

Summary of the Laboratory Accreditation Body Expert Committee Meeting
Forum on Laboratory Accreditation San Antonio, TX
Wednesday, January 19, 2022 8:00 am Central

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. He noted that many long term members of the committee have reached the maximum term limits, including himself. While the committee remains in balance, at the end of conference there will be only eight voting members, and an additional member of the “other” stakeholder category is especially sought.

2. 2021 Accomplishments and Plans for 2022

Carl summarized the committee’s accomplishments during the previous year and its plans for the coming year. Virtually all activities will focus on completing and finalizing the standard module. See Attachment 2 for an outline of the presentation – accomplishments and plans are among the first few slides.

3. Changes to the Draft Standard as a Result of Comments

Carl displayed the relevant text as he discussed each comment and whether it was ruled persuasive or non-persuasive. The text (as modified, if changes were made) is displayed in the outline of the presentation found in Attachment 2 below.

For section 4.2, Carl noted that those requirements are to be placed on the labs, and asked Lynn to make certain that the language is referred to Quality Systems Expert Committee for that purpose. NOTE: As Lynn was uncertain this was previously done, it was done as these minutes were prepared.

Also, there were several locations identified where the TNI language did not spell out a number when describing a timeline; all numbers will be spelled out, to be consistent with the ISO text.

As Carl completed reviewing the changes made in response to comments that have been ruled upon and resolved, TNI’s Database Administrator, Dan Hickman, rose to ask about incorporating a requirement for ABs to report primary and secondary accreditations into the LAMS database. This was an explicit requirement in the 2003 NELAC Standard, but when the transition was made to base our Standard on ISO/IEC 17011, the determination had been made to omit requirements that would pertain only to NELAP, putting those in policies and procedures for NELAP instead. Dan noted that a recent SIR asked about such a requirement, and while the PT module of Volume 2 (V2M2) does require reporting “accreditations” into the database, it does not mention secondary accreditations. Carl explained that the Expert Committee consensus at the time the legacy 2003 NELAC Chapter 6 requirements were considered was not to include any Chapter 6 requirements into V2M1 and to refer requirements from the 2003 NELAC Standard Sections 6.2.2 and 6.8 to the Quality Systems Expert Committee for possible inclusion into V1M2 lab requirements, and specifically not to include anything in the Standard about a using a TNI universal laboratory accreditation application such as LAMS. Carl noted that LAB could revisit that decision. Dan suggested that language should go into section 8.2.5, and that he would provide draft language. NOTE: This was discussed in the NELAP AC meeting, later in the day, and the Council will include language in its Mutual Recognition Policy POL 3-100 instead. Dan has provided language to the Council for that purpose.

Carl then addressed the comments where a decision on how to revise the language of the Draft Standard has been discussed but postponed until all other comments are addressed. This is primarily the competency and training requirements for assessors. Carl explained that the

original Draft Standard fell somewhere between “nothing extra beyond ISO” and the very detailed requirements of 2003 NELAC, but met with many objections from ABs. One suggestion from a committee member was to handle assessor competency in the same way as the Competency Task Force is seeking to handle the Technical Manager/Technical Expert competency (part of the next day’s Special Session discussion). Carl asked for other ideas and suggestions, and made a point of asking for those registrants who view only the recorded session to respond to his request for more ideas.

Following that, Carl briefly summarized the remaining comments that must be addressed. There are approximately ten of these, and in the outline in Attachment 2, they are identified as “Remaining Comments”. One comment from a participant was that the ISO language always spells out “conformity assessment body” while the TNI language generally uses “CAB” instead, and that the TNI language should be changed to be consistent with the ISO language.

There were no further questions, so Carl thanked everyone for their participation and stated that the session was concluded and would not resume after the break.

4. Next Meeting

The next teleconference meeting will be **Tuesday, February 15, 2022, at 1:00 pm Eastern.** An agenda and documents will be distributed prior to the meeting.

Attachment 1

LAB Expert Committee Roster

Name/Email	Term ends	Affiliation	Present?
Aaren Alger Aaren.s.alger@gmail.com	1/30/2023	Other – Alger Consulting & Training	No
Socorro Baldonado sbaldonado@mwdh2o.com	1/30/2023 (1 st term)	Lab – Metropolitan Water District, La Verne, CA	No
William Batschelet wbatsche@aol.com	1/30/2022 (2 nd term)	Other – Retired from US EPA R8	No
Nilda Cox nilda.cox@eurofinset.com	1/30/2022 (1 st term)	Lab – Eurofins Eaton Analytical LLC	No
Yumi Creason ycreason@pa.gov	1/30/2025 (1 st term)	AB – Pennsylvania	No
Sviatlana Haubner Sviatlana.Haubner@cincinnati-oh.gov	1/30/2025 (1 st term)	LAB – Cincinnati Metropolitan Sewer District	No
Catherine Katsikis catherinekatsikis@gmail.com	1/30/2022 (2 nd term)	Other – Laboratory Data Consultants	No
Carl Kircher, Chair carl_kircher@flhealth.gov	1/30/2022 (3 rd term, extended)	AB – Florida Department of Health	Yes
Marlene Moore mmoore@advancedsys.com	1/30/2022 (2 nd term)	Other – Advanced Systems, Inc., Newark, DE	No
Michael Perry michael.perry@lvvwd.com	1/30/2023 (1 st term)	Lab – Southern Nevada Water Authority	No
Zaneta Popovska zpopovska@anab.org	1/30/2022 (1st term)	AB – ANAB	Yes
Alia Rauf arauf@utah.gov	1/30/2024 (2nd term)	AB – Utah Department of Health	No
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com	1/30/2022 (2 nd term)	Other – Shepherd Technical Services	Yes
Nicholas Slawson nslawson@a2la.org	1/30/2022 (1st term)	AB – A2LA	No
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		No
Associate Members:			
Scott Haas shaas@etilab.com		Lab – Environmental Testing, Inc., and Chair, FAC	No
Paul Junio paulj@nlslab.com		LAB – Northern Lake Services	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 – Outline of Presentation

Moving toward Draft Standard V2M1, Rev. 1

Carl Kircher, Chair (NELAP AB) (rotating off)
Mei Beth Shepherd, Vice-Chair (Other) (rotating off)
Marlene Moore (Other) (rotating off)
Zaneta Popovska (Non-gov't AB) (renewed for 2nd term)
William Batschelet (Other) (rotating off)
Catherine Katsikis (Other) (rotating off)
Alia Rauf (NELAP AB) Michael Perry (Lab)
Socorro Baldonado (Lab)
Nilda Cox (Lab) (renewed for 2nd term)
Aaren Alger (Other) (Chair-elect)
Nicolas Slawson (Non-gov't AB) (rotating off)
Yumi Creason (NELAP AB) (Vice Chair-elect)
Sviatlana Haubner (Lab) (new member)

Executive Summary

- 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

2022 Goals

- Finish review of comments received
- Publish Draft Standard EL Volume 2, Module 1, Revision 1
- Discuss and rule on any comments
 - Persuasive or Non-persuasive
- If controversies identified – publish Revision 2 of Draft Standard and receive/review comments again
- Committee vote for Final Standard
- Adoption by relevant TNI Programs

Persuasive

1.0 SCOPE (ISO/IEC 17011:2017(E), Clause 1)

...

In this document, the following verb forms are used:

- "shall" indicates a requirement;
- "must" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

Non-Persuasive

2.0 NORMATIVE REFERENCES (ISO/IEC 17011:2017(E), Clause 2)

...

Note: ISO/IEC Guide 99, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM, latest edition), may also be used as a reference.

Non-Persuasive

3.1 *Accreditation* (ISO/IEC 17011:2017(E) Clause 3.1)
Plus the additional definitions

...
[SOURCE: ISO/IEC 17000:2004, 5.6]

Persuasive

3.4 *Conformity Assessment Body (CAB)* (ISO/IEC 17011:2017(E) Clause 3.4)

...
NOTE 2: This module is concerned with conformity assessment bodies (CAB) commonly known as laboratories providing services in a fixed or mobile setting. The on-site assessment of field sampling and measurement organizations is detailed in TNI Field Sampling and Measurement Organization Sector, Volume 2.

Persuasive

3.6 *Scope of Accreditation* (ISO/IEC 17011:2017(E) Clause 3.6)

...
(Also called Field of Accreditation)

Fields of Accreditation are those matrix, technology/method, and analyte combinations for which the accreditation body offers accreditation.

Persuasive (2 comments)

3.8 *Accreditation Scheme* (ISO/IEC 17011:2017(E) Clause 3.8)

...
NOTE 2: For TNI's The NELAC Institute's Environmental Laboratory Sector (EL ELS) standards, the accreditation scheme requirements include only Volume 1, "Management and Technical Requirements for Laboratories Performing Environmental Analysis" and Volume 2, "General Requirements for Accreditation Bodies Accrediting Environmental Laboratories".

Non-Persuasive

3.10 *Impartiality* (ISO/IEC 17011:2017(E) Clause 3.10)

...
NOTE 2: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflicts of interest", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

Non-Persuasive

3.20 *Complaint* (ISO/IEC 17011:2017(E) Clause 3.20)

Expression of dissatisfaction, other than appeal (3.21), by any person or organization, to an accreditation body (3.2), relating to the activities of that accreditation body or of an accredited conformity assessment body (3.4), where a response is expected.

[SOURCE: ISO/IEC 17000:2004, 6.5, modified – The words "to a conformity assessment body or accreditation body, relating to the activities of that body" have been replaced by "to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body."]

Persuasive (4.2(a))

4.2 *Accreditation Agreement* (ISO/IEC 17011:2017(E), Clause 4.2)

The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

a) *to commit to fulfill continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfillment. This includes agreement to adapt to changes in the requirements for accreditation;*

NOTE: See clause 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.

Non-Persuasive (4.2(e)) (2 comments)

4.2 Accreditation Agreement (ISO/IEC 17011:2017(E), Clause 4.2)

The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

...

c) to provide access to conformity assessment body personnel, locations, equipment, information, documents, and records as necessary to verify fulfillment of requirements for accreditation;

...

e) to have, where applicable, legally enforceable arrangements with their clients that commit the clients to provide, on request, access to accreditation body assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities at the client's site;

Non-Persuasive

4.2 Accreditation Agreement (ISO/IEC 17011:2017(E), Clause 4.2)

The accreditation body shall establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

...

i) to inform the accreditation body without delay of significant changes relevant to its accreditation;

NOTE: Such changes can concern:

- its legal, commercial, ownership, or organizational status;
- the organization, top management, and key personnel;
- resources and location(s);
- scope of accreditation;
- other matters that can affect the ability of the conformity assessment body to fulfill requirements for accreditation.

Persuasive (2 comments)

ISO/IEC 17011:2017(E), Clause 4.3.2

When an accreditation body has an accreditation symbol, the accreditation body shall have the legal right to use it and the accreditation symbol shall be legally protected.

ISO/IEC 17011:2017(E), Clause 4.3.3

The accreditation body shall have a documented policy governing the use of the accreditation symbol and claims of accreditation status. This policy shall specify as a minimum:

- a) requirements for the use and monitoring of the accreditation symbol in combination with any conformity assessment body mark;
- b) that the accreditation symbol is not affixed on its own or used to imply that a product, process, or service (or any part of it) has been certified or approved by the accreditation body;
- c) requirements for reproduction of the accreditation symbol;
- d) requirements for any reference to accreditation;
- e) requirements for the use of the accreditation symbol and claims of accreditation status in communication media;
- f) that the conformity assessment body only uses the accreditation symbol and claims of accreditation status for the specific activities covered by the scope of accreditation.

NOTE: Compliance with TNI policy on the use of its symbols and marks can satisfy the requirements of clauses 4.3.2 and 4.3.3.

Non-Persuasive

4.4.3 ISO/IEC 17011:2017(E) Clause 4.4.3

The accreditation body shall have top management commitment to impartiality. It shall document and make public an impartiality policy which includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest, and ensuring objectivity of its accreditation activities.

Persuasive (edits; also in 6.3 & 7.6.2)

Non-Persuasive (content)

4.4.5 ISO/IEC 17011:2017 (E) (F) Clause 4.4.5

The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.

Non-Persuasive

(EL Volume 2 Title is sufficient)

4.4.9 ISO/IEC 17011:2017(E) Clause 4.4.9

When an unacceptable risk to impartiality is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided.

Persuasive (4 comments)

4.4.11 ISO/IEC 17011:2017(E) Clause 4.4.11

The accreditation body and any part of the same legal entity shall not offer or provide any service that affects its impartiality, such as:

- a) those conformity assessment activities covered by accreditation which include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification;*
- b) consultancy.*

NOTE: An accreditation body and related bodies within a Government department or entity might provide conformity assessment activities as directed by Government. In such cases, the accreditation body should have effective measures to manage impartiality risks.

Persuasive (2 comments)

4.4.12 ISO/IEC 17011:2017(E) Clause 4.4.12

In case the accreditation body is linked to a body offering consultancy or undertaking those conformity assessment activities mentioned in 4.4.11 bullet a), the accreditation body shall have:

- a) different top management (see 5.7);*
- b) different personnel performing the accreditation decision-making processes (see Clause 5);*
- c) distinctly different name, logos, and symbols;*
- d) effective mechanisms to prevent any influence on the outcome of any accreditation activity.*

NOTE: An accreditation body and related bodies within a Government department or entity might not have a distinctive name, logo and/or symbol.

NOTE: An accreditation body and related bodies within a Government department or entity might not have different top management.

Non-Persuasive

“Scheme Owner” use in Clauses 3.33 and 4.4.13

Definition available on www.iso.org browsing platform

(don't need definition in V2M1 since the “scheme owner” usages were in Notes)

Person or organization responsible for developing and maintaining a specific certification (or accreditation) scheme.

Persuasive (2 comments)

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

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

Non-Persuasive

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.

Persuasive

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.

...
Non-Persuasive

6.1.3.5 *ISO/IEC 17011:2017(E) Clause 6.1.3.5*

The accreditation body shall monitor each assessor considering each accreditation scheme for which the assessor is authorized. The documented monitoring process of assessors shall include a combination of on-site evaluation, review of assessment reports, and feedback from personnel, conformity assessment bodies, or from other interested parties.

Persuasive (covered in 6.3)

6.1.3.7 The accreditation body shall maintain records for assessing and monitoring for all assessors.

Persuasive

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

- ...
e) not solicit or accept any gift or other item of monetary value from any CAB, which would compromise the impartiality or objectivity of the accreditation process 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;

Non-Persuasive

7.4.4 *ISO/IEC 17011:2017(E) Clause 7.4.4*

...
NOTE: Each fixed-base branch or subsidiary of a CAB with multiple locations is customarily accredited separately by accreditation bodies and requires separate surveillance and reassessments. Mobile facilities of fixed-base CABs or mobile facilities not directed by or attached to a fixed-base CAB may be required to maintain distinct accreditations by different accreditation bodies and may require separate surveillance and reassessments.

Persuasive

7.5.2 *ISO/IEC 17011:2017(E) Clause 7.5.2*

The accreditation body can decide not to proceed with further assessment based on the review of the documented information. In such cases, the results with their justification shall be reported in writing to the conformity assessment body.

7.5.3 NOTE: Accreditation bodies shall should inform CABs of a cancellation of an assessment as soon as feasible.

Persuasive

7.6.2 ISO/IEC 17011:2017(E) (F) Clause 7.6.2

For an assessment, whether performed on-site or remotely, the assessment team shall commence the assessment with an opening meeting at which the purpose of the assessment and accreditation requirements are clearly defined, and the assessment plan as well as the scope for the assessment are confirmed.

7.6.2.1 Attendance at the opening meeting ~~conference~~ shall be documented.

Persuasive

7.6.3.2 The assessment team shall provide or make available the following types of documents before a scheduled announced assessment or before the conclusion of the on-site portion of the CAB assessment:

a) 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.

b) 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.

Persuasive (3 comments)

7.6.4.1 In the event the assessment team observes possible improper and/or potentially illegal activities, the team shall present such information to the accreditation body for appropriate action(s) as defined by the accreditation body's procedure. The information must be carefully documented by the team. The assessment team shall continue to gather the information necessary to complete the accreditation assessment and present the information as defined by the accreditation body's procedures.

During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information must be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team shall present such information to the accreditation body for appropriate action(s). These issues, at the discretion of the accreditation body, may or may not be subjects or issues at the closing conference. However, the assessor shall continue to gather the information necessary to complete the accreditation assessment.

Persuasive

7.6.6 ISO/IEC 17011:2017(E) Clause 7.6.6

The accreditation body's documented reporting procedures shall require the following.

a) *For an assessment, whether performed on-site or remotely, a meeting shall take place between the assessment team and the conformity assessment body at the end of the assessment. At this meeting, the assessment team shall report on the findings identified during the assessment and detail in writing any nonconformities. An opportunity shall be provided for the conformity assessment body to seek clarification on the findings including the nonconformities, if any, and their basis.*

...

(2) Attendance at the closing meeting ~~conference~~ shall be documented.

Persuasive (4 comments)

7.6.6 ISO/IEC 17011:2017(E) Clause 7.6.6

The accreditation body's documented reporting procedures shall require the following.

...

b) ...

...

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

...

- Key Laboratory Personnel as defined by the accreditation body
(e.g., technical manager, QA officer, etc.)

Persuasive (2 comments)

7.6.11 If the accreditation body allows the conformity assessment body to submit additional or amended responses to correct any unresolved nonconformities, the accreditation body shall issue the report detailing the unresolved nonconformities that require additional or amended responses within thirty calendar days.

7.6.11.1 The accreditation body shall advise the conformity assessment body that this particular response is required within 30 calendar days.

7.6.11.2 The accreditation body shall review those additional or amended responses within thirty calendar days of receipt.

7.6.12 If any part of the amended corrective action report is proposed or revised submittals are considered insufficient or inappropriate to resolve the nonconformity(ies), the accreditation body shall implement its procedures to deny, suspend, withdraw, or reduce accreditation for the Scope of Accreditation that is affected (clause 7.7).

Persuasive

7.6.13 When the last day of a the thirty calendar day timeframes specified within this section in clauses 7.6.6(b)(1), 7.6.10, or 7.6.11 occurs on a non-business day, such as a holiday or weekend, the due date for completion of the action is extended to the required accreditation body actions performed on the next business day shall be considered to meet the timeframe requirements. Any other extensions to the timeframe requirements shall be justified by prevailing statutory regulations or by documented, exceptionally permitted reasons for the delay. The accreditation body shall communicate such extensions to the conformity assessment body with information on the expected date of completion.

7.6.14 Persistent failure by the accreditation body to meet the requirements within the timeframes specified in this section clauses 7.6.6(b)(1), 7.6.10, 7.6.11, and 7.6.13 shall necessitate the accreditation body to implement the management system requirements in clause 9.5.

Persuasive (2 comments)

7.11.1.4 The accreditation body shall change the CAB's accreditation status from suspended to accredited within 30 calendar days after when the CAB demonstrates to the accreditation body that it complies with the relevant requirements.

7.11.1.5 If the CAB fails to correct the causes of suspension within six months after the effective date of the suspension or by the end of the period of accreditation (whichever comes first is longer), the accreditation body shall withdraw or reduce the CAB's accreditation for the Scope of Accreditation for which the CAB has failed to correct the causes of the suspension. If the CAB wishes to subsequently be accredited for the withdrawn or reduced Scope, the accreditation body shall require and the CAB is required to reapply for accreditation.

Persuasive (2 comments)

7.12.1 *ISO/IEC 17011:2017(E) Clause 7.12.1*

The accreditation body shall have a documented process to receive, evaluate, and make decisions on complaints. The accreditation body shall, where appropriate, ensure that a complaint concerning an accredited conformity assessment body is first addressed by the conformity assessment body.

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.

Persuasive (3 comments)

7.13.1 ISO/IEC 17011:2017(E) Clause 7.13.1

The accreditation body shall have a documented process to receive, evaluate, and make decisions on appeals.

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.

Persuasive

7.14.2 ISO/IEC 17011:2017(E) Clause 7.14.2

The accreditation body shall have a documented policy and documented procedures on the retention of records. Records of conformity assessment bodies shall be retained at least for the duration of the current cycle plus the previous full accreditation cycle.

7.14.3 The accreditation body shall maintain records on conformity assessment bodies for a minimum of five (5) years.

Non-Persuasive (9.7 & 9.8)

Internal Audit & Mgmt. Review reports documented?

9.1.2 ISO/IEC 17011:2017(E) Clause 9.1.2

The accreditation body's management shall establish and document policies and objectives related to competence, consistency of operation, and impartiality. The management shall provide evidence of its commitment to the development and implementation of the management system in accordance with the requirements of this document. The management shall ensure that the policies are understood, implemented, and maintained at all levels of the accreditation body's organization.

Questions so far?

Still-to-be-Addressed Comments: Laboratory Assessor Competency

The current Standard: TNI EL Volume 2, Module 3

4.2.3 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.

4.2.4 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 systems and all 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, radiochemistry, and field activities.

Still-to-be-Addressed Comments: Laboratory Assessor Competency

Draft Standard: Volume 2, Module 1, rev. 0

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 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.

6.1.2.9.2 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.

NOTE: Examples of technical discipline assessment training 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).

Remaining Comments (7.6.6(d))

7.6.6 ISO/IEC 17011:2017(E) Clause 7.6.6

...

- c) *If the report on the outcome of the assessment [see bullet (b) above] differs from the outcome delivered at the close of the assessment [see bullet (a) above], the accreditation body shall provide an explanation to the assessed conformity assessment body, in writing.*
- d) If additional nonconformities are identified after the assessment is concluded, these nonconformities shall be communicated to the laboratory in writing.

Remaining Comments (7.6.7.1)

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.

Remaining Comments (7.8.3(d) and Note)

7.8.3 ISO/IEC 17011:2017(E) Clause 7.8.3

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.

The scope of accreditation shall, at least, identify the following:

...

- d) *For testing laboratories (including medical laboratories):*
 - *materials or products tested;*
Matrix
 - *component, parameter, or characteristic tested;*
Analyte
 - *tests or types of tests performed and, where applicable, the techniques, methods, and/or equipment used.*
Technology / Method

Remaining Comments (7.9.3)

7.9.3 ISO/IEC 17011:2017(E) Clause 7.9.3

The assessment program shall ensure that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the scope of accreditation shall be assessed taking risk into consideration. A sample of the scope of accreditation shall be assessed at least every two years. The time between consecutive on-site assessments shall not exceed two years. However, if the accreditation body determines that an on-site assessment is not applicable, it shall use another assessment technique to achieve the same objective as the on-site assessment being replaced and justify the use of such techniques (e.g. remote assessment).

NOTE: "Other assessment techniques" may include 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.

Remaining Comments (7.9.4.2 & 7.9.5)

7.9.4.2 All requirements specified in clauses 7.4 through 7.6 (inclusive) shall apply to reassessments, including the requirement in clause 7.4.7.1 to comply with the Safe Drinking Water Act.

7.9.5 *ISO/IEC 17011:2017(E) Clause 7.9.5*

The accreditation body may conduct extraordinary assessments as a result of complaints or changes, or other matters that may affect the ability of the conformity assessment body to fulfill the requirements for accreditation. The accreditation body shall advise conformity assessment bodies of this possibility.

NOTE: Examples of changes could include changes in the CAB's ownership, key personnel, location, and scope of accreditation.

Remaining Comments (8.1.1, reinstating the Note)

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 publicly 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.

NOTE: The confidentiality of documents and records may be challenged in specific instances by public information requests under state or federal laws.

Remaining Comments (8.2.2)

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).*

Remaining Comments (9.7.2)

9.7.2 *ISO/IEC 17011:2017(E) Clause 9.7.2*

Internal audits shall be performed normally once a year. An audit program shall be established, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

Remaining Comments (reinstate 9.7.5, first 2 sentences)

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.

Any Further Questions?
Thank You