**SUMMARY OF
THE NELAC INSTITUTE
ON-SITE ASSESSMENT COMMITTEE MEETING
February 1, 2007**

The On-Site Assessment (OSA) Committee of The NELAC Institute (TNI) met on February 1, 2007, at 3:30 PM (MT) at the Westin Tabor Center, Denver, CO.

Chairperson Mr. Alfredo Sotomayor, of the Wisconsin Department of Natural Resources, led the meeting. A list of committee members is given in Attachment A. The meeting agenda is included in Attachment B.

Introductions and Committee Activities since Kansas City Forum

The committee members introduced themselves to the audience.

After the Kansas City meeting the committee reviewed once more all the comments received with the ballots and determined whether they were persuasive. The committee published its response to the comments and made the agreed changes to the module.

John Gumpper and Elizabeth (Betsy) Ziomek were accepted as new committee members.

Highlights of Changes to the OSA Module

The committee received 54 comments and 31 of them were considered persuasive triggering changes to the module. The module is now an interim standard and is ready for a final vote of endorsement by the membership. No further changes can be made to the module before the final vote. The following were the most notable changes the committee made to the module.

- Following the direction of the membership and the votes received, the committee consolidated the former two on-site assessment modules into a single one that is now part of the Accreditation Body Volume.

- The committee reinforced that all notes in the module are non-prescriptive and are used to clarify or provide examples. At the request of the committee, an explanation on the purpose of the notes was added to all TNI Standard Modules.

- The committee modified *Clause 4.2.4* to read that assessors must be trained in *all* technical disciplines they assess. The note on the clause was added to clarify what constituted technical disciplines. The committee reviewed the disciplines defined in the 2003 NELAC Standard and consolidated them into eight major technical disciplines.

- The committee modified Note 2 in *Section 3.7 a)* to specify that initial assessments had to be announced. After modifying the note, the committee discovered that the State of Virginia requires all assessments

- to be unannounced. An attendee also remarked that the specification to make initial assessments announced was in a note and thus could not be strictly required. The committee will discus this item during the next module revision cycle.

Future Activities of OSA Committee

The committee feels its module is fairly complete and requested feedback on activities, beyond standards development, that it could undertake during this year. The committee prepared a list of suggested activities knowing that many of them would require cooperation with other programs or committees and that some should be referred to other programs or committees. Attendees were asked to determine whether the suggested activities should be undertaken by TNI and to be less concerned about the specific committee or program that could complete the activity.

Activities were grouped into general categories. The number of attendees that favored each idea included along with the total number of attendees present at the session during the discussion. A summary of comments offered follows ideas discussed by the audience.

I.   *Training for Assessors (The Getting of Wisdom)*

    1.   Develop curricula of technical courses for assessors   Vote-12/17

       Courses could be reviewed and endorsed by TNI which would improve consistency across various training programs. Theory and practical training were considered important for these types of courses and the desire to avoid becoming checklist assessors was stressed.

    2.   Revise curricula of basic training course for assessors   Vote-8/17

       Past training reviewed the standard thoroughly. A new course will need to be developed (based on ISO 17025) to follow the new standard. Participants agreed that an assessor should assess not only to the quality system, but also to data quality and methodology. A section of training should emphasize standard operating procedures (SOPs) and methods, and dealing with data packages, as well as how to interview staff, gather information, and use data in the process of assessing. Basic Assessor courses should be an introduction to assessment and not be overly technical. It was also noted that basic training is difficult to find and courses should be scheduled so as not to overlap.

    3.   Develop prototype exams for basic and technical courses   Vote-8/17

    4.   Develop a TNI endorsement procedure for assessor training courses Vote-8/17

       A commenter noted that TNI had to be careful about endorsing specific technical courses and not to exclude vendors. Accreditation bodies

should determine if a course is acceptable and useful. It was emphasized that any course should train to the standards. An attendee emphasized the need to be liberal with endorsements at first and that TNI could become more exclusive as courses became more prevalent.

5. <u>Conduct an electronic forum for assessors</u> Vote-3/17

II. Tools for Assessors *(If I Had a Hammer)*

1. <u>Write a model SOP on how to perform on-site assessments</u> Vote-14/21

   An attendee offered that, with the exception of the standard, the most important priority of this committee should to write an SOP and manual for on-site assessments.

2. <u>Establish an electronic bulletin for assessors</u> Vote-6/21

   This would be a newsletter, possibly on the TNI website. Some concerns shared included receiving contradictory answers to questions posed and the lack of resolution when issues arise. It was also noted that the Laboratory Accreditation Committee has been asked to develop an SOP for standards interpretation which could aid in the resolution of contradictions.

3. <u>Draft a manual for assessor</u> Vote-10/21

   See item 1 for comments

4. <u>Develop a standard template for on-site assessment reports</u> Vote-11/21

5. <u>Author a "Meet your Assessor" column</u> Vote-0/21

6. <u>Author a "Dear Abby" column for assessors</u> Vote-1/21

7. <u>Conduct a survey for assessors on the effectiveness of assessment process</u> Vote-7/21

8. <u>Compile a list of tips on how to assess to specific requirements</u> Vote-6/17

9. <u>Establish a repository of method checklists</u> Vote-13/17

III. Assessors' Interactions (Getting to Know You)

1. <u>Sponsor an assessors conclave</u> Vote-4/19

2. <u>Establish a mentoring program for assessors</u> Vote-9/19

3. Sponsor a program for assessors to observe other peers conducting assessments Vote-12/19

4. Sponsor workshops on targeted topics for assessors Vote-13/19

5. Facilitate a residency program at Federal or State agencies for assessors Vote-6.5/19

   A member of the audience requested a plan for funding these programs and the committee reminded the audience that these were only initial ideas for further investigation.

IV. Tools for Laboratories and Other Ideas (Sometimes a Great Notion)

1. Conduct a survey for laboratories on the effectiveness of the assessment process Vote-11/19

2. Develop guidance about on-site assessments for laboratories Vote-7/19

3. Develop checklist for conducting internal audits for laboratories Vote-8/19

4. Revise Quality Systems checklist No Vote

   The committee decided that it would not continue to have this responsibility and noted that the current NELAP Board had assumed this activity.

5. Offer an "assessor of the year" award Vote-0

6. Establish a national registry for assessors Vote-0

7. Record oral history of assessors Vote-0

8. Review AB on-site assessment SOPs for consistency Vote-5/19

Next Steps

The comments and information gathered will be used by the committee to prioritize its activities. The committee will communicate with other concerned and appropriate committees and programs to refer or develop the ideas.

Adjournment

The meeting was adjourned at 4:55 (MT).

Members
TNI
On-Site Assessment Committee
February 1, 2007

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The NELAC Institute
On-Site Assessment Committee
Consensus Standard Development Program
Forum on Laboratory Accreditation
Thursday, February 1, 2007
3:30 –5:00 PM

3:30   Welcome, Introductions, Logistics

                     Committee Activities since Kansas City Forum

3:35   Current Status of OSA Module

                     Highlight of Changes to OSA Module

                     --Single AB OSA Module
                     --Technical Training for Assessors
                     --Redefinition of Technical Disciplines
                     --Initial On-Site Assessments
                     --Nature of Notes in the Module
                     --Others

4:00   Future Activities of OSA Committee

                     Introduction

                     Discussion and Feedback from Attendees

                     --Training for Assessors
                     --Tools for Assessors
                     --Assessors' Interactions
                     --Tools for Laboratories and Other Ideas

                     Summary

4:55   Next Steps

5:00   Adjournment