

**Summary of the Laboratory Accreditation Body Expert Committee Meeting
Forum on Laboratory Accreditation, Wednesday, January 30, 2019**

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting and welcomed the audience. Attendance is recorded in Attachment 1.

2. TNI Language Moved from 2009 V2M1/V2M3 into ISO/IEC 17011:2017

Using a PowerPoint presentation along with hand-outs of the TNI language, Carl led a discussion with committee members and audience participants about changes and relocations of the TNI additional language that had been in the 2009 TNI Standard. He explained that the TNI text from V2M1 is plain text (versus ISO's italicized text), and that TNI text from V2M3 is underlined; beyond that, language that was modified or inserted is identified by a double underline. These markings are used in the PowerPoint presentation, which is included in outline format in Attachment 2, below. The slides will also be posted to the conference website later in the year.

One participant explained that the Board-chartered Mobile Lab Task Force plans to provide some clarifying language for mobile labs in May or June of this year, for V2M1.

The slide numbers noted below prompted discussion, as summarized here.

6 – ISO/IEC 17025 now includes sampling, and one committee member asked whether sampling should become part of the V2M1 definition of the term “scope of accreditation”. This issue remains to be considered by the full committee.

7 – Will NELAP ABs adapt to flexible scopes of accreditation? NGABs use it now (having moved to the 2017 revisions of ISO/IEC 17011), so the NGAB usage needs to be accommodated in this module (not directly relevant to the text of slide 7)

10 (assessor qualifications) – 2nd bullet requires clarification of “verified assessment”. 3rd bullet – is a test adequate or must there be assessor training followed by a test? One participant commented that the “test only” concept was a way of grandfathering in the existing assessors but should no longer be relevant. Is it adequate to accept a certificate of training for the hiring of an experienced assessor without requiring a repeat of training, but possibly with a test (or test results/score from that training demonstrated by certificate)? (Possibly John Gumpfer will provide draft language for this, §6.1.2.9.1 or § 6.1.3.2.1.) Another participant commented that her AB hires assessors from its state lab, so that they are already trained in the methods, and thus should only need to demonstrate knowledge by passing a test, expressing a strong sentiment that the AB itself should be able to determine who is qualified. Yet another participant commented that training would better ensure consistency in assessments.

11 – One participant wants there to be a combination of training and experience for the evaluation of assessor capabilities. (Mohan from IAS offered to provide some draft language for this.)

12 – Make this new language into active voice.

13 – 2nd bullet – is there still a need for a signed statement for every assessment? Suggestion that a hand-inscribed signature on paper is overkill. An AB commented that the AB needs to have procedures for determining whether a conflict of interest exists, or not; having specific language in the module may not work for all ABs and should probably be deleted.

17 – Note 2 is not appropriate.

18 -- §7.4.2.1 – preferred language would be “ABs are allowed to conduct...” and the text about “initial assessments shall be announced” conflicts with at least one AB’s regulations (*either PA or VA, notes are unclear*) and must be removed. The Chair requested proposed wording for both the note and normative language; the issue was not resolved in the session.

19 – Participant requests that the reason for deleting this language be noted in the outline of proposed changes.

20 – Considerable discussion about whether the appropriate term is “document” or “record” (both verbs here). ISO does not use “record” and “document” is always followed by a process. Suggest revising the language to say that the “AB should retain a record of...”, thus using the noun word instead.

22 – The term “team leader” in ISO language adds confusion with how that term is used in AB personnel structures. Request to use “assessment team leader” or rephrase to say “assessment team should consult”. Again, the Chair requested that someone submit draft language.

23 – one participant objects to §7.6.6.a, the note, that assessors must take their findings to the AB before releasing the written report, and also NGABs sometimes DO leave a written report at the closing meeting. Requests making the note the normative language, something like “the AB shall be considered to have met this requirement by providing [oral report at closing meeting followed by written report later] and deleting the current normative language. (This was done in the draft module as distributed to the committee after conference.)
For §7.6.6.b, there was a clear desire to allow exceptions to the 30 day “for good cause” or to consider changing it to accommodate holidays (perhaps 30 business days?) – proposed language was that the “AB may extend the time on request due to unforeseen circumstances. Another participant requested adding language about communicating delays and the reason for them, between the lab and the AB.
The proposed deleted language about report sharing brought comments that TX needs it but it violates PA and FL law/regulations. ABs may need to share for purposes of mutual recognition but there may also be other reasons. ABs might be satisfied with exception language, saying “unless superseded by state regulations”. (*Aaren Alger agreed to submit draft language.*) Also, a cross-reference with §8.1 may provide adequate exception.

25 – Participants requested eliminating the word “reasonable”. Also, while ISO does not address secondary accreditations, this language may have more applicability to secondary accreditations, since denials are already allowed but not required. NOTE: ensure that primary AB is defined in the glossary, as well as secondary AB.
§73831 – the point was made that “scope” defines matrix/technology-method/analyte, as defined in the standard but that may not be information that needs to be provided to the labs. Additionally, there were objections to LAMS nomenclature being enforced for use by the ABs. This language may not be needed here but rather in §7.8.3.d, with the LAMS reference removed (please).

26 – A request was made to put the note at the top of the section. Also, eliminate mention of Volume 4 in this module.

27 – “Surveillance” is no longer a concept in the ISO language and has thus been removed. In the 3rd bullet, remove “reasonable”.

29 – Remove the 2nd bullet, as it is redundant, and note the reason for deletion in the outline.

30 – Rephrase to include “or reference through applicable laws or regulations” – it’s not clear that a regulation would qualify as the ISO-required “document” that requires a procedure or process, as currently written.

31 – Note that “redundant” is the reason for deletion in the outline.

The completion of slide review coincided with expiration of the session’s time. There were no comments on slides 32 through 38.

6. Next Meeting

The next teleconference meeting will be **Tuesday, February 19, 2019, at 1:00 pm Eastern.** An agenda and documents will be distributed prior to the meeting.

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
William Batschelet Batschelet.william@epa.gov	12/31/2021 (2 nd term)	Other – Retired from US EPA R8	No
Nilda Cox nildacox@eurofinsus.com	12/31/2021 (1 st term)	Lab – Eurofins Eaton Analytical LLC	Yes
Charles Hartke Charles.hartke@sgs.com	12/31/2020 (1st term)	Lab – SGS Accutest, Dayton, NY	No
Oommen Kappil okappil@emsl.com	12/31/2019 (1st term)	Lab – EMSL Laboratories, Inc.	No
Catherine Katsikis catherinekatsikis@gmail.com	12/31/2021 (2 nd term)	Other – Laboratory Data Consultants	Yes
Carl Kircher, Chair carl_kircher@flhealth.gov	12/31/2021 (3 rd term, extended)	AB – Florida Department of Health	Yes
Marlene Moore mmoore@advancedsys.com	12/31/2021 (2 nd term)	Other – Advanced Systems, Inc., Newark, DE	Yes
Zaneta Popovska zpopovska@anab.org	12/31/2021 (1st term)	Other – ANAB	No
Alia Rauf arauf@utah.gov	12/31/2020 (1st term)	AB – Utah Department of Health	No
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com	12/31/2021 (2 nd term)	Other – Shepherd Technical Services	Yes
Nicholas Slawson nslawson@a2la.org	12/31/2021 (1st term)	AB – A2LA	No
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Yumi Creason ycreason@pa.gov		AB – Pennsylvania	No
June Main jmain@dep.nyc.gov		Lab – NYC DEP	No
Bill Ray bill_ray@williamrayllc.com		Other – William Ray Consulting, LLC	No
Aurora Shields Aurora.Shields@kcmo.org		Lab – KC Water	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No

Attachment 2 – Slides from PowerPoint Presentation Used in Conference Session

Title Slide -- **TNI Laboratory Accreditation Body Expert Committee** -- *Additional Normative Language specific for Environmental Testing Laboratory Accreditation* -- **January 30, 2019**

Slide 2 – 2019 Goals

- Publish Outline – Receive Comments
 - Incorporate comments
- Publish Voting Draft Standard – Receive Comments
 - Discuss and rule on comments
 - Modified Voting Draft Standard?
- Publish Interim Standard – Receive Comments
 - Discuss and rule on comments
 - Modified Interim Standard?
- FINAL TNI STANDARD?

Slide 3 -- Executive Summary

- The revised TNI ELS Volume 2 Standard combines the general requirements for the Accreditation Body in Module 1 and the specific laboratory on-site assessment requirements in Module 3 into one module.
- This Standard also updates and incorporates the newly-revised international standard for accreditation bodies in ISO/IEC 17011:2017(E).
- Much of the additional normative language by The NELAC Institute (TNI) that is specific for accreditation bodies that accredit environmental testing laboratories has been retained or revised for improvements, and then moved into the appropriate sections of the Standard.
- Some TNI additional requirements that are now deemed redundant, obsolete, or no longer needed have been proposed for elimination.

Slide 4 -- 2019 Goals

- Publish Outline – Receive Comments
 - Incorporate comments
- Publish Voting Draft Standard – Receive Comments
 - Discuss and rule on comments
 - Modified Voting Draft Standard?
- Publish Interim Standard – Receive Comments
 - Discuss and rule on comments
 - Modified Interim Standard?
- FINAL TNI STANDARD?

Slide 5 -- 3.4 Conformity Assessment Body definition

Slide 6 -- 3.6 Scope of Accreditation definition

- ISO/IEC 17011 definition
- (See also called Field of Accreditation)
- Fields of Accreditation are those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.
 - Kept V2M3 definition & deleted the V2M1 definition
- TNI “Field of Accreditation” definition proposed for deletion

Slide 7 -- 3.22 Assessment definition

- NOTE proposed for deletion

NOTE 2: Accreditation bodies perform the following types of on-site assessments:

- a) Initial assessments: These are comprehensive and involve reviewing all key activities performed by a CAB applying for accreditation for the first time. Initial assessments are announced.
- b) Reassessments: These are similar in scope to initial assessments except that the experience gained during previous assessments may be taken into account.
- c) Surveillance on-site assessments: These are less comprehensive than reassessments and occur as needed in between an initial assessment and a reassessment or between reassessments.
- d) Follow-up assessments: These are undertaken to verify effective implementation of corrective actions.
- e) Extraordinary assessments: These are conducted as a result of complaints or changes such as ownership, key personnel, location, scope of accreditation, or other matters that may affect the ability of a CAB to fulfill accreditation requirements.

Slide 8 -- Clause 4 GENERAL REQUIREMENTS

TNI retained language

- 4.4.12 NOTE 3: An accreditation body and related bodies within a Government department or entity might not have a distinctive name, logo and or symbol. [from V2M1, 4.3.7]
- 4.4.14 The accreditation body also shall require accredited CAB's to maintain impartiality and integrity. [from V2M1, 4.3.3.1]
- 4.4.15 Unless required by applicable regulations, accreditation bodies and their contractors shall confine their requirements, assessments and decision making process for an accredited CAB to those matters specifically related to the fields of accreditation being sought or maintained by a CAB. [from V2M1, 4.3.8]

Slide 9 -- Clause 5 STRUCTURAL REQUIREMENTS

TNI retained language

- 5.1 NOTE 1: In all cases, accreditation bodies are governmental organizations at the territory, state or federal levels.
- NOTE 2: A territorial, state or federal entity may designate the appropriate agencies or departments as its designated accreditation body for the fields of accreditation for which recognition is being sought. [from V2M1, 4.2.1]
- 5.5.1 An accreditation body shall not delegate authority for granting, maintaining, suspending or revoking a CAB's accreditation to an outside person or body. Portions of the accreditation process may be contracted out; however, the authority to grant, maintain, suspend or revoke accreditation shall remain with the accreditation body. [from V2M1, 4.2.2.1]
- 5.7 NOTE: In the case of an accreditation body within a government department or entity, top management refers to the management of the organizational unit (and not the department or entity) having authority and responsibility for the accreditation program. [from V2M1, 4.2.5]

Slide 10 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.1.2.6 NOTE 2: Assessors that are able to communicate effectively through a translator or interpreter are considered to have complied with this requirement. [from V2M3, 4.2.7]

- 6.1.2.9.1 An assessor shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by working in an environmental laboratory and having performed verified assessments of environmental CABs. [from V2M3, 4.2.3]
- 6.1.2.9.2 An assessor shall have completed and attained a passing score on the written examination of courses approved by the employing accreditation body on assessing quality management systems and all applicable technical disciplines comprising a technology or combination of method and technology that the assessor will assess.
- NOTE: Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, and radiochemistry, and field activities. [from V2M3, 4.2.4]

Slide 11 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.1.2.9.3 The accreditation body shall establish the ongoing training required to assure the continuing competence of its assessors.
 - NOTE: Written examinations may not be required for ongoing (refresher) training of assessors.

NEW LANGUAGE!

- 6.1.2.9.4 Assessors shall sign qualification statements attesting the assessors meet the education and training required by this Standard. Accreditation bodies shall provide those statements to CABs upon request. [from V2M3, 4.3.2]

Slide 12 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.1.3.2.1 Before an assessor is allowed to perform unsupervised assessments for an accreditation body, the assessor shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by the accreditation body. The qualified assessor shall observe the candidate assessor performing:
 - a) at least one assessment, for those assessors that have previous documented experience performing environmental CAB assessments; or
 - b) at least two assessments, for those assessors that have no documented experience performing environmental CAB assessments.
- NOTE: A qualified assessor may evaluate the ability of an assessor to perform unsupervised assessments by: direct observation, observing the assessor perform an assessment in its entirety; or by limited observation, observing the assessor performing parts of an assessment and allowing the assessor to conduct some parts of the assessment independently.
- c) The supervising qualified assessor shall document his or her conclusions to the accreditation body employing the candidate assessor. The accreditation body shall use the qualified assessors' conclusions to determine if an assessor candidate may perform unsupervised assessments or if additional supervised assessments beyond the minimum specified in this Standard are required to qualify the candidate assessor. [from V2M3, 4.2.5]
- 6.1.3.7 Records for assessing and monitoring for all assessors must be maintained.

NEW LANGUAGE!

Slide 13 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.2.2.1 Assessors and experts shall conform to professional and ethical standards of conduct. Assessors and experts shall:

- a) have no interests at play other than those of the accreditation body during the entire accreditation process;
- b) act impartially and not give preferential treatment to any organization or individual;
- c) provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and disability;
- d) not use their position for private gain;
- e) not solicit or accept any gift or other item of monetary value from any CAB, CAB representative or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accreditation body;
- f) not hold financial interests that conflict with the conscientious performance of their duties;
- g) not engage in financial transactions using information gained through their positions as assessors to further any private interest;
- h) not seek or negotiate employment or attempt to arrange contractual agreements with a CAB that would conflict with their duties and responsibilities as assessors;
- i) not knowingly make unauthorized commitments or promises of any kind purporting to bind an accreditation body; and
- j) attempt to avoid any actions that could create the appearance that they are violating any of the standards of professional conduct outlined here. [from V2M3, 4.4.2]

Slide 14 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.2.2.2 The accreditation body shall require assessors employed directly or under contract to affirm this commitment before they participate in their first assessment for the accreditation body or whenever the rules of the accreditation body pertaining to the accreditation of CABs change. [from V2M3, 4.1.5]
- 6.2.2.3 Before conducting an assessment, an assessor shall sign statements certifying the assessor has no conflict of interest with the CAB to be assessed and provide such statements, upon request, to the CAB. [from V2M3, 4.3.3]
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- NOTE: Assessors are employed by or are contracted by on behalf of accreditation bodies to determine the competence of a CAB in meeting the TNI Environmental Laboratory this Standard Volume 1. The initial accreditation of a CAB is based primarily on the findings and observations of assessors. In many accreditation bodies, assessment team members can also be responsible for deciding the accreditation status of a CAB. [from V2M3, 4.3.5]

Slide 15 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.2.3.1 The accreditation body shall have documented procedures for assigning assessors to CABs. Such procedures shall consider the scope of accreditation and the complexity of operations of the CABs. [from V2M3, 4.1.2]
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- 6.2.3.2 Length of Assessment
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- Accreditation bodies shall assign an adequate number of assessors to complete an assessment within a reasonable period.

NOTE: The length of an on-site assessment is determined by the scope of accreditation

of a CAB, the number of assessors in an assessment team, the size of a CAB, the number of findings encountered during the previous on-site assessment, and the cooperativeness of the CAB staff. [from V2M3, 6.7]

Slide 16 -- Clause 6 RESOURCE REQUIREMENTS

TNI retained language moved from Module 3

- 6.3 Personnel Records
- NOTE: These records may be available to outside parties, upon request, subject to the rules of confidentiality of personnel records and the open records laws requirements of an accreditation body. [from V2M3, 4.3.1]
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- 6.4.6 NOTE 3: External individual assessors and experts become part of the accreditation body assessment team and using them in this manner is not considered outsourcing subcontracting. Hiring an external organization to perform entire assessments on behalf of an accreditation body is considered outsourcing subcontracting. [from V2M3, 6.2]

Slide 17 -- Clause 7 PROCESS REQUIREMENTS

- 7.2 Application for Accreditation
- NOTE 1: Accreditation Bodies may require additional information about the conformity assessment body in the formal application.
- NOTE 2: In the absence of any prohibitive regulatory requirements, use of the Generic Application from The NELAC Institute is encouraged. This document is available at "www.nelac-intitute.org".

NEW LANGUAGE!

Slide 18 -- Clause 7 PROCESS REQUIREMENTS

- 7.4.2
 - NOTE: Accreditation bodies may conduct unannounced assessments. The requirement to notify the CAB in advance of the names of the members of the assessment team does not apply to unannounced assessments. An unannounced assessment should not be used by an accreditation body to appoint a known objectionable assessment team. The policy established for dealing with objections from a CAB to the appointment of an assessor or expert to the assessment team should specify the type of objections under which an accreditation body may consider assigning a different assessor or expert. When assembling a team for an unannounced assessment, accreditation bodies should consider previous objections to an assessor made by the CAB. A CAB retains the right to raise an objection to an assessor or expert at the time of the unannounced assessment but should not raise objections to avoid or delay an unannounced assessment. [from V2M3, 6.3.3]
 - <identical Note from V2M3, 6.3.8 to be deleted>*
 - The CAB shall have the right to exclude a third party assessor if there is a conflict of interest. [from V2M1, 7.4.2.1]
 - 7.4.2.1 Although most assessments are announced, accreditation bodies have authority to conduct unannounced assessments. [from V2M3, 6.13.4]
 - Accreditation bodies have authority to conduct unannounced assessments. Initial on-site assessments shall be announced. [from V2M3, 5.2]
 - NOTE 3: Proficiency testing can occur and be administered by assessors during an on-site assessment of a CAB. [from V2M1, 7.11.3]

Slide 19 -- Clause 7 PROCESS REQUIREMENTS

- 7.4.5
 - NOTE: Accreditation bodies should establish procedures for selecting systems, methods and analytical activities that will be observed during an on-site assessment based on the accreditation scope and complexity of the CAB to be assessed. Assessors should strike a balance between thoroughness and practicality while determining the extent to which CABs meet this Standard. The examination of the systems, processes and procedures of the CAB should give a general sense of its past and present capabilities to perform work of known and documented quality. [from V2M3, 6.3.5]
 - 7.5.2
 - NOTE: The assessment team assigned to the CAB usually makes a recommendation to the accreditation body to not proceed with an initial assessment when it encounters significant nonconformities during document and record review. Accreditation bodies should inform CABs of a cancellation of an initial on-site assessment for those conditions as soon as feasible. For other types of assessments, nonconformities found while reviewing documents and records before an on-site assessment would not result in cancellation of an on-site assessment. [from V2M3, 6.4.2]

Slide 20 -- Clause 7 PROCESS REQUIREMENTS

- 7.6.2.1 Attendance at the opening conference shall be documented in sheets or forms provided by the assessment team. [from V2M3, 6.8]
- NOTE: Additional items that may be covered or addressed during an opening meeting include: identification of records and operating procedures to be examined and the responsible CAB individuals who that will provide the assessment team with the necessary documentation, procedures to be followed when a CAB claims information to be confidential business information (CBI), and safety procedures that the CAB may think necessary for the protection of the assessment team.
- 7.6.3.1 While on site, assessment teams may become aware that a CAB may be in violation of an environmental law or regulation. The assessment team shall present this information and any associated documentation to the accreditation body for appropriate action.
- NOTE: Some regulatory body assessment team members have the ability to act as enforcement agents for their accreditation bodies. These activities are outside the scope of this standard. [from V2M3, 4.4.3]

Slide 21 -- Clause 7 PROCESS REQUIREMENTS

- 7.6.3.2 Documents Provided to CAB
- The assessment team shall provide or make available the following types of documents before a scheduled announced on-site assessment or before the conclusion of the on-site portion of the CAB assessment:
- a) Assessment Confidentiality Notice: a document advising the CAB that it has the right to declare information gathered during an assessment as confidential business information according to procedures established by the accreditation body or to restrict access to information requested during an assessment when such information directly affects national security.
- b) Checklists: any standard forms that the assessment team will use to evaluate conformance with this Standard or to document assessment findings.
- c) Assessment Appraisal Form: a document used by the accreditation body to obtain feedback from CABs about the adequacy and the effectiveness of the assessment process, including the performance of the assessment team.
- d) Notice of Announced Assessment: an appointment letter, electronic mail message or a published schedule informing the CAB about an upcoming assessment and identifying

members of the assessment team with sufficient time to allow for potential objections from a CAB to members assigned to the assessment team. [from V2M3, 6.5]

Slide 22 -- Clause 7 PROCESS REQUIREMENTS

- 7.6.3.3 It is possible that during an on-site assessment, assessors or CAB personnel become aware of previously unforeseen conflicts of interest. When this happens, the team leader lead assessor shall consult with the accreditation body, as soon as practicable, to determine how to proceed. The accreditation body shall take action to ensure that the assessment can proceed without compromising its integrity and impartiality or shall request that the assessment team terminate the assessment. If it is necessary to appoint a new assessment team, the accreditation body shall appoint it as soon as practicable without jeopardizing the CAB's request for accreditation. [from V2M3, 4.3.4]
- 7.6.3.4 NOTE: Assessment team members shall have the authority to conduct interviews with any or all CAB staff. [from V2M3, 6.9.2]
- 7.6.4.1 NOTE: It is customary and permissible for assessors to provide instruction or guidance on the meaning of accreditation and method requirements during the on-site assessment process. Offering such instruction and advice does not constitute consultancy. Assessors must should not prescribe specific tasks on how to develop or implement management systems or operational procedures to comply with accreditation or method requirements to avoid engaging in consultancy. [from V2M3, 6.10.1]

Slide 23 -- Clause 7 PROCESS REQUIREMENTS

- 7.6.6(a)
- (1) Attendance at the closing conference shall be documented in sheets or forms provided by the assessment team. [from V2M3, 6.11.1(a)]
- The assessment team shall provide only preliminary determinations of potential findings and shall inform the CAB that final determinations concerning the number, nature and extent of assessment findings shall be made by the accreditation body after reviewing reported findings. [from V2M3, 6.11.1(b)]
- NOTE: The assessment team may only provide a preliminary written or oral report at the closing meeting because all final determinations of findings are subject to the approval of the accreditation body. [from V2M3, 6.11.1(b)]
- 7.6.6(b)
- (1) The accreditation body or its authorized representative shall present to the CAB within thirty calendar days of the last day of the on-site assessment a final assessment report identifying all confirmed findings. [from V2M3, 6.12.2]
- 7.6.7.1 Only accreditation bodies are allowed to release assessment reports initially. An assessment report shall not be released to the public by an accreditation body until the report has been provided to the CAB, and until the findings of the assessment and the associated corrective actions have been finalized.
- NOTE: The on-site assessment process concludes when a CAB addresses all findings in the on-site assessment report to the satisfaction of the accreditation body. [from V2M3, 6.12.6]

Slide 24 -- Clause 7 PROCESS REQUIREMENTS

- 7.6.8.1 The accreditation body shall require the CAB to shall provide to the accreditation body a plan of corrective action to address findings in the assessment report within thirty calendar days from its receipt. The accreditation body shall require the CAB to provide the date for implementation of corrective action as part of the response.

- NOTE: Customarily, a CAB that does not address all findings satisfactorily within two responses is scheduled for a follow-up evaluation or is subject to administrative procedures that deny accreditation to the CAB or that reduce its scope of accreditation. [from V2M3, 6.12.4]
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- 7.6.8.2 The accreditation body shall require the CAB's implementation of each corrective action to be due as specified in the submitted corrective action plan or as specified in the accreditation body's policy.

NEW LANGUAGE!

- 7.6.9
- NOTE: The accreditation body should may consult with the assessment team while reviewing CAB responses to nonconformities and before arriving at decisions on the accreditation status of a CAB. [from V2M3, 6.12.7]

Slide 25 -- Clause 7 PROCESS REQUIREMENTS

- 7.7.5.1 Denial of Accreditation
- Reasons to deny an initial application shall include, but are not limited to:
- 7.7.5.1.11 failure to provide documents requested by the accreditation body for review in a reasonable timeframe requested by the accreditation body prior to the on-site assessment.
- 7.7.6
- NOTE: An accreditation body would not be required to accept or recognize the primary accreditation of the CAB if the accreditation body has a legal action that precludes the accreditation body from granting any accreditation to a particular CAB for a specific field of accreditation , in recognizing the accreditation granted by another accreditation body, which has a law or decision resulting from a legal action, the legal effect of which precludes the accreditation body from granting any accreditation to a particular CAB, would not be required to accept the accreditation of this CAB. [from V2M1, 7.5.2]
- 7.8.1 *The accreditation body shall provide information on the accreditation to the accredited conformity assessment body that shall identify the following:*
- h) the matrix, technology/method, and analyte as defined in the TNI Laboratory Accreditation Management System (LAMS), however named.

Slide 26 -- Clause 7 PROCESS REQUIREMENTS

- 7.8.3 *The scope of accreditation shall, at least, identify the following:*
- d) *For testing laboratories (including medical laboratories):*
 - *materials or products tested;*
 - *component, parameter, or characteristic tested;*
 - *tests or types of tests performed and, where applicable, the techniques, methods, and/or equipment used.*
- e) *For proficiency testing providers:*
 - *schemes that the proficiency testing provider is competent to provide;*
 - *type of proficiency testing items;*
 - *the measurand(s) or characteristic(s) or, where appropriate, the type of measurand(s) or characteristic(s) that are to be identified, measured, or tested.*
- NOTE: In the context of this Volume in TNI's Environmental Laboratory Sector standards, only clause 7.8.3(d) is applicable. Clause 7.8.3(e) is applicable to Volume 4 in this Sector.

Slide 27 -- Clause 7 PROCESS REQUIREMENTS

- 7.9.3

- NOTE: “Other assessment techniques surveillance activities” may include, among other things, review by the accreditation body of internal audit reports and managerial reviews or continuing demonstration of corrective actions, or proficiency testing performed by the CAB. [from V2M1, 7.7.2]
- 7.9.4.1 After an initial assessment for accreditation, accreditation bodies shall perform reassessments at intervals of two years plus or minus six months. Once a CAB is accredited, accreditation bodies reserve the right to assess a CAB at any time during the accreditation cycle period. [from V2M3, 5.1 & 6.13.3]
- 7.9.4.2 NOTE: A strict timeline defines enforceable deadlines commensurate with the severity of a finding. [from V2M3, 6.13.6]
- 7.9.5
- NOTE: Examples of changes could include Extraordinary assessments may be performed when accreditation bodies receive complaints about CABs or when CABs experience changes in the CAB's ownership, key personnel, location, and scope of accreditation. [from V2M3, 6.13.8]

Slide 28 -- Clause 7 PROCESS REQUIREMENTS

- 7.11.1.2 Subject to applicable laws, regulations and due process requirements, an accreditation body may suspend, withdraw or reduce a CAB’s accreditation if the CAB fails to meet the standards for accreditation. The CAB shall retain accreditation for the scope of accreditation, where it continues to meet the requirements of the Standard. Reasons for suspension, withdrawal or reduction shall include but are not limited to:
- 7.11.1.2.3 failure to notify the accreditation body of any changes in key accreditation criteria as referenced in Clauses 4.2 and ISO/IEC 17011:2004(E) Clause 7.2.1;
- 7.11.1.2.8 Failure to provide documents requested by the accreditation body for review in a reasonable timeframe requested by the accreditation body prior to the on-site assessment.
- Failure to pass an on-site assessment conducted by an accreditation body;

Slide 29 -- Clause 7 PROCESS REQUIREMENTS

- 7.13.8
- NOTE: An independent person, or group of persons, may consist of another group within the accreditation body organization whose responsibility is to handle investigations and appeals. Alternatively, the matter can be addressed by an external group of peers called together for this purpose, and following a documented policy and procedure consistent with this Standard and agreed upon by all participants. [from V2M1, 7.6.2]
- 7.14.3 <requirements covered in 7.14.1 & 7.14.2>
- The accreditation body shall have a policy and procedure for retaining accreditation records for a minimum length of time as required by contractual obligations or pertinent territorial, state or federal laws and regulations. [from V2M1, 7.10.4]

Slide 30 -- Clause 8 INFORMATION REQUIREMENTS

- 8.1.1
- NOTE: The confidentiality of documents and records may be challenged in specific instances by public information requests under state or federal laws. [from V2M1, 7.10.2]
- 8.1.5 Confidential Business Information
- Accreditation bodies shall have documented procedures for processing and evaluating claims made by CABs of confidential business information (CBI) referencing applicable laws and regulations, the procedures a CAB shall follow to make a claim, the parties that will determine the validity of the claim, and the appeals process to be invoked when a CAB disagrees with the disposition of a claim. [from V2M3, 6.6]

Slide 31 -- Clause 9 MANAGEMENT SYSTEM REQUIREMENTS

- 9.7.5 One element of the annual internal audit shall be to review the effectiveness of the quality systems required. The internal audit shall include a review of the quality manual and associated written quality procedures. The frequency of internal audits may be reduced if the accreditation body can demonstrate acceptable performance during on-site evaluations. If this audit frequency is extended to a period longer than one year, the accreditation body shall document the frequency in their policies, procedures or quality manual. [from V2M1, 5.7.4]

Slide 32 -- Former ISO/IEC 17011:2004 Requirements

- NONE proposed for retention as TNI additional 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)

Slide 33 -- Former NELAC Chapter 6 Requirements

- Sections 6.2.1 & 6.2.2
 - Present to TNI Membership for consideration
 - Covered by TNI NELAP Mutual Recognition Policy?
- Sections 6.2.2 & 6.8
 - Forward to Quality Systems Committee for possible inclusion into ELS Volume 1, Module 2
- ALL other Sections
 - NOT proposed for inclusion into this Standard

Slide 34 -- NELAC Section 6.2.1

- NOT Recommended for Inclusion by this Committee (i.e., no longer needed)
- 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.

Slide 35 -- NELAC Section 6.2.2

Forwarded to Quality Systems Committee:

- 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 of 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. (this Expert Committee to consider further?)

Slides 36 & 37 -- Standard Interpretation Requests

- SIR 71 (2003 NELAC Sec. 3.6.4): Third-party assessor potential conflicts of interest
 - (Lab AB: accommodated in Clauses 4.4 and 6.4.4)
- SIR 136 (V2M3, 4.2.4): Technical training courses and requirements
 - (Lab AB: accommodated in Clause 6.1.2)
- SIR 165 (V2M1, 7.7.2 and V2M3, 6.13.2): Surveillance on-site assessments and Reassessments
 - (Lab AB: accommodated in Clauses 3.24, 7.6, and 7.9)
- SIR 194 (V2M1, 7.7.3 and V2M3, 5.1): Surveillance on-site assessments and reassessments
 - (Lab AB: accommodated in Clause 7.9.4.1)
- 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: addressed in State Accreditation Body regulations; forward to Quality Systems Expert Committee to consider)
- Standard Interpretation Requests
- 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: deemed inappropriate for this Expert Committee 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: made a normative requirement for AB to establish the ongoing training and added a note that written examinations may not be required for refresher training)
- 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: adequately covered in Clauses 7.9.2-7.9.4)
- 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: see SIR 216; adequately covered with the changes made to Clauses 6.1.2.9.3-6.1.2.9.4)

Slide 38 -- Parking Lot Issues

- Handling requests to extend deadlines in a standard where timelines are specified
- Communication policy to allow advance notice to other recognized NELAP accreditation bodies of cost increases or other changes in the AB's program
- Policy on secondary accreditations to mobile laboratories
- Timeframes for accreditation bodies to require of laboratories to complete corrective actions to non-conformances identified during on-site assessments
- Policy outlining qualifications and credentials needed for contract assessors, or for ALL accreditation body assessors
- Minimum requirements for enforcements against non-conforming environmental laboratories