additionally, some figures were assembled using statistical properties derived from each data set:

Data collected using the 10" x 24" skirt (Biobag):

Biobag Skirt - Low Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	335	334	334	332	331	333	4 | 0.12 %	6.0	0.005
36"	334	337	335	335	333	335	4 | 0.12 %	6.0	0.004
24"	335	329	334	333	338	334	9 | 0.27 %	6.0	0.004
18"	336	331	335	334	336	334	5 | 0.15 %	6.0	0.004
12"	340	338	336	337	335	337	5 | 0.15 %	6.0	0.004
6"	338	334	339	346	343	340	12 | 0.35 %	6.0	0.005
2"	346	318	320	336	342	332	28 | 0.84 %	6.0	0.017

Table 1.A

Biobag Skirt - High Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	357	355	354	359	358	357	5 | 0.14 %	8.0	0.004
36"	357	360	359	360	361	359	4 | 0.11 %	8.0	0.004
24"	365	357	358	356	355	358	10 | 0.28 %	8.0	0.004
18"	359	360	360	357	359	359	3 | 0.08 %	8.0	0.004
12"	362	362	360	356	358	360	6 | 0.17 %	8.0	0.003
6"	366	368	365	364	365	366	4 | 0.11 %	8.0	0.004
2"	368	350	349	348	364	356	20 | 0.56 %	8.0	0.015

Table 1.B

Biobag Skirt - Low Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	336	335	333	335	334	335	3 | 0.09 %	5.9	0.003
36"	332	335	334	335	333	334	3 | 0.09 %	6.0	0.003
24"	335	337	332	338	334	335	6 | 0.18 %	6.0	0.003
18"	334	336	338	336	335	336	4 | 0.12 %	5.9	0.003
12"	333	332	338	335	337	335	6 | 0.18 %	5.9 +/- 0.1	0.003
6"	343	344	339	343	340	342	5 | 0.15 %	6.0	0.004
2"	324	315	336	328	308	322	28 | 0.87 %	6.0	0.013

Table 1.C

Biobag Skirt - High Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	354	356	358	359	360	357	6 | 0.17 %	8.0	0.004
36"	353	357	351	356	358	355	7 | 0.2 %	8.0	0.004
24"	358	357	362	358	360	359	5 | 0.14 %	8.0	0.003
18"	363	361	360	361	358	361	5 | 0.14 %	8.0	0.004
12"	359	357	356	359	357	358	3 | 0.08 %	8.0	0.003
6"	367	366	368	365	368	367	3 | 0.08 %	8.0	0.004
2"	371	363	354	339	330	351	41 | 1.17 %	8.0	0.014

Table 1.D

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Presenting of Data:

The data was recorded and organized into the tables on the next several pages, grouped by a variety of parameters for clarity. Additionally, some figures were assembled using statistical properties derived from each data set:

Data collected using the 12" x 48" skirt:

12" x 48" Skirt - Low Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	327	327	322	324	326	325	5 | 0.15 %	6.0	0.004
36"	326	324	328	326	328	326	4 | 0.12 %	6.0	0.004
24"	326	326	327	326	327	326	1 | 0.03 %	6.0	0.005
18"	329	327	325	325	327	327	4 | 0.12 %	6.0	0.004
12"	329	327	329	333	332	330	6 | 0.18 %	6.0	0.004
6"	334	335	335	332	336	334	4 | 0.12 %	6.0	0.005
2"	343	329	328	332	338	334	15 | 0.45 %	6.0	0.029

Table 2.A

12" x 48" Skirt - High Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	360	358	361	359	359	359	3 | 0.08 %	8.0	0.004
36"	360	364	362	367	367	364	7 | 0.19 %	8.0	0.004
24"	365	363	366	363	367	365	4 | 0.11 %	8.0	0.004
18"	371	368	367	367	365	368	6 | 0.16 %	8.0	0.004
12"	369	366	367	368	371	368	5 | 0.14 %	8.0	0.004
6"	374	369	364	371	372	370	10 | 0.27 %	8.0	0.005
2"	374	363	342	346	353	356	32 | 0.9 %	8.0	0.029

Table 2.B

12" x 48" Skirt - Low Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	326	326	327	325	323	325	4 | 0.12 %	5.9 +/- 0.1	0.005
36"	323	329	324	326	327	326	6 | 0.18 %	5.8	0.005
24"	330	327	322	326	329	327	8 | 0.24 %	5.9	0.005
18"	330	327	331	330	333	330	6 | 0.18 %	5.9 +/- 0.1	0.005
12"	328	326	323	327	330	327	7 | 0.21 %	5.9	0.004
6"	335	333	333	337	333	334	4 | 0.12 %	5.9	0.005
2"	340	340	343	337	344	341	7 | 0.21 %	5.8	0.009

Table 2.C

12" x 48" Skirt - High Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	365	363	364	360	364	363	5 | 0.14 %	8.0	0.005
36"	359	365	364	361	359	362	6 | 0.17 %	8.0	0.004
24"	362	361	363	360	363	362	3 | 0.08 %	8.0	0.005
18"	363	360	360	361	366	362	6 | 0.17 %	8.0	0.004
12"	370	366	368	371	370	369	5 | 0.14 %	8.0	0.004
6"	372	371	369	367	371	370	5 | 0.14 %	8.0	0.005
2"	348	352	380	361	365	361	32 | 0.89 %	8.0	0.028

Table 2.D

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Presenting of Data:

The data was recorded and organized into the tables on the next several pages, grouped by a variety of parameters for clarity. Additionally, some figures were assembled using statistical properties derived from each data set:

Data collected using no skirt:

No Skirt - Low Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	337	340	339	332	333	336	8 | 0.24 %	6.0	0.002
36"	336	333	330	337	337	335	7 | 0.21 %	6.0	0.002
24"	334	330	338	336	334	334	8 | 0.24 %	6.0	0.002
18"	335	337	329	333	337	334	8 | 0.24 %	6.0	0.003
12"	338	338	329	328	337	334	10 | 0.3 %	6.0	0.002
6"	340	339	340	339	342	340	3 | 0.09 %	6.0	0.003
2"	372	351	363	359	359	361	21 | 0.58 %	6.0	0.011

Table 3.A

No Skirt - High Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	358	357	355	356	356	356	3 | 0.08 %	8.0	0.003
36"	355	355	356	360	358	357	5 | 0.14 %	8.0	0.003
24"	353	347	346	353	353	350	7 | 0.2 %	8.0	0.004
18"	356	359	353	355	350	355	9 | 0.25 %	8.0	0.004
12"	357	357	360	360	363	359	6 | 0.17 %	8.0	0.003
6"	362	362	359	363	362	362	4 | 0.11 %	8.0	0.004
2"	391	388	394	391	378	388	16 | 0.41 %	8.0	0.015

Table 3.B

No Skirt - Low Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	335	336	336	337	338	336	3 | 0.09 %	6.0	0.003
36"	335	341	339	336	336	337	6 | 0.18 %	6.0	0.003
24"	336	338	336	338	335	337	3 | 0.09 %	6.0	0.003
18"	334	333	341	337	343	338	10 | 0.3 %	6.0	0.003
12"	334	334	334	335	336	335	2 | 0.06 %	6.0	0.003
6"	332	341	337	338	342	338	10 | 0.3 %	6.0	0.003
2"	364	370	364	364	360	364	10 | 0.27 %	6.0	0.015

Table 3.C

No Skirt - High Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	360	356	357	359	360	358	4 | 0.11 %	8.0	0.003
36"	357	356	351	358	355	355	7 | 0.2 %	8.0	0.003
24"	351	354	354	357	355	354	6 | 0.17 %	8.0	0.003
18"	356	358	362	361	360	359	6 | 0.17 %	8.0	0.003
12"	356	355	357	358	362	358	7 | 0.2 %	8.0	0.003
6"	361	356	355	363	356	358	8 | 0.22 %	8.0	0.003
2"	396	403	386	395	405	397	19 | 0.48 %	8.0	0.016

Table 3.D

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Comparing the airflow volume averages by flow hood configuration:

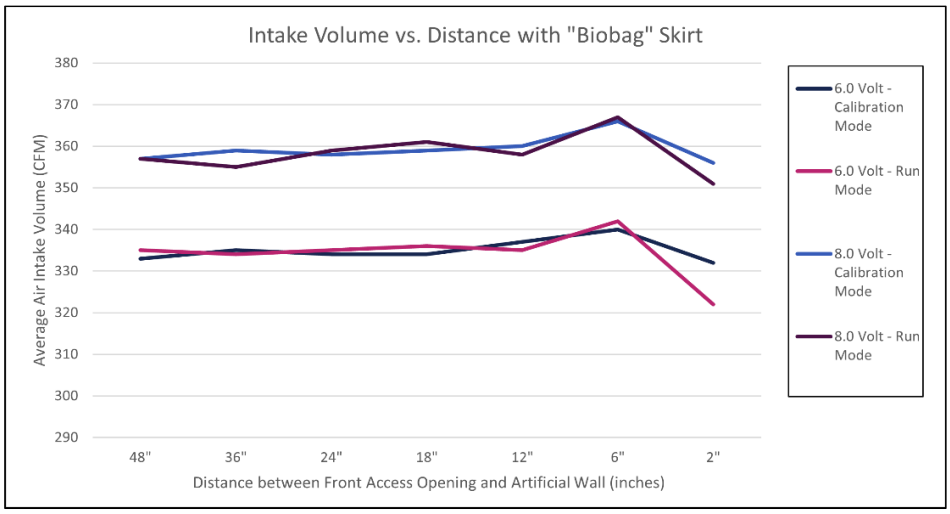

Figure 1:
10”x24” (Biobag) Skirt

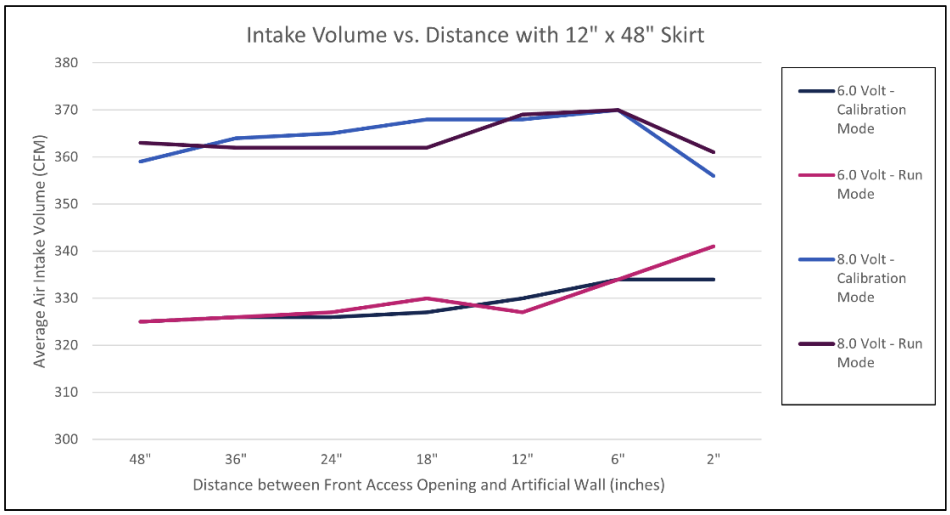

Figure 2:
12”x48” Skirt

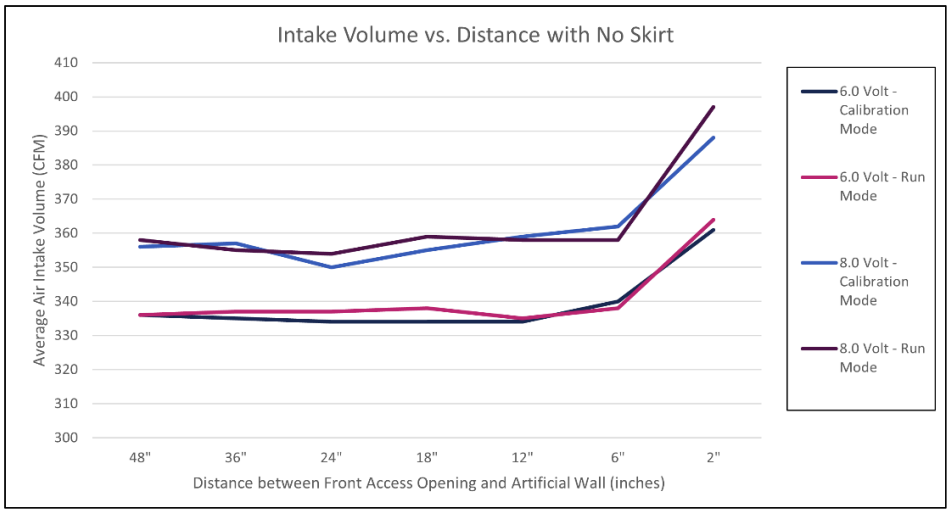

Figure 3:
No Skirt

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Data Analysis:

The experiment went as expected with no unusual events that would have introduced error. The volumetric flow rate of air entering the biosafety cabinet was recorded in cubic feet per minute on Tables 1-3. The average intake volume is an arithmetic mean across all readings at the same distance from the wall. These averages are the values that were further used in the remaining figures. Aside from the intake volume, two accessory readings were taken to document the DC voltage across the blower at each stage, as well as the differential of pressure from the workspace of the biosafety cabinet to the exterior. All this data was taken from the original twelve tables and further used to draw an analysis on the effects of an obstruction at various distances from the front access opening of the biosafety cabinet.

Arguably the most important metric to determine whether a difference occurs at various distances of an obstruction is the average airflow intake volume for the cabinet under a variety of circumstances. This is obvious as it is the property one is directly interested in when using a flow hood for testing intake velocity on a biosafety cabinet. This data was assembled into Figures 1-3 based on the flow hood skirt configuration used for testing. In all three figures, there is a fair consistency in airflow volume until the obstruction comes within six inches of the biosafety cabinet. In the cases when a skirt was used, an upward trend is observed at six inches, but then takes a sharp drop at two inches to levels below the previous average. This behavior is not observed in the case when no skirt was used; From six inches and closer, a strictly increasing monotonicity can be observed in the data indicating a constant increase in the rate of change for the data starting at two inches. By only considering the case most applied by field technicians will apply (Biobag), there is no overwhelming evidence to indicate that a biosafety cabinet needs more than six inches of clearance at the front access opening for proper function.

The averages were grouped by the configuration of the flow hood used for taking readings, and further separated by the set voltage of the blower and the operation mode which the biosafety cabinet was set to: Calibration or Run. In Figures 1-3, these values were all regrouped to visualize how they compare with the rest of the testing of similar configurations. Through application of the continuity equation, it can be determined that there must be an increase in linear velocity at the flow hood, and subsequently at the intake of the biosafety cabinet since the cross-sectional area remains constant throughout the duration of the experiment.

Q=V*A (Continuity Equation)

Fluid Volume Rate=Linear Velocity *Cross-Sectional Area

It can be determined that the linear velocity of air entering the biosafety cabinet must be affected when considering this equation with our results, specifically increasing as the wall is brought closer. Due to the fixed cross-sectional area programmed in the flow hood, there is only one logically relevant reason this could have occurred; an increase in the linear velocity of the air entering the cabinet. There is data that shows an undeniable increase in the differential pressure, which theoretically would encourage air to pass through the flow hood at an increased rate. However, we could not find any proportionality between the increase in differential pressure and the increase in intake volume to confirm this to be the entire cause of increase.

As far as how the distance between an obstruction and the front access opening of the biosafety cabinet affects the differential pressure across the biosafety cabinet, our data from Tables 1-3 clearly indicates an increase in the pressure differential as the obstruction got closer to the front access opening. This is evident in every single testing set-up that was performed. While there was minor variability as the obstruction came closer, the minimum increase in pressure observed at two inches was 80% whereas the maximum increase was a staggering 625%. However, a chart detailing the correlation coefficient between the airflow volume and the pressure was assembled and included below as Figure 7.:

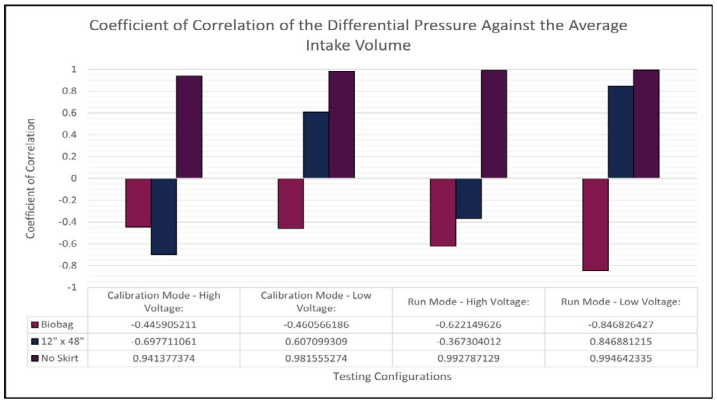

Figure 7: Coefficients of correlations across data sets.

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AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

A coefficient of correlation is a numeric value between -1 and 1 which indicates how similarly two sets of data change, where 1 means the sets trend identically, and -1 implies the two sets trend in opposing directions, and 0 means no common trend. Intuitively, one would expect to see all the correlation coefficients very close to 1, indicating a high correlation, because of a fluid's affinity to flow from higher to lower pressure regions, given that the interior of the cabinet is at a lower pressure than the environment outside of the cabinet. However, only the flow hood without a skirt has a high correlation, indicating that the set-up without a skirt was the only setup in direct noncompliance with Bernoulli's Principle which states an increase in the speed of a fluid occurs with the increase in static pressure. While Bernoulli's Principle is commonly applied to a closed fluid duct, consider the entirety of the cabinet and flow hood set-up to act as the hypothetical fluid duct since the cabinet should be completely contained everywhere between the air intake point and the air exhaust point. Instead of coefficients close to 1, most of the relevant points have a negative correlation, otherwise implying that the air intake rate and the differential pressure across the cabinet are inversely proportional.

Another aspect of our data that can be analyzed is the standard deviation across each series of testing. These values were all collected and presented in Figures 4-5. Figure 4 simply shows the standard deviation across all data collected, whereas Figure 5 shows the same, but with all data from two inches omitted. Standard deviation can be thought of as a metric for how similar, or tight a set of data is. In our application, a higher standard deviation means a larger variation in the readings, whereas a lower standard deviation means all the readings were very close to the average. For our sake, as low of a standard deviation as possible is desired, which correlates to all our readings being tight. Looking at Figure 4., an observed low standard deviation in the experiments using the various skirt configurations. However, when the skirt was removed our standard deviation took a significant rise. This indicates to us that the measurements are much more stable and vary less when a skirt is used to funnel the airflow into the biosafety cabinet. Although there is no current metric to determine when the standard deviation is too high, a configuration with a skirt would statistically perform more favorably compared to one without the skirt.

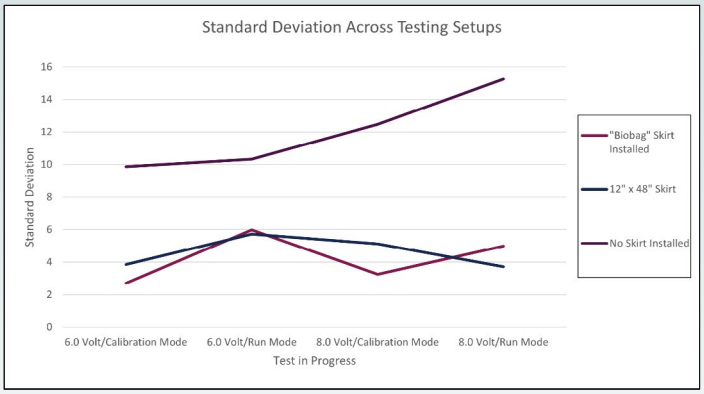

Figure 4: Standard Deviations of each cabinet mode/configuration.

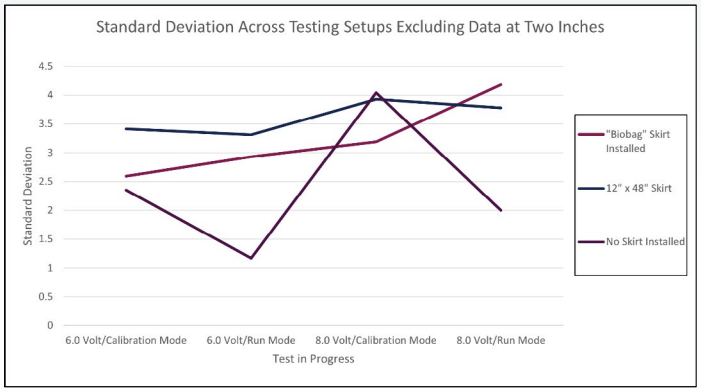

Figure 5: Standard Deviations of each cabinet mode/configuration excluding all data from two inches.

Finally, in Figure 5., all data from two inches was omitted because of the amount of outlying data recorded out of curiosity to see how the standard deviation curves change. When comparing Figures 4 and 5, the curves fit much more tightly together in the figure excluding the data from two inches, as well as a noticeably lower standard deviation across the board. This figure denotes that the data collected at two inches does not fit our set well at all, implying that the next closest distance (six inches) is where the accuracy in readings is maintained at a variety of distances.

An initial hypothesis regarding this testing was that as the blower speed increased, the standard deviation of the testing session would increase allowing for acceptance of a larger range of readings. However, Figure 4 directly contradicts this hypothesis. The figure shows a beginning trend of increasing the standard deviation as blower speed increased, but the trend became inconsistent as there are multiple tests done at 6.0 Volts which return a standard deviation closer to those returned with a blower set at 8.0 Volts. However, as

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

mentioned above, it seems to be the skirt which had the biggest effect on standard deviation. This figure does well to refute the previous conjecture, as well as invalidate any notion of acceptance with a two-inch clearance.

Conclusion:

The set of experiments conducted yielded a variety of interesting results. When it comes to using a skirt for airflow intake volume measurement, our data concluded that the skirts are much more favorable in recording data than any configuration without the skirt. Additionally, it can be concluded that the differential of pressure across the biosafety cabinet definitively increases when an obstruction is present at the front access opening, the effects of the change in pressure does not directly affect the airflow as observed in the cases above. In the results, there was no notable change in the air intake rate until the wall came within less than six inches from the biosafety cabinet. In conclusion, a cabinet with an obstruction at six inches would perform similarly enough to a cabinet with an obstruction at eighteen inches to continue safe operations. ■

FINANCIAL REVIEW 2024

CETA Members,

Wow, where has the year gone? It was great seeing so many of you at this year's conference in Reno. The annual conference is always such a great time to connect and learn from the many talented individuals who make up and support our organization. It should not come as a surprise to hear that attendance and feedback were very strong, while our operating costs remained well within budget. And who didn't have a blast at the closing reception/cornhole tournament!? Already looking forward to next year's meeting in Orlando – hope to see all of you there.

Turning to CETA financials. Those of you who joined the annual business meeting in Reno will recall that the Treasurer/Secretary 'torch' has formally been passed to me by Erin Thane. Erin served as Treasurer/Secretary for the previous two years - a big thanks is owed to her for her service and financial guidance for our organization. Erin led several great financial initiatives, including the dubious task of budgeting as well as setting up our first-ever investments in two CDs.

Looking ahead, we're quite excited about several new initiatives that have been made possible through CETA's healthy and stable financial position. The Board of Directors is continually looking for ways to benefit our membership and industry. One of those initiatives is the funding of CETA's newly-created Grant program. A board vote earlier this year kicked off the program, which allows for funding of unique research projects that seek to address key industry topics that directly benefit our membership and industry. We hope to see many submissions to this unique program.

CETA is also planning to renew our CDs, while also looking at expanding our investment plans to help our money stretch further in support of our annual conference, CNBT, CAGs, and beyond. These programs add tremendous value to our certification community and we continue to grow them every year.

With lots in the works, we hope you will all have a chance to benefit from CETA activities over the course of the next year. And if you have a question or suggestion, be sure to reach out at any time. Thank you all for being an active part of our organization – see you in Orlando! ■

David Wasescha
CETA Treasurer

HEPA – IN THIS ISSUE'S HEPA, WE ASKED 5 QUESTIONS OF CERTIFICATION TECHNICIANS FROM CONTROLLED ENVIRONMENT CONSULTING.

Adam Costa, CNBT
Jason Scrafano
Robert (Bob) Timer, NSF Accredited , CNBT Accredited
Anh Huynh, CNBT

Here's what they had to say!

1. **Many certifiers enter the field without knowing anything about the industry. What is your certification technician "origin story"? How did you get to be where you are today?**

   JASON – I had also not heard of this industry prior, and it only became known to me from a job posting. I went to school and became certified for HVAC/R, but eventually pivoted into jobs focusing on different aspects of air quality. Upon learning about this industry, I thought it would be a good fit for my background and seemed like an interesting and useful field.

2. **As a newer technician, how would you describe the certifier's role?**

   BOB – Ensure that all the PECs and cleanrooms are operating with specifications.

   ANH – Most of the time you feel like a jack of all trades, as you need to bring together theory and practice.

3. **Which is your favorite and least favorite test to perform, and why?**

   ADAM – I don't think I have one test that stands out as a favorite, but my least favorite test would be smoke studies or particle counting.

   BOB – Leak testing of the HEPA filters is my favorite since we are verifying that clean air is being delivered in critical sites or cleanrooms where medicine can be made. USP smoke study of PECs is my least favorite since pharmacy techs don't like doing it with you.

4. **Looking back on the training you received, which test was the hardest to learn/master and why? How could your training have been different to assist in your learning?**

   JASON –The hardest to learn/master, in my opinion, was BSC related testing. This is mainly because there are many types and manufacturers, most of whom require they be tested and/or adjusted in different ways. I am not sure my training could have been any different in a way to help me understand it better in the moment. This is one of those things where you need to see each and every one in the field, as having each iteration in a training area is probably unrealistic.

5. **What advice do you have for certification technicians new to the industry?**

   JASON – Use a notepad app or something equivalent and take notes while in the field. You are going to be absorbing a massive amount of information as someone completely new, and this will save you.

   ANH – Mastering aseptic technique is key to quality work and will provide better peace of mind. While all clients will typically triple clean after you leave a job site, you still do not want to leave anything or take anything with you. Gives a new meaning to "leave work at work."

   BOB – There are a lot of specifications and situations that you will run across. It will take time. Ask other technicians for advice to master the skill.

   ADAM – Absorb all the information you can.

RENO

APRIL 19 - 22

CETA Controlled Environment Testing Association

NEVADA

2024 CETA ANNUAL CONFERENCE

Scenes from Reno!

QUICK REFERENCES FOR CETA

Provided by Kyle Mulder

Contact Numbers

NuAire- 800-328-3352
Baker- 800-992-2537
Kewaunee- 704-873-7202 or 704-871-3271
Labconco- 800-821-5525
Thermo- 800-848-3080
Germfree- 800-888-5357
Esco- 215-441-9661
Envirco- 800-884-0002
Airclean- 800-849-0472
Biobase- rd@biobase.cn

Conversions

1 foot (AKA ') = 0.3048 meters
1 inch (AKA ") = 2.54 centimeters
1 square meter = 10.76 square feet
1 square foot = 144 square inches
1 cubic foot = 0.028 cubic meter
1 cubic meter = 35.315 cubic feet
1 cubic foot = 1728 cubic inches
Degree F = (degree C x 1.8) + 32
1 in WC = 1" WG = 249.09 Pa = 0.036 PSI
1 torr = 1 mm HG = 0.535" WC
1 bar = 401.463"WC
1 CFM = 28.317 LPM
TCs: J=Black K=Yellow T=Blue

Equations

Area= length multiplied by width
Patch %= (total area of patches ÷ effective area of filter) move decimal 2 places →for %
Area of a circle= π (3.14) x radius squared (multiply radius by radius first). Radius is ½ the diameter.
Ft² of right-angle triangle= length x width ÷ 2
Volume=length multiplied by width multiplied by height
Q = VxA, air volume = velocity times area
Air changes per hour= (total dominant room CFM x 60) ÷ room ft³
K_V= (air volume ÷ area) ÷ measured velocity = number to multiply measured velocity by
P_T=P_V+P_S total pressure = velocity pressure + static pressure
Velocity from velocity pressure=4005 x $\sqrt{P_V}$
PAO challenge = generator output (standard 13,500 per nozzle)/total CFM per plenum
PC min sample volume = (20÷Largest particle size class limit) x 1,000. or 1 minute and 2 liters, whichever is greater.
Min # of PC locations for >1000 m² rooms= (m²÷1,000) x 27
Volts = current x resistance, V= I x R
RSD is from AVERAGE, not ranges.

Grids

#= number of locations
L= length of area at plane of testing
With vignette (BSC DF, CB);
#=(L-(2x vignette)) ÷ space max) round up+1
Spacing=(L-(2x vignette) ÷ (#-1) round to 0.00"
Without vignette (fume hood, BSC RA);
#=(L÷ space max) round up to whole number
Spacing=(L÷ space max) round to 0.00"

Standards and Procedures

Fume hood: normally 12-18" sash Readings <12" apart equally spaced
-OSHA; 60-100 fpm.
-CAL OSHA; 100 min, no point lower than 70 and must have an airflow monitor. Carcinogenic use requires 150 min with no point lower than 125.
-SEFA; 60-100 fpm, 20fpm "flyers". Cross drafts must be less than 30fpm.
-ANSI/AIHA Z9.5; 80-120 fpm with 20%RSD.
-ASHRAE 110; no velocity spec. Tracer gas with mannequin. 9µL gas inject. Cross drafts at 18" out at sash height. Critical orifice 4 LPM. Gas ejector 12" from walls and 6" behind sash. Gas detector probe 3" from sash 22" up from work-deck. 0.1 PPM common max leakage.
-NIH; 90-120 fpm. Low volume hoods no less than 80.
-NFPA; 80-120 fpm.
-NIOSH; 100-150 fpm.
-ACGIH; 80-100 fpm.
-National research council; 80-100 fpm, 120 recommended for high toxicity, but should not exceed 150 fpm.
Clean bench: Grid 6" from sides <12" apart 6-12" off filter (not handheld). Leakage <0.01%
IEST-RP-CC002. 90 ± 10 fpm, or MFR spec
Class 1 BSC (single pass): Grid 6" from sides <12" apart. Normally 75-100 FPM MFR spec is primary. Gross leakage <0.01% or MFR spec
IEST-RP-CC034=basic HEPA leak 0.01% and patches less than 3% total, smaller dimension of patch <1.5". *0.005% is only for Class II hoods*.
Class 2 BSC: MFR spec airflows. No hand-held air measurements, work area empty.
NSF/ANSI 49 Annex N5
Grid is per data plate, if no data plate; downflow 6" from sides <6" apart and sash height (newer than 2002 units normally 4" above sash), **exhaust filter inflow;** 4" from sides <4" apart 4" from filter, **RA** no less than 2 per 12". **Scan HEPA leak;** 2" per second 1" from filter <0.01%, **Duct HEPA leak;** sweep entire duct <0.005%. **B2 interlock;** Shut down total exhaust for alarm 15 second test, then bring back up to supply reactivation and slowly go back to for % drop calc. Must alarm ≤20% of total exhaust. Interlock must activate at same time of alarm **Smoke tests**; Work opening edge retention; 1.5" out around the perimeter of the access opening. No smoke should spill/flow onto/over work tray. View screen retention: 6" up from sash edge 1" inside, no smoke can escape access area or reflux upward. Sash/window seal; along the top of the sash at wiper and along sash sides, no smoke can escape cabinet. Down flow uniformity: 4" up from sash along the center of the work tray no refluxing or dead spots. **Pressure decay;** on any positive plenum adjacent to common space units (A1). Seal off intakes and exhaust. Use drain valve and compressor to increase to 2.00" w.c. hold for 30 minutes, ,10% loss is pass. **Secondary tests (per NSF 49); Light;** Samples taken 6" from sides and <12" apart on the work deck centerline. Lights and blower off; Lights and blower on; Acceptance criteria: lights on is >45fc greater than background <15fc.
Sound; two readings taken 15" up from work deck, 12" out from leading edge of access opening. First reading with motor off - dbA. Second reading with motor on - dbA. Acceptance criteria: <70dbA after NSF correction factor (0-2=reduce background, 3=-3, 4 or 5=-2, 6-10=-1) with motor on.
Vibration; Two readings taken at geographical center. Motor off - 0.00000" rms. Motor on - 0.00000" rms. Acceptance= <0.002" rms. Your meter will probably require a conversion.
UV Light; Two readings at the center of the work tray. One lights off. One with UV light on and warmed up (wait for reading to level out). Acceptance = >40 microwatts per square centimeter.
GFCI; Ground polarity is correct. Acceptance criteria: Unit trips, but not at 1, 2, or 3 ma gnd.
Isolator/RABS: CAI/CACI CAG-002 required tests.
Airflow; MFR spec (grid too)
Chamber pressure: unit maintains neg or pos press with each passthrough door open (at a time) and when gauntlets are extended in or out (pressure specific) from sash over 3 seconds.
Site installation; Exhaust alarm function, proper ducting (negative), functional passthrough interlock.
Chamber integrity: outside must fail ISO 8, use Laskin nozzle if needed. Then scan all potential penetrations with particle counter. Acceptance, no penetration fails ISO 5 with probe held 1" away. (CACI only)
Smoke pattern; shows smooth downflow, no refluxing or inward air from penetrations.
Prep ingress egress; probe 6-8" high and 2" in from door path. During passthrough of previously particle saturated tray, counts cannot exceed ISO class 5.
Particle counts: passthrough and main chamber meet ISO 5. Both static and dynamic conditions in the main chamber, static = 5 loc dynamic =1 (per DCA)

QUICK REFERENCES FOR CETA

Provided by Kyle Mulder

Gauntlet breach: (not required), one gauntlet removed, 3 readings center of hole. Acceptance >100fpm (normally).
ISO 14644-1: classification of any space See reverse side for min # of locations. 1 count per location minimum 2 liters and 1 minute per count. Locations are set in equally divided sections of the area. Particle counts are the only thing REQUIRED to classify an area. Certifiers do not count as occupants.

Viable Samples/EM:

The sampling plan must be risk based and owned by the user.
Dual media can utilize two TSA plates if approved by the client.
Air: Dynamic requires normal quantities of compounders performing all actions normal in tested area (entry, gowning, staging, media fill).
Surface: Dynamic is after a process and BEFORE cleaning in PECs. Aseptically clean and disinfect surface locations.
Fingertip; Roll each gloved finger pad on media w/o breaking media.
Action levels; Air; ISO 8 >100, ISO 7 >10, ISO 5 >1. Surface; ISO 8 >50, ISO 7 >5, ISO 5 >3.

Equipment

Thermal anemometer (hotwire); dot into the wind, actual absolute pressure (HG) found on Shortridge abs press) and temp when above 1,000ft otherwise 29.92 HG if <1,000 ft.
Capture hood (Flow hood or Balometer): Must seal entire area being tested (not gas tight). Uncorrected for BSCs or exhaust
Particle counter; always read cumulative, particles per cubic meter. Point probe towards airflow in unidirectional devices, otherwise always point up. Locations should be about 6-12" above work areas or about 48" above the floor.
Particle generator: normal output equation is total CFM in plenum challenged divided INTO 13,500 (or actual output of the generator) per nozzle. Step downs are not allowed unless taking upstream readings. Should not be restricted smaller than ½"

Decontamination

Paraformaldehyde: >60% rh >70° F/15° C. Total vol (ft^3) x 0.3 = g of PF. Total vol x 0.33 g Amm carb/ 0.48 g Amm bicarb. 6-hour contact 1 hour neutralize. <0.75 PPM PEL
Chlorine Dioxide (bowl/wet); >40% rh. >60° F/15°C. 6.5 packet for <50 ft^3, 9.75 for <75 ft^3. 2-hour contact (80 minute possible). <2 PPM PEL.
VHP; <30% (<20% ideal) rh. > 86°F/30°C. 1mL per ft^3 or 0.5 mL for room and incubator. 1mL of HP = 1.13g. 2-hour contact. <1 PPM PEL-TWA

Passwords/sequences/codes:

DO NOT CERTIFY IN ADJUSTMENT/MANUAL MODES!

↑↑↓↓←→←→BA start

NuAire;

9876 for touch screen
NuAire flag or earth hidden button for triple digital display and incubators.
LED display: Hold silence, press flag, blower start, then up arrow.
Digital display: Silence, enter, up, down
ES series/DC motor; a small button at bottom right of speed control must be pressed till light to adjust speed.
Digital exhaust alarm: Hold up and down arrows to enter cal mode, reset to enter value. Hold down arrow to set low alarm point. Hold up arrow to set high alarm.

Baker;

Dipswitch position: left dipswitch (white switches in blue box of 2 switches) down for manual mode (flashing green light), adjust with potentiometer next to switch, wait 1 minute, put dipswitch back to auto (solid green light)
Multi pot; third pot up from bottom/closest to you turned CW till stop for manual mode, bottom pot is then speed control, wait 1 minute and turn same third pot up CCW to return to auto mode.
Red button: press for blinking green light for manual adjustment, adjust with white screw, wait 2 minutes after adjustment and press red button again for solid green light to return to auto mode.

Labconco;

All units: DFs 4' above sash if data plate is up top, at sash height if data plate by elbows.
Blue Delta w/ switches; Turn off unit, hold silence, turn on unit, unit will start beeping, let go of silence, adjust speed control behind plate on top power box (two blue square buttons). Press silence to exit.
Units after blue Delta; Light, UV, timer, timer, OK.
Logic Vue; Light, up, timer, timer, OK
Clean bench & touchscreens; 1925

Thermo;

1300 Series A2; hold silence and light for 10 seconds till beep for service mode before measuring velocities. S1=DF blower, S2=exhaust blower, S3=DF alarm point, S4=inflow alarm point. ON button to save when "set" shows. Silence button to exit service mode. Order: S2, S4 (to note value), S1, S3, reenter/resave noted S4 at the end.
Silence button to exit service mode.
1400 series; Program (arrow pointing right) and hidden button (to the right of silence) simultaneously followed by enter to start CH mode (will show a wrench). Same sequence to exit (faces will appear).
Herasafe; 6363

ESCO;

0009 admin pin
0019 for factory calibration of airflow sensor (when all else fails)

Kewaunee

Interceptor; 9999 and/or 1001

Airclean;

HEPA filter 2 year reset codes;
6 digits; 833673
11 digits; 1B9-CBA4-C014
Or call Airclean

Biobase

Fan speed; settings button, password 1234, first row for fan speed adjustment, second row for pressure display, third row for air display. NSF A unit, while in off hold fan button for 5 seconds and fan speed screen will populate.

Airflow alarms:

TEL 500; Set airflow to alarm point. Hold enter for 5 seconds (lights will flash, and beeping will start). Press and hold both enter and set for 5 second sample time. Two beeps = good cal. ***500 BSC is the same, but at setpoint airflow with internal 80% alarm point.***
TEL 1,000; Hold enter and use +- keys to highlight setup, select calibration, password is 0000. Adjust to match measured airflows at normal and press enter. Lower sash, measure velocities, match reading, press enter. Back to run/setup = good calibration.
Apex 1,000(TSS); Mute button for 3 seconds shows mode (1 LED = mode 1 where unit is calibrated to actual air flows, 2 LED = mode 2 where unit is calibrated to calculated 20% loss). Mute button for 15 seconds turns off buzzer till repeated. Cal button (paperclip button) toggles modes, 5 seconds starts alarm cal, 10 seconds 0s sensor (sensor must be blocked, re-zero is not needed often). To calibrate hold mute for 3 seconds and press cal button to sample.
Lab Crafters Air Sentry: Password is 00000

BSC airflow corrective actions

TYPE	STATUS	OPEN EX DMPR	CLOSE EX DMPR	RAISE MAIN SC	LOWER MAIN SC
A1/A2	Low inflow, good downflow	O		O	
A1/A2	Good inflow, low downflow		O	O	
A1/A2	High inflow, good downflow		O		O
A1/A2	Good inflow, high downflow	O			O
A1/A2	Low inflow and downflow	P	P	Y	
A1/A2	High inflow and downflow	P	P		Y
A1/A2	High inflow, low downflow		Y	P	P
A1/A2	Low inflow, high downflow	Y		P	P
B2	Low inflow, good downflow	Y			O
B2	Good inflow, low downflow	P		Y	
B2	High inflow, good downflow		Y	O	
B2	Good inflow, high downflow		P		Y
B2	Low inflow and downflow	Y		Y	
B2	High inflow and downflow		Y		Y
B2	High inflow, low downflow			Y	
B2	Low inflow, high downflow				Y

Y=Yes

P=Possibly, see other status with post adjustment findings.

O= a possible option

Table 1 — ISO Classes of air cleanliness by particle concentration

ISO Class number (*N*)	Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below[a]					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
1	*10*[b]	d	d	d	d	e
2	100	*24*[b]	*10*[b]	d	d	e
3	1 000	237	102	*35*[b]	d	e
4	10 000	2 370	1 020	352	*83*[b]	e
5	100 000	23 700	10 200	3 520	832	d, e, f
6	1 000 000	237 000	102 000	35 200	8 320	293
7	c	c	c	352 000	83 200	2 930
8	c	c	c	3 520 000	832 000	29 300
9g	c	c	c	35 200 000	8 320 000	293 000

Table A.1 — Sampling locations related to cleanroom area

Area of cleanroom (m^2) less than or equal to	Minimum number of sampling locations to be tested (N_L)
2	1
4	2
6	3
8	4
10	5
24	6
28	7
32	8
36	9
52	10
56	11
64	12
68	13
72	14
76	15
104	16
108	17
116	18
148	19
156	20
192	21
232	22
276	23
352	24
436	25
636	26
1 000	27
> 1 000	See Formula (A.1)

NOTE 1 If the considered area falls between two values in the table, the greater of the two should be selected.

NOTE 2 In the case of unidirectional airflow, the area may be considered as the cross section of the moving air perpendicular to the direction of the airflow. In all other cases the area may be considered as the horizontal plan area of the cleanroom or clean zone.

ALTERNATIVE CLEANROOM CLASSIFICATION PHASES

MATTHEW LEMIEUX, VTG, LLC.

Traditionally, as described by Federal Standard 209 and ISO 14644-1, cleanroom classification phases are defined in three ways.

The first, As Built, means that the cleanroom construction is finished, and the room mechanical systems are operational. However, the room is empty of both client production equipment and operation personnel. In the second phase, At Rest, the as-built cleanroom is populated with client production equipment, which is operational, but client personnel are not present. In the third phase, Operational, the at rest cleanroom is occupied by the expected contingent of client operating personnel. The life science industry prefers two phases, static and dynamic. Static is most closely associated with the at rest phase and dynamic corresponds with operational.

With the customary site complications of equipment installation, hookup, commissioning, qualification, pressure balancing and other occupations, the strict conditions of the various phases are seldom actually present. To address these real-world difficulties, six alternative certification phases are suggested by the author.

1. **Remunerative –** In this mode, the cleanroom contractor is urgently attempting to classify a portion of the project for client turnover before the entire contiguous space is constructed. This is usually attempted with installation of temporary plastic wall barriers. The exterior building shell may be open to the elements and the cleanroom may graciously shelter displaced members of the local fauna, both terrestrial and avian.

2. **Unpressurized –** The cleanroom is to be classified before the air balancing contractor has had the opportunity to final balance the minuscule air pressure differences indicated in the design. This is often due to contractor disagreements concerning responsibility for architectural finish details without which pressurization cannot be achieved. This state is often found contemporaneous with the remunerative state. The general contractor may be clearly seen through the gap in the astragal confidently assuring the certifier that the room has been thoroughly balanced.

3. **Unfiltered –** This situation occurs when job-site pressure mandates the classification of cleanrooms despite knowingly having HEPA filter integrity leaks which have yet to be addressed and remediated. It is essential during this phase that all cleanroom personnel adhere to strict gowning classification protocol and traffic patterns so as not to contaminate the room while the general contractor is removing damaged hepa filter media.

4. **Unsecured –** During this mode, there are un-garbed contractor and client employees entering and exiting the cleanroom spaces during the classification. They often bear cardboard boxes, cutting torches, saws, drills, and surface grinders. It is prudent for the certification technicians to wear OSHA-approved hearing and eye protection during this delicate classification mode.

5. **Janitorial –** The cleanroom cleaning personnel are present in an overcrowded, claustrophobic density and are actively utilizing vacuum cleaners, paper towels, brooms, mops, and bountiful spray IPA bottles. Those certification technicians tragically encumbered by alcohol addiction are judiciously advised to seek out other project responsibilities during this phase.

6. **Helicopter –** During this modality, the ungarbed responsible contractor supervisor personnel and/or client representatives are hovering intrusively around the particle counter inlet sampling probe emphatically gesticulating and conversing with each other whilst eagerly inquiring of the certification technician – "Did we pass?"

In closing, the esteemed editorial board strongly suggested that I emphasize the satirical nature of this submission, prior to publication, lest the suggestions detailed herein be seriously undertaken by the governing bodies.

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TAB C5

Personnel Protection Updates

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.

The personnel protection test was discussed during the 2024 JC meeting. A task group was established to work on updating all three of the biological tests under Standard 49. Cross and Product Protection are much simpler, with the possibility to propose specific language to improve them. Therefore, a separate issue paper was submitted to get that work under way. Potential changes to the Personnel Protection test require discussion and method development testing.

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.

This issue paper asks the Biological measurements TG to develop new methods to improve the personnel protection test. Possible improvements include but are not limited to:

- Eliminating impingers as a sampling tool. Possible replacement – impaction samplers.
- Considering position of the nebulizer.
- Consider measuring by ATP.

After an initial round of proposed changes to the test is ready, establish a plan for method development.

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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Signature*: Stephen Williams
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Submission Date: 6/2/25
Type written name will suffice as signature

Email completed form to Al Rose

Item No. BSC-2025-07

(For NSF International internal use)
03/2013

Tab D

Open Topics

TAB D1

EN 12469 – update on publication

B.Peters and S.Schneider

New EN 12469

Svenja Schneider
convenor of CEN/TC 332/WG 8 - Safety cabinets and isolators

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Disclaimer

This document is intended solely for internal use within the standard committee and is not for external distribution.

Parts and Deadlines

The standard is divided into sub-parts, of which the following parts are currently being finalized:

- EN 12469-1: Biological safety cabinets — Part 1: Classes and basic requirements
- EN 12469-2: Biological safety cabinets — Part 2: BSC class II
- EN 12469-5: Biological safety cabinets — Part 5: Installation, commissioning and routine testing

Major steps for publication (may vary):

- 2025-09-16: Closure of formal vote (The standard must be accepted by the CEN member countries)
- 2025-11-12: Final text available (if formal vote was positive)
- 2026-05-31 Completion of al nat. Publication

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Major changes for class II cabinets

Extract

- test grid for lighting
- test set up for sound and alarm measurement
- labelling requirements
- acceptance criteria for filter testing
- description of which tests are carried out for which test type (e.g type test, installation)
- Test procedures for flow visualization.
- Requirements for filter-testing (Reference to ISO 14644-3)

- Test grid for downflow (The number of measuring points depends on the dimensions of the working surfaces)
- Measuring procedures for Inflow

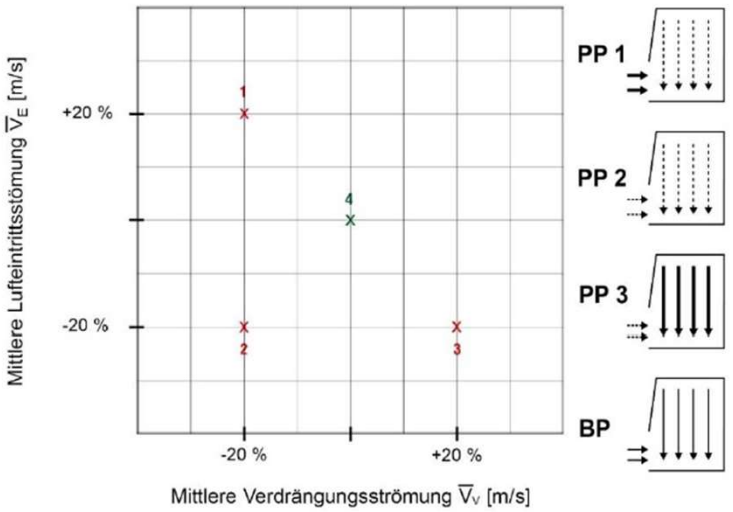
New test setup for microbiological testing

Added: Stability of protective functions

Additional test must be carried out by vary the airflows :

PP1 [V_{dfl} –20 %; V_{ifl} +20 %] – product protection
PP2 [V_{dfl} –20 %; V_{ifl} –20 %] – product protection + personal protection
PP3 [V_{dfl} +20 %; V_{ifl} –20 %] – personal protection

Removal of the minimum requirements for downflow and inflow
→ The microbiological test must pass.



Source: DIN 12980:2017

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Complete new part 5

This document gives requirements and recommendations for:

Installation

Commissioning

routine testing

Recommendations for placement of BSC

Requirements for a measurement protocol

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Future

Start of the projects

EN 12469-3: Biological safety cabinets — Part 3: BSC class III
EN 12469-4: Biological safety cabinets — Part 4: BSC class I

If anyone would like to support the standards work financially. Please feel free to contact:

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TAB D2

ATP Method – discussion of use in biological measurements

B.Powitz