



Environmental Measurement Symposium Laboratory Accreditation Body Expert Committee

August 2, 2021 9 am PDT
A Hybrid In-person and Virtual Event

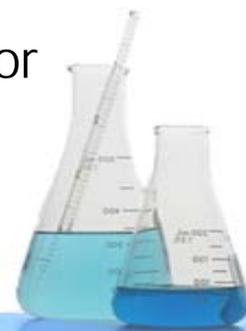
Carl Kircher, PhD, Florida Dept. of Health, Chair





Laboratory Accreditation Body Expert Committee

- Carl Kircher, Chair (NELAP AB)
- Mei Beth Shepherd, Vice-Chair (Other)
- Marlene Moore (Other)
- Zaneta Popovska (Non-governmental AB)
- William Batschelet (Other)
- Catherine Katsikis (Other)
- Alia Rauf (NELAP AB)
- Michael Perry (Lab)
- Socorro Baldonado (Lab)
- Nilda Cox (Lab)
- Aaren Alger (Other)
- Nicolas Slawson (Non-governmental AB)
- Interested Associates
- Lynn Bradley
TNI Program Administrator





Agenda

- Welcome and Roll Call
- Approval of Agenda
- Approval of July minutes
- Discussion of Select Comments on V2M1 Draft Standard
- New Business
- Adjourn





TNI ELS V2M1 – General Requirements for Accreditation Bodies Accrediting Environmental Laboratories

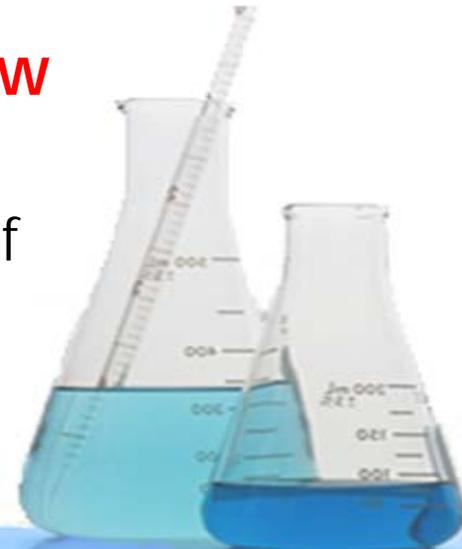
- General requirements for the Accreditation Body in Module 1 and specific laboratory on-site assessment requirements in Module 3 combined into one module.
- The recently-revised international standard for accreditation bodies in ISO/IEC 17011:2017(E) incorporated.
- Additional TNI normative language specific for environmental testing laboratory accreditation bodies retained or revised for improvements, and then moved into the appropriate sections of the Standard.
- Some requirements now deemed redundant, obsolete, or no longer needed proposed for elimination.





Where LAB is, in the Standards Development Process

- Presentation of Draft Standard *TNI ELS V2M1 "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories"* – December 2020
- Received Comments on Draft Standard – March 2021
- **Discuss and rule on comments – underway now**
 - **Persuasive or Non-persuasive, Editorial**
- If controversies identified – publish updated version of Draft Standard and receive/review comments again
- Committee vote for Final Standard – 2022?
- Adoption by relevant TNI Programs





Consensus Standard Development

- Major Issues Commented Upon in Draft Standard
 - Assessor competency requirements
 - Laboratory Assessment Report contents
 - Confidential and Publicly Available Information requirements





Assessor Competency Requirements

- Lab considered both extremes
 - No requirements – let the AB decide
 - Former prescriptive requirements from 2003-version NELAC Standards, Chapter 3 with its Appendices





The Compromise Draft Standard

- Clause 6.1.2.9.1 Education and Experience Requirements
An assessor shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by having performed verified assessments of environmental CABs (see 6.1.3.2.1). An accreditation body that chooses to evaluate an assessor's educational qualifications using the "commensurate experience" allowance shall have documented procedures for evaluating what constitutes commensurate experience. These procedures must define how this practice is applied within the organization and document the decision-making process used to approve the assessor.





Assessor Competency Requirements – Basic Qualifications

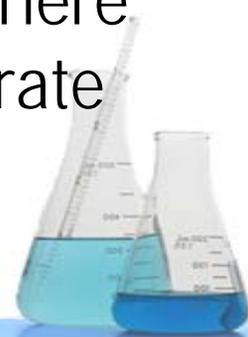
- Assessor Education and Experience
- Bachelor's Degree in a scientific discipline
- Alternatively, “commensurate” experience
 - AB decides if commensurate experience is allowed
 - AB defines & documents what “commensurate” means
 - AB defines how this practice is applied & documents its decision process for approving the assessor





Summary of Comments on Assessor Competency Requirements

6.1.2.9.1 is totally unequitable and non-uniform when compared to the insistence among ABs that laboratory Technical Managers be required to have Bachelors Degrees as well as specified credits in various disciplines. If commensurate experience is allowed for those who would assess laboratories, then commensurate experience **MUST** be allowed for those who are running those laboratories. There cannot be this unequitable ability to rely on commensurate experience on the one hand, but not on the other.





Assessor Competency Requirements – Training: The Proposed Compromise Draft Standard

□ Clause 6.1.2.9.2 Training Requirements for New Assessors

An assessor shall complete and pass assessor training courses that include obtaining a passing score on the written examination at the conclusion of the course. These training courses shall include, but not be limited to:

- (a) TNI proficiency testing and quality management systems assessment training (specifically, TNI ELS Volume 1, Modules 1 and 2);
- (b) TNI technical module assessment training (e.g., TNI ELS Volume 1, individual Modules 3 through 7); and
- (c) Technical discipline assessment training as required by the Accreditation Body for the accreditation scheme(s) supported.





Assessor Competency Requirements – Assessor Training

- New ABs seeking NELAP or TNI Recognition
 - Assessors trained per the Standard, complete by time AB gets “Recognized” & assessors begin laboratory assessments
- Existing NELAP & TNI Recognized ABs that hire new assessors
 - New assessors trained per 6.1.2.9.2, complete by the time the new assessor performs unsupervised assessments
- Existing NELAP & TNI Recognized ABs with previously-trained and competent assessors
 - Train assessors in any & all revisions to TNI Volume 1 during mandatory refresher training
- All assessors must be trained in the NELAP accreditation scheme, no legacy employee training accepted





Assessor Competency Requirements – Assessor Training, cont'd

Initial Training Requirements – passing score on written examinations required

- TNI proficiency testing and quality management systems assessment training (specifically, TNI ELS Volume 1, Modules 1 and 2)
- TNI technical module assessment training (e.g., TNI ELS Volume 1, individual Modules 3 through 7)
- Technical discipline assessment training as required by the Accreditation Body for the accreditation scheme(s) supported
 - could include the U.S. EPA Safe Drinking Water Act Certification Officers training courses in Microbiology, Inorganic Chemistry, and Organic Chemistry or technical assessment training courses approved and offered by The NELAC Institute (TNI) – the AB will decide the scope & content of technical discipline assessment training required





Summary of Comments on Assessor Training

- The list here includes training courses that may not yet exist, and thus cannot be required. If the intent is to require certain courses, then the list must be specific (i.e. course name and/or number). If the intent is to provide examples, then the above wording must be changed. Finally, terms such as "TNI technical module assessment training" are undefined.
- AB considers "basic assessor training" to be necessary but does not believe each assessor needs to pass a written exam on each module. AB does not agree the draft language will increase consistency. We believe the draft language will require NELAP accreditation bodies to develop their own training materials, in part because the current training catalog available to assessors through TNI or other groups is limited. AB strongly recommends dropping the requirement for TNI training on specific modules and adopting language that is more general to give the accreditation body options. We also recommend removing the requirement for passing a written exam for technical discipline assessment training.
- Language in this section should be reverted to the language currently in V2M3 4.2.4.





Summary of Comments on Assessor Training, cont'd

- The NOTE from 2009 TNI V2M3 4.2.4 stating “Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, radiochemistry, and field activities” was indicated under 6.1.2.9.3 as being removed language. This NOTE provided helpful clarity to ABs regarding how the requirement for “technical discipline” training would be evaluated and should remain in the Standard under 6.1.2.9.2 to help preserve consistency of interpretations of this requirement in the future.
- The addition of a description of what an AB needs to do if “commensurate experience...” option is used is an improvement over the current standard which does not require this record of justification. Please leave that phrasing in, should this section be otherwise edited / reverted to the previous language.
- Any change in qualifications for a position already held needs to include language which exempts those already deemed qualified for the position prior to the implementation of the new requirement. (The added training or newly available training should be recommended but not required for these staff members.)





Assessor Competency Requirements – Assessor Training, cont'd

Clause 6.1.2.9.3 On-going Training Requirements for Current Assessors

An assessor shall complete on-going refresher training that includes any revisions to the TNI ELS Volume 1 Standard, plus any additional refresher training as required by the Accreditation Body.

NOTE: The Accreditation Body may require a written examination with a passing score as evidence for the ongoing (refresher) training of its assessors.





Assessor Competency Requirements – Assessor Training, cont'd

- Assessor Training
- On-going Training -- written examinations optional
 - On-going refresher training that includes any revisions to the TNI ELS Volume 1 Standard
 - Any additional refresher training as required by the Accreditation Body





Summary of Comments, Ongoing Training

- The note may be misleading and subject for interpretation as requiring the assessor to participate in a written examination with a passing score. Suggestion to notes: “NOTE: The Accreditation authority may introduce a written examination with a passing score as evidence for the ongoing (refresher) training of its assessors.”





Assessment Report Contents

7.6.6.b.2 (2) The assessment report shall contain the following minimum contents:

- Assessment Date(s)
- Laboratory Name and Physical Address
- Laboratory ID Number (as assigned by the Accreditation Body)
- Scope of Accreditation Matrices that were assessed
- Test Methods that were assessed, including preparation methods when separate or different from the analytical method
- Key Laboratory Personnel (e.g., technical manager, QA officer, etc.)
- Laboratory personnel interviewed at the time of the assessment

- For each nonconformity reported, the specific Standard citation, regulatory requirement, or test method section where the observed laboratory activity is not in conformance

(3) If the report is not issued by the accreditation body itself, the accreditation body shall develop and implement procedures to outsource the issuance of assessment reports to conformity assessment bodies, as described in clause 6.4.

c) *[ISO language]*.

d) If additional nonconformities are identified after the assessment is concluded, these nonconformities shall be communicated to the laboratory in writing.





Assessment Report Contents, cont'd

- Assessment Date(s)
- Laboratory Name and Physical Address
- Laboratory ID Number (as assigned by Accreditation Body)
- Scope of Accreditation Matrices that were assessed
- Test Methods that were assessed, including preparation methods when separate or different from analytical method
- Key Laboratory Personnel (e.g., technical manager, QA officer, etc.)
- Laboratory personnel interviewed at time of assessment
- For each nonconformity reported, the specific Standard citation, regulatory requirement, or test method section where the observed laboratory activity is not in conformance





Summary of Comments on Report Contents

- 7.6.6.b)(2) -- AB is concerned the list of contents for assessment reports is too prescriptive. AB recommends striking the following elements from 7.6.6.b.2:
 - Physical Address;
 - Scope of Accreditation Matrices that were assessed;
 - Test Methods that were assessed, including preparation methods when separate or different from the analytical method;
 - Key Laboratory Personnel; and
 - Laboratory personnel interviewed at the time of the assessment.
- What is the perceived benefit of including this information in the report? Accreditation bodies maintain this information in other ways, so there is no improvement in record keeping or traceability. AB believes this will make reports longer without adding any value and increases the risk of transcription errors in accreditation records. Without the above elements, the report will still be traceable to the laboratory and indicate the degree of compliance or non-compliance to The Standard, which is the sole purpose of the assessment report.





Issuing Assessment Reports

7.6.7.1 The accreditation body shall develop procedures for the review and approval of assessment reports. If the accreditation body finds that any portion of the report issued to the conformity assessment body requires amendment, the accreditation body shall issue an amended report to the conformity assessment body and explain why an amended report is being issued. Issuing an amended report does not reset the timeline for a conformity assessment body to provide a plan of corrective action, as required in clause 7.6.8.1, for the portions of the report that are not amended.





Issuing Assessment Reports, cont'd

- Who issues on-site assessment reports to laboratories?
 - AB responsible for the report contents in all cases
 - AB documents procedures for review & approval of reports
- Nonconformities identified after the assessment is formally concluded (possibly after accreditation decision was made)
 - In each case, laboratory is notified in writing
- Amended reports
 - Explanation provided on why amended report is issued and/or additional nonconformities are cited that require laboratory corrective action
 - Timelines adjusted if appropriate





Summary of Comments on Issuing Reports

- 7.6.7.1 Why are we allowing anybody but the accreditation body to release a final report?
- Why is the language in 7.6.7.2 where the report has to be released by the accreditation body being removed? This also seems to go against 7.6.6 b)1
- The final report should not be being released to the CAB before being reviewed by the AB. A final report should not be issued to a CAB by a third party or contract assessor for an AB.





Confidential and Publicly Available Information

Clause 8.1 Confidential Information

8.1.1 ISO/IEC 17011:2017(E) Clause 8.1.1

The accreditation body shall be responsible through legally enforceable agreements for the management of all information obtained or created during the accreditation process. The accreditation body shall inform the conformity assessment body, in advance, of the information it intends to place in the public domain. Except for information that the conformity assessment body makes publically available, or when agreed between the accreditation body and the conformity assessment body (e.g., for the purpose of responding to complaints), all other information obtained during the accreditation process is considered proprietary information and shall be regarded as confidential.

8.1.2 ISO/IEC 17011:2017(E) Clause 8.1.2

When the accreditation body is required by law or authorized by contractual arrangements to release confidential information, the conformity assessment body shall, unless prohibited by law, be notified of the information provided.





Confidential and Publicly Available Information, cont'd

Clause 8.1 Confidential Information, cont'd

8.1.3 ISO/IEC 17011:2017(E) Clause 8.1.3

Information about the conformity assessment body obtained from sources other than the conformity assessment body (e.g. complainant, regulators) shall be confidential between the conformity assessment body and the accreditation body. The provider (source) of this information shall be confidential to the accreditation body and shall not be shared with the conformity assessment body, unless agreed by the source.

8.1.4 ISO/IEC 17011:2017(E) Clause 8.1.4

Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the accreditation body's behalf, shall keep confidential all information obtained or created during the performance of the accreditation body's activities, except as required by law.

8.1.5 Accreditation bodies shall have documented procedures for processing and evaluating claims made by CABs of confidential information referencing applicable laws and regulations.





Confidential and Publicly Available Information, cont'd.

Clause 8.2 Publicly Available Information

8.2.1 ISO/IEC 17011:2017(E) Clause 8.2.1

The accreditation body shall make publicly available through publications, electronic media, or other means, without request, and update at adequate intervals, the following:

a) information about the accreditation body:

1) information about the authority under which the accreditation body operates;

2) a description of the accreditation body's rights and duties;

3) general information about the means by which the accreditation body obtains financial support;

4) information about the accreditation body's activities, other than accreditation;

5) information about international recognition arrangements in which it is involved.

b) information about accreditation process:

1) detailed information about its accreditation schemes, including its assessment and accreditation processes;

2) reference to the documents containing the requirements for accreditation;

3) general information about the fees relating to accreditation;

4) a description of the rights and obligations of conformity assessment bodies;

5) information on procedures for lodging and handling complaints and appeals;

6) information on the use of the accreditation symbol or other claims of accreditation.





Confidential and Publicly Available Information, cont'd.

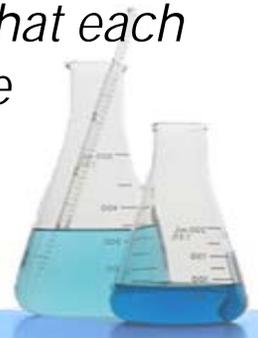
Clause 8.2 Publicly Available Information, cont'd.

8.2.2 ISO/IEC 17011:2017(E) Clause 8.2.2 As a minimum, the accreditation body shall make publicly available, without request, information on conformity assessment bodies as described in 7.8.1 and, where applicable, information on suspension or withdrawal of accreditation, including dates and scopes.

NOTE: In exceptional cases, access to certain information can be limited upon the request of the conformity assessment body (e.g. for security reasons).

8.2.3 ISO/IEC 17011:2017(E) Clause 8.2.3 The accreditation body shall give due notice of any changes to its requirements for accreditation. It shall take account of views expressed by interested parties before deciding on the precise form and effective date of the changes.

8.2.4 ISO/IEC 17011:2017(E) Clause 8.2.4 Following a decision on, and publication of, the changed requirements, the accreditation body shall verify that each accredited body conforms to the changed requirements.





Summary of Comments on Confidential and Publicly Available Information

V2M1 8.1.1 -- In general, public information laws make much of section 8.1.1 moot for governmental accreditation bodies. AB strongly recommends keeping the note under section 8.1.1.

V2M1 8.2.2 -- AB is concerned about the requirement to make publicly available, without request, information on suspensions and withdrawals of accreditation, including dates and scopes. AB has been led to believe that “without request” generally means we must post this information on our website. If we had to post the notices on the website, this would be a significant amount of work to track. AB proposes allowing accreditation bodies to use the Laboratory Accreditation Management System (LAMS) to make this information available. Currently, LAMS shows the suspended analytes and shows which laboratories are currently accredited. AB strongly proposes adding a note about LAMS under section 8.2.2. Proposed Revision: ***“NOTE 2: Accreditation bodies may use the Laboratory Accreditation Management System (LAMS) to make this information publicly available.”***

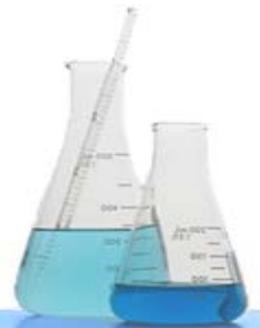




Discussion Time

**Q&A submitted through WebEx
will be addressed**

Please submit written comments to
Carl.Kircher@FLhealth.gov and lynn.bradley@nelac-institute.org
so that we have a record of your comment





Thank You

