

Meeting Summary
Steering Committee, NSF International Biosafety Cabinet Field Certifier Accreditation Program
Orlando, Florida
October 22, 2012

Introduction

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

Steering Committee Membership

Ms. Roush provided the group with a list of the current Steering Committee members and discussed the three main stakeholder groups used both for this Steering Committee and for NSF's general standards development activities. The three stakeholder groups include users, manufacturers, and public health officials. The Steering Committee has traditionally considered users of Accredited field certifiers to be de facto "public health officials", since there are no overarching federal requirements for NSF Accreditation. Instead of regulatory requirements, NSF Accreditation may be listed as a requirement/preference in RFPs issued by individual facilities or entities.

The current Steering Committee membership includes five users, seven manufacturers (four equipment manufacturers and three field certifiers), and one regulatory official. The group discussed the unique nature of the Accreditation program, and questioned whether it would make better sense to have four major stakeholder groups: users, equipment manufacturers, field certifiers, and regulatory officials (in which case the current ratio stands at 5:4:3:1). Whether three stakeholder categories are maintained or a fourth one is added, it is important to balance the group to ensure that all stakeholder interests are well represented.

Even within the equipment manufacturer category, there is a wide variety of technological expertise to be addressed. For example, it is important that the Steering Committee include representation from biosafety cabinet manufacturers, since their products are maintained by Accredited personnel, but it is equally important to have expertise related to HEPA filter design, construction, and performance, which in this case is provided by Gene Klingbeil (Filtration Group, Inc.).

Ideas for increasing regulatory / public health membership on the Steering Committee included adding representatives from NIOSH, NIH, and CDC. Dave Phillips (Thermo Fisher Scientific) suggested asking ABSA to send someone to Steering Committee meetings as a representative for their organization, especially since there is a similar ABSA liaison to CETA. Finally, it was recommended that representatives from The Eagleson Institute and Agape Instrument Services be offered the opportunity to apply to serve on the Steering Committee, since their training programs are well-integrated with NSF's Accreditation testing procedures.

Currently, there are no term limits for individuals serving on the Steering Committee, nor is there a quorum requirement. After discussion, there was support for requiring that Steering Committee members be able to attend the semiannual meetings in person (within reason, and giving consideration to the limited availability of travel funds for some, illnesses, family emergencies, etc.). Steering Committee members may be asked to step down from the committee if they miss three consecutive votes. In addition, it was suggested that Steering Committee members sign an affidavit of interest in remaining on the committee every three years.

Stephen Dahl (Johns Hopkins Institutions) proposed capping the Steering Committee membership at 20.

The membership ideas discussed above will be reviewed with the Steering Committee members and balloted prior to the next meeting.

Practical Examination Proctors

NSF recently reopened and reviewed its Standard Operating Procedure for the approval of practical examination proctors for the Accreditation Program. Ms. Roush described the requirements for proctors, which included:

- They must pass both the written and practical examinations for Accreditation;
- They may not maintain a personal NSF Accreditation (as it could pose a conflict of interest);
- They must have completed double blind studies with approved proctors; and
- They must sign an ethics statement.

The related SOP can be forwarded to Steering Committee members for review/comment, upon request.

Written Examination Rewrite - Update

The recent subcommittee review of more than 400 written examination questions has been completed and the database of questions has been updated accordingly. The database will continue to be updated over time, as NSF/ANSI Standard 49 and other relevant standards evolve.

Electrical Troubleshooting – the written examination still includes electrical testing and troubleshooting questions even though references within the Standard were removed (there is a task group that is currently looking into adding language back to Annex F). Because of this, NSF/ANSI Standard 49 – 1992 will remain an allowed open book reference during the written exam.

HEPA filter patching requirements – the most recent version of NSF/ANSI Standard 49 added a list of acceptable materials for use when patching leaks. The Steering Committee recommended reviewing the written examination questions again to ensure that none need to be updated as a result. If there aren't yet questions related to acceptable patch materials, one or more should be added.

Written Examination – Issues Related to Translation/Foreign Languages

The Steering Committee voted to allow professional translators during written examinations, provided that individuals providing translations are relatively unfamiliar with biosafety cabinet field certification procedures (i.e. they should provide strict translation services) and are hired by NSF or its subcontractor. In addition, because it takes longer to translate questions and read them aloud (as opposed to English-speaking candidates who can simply read the written examination questions in their heads), non-English speaking candidates will be given additional time to complete their written examinations. NSF will examine how long it takes to read a couple of questions and their answers and multiply it by the total number of questions in order to determine how much additional time will be offered.

Program References / Materials for Written Examination

Bill Peters (NuAire, Inc.) volunteered to review the Industrial Ventilation document (“Testing of Ventilation Systems”) to ensure that the written examination questions related to it are still current.

CETA's Troubleshooting Guide was written around 1992. However, it is still a useful helpful document. The group recommended that it be scanned and made publicly available/downloadable from either CETA's website or NSF's. NSF will approach CETA to discuss this action item further.

It was recommended that individual Steering Committee members volunteer to monitor the recommended study materials on an ongoing basis. At each meeting, they should come prepared to update the group on any recent updates to their documents.

NSF should provide more transparent information regarding which open book materials are allowed during written examinations. All previous versions of NSF/ANSI Standard 49 are permitted, along with a copy of the NSF Accreditation policies. Mr. Roush assured the group that this information would be posted on the Accreditation Program website, along with a list of recommended study materials.

New Business – Chlorine Dioxide Decontamination

Dennis Miller (AABC Testing) described some issues he had experienced with CD decontamination and asked whether NSF/ANSI Standard 49 addresses material compatibility. Mr. Peters explained that material compatibility is detailed in Annex K, section 5, of the standard. Material compatibility studies should demonstrate that at least 10 decontamination cycles performed on a cabinet lead to no deleterious effects on the equipment's functioning and at most limited cosmetic issues.

Mr. Miller emphasized that the method of CD introduction to the cabinet being disinfected can have an impact on materials (see NSF/ANSI Standard 49, section G.1.3.2.1). He described his experience in which the "bomb" method for CD negatively impacted a downflow diffuser made of anodized metal. His solution to this problem was to remove the diffuser prior to sealing the cabinet and disinfecting it. He recommended that Annex G be revised to include introduction methods for decontamination agents, since Injection location and methodology are essential to the success of a given decontamination procedure. Ms. Roush will pass this recommendation along to NSF's Standards development group.

Recommended Study Materials

Many sincere thanks to ENV Services for providing the following list of study materials for the written examination:

1. [Treatment of Gaseous Effluents at Nuclear Facilities, Chapter 2-Removal of Airborne Particles.](#)
 - a. [Read 2.2 A Brief History of the Development of Nuclear Aerosol Treatment Technology \(7 Pages\)](#)
 - b. [Read 2.3 Development of Filter Test Methods in the USA \(3 Pages\)](#)
 - c. [Read 2.4.3 Filtration Mechanisms \(4 Pages\)](#)
 - d. [Read 2.5 Construction and Service Characteristics of HEPA filters \(5 Pages\)](#)
2. [IEST-RP-CC013-86-T \(10 pages\) Now version 2](#)
3. [Industrial Ventilation, Chapter 9 – Testing of Ventilation Systems](#)
 - a. [Read 9.1 through 9.4 \(17 Pages\) Review Latest Version](#)
4. **Selections from NSF/ANSI 49-2002, Or 2011 Version as the new written is based upon that one.**
 - a. Section 1 – General (1 Page)
 - b. Section 3 – Definitions (7 Pages)
 - c. Section 5 – Design and Construction (7 Pages)
 - d. Section 6 – Performance (4 Pages)
 - e. Annex A – Performance Tests (40 Pages)

- f. Annex B - Method to verify fitness for use of potential direct inflow measurement devices (1 Page)
- g. Annex E – Recommendations for Installation (9 Pages)
- h. Annex F – Field Tests (13 Pages)
- i. Annex G – Recommended Microbiological Decontamination Procedure (3 Pages)
- j. Annex H - Recommended materials, finishes, and construction (2 Pages)
- 5. (4th BMBL) We should review the 5th Edition**
 - a. *Sections I to III (53 Pages)*
 - b. *Section VII-D: Prions (14 Pages)*
 - c. *Appendix A – Primary Containment – Biological Safety Cabinets (14 Pages)*
- 6. IEST-RP-CC001-3 (23 Pages)**
- 7. NSF Accreditation Policies (20 Pages)**
 - 8. Selections from NSF 49-1992
 - a. Section 2 – Definitions (6 Pages)
 - b. Section 4 – Design and Construction (11 Pages)
 - c. Annex F – Field Tests (19 Pages)
- 9. OSHA’s Bloodborne Pathogen Standard (13 Pages)**
- 10. OSHA’s Formaldehyde Standard (12 Pages)**
- 11. Selections from CETA’s Troubleshooting Guide**
 - a. Section 2 – Airflow Rates and Proper Balance (5 Pages)
 - b. Section 4 – Noise and Vibration (1 Pages)
 - c. Section 5 – Motor and Speed Controller Systems (7 Pages)
 - d. Section 7 – Electrical Safety (2 Pages)
 - e. Section 10 – Unique Troubleshooting Problems with Cabinets (3 Pages)