

**1SUMMARY OF THE
INELA
ON-SITE ASSESSMENT COMMITTEE MEETING**

OCTOBER 16, 2006

The On-Site Assessment (OSA) Committee of the Institute for National Environmental Laboratory Accreditation (INELA) met on October 16, 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.

ANNOUNCEMENTS AND BRIEF UPDATE ON SELF SUFFICIENCY EFFORT

The Partnership Planning Team continues to meet and has completed the first draft of a report that is now being considered by the Boards of INELA and the National Environmental Laboratory Accreditation Conference (NELAC). The PPT also completed the revisions to the INELA Bylaws. The report also identifies core programs of the new organization and proposes a structure for each one. The PPT received comments from the NELAC Accrediting Authority (AA) Task Group. It is expected that the two Boards will have additional suggestions for the report. Once these are considered, a final version will be available for distribution electronically.

Mr. Sotomayor also mentioned that the process for forming the new organization required that all existing committees be reconstituted. New committees will also be formed.

DISPOSITION OF COMMENTS RECEIVED

The committee continued reviewing the comments received during the voting process considering the input received at the Kansas City Forum. The comments were reviewed in the order in which they were discussed in Kansas City.

VOLUME 1, MODULE 2

Comment 8: Clause 3.7a

The commenter wanted to make all initial assessments to be announced assessments.

The committee remarked that this was a note and it should not contain requirements. To require that initial assessments be always announced, clause 5.2 would have to be amended.

The committee considered the practicality of performing an unannounced initial assessment and noted that an accreditation body (AB) would not likely choose that option. Mr. Donald Cassano offered that if an AB needed to conduct an unannounced visit to a laboratory before granting it accreditation, the AB could perform an unannounced "surveillance" on-site assessment or an

“extraordinary” on-site assessment. The committee also noted that laboratories applying for the first time would not have a certificate to operate. The application process would allow ABs to not proceed to the on-site evaluation if they felt a laboratory was not or could not be in substantial compliance with a standard.

The committee agreed with the intent of the comment and recommended amending section 5.2 to require initial on-site assessments to be announced and to make the note at “3.7a” reflect that.

Comment 9: Clause 4.1.3 NOTE

The commenter wanted to ensure that should a team need to terminate an assessment because a previously unforeseen conflict of interest had arisen, that the accreditation body would assign another team within a time frame that would not jeopardize the laboratory’s request for certification.

The committee commented that the note contained mandatory language. After some discussion on the intent of the note and the comment received, the committee recommended changing the text of the note into a clause, and to add a note under the new clause regarding the timeliness of the appointment of a new assessment team, should it be necessary to select another assessment team. Mr. Sotomayor will provide draft language for the new note.

Comment 10: Clause 4.2.1 NOTE

The commenter offered that it was not appropriate for assessors to offer recommendations and suggested deleting the introductory part of the statement.

The committee felt that the commenter was confusing recommendations made by the assessment team during an assessment, and the recommendation that an assessment team might offer an AB on the accreditation status of a laboratory. The intent of the note was to clarify that in some ABs the assessors are also the deciders of the accreditation status of a laboratory. To convey this information more clearly, the committee recommended eliminating the first part of the last sentence. The last sentence would read: “In many accreditation bodies, assessment team members can also be responsible for deciding the accreditation status of a laboratory.”

Comment 12: Clause 5.1

The commenter requested altering the language to indicate that reassessments, not initial assessments, occurred at two year intervals, since an initial assessment could only happen once. The commenter also added that other types of assessments could happen, if warranted.

The committee agreed with the sentiment expressed by the comment. Ms. Denise Rice suggested changing the first sentence of the clause to read: “After an initial assessment for accreditation, accreditation bodies perform reassessments at intervals of two years plus or minus six months.”

Comment 14: Clause 6.1.2

The commenter wanted to limit the reasons used by laboratories to object to an assessor assigned to a team.

The committee did not wish to list the reasons that could be used for objecting to an assessment team. The committee felt that the note associated with the clause warning ABs and laboratories not to abuse the process for raising objections, should address the implied concern in the comment. The committee recommended declaring the comment not persuasive.

Comment 17: Clause 6.1.4

The commenter inquired whether the clause allowed assessors to narrow the scope of an assessment.

The committee recommended retaining the clause as written because it and the accompanying note specified selecting systems, methods, and activities commensurate with the complexity of laboratory operations. The text did not imply that an assessment scope could be narrowed, but rather indicated that the scope of the assessment had to be in harmony with the accreditation scope of a laboratory.

NEXT STEPS

The committee will meet again on November 1 at 12:00 Noon (ET). At the next meeting, the committee should finish discussing the comments and should start making the necessary textual changes.

CONCLUSION

The meeting was adjourned at 1:25 PM (ET).

Attachment A

**PARTICIPANTS
INELA
ON-SITE ASSESSMENT COMMITTEE
OCTOBER 16, 2006**

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ACTION ITEMS GENERATED AT THIS MEETING

Item No. Meeting Date	Action	Date to be Completed
1. 10/16/06	Mr. Sotomayor will provide preliminary language for a note addressing the timeliness of the appointment of a new assessment team when a raised objection is sustained.	11/01/06

UNCOMPLETED ACTION ITEMS FROM PREVIOUS MEETINGS

Item No. Meeting Date	Action	Date to be Completed
2. 04/11/06	Mr. Sotomayor will develop a master document for tracking comments received and the committee's decision on them.	06/27/06
2. 09/12/06	The committee will vote on the persuasiveness of all comments received on the draft interim standard.	11/22/06

INELA
On-Site Assessment Committee
October 16, 2006
12:00 – 1:25 am (ET)

AGENDA

- 12:00 Attendance
- 12:05 Announcements, Update on Self-Sufficiency Efforts
- 12:15 Disposition of Comments Received
- 1:20 Next Steps
- 1:25 Adjournment