Meeting Summary Steering Committee NSF International Biosafety Cabinet Field Certifier Accreditation Program Kansas City, Missouri October 21, 2013

Introduction

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

Jyl Burgener (Grifols) attended the meeting via phone conference. The rest of the meeting participants, both Steering Committee members and other interested parties, are noted in the sign-in sheet (attached). The minutes from the last meeting were approved.

Membership

Stephen Dahl (Johns Hopkins) made a motion that the Steering Committee define a quorum of 50 percent. This motion was seconded and was approved unanimously. In addition, Mr. Dahl recommended that the committee seek to have each of the four major stakeholder groups — users of biosafety cabinets, field certifiers, manufacturers, and public health representatives - represented at all meetings.

Stephen Dahl provided a summary of the Membership Task Group's activities. Four new applications for membership on the Steering Committee were submitted between April 2013 and October 2013. The committee has room to add these new members without giving one stakeholder group a disproportionately high level of representation. All four applicants were accepted as new members of the Steering Committee.

Only one of the applicants - Bob Jones (Eagleson/formerly with The Baker Company/NSF practical examination proctor) - was present. Therefore, the names of the other new members were not announced at the meeting. NSF would like to welcome Chandler Papas (C-Scan Technologies), Dennis Miller (Associated Air Balance and Certification), and Kyle Mulder (ProTech Services) to the Steering Committee, along with Bob Jones, who was welcomed in person at the October Steering Committee meeting.

The Steering Committee still seeks additional participation from the regulatory community. Stephen Dahl offered to reach out to NIH, CDC and other similar organizations for new committee members. Mr. Dahl will update the rest of the Steering Committee on these efforts via email in the months to come.

There was support for holding future Steering Committee meetings during daytime hours, possibly during lunch breaks at the annual American Biological Safety Association (ABSA) and Controlled Environment Testing Association (CETA) conferences, as opposed to the traditional evening meetings. This will better enable Steering Committee members who do not have funds or approval to travel to participate in the meeting via conference call. It is hoped that this option will serve regulatory members of the committee well.

The Steering Committee unanimously approved a motion to request that members step down if they miss three consecutive meetings (not attending the meetings in person or via phone). This policy is in effect starting with the October 2013 meeting.

Decontamination Test

Dave Phillips (Thermo Fisher Scientific) and Bob Jones agreed to head up a new task group to develop practical examination test procedures for decontamination. This new test will replace the pressure leak test, in response to a motion that was passed at the April 2013 Steering Committee meeting. Mr. Phillips and Mr. Jones will provide email updates on their efforts between now and the next Steering Committee meeting in April 2014. Other individuals who volunteered to assist with this effort at the April 2013 meeting included Andy Ciupek (Andy Testing and Consulting Inc.), Kyle Mulder, and Dennis Miller.

Mr. Phillips proposed having a 15 minute update on this issue at the next CETA meeting so that NSF can obtain input from CETA's members, who perform the bulk of BSC decontaminations in the field. Nick Flynn (B & V Testing) also suggested communicating with the CETA membership via the publication, *Performance Review*. If the Decontamination Test Task Group can forward some basic information to him, he will get the information on the radar.

Data Sheets

A task group was formed at the April 2013 meeting to review and revise the data sheets that are publicly available on the NSF website to be used as references by field certifiers, if so desired. Bill Sage (NSF International) and Todd Urton (Agape Instrument Services) have initiated work in this area, exchanging their companies' basic report formats with one another. More work still needs to be done in this area. Dave Phillips and Stephen Williams (NSF) volunteered for this task group moving forward.

International Clients

The Accreditation Program continues to grow internationally and with this growth comes a set of difficult questions about the intended audience of the program and how to best level the playing field when international clients face additional obstacles such as language barriers and high travel expenses to attend test sessions. One of the largest challenges facing international clients of the Accreditation Program is the lack of type B biosafety cabinets available to train on outside of North America. This is critical because accreditation candidates must submit a minimum of five test reports from type B cabinets with their application to NSF just to qualify to take the Accreditation examinations. Later, candidates are evaluated on type B cabinets during their practical examinations. If a field certifier has little experience with type B cabinets going into the NSF tests, he or she is at a considerable disadvantage.

Those present at the October 2013 Steering Committee meeting disagreed on the prevalence of type B cabinets overseas. Bob Jones, who travels extensively worldwide to provide training, said that he rarely runs across type B cabinets. Bill Peters (NuAire, Inc.) said that there are hundreds of type B cabinets in China. Jim Hunter (Labconco Corporation) supported this assertion and said that there are a considerable number of type B cabinets in Japan as well. Mr. Peters told the group about a Brazilian

standard that requires type B cabinets to be used with tuberculosis samples. Ken Waterhouse (ENV Services) explained that even U.S. based field certifiers can have a difficult time gaining experience with type B cabinets if they service a rural area, but explained that they make allowances to travel to areas with type B cabinets in order to further their professional development.

Maren Roush explained that NSF already has the capability to offer individuals test-only services, such as evaluating candidates on the practical examination only (excluding the written examination which is only available in English), or offering a truncated practical examination, including only tests that apply to type A cabinets. This would not be a path to NSF Accreditation, but NSF could provide customers with certificates of proficiency in the tested areas. Bob Jones countered that in his opinion, these individuals do not want certificates. They want NSF Accreditation.

Bob Jones suggested offering two tiers of Accreditations: the traditional NSF Accreditation and one that is tailored to international customers who will likely see only type A cabinets in their daily work. Nick Flynn suggested that this may lead to confusion regarding the different NSF Accreditations. Will some companies misrepresent their qualifications (i.e. certify type B cabinets and represent themselves as NSF Accredited in this area, when they were only evaluated by NSF on type A cabinets)? Would it be beneficial to offer a certificate for this second tier of Accreditation, instead of an official website Listing? There was general concern, both at this meeting and at previous Steering Committee meetings, about the potential for "dilution of the brand".

Nick Flynn reminded the group that all field certifiers seeking NSF Accreditation are currently evaluated on their ability to pressure test biosafety cabinets and perform secondary tests. Yet these same individuals may not perform these tests in the field for many years after they are Accredited.

Dave Phillips suggested that all North American field certifiers Accredited by NSF should be tested on both type A and type B cabinets, as has traditionally been done, but further stated that it may be possible that to have offer type A only Accreditations in other countries. There was support for this idea, but the group remained divided. Stephen Dahl suggested calling the new, international Accreditation an "NSF Restricted Accreditation". Jim Hunter built on this idea by suggesting the following categories: "Unlimited Accreditation" (required for North American field certifiers) and "Restricted Accreditation" (i.e. restricted to type A cabinets only).

Before discussing a new Accreditation offering further, Bill Peters suggested conducting a survey to gauge interest in a type A only Accreditation Program. Stephen Dahl suggested coupling this with data mining replacement parts shipped overseas to determine the prevalence of type B cabinets in different regions of the world. Bob Jones, Bill Peters, Jim Hunter and Dave Phillips agreed to work together to gather this information.

The meeting was adjourned. The next meeting of the Steering Committee for the NSF Biosafety Cabinet Field Certifier Accreditation Program will take place in conjunction with the next CETA meeting in April 2014. Time and meeting location are TBD.



SIGN IN SHEET

Biosafety Cabinet Field Certifier Accreditation Program Steering Committee Meeting October 21, 2013 from 5:30 to 7:00 p.m.

Name	Company ,	Email Address	SC Mem	ber (<u>Y/</u> N)
1. Nick Flynn	BHU Testing In	C. Rick. Flynn	obandutesting con	(NO)
2. Stephan Dahl	Johnstodin Bio	sall Solahla	2'hu.edy	_(Yes)
3. Allan Bull				
4. ISILI PETERS	White The	breters	muaire, com	NES
5. There William	~s NSF			(10)
6. Jim Huntz	en LABCONEO	Jh mot	Erelabconco, a	m Ys
7. Dave Phillip				fisher con
8. GENERLIN	GBEIL AAF IN	UTL GILLING	beil OMFINTL	. am
9. KEN WATE	ERHOUSE ENV	SELVICES"	KNAMERHOUSERS	Mishim
10. TERRY LEWI	s lewistesfin	g terry@le	wistesting.com	ع عر الله
11. Bob Tones		1 bobjene	s @ Metro instruct	
12. Leslie Ma	rckay (su	gried by	m. Rough)	
13. Jul Burge	ener (phos	re in		
14.			- 100	
15				
16				
17				
18				
19				<u> </u>
20	·			
21				
22				
23				_
24				_
25		•		