Summary of the TNI CONSENSUS STANDARDS DEVELOPMENT BOARD (CSD) MEETING February 2, 2007 Denver Forum on Laboratory Accreditation

Ken Jackson commenced the meeting by welcoming participants and reviewing TNI meeting ground rules, and the CSD Board members gave self-introductions.

Ken reviewed the composition of the CSD Board as defined by the TNI By-laws. The Board is essentially a continuation of the former INELA Standards Coordination Committee. Ken also noted that the Board had identified the need for the formation of two ad hoc committees – one for Standard Policy Development and Review and another for Uniformity of Standards. Volunteers are being sought for these two ad hoc committees.

At the present the Expert Committees (EC) are managing the TNI standards development process for Interim Standards (IS) modules for On Site Assessment, Accreditation Body and Field Activities. Quality Systems and Proficiency Testing have modules in the Working Draft Standard (WDS) stage. Each Expert Committee Chair gave a brief overview of the work or their committee.

Field Activities:

This Committee has produced two Interim Standards – General Requirements for Field Sampling and Measurement Organizations, and Accreditation Body Requirements for Field Sampling and Measurement Organizations. These modules will be subject to TNI membership vote this spring. Next steps for the Committee are to develop guidance documents and policies to support the implementation of the standards.

Proficiency Testing:

This Committee has four modules under development. At the Denver Forum, many verbal comments were provided on the WDS, primarily on Volumes 3 and 4 for PT providers and PT oversight. Additional comments can be submitted until February 19.

Quality Systems:

This Committee has six modules, all in WDS status. Most comments raised at the Denver Forum were new issues, so it appears major problems identified in last year's review have been resolved. Substantive new issues have not been raised to date. Additional comments can be submitted until February 19.

On Site Assessment:

The Volume 2 On Site Assessment module is in Interim Standard status and will be voted on by TNI membership this spring. The Committee focused their Forum meeting on the identification of other activities that can be undertaken, and working cooperatively with other committees as needed.

Accreditation Body:

The Volume 2 General Requirements module is in Interim Standard status and will be voted on by TNI membership this spring. The Committee worked through its updated charter and identified next steps. Many items have been pulled from Chapter 6 of the NELAC standard and need to find new homes. The Committee plans to work with the Laboratory Accreditation Committee on that exercise.

Procedures for Expert Committee Operations document:

Ken reviewed the purpose of the document. This material was taken from the former INELA Standards Development Policies, and it is the procedures that define the operation of meetings to ensure openness. Ken reminded meeting attendees that all TNI members are associate members, and can participate in all Expert Committee meetings. Schedules for EC meetings will be posted on the TNI website with information on how to request information on participating in the meeting as a sufficient number of call-in lines need to be reserved in advance. Minutes of each Expert Committee meeting will also be posted on the website following approval by the Committee.

Comments offered on the document included a review of 2.4 for the specificity of the date requirements. Bob DiRienzo noted that Chairs need discretion and flexibility to add new members at any time of the year. It was agreed that the document could be approved as is, and revisited at the next Forum in Cambridge. Martin Tait moved to accept the document and was seconded by Sharon Mertens. The motion passed unanimously.

Next Steps:

Ken invited comments from the meeting participants regarding proposed next steps for the CSD Board.

Steve Stubbs of Texas asked whether TNI plans to submit the TNI standards modules for approval as ANSI standards (recognized by American National Standards Institute). He noted that ANSI status makes it easier for his state to recognize consensus standards in regulation. Ken noted that TNI has not made that decision as of yet, and will consider it once the pending appeal of ANSI accreditation status has been decided. Ken suggested that the CSD Board should seek the input of other Accrediting Authorities on this topic.

RaeAnn Haynes of Oregon asked whether the CSD Board should be expanded such that it represents a coordination of all consensus activity within TNI. Other Committee Chairs could benefit from a greater understanding of consensus processes. Alfredo Sotomayor suggested that this is an issue that would be better addressed by the Policy Committee.

George Detsis of DOE asked where TNI is in the process of replacing the 2003 NELAC standard. Will pieces of the NELAC standard be retired as TNI modules are completed, or will the standard be replaced in its entirety when the TNI standard is completely finalized? Ken noted that the goal is to replace the 2003 NELAC standard with the TNI

standard, but the timing of this is a topic for consideration by the NELAP Board. As pieces are completed they can also be adopted for use by other organizations.

Several participants asked whether the collection of TNI modules will be considered to be a single standard or multiple stand alone documents. If it is considered one standard, there are some issues with conflicting definitions. Ken noted that the Expert Committees were using the ISO definitions wherever possible. The CSD Board also has a role in ensuring consistency across modules – this will be a responsibility of the Uniformity of Standards Committee. The intent is to pull terms into a separate glossary that applies to all the modules. The same term should not be used in different ways among the modules. Alfredo noted that it depends on which ISO document is being used. ISO 17025 has its own list of definitions, and there is also ISO 17000, which is a general glossary. Carl Kircher of Florida DOH volunteered for the Uniformity of Standards Committee.

Participants had further discussion on whether the TNI documents will be considered one standard or a series of standards. Besides the practical consideration of consistency across modules, management of multiple revision dates is another challenge. A need for a Committee "roadmap" of the TNI structure and organization was noted.

JoAnn Boyd reviewed the decision to withdraw the Accreditation Process module as a standard, and its conversion to a guidance document. Stakeholders have recognized the need for this guidance, but NELAP policies and procedures need to be established that will impact the content of the guidance document. The guidance is premature until NELAP and other committees have their operations in place. Questions arose in other committee meetings regarding whose responsibility it is to write these types of documents. It was also discussed whether the guidance documents should be provided as part of the standard, or a separate publications. It was also noted that the perspective of small business should be considered in overall costs of the program.

The meeting was adjourned at 10:00 am.

BOARD REPRESENTATIVES PRESENT:

Ken Jackson (Chair), Jane Wilson (Program Administrator), JoAnn Boyd (Accreditation Process); Martin Tait (Field Activities); Alfredo Sotomayor (On-site Assessment); Anand Mudambi (Proficiency Testing); Robert Di Rienzo (Quality Systems); Sharon Mertens (Accreditation Body)