Summary of the Laboratory Accreditation Body Expert Committee Meeting
Tuesday, August 6, 2018 Environmental Measurement Symposium, New Orleans, LA

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The minutes of July 17, 2018, were approved with a correction to the date of the next teleconference meeting.

2. Review of Selected Sections from the Outline of Proposed Changes

From Section III of the draft outline, Carl led the committee and audience participants through a discussion of individual sections of the 2004 version of ISO 17011 that will be omitted in the new revision. The specific sections and the consensus after discussion are itemized below.

V2M1, 4.2.6 – ok to omit

V2M1, 5.1.2 – the 2017 version is moving away from mandatory documentation; this could just be a training process. Several NELAP ABs supported being required to have documentation as stringent as that required by labs

V2M1, 6.1.3 (and V2M3, 4.1.3) – this was moved to Annex A in 2017 version (informative)

V2M1, 6.2.3 (and V2M3, 4.2.6) – currently use matrix and technology. If this section is eliminated, a detailed table may not be required. (LAB for now retains the "note" from old V2M3 but relocated it)

V2M1, 6.2.4 (and V2M3, 4.2.7) – covered by other language

V2M1, 6.4.2 (and (V2M3, 4.3.1) – same comment as 6.2.3

V2M1, 7.4.2(c) – a and b are covered in 2017 version

V2M1, 7.10.2 – confidentiality requirements are beefed up in Clause 4 of 2017 version

V2M1, 7.10.3 – 2017 version requires "records" (7.14.1) and it's up to each AB to determine what records need to be kept to ensure the ability to demonstrate that accreditation process was consistent and verified

V2M1, 7.11 – all of this language is in V2M2; the new V2M1 should make some reference to the PT module

V2M1, 8.1.1(d) – move reference to national database to new 8.2.2

V2M1, 8.2.1 – ok to omit

V2M1, 8.2.2 -- ok to omit

V2M1, 8.3.2(b&d) – one NELAP AB requests to keep this language in the standard – LAB to determine whether 4.3 of 2017 version is adequate

V2M3, 4.3.5 – 2017 language is better

V2M3, 4.4.1 – found in 4.4.6 of 2017 version

V2M3, 6.3.2 – found in 2017 version

V2M3, 6.9.1 – the "old" language conflicts with assessment plan description in "new" revision. The assessment plan can require an initial on-site; new language allows more options

V2M3, 6.9.2 – omit including note; witnessing (observation) is one of the possible assessment technologies

V2M3, 6.12.3 – the specific language should be omitted. Marlene requested input on "flexible scopes of accreditation" and stated that these are used by NGABs. For instance, a lab would apply for GC/MS accreditation, and provide validation procedure, then could be accredited for any method/analyte detected by GC/MS. LAB needs to rule this possibility in or out. Suggestion made that it might help with SW 846 method versions

Additional topics raised:

There could be an additional accreditation scheme for Good Laboratory Practices (as used by EPA pesticides and toxic substances as well as some FDA programs, and internationally/OECD)

Discussion followed, with no resolution, about whether the standard itself is the accreditation scheme, or the program operations using the standard. Presently, the Chair believes that the revised V1 will not define an accreditation scheme for NELAP

If the standard is to be the accreditation scheme, do some of the 2003 NELAC requirements need to be brought back into the standard?

Following that discussion, the committee and audience reviewed portions of 2003 NELAC language that were dropped for the 2009 TNI standard, to determine whether they should be brought back into this revision. Comments validated the LAB committee's earlier decision that the language of NELAC sections 6.2.1 and 6.2.2, inclusive, do not belong in the V2M1 revision. Language from NELAC sections 6.3 and 6.4 does not belong in the ISO standard, but is adequately replaced by the NELAP evaluation SOP and related policies.

A brief attempt to review Standard Interpretation Requests was aborted when participants realized that the language of the incoming question and the approved response were not available for discussion.

Several historical "parking lot" issues were raised, per section VI of the draft outline of proposed changes. Participants agreed that automation issues are adequately addressed in language about remote assessments, and a discussion about the wording of "failure to pass" an assessment was undefined and that the phrasing should refer to non-compliance with requirements of the standard; this language should be included in Volume 1 so that labs can see it, as well. Sections 7.7.5 and 7.11.1 define not meeting the requirements for accreditation in the 2017 version of ISO 17011. Also, the revised V2M1 should keep the note (formerly 7.8.1.h) about encouraging ABs to upload CAB fields of accreditation into LAMS.

3. Next Meeting

The next teleconference meeting will be **Tuesday, September 18, 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 Batschelet.william@epa.gov	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 catherinekatsikis@gmail.com	12/31/2018	Other – Laboratory Data Consultants	Yes
Carl Kircher, Chair carl_kircher@flhealth.gov	12/31/2018	AB – Florida Department of Health	Yes
Marlene Moore, Vice Chair mmoore@advancedsys.com	12/31/2018	Other -- Advanced Systems, Inc., Newark, DE	Yes
Alia Rauf arauf@utah.gov	12/31/2020	AB – Utah Department of Health	Yes
Mei Beth Shepherd mbshep@sheptechserv.com	12/31/2018	Other -- Shepherd Technical Services	Yes
Aurora Shields ashields@lawrenceks.org	12/31/2018	Lab – City of Lawrence, KS	Yes
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Nilda Cox nildacox@eurofinsus.com		Lab – Eurofins Eaton Analytical Inc.	Yes
Yumi Creason ycreason@pa.gov		AB – Pennsylvania	No
Charles Hartke Charles.hartke@sgs.com		Lab -- SGS Accutest, Dayton, NY	Yes
June Main jmain@dep.nyc.gov		Lab – NYC DEP	No
Zaneta Popovska zpopovska@anab.org		AB – ANSI-ASQ National Accreditation Board	Yes
Bill Ray bill_ray@williamrayllc.com		Other – William Ray Consulting, LLC	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No

Attachment B – Draft of Outline After May 15 Meeting (used for review at this meeting)

OUTLINE OF CHANGES TO TNI ELS VOLUME 2, MODULES 1 AND 3 (V2M1 and V2M3)

I. ISO/IEC 17011:2004(E) REPLACED BY ISO/IEC 17011:2017(E)

Terms DELETED from the 2004-version ISO/IEC 17011:
- Accreditation Certificate
- Surveillance

NEW Terms Defined in the 2017-version ISO/IEC 17011:
- Conformity Assessment Activity
- Flexible Scope of Accreditation
- Accreditation Scheme
- Accreditation Activity
- Impartiality
- Accreditation Process
- Accreditation Decision
- Granting Accreditation
- Maintaining Accreditation
- Reassessment
- Assessment Techniques
- Remote Assessment
- Assessment Programme
- Assessment Plan
- Accreditation Body Personnel

Legal Entity (4.1): similar to 2004-version Sec. 4.1, but adds "legal responsibility" for accreditation activities

Accreditation Agreement (4.2): similar to 8.1 Obligations of the CAB

Additions:
- 4.2(e) (AB has access to CAB's client site(s))
- 4.2(g) (CAB follows AB's policy on use of accreditation symbol)
- 4.2(k) (CAB assists in the investigation of complaints about the CAB's performance)

Essentially unchanged:

2017 version	2004 version
4.2(a)	8.1.1(a)
4.2(b)	8.1.1(b)
4.2(c)	8.1.1(c)
4.2(d)	8.1.1(e)
4.2(f)	8.1.1(f)
4.2(h)	8.1.1(g)
4.2(i)	8.1.2 (and V2M3, 7.0)
4.2(j)	8.1.1(h)

Use of Accreditation Symbol; Claims of Accreditation (4.3): similar to 8.3 in previous version

Additions:
- 4.3.1(e): AB makes sure that CABs inform affected clients of suspension/reduction/withdrawal of accreditation
- 4.3.2: If AB has an accreditation symbol, it shall be legally protected
- 4.3.3(a)-(f): Minimum elements of AB policy on accreditation symbol use and CAB claims of accreditation status specified

Essentially unchanged:	2017 version	2004 version
	4.3.1(a)	8.3.2(a)
	4.3.1(b)	8.3.2(c)
	4.3.1(c)	8.3.2(e)
	4.3.1(d)	8.3.2(f)
	4.3.3	8.3.1
	4.3.4	8.3.1
	4.3.5	8.3.3

Impartiality Requirements (4.4): NEW and REINFORCED REQUIREMENTS

4.4.1: accreditation undertaken impartially
4.4.2: AB responsible for impartiality, organized so as to provide accreditation impartially
4.4.3: top management committed to impartiality, AB documented policy on impartiality
4.4.6: AB process to deal with risks to impartiality
4.4.7: AB eliminates or minimizes risks & documents any remaining residual risks
4.4.8: AB top management determines if any residual risks are acceptable risks
4.4.9: AB does not provide accreditation if unacceptable risks cannot be mitigated to acceptable levels

Areas of reinforcement:	2017 version	2004 version
	4.4.4	4.3.4
	4.4.5	4.3.2
	4.4.10	4.3.3
	4.4.11	4.3.6
	4.4.12	4.3.7
	4.4.13	4.3.6

Financing and Liability (4.5): essentially the same as the existing 4.5

Establishing Accreditation Schemes (4.6): REVISED (2004-version Sec. 4.6: "Accreditation Activity")

Structural Requirements (5):	2017 version	2004 version
	5.1	4.2.1 & 4.3.1
	5.2	4.2.8
	5.4	4.2.3
	5.5	4.2.2
	5.6	4.2.4
	5.7	4.2.5
	5.8	4.2.7

Resource Requirements (6): NEW REQUIREMENTS

6.1.1: competence of personnel for the accreditation scheme and operating region
6.1.2.1: documented process for determining & documenting competence criteria
6.1.2.2: knowledge of assessment principles & practices, and general management systems
6.1.2.3: knowledge of AB's rules & processes, accreditation scheme requirements, conformity assessment scheme requirements
6.1.2.4: knowledge of risk-based assessment principles
6.1.2.5: knowledge of general regulatory requirements
6.1.2.6: knowledge of CAB business environment, communication skills, reporting skills, opening/closing meeting skills, interviewing skills, assessment management skills
6.1.2.8: competence to evaluate assessment outcomes

6.1.2.9: additional criteria for specific accreditation schemes
6.1.3.3: identify training needs & giving access to specific training
6.2.3: up-to-date documented procedures for providing assessment instructions

Essentially unchanged:	2017 version	2004 version
	6.1.3.1	6.2.1 (and V2M3, 4.2.1)
	6.1.3.2	6.2.2 (and V2M3, 4.2.2)
	6.1.3.4	6.3.1
	6.1.3.5	6.3.2
	6.1.3.6	6.3.2
	6.2.1	6.1.1 and 6.1.2 (and V2M3, 4.1.1)
	6.2.2	6.1.4 (and V2M3, 4.1.4)
	6.3	6.4.1
	6.4	7.4
	6.4.1	7.4.1 (and V2M3, 6.2)
	6.4.2	7.4.1 (and V2M3, 6.2)
	6.4.3	7.4.1 (and V2M3, 6.2)
	6.4.4	7.4.1 (and V2M3, 6.2)
	6.4.5	7.4.2
	6.4.5(a)	7.4.2(a)
	6.4.5(b)	7.4.2(b)
	6.4.5(c)	7.4.2(d)
	6.4.6	7.4.3

Process Requirements (7): MANY NEW REQUIREMENTS

7.2.3: AB rejects CAB application if evidence of fraudulent behavior or submittal of false information
7.4.4: AB documented procedures to assess CAB confidence sufficient to provide confidence in the conformance with the scheme
7.4.6: Assessment activities selected considering risk
7.4.7: AB develops assessment plan, and AB justifies where witnessing is not applicable
7.6.1: AB develops documented procedures for describing the assessment techniques used
7.6.3: Assessment is conducted according to the assessment plan
7.6.6(c): Written explanation provided if written outcome of assessment differs from outcome communicated at the closing conference
7.6.8: AB defines time limits for corrective actions, and requires CAB to determine extent & cause of nonconformities
7.7.1: AB describes the accreditation process for all types of schemes
7.7.3(i): Information to be reviewed includes the further information needed after the initial review
7.8.2: accreditation effective date is the date of or after the accreditation decision
7.8.3: scope of accreditation for testing laboratories
7.8.4: flexible scopes of accreditation
7.9: "accreditation cycle" replaces the current concepts of "surveillance and reassessment" (2004-version Sec. 7.11 (V2M1, 7.7 and V2M3, 6.13))
7.10 Extending accreditation: expanded requirements, AB documented procedure (2004-version Sec. 7.12 (V2M1, 7.8) is closest equivalent)
7.11.2: CAB accreditation withdrawn if evidence of fraudulent behavior or submittal of false information
7.11.3: AB documented procedures and criteria for lifting suspensions
7.12 Complaints: requirements revised to match the similar requirements for Appeals (2004-version Sec. 5.9 is closest equivalent)
7.13 Appeals: requirements greatly expanded upon (2004-version Sec. 7.10 (V2M1, 7.6) is closest equivalent)
7.14.2: AB documented policy/procedure on records retention, >= current & previous accreditation cycles

Essentially unchanged:	2017 version	2004 version
	7.1	7.1.1
	7.2.1	7.2.1
	7.2.2	7.2.2 revised
	7.2.3	7.2.3
	7.2.4	7.5.1
	7.3.1	7.3.1 (V2M1, 7.3.1 & V2M3, 6.1.1)
	7.3.2	7.3.2 (V2M1, 7.3.2 & V2M3, 6.1.2)
	7.4.1	7.5.2 (V2M3, 6.3.1)
	7.4.2	7.5.4 (V2M3, 6.3.3)
	7.4.3	7.5.5 (V2M3, 6.3.4)
	7.4.5	7.5.6-7.5.8 (V2M3, 6.3.5-6.3.7)
	7.4.8	7.5.9 (V2M3, 6.3.8)
	7.4.9	7.5.10 (V2M3, 6.3.9)
	7.5.1	7.6.1 (V2M3, 6.4.1)
	7.5.2	7.6.2 (V2M3, 6.4.2)
	7.6.2	7.7.1 (V2M3, 6.8)
	7.6.4	7.8.1 (V2M3, 6.10.1)
	7.6.5	7.8.2 (V2M3, 6.10.2)
	7.6.6(a)	7.8.3(a) (V2M3, 6.11.1(a))
	7.6.6(b)	7.8.3(b) (V2M3, 6.12.1 + Additional requirements)
	7.6.7	7.8.4 (V2M3, 6.12.5)
	7.6.9	7.8.5 (V2M3, 6.12.7)
	7.7.2	4.3.5
	7.7.3	7.8.6 (V2M3, 6.12.8)
	7.7.4	7.9.1 (V2M1, 7.5.1)
	7.7.5	7.9.2 (V2M1, 7.5.2)
	7.7.6	7.9.3 (V2M1, 7.5.3)
	7.8.1	7.9.4 (V2M1, 7.5.4)
	7.8.3	7.9.5 (V2M1, 7.5.5)
	7.9.5	7.11.7 (V2M1, 7.7.7 and V2M3, 6.13.8)
	7.11.1	7.13 (V2M1, 7.9)
	7.14.1	7.14.1 (V2M1, 7.10.1)

Information Requirements (8): mostly the same as 2004-version requirements

New: 8.1: Confidentiality (greatly expanded upon from 2004-version Sec. 4.4)
8.2.1(a)(4): AB makes publicly available information about AB's activities other than accreditation

Essentially unchanged:	2017 version	2004 version
	8.2.1(a)	7.1.2(g,h,i,j)
	8.2.1(a)(5)	8.2.3
	8.2.1(b)	7.1.2(a,b,c,d,f)
	8.2.2	7.1.2(e)
	8.2.3	8.2.4
	8.2.4	8.2.4

Management System Requirements (9): mostly the same as 2004-version requirements

New: 9.1.4: Option A
9.1.5: Option B
9.2.2: AB continually improves the effectiveness of the management system

Essentially unchanged:	2017 version	2004 version
	9.1.1	5.1.1
	9.1.2	5.2.1
	9.1.3	5.2.3
	9.2.1	5.2.2
	9.3	5.3
	9.4	5.4
	9.5	5.5
	9.6 "Improvement"	5.6 "Preventive Actions"
	9.7	5.7
	9.8	5.8

II. ADDITIONAL TNI NORMATIVE LANGUAGE CHANGES

3.4 NOTE 2: Note from the existing V2M1 and V2M3 for the “Accreditation Body” definitions retained and clarity added by the Expert Committee.

3.4 NOTE 3: Notes from the existing V2M3, 6.3.6 and 6.3.7 retained, moved to here, and merged. Clarity provided by the Expert Committee.

3.6 NOTE: Note from the existing V2M1 and V2M3 for the “Scope of Accreditation” definitions retained and clarity added by the Expert Committee.

3.22 NOTE 2: Note from the existing V2M3 for the “Assessment” definition proposed for deletion.

Definition for “Field of Accreditation” deleted.

4.4.12: NOTE from V2M1, 4.3.7 retained and moved to here.

4.4.14: Language from V2M1, 4.3.3.1 moved to create this new section.

4.4.15: Language from V2M1, 4.3.8 moved to create this new section.

5.1: NOTE 1 to existing V2M1, 4.2.1 to be deleted, to accommodate the non-governmental NELAP accreditation bodies.

5.1: NOTE 2 from the existing V2M1, 4.2.1 retained and moved to here.

5.5.1: Language from V2M1, 4.2.2.1 moved to create this new section.

5.7: NOTE from existing V2M1, 4.2.5 retained and moved to here.

6.1.2.6: NOTE 2 from V2M3, 4.2.7 retained and moved to here.

6.1.2.9.1: Language from V2M3, 4.2.3 moved to create this new section.

6.1.2.9.2: Language from V2M3, 4.2.4 and NOTE moved to create this new section. Additional NOTE 2 added to make written exam for assessor refresher training optional.

6.1.2.9.3: Language from V2M1, 4.3.2 moved to create this new section.

6.1.3.2.1: Language from V2M1, 4.2.5 moved to create this new section (in its entirety, inclusive of (a), (b), (c), and NOTE).

6.1.3.7: Added additional requirements that the AB must maintain records for the assessing and monitoring of laboratory assessors.

6.2.2.1: Language from V2M3, 4.4.2 moved to create this new section (in its entirety).

6.2.2.2: Language from V2M3, 4.1.5 moved to create this new section.

6.2.2.3: Language from V2M3, 4.3.3 moved to create this new section.

6.2.2.3 NOTE: Note from existing V2M3, 4.3.5 moved to here, with clarity added by the Expert Committee.

6.2.3.1: Language from V2M1, 4.1.2 moved to create this new section.

6.2.3.2: Language from V2M3, 6.7 moved to create this new section (in its entirety, inclusive of the NOTE, with clarity added by the Expert Committee).

6.3 NOTE: Note from the existing V2M3, 4.3.1 retained and clarity added by the Expert Committee.

6.4.6 NOTE 2: Note 2 from the existing V2M3, 6.2 retained and moved to here.

7.4.2 NOTE: Note from the existing V2M3, 6.3.3 moved to here, with clarity added by the Expert Committee.

The existing V2M1, 7.4.2.1 is proposed for deletion, which would have allowed the CAB to exclude a third-party assessor if there is a conflict-of-interest.

7.4.2.1: Language from V2M3, 6.13.4 and 5.2 moved to create this new section, but Expert Committee removed duplicative language about unannounced assessments.

7.4.2.1 NOTE: NOTE from V2M3, 6.3.8 proposed for deletion.

Expert Committee is proposing deletion of V2M1, 7.11.3 NOTE 3 about proficiency testing occurring and administered by assessors during on-site assessments.

7.4.5 NOTE: Note from the existing V2M3, 6.3.5 moved to here, with clarity added by the Expert Committee.

7.5.2 NOTE: Second sentence from the Note to the existing V2M3, 6.4.2 retained and moved to here, with clarity added by the Expert Committee.

7.6.2.1: Language from V2M3, 6.8 moved to create this new section (in its entirety, inclusive of the NOTE, with clarity added by the Expert Committee).

7.6.3.1: Language from V2M3, 4.4.3 moved to create this new section (in its entirety, inclusive of the NOTE, with clarity added by the Expert Committee).

7.6.3.2: Language from V2M3, 6.5 moved to create this new section, but requirements for "Checklists" proposed for deletion.

7.6.3.3: Language from V2M3, 4.3.4 moved to create this new section (in its entirety).

7.6.3.4: Note from the existing V2M3, 6.9.2 changed into a requirement and moved to here.

7.6.4.1: Note from the existing V2M3, 6.10.1 made into a requirement, with clarity provided by the Expert Committee.

7.6.6(a)(1): TNI language from V2M3, 6.11.1(a) and NOTE from V2M3, 7.8.3(b) moved to create this new section (with clarity added by the Expert Committee).

7.6.6(a)(2): Language from V2M3, 6.11.1(b) proposed for deletion.

7.6.6(b)(1): Language from V2M3, 6.12.2 moved to create this new section (with clarity provided by the Expert Committee).

7.6.7.1: Language and NOTE from V2M3, 6.12.6 proposed for deletion.

7.6.8.1: Language from V2M3, 6.12.4 moved to create this new section (with clarity added by the Expert Committee); NOTE proposed for deletion.

7.6.9 NOTE: Note from the existing V2M3, 6.12.7 retained and moved to here.

7.7.5.1 and 7.7.5.2: Language from V2M1, 7.5.6 moved to create this new section (in its entirety).

7.7.6 NOTE: Note from the existing V2M1, 7.5.2 moved to here, with clarity added by the Expert Committee.

7.8.1(h) ADDITION: Additional language from the Expert Committee to require matrix, technology/method, and analyte as defined in LAMS, however named.

7.8.3: NOTE added to denote the applicable sections for the TNI Environmental Laboratory Sector.

7.9.3 NOTE: Note from the existing V2M1, 7.7.2 retained and moved to here; "surveillance activities" replaced by "assessment techniques."

7.9.4.1: Language from V2M3, 5.1 and 6.13.3 moved to create this new section (VETO expected if the reassessments shall be performed at intervals longer than 2 years +/- 6 months).

7.9.4.2: Language from V2M3, 6.13.6 moved to create this new section (Expert Committee added language for AB to require Plan of Correction submittal by laboratory within 30 days of receipt and removed any designation of a NOTE).

7.9.4.3: Expert Committee added language for AB to require laboratory to implement and complete the Plans of Correction as specified in the Plan of Correction or according to the AB's policy.

7.9.5 NOTE: Note from the existing V2M3, 6.13.8 moved to here; duplicate language now present in the main clause proposed for deletion in this Note.

7.11.1.1 through 7.11.1.7: Language from V2M1, 7.9.4 moved to create these new sections (in its entirety).

7.13.8 NOTE: Note from the existing V2M1, 7.6.2 retained and moved to here.

7.14.3: Language from V2M1, 7.10.4 moved to create this new section.

Expert Committee is proposing deletion of NOTE with V2M1, 7.10.2.

8.1.5: Language from V2M3, 6.6 moved to create this new section.

9.7.5: Language from V2M1, 5.7.4 moved to create this new section (plus some clarifying language from the Expert Committee).

III. ISO LANGUAGE TO BE ELIMINATED (unless kept as TNI additional normative language):

V2M1, 4.2.6
V2M1, 5.1.2
V2M1, 6.1.3 (and V2M3, 4.1.3)
V2M1, 6.2.3 (and V2M3, 4.2.6)
V2M1, 6.2.4 (and V2M3, 4.2.7)
V2M1, 6.4.2 (and (V2M3, 4.3.1)
V2M1, 7.4.2(c)
V2M1, 7.10.2
V2M1, 7.10.3
V2M1, 7.11
V2M1, 8.1.1(d)
V2M1, 8.2.1
V2M1, 8.2.2
V2M1, 8.3.2(b)
V2M1, 8.3.2(d)
V2M3, 4.3.5
V2M3, 4.4.1
V2M3, 6.3.2
V2M3, 6.9.1
V2M3, 6.9.2
V2M3, 6.12.3

IV(A). FORMER 2003 NELAC CHAPTER 6 REQUIREMENTS CONSIDERED FOR INCLUSION BY THE NELAP ACCREDITATION COUNCIL (AND EXPERT COMMITTEE RECOMMENDATIONS)

- Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent on-site assessments (retain as NELAP Accreditation Council (AC) Policy, not include in the Volume 2 Standard; however, see the ISO/IEC 17011 requirements in Clause 7.9.4)

- How to assess different Fields of Accreditation (NELAP AC Policy)

- Accreditation of sample preparation methods and accommodating the varied approaches by Accreditation Bodies (NELAP AC Policy)

- Using technologies as the basis for PT samples and Fields of Proficiency Testing tables (responsibility of the PT Expert Committee and the PT Program Executive Committee)

- Assessing laboratory accreditation scopes by matrix/method/analyte by governmental and non-governmental Accreditation Bodies (NELAP AC Policy and TNI NELAP Recognition Committee Policy)

- What to do about PT requirements for scopes where there are no approved PT providers, such as Biological Tissues as a matrix and DW Asbestos (responsibility of the PT Expert Committee and the PT Program Executive Committee)

- Assessing a sampling of the laboratory's testing to ensure that all accreditation requirements are fulfilled for the entire accreditation scope (NELAP AC Policy)

- Allowance to grant interim accreditation status to laboratories (do not address at all)

- Handling requests to extend deadlines in any standard where timelines are specified (YES, Lab AB to consider)

- Requirement for laboratory to seek NELAP Primary Accreditation in the state in which it resides, if that state has a recognized NELAP AB for the fields of accreditation requested (YES, to be considered for inclusion as Standard, but in Volume 2 or in Volume 1?)

- Allowance for NELAP Recognized Accreditation Bodies' personnel to perform accreditation functions for each other (don't include, covered by the ISO/IEC Standard)

- Process for expanding the scope of recognition for each NELAP AB to offer as primary accreditation to applicant laboratories (YES, but ISO/IEC 17011 already has the requirements for AB to have the process for extending accreditations)

- Communication policy to allow advance notice to other recognized NELAP accreditation bodies of cost increases or other changes in the AB's program (YES, Lab AB expert committee to consider)

- Policy on secondary accreditations to mobile laboratories (Yes, Lab AB to consider but in conjunction with NEFAP and the Field Activities expert committee?)

- Generic accreditation application form that will be used or acceptable to all recognized NELAP accreditation bodies (already addressed and state NELAP accreditation bodies will handle)

- Requirements on the content and frequency for updating information to the National Database on NELAP accredited laboratories (covered by NELAP AC Mutual Recognition Arrangement Policy)

- Policy on secondary accreditations (do not address at all)

- Timeframes for accreditation bodies to require of laboratories to complete corrective actions to non-conformances identified during on-site assessments (YES, Lab AB to consider)

- Policy outlining qualifications and credentials needed for contract assessors, or ALL AB assessors (Yes, Lab AB to consider)

- Scope of Accreditation definitively defined at a minimum as matrix – method / technology – analyte (already addressed in ISO/IEC 17011 for testing laboratories)

- Minimum requirements for training courses to train and qualify assessors, and accreditation decision-makers (covered already by TNI guidance issued in 2010 from the former On-Site Assessment Committee)

- Minimum requirements for enforcements against non-conforming environmental laboratories (YES, Lab AB to consider)

IV(B). OTHER 2003-NELAC CHAPTER 6 REQUIREMENTS (and Expert Committee recommendations)

6.1: AAs required to administer environmental laboratory accreditation program that meets the requirements of this chapter and to require that laboratories meet the NELAC Standards in chapters 2-5.

6.2(a): AAs are governmental organizations at state, federal, or territorial levels.

6.2(b): State, federal, territorial entity designates the appropriate agencies or departments to be the AA.

6.2(c): AA shall not delegate accreditation decision-making authority to outside body; portions of accreditation process may be contracted out as long as 6.3.3.1.2 and 6.3.3.1.3(b)(3) met.

6.2(d): AA processes administered in impartial and non-discriminatory manner; AA requires accredited labs to maintain impartiality & integrity; AA shall have no rules that restrict the size of labs seeking accreditation, require membership in any organization or professional association, impose financial conditions other than the fees authorized by law, or conflict with any laws regarding discrimination.

6.2(e): AA & contractors confine accreditation activities to the specific fields of accreditation requested by the lab.

6.2(f): Any display of the NELAP insignia accompanied by the phrase "NELAP-recognized."

6.2(g): If within scope & applicability of rules and regulations, technical committees established to advise the AA; if established, AA has formal rules regarding the committee, members chosen to provide technical support & impartiality, and AA has mechanism for publishing the interpretations & recommendations.

6.2(h): All singular tense nouns can also mean the plural, and visa versa.

6.2(i): Timelines can be extended by NELAP Director; written rationale includes the justification for the extension & maintained in the NELAP official record.

6.2(j): Extensions of NELAP Recognition can be granted by NELAP Director; written rationale includes the justification for the extension & maintained in the NELAP official record.

6.2.1(a): NELAP secondary AAs shall grant accreditation to labs accredited by any other NELAP primary AA, on a lab-by-lab basis, considering only the current certificate issued by the primary AA.

6.2.1(b): NELAP secondary AA shall only grant reciprocal accreditation for the fields of accreditation for which the lab holds primary NELAP accreditation & issue certificates to the lab within 30 days of the application date.

6.2.1(c): Lab pays all fees as required by the secondary NELAP AA.

6.2.1(d): Lab not required to meet additional PT, QA, or on-site assessment requirements for fields of accreditation for which primary NELAP accreditation is held.

6.2.1(e): If NELAP secondary AA notes lab non-conformity with the NELAC Standards, it notifies NELAP Primary AA in writing.

6.2.1(f): Upon receipt of this notification, the primary AA reviews & investigates the non-conformance, takes appropriate action, & responds to the secondary AA & NELAP Director in writing within 20 days, to include initial report of findings, actions to be taken, & schedule for implementation for further action if needed.

6.2.1(g): Within 20 days NELAP Director reviews the nonconformance & take action per Chapter 6 requirements.

6.2.1(h): Federal AAs shall only accredit governmental laboratories.

6.2.1(i): County, municipal, & non-governmental labs cannot claim primary or secondary accreditation by a federal agency.

6.2.2(a): County, municipal, & non-governmental labs seeking NELAP accreditation must apply for accreditation through their home state AA.

6.2.2(b): Labs located in state that is not NELAP-recognized may seek accreditation through any NELAP-recognized state or territorial AA.

6.2.2(c): State government labs may apply for NELAP accreditation through home state, home territory, or federal NELAP recognized AA.

6.2.2(d): Federal government labs located in a federal department or agency that has NELAP recognized AA shall follow that agency's policy on NELAP accreditation or renewal.

6.2.2(e): Federal government labs not located in department or agency that has Primary AA may seek accreditation from any federal or state NELAP Primary AA, provided no conflict of interest exists.

6.2.2(f): Labs located in state where AA has lost its NELAP Recognition may apply for NELAP accreditation from any other state Primary NELAP AA & accreditation status is maintained through the time period specified on that current accreditation certificate.

6.2.2(g): Labs located in state that becomes NELAP Recognized must apply for accreditation from that home state AA at the time of accreditation renewal; accreditation valid through the date specified on the current certificate.

6.2.2(h): Governmental labs that are part of the same agency or department where the AA is located or have other institutional conflicts of interest shall demonstrate that they do not report through the same chain of command as the AA, demonstrate that no conflicts or interest exist, or apply for NELAP accreditation through another Recognized AA.

6.2.2(i): Recognized AAs process applications in the chronological order that the applications are received.

6.2.3(a): AAs maintain documents describing the accreditation program; documents reviewed annually; documents include authority to grant accreditations, requirements for labs to be accredited, information on AA's assessor training and internal audits, list of qualified assessors & technical support personnel with education & experience, information on requirements for various accreditation decisions, information on the accreditation process, information on fees charged, information on rights & duties of accredited labs, and list of NELAP accredited labs and scopes of accreditation.

6.2.3(b): AA updates within 30 days of the above annual review reveals changes in the program.

6.2.3(c): Documents are made readily available upon request.

6.2.3(d): AA has arrangements to safeguard information claimed by labs as confidential.

6.3.1(a): AA requesting initial NELAP Recognition submits application & supporting documentation.

6.3.1(b): Required content on the application.

6.3.1(c): Application signed by highest ranking individual in the department or agency responsible for lab accreditation activities; attestation of the validity of the information in the application & supporting documents.

6.3.1(d): AA submits renewal application every 3 years for maintaining recognition; NELAP sends application >= 270 days prior to expiration of the current recognition, application content the same as (b) above, and application returned within 30 days of receiving the renewal notification.

6.3.2(a): NELAP only sends notices to recognized AAs and AAs who have submitted application to become recognized.

6.3.2(b): If completed application not submitted, AA notified; if not then submitted within 20 days, NELAP recognition will not be renewed.

6.3.2(c): NELAP completes a review to determine that the required application information and supporting documentation is included.

6.3.2(d): Within 30 days of determining that application is complete, NELAP does technical review of the application & supporting documents.

6.3.2(e): NELAP evaluation team reviews the application & supporting documents to determine whether the AA requires accredited labs to meet the NELAC Standards, Chapters 2-5.

6.3.2(f): If there are questions or if additional information is needed, NELAP evaluation team must seek this info from AA.

6.3.2.1(a): NELAP review is to ensure AA's accreditation program meets requirements in (b)-(m).

6.3.2.1(b): AA shall be legally identifiable governmental entity.

6.3.2.1(c): AA has authority, rights, & responsibilities necessary to carry out a lab accreditation program.

6.3.2.1(d): AA has arrangements to cover liabilities & workers comp claims.

6.3.2.1(e): AA has financial stability and resources necessary required to operate the lab accreditation program; AA makes available upon request a description of how it receives financial support; AA has resources necessary to complete action on lab accreditation application within 9 months of receipt.

6.3.2.1(f): Required information that the AA has to keep on assessors.

6.3.2.1(g): AA has system to evaluate assessor performance demonstrating compliance with NELAC Ch. 3.

6.3.2.1(h): AA identifies one individual responsible for day-to-day management of the accreditation program; must be employee of AA & have the technical expertise listed.

6.3.2.1(i): AA has arrangements to ensure that its personnel are free of pressures that influence the results of the accreditation process & are subject to conflict of interest disclosure requirements.

6.3.2.1(j): AA has procedures for conducting annual internal audits & review effectiveness of its quality systems.

6.3.2.1(k): AA resignates individual responsible for the quality system & maintaining the quality documentation.

6.3.2.1(l): AA has SOPs to deal with appeals, complaints, & disputes on adverse accreditation decisions, from users of accredited labs, or other matters.

6.3.2.1(m): AA requires accredited labs to participate in PT program that meets Chapter 2 requirements.

6.3.2.1(n): AA or its contractors do not offer consultancy or anything that would compromise objectivity & impartiality in accreditation process & decisions.

6.3.2.1(o): AA has documented procedure to address 6.2.2(g).

6.3.2.1.1(a): AA establishes & maintains records for each lab that covers all aspects of accreditation process.

6.3.2.1.1(b): AA has policy & procedure to maintain records for at least 10 years or longer if required by contract, prevailing laws, and regulations.

6.3.2.1.1(c): AA has policy & procedures concerning access to records as prescribed by state, territorial, or federal regulations where the AA resides.

6.3.2.1.1(d): AA has policy & procedures for updating the national database with NELAC-required information specific to labs every two weeks, inclusive of submitting a report that no changes were needed.

6.3.2.1.2(a): AA ensures & requires by signed contract or binding document that all lab accreditation functions performed by the contractor on behalf of the AA are carried out in accordance with the NELAC Standards.

6.3.2.1.2(b): When accreditation activities are contracted out, AA still takes full responsibility for the contracted work, ensures that contractor & its employees are competent & comply with the NELAC Standards, ensure that contractor & employees comply with confidentiality requirements of the AA and NELAC, and ensure that contractor & employees are not directly involved with the lab seeking accreditation or with any other affiliation that would compromise impartiality in the NELAP accreditation process.

6.3.2.1.3(a): AA has quality system appropriate to the type, range, and volume of work performed.

6.3.2.1.3(b): Quality system documented in a quality manual that is available for use by AA staff; listed required content in the quality manual.

6.3.2.1.4: Under mutual agreement, a NELAP AA may perform accreditation functions on behalf of another NELAP-recognized AA.

6.3.2.2: NELAP AA application technical review process

6.3.3 <reserved>

6.3.4(a): NELAP Director notified as to changes in AA's authority, organizational structure including key personnel, rules/regulations/SOPs, physical demographics, and contractual arrangements.

6.3.4(b): Notification is within 30 days of the change.

6.3.4(c): NELAP Director may require additional documentation or conduct on-site evaluation of the AA.

6.4(a): On-site evaluation of AA occurs with the initial application for NELAP recognition & every 3 years thereafter.

6.4(b): On-site evaluation scheduled at the mutual convenience of all parties.

6.4(c): NELAP evaluation team may make subsequent or unannounced on-site evaluations of the AA if necessary.

6.4(d): At least one NELAP evaluator will observe an AA's assessor conducting an on-site assessment of a lab seeking NELAP initial or renewal accreditation.

6.4.1: Protocol for scheduling the on-site evaluation.

6.4.2: Protocol for conducting the on-site evaluation.

6.4.3: Protocol for reporting the results of the on-site evaluations, reviewing plans of corrective actions to any identified non-conformities, and recommending recognition status.

6.5: Protocol for handling AA requests for extensions of time to comply with the NELAC Standards.

6.6: Protocol for NELAP evaluation team submitting recommendations to the NELAP Director, and the NELAP Director making the AA recognition decision.

6.7: Content of the certificate issued to the recognized NELAP AA.

6.8(a): AA has requirements on lab ownership, use, and display of NELAP logo & AA's accreditation documents, inclusive od display in prominent place in lab, make accurate statements on lab's accreditation status & accredited fields of accreditation, accompany the NELAP logo with "NELAP accredited" & accreditation identifier, and not imply use of accreditation as endorsement by the AA.

6.8(b): AA ensures that labs distinguish between accredited testing and testing that is not accredited, and include accreditation number or other identifier.

6.8(c): AA ensures that labs that have had accreditation suspended, revoked, or withdrawn discontinue all use of NELAP accreditation status in all references & return accreditation certificates to the AA.

6.8(d): AA takes suitable action against labs that incorrectly reference NELAP accreditation status, misuse that status, & use the NELAP logo in unauthorized manner.

6.9: Requirements & qualifications of NELAP evaluation team; requirements of NELAP Director.

6.10: Protocol for appealing findings based on standards interpretation.

6.11: Protocol for appealing decisions to deny or revoke NELAP recognition.

Appendix A to Chapter 6: Questions of uniformity procedure; protocol to follow when parties cannot agree on the interpretation of a standard.

V. STANDARD INTERPRETATION REQUESTS

SIR 71 (2003 NELAC Sec. 3.6.4): Third-party assessor potential conflicts of interest (Lab AB to consider)

SIR 136 (V2M3, 4.2.4): Technical training courses and requirements (Lab AB to consider)

SIR 165 (V2M1, 7.7.2 and V2M3, 6.13.2): Surveillance on-site assessments and Reassessments (Lab AB to consider)

SIR 194 (V2M1, 7.7.3 and V2M3, 5.1): Surveillance on-site assessments and reassessments (Lab AB to consider)

SIR 200 (V2M1, 8.1.2(b) and V2M3, 7.0(b)): QA officer as key laboratory personnel and requirement to notify AB of a change in QA officer (Lab AB to consider)

SIR 203 (V2M1, 4.1-4.2.2.1): ability of NELAP governmental AB to accept the Primary Accreditation granted by a non-governmental NELAP AB (Lab AB to consider)

SIR 216 (V2M3, 4.2.4): training requirements and examination passing score requirements for basic assessor training, technical training, and refresher training (Lab AB to consider)

SIR 254 (V2M3, 6.3.5): AB assessors evaluate all methods and analytical activities on the lab accreditation scope or just a sampling of the scope if adequate to ensure competence of the lab for entire scope (Lab AB to consider)

SIR 305 (V2M1, 6.2.3): AB identifies specific scopes that assessors are deemed competent to assess; scope here applies to what level of detail: technologies, scientific discipline (microbiology, inorganic, organic, etc.), matrix (Lab AB to consider)

VI. PARKING LOT ISSUES

- Make increasing use of automation in lab assessments, versus on-site lab assessments

- Re-word Clause 7.13.4.2.8 "Failure to pass an on-site assessment conducted by an accreditation body" (reasons to suspend/withdraw/reduce accreditation)

- Add requirements for AB to load data into LAMS at the proper frequency and contents

- Consider whether V2M3, 4.3.2 is needed in this revised Standard (assessors sign qualification statements)

VII. CARRY-OVER FROM THE PREVIOUS CONSENSUS STANDARD DEVELOPMENT ON VOLUME 2 (section numbers refer to the current TNI Standard and not to the voting draft)

V2M1, 7.7.3 and V2M3, 5.7: Module 1 contains the ISO/IEC 17011 language in Clause 7.11.3, but Module 3 says this clause is not applicable.

V2M1, 7.9.4: Repeat findings during an assessment should be grounds for suspension.

V2M1, 7.9.4.2.3: What is "key accreditation criteria" (failure to notify AB of changes in key accreditation criteria)?

V2M1, 7.10.4: The standard should include a minimum length of time that ABs must retain records. Regulatory laws may not specify a minimum time. (e.g., retain for at least 5 years?)