Proposed Changes to Environmental Sector Standard Volume 2: General Requirements for Accreditation Bodies (ABs) Accrediting Environmental Laboratories (2009)

The TNI Laboratory Accreditation Body (LAB) Expert Committee has initiated efforts to modify to Volume 2 of the 2016 standard. Stakeholders are invited to provide comments and input. All input received by June 16, 2019 will be considered by the committee in its preparation of a Voting Draft Standard.

This announcement summarizes the changes and describes the benefits of the proposed changes.

1. Consolidation of Modules 1 and 3 and Updating to ISO/IEC 17011 (2017)

The current standard has the requirements for ABs in three separate modules, one for general requirements one for proficiency testing and one for the on-site assessment. Modules 1 and 3 both contain language from ISO/IEC 17011 (2004). When these modules were developed in 2007, they were developed by two separate committees that have merged into one. The 2009 Standard thus contains repetitive language and in some cases sections that conflict with each other.

By merging the two modules into one, the revised standard will be easier to read and any confusing language will be clarified.

The current standard is based on the 2004 version of ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies.* In 2017, ISO/IEC revised this standard. The new ISO standard
- Aligns the standard with the common structure of other ISO standards,
- Incorporates the mandatory wording required of ISO standards,
- Identifies Proficiency Testing as an accreditation activity,
- Incorporates, where appropriate, other reference documents such as documents from the International Accreditation Forum (IAF),
- Adds new definitions,
- Introduces the concept of risk and risk-based assessments, and
- Incorporates competence criteria for accreditation body assessors in the main body of the standard as well as an Informative Annex pertaining to knowledge and skills.

Below is a summary of the organization of the 2009 and 2016 Standards for comparison with this draft revision. The LAB Expert Committee is soliciting comments on both the proposed new organization of Module 1 and the use of the new ISO 17011 language. Appendix A contains a detailed outline of the proposed changes.

Organization of the 2009 and 2016 Standards

Module 1: General Requirements
1.0   INTRODUCTION, SCOPE AND APPLICABILITY
2.0   NORMATIVE REFERENCES
3.0   TERMS AND DEFINITIONS
4.0   ACCREDITATION BODY
5.0   MANAGEMENT
6.0   HUMAN RESOURCES
7.0   ACCREDITATION PROCESS
8.0   RESPONSIBILITIES OF THE AB AND THE CAB
Module 3: On-Site Assessment
1.0   INTRODUCTION, SCOPE AND APPLICABILITY
2.0   NORMATIVE REFERENCES
3.0   TERMS AND DEFINITIONS
4.0   ON-SITE ASSESSMENT HUMAN RESOURCES
5.0   FREQUENCY OF ON-SITE ASSESSMENTS

6.0   ON-SITE ASSESSMENT PROCESS
7.0   CHANGES IN CAB CAPABILITIES

Organization of the Draft Revised Standard

Clause 1: Scope
Clause 2: Normative References
Clause 3: Terms and Definitions
Clause 4: General Requirements
Clause 5: Structural Requirements
Clause 6: Resource Requirements
Clause 7: Process Requirements
Clause 8: Information Requirements
Clause 9: Management System Requirements
Annex A (Informative): Required Knowledge and Skills for Functions in the Accreditation Process

2. Accreditation Process Policies

As part of this standard development process, the LAB Expert Committee has the option of writing in policies and requirements for the accreditation bodies that will use this standard in conjunction with accrediting environmental laboratories. These topics were addressed as requirements written into the 2003 version of NELAC Chapter 6 but were not included in the 2009 TNI version of Volume 2. This list was identified and delineated by the NELAP Accreditation Council as needed for policies by which its accreditation bodies operate. The LAB Expert Committee considered each of these items along with TNI stakeholder input in 5 face-to-face meetings at conferences as well as in its regular monthly teleconferences in the preparation of this first standard draft. Nevertheless, if you have any second thoughts as to what was concluded within the last 2 years or not included in the draft revision of this standard, please provide your comments and recommended standard language that should be considered for the following:

- Assessing all methods versus selected methods for drinking water and other fields, at initial and subsequent on-site assessments (subject of a SIR and also a policy currently before LASEC)
- How to assess different Fields of Accreditation
- Accreditation of "prep methods" and accommodating the varied approaches by Accreditation Bodies (ABs)
- Using technologies as the basis for PT samples and Fields of Proficiency Testing (FoPT) tables
- Assessing laboratory accreditation scopes by matrix/method/analyte (by governmental and nongovernmental ABs)
- 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)
- NELAP policy on AB conformance to the current V2M3, Section 6.3.5 (current ISO/IEC 17011, Clause 7.5.6)
- Allowance to grant interim accreditation status to laboratories
- Allowance to extend deadlines in any standard through which timeframes are specified
- Requirement for the 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
- Allowance for NELAP Recognized ABs' personnel to perform accreditation functions for each other
- Process for expanding the scope of recognition for each NELAP AB to offer as Primary Accreditation to applicant laboratories
- Communication policy to allow advance notice to other recognized NELAP ABs of cost increases or other changes in the AB's program
- Policy on secondary accreditation to mobile laboratories
- Generic accreditation application form that will be used or acceptable to all recognized ABs

- Requirements on the content and frequency for updating information to LAMS (the National Database) on NELAP-accredited labs
- Policy on secondary accreditations (scope of accreditations)
- Timeframes for ABs 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 ALL AB assessors
- Scope of Accreditation definitively defined (at a minimum) as matrix – method (technology?) – analyte (or analyte group, or not at all?)
- Minimum requirements for training courses to train and qualify assessors (and accreditation decision-makers?)

APPENDIX A - EXECUTIVE SUMMARY OF POTENTIAL CHANGES AND IMPROVEMENTS

This appendix consists of the following sections:
- An outline of the revised Module 1 showing in detail where changes are proposed. Note this outline does not include sections where the language was unchanged, but the section number changed.
- A list of sections deleted from the current Volume 2 based on changes to ISO/IEC 17011.
- A list of Standard Interpretation Requests that will be considered for the new standard.
- A list of "parking lot" issue that will be considered.
- A review of Chapter 6 of the 2003 NELAC standard with recommendations concerning incorporating language from this standard.

TNI V2M1 DETAILED OUTLINE OF CHANGES

- The revised TNI 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.

CLAUSE 3   DEFINITIONS

3.2 Note 1 – removed by ISO CASCO (International Organization for Standardization's Conformity Assessment Committee) Work Group (WG) 42

3.4 Note 2 – eliminated by ISO CASCO WG 42 but retained and amended by this Committee; reference to NEFAP added.

3.4 Note 3 – Notes from the existing Volume 2, Module 3, Sections 6.3.6 and 6.3.7 (V2M3, 6.3.6 & 6.3.7) retained, moved to here, and merged. Clarity also provided by this Committee.

3.5   Conformity Assessment Activity – new definition from ISO CASCO WG 42

3.5 Note 1 – new language from ISO CASCO WG 42

3.6 TNI additions – TNI additional language from V2M3 retained; language from the V2M1 definition eliminated.

3.7   Flexible Scope of Accreditation – new definition from ISO CASCO WG 42

3.8   Accreditation Scheme – new definition from ISO CASCO WG 42

3.8 Note 1 – new language from ISO CASCO WG 42

3.8 Note 2 – new language from this Committee to say that the accreditation scheme requirements for environmental laboratories are in ELS Volumes 1 & 2.

3.9   Accreditation Activity – new definition from ISO CASCO WG 42

3.9 Note 1 – new language from ISO CASCO WG 42

3.10   Impartiality – new definition from ISO CASCO WG 42

3.10 Note 1 – new language from ISO CASCO WG 42

3.10 Note 2 – new language from ISO CASCO WG 42

3.11   Accreditation Process – new definition from ISO CASCO WG 42

3.13   Accreditation Decision – new definition from ISO CASCO WG 42

3.14   Granting of Accreditation – new definition from ISO CASCO WG 42

3.15   Maintaining Accreditation – new definition from ISO CASCO WG 42

3.16   Extending Accreditation – revised by ISO CASCO WG 42

3.19   Withdrawing Accreditation – definition revised and Note eliminated by ISO CASCO WG 42

3.21   Appeal – definition unchanged but Note eliminated by ISO CASCO WG 42

3.22   Assessment – definition essentially unchanged but Note 1 eliminated by ISO CASCO WG 42

3.22 TNI additions – Note 2 from TNI V2M3, 3.7 and "Field of Accreditation" definition proposed for elimination by this Committee

3.23   Reassessment – new definition from ISO CASCO WG 42

3.24   Assessment Technique – new definition from ISO CASCO WG 42

3.24 Note 1 – new language from ISO CASCO WG 42

3.25   Witnessing – definition essentially unchanged

3.26   Remote Assessment – new definition from ISO CASCO WG 42

3.26 Note 1 – new language from ISO CASCO WG 42

3.27   Assessment Program – new definition from ISO CASCO WG 42

3.28   Assessment Plan – new definition from ISO CASCO WG 42

3.29   Accreditation Body Personnel – new definition from ISO CASCO WG 42

3.30   Assessor – definition revised slightly by ISO CASCO WG 42, with the Note deleted

3.31   Team Leader – revised definition from ISO CASCO WG 42 for the former term "Lead Assessor"

3.32   Technical Expert – revised definition from ISO CASCO WG 42 for the former term "Expert"

3.33   Interested Party – definition essentially unchanged

3.33 Note 2 – new language from ISO CASCO WG 42

3.34 Note – TNI language retained by this Committee

"Accreditation Certificate" and "Surveillance" – definitions deleted by ISO CASCO WG42 and not retained by this Committee.

CLAUSE 4   GENERAL REQUIREMENTS

4.1 – similar to the current V2M1 4.1, but ISO CASCO WG42 added "legal responsibility" for accreditation activities.

4.1 Note 2 – additional explanation provided by ISO CASCO WG42

4.2(a) – similar to the current V2M1, 8.1.1(a), but ISO CASCO WG42 also requires CABs to "have legally enforceable arrangements" on items (a)-(k) and to "commit to provide evidence of fulfillment" on item (a).

4.2(b) – similar to the current V2M1, 8.1.1(b)

4.2(c) – similar to the current V2M1, 8.1.1(c)

4.2(d) – similar to the current V2M1, 8.1.1(e)

4.2(e) – new item added to the list in ISO/IEC 17011 by CASCO WG42

4.2(f) – similar to the current V2M1, 8.1.1(f)

4.2(g) – new item added to the list in ISO/IEC 17011 by CASCO WG42

4.2(h) – similar to the current V2M1, 8.1.1(g)

4.2(i) – similar to the current V2M1, 8.1.2 and V2M3, 7.0

4.2(i) Note – Current listing of items (a)-(f) expressed by ISO CASCO WG42 as bullet items here so as not to limit what "significant changes" pertain to.

4.2(j) – similar to the current V2M1, 8.1.1(h)

4.2(k) – new item added to the list in ISO/IEC 17011 by CASCO WG42

4.3.1(a) – essentially unchanged from V2M1, 8.3.2(a)

4.3.1(b) – essentially unchanged from V2M1, 8.3.2(c)

4.3.1(c) – essentially unchanged from V2M1, 8.3.2(e)

4.3.1(d) – essentially unchanged from V2M1, 8.3.2(f)

4.3.1(e) – new item added to the list in ISO/IEC 17011 by CASCO WG42

4.3.2 – new requirement added to ISO/IEC 17011 by CASCO WG42

4.3.3 – essentially unchanged from V2M1, 8.3.1

4.3.3(a) – specified requirements for use of the accreditation symbol and claims of accreditation status added to ISO/IEC 17011 by CASCO WG 42

4.3.3(b) – specified requirements for use of the accreditation symbol and claims of accreditation status added to ISO/IEC 17011 by CASCO WG 42

4.3.3(c) – specified requirements for use of the accreditation symbol and claims of accreditation status added to ISO/IEC 17011 by CASCO WG 42

4.3.3(d) – specified requirements for use of the accreditation symbol and claims of accreditation status added to ISO/IEC 17011 by CASCO WG 42

4.3.3(e) – specified requirements for use of the accreditation symbol and claims of accreditation status added to ISO/IEC 17011 by CASCO WG 42

4.3.3(f) – specified requirements for use of the accreditation symbol and claims of accreditation status added to ISO/IEC 17011 by CASCO WG 42

4.3.4 – essentially unchanged from V2M1, 8.3.1

4.3.5 – essentially unchanged from V2M1, 8.3.3

4.4.1 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42

4.4.2 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42

4.4.3 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42

4.4.4 – revisions & reinforcements to the current V2M1, 4.3.4 by ISO CASCO WG42

4.4.5 – revisions & reinforcements to the current V2M1, 4.3.2 by ISO CASCO WG42

4.4.6 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42 (including 2 Notes)

4.4.7 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42

4.4.8 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42

4.4.9 – new requirements on Impartiality added to ISO/IEC 17011 by CASCO WG42

4.4.10 – essentially unchanged from the current V2M1, 4.3.3

4.4.10 Note – added by ISO CASCO WG42

4.4.11 – revisions & reinforcements to the current V2M1, 4.3.6 by ISO CASCO WG42

4.4.12(a) – essentially unchanged from the current V2M1, 4.3.7(a)

4.4.12(b) – essentially unchanged from the current V2M1, 4.3.7(b)

4.4.12(c) – essentially unchanged from the current V2M1, 4.3.7(d)

4.4.12(c) Note – TNI language from the current V2M1, 4.3.7 Note 3 retained by this Committee.

4,4.12(d) – revisions & reinforcements to the current V2M1, 4.3.7(c) by ISO CASCO WG42

4.4.13 – essentially unchanged from the current V2M1, 4.3.6

4.4.13 Note – added by ISO CASCO WG42

4.4.14 – TNI additional language from V2M1, 4.3.3.1 retained by this Committee and moved to here

4.4.15 – TNI additional language from V2M1, 4.3.8 retained by this Committee and moved to here

4.5.2 – essentially unchanged from V2M1, 4.5.1 but ISO CASCO WG42 also adds language to require AB to evaluate risks arising from its activities.

4.6.1 – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.2 – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.2 Note 1 – language added by ISO CASCO WG42

4.6.2 Note 2 – language added by ISO CASCO WG42

4.6.3 – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4 – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(a) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(b) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(c) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(d) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(e) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(f) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.4(g) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.5(a) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.5(b) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.5(c) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.5(d) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

4.6.5(e) – new requirements on Establishing Accreditation Schemes added to ISO/IEC 17011 by CASCO WG42 to replace the former requirements in V2M1, 4.6 on Accreditation Activity

CLAUSE 5   STRUCTURAL REQUIREMENTS

5.1 – revised, streamlined language from V2M1, 4.2.1 & 4.3.1 from ISO CASCO WG42

5.1 Note 1 – TNI Note 1 from V2M1, 4.2.1, restricting ABs to being government organizations, proposed for deletion by this Committee (to accommodate the non-governmental accreditation bodies).

5.1 Note 2 – TNI Note 2 from V2M1, 4.2.1 retained by this Committee and moved to here

5.3 – new language for ISO/IEC 17011 from CASCO WG42

5.5 – essentially the same requirements as V2M1, 4.2.2 but with more detail

5.5.1 – TNI language from V2M1, 4.2.2.1 retained by this Committee and moved to here

5.6 – essentially unchanged from V2M1, 4.2.4

5.7(b) – essentially unchanged from V2M1, 4.2.5(b)

.7(d) – new item added to the list in ISO/IEC 17011 by CASCO WG42

5.7(f) – new item added to the list in ISO/IEC 17011 by CASCO WG42

5.7(g) – new item added to the list in ISO/IEC 17011 by CASCO WG42

5.7(i) – new item added to the list in ISO/IEC 17011 by CASCO WG42

5.7(k) – new item added to the list in ISO/IEC 17011 by CASCO WG42

5.7 Note – TNI Note from V2M1, 4.2.5 retained by this Committee and moved to here

CLAUSE 6   RESOURCE REQUIREMENTS

6.1.1 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.1 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.2 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.3 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.4 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.5 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.6 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.6 Note – TNI language from V2M3, 4.2.7 Note 2 unchanged & moved to here

6.1.2.7 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.8 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.9 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.2.9.1 – TNI language from V2M3, 4.2.3 retained & revised by this Committee and moved to here

6.1.2.9.2 – TNI language from V2M3, 4.2.4 retained & revised by this Committee and moved to here

6.1.2.9.2 Note – TNI Note from V2M3, 4.2.4 retained & revised by this Committee and moved to here

6.1.2.9.3 – Requirement added by this Committee: AB must establish requirements for ongoing training to assure assessors' continuing competence.

6.1.2.9.3 Note – additional language added by this Committee (written exam may not be required)

6.1.2.9.4 – TNI language from V2M3, 4.3.2 retained by this Committee and moved to here

6.1.3.1 – revisions & reinforcements to the current V2M1, 6.2.1 & V2M3, 4.2.1 by ISO CASCO WG42

6.1.3.2 – revisions & reinforcements to the current V2M1, 6.2.2 & V2M3, 4.2.2 by ISO CASCO WG42

6.1.3.2 Note – additional language from ISO CASCO WG42

6.1.3.2.1 – TNI language from V2M3, 4.2.5 retained by this Committee and moved to here

6.1.3.2.1(a) – TNI language from V2M3, 4.2.5(a) retained by this Committee and moved to here

6.1.3.2.1(b) – TNI language from V2M3, 4.2.5(b) retained by this Committee and moved to here

6.1.3.2.1(b) Note – TNI Note from V2M3, 4.2.5 retained by this Committee and moved to here

6.1.3.2.1(c) – TNI language from V2M3, 4.2.5(c) retained by this Committee and moved to here

6.1.3.3 – new requirements on Competence of AB Personnel added to ISO/IEC 17011 by CASCO WG42

6.1.3.4 – revisions & reinforcements to the current V2M1, 6.3.1 by ISO CASCO WG42

6.1.3.5 – revisions & reinforcements to the current V2M1, 6.3.2 by ISO CASCO WG42

6.1.3.6 – revisions & reinforcements to the current V2M1, 6.3.2 by ISO CASCO WG42

6.1.3.7 – Requirement added by this Committee: Records for monitoring of all assessors must be maintained.

6.2.1 – revisions & streamlining of the current V2M1, 6.1.1 & 6.1.2 and V2M3, 4.1.1 by ISO CASCO WG42

6.2.2 – revisions & reinforcements to the current V2M1, 6.1.4 & V2M3, 4.1.4 by ISO CASCO WG42

6.2.2.1(a)-(j) – TNI language from V2M3, 4.4.2 retained by this Committee and moved to here

6.2.2.2 – TNI language from V2M3, 4.1.5 retained by this Committee and moved to here

6.2.2.3 – TNI language from V2M3, 4.3.3 retained by this Committee and moved to here

6.2.2.3 Note – TNI language from the V2M3, 4.3.5 Note revised by this Committee and moved to here

6.2.3 – new requirements added to ISO/IEC 17011 by CASCO WG42

6.2.3.1 – TNI language from V2M3, 4.1.2 retained by this Committee and moved to here

6.2.3.2 – TNI language from V2M3, 6.7 retained by this Committee and moved to here

6.2.3.2 Note – TNI language from the V2M3, 6.7 Note retained by this Committee and moved to here

6.3 – revisions & reinforcements to the current V2M1, 6.4.1 by ISO CASCO WG42

6.3 Note -TNI language from the V2M3, 4.3.1 Note retained & revised by this Committee and moved to here

6.4.1 – essentially unchanged from V2M1, 7.4.1

6.4.2 – revisions & reinforcements to the current V2M1, 7.4.1 by ISO CASCO WG42

6.4.3 – essentially unchanged from V2M1, 7.4.1

6.4.4 – essentially unchanged from V2M1, 7.4.1

6.4.5(a) – revised & streamlined from the current V2M1, 7.4.2(a) by ISO CASCO WG42

6.4.5(b) – essentially unchanged from V2M1, 7.4.2(c)

6.4.5(c) – essentially unchanged from V2M1, 7.4.2(d)

6.4.6 – additions, revisions, & reinforcements to the current V2M1, 6.1.4 & V2M3, 4.1.4 by ISO CASCO WG42

6.4.6 Note 1 – language added by ISO CASCO WG42

6.4.6 Note 2 – language added by ISO CASCO WG42

6.4.6 Note 3 – TNI language from the V2M3, 6.2 Note 2 retained, revised by this Committee, & moved to here

CLAUSE 7   PROCESS REQUIREMENTS

7.1 – essentially unchanged from V2M1, 7.1.1

7.2.1(a) – essentially unchanged from V2M1, 7.2.1(a)

7.2.1(b) – essentially unchanged from V2M1, 7.2.1(b)

7.2.1(c) – essentially unchanged from V2M1, 7.2.1(c)

7.2.1(d) – essentially unchanged from V2M1, 7.2.1(d)

7.2.1 Note – Additional explanatory language recommended from this Committee.

7.2.2 – revised, streamlined language to V2M1, 7.2.2 from ISO CASCO WG42

7.2.3 – essentially unchanged from V2M1, 7.2.3

7.2.4 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.2.5 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.3.1 – essentially unchanged from V2M1, 7.3.1 & V2M3, 6.1.1

7.3.2 – ISO CASCO WG42 added a requirement to the existing language in V2M1, 7.3.2 & V2M3, 6.1.2

7.4.1 – essentially unchanged from V2M3, 6.3.1

7.4.1(a) – essentially unchanged from V2M3, 6.3.1(a)
7.4.2 – essentially unchanged from V2M3, 6.3.3 but supporting justification required for any objections

7.4.2 Note – TNI language from V2M3, 6.3.3 Note retained by this Committee except for the 1st sentence and moved to this section

7.4.2.1 – TNI language from V2M3, 5.2 & 6.13.4 retained by this Committee and moved to here; TNI language in V2M1, 7.4.2.1 recommended for deletion by this Committee (CAB's right to exclude a 3rd-party assessor)

"7.4.2.1 Notes" – TNI language from Notes in V2M1, 7.11.3 and V2M3, 6.3.8 proposed for deletion by this Committee.

7.4.3 – only 1st sentence from V2M3, 6.3.4 retained, but unchanged, by ISO CASCO WG42

7.4.4 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.4.5 – revised & streamlined requirements from V2M3, 6.3.5-6.3.7 from ISO CASCO WG42

"7.4.5 Note" – TNI language from the V2M3, 6.3.5 Note proposed for deletion by this Committee (no longer needed; redundant with ISO)

7.4.6 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.4.7 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.4.8 – revised & streamlined requirements from V2M3, 6.3.8 from ISO CASCO WG42

7.4.9 – essentially unchanged from V2M3, 6.3.9

7.5.1 – essentially unchanged from V2M3, 6.4.1

7.5.2 – essentially unchanged from V2M3, 6.4.2

7.5.2 Note – most TNI language from the V2M3, 6.4.2 Note recommended for deletion by this Committee; only the recommendation to notify CABs of an assessment cancelation retained & moved to here

7.6.1 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.6.2 – essentially unchanged from V2M3, 6.8

7.6.2.1 – TNI language from V2M3, 6.8 retained & moved to here, but only has requirement to document opening conference attendance.

7.6.2.1 Note – TNI language from the V2M3, 6.8 Note retained & moved to here, but removes the phrase on CBI handling procedures.

7.6.3 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.6.3.1 – TNI language from V2M3, 4.4.3 retained, moved to here, but modified slightly; essentially unchanged

7.6.3.1 Note – TNI language from V2M3, 4.4.3 Note retained & moved to here; additional sentence added by this Committee

7.6.3.2(a) – TNI language from V2M3, 6.5(a) retained & moved to here

7.6.3.2(b) – TNI language from V2M3, 6.5(c) retained & moved to here (however, this Committee proposes to delete V2M3, 6.5(b) which pertains to providing checklists)

7.6.3.2(c) – TNI language from V2M3, 6.5(d) retained & moved to here

7.6.3.3 – TNI language from V2M3, 4.3.4 essentially unchanged & moved to here (but changed "lead assessor" to "assessment team leader")

7.6.3.4 – TNI Note from V2M3, 6.9.2 moved to here & recommended by this Committee to become a normative requirement (authority to conduct interviews of CAB staff)

7.6.4 – shortened & streamlined requirements to current V2M3, 6.10.1 from ISO CASCO WG42

7.6.4.1 – TNI Note from V2M3, 6.10.1 moved to here & recommended by this Committee to become a normative requirement (assessor conduct to provide instruction & guidance as opposed to consultancy)

7.6.6(a) – essentially unchanged from V2M3, 6.11.1(a)

7.6.6(a)(1) – Made TNI language from V2M3, 6.11.1(b) Note to be normative, in addition to retention by this Committee & moved to here; language added to permit AB's assessment team to present findings orally, and not just in writing, at the assessment closing conference

7.6.6(a)(2) – TNI language from V2M3, 6.11.1(a) retained & moved to here, but only has requirement to document closing conference attendance (no longer necessarily on forms provided by assessment team)

"7.6.6(a)(2)" – TNI normative language from V2M3, 6.11.1(b) proposed for deletion by this Committee.

7.6.6(b) – additional requirements added to V2M3, 6.12.1 by ISO CASCO WG42

7.6.6(b)(1) – TNI language from V2M3, 6.12.2 retained & moved to here, but modified slightly

7.6.6(c) – new requirements added to ISO/IEC 17011 by CASCO WG42

7.6.7 – shortened & streamlined requirements to current V2M3, 6.12.5 from ISO CASCO WG42

7.6.7.1 & Note – this Committee proposes deletion of the current TNI language in V2M3, 6.12.6 and its Note

7.6.8 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.6.8.1 – TNI language from V2M3, 6.12.4 retained & moved to here; this Committee is proposing adding the requirement for the CAB to provide implementation date(s) for the proposed corrective actions

7.6.8.1 Note – TNI language from the V2M3, 6.12.4 Note proposed for deletion by this Committee

7.6.8.2 – This Committee recommends this additional normative TNI language (CAB corrective action implementation is due as specified in the submitted corrective action or in the AB's policy)

7.6.9 – essentially unchanged from V2M3, 6.12.7

7.6.9 Note – TNI language from current V2M3, 6.12.7 Note retained & moved to here; essentially unchanged

7.7.1 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.7.2 – additional requirements added to V2M1, 4.3.5 by ISO CASCO WG42

7.7.3(b) – unchanged from V2M3, 6.12.8(b) but ISO CASCO WG42 adds "type(s) of assessment(s)"

7.7.3(c) – essentially unchanged from V2M3, 6.12.8(c)

7.7.3(d) – essentially unchanged from V2M3, 6.12.8(d)

7.7.3(e) – essentially unchanged from V2M3, 6.12.8(e)

7.7.3(h) – current V2M3, 6.12.8(h) revised slightly by ISO CASCO WG42 to be more result-oriented & complete

7.7.3(i) – essentially unchanged from V2M3, 6.12.8(i) but ISO CASCO WG42 removed the current language from V2M3, 6.12.8(j) about applicable proficiency testing

7.7.3(j) – essentially unchanged from V2M3, 6.12.8(k)

7.7.5 – current language from V2M1, 7.5.2 unchanged but additional requirement added by ISO CASCO WG42

7.7.5.1 – TNI language from V2M1, 7.5.6.1 moved to here; Committee recommends addition of a new item (7.7.5.1.11) for "failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the on-site assessment."

7.7.5.2 – TNI language unchanged from V2M1, 7.5.6.2 & moved to here

7.7.6 – essentially unchanged from V2M1, 7.5.3

7.7.6 Note -TNI language from the current V2M1, 7.5.2 Note revised by this Committee & moved to here

7.8.1 Note – new TNI language recommended by this Committee (denoting applicable TNI ELS sections)

7.8.1(a) – essentially unchanged from V2M1, 7.5.4(a) but ISO CASCO WG42 replaces "accreditation certificate" with "information on the accreditation" to all points in this section

7.8.1(b) – essentially unchanged from V2M1, 7.5.4(b) but ISO CASCO WG42 replaces "unique identity" with "name … and name of the legal entity, if different"

7.8.1(c) – essentially unchanged from V2M1, 7.5.4(f) but made more definitive by ISO CASCO WG42

7.8.1(d) – essentially unchanged from V2M1, 7.5.4(c)

7.8.1(e) – essentially unchanged from V2M1, 7.5.4(d)

7.8.1(f) – essentially unchanged from V2M1, 7.5.4(e)

7.8.1 Note – new language provided by ISO CASCO WG 42

7.8.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.8.3 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.8.3(d) – Matrix, Analyte, and Technology / Method added to the ISO/IEC list in the appropriate places by this Committee

7.8.4 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.9 throughout – ISO CASCO WG42 replaces the concepts of "Reassessment and Surveillance" currently in V2M1, 7.7 and V2M3, 6.13 with "Accreditation Cycle"

7.9.3 Note – TNI language from V2M1, 7.7.2 Note retained & moved to here, but this Committee changes "surveillance activities" to "assessment techniques"

7.9.4.1 – TNI language unchanged from V2M3, 5.1 & 6.13.3 & moved to here (NELAP AC VETO expected if intervals are longer than 2 years +/- 6 months)

7.9.4.2 – TNI language from V2M3, 6.13.6 Note recommended for deletion since no more ISO language regarding "strict timelines."

7.9.5 – essentially unchanged from V2M1, 7.7.7 but ISO CASCO WG42 adds that "other matters that affect ability of the CAB to fulfill requirements for accreditation" is also grounds for extraordinary assessments

7.9.5 Note – revised TNI language for the V2M3, 6.3.8 Note is proposed by this Committee & moved to here

7.10.1 – revisions to V2M1, 7.8 made by ISO/IEC 17011 by CASCO WG42

7.10.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.11.1 – revisions to V2M1, 7.9.1-7.9.3 made by ISO/IEC 17011 by CASCO WG42

7.11.1.1 – TNI language unchanged from V2M1, 7.9.4.1 & moved to here

7.11.1.2 – TNI language mostly unchanged from V2M1, 7.9.4.2 & moved to here, but this Committee recommends removal of the item "failure to pass an on-site assessment" (current 7.11.1.2.8) from the list and addition of a new item (7.11.1.2.10) for "failure to provide documents requested by the accreditation body for review in a timeframe requested by the accreditation body prior to the on-site assessment"; ISO/IEC 17011 references in 7.11.1.2.3 updated

7.11.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.11.3 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.1 – language from V2M1, 5.9 revised by ISO CASCO WG42; V2M1, 5.9(b) left unchanged; TNI language in V2M1, 5.9.1 now redundant if "disputes" also considered as a "complaint"

7.12.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.3 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.4(a) – ISO language from V2M1, 5.9(a) revised by ISO CASCO WG42

7.12.4(b) – essentially unchanged from V2M1, 5.9(d)

7.12.4(c) – ISO language from V2M1, 5.9(c) revised by ISO/IEC 17011 by CASCO WG42

7.12.5 – ISO language from V2M1, 5.9(e) revised by ISO CASCO WG42

7.12.6 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.7 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.8 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.9 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.12.10 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.13.1 – ISO language from V2M1, 7.6.1 expanded by ISO CASCO WG42 to be more complete

7.13.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.13.3 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.13.4 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.13.5(a) – ISO language from V2M1, 7.6.2(b) revised by ISO CASCO WG42

7.13.5(b) – ISO language from V2M1, 7.6.2(e) revised by ISO CASCO WG42

7.13.5(c) – ISO language from V2M1, 7.6.2(d) revised by ISO CASCO WG42

7.13.6 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.13.7 – ISO language from V2M1, 7.6.2(c) revised by ISO CASCO WG42

7.13.8 – ISO language from V2M1, 7.6.2(a) expanded by ISO CASCO WG42 to be more complete

7.13.8 Note – TNI language in V2M1, 7.6.2 Note unchanged & moved to here

7.13.9 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.14.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

7.14.3 – TNI language from V2M1, 7.10.4 proposed for deletion by this Committee (redundant now)

CLAUSE 8   INFORMATION REQUIREMENTS

8.1.1 – greatly expanded requirements added to V2M1, 4.4 by ISO CASCO WG42

8.1.1 Note – TNI language from V2M1, 7.10.2 Note recommended for deletion by this Committee

8.1.2 – greatly expanded requirements added to V2M1, 4.4 by ISO CASCO WG42

8.1.3 – greatly expanded requirements added to V2M1, 4.4 by ISO CASCO WG42

8.1.4 – greatly expanded requirements added to V2M1, 4.4 by ISO CASCO WG42

8.1.5 – TNI language from V2M3, 6.6 revised & streamlined by this Committee (deletion of obsolete language)

8.2.1(a)(4) – revised & streamlined ISO language to V2M1, 7.1.2(j) by ISO CASCO WG42

8.2.1(a)(5) – essentially unchanged from V2M1, 8.2.3

8.2.1(b)(1) – revised language to V2M1, 7.1.2(a) by ISO CASCO WG42

8.2.1(b)(2) – revised & streamlined language to V2M1, 7.1.2(b) by ISO CASCO WG42

8.2.1(b)(6) – new item added to the list by ISO CASCO WG42; ISO language from V2M1, 7.1.2(k) removed from the list

8.2.2 – essentially unchanged from V2M1, 7.1.2(e)

8.2.2 Note – new language added by ISO CASCO WG42

8.2.4 – essentially unchanged from V2M1, 8.2.4

CLAUSE 9   MANAGEMENT SYSTEM REQUIREMENTS

9.1.1 – essentially the same as V2M1, 5.1.1

9.1.2 – ISO language in V2M1, 5.2.1 revised by ISO CASCO WG42

9.1.3(a) – essentially unchanged from V2M1, 5.2.3(a) but ISO CASCO WG42 added "implemented, & maintained" to the existing requirement for "established"

9.1.4 – new requirements added to ISO/IEC 17011 by CASCO WG42 (for "Option A")

9.1.5 – new requirements added to ISO/IEC 17011 by CASCO WG42 (for "Option B")

9.2.2 – new requirements added to ISO/IEC 17011 by CASCO WG42

9.3 – unchanged from V2M1, 5.3 (including (a)-(g)), but procedures now must be "documented procedures"

9.4.1 – essentially unchanged from V2M1, 5.4.1

9.4.2 – essentially unchanged from V2M1, 5.4.2

9.5 – unchanged from V2M1, 5.5 (including (a)-(g)), but procedures now must be "documented procedures"

9.6 – ISO language from V2M1, 5.6 revised by ISO CASCO WG42; "Preventive Actions" now called "Improvement," with reference to the "Impartiality" section

9.7.1 – essentially unchanged from V2M1, 5.7.1, but procedures now must be "documented procedures"; ISO CASCO WG42 removed the Note in this section

9.7.2 – essentially unchanged from V2M1, 5.7.2

9.7.3 – essentially unchanged from V2M1, 5.7.2

9.7.4 – essentially unchanged from V2M1, 5.7.3 (including (a)-(e))

"9.7.5" – TNI language from V2M1, 5.7.4 recommended for deletion by this Committee (no longer needed; redundant with ISO/IEC requirements)

9.8.1 – essentially unchanged from V2M1, 5.8.1, but these reviews must now occur at least once per year

9.8.2(d) – new item added to the list by ISO CASCO WG42

9.8.2(h) – unchanged from V2M1, 5.8.2(g) but "corrective actions" only

9.8.2(i) – new item added to the list by ISO CASCO WG42

9.8.2(m) – essentially unchanged from V2M1, 5.8.2(k)

Annex A (informative) – section added by ISO CASCO WG42

ISO Language in the 2004 Version of ISO/IEC 17011 that was deleted by CASCO WG42:

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

The Laboratory Accreditation Body Expert Committee also recommends non-inclusion of these sections as they are no longer needed.

TNI STANDARDS INTERPRETATION REQUESTS (SIRs)

SIR #	Current Standard cited	Proposed V2M1 Standard Clauses that Resolve the Issue
71	2003-NELAC 3.6.4	4.4.4, 6.2.2.1-6.2.2.3, 7.4.2
136	V2M3, 4.2.4	6.1 as a WHOLE, Annex A (Personnel Competence)
165	V2M1, 7.7.2 & V2M3, 6.13.2	7.9 as a WHOLE (Accreditation Cycle)
194	V2M1, 7.7.3 & V2M3, 5.1	7.9 as a WHOLE (Assessment Program & Techniques)
200	V2M1, 8.1.2(b) & V2M3, 7.0(b)	4.2, 7.2.1, 7.11.1.2

203	V2M1, 4.1 – 4.2.2.1	Cannot Be Addressed (accreditation scheme issue)
216	V2M3, 4.2.4	6.1 as a WHOLE, Annex A
254	V2M3, 6.3.5	7.9 as a WHOLE (requirements for Reassessments)
305	V2M1, 6.2.3	former clause to be deleted; See 6.1 as a WHOLE

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

2003 NELAC Chapter 6 Language

Sections the Laboratory Accreditation Body Expert Committee recommends non-inclusion of these sections as they are no longer needed.

6.1
6.2(a)-(j)
6.2.1(a)-(i)
6.3.1(a)-(d)
6.3.2(a)-(f)
6.3.2.1(a)-(o)
6.3.2.1.1(a)-(d)
6.3.2.1.2(a)-(b)
6.3.2.1.3(a)-(b)
6.3.2.1.4
6.3.2.2
6.3.3
6.3.4(a)-(c)
6.4(a)-(d)
6.4.1
6.4.2
6.4.3
6.5
6.6
6.7
6.9
6.10
6.11
Appendix A

Sections the Laboratory Accreditation Body Expert Committee recommends these sections be forwarded to the Quality Systems committee for consideration.

6.2.2(a)-(i)
6.8(a)-(d)