

**Onsite Assessment Expert Committee Meeting
January 27, 2010
Chicago Forum on Laboratory Accreditation**

Committee members present:

Denise Rice, Chair
Don Cassano (via teleconference)
John Gumpfer
Nilda Cox

Denise welcomed the participants and introduced the Expert Committee members. She reviewed the agenda for the meeting.

After completion of the Onsite Assessment Module (V2M3), the committee has developed three guidance documents:

- 1) The laboratory assessment module from NELAC 2003 has been converted into a guidance document.
- 2) Appendices A and B from NELAC 2003 have been converted into guidance documents for the basic and technical assessment training.

Denise reviewed the committee's plans for another round of laboratory and assessor surveys. The surveys were first performed a couple years ago but didn't get a very good response. The committee is interested in a range of responses from the bench chemist to the lab director. Analysts don't typically attend this conference so this is another way to get input from that level. Historically the committee wanted to start the surveys when the NELAC standard was still in place to create a baseline for comparison after implementation of the TNI standard. The committee also wants to understand the assessor view point to use for future refinement of the TNI standard.

The committee plans to send the surveys around March 1 for a period of 45 days. Denise indicated they are trying to collect email lists for the relevant audience in order to achieve a better response to this version. It will be an on-line survey for ease of completion and compilation of the responses and responders do not have to be a TNI member to fill it out.

Audience Question: Are the previous survey responses available for review? Denise responded that due to the low response rate the committee was not sure of the bias of the responses and didn't make the results publicly available.

Audience Question: For an onsite assessment, the attendee's lab was supplied with checklists for each method – did these come from TNI? Most likely the checklists came from the state doing the assessment. These types of tools are often shared among the NELAP states. Florida has a comprehensive list that is publicly available. Oregon also has these types of checklists.

Checklist Development for V2M3

Denise explained that at the TNI summer 2009 meeting, it was determined that each expert committee should develop any checklists that are appropriate for their assigned modules. The Quality Systems Committee was already working on a draft for the QS modules, and the OSA committee looked at the QS format in addition to looking at the old version for the NELAC 2003 standard. The newer QS checklist format was preferred as the spreadsheet had additional columns of information.

Denise began development of the checklist by including everything from the V2M3 standard. Some of the requirements could function as reminders, such as reminders to conduct opening and closing meetings. The checklist could also be used by assessment teams evaluating ABs.

Denise reviewed column headings on the spreadsheet, including “section”, “compliance”, “comments”, etc.

Denise asked for feedback on whether to include the Section 1 material (introduction and informational statements) in the checklist. Quality Systems is likely to remove this same type of material since it wouldn't be used as part of the assessment. Having it in the checklist may result in the user not reading the actual standard as well as the checklist. Another option is to include the material as information, but not as a functional part of the checklist. It was also noted the checklist does have ISO language in it and labs don't routinely have access to ISO 17011 for accreditation bodies. A straw vote was tied on whether to take it out. The committee elected to keep it in at this time.

Denise noted that she did not include V2M3 Sections 2 and 3 (references and terms/definitions) in the checklist. Participants agreed on not including these sections.

Section 4 Requirements:

4.1.1 Number of assessors requirement – participants discussed if and how this can be assessed

4.1.2 Procedures for assigning assessors – keep in checklist

4.1.3 Making duties and authorities accessible – keep in checklist

4.1.4 AB requirements for confidentiality and conflict of interest – keep in checklist

4.1.5 AB requirements for contractors for confirming commitments before first assessment and changes in rules pertaining to CABs. This requirement is not relevant all the time – an example would be if state regulations change – keep in checklist

4.2.1 The participants discussed whether to leave the material as all one entry or to split it on separate lines. Denise proposed leaving space for recording the activities. It was also suggested to clarify what is meant by an activity. The AB has to establish what they

consider to be adequate training. Assessment activities are provided in standard. Activity generally refers to activity in the laboratory. Method preparation is one area of focus and it was noted that it is difficult to identify assessors with experience in a broad range of disciplines. The disciplines are listed in 4.2.4 and the laboratory guidance document breaks it down further. Labs should follow up with AB if they feel the assessor does not have the appropriate expertise. Denise offered that OSA could be a starting point for a dispute resolution process. The committee will also keep an eye on what comes out of TNI Policy Committee for complaint resolution. The OSA committee could provide regular feedback to ABs on the types of issues being raised.

4.2.2 AB must have procedures of qualifying experts as assessors – keep in checklist

4.2.3 Assessors must have a BS or relevant experience – keep in checklist

4.2.4 Specific qualifications of assessors for courses/exams they have to take for qualification. These courses are generally available from EPA, etc. – keep in checklist (include the note as well)

4.2.5 Minimum requirements to be able to assess on their own – keep in checklist (Note should probably be removed.)

4.2.6 This item is assessable – keep in checklist

4.2.7 Reference to required languages and appropriate personal attributes (part of assessor training). It was suggested to insert those attributes in the checklist from ISO 19011. The committee should consider how to approach this and the intention is not to require users to have to buy another ISO standard. A2LA requires documents in English by policy. Some states may have requirements about assessments in multiple languages. The committee will leave this requirement in the checklist for the time being. They will consult with Jerry and possibly Marlene Moore about the ISO reference and use of language requirements.

4.3 Records on assessments

4.3.1 The subsections appear to be assessable. It was suggested to leave the note in as a reminder to assessors.

4.3.2 This is assessable – keep in checklist

4.3.3 and 4.3.4 Conflict of interest issues (also reference 4.4.2 below)

4.3.5 Consultancy to lab, etc. Keep in checklist but delete the Note as not relevant to checklist.

4.4 Professional conduct

4.4.1 Competitive position – keep in checklist.

4.4.2 List of prohibited activities and performances – all need to be in there. The participants discussed how to assess this as it's trying to prove a negative. It goes back to the conflict of interest statement. Ways to assess include review of documentation of training on the issue (ethics training) and direct questioning of these requirements.

4.4.3 The assessment team shall note and report any regulatory violation. Some ABs give assessors the authority to stop operations if there are violations. The participants agreed this is not a requirement that needs to be assessed, so it can come out of the checklist.

5.0 Frequency

Both sections 5.1 and 5.2 are assessable – keep in checklist.

6.0 Process Review

6.1 AB has to review itself for competency and create a record – keep in checklist.

6.2 Subcontracting - split this into two parts. Assess it as the subcontracting decision and the other requirements. Leave the Note and Note 2 in the checklist.

6.3.1 Preparation for assessment. The participants recommended adjusting the text to split the requirements. This refers to preparation of the team as a whole rather than an individual assessor.

6.3.2 Assessors shall act in a non-discriminatory manner (redundant to 4.3.5, etc.) The committee should look at how to consolidate these sections. The specific wording could be removed here with a note that requirements are the same as item 4.3.5. Leave the introductory sentence and then note the rest is covered by the records section.

6.3.3 Notification of identification of assessment team – can delete the note in checklist as not appropriate to the checklist.

6.3.4 The participants discussed whether this is assessable. The second sentence is assessable as it defines the task for the assessment team. Denise asked which approach is preferred – include everything from the standard or just checklist/auditable material. Or it could be split into two separate lines.

6.3.5 Sampling here is used in the context of the assessment is a sampling of the records, etc. Delete the Note but reference that it is in the standard.

6.3.6 Would these activities apply to 4.2.1? This doesn't include all the activities and is referring to different activities than previously described. Leave note 1 but delete note 2 from the checklist.

6.3.7 The Note can be deleted from checklist.

6.3.8 Scheduling of the assessment – keep in checklist. The Note can be deleted.

6.3.9 Assessable – keep in checklist.

6.4 Document and record review

6.4.1 Is this redundant to the previous 6.3.4? It was recommended to leave it in this section and delete it from 6.3.4.

6.4.2 This is assessable – keep in checklist but delete the note.

6.5 Documents Provided to CAB

6.5.1 The participants recommended just having list and deleting the definitions of the documents to consolidate this item.

6.6 CBI – keep in checklist.

6.7 It isn't clear how to define the length of the assessment – keep in checklist but delete the Note.

6.8 Opening conference. The Note on additional items could be deleted and will be in the standard.

6.9 Assessment activities – keep both parts but the Note can be deleted.

The participants stopped review at item 6.10 of the checklist.

Denise noted the need to clarify that this checklist is for auditing AB onsite activities.

Denise is handing over the Chair of the OSA committee in August to John Gumpper.