Summary of the Laboratory Accreditation Body Expert Committee Meeting Tuesday, September 21, 2021 1:00 pm Eastern

1. Welcome and Roll Call

The Chair, Carl Kircher, opened the meeting. Attendance is recorded in Attachment 1. The meeting agenda (Attachment 2) was approved by acclamation as presented. The minutes of August 17 were approved by unanimous vote.

2. Discussion of Comments on Section 6.1.2.9

In order not to display the names and comments of all submitters, only the portion of the complete response to comments spreadsheet that contains the relevant comments was distributed for this meeting. This spreadsheet is based on the template provided in the Standards Development SOP 2-100. (See Attachment 4, below.) All who commented on §6.1.2.9 were invited to participate in the meeting, and the names of those who were able to join the teleconference are provided below.

Prior to the meeting, Yumi had offered to work with the commenters to clarify their concerns. This resulted in the group providing draft revised language that would address all of the relevant comments (comment numbers 29, 35, 47, 48, 49, 50, 72, 78, 82 and 87).

Discussion points were as follows:

- How will training requirements be enforced, what type of documentation is required for compliance, and what documents a passing score?
- Maybe add a note that the AB must retain some evidence of passing score, as the AB is unlikely to have a copy of the test if it's a vendor training.
- If the AB does not require technical discipline training (as initially worded), is that acceptable (subsection "d")? No one intended this to be optional, so reword to say that ABs can provide the training as they see fit, so long as it is done.
- About comment 49, ABs want the note about what technical disciplines are to be
 restored, so that they know what requires documentation. There was discussion about
 whether the accreditation scheme covers this (no) or if it is satisfactorily identified in the
 scope of recognition for an AB (probably not easily determined, but adding "scope of
 recognition" terminology and concepts into V2M1 would require far more than text edits of
 this section).

At this point, Mei Beth moved to withdraw the approval of language suggested at conference and restore the original language of the Draft Standard. Mike seconded the motion and approval was unanimous with Carl and Bill abstaining.

Mei Beth recommended that the committee work on refining the proposed draft language, while the commenters were present, and then vote on persuasiveness and approval of final language later.

Further discussion points were:

There would be no need for any exceptions to permit retention of legacy employees with the proposed language.

The distinction between "a" and "b" is that "a" is only quality systems assessment training and could be ISO 17025 only (or the TNI Basic Assessor training), while "b" would include the TNI-specific language for quality systems and proficiency training (which is part of the TNI Basic Assessor Training course), but there is no mandate to take the TNI course itself.

At present, the TNI Basic Assessor Training course does not have a test associated with it. A suggestion was made to add examples of suitable courses as a note under "a", "b", and "c".

Another suggestion was that "passing score" would be represented by the award of a Certificate of Completion for the course (as opposed to a Certificate of Attendance).

Consistent qualifications across all ABs should be the goal, not having each AB set its own qualifications.

Decide what we want the training to be, then articulate it clearly.

In 6.1.2.9.2.d, remove the suggestion that each AB can set its own approval, and just state "technical disciplines for which the assessor is approved to assess" and restore the note that identified those separate disciplines.

Consensus was to restore the note about technical disciplines.

At this point, Yumi emailed a revision of the proposed draft, based on the discussion thus far, to all who received the meeting reminder. Participants determined that further word-smithing was not needed, and the committee has enough information to finalize the wording once the individual comments are ruled as persuasive or non-persuasive.

3. Votes on Comments and Replacement Language

As the details of the vote on whether or not a comment is persuasive and how it should be addressed if persuasive are not needed for commenters or the public to consider the actual outcome of the discussion for each comment, those details are not included in the formal Response to Comments spreadsheet, but are noted here in the minutes for the meeting(s) where comments are addressed. NOTE: the comment numbers in the table below refer back to the order of submission, so that when the spreadsheet is sorted by comment number, all comments from each submitter will be clustered, but for addressing the comments, it works best to follow the sequence of the standard itself.

As Carl needed to depart early, Mei Beth chaired the last 15 minutes of the meeting, taking over after comment number 29 was voted on.

| Comment | <u>Section</u> | Proposed Decision | <u>Motion</u> | <u>Motion</u> | <u>Vote</u> |
|---------|----------------|----------------------------|---------------|---------------|-------------|
| Number | Number | (P/NP/editorial as | <u>Made</u> | Seconded | |
| | | determined) | | | |
| 72 | 6.1.2.9.2 | Persuasive | Mei Beth | Bill | Unanimous |
| 78 | 6.1.2.9.2 | Persuasive | Mei Beth | Mike | Unanimous |
| 29 | 6.1.2.9.2 | Persuasive | Mike | Bill | Unanimous |
| 35 | 6.1.2.9.2 | Persuasive | Mike | Alia | Unanimous |
| | | | | | with Bill |
| | | | | | abstaining |
| 47 | 6.1.2.9.2 | Persuasive | Mike | Catherine | Unanimous |
| 49 | 6.1.2.9.2 | (Comments 47, 49 and 50 | | | |
| 50 | 6.1.2.9.2 | were voted together, as | | | |
| | | they are nearly identical) | | | |
| 48 | 6.1.2.9.2 | Withdrawn by Submitter | | | |
| | | during the meeting | | | |
| 82 | 6.1.2.9.2 | Not voted upon until the | | | |
| | | absent submitter can be | | | |
| | | consulted | | | |
| 87 | 6.1.2.9.2 | Persuasive | Zaneta | Mike | Unanimous |

New Business

There was one suggestion made during NELAP AC discussion, that the NELAP policies and SOPs should be considered for inclusion in the next version of the Draft Standard. Even though this comment was not provided during the formal comment period, Mei Beth asked that the Accreditation Council members present please advise LAB which particular items should be

included, and whether LAMS reporting should be among them, or conversely, which items they do not want to have included in the Draft Standard.

Mike moved and Nilda seconded that the meeting be adjourned at 2:30 pm.

4. Next Meeting

The next teleconference meeting will be <u>Tuesday, October 19, 2021, at 1:00 pm Eastern.</u> 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 | yes |
| Socorro Baldonado sbaldonado@mwdh2o.com | 1/30/2023 (1 st term) | Lab – Metropolitan Water District, La Verne, CA | Yes |
| William Batschelet wbatsche@aol.com | 1/30/2022 (2 nd term) | Other – Retired from US EPA R8 | Yes |
| Nilda Cox nildacox@eurofinsus.com | 1/30/2022 (1 st term) | Lab – Eurofins Eaton Analytical LLC | Yes |
| Catherine Katsikis catherinekatsikis@gmail.com | 1/30/2022 (2 nd term) | Other – Laboratory Data Consultants | Yes |
| 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 | Yes |
| 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 | Yes |
| 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 | | Yes |
| Associate Members: | | 1 | |
| Yumi Creason ycreason@pa.gov | | AB – Pennsylvania | Yes |
| Scott Haas shaas@etilab.com | | Lab – Environmental Testing, Inc., and Chair, FAC | No |
| Sviatlana Haubner Sviatlana.Haubner@cincinnati-oh.gov | | LAB – Cincinnati Metropolitan Sewer District | No |
| Paul Junio paulj@nlslab.com | | LAB – Northern Lake Services | No |
| Bill Ray bill_ray@williamrayllc.com | | Other – William Ray Consulting, LLC | No |
| Aurora Shields Aurora.Shields@kcmo.org | | Lab – KC Water | No |
| Ilona Taunton <u>Ilona.taunton@nelac-institute.org</u> | | Other – TNI Program Administrator | No |

Guests (Associate Members not normally participating):
Steve Arms, NELAP Lead Evaluator
David Caldwell, OK DEQ
Steve Gibson, TCEQ
Jody Koehler, TCEQ
Cathy Westerman, VA DCLS

Attachment 2 - LAB Expert Committee Meeting Agenda, September 21, 2021

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (August minutes attached)
- Discussion of Comments on Section 6.1.2.9 commenters invited to participate in call
 - Please see three attached files: V2M1-DSoriginal-Comments on Assessor
 Qualifications..., Revised Comment V2M1, and V2 Labdraft DSrev1 cleaned....
- Votes on Comments and Replacement Language
- New Business, if any
- Adjourn

Attachment 3 – Draft Proposed Language from Commenters on §6.1.2.9, as revised during the meeting and sent by Yumi to all participants prior to beginning of voting on persuasiveness of the individual comments

Comment: V2M1: 6.1.2.9.2: We believe this section of the standard is overly prescriptive and has not added value to assessor performance or accreditation body consistency since a written examination has been required by Volume 2. With the addition of competency management in section 6.1.3, we believe the following language would improve consistency and allow an accreditation body to evaluate an assessor's full abilities rather than its ability to memorize material and pass a written examination.

6.1.2.9 ISO/IEC 17011:2017(E) Clause 6.1.2.9

Where additional specific competence criteria have been established for a specific accreditation scheme, these shall be applied.

- 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 have documented training that includes:
 - (a) A passing score on the written examination of a course approved by the accreditation body on assessing quality systems
 - NOTE: Examples of courses on assessing quality systems could include the Basic Assessor Course or ISO 17025 training course.
 - NOTE: A certificate of completion for a quality systems course may be an acceptable alternative to a passing score.
 - (b) TNI proficiency testing and quality management systems (specifically, TNI ELS Volume 1, Modules 1 and 2);
 - (c) TNI technical modules (e.g., TNI ELS Volume 1, individual Modules 3 through 7); and
 - (d) Technical disciplines for which the assessor has been approved by the accreditation body.
 - 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).
 - NOTE: Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, radiochemistry, and field activities.
- 6.1.2.9.3 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.

Attachment 4 – Committee Decisions on Comments for July 20, 2021

| Comment Number | Vote & Justification (Persuasive/non-persuasive) | Editorial (Y/N) | Section/Clause | Comment | Committee Action | Date Addressed | Committee Comment |
|----------------|---|-----------------|----------------|---|--|----------------|--|
| 72 | P | | 6.1.2.9.2 | The following language should be removed so competency and training can be determined by the TNI Competency Task Force as no training course currently exists: "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 Body for the accreditation scheme(s) supported. NOTE: Examples of technical discipline assessment training could include the U.S. | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2; b) assessment to TNI EL Volume 1 modules 3 through 7 (and any subsequent modules that may be developed); |

| | 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). " | | | |
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| 78 | P | 6.1.2.9.2.b | TNI V2M1 section 6.1.2.9.2 (b) – TNI technical module assessment training (e.g., TNI ELS Volume 1, individual Modules 3 through 7). This language is acceptable however this requirement is not yet achievable within the TNI organization. To better implement this requirement an implementation date should be set in place until TNI have developed all module training tools. Suggested language should be in the form a note: "Note: This requirement will not available until all TNI training modules have been developed and approved for use. Implementation of this section will occur when TNI has a robust completed training program." | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| 11 | NP | 6.1.2.6 | 6.1.2.6 Note 2 has been stricken. Is it the intent of the Standard to eliminate the ability of an assessor to communicate through a translator or interpreter? | 6/15/2021 | The standard is silent on the use of translators or interpreters, thus their use is allowed. |

| 12 | 6.1.2. | 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. | discussed at August 2 conference session; determination of persuasive/non- persuasive postponed |
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| 29 | P | | 6.1.2.9.2 | 6.1.2.9.2: "These training courses shall include, but not be limited to:" 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. What is meant by TNI training? TNI approved? Listed on the TNI website? Based on the TNI standards? | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| 35 | P | 6.1.2.9.2 | V2M1 6.1.2.9.2 ORELAP believes this section is too prescriptive. ORELAP considers "basic assessor training" to be necessary but does not believe each assessor needs to pass a written exam on each module. At that point we're just giving the assessor a reading test. ORELAP was led to believe these proposed revisions were added to increase consistency among assessors. ORELAP 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. ORELAP 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. Proposed revision: "6.1.2.9.2 An assessor shall complete assessor training courses, including, but not limited to: (a) Basic assessor training with emphasis on the TNI Standard, with a | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| | | passing score on a written examination at the conclusion of the course; (b) Technical discipline assessment training as required by the Accreditation Body for the accreditation scheme(s) supported. | | |
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| 47 | Р | | 6.1.2.9.2 | 6.1.2.9.2 Issue 1: Language in this section should be reverted to the language currently in V2M3 4.2.4. The change to addition of written tests in the technical modules, when they do not currently exist, is unnecessary. TNI should consider this addition to the basic assessor course or consider creating an additional course. However, the idea of creating a requirement then creating training that meets it, for training that MAY OR MAY NOT bring added value to assessor performance, is poor practice. (Once the training is built and is determined by ABs to have added value for training of new staff, perhaps THEN the requirement will be added to a future revision of Volume 2.) | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| 48 | withdrawn | | 6.1.2.9.2 | 6.1.2.9.2 Issue 2: 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.) Language for this provision can be modeled after TNI 2016 V1M2 5.2.6.2.c. | withdrawn by commenter during LAB meeting | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| 49 | P | | 6.1.2.9.2 | 6.1.2.9.2 Issue 3: 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. | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| 50 | P | | 6.1.2.9.2 | 6.1.2.9.2 Comment: 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. | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| | | preserve consistency of interpretations of this requirement in the future. If this note is removed every evaluation team will interpret this differently. | | |
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| 87 | P | 6.1.2.9.2 | Section 6.1.2.9.2: The standard is requiring assessors to complete training courses that do not currently exist. As such, ABs would not be able to conform to the standard as written. Additionally, because the training does not exist, it is impossible to determine if the requirement to pass a written exam in these trainings is an improvement to the existing training requirements in the standard. Because of the uncertainty in the availability of and the resulting improvement of the training, we suggest that the language should be reverted to the language currently in V2M3 4.2.4 of the TNI Standard. The language can be changed in future revisions once the training courses are established and proved to be beneficial. If the requirement to complete the training is retained, we suggest adding language to deem an assessor as having satisfied the requirements of the standard if they were deemed competent prior to the implementation of this standard. | specific language TBD at later date | 9/21/2021 | At the 8/17/21 committee meeting, language discussed at conference was approved as follows, but comments were not ruled persuasive or non-persuasive. 6.1.2.9.2These training courses shall include, but not be limited to: a) assessment to TNI EL V1 Modules 1 and 2 (proficiency testing and quality management systems); b) assessment to TNI EL Volume 1 modules 3 through 7 and any subsequent modules that may be developed; |
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| 13 | Р | 6.1.2.9.3 | 6.1.2.9.2 and 6.1.2.9.3 both use the acronym TNI ELS Volume 1. The Environmental Laboratory Modules are referenced as TNI EL V#, rather than TNI ELS V#. See the header to this Draft Standard for such usage. | | 9/21/2021 | determined persuasive 3/16/21; to be addressed later along with §3.8 comments |
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| 79 | P | 6.1.2.9.3 | TNI V2M1 6.1.2.9.3 "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." Comments: The note may be miss leading 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." | revise wording of note to read "The Accreditation Body may choose to require a written examination with a passing score as evidence for the ongoing (refresher) training of its assessors." | 8/17/2021 | |