Meeting Summary
Steering Committee
NSF International's Biosafety Cabinet Field Certifier Accreditation Program
Orlando, Florida
April 14, 2013

Introduction

Maren Roush (NSF International) read NSF's Anti-Trust Statement and initiated the meeting.

Steering Committee Membership

Participants discussed the current membership of the Steering Committee and how effectively / fairly the major stakeholder groups of the Accreditation Program are represented. In terms of individual people on the committee, there is inadequate representation from regulatory officials, with only one person representing the group. Some members suggested that it will be difficult to increase regulatory representation on the Steering Committee, as regulatory officials typically have limited funds for travel expenses and limited authority to represent their organization in a public forum such as this one. It was also suggested that public health officials may be reticent to vote on contentious issues. However, the group decided that, even if they may be difficult to fill, the Steering Committee should keep spots open for stakeholders that fall under the category of regulatory officials. It was suggested that NSF ask CETA how it is lobbying regulatory agencies to gain acceptance/adoption of CAG003, *Certification Guide for Sterile Compounding Facilities*, and follow CETA's example(s).

A list of the current members of the Steering Committee is provided as an addendum to this meeting summary.

At the time of the April 2012 meeting, two applications for membership on the Steering Committee had been received. Since that time, the total number of applications received has increased to four. Ken Barkley (BGE Service & Supply Ltd.) and Stephen Dahl (Johns Hopkins University) volunteered to serve on a task group to review membership applications. If any other Steering Committee members would like to serve on this task group, please notify Maren Roush at mroush@nsf.org upon receipt of this meeting summary.

It was suggested that NSF lock in a maximum of five representatives for each of the four major stakeholder groups (field certifiers, manufacturers of equipment, regulatory authorities, and users of BSCs/field certification services).

Ken Barkley made a motion that there be equal representation for the major stakeholder groups on the Steering Committee, and that the committee membership be capped at 20. Stephen Dahl seconded the motion and it passed unanimously.

Replacing the Pressure Test with a Decontamination Test

Bob Jones, who is an approved proctor and long-term supporter of NSF's Accreditation Program, emailed the following comments to NSF International in advance of the meeting for discussion:

> "I would like to eliminate the cabinet leak test and add a decontamination test to the NSF practical exam. I believe the decontamination test should be a test to determine the candidate's knowledge on his or her company's policies on decontamination. The

candidates should have to submit their company's SOP for decontamination with their application and the proctor would test the candidate to their company's procedures.

"The second order of business should be to change the method for determining cabinet intake in a B2 cabinet. We should not be promoting measuring total flow and supply flow and subtracting one from the other to get intake flow. You should never measure two larger flows to determine a smaller flow because of the inherent error in the process. Smaller flows such as intake should be measured directly.

"Third, I think we should be able to let candidates test a cabinet with their own test reports from beginning to end, including making adjustments, so the testing is more representative of what truly happens in the field. In this case you would test both a Type A and B cabinet from beginning to end. Now I am pushing it but then you could possibly have two listings for people, one for an A cabinet and a second listing for both cabinet types.

"The attachment includes a sample of a Type A and B test report that we could use if we don't allow the candidates to use their own reports. Also included are the observations the proctor must make for each of the individual tests and list of the reason for failing the test or losing points from their final score. I am not saying that the attached forms are complete or perfect but they can be used a starting point for discussion."

The group discussed the possibility of replacing the current cabinet leak test in the practical examination with a decontamination test. In general, there was little support for conducting the test against an individual company's SOP, as it would be subjective rather than objective and would not evaluate the efficacy of the method. There was support for using Annex G of NSF/ANSI Standard 49 for developing a decontamination test, with some restrictions. For example, Jeff Smith (Agape Instrument Services) explained that his company's insurance would not cover the use of formaldehyde or other chemicals as part of the testing process (and Agape is a major test center for the Accreditation Program). It is doubtful that any facility would support Accreditation testing with chemicals, especially since the test candidates may not be proficient in the appropriate procedures (i.e. what about test failures?). The group agreed that there are inherent risks associated with the use of dangerous chemicals during decontamination procedures.

Two alternatives were proposed: 1) NSF could offer a written practical examination for the decontamination procedures or 2) NSF could work with a task group to develop a decontamination test that would use a safe surrogate, such as peppermint oil. The proctor could then evaluate candidates by verifying that appropriate temperature and humidity conditions were achieved during the mock procedures. For a simulation of decontamination using chlorine dioxide gas, the proctor could verify that "gas" is recirculated throughout the cabinet as intended and that scrubbing procedures are followed properly. This approach may require that field certifiers bring an additional blower with them to the practical exam.

Ken Barkley made a motion to create a task group to develop a decontamination test that would replace the cabinet leak test for Accreditation candidates. The new test would be based on Annex G of NSF/ANSI Standard 49 (not SOPs) and not use live chemicals. Dave Phillips (Thermo Fisher Scientific) seconded the motion and it passed unanimously. Kyle Mulder (Protech Services LLC), Andy Ciupek (Andy Testing and Consulting Inc.), Dave Phillips, Dennis Miller (Associated Air Balance and Certification,

Inc.) and Bob Jones (after the meeting) volunteered to serve on the task group. If any other Steering Committee members or interested parties would like to serve on this task group, please notify Maren Roush at mroush@nsf.org upon receipt of this meeting summary.

Language Translation / International Issues

NSF's Accreditation Program continues to grow overseas. As of the date of this meeting summary (September 2013), a fourth practical examination proctor has been added to the roll. His name is Y K Wan and he is located in Hong Kong.

Since type B cabinets are uncommon outside of North America, not only do NSF's international customers have to overcome (in most cases) a language barrier in order to successfully complete the written examination, but they are also evaluated on equipment that they rarely, if ever, encounter in the field. NSF does offer test-only services across its various programs. If a field certifier would like to take the practical examination (without the written examination), or would like to demonstrate proficiency in a subset of practical examination tests, NSF will assist him or her in securing those services. The end result of the abbreviated tests would not be an Accreditation, but a certificate of proficiency, clearly labeled to list those individual tests that were successfully completed.

There was support during the meeting for establishing a "not valid in North America" Accreditation Program that would not involve testing type B cabinets.

New Business

NSF has been asked to update the data sheets utilized by students and proctors during practical examinations. New data sheets will be posted on the internet when they are available. Bill Sage from NSF offered to begin a review of the data sheets and propose updates based on other comprehensive data sheets that have been developed and maintained internally for NSF Certification testing of biosafety cabinet models. These NSF Engineering Laboratory data sheets are markedly different than the Accreditation Program's data sheets and, in the opinion of NSF staff, easier to use. If any other Steering Committee members or interested parties would like to assist with this task, please notify Maren Roush at mroush@nsf.org upon receipt of this meeting summary.

Jeff Smith requested that NSF establish a deadline following which NSF Accredited field certifiers may no longer certify type A cabinets with canopy connections if they do not have alarms. He explained that the memorandum prepared by Tom Bruursema in 2011, explaining that alarms for canopy connections are recommended for cabinets in the field (to bring them into compliance with the current requirements of NSF/ANSI Standard 49), does not include strong enough language to sway the opinions of some customers, who choose not to retrofit their machines.

Some meeting participants suggested that field certifiers attach the original memorandum as an addendum to their companies' test reports and require that any customers choosing to ignore the alarm requirement sign off on the memo.

Ken Barkley proposed that the group ask NSF to write an updated letter stating that, now that a couple of years have passed since the alarm requirements were added to NSF/ANSI Standard 49, a new deadline of 12 months from the date of the new letter be established. Dave Phillips seconded that motion and it was approved unanimously.