Task Group on Secondary Inflow Method
Teleconference Meeting Summary
April 10, 2023

Participating Members:

Steve Williams (NSF)	Bill Sage (NSF)
Brent Griffith (Labconco Corp.)	Bill Peters (NuAire, Inc.)
Aaron Johnson (The Baker Company, Inc.)	Nicolas Rose (Midwest Associations)
Jim Wagner (Controlled Environment Consulting)	Justice Lambon (USPHS)
Dave Phillips (Thermo Fisher Scientific)	Cary Binder (NSF)
Joshua Greenberg (National Institutes of Health)	

Absent Members:
Bob Jones (Eagleson Institute)

Participating observers:

Al Rose (NSF)	Eliza Nejad (NSF)
Tanya Ibrahim (NSF)	Erin Bagosy (NSF)
Brandon Gray (Labconco Corp.)	Jim Hunter (Emeritus)
Matt Squire (NuAire, Inc.)	
Theresa Bell (Frederick National Laboratory for Cancer Research)	

Supplemental Materials Referenced
1) Agenda - Secondary Inflow Method - TG - 2023-04-10.pdf
2) History of Secondary Inflow Method - Bob Jones - 2023-04-10.pdf
3) Draft Performance Criteria - SW - 2023-04-07.docx
4) Face velocity questionaire questions, including feedback - 2023-03-29.docx
5) Meeting Summary - Secondary Inflow Method - TG - 2023-02-27.pdf
6) RE_ DIM wall interference.pdf

Discussion
S.Williams is the TG Chair, welcomed everyone and called the meeting to order. A.Rose read the anti-trust statement and took attendance. Eleven of the 12 voting members were present (92%) representing a quorum. S.Williams opened the meeting by seeking a motion to accept the previous meeting summary

Motion, Cary:	Accept the previous meeting summary
Second:	S.Williams
Discussion:	None
Vote:	Eleven in favor, zero opposed, zero abstentions

New member Nick introduced himself

S.Williams then recapped the previous meeting and action items and began with the first subtopic regarding the development of the questionnaire. A.Rose presented the final questions and the group agreed this was an appropriate list:

Have you ever used the secondary inflow method?
Do you use the primary or the secondary method more often?
What is the default method of determining face velocity employed by the company you work for?
What if any situations have caused you to have to use the secondary inflow method?
What if any customer complaints have you had about using the primary method?
If using the secondary method, how is the probe supported when taking the readings?

A.Rose confirmed these would go out shortly once the contact list was confirmed with L.Pollard.

Action Item:
A.Rose to confirm contact list with L.Pollard and send out survey.

S.Williams then presented the meeting comments shared from B.Jones who was unavailable to join today's meeting. S.Williams indicated this seems a bit removed from the scope of this but understands his point. Regarding the last paragraph . . .

> Important side Note: It is my very strong opinion we are using the wrong criteria to set the cabinet airflows. We are using velocity which works fairly well at sea level, but the performances of the cabinet are being dictated by mass airflow not strictly velocity. Measuring velocity has a huge Impact when it comes to cabinet that are several hundred or thousand meters above sea level. We end up turning down the motor speed on new cabinets as a correction for altitude which makes the performance much worse.

D.Phillips suggested the crux of what B.Jones is saying is to determine whether it's the velocity or the quantity of air moving through that should be measured and understood. B.Peters indicated that NuAire did a form of this testing in the 90s and agreed using altitude correction is the correct way to go.

S.Williams said that due to the fact this isn't within the scope of this Task Group, this was enough discussion here today and asked A.Rose to report back to B.Jones suggesting he put in a new issue paper if he would like to discuss further.

Action Item:
A.Rose to report back to B.Jones

D.Phillips asked S.Williams to confirm the scope of what this group is to do. S.Williams indicated the group is charged with developing a process to validate a manufacturers' secondary method when they request a validation. Also, for manufactures who do not want it validated, we need to decide whether the certifier should even do the test.

A.Johnson asked S.Williams if he was confirming that the alternate method is not necessary. Answer is yes, it is not. B.Sage added that even though it doesn't need to be completed, when it is completed it must be validated.

S.Williams presented his draft performance criteria language, confirming this would be put into NSF policy sometime this week, whether or not it eventually ends up in some form within the Standard.

> Beginning with a possible new definition:

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

> S.Williams explained his intent of the language as well and presented that:

>> BSC manufacturers have the option of having the certification body verify their secondary method for measuring the inflow velocity. Verification shall follow these rules:

- The manufacturer shall submit a minimum of 10 inflow velocity data sets. No more than 40 percent of the inflow velocity data sets shall be generated on a single BSC. In other words, there shall be at least 3 unique serial numbers for the different BSC's used to generate the data. A minimum of 3 different trained test technicians shall be used to generate the data and each test technician shall not be responsible for generating more than 40 percent of the data submitted. The BSC's shall be balanced within listed ranges for inflow and downflow velocity. Each inflow velocity data set shall include the following information:
  - Cabinet model number and serial number
  - Name of test technician
  - Date of testing
  - Measured downflow velocity (this could be measured by a different technician on the same day)
  - Primary method inflow velocity
  - Uncorrected secondary method inflow velocity
  - Fully corrected secondary method inflow velocity
- NSF shall evaluate the submitted inflow velocity data sets and compare the submitted data sets to the data sets generated during qualification and 5-year testing. The evaluation shall include the following:
  - Evaluate the difference between the primary method inflow velocity and the fully corrected secondary method inflow velocity for each submitted inflow velocity data set.
  - Evaluate the difference between the primary method inflow velocity and the fully corrected secondary method inflow velocity for each inflow velocity data set generated by NSF.
- A manufacturer's secondary method for measuring inflow velocity will be considered validated when:
  - The difference between the primary method inflow velocity and the fully corrected secondary method inflow velocity for each inflow velocity data set (both NSF and manufacturer generated) is 5 ft/min or less.

The group agreed this was a good start and began discussing the language itself.

D.Phillips explained some possible issues found with certain BSCs, including some odd impacts in certain areas where the cabinets are installed. S.Williams indicated that ultimately it is up to the BSC manufacture to submit the values and approach for using the Secondary Method.

J.Hunter asked the group to discuss how we can explain possible inaccuracies to the field certifiers. D.Phillips suggested this is precisely why there is a bias toward the DIM over the secondary because those inaccuracies are minimized.

S.Williams reiterated that this TG is not proposing to change the methods procedures, only to lock down a procedure for manufacturers who want to have a secondary method validated.

S.Williams also reiterated he is not sure this is even needed to be written within the standard.

D.Phillips suggested that in a perfect world it should be rare to move back and forth from DIM to Secondary as the Secondary should only be used occasionally.

The group then discussed the values in the language and the challenge with gathering bigger data sets, especially as it relates to new BSCs.

This discussion included the possible flexibility of testing the secondary method over time with new BSCs, maybe with video witness testing rather than sending in another BSC just for the secondary testing, and adjusting the value given to the field over time as more data was gathered.

The group then opined the challenges with retroactively changing the values.

S.Williams indicated that currently the standard requires substantial information on the data plate so that would have to be changed.

J.Lambon asked S.Williams at what point do field certifiers decide which method to use. S.Williams indicated we always use the primary method here at NSF, per the Standard. This is the testing performed at NSF HQ in order to allow the mark to be applied to the BSC. S.Williams then presented the language in 49 regarding the data plate.

N-5.1.1.1 Alternate inflow measurement methods

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

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

— the space between the face of the BSC and permanent fixture directly opposite the access opening is less than 42 in (1.1 m);

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

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

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

The DIM shall be used in all other circumstances.

A.Johnson reminded the group of his concern about taking away the secondary method, asking what the risk is to public health in reality, and the other risk of losing certifiers because we're making the method to onerous.

To this, S.Williams once again confirmed that removing the secondary method from the standard is completely off the table. He suggested that there would certainly be proponents for removing it, but that's simply not an option.

J.Wagner said that regarding the use of data plates, there are certain places like clean rooms which have little or no internet signal so simply updating via a QR code is not a great idea.

D.Phillips said that while it's not ideal to put out the correction factor with only 3 BSCs being tested, the data plate could be updated after a few months of testing and there would be very few BSCs out in the field by then. It comes down to what level of statistical robustness do we want. He suggested that ultimately, we need to have flexibility to adjust the data plate as more information is gathered.

The group discussed the changing of data plates in reality, the evolution of it already changing today, and data already on the plates of the BSCs in the field.

S.Williams suggested that if there are large correction factor changes, there will need to be new testing completed and validated at NSF.

S.Williams posed the question of whether at the 5 year requalification, should this be retested now that there is a lot of data. B.Peters suggested that would depend on the new data.

With time running out, S.Williams thanked the group for the great discussion. He then confirmed he is not proposing any of this language go into the standard, and those on this group can request that separately if desired.

He then asked the group specifically to confirm whether it be a requirement that the secondary method be validated. The group agreed it has to be voluntary.

S.Williams then stated that in the end if a validated secondary method is not completed, it cannot be put on the data plate.

S.Williams suggested that based on the discussion, we'll have to make some minor updates to the standard and gave himself an action item.

Action item:
S.Williams to write up a straw ballot for this group based on today's discussion.

S.Williams asked if there were any other comments or questions; there were none and the meeting adjourned.