Task Group on Secondary Inflow Method
Teleconference Meeting Summary
February 27, 2023

Participating Members:
Steve Williams (NSF)
Brent Griffith (Labconco Corp.)
Aaron Johnson (The Baker Company, Inc.)
Jim Wagner (Controlled Environment Consulting)
Bill Sage (NSF)
Bill Peters (NuAire, Inc.)
Nicolas Rose (Midwest Associations)

Absent Members:
Dave Phillips (Thermo Fisher Scientific)
Joshua Greenberg (National Institutes of Health)
Justice Lambon (USPHS)
Cary Binder (NSF)
Bob Jones (Eagleson Institute)

Participating observers:
Al Rose (NSF)
Eliza Nejad (NSF)
Matt Squire (NuAire, Inc.)
Brandon Gray (Labconco Corp.)
Bob Powitz (R.W. Powitz & Assoc., P.C.
Erin Bagosy (NSF)
Jim Hunter (Emeritus)

Supplemental Materials Referenced
1) Agenda - Secondary Inflow Method - TG - 2023-02-27.pdf
2) SC-2023-01 - Secondary Inflow Method.pdf
3) BSC-2023-02 - Secondary Inflow Method 2.pdf
4) 49i175r1 - Secondary Inflow Method - JC memo and Ballot.pdf
5) 49i175r1 - Secondary Inflow Method - Comments.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. Seven of the 12 voting members were present (58%) representing a quorum. S.Williams opened the meeting by explaining the reason for the issue paper and subsequent establishment of this task group.

He described that the NSF QA department found there were some things they were doing and/or not doing with regard to the secondary method that didn't match up exactly with the policy. He added that since this discovery we've since come to an agreement that what we're doing is indeed in compliance with the standard.

S.Williams confirmed when the initial issue paper that ruffled a lot of feathers went out as a ballot, it was clear this was a larger issue than first considered. Now that we know we are in compliance with the standard, the urgency is gone. Nevertheless, we're updating our SOP's and still feel it best to come up with a better process, one that is spelled out in the Standard.

Going into specific language, when validating manufacturers BSCs, secondary methods for measuring inflow velocity, the standard uses the term "validated" and there's no definition of success tied to it. He indicated that years ago Greg had done initial work and sorted out a process for success. What that meant in the NSF lab was: making one measurement, applying the correction factor, if any, and then if it was within 3 feet per minute of the DIM inflow measured on the same day, then it was deemed successful. That being said, it is not altogether clear if that would be considered "validated"

If one examines the data over the last 10 years or so, applying the same criteria, then that success criteria would not hold up as maybe only 10% of the time the manufacturer's product falls within the 3 foot per minute tolerance and often it's way off. B.Sage agreed.

S.Williams indicated the goal here then is to find out how close we need to be using the method, and what we need to do to best serve public health. He then provides an example whereby if NSF measures the inflow velocity using the DIM and it's 107, then the secondary method measures 135, does this equate to a public health issue.

J.Wagner suggested that those values are perfectly ok if the secondary method acceptance criteria is published as 135 feet per minute. S.Williams indicated that what he actually meant was the 135 was after applying the correction factor and still off by that much. S.Williams then said sometimes these are only off by 5 or 7 fpm and sometimes 25 or more.

J.Wagner then added that one of his questions was with the procedure stating that there would be 10 replicate tests to show repeatability with the secondary method. Will this be something the manufacturers will be responsible for or NSF? Earlier it was indicated that there was only one measurement.

S.Williams said that is how it's written in the standard, and yes, we only do one set of data on one sample. He added the way it's written currently nobody is obligated or responsible. At this point if the manufacturer chooses to submit ten sets, then we will review them and apply whatever criteria we make up in absence of the Joint Committee giving us some criteria, the latter of which is what would be preferred. So as written, the manufacturers are not obligated to submit secondary method data, but if they do, we have to evaluate it.

At this point A.Johnson asked S.Williams, whether anyone is using the method above the exhaust filter to which S.Williams indicated there is no longer anyone doing that.

A.Johnson indicated that back in 2019, the standard was revised for both Normative Annex 1, which is basically the manufacturers testing as well as the field tests, normative Annex 5, or formally Annex F. this is where we were required to use a fixture properly to discourage the probe from being held by someone's hand. A.Johnson then asked if this was the method used to gather the data that S.Williams said was within 3 fpm only about 10% of the time. S.Williams confirmed that the probe has never been handheld by NSF. S.Williams added that since starting in 2002, and even prior within Greg's work, there is no mention of hand holding even back then. He further added that back in 2002, 30 or 40% of the manufacturers provided some kind of specific fixture, and the rest use a clamp and ring stand.

A.Johnson thanked S.Williams for the clarification adding that when the ballot started, he was taken aback because as a manufacturer, providing this information is a service that a certifier could use. And although the data that we've collected over the past and continue to collect through the Eagleson Institute training sessions really show how when the correction factor is applied, it works. It's not correct 100% of the time, however.

A.Johnson added that if there's any room turbulence or other slight thing happening at the time, it can influence the reading.
He then confirmed his biggest concern is how this will impact the field. Public health is the greatest concern but does this ultimately influence public health. What about our certifying community and the affect there. It's important to have the certifier community discuss this too before it's removed entirely from the Standard.

S.Williams indicated that in retrospect, the reaction to send this to ballot was a bit hasty and an effort to answer some questions coming from NSF quality assurance. The relative inconsistency in the testing has been frustrating for quite some time and maybe the best approach would be to give the responsibility of the secondary method to the manufacturers, which is something that we can discuss in this group. Of course, in a different manner than postulated in the initial ballot. A.Johnson agreed with that approach.

To this S.Williams indicated he would like to start by defining what success is, and if NSF is indeed involved, define what the term validated means. And if necessary, better define what is meant by ten sets of data. Internally, NSF had a definition of sets of data, as in a unique cabinet serial number and a unique test technician, that sort of thing. So, for instance a cabinet serial number 12, tested by A.Johnson and Ron would generate two sets of data and then A.Johnson and Ron could test cabinet serial number 13 and generate 2 more. And we've always said internally if submitting sets of data, there would have to be at least two unique serial numbers and at least two unique technicians.

J.Hunter suggested some discussion about the statement “no fewer than 10 replicate tests”. He is assuming that's being done at the manufacturer but based upon some of the comments that might not be the case. The important thing is to get repeatable results. A.Johnson indicated from his point of view, like downflow velocities, a problem in the field isn't an NSF problem, it's a manufacturer's problem, and I think all the other manufacturers can agree with that. Thus, if we don't do enough due diligence, whether it's down flow velocities for zones or just the range for the secondary method in this case, we are going to end up being the one that has to fix the problem or explain it to the customer and then to NSF. So, what we would do as a manufacturer is, we would build 5 cabinets, and have again two people test them correctly. But there’s no real requirements for that. In fact, we can build one cabinet and test it 10 times by the same person as this is written and possibly interpreted.

S.Williams was asked to describe how this is currently handled at NSF. He confirmed they use 10 samples at each location. this involves using the anemometer and the time constant. The probe is positioned for each location with about a minute to stabilize and then hit the button to record each measurement.

A.Johnson asked if these measurements vary over that period of time, and S.Williams said yes, they vary but not hugely for instance the values may vary from 330 to 348 feet per minute.

A.Johnson indicated he didn’t mind going back and looking at data again. There are other BSC manufacturers on the call that can speak for their own points, but it seems that the only certifier here is J.Wagner, and he asked him if he ever used the secondary method, and the answer was no. Jim then asked the group what the risk to public health changing this procedure. Specifically, if we keep things as is would there be a risk to public health. A.Johnson added an example asking the group to question if the secondary method was enough to match the primary method and provide a level of safety to the user. Specifically: if the DIM yields 105 feet per minute, is a worst case measurement with the secondary method is 85 feet per minute or 135 feet per minute. 135 may actually be worse because if that’s believed to be the actual reading flow might be dialed back inadvertently. These are the types of things that we want to keep in mind. S.Williams agreed clarifying to be fair that some manufacturers who are consistently within 3 feet per minute, however there are examples of these wide fluctuations, for example deviating by 30 fpm from the DIM measurement.

B.Sage reminded the group that in 2019 language was revised with a different secondary method task group that requires field certifiers to enter a reason for using the secondary method on their datasheet. Furthermore, they must use the DIM if at all possible so in essence use of the secondary method should be minimal at this point. A.Johnson agreed and S.Williams added that this is the case at least in North America.

S.Williams indicated in the cases were there are installations where the DIM simply doesn’t fit, based on work he and B.Sage completed, the values taken 4 or 5 inches between a wall and the back of the DIM should be very much the same as if the measurements taking place four feet away.

J.Wagner said this is an interesting point and should be further discussed because most of the certifier community believes that number to be 18 inches. No idea where that 18 inch value originated, and a number that has been bantered about while teaching classes. When people ask for an adequate clearance, this is the number thrown out. If we do believe it to be much tighter, then we should make this clear to the community at large. S.Williams suggested the data from that

testing could be found and would share it with the group. He added he wasn't certain if the work was for the other TG or just for our own satisfaction and described the process of moving the DIM closer and closer to the wall to establish an effect. The group was very interested in this information.

S.Williams said they were surprised at how close they could actually get, and J.Wagner suggested this data would further support there is even fewer circumstances where the DIM cannot be used in the field. He reminded the group there are places like clean rooms where the manager won't allow the DIM to enter for that purpose, but that has nothing to do with clearance. There was a bit of further discussion about certifying in clean rooms and some current standard language which doesn't necessarily make sense in these situations, and S.Williams suggested this discussion is opened up so let's say everything is on the table for rewording.

N.Rose indicated lack of clearance with the DIM and very rarely does it influence performance. He then asked from a public safety consideration, was the secondary method acceptable and publicly safe before the DIM became the primary method. J.Hunter indicated not really adding the method is to measure exhaust velocity and calculate the volume, then divide that by the open area of the access opening.

J.Hunter suggested the problem started when the secondary method was adapted. At the time it was voted in because some certifiers argued they had no plans to buy or shortridge. And they successfully argued to adoption of a secondary method that still used a thermal anemometer. Since that time, others have raised the issue of clearance, others of cleanability. We completed some work at Labconco a few years ago to test reproducibility, and the shortridge certainly was, so I have to ask here is this really an issue of space or cleanability or is this an issue of certifiers refusing to carry around the shortridge all the time.

S.Williams thought this was a good question and from his understanding the issue which is largely resolved in North America. However, internationally, especially in low resource countries use of a DIM is less universal. For example, there are places where the certifiers would have to carry the equipment up 7 flights of stairs because there are no elevators. J.Hunter indicated they already carrying up an aerosol photometer, generator, and a compressor up 7 flights of stairs, to which S.Williams said exactly, and this is one more bulky thing.

There was a bit of discussion about various limitations in the markets and S.Williams said his hope would be that in the long run we can further minimize use of the secondary method, but he accepts that there are strong voices for maintaining it as is for the time being.

J.Hunter indicated he understood the international limitations but asked S.Williams if the secondary method were developed domestically using the DIM without the skirt, would that be unacceptable? S.Williams suggested he felt it would be acceptable. Jim said this was his point exactly. Domestically we've killed the clearance and cleanroom issues, so will there still be pushback about this type of secondary method.

S.Williams asked for J.Wagner's opinion.

J.Wagner explained they do a lot of sterile compounding facilities, where we use a biobag for the skirting and don't have any issues. There is some whining from the techs because we have to clean them every time we go in, but we do it every day.

B.Gray suggested the real question as evidenced early in the conversation is "how to define a successful secondary method?" anyone who completes this type of testing over and over will confirm the DIM is very reproducible where as the secondary method may not be. Moving goal posts is not a valuable place for this JC to be in.

S.Williams said this was a very good point, and the discussion itself has been great, but at some point, we need to do exactly what B.Gray said, which is to define success. S.Williams suggested that after this discussion he could put together some language for this group to discuss during the next meeting.

J.Wagner said he would start the process by stating what he's felt all along. There were 10 replicate tests to show that reproducibility between the two methods, because what's really important is replication of what the manufacturer got when they did the micro tests. That's why the Shortridge became the primary method because it was the most repeatable.

The assumption is our goal is to relate back to when the manufactures or NSF did the microbiological test, so success would be reproducibility using a correction factor. The 10 feet per minute range that you do with those tests compared to the five feet per minute that we do for certification and then we have a performance envelope around that. I would think there's enough data out there that could support that to be adequate.

S.Williams agree further proposing 5 feet per minute thus the minimum would be 95 feet per minute in the field.

The group questioned which method typically measured higher, and the agreement was the secondary method usually measured lower.

J.Hunter said he was concerned that this group is discussing the topic but not getting to the root of the issue, which is the need for the secondary method in the first place. We should define the need/purpose for having a secondary method first, and the language can come from that.

J.Hunter added there was a lot of discussion several years ago about the use of a particle counter and the group decided to drop that discussion because we determined it wasn't a suitable test,. And yet here we are still entertaining the secondary method; where's the justification.

There was a bit of discussion about what the reaction would be from the certifying community of making the secondary method simply take the skirt off the shortridge with adjustments to the front of the cabinet. If that were to work, then over time would that become the primary method. A.Johnson suggested it comes down to finding something that's reproducible over and over, and we know that the secondary method has variability. Further he added we need to make certain the certifiers have a voice on this. There are many customers out there that couldn't care less about NSF certification and listing. That's a shame, but it's true and we need to make sure in any case that they are represented.

Nick said it sounds like the group here should be focused on the number of repetitions, be it 5 or 10. in the end, we shouldn't cheapen the process just because we want to. Shortening the certification times would be great, but if it's less reliable and repeatable, would it be worth it. Another approach would be a faster but less reproducible approach done twice each year instead of once.

S.Williams thought that was an interesting approach and added that recertification intervals are not currently governed by Standard 49. That may come from institutions. J.Wagner confirmed that stating that some already do every 6 months.

B.Gray to S.Williams: it sounds like a good next step would be inviting a public forum through the certification community to help understand their viewpoints and rationale for using a secondary method in the certification of a BSC, either at CETA conference or elsewhere. It seems we keep discussing the why of the secondary method, and maybe there's a very good reason we're just not aware of it. But if there's not, that might answer our questions. S.Williams said that was a good idea.

S.Williams indicated that everyone including the field certifiers were invited to participate in this TG, even though there is a limited number today. Maybe a show of hands here however to see how much input we already have, understanding it's mainly J.Wagner. J.Wagner suggested that what the other field certifiers are likely to say is that there must be a secondary method because there are times when we can't use the DIM for the various reasons already discussed.

S.Williams maybe the question to ask them then would be that if the secondary changed from 3 the inch constricted opening To using a seal with the Shortridge would that be acceptable.

B.Gray suggested that was his point. if we make a very concerted effort to get feedback from the widest breadth of the certification community as reasonably possible, you will harness all of those reasons, all the reasons that a Shortridge cannot be used and that is great input to the task group. If we cannot provide reasonable means to overcome those, then we have to continue to support the secondary method.

S.Williams asked the group how they would like to approach the certifiers. He said NSF has a very good list of field certifiers, maybe 500 or 600 in total. We could certainly send out a real brief survey to them if we wanted this group to craft a survey. And then maybe based on the response, we could invite some portion of them to participate in a discussion as well. B.Sage added that a live discussion would be best for back and forth, but it was agreed that few would have time during a typical Monday afternoon to make this happen. J.Hunter suggested a sizable group would be at the CETA conference and a room could be set up that would attract a lot of interest. The group agreed.

J.Wagner asked if NSF would have the typical involvement this year. S.Williams said he wasn't involved but Cary was and although he is not on this call right now, would expect the typical involvement. S.Williams added that B.Sage and he could call in to the conference discussion. J.Wagner said he strongly supports this idea, but suggested the group not forget about the specific NSF list of certifiers. The people that attend CETA are typically the owners and not necessarily the guys in the field every day.

S.Williams agreed and indicated we will still plan to send the survey to the group in addition to a discussion at CETA. S.Williams then asked for a volunteer to come up with some survey questions. N.Rose, J.Wagner and B.Gray agreed to work on this.

Action Item:
N.Rose to come up with 3 to 5 survey questions and share with A.Rose
A.Rose to share with J.Wagner and B.Gray for more feedback.

S.Williams confirmed the next meeting of this task group was April 10 and we could get the questions finalized then at the latest. Ideally, if these were sorted out as early March 10 or so that would give us a couple weeks to send out the survey and have results by the next meeting. If not, then at least we can discuss questions at the next meeting. And if CETA isn't until late April we could have the survey results for before that. J.Wagner confirmed CETA is April 20 - 25.

J.Wagner asked what the goal of the survey was. Is it to question the need for a secondary method to begin with or to ask if simply removing the skirt would in fact be a satisfactory secondary method. A.Johnson suggested both questions be asked.

J.Hunter said another question to ask might be to describe reasons why the primary method cannot be used.

The group agreed both the targeted survey and the general discussion during CETA was a good approach to give the certifiers a chance to voice their opinions.

S.Williams indicated that J.Hunter raised the issue of cutting corners when using the secondary method so maybe another thing the group should consider is additional requirements for how that method is approached and make it essentially more cumbersome so there is less incentive to use that method. J.Hunter indicated his primary concern isn't the time difference. If the method is equally reproduceable it shouldn't matter.

A.Johnson indicated they have an Eagleson course coming up this month and would capture some data. See what the difference is between the eight people on one BSC when the room conditions are not changing.

At this point S.Williams captured the action items. In addition to the 2 mentioned previously:

S.Williams to communicate with Leah and Cary about adding this topic to discussion during the NSF meeting at CETA next month.
S.Williams to develop initial criteria to propose to be revised in the Standard, what might be called 'validation of manufacturers data.

J.Wagner suggested if the plan is to use the survey questions during the CETA meeting, there is a time frame with which to consider prior to the next TG call on April 10.

Nick and J.Wagner agreed to a 2 weeks turnaround of the questions.

In the end the plan is:

Nick to send initial questions to A.Rose around March 8
J.Wagner and B.Gray to have a week after that to add feedback.
After revising, the remainder of the TG will have another week to comment then send out the survey.

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