

**Summary of the Laboratory Accreditation Body Expert Committee Meeting  
Forum on Laboratory Accreditation, Albuquerque, NM  
Monday, January 22, 2018 1:00 pm MT**

**1. Welcome and Roll Call**

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The committee remains balanced, with two each lab and AB stakeholders and four “others.” More members are needed, with an additional lab or AB stakeholder being priority.

**2. Review of Revised ISO 17011 with TNI Language Inserted**

Carl provided session attendees with a printed document showing all of the TNI language (from the combined V2M1&M3 module previously approved) and displayed portions of the text of the revised ISO/IEC 17011 with the TNI language inserted on screen for participants to consider. He focused on sections thought most likely to benefit from stakeholder input, and included some discussion of new concepts and terms in the restructured 17011 document. The individual sections are itemized below, and comments from the discussion are summarized for each section.

*Clause 7.9 – Accreditation Cycle*

Clause 7.9.1 – Accreditation Cycle (described, <= 5 years)

The concept of accreditation cycle replaces use of the terms surveillance assessment and reassessment. As the ISO language is written, there is no leeway for the plus/minus six months that NELAP ABs have previously used, since some assessment technique must be performed by the two-year mark of the accreditation cycle. Assessment techniques are elsewhere defined, but include review of PT results, document reviews and other sub-sets of what we consider a full assessment.

Consider adding a new sub-section to address the reporting and corrective action parts of the accreditation cycle (and possibly other items now removed from 17011.)

Be sure that all requirements for the laboratory are placed into Volume 1 as soon as possible, but no later than the next V1 revision cycle.

Clause 7.9.2 – Assessment Program (AB applies to each accredited lab)

Each lab must have an individual assessment program that covers activities for the five-year accreditation cycle (or less.) The AB is expected to consider risk management when designing this assessment program, for each lab, so that not every assessment program will be identical but rather customized for the laboratory and its activities and the AB’s judgement about the level of risk to be controlled or managed.

Clause 7.9.3 – Sampling during a lab assessment

Essentially, the former surveillance assessments are replaced by “other assessment techniques.” The TNI note carried from V2M1 7.7.2 was placed here – one AB asked that the phrase “among other things” be deleted and that

the term surveillance (which no longer has a definition in the revised standard) be replaced (with “assessment technique,” probably.)

Also, there was a request that the plus/minus six months be written into the TNI language here. This is the first use of “assessment technique” (use of techniques other than on-site documented, achieve same objectives as on-site, and justified.)

#### Clause 7.9.4 – Reassessments (description, purpose, content requirements)

§7.9.4.1 (inserted TNI language) -- The NELAP ABs formed consensus around having reassessments be required on or before the 3 year time period, and prefer the two-years-plus-or-minus-six-months language that stands for NELAP now. There were no strong objections to the need to apply other assessment techniques prior to the two-year timeframe, just some dissatisfaction.

7.9.4.2 (inserted TNI language) – eliminate reference to surveillance and just refer to the assessment report (general agreement on this.)

7.9.4.3 (inserted TNI language) – while the main clause seems appropriate, a suggestion was made that the note might belong elsewhere. One suggestion was that it could be in section 3.10 of the old V2, wherever that fits)

#### Clause 7.9.5 – Use of Extraordinary Assessments

Reword the note to say that “examples of changes triggering extraordinary assessments could include ....”

#### *Presentation of the appropriate definitions (Clause 3)*

#### Clause 3.22 – Assessment (plus TNI Note)

Eliminate the term surveillance in the note. Remove the number 2, since there is only one note present. Perhaps as examples of an extraordinary assessment, include items that might formerly have triggered a surveillance assessment. Remove the term follow-up assessment, since that is just another variant of an extraordinary assessment. Verify that surveillance and follow-up terms are not carried over into other sections of TNI language. Modify extraordinary assessment to encompass full or partial assessment. Note that reassessment has its own definition elsewhere.

Consider deleting the entire note and having all further details go into the ABs’ assessment programs (there was consensus around this last idea.)

#### Clause 3.23 – Reassessment

See comment on 3.22

#### Clause 3.24 – Assessment Techniques

These are ISO examples of options that the AB can use along with, or in lieu of, the usual on-site assessments that most ABs currently use.. NOT a TNI note.

### Clause 3.25 – Witnessing

This could be watching the method run for a PT sample – it is one specific assessment technique.

### Clause 3.26 – Remote Assessment

Just document how and why the AB is using remote assessment techniques and justify the equivalence to a physical site visit.

Clauses 3.8 and 4.6 – Accreditation Scheme – should the TNI standard seek to define the NELAP accreditation scheme or leave that to NELAP to define for itself?

NELAP, PT, NGAB, NEFAP are all accreditation schemes, as is drinking water certification in non-NELAP states, plus the Defense Department and Energy Department accreditations. One commenter noted that the TNI language within ISO 17011 defines the NELAP accreditation scheme sufficiently.

Perhaps a Note 2 to 3.8 should say that TNI ELSS Volume 1 defines the NELAP accreditation scheme?

To meet clause 4.6.3, ABs could simply add a sentence to their quality manual saying that they implement the NELAP accreditation scheme.

### *Continuation of concepts & solicitation of participant feedback*

Clause 7.4.4 – AB documented procedures to assess labs, plus assessment techniques to be used

The note is in the correct place, but should be unnumbered.

Clause 7.4.5 – “sample of conformity assessment activities” and “sample of locations and personnel”

Keep the note, as edited

Clause 7.4.7 – AB develops the assessment plan and assessment techniques to be used (could vary by lab!)

Suggest writing into the plan the opportunity to modify it if warranted. Departure from the plan would need approval from the AB itself. Make the note a requirement (“shall have”) and move it to 7.6.3 or 7.6 somewhere.

Clause 7.6.1 – AB describes assessment techniques used, circumstances when they’re used, and rules for on-site assessment durations

No comments offered.

Clause 7.6.3 – OSA conducted based on the assessment plan

7.6.3.1 – fits better under 6.2.2. Also would prefer that it apply to others beyond assessors. Be clear that assessors are included.

7.6.3.3 – specify a blank checklist or eliminate the checklist. About a “standard form?” What if a non-standard form is used? How does one transfer the checklist/form from a tablet computer used to record the site visit observations? Consensus was to remove section b from the TNI language part (b is about checklists.)

Clause 7.10 – Extending accreditation (AB documented procedures, appropriate assessment techniques to apply, adjustment in the lab’s assessment program for the subsequent reassessment)

No additional comments.

Clause 7.14.3 – Additional TNI language

This section should apply to assessments, not reassessments. Timing should be previous two assessment cycles. ABs prefer that it be a specific number of years. Several ABs noted that their state laws or regulations may direct that records be retained (or destroyed) in a timeframe different than that is specified in this TNI language, and that they will have to comply with state requirements, so this language should be revised to state that the minimum time is either what the state specifies or the ISO language.

In closing, Carl noted that he still plans to review comments from development of the 2006/2009 TNI standard for parking lot issues, and that the committee should review Chapter 6 of the 2003 NELAC standard since those issues were never addressed in the TNI 2009 standard.

Carl thanked everyone for their involvement and invited all participants to join in the LAB Expert Committee calls.

### 3. **Next Meeting**

The next teleconference meeting will be **Tuesday, February 20, 2018, at 1:00 pm Eastern.** An agenda and documents will be distributed prior to the meeting.

## Attachment A

## LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
William Batschelet <a href="mailto:Batschelet.william@epa.gov">Batschelet.william@epa.gov</a>	12/31/18	Other – US EPA R8, Lab QAO	No
Oommen Kappil okappil@emsl.com	12/31/19	Lab – EMSL Laboratories, Inc.	No
Catherine Katsikis <a href="mailto:ckatsikis@ldcfl.com">ckatsikis@ldcfl.com</a>	12/31/2018	Other – Laboratory Data Consultants	Yes
Carl Kircher, Chair <a href="mailto:carl_kircher@flhealth.gov">carl_kircher@flhealth.gov</a>	12/31/2018	AB – Florida Department of Health	Yes
Marlene Moore <a href="mailto:mmoore@advancedsys.com">mmoore@advancedsys.com</a>	12/31/2018	Other -- Advanced Systems, Inc., Newark, DE	No
Mei Beth Shepherd <a href="mailto:mbshep@sheptechserv.com">mbshep@sheptechserv.com</a>	12/31/2018	Other -- Shepherd Technical Services	Yes
Aurora Shields <a href="mailto:ashields@lawrenceks.org">ashields@lawrenceks.org</a>	12/31/2018	Lab – City of Lawrence, KS	No
Program Administrator: Lynn Bradley <a href="mailto:Lynn.Bradley@nelac-institute.org">Lynn.Bradley@nelac-institute.org</a>	N/A		Yes
<b>Associate Members:</b>			
Nilda Cox <a href="mailto:nildacox@eurofinsus.com">nildacox@eurofinsus.com</a>		Lab – Eurofins Eaton Analytical Inc.	Yes
Yumi Creason <a href="mailto:ycreason@pa.gov">ycreason@pa.gov</a>		AB -- Pennsylvania	No
June Main <a href="mailto:jmain@dep.nyc.gov">jmain@dep.nyc.gov</a>		Lab – NYC DEP	No
Donna Ruokonen <a href="mailto:donna.ruokonen@microbac.com">donna.ruokonen@microbac.com</a>		Lab – Microbac	No
Bill Ray <a href="mailto:bill_ray@williamrayllc.com">bill_ray@williamrayllc.com</a>		Other – William Ray Consulting, LLC	Yes