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SUMMARY OF THE
TNI
ON-SITE ASSESSMENT COMMITTEE MEETING

NOVEMBER 21, 2006

The On-Site Assessment (OSA) Committee of The NELAC Institute (TNI) met on November 21, 2006 at 12:00 PM (ET) by teleconference.

Chairperson Mr. Alfredo Sotomayor, of the Wisconsin Department of Natural Resources, led the meeting. A list of participants is given in Attachment A. A list of the action items generated during this meeting and uncompleted items from previous meetings is included in Attachment B. The meeting agenda is given in Attachment C.

WELCOME TO TNI

Mr. Sotomayor welcomed all members to the TNI On-Site Assessment Committee. He offered a brief summary of the activities that took place at the Summit in Chesapeake leading to the formation of TNI. The TNI Transition Board of Directors retained all Directors from the Institute for National Laboratory Accreditation (INELA) and the National Environmental Laboratory Accreditation Conference (NELAC) Boards. Several programs have been established under TNI: Advocacy, Technical Assistance, the National Environmental Laboratory Accreditation Program (NELAP), Laboratory Accreditation System, Proficiency Testing (PT), and Consensus Standards Development (CSD).

Recognition of Accreditation Bodies falls under NELAP, which is composed of recognized Accrediting Authority representatives and has its own Board. Other functions necessary for maintaining a viable accreditation program are under the purview of the Laboratory Accreditation System Program. The CSD Program incorporates the standards development worked done under INELA. The OSA Committee is part of the TNI CSD Program.

Elizabeth Ziomek, from the Virginia Department of Environmental Quality (DEQ), joined the TNI OSA Committee. Marlene Moore became a committee associate. Mr. Sotomayor had approached another candidate for membership and expected to receive a decision by the next OSA meeting.

COORDINATION COMMITTEE MEETING

The chairs of the CSD Program committees met on November 16 and discussed progress made in addressing the comments received during balloting. The Field Activities Committee had addressed all the comments it received. During the meeting, modifications were made to the template devised for consolidating actions to comments. The documents that Mr. Sotomayor distributed before the teleconference contained the modifications approved by the Coordination Committee. The Accreditation Body, On-Site Assessment, and Field Activities Committees are

required to post responses to comments. The Quality System and Proficiency Testing Committees will produce a new Draft Interim Standard.

DISPOSITION OF COMMENTS RECEIVED

The committee continued reviewing the comments received during the voting process considering the input received at the Kansas City Forum. Mr. Sotomayor had integrated the responses already formulated by the committee into the template designed by INELA staff.

VOLUME 1, MODULE 2

Comments 3, 7, 19, and others:

The commenters offered that the module contained many requirements that applied to accreditation bodies and felt that those clauses should not be part of the Laboratory Volume.

The committee noted that the accreditation body provisions of the module were included to inform laboratories of them, in accordance with the direction given to the committee at previous meetings. However, the decision made by the committee to combine both modules into a single one in the Accreditation Body Volume would resolve the concerns of all commenters.

Comment 2:

The commenter requested an editorial change to the first sentence of Section 1.0.

The committee concurred with the suggestion and agreed to make the language in the combined module reflect that the Standard was based on ISO/IEC 17011.

Comment 13 and others:

The commenters were concerned that the language in clauses 3.7 (a) and 5.2 were not clear as to whether initial assessments were announced. One of the commenters requested that all initial assessments be announced.

The committee decided previously that it would change the standard to make all initial assessments be announced.

Comments 15, 16:

The commenters requested that the committee avoid the term CAB and to refrain from using acronyms and abbreviations.

The committee is bound to use ISO 17011 language and cannot change the terminology and editorial style of the ISO standard.

Comment to Note on Clause 6.1.4:

The commenter requested a clarification of the meaning of past capabilities of a laboratory to perform work of known and documented quality. The commenter suggested reviewing systems to evaluate the capability of a laboratory to perform work of known and documented quality since the last on-site assessment.

The committee disagreed with the suggestion and did not want to limit the examination of systems to the last two year period, reasoning that there could be legitimate grounds for examining systems before that period of time.

Comment on Clause 6.3.1:

The commenter felt that advising a laboratory about the right to declare information confidential would undermine the transparency of an accreditation program.

The committee noted that the standard did not automatically grant confidentiality, but required advising laboratories of their right to make a claim of confidentiality for evaluation by the accreditation body. The committee agreed to retain the clause as written.

Comment on Clause 7.3.2:

The commenter felt the clause limited an assessor's ability to educate a laboratory.

The committee felt that the note explained the type of education and support that assessors could offer without engaging in consultancy. ISO 17011 has strict prohibitions about assessors engaging in consultancy. The committee agreed to retain the clause as written.

Comment on Clause 7.5.3:

The commenter noted that the clause did not offer a timeline for responses to assessment findings.

The committee agreed with the comment and noted that the timeline was established in V2 M3. Combining the two modules will resolve the issue.

Several Additional Editorial Comments:

The commenters felt that the committee should review the text for usage of "mandatory" language and noted several typographical errors.

The committee agreed to review the combined module for use of "mandatory" language and will forward the final version of the module to the Chair and Program Manager of the CSD Program for editorial review.

VOLUME 2, MODULE 3

General Comment on Requirements for Assessors

The commenter felt that the education and training requirements for assessors, combined with the need to be supervised during at least one assessment was burdensome.

The committee noted that the requirements for supervised assessments had been scaled down from those mandated by the NELAC standard. The committee did not agree that these requirements were unduly burdensome and offered that accreditation bodies had flexibility on how to provide training for its assessors.

Comment 1, Clause 3.7:

The commenter asked whether the assessments referenced in the clause were the only ones that could be performed and requested clarification on how the different types of assessments were related.

The committee noted that those were the types of assessments recognized in ISO 17011 and that the notes were included to clarify the purpose of the different assessments and how they were related. The committee made modifications to the clause responding to other comments.

Comment on Clause 4.2:

The commenter felt the clause did not clearly indicate who would be considering scope of accreditation.

To clarify the meaning of the clause, the committee agreed to divide the sentence in two: “The accreditation body shall have documented procedures for assigning assessors to laboratories. Such procedures shall consider the scope of accreditation and the complexity of the operations of the laboratories.”

Comment on 4.7:

The commenter proposed a “performance-based” approach to assessor training because the stated requirements did not add value to the quality of data or could conflict with “union-approved” job descriptions.

The committee disagreed with the comment and noted that many accreditation bodies had met similar or more stringent requirements.

Several Editorial Comments:

The commenters felt that the committee should review the text for usage of “mandatory” language and noted several typographical errors.

The committee agreed to review the combined module for use of “mandatory” language and will forward the final version of the module to the Chair and Program Manager of the CSD Program for editorial review.

NEXT STEPS AND CONCLUSION

Mr. Sotomayor will finalize the response to comments document and will forward it to the committee in time to make a decision on it by December 4. The combined OSA module will be reviewed by the committee at the December 12 meeting. Mr. Sotomayor will forward both documents to Dr. Kenneth Jackson by December 13.

The committee will meet again on December 12 at 12:00 Noon (ET). The meeting was adjourned at 1:25 PM (ET).

**PARTICIPANTS
TNI
ON-SITE ASSESSMENT COMMITTEE
NOVEMBER 21, 2006**

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**INELA
ON-SITE ASSESSMENT COMMITTEE MEETING
NOVEMBER 21, 2006**

ACTION ITEMS GENERATED AT THIS MEETING

Item No. Meeting Date	Action	Date to be Completed
1. 11/21/06	Mr. Sotomayor will forward the completed Response to Comments Document to the Committee.	11/27/06
2. 11/21/06	The Committee will make a final decision on the Response to Comments Document.	12/04/06
3. 11/21/06	Mr. Sotomayor will produce a combined OSA module incorporating the approved changes.	12/11/06
4. 11/21/06	The Committee will endorse the combined OSA module	12/12/06

UNCOMPLETED ACTION ITEMS FROM PREVIOUS MEETINGS

Item No. Meeting Date	Action	Date to be Completed
2. 09/12/06	The committee will vote on the persuasiveness of all comments received on the draft interim standard.	11/22/06
1. 11/01/06	Mr. Sotomayor will integrate the responses the committee has formulated to the comments considered into the master document provided by INELA staff.	11/21/07

The NELAC Institute (TNI)
On-Site Assessment Committee
November 21, 2006
12:00 – 1:25 am (ET)

AGENDA

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| 12:00 | Attendance |
| 12:05 | Welcome to TNI |
| 12:10 | Minutes of November 1 Meeting; Action Items
Coordination Committee Meeting |
| 12:15 | Disposition of Comments Received |
| 1:20 | Next Steps |
| 1:25 | Adjournment |