

Summary of the Laboratory Accreditation Body Expert Committee Meeting
Friday, October 20, 2023 1:00 pm Eastern

1. Welcome and Roll Call

Aaren welcomed everyone to this rescheduled meeting. The agenda was approved by unanimous consent. The minutes of September 19 were approved unanimously after a motion by Yumi, seconded by Zaneta. Attendance is noted in Attachment 1 and the agenda as distributed is in Attachment 2.

2. Presentation of Internal Audit Results and Proposed Corrective Action

A spreadsheet of the internal audit results was shared with the committee and Lynn discussed the one item (#60) that was out of compliance, along with its corrective action. The Standards Development SOP 2-100 requires that “all submitted comments from all stages of the most recent previous standards development activity” be gathered and maintained, but those records could not be located. While there is no way to correct the past, present and future Draft Standards and response-to-comments files for all stages of a standard’s development will be archived in TNI’s Dropbox cloud storage, and thus readily located for the next revision cycle.

3. Discussion of Florida’s Comments on the V2M1 Draft Standard Revision 1

Florida submitted two comments, both about the newly added requirement that an AB issue the assessment report. Vanessa Soto-Contreras discussed Florida’s position, along with Carl Kircher.

Comment	Section #	Additional Detail of Comment
<p>#2 (Carl) -- The underlined new text places an unfair burden on the full-time employees that remain in the State of Florida Department of Health’s (FL-DOH’s) laboratory certification program. The purpose of outsourcing the routine laboratory assessments at all was to ensure that accredited laboratories get inspected at least every 2 years as required by TNI Standard and by FL Administrative Code Rule yet enable the reduced staff of state employees to review applications, evaluate proficiency testing results, provide technical guidance where necessary, and make necessary certification decisions. However, the accredited laboratories have had to absorb incredibly higher costs for private Providers to arrange for and conduct these biennial assessments. It is thus equally fair that the contract Providers to also prepare and issue the assessment reports, review laboratory corrective action plans, and make final recommendations as to laboratory certification status as part of the costs that laboratories are required to pay to the Provider. These requirements are currently written into the</p>	<p>6.4.4.1</p>	<p>Per Florida’s contracts with its third party assessors, the assessment report goes to the AB staff simultaneously with its delivery to the laboratory. The AB reviews the report promptly (no timeframe is established but typically within 3 days) and if revision is needed, the assessor is asked to issue an amended report. If a finding is modified, the timeframe for submitting a corrective action response is extended to correspond with the date of the amendment, but other corrective action responses are held to the original date. FL believes that its assessors are thoroughly reviewed prior to being accepted (having contracts to assess) and that this process is most efficient and effective. Amendments are few and most are editorial, not altering findings.</p>

<p>contracts with the Providers, and the underlined new language is not part of the contract language that the Providers have originally signed. The current practice has also allowed Florida as Accreditation Body to ensure that assessment reports are issued, corrective actions are reviewed, and certification decisions are made within the timeframes required by Standard. The full-time staff at FL-DOH do conduct peer-reviews of the Providers' assessment reports, but after the reports have been issued. If the reports contain shortcomings or otherwise require amendment, we notify the Provider of the changes needed, and the amended report is issued. FL-DOH notes that proposed new language in Section 7.2.1.1 seems to make allowances for accreditation bodies with limited staff in making certification decisions. If such an allowance is made for the same person performing assessments to make the final certification decisions, then we believe that a similar allowance should be made for the contract Providers that perform assessments to review and approve the issuance of assessment, rather than forcing FL-DOH to do so, as part of the ISO-allowed outsourcing of that particular accreditation activity. Thus, we recommend that the TNI-additional language in V2M1, Section 6.4.1.1 revert back to the original language: "Portions of the accreditation process may be contracted out; however, the authority to grant, maintain, suspend or revoke accreditation shall remain with the accreditation body."</p>		<p><u>Discussion:</u> The current language of the Draft Standard (DS) does not require that the AB write the report. Many ABs (including NGABs) have in-house staff review reports prior to issue. If a lab issued analytical reports subject to later amendment, its accreditation would be withdrawn. FL monitors revisions to ensure that its assessment providers are performing well; if not, contracts are not renewed. FL provides contract assessors with application materials and PT reports, and advises if the lab has a "problematic history". The AB is ultimately responsible for the content of the report, not the contractor. If the 30-day window for delivering site reports is the reason for allowing contractors to issue them directly, perhaps a longer timeframe should be provided, or else the contractor given a shorter time window to provide the draft report to the AB for its review. When the AB staff perform assessments, reports are issued within 30 days, but those are typically assessments done in emergencies or in response to complaints, with reports specific to the issue examined.</p>
<p>#3 (Vanessa) Although I would have used the selection of few words, Carl expressed Florida's point. I also want to add that our providers have to go through an application process that includes preparing reports. We have checked efficiency of the providers writing reports and if that was not part of the contract we would probably not even have providers. The providers are the ones that observe everything going on, they receive the data, they interview and their brains have a lot of information of what is going on at the lab - if their notes are not perfect sentences, then how can they transmit the messages for us to write an accurate report, and if they are going to spend the time to spell what they have observed to give it to us all the information to write an accurate report, they might as well</p>	<p>6.4.4.1</p>	<p>FL was asked if EPA Region 4's drinking water program had provided any instruction to FL about issuing audit reports, and the answer was no, and R4 is aware of FL's process. It does appear that FL is meeting the requirements of the current standard and carrying out its responsibilities satisfactorily. Aaren recommends thinking this over and voting on persuasiveness at the November meeting.</p>

<p>write the reports. As the AB, we could “Approve” the reports or we could “agree” or what we do, review and accept, by replying to the providers. That would show that the AB is aware of what the report contains and the status of the lab.</p>		
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After the discussion of Florida’s comment, committee members began reviewing and voting on the persuasiveness of other comments, as Paul Junio had not arrived. Paul arrived late, and that discussion was suspended to allow for discussing his comments. After Paul completed his discussion, consideration of comments resumed – all of the votes on comments are consolidated in Item 5 to simplify the organization of these minutes.

4. Discussion of Paul Junio’s Comments on the V2M1 Draft Standard Revision 1

Comment	Section #	Additional Detail of Comment
<p>#13 -- I’ll try to not re-argue my earlier submittal regarding the definition of complaint, but I am adding additional information to my original comment in order to clarify a potential problem that will arise if not addressed. Comment 5 was ruled non-persuasive due to it being ISO language. The problem is that ISO refines its definition per the specific standard in use, as noted in the NOTE that is being deleted. Cites definition from V2M1 - 3.16 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.”]—This problem is made clear when you consider that Volume 1 Module 2 – Quality Systems, will ALSO be using a definition of complaint that is from ISO. However, it is the laboratory definition, and is modified to apply to laboratories: V1M2 - 3.2 complaint “expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected”. [SOURCE: ISO/IEC 17000:2004, 6.5, modified — The words “other than appeal” have been deleted, and the words “a conformity</p>	<p>3 – definitions</p>	<p>We need a definition of complaint that fits the module where this is being used. As we cannot modify the ISO definition in ISO/IEC 17000:2020, which is broad enough to encompass every possible ISO/IEC standard, we can clarify what it means for ISO/IEC 17011 by adding a “note” to the definition. Paul agreed to provide draft language for such a note, and did so after the meeting, as follows: <u>Most recent definition (ISO/IEC 17000:2020)</u> -- Expression of dissatisfaction, other than appeal (3.21), by any person or organization, to a conformity assessment body (3.18) or an accreditation body (3.2), relating to the activities of that body, where a response is expected. <u>NOTE:</u> When referring to an accrediting body, the words “to a conformity assessment body or accreditation body, relating to the activities of that body” are to be replaced by “to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body”. When referring to a laboratory, the words “other than appeal” are to be deleted, and the words “a conformity</p>

<p>assessment body or accreditation body, relating to the activities of that body” have been replaced by “a laboratory, relating to the activities or results of that laboratory”.] As an organization, we should not (must not) have two different definitions for the same term. The simple solution is to use the 17000:2020 definition for complaint in both Volume 2 Module 1 and Volume 1 Module 2: complaint (PROPOSED for V1M2 and V2M1) “expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected”. Each Module could add a TNI note indicating how its version of ISO (i.e., 17011 or 17025) has modified the definition of complaint, such as: “V2M1 – complaint - expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected</p>		<p><i>assessment body or accreditation body, relating to the activities of that body” are to be replaced by “a laboratory, relating to the activities or results of that laboratory”.</i></p>
<p>#14 -- TNI Note – For this module, the words “to a conformity assessment body or accreditation body, relating to the activities of that body” are replaced by “to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body.”” “V1M2 - complaint - expression of dissatisfaction, other than appeal, by any person or organization to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected”. TNI Note – For this module, the words “other than appeal” are deleted, and the words “a conformity assessment body or accreditation body, relating to the activities of that body” are replaced by “a laboratory, relating to the activities or results of that laboratory.” If there is a difference between the definition of the same term, that inconsistency will come up in the final review by CSDP EC.</p>	<p>Not given</p>	<p>Paul explained that if the definition is modified as above, this comment will be addressed.</p>

5. Persuasive/Non-persuasive Determinations for Comments

The following table documents the decisions made during this meeting of the LAB committee about the comments indicated. A quorum was present and a simple majority vote was taken for each row of the table.

Com-ment #	Section	Per sua-sive/ Non	Motion and Vote	Discussion	Assignment to Revise, if persuasive
43 & 55	1.0	Y	Yumi/Nilda Unanimous	Comment is editorial	Editorial only
68	6.1.2.11.c	Y	Nilda/Yumi unanimous	Comment is editorial	Editorial only
9	6.1.2.11	Y	Nilda/Yumi unanimous	Comment is editorial	Editorial only
10	7.6.6	Y	Yumi/Nilda Unanimous	Comment is editorial	Editorial only

6. Next Meeting

The next planned teleconference meeting is tentatively scheduled for **Tuesday, November 21, 2023, at 1:00 pm Eastern** but may be rescheduled for Tuesday, November 28, depending on members' availability and the availability of the scheduled commenter. Aaren asks that committee members unable to attend please notify her and Lynn prior to the meeting date. 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, Chair Aaren.s.alger@gmail.com	1/30/2026 (2nd term)	Other – Alger Consulting & Training	Yes
Socorro Baldonado sbaldonado@mwdh2o.com	1/30/2026 (2nd term)	Lab – Metropolitan Water District, La Verne, CA	Yes
Nilda Cox nilda.cox@et.eurofinsus.com	1/30/2025 (2nd term)	Lab – Eurofins Eaton Analytical LLC	Yes
Yumi Creason, Vice Chair ycreason@pa.gov	1/30/2025 (1 st term)	AB – Pennsylvania	Yes
Bill Hall george.w.hall@des.nh.gov	1/30/2026 (1st term)	AB – NH DES	Yes
Sviatlana Haubner Sviatlana.Haubner@cincinnati-oh.gov	1/30/2025 (1 st term)	LAB – Cincinnati Metropolitan Sewer District	No
Michella Karapondo Karapondo.michella@epa.gov	1/30/2025 (1st term)	Other – EPA OGWDW TSC/Cincinnati	No
Michael Perry michael.perry@lvvwd.com	1/30/2026 (2nd term)	Lab – Southern Nevada Water Authority	No
Zaneta Popovska zpopovska@anab.org	1/30/2025 (2nd term)	AB – ANAB	Yes
Program Administrator: Lynn Bradley Lynn.Bradley@nelac-institute.org	N/A		Yes
Associate Members:			
Paul Bergeron Paul.bergeron@la.gov		AB – LDEQ	Yes
Scott Haas shaas@etilab.com		Lab – Environmental Testing, Inc., and Chair, FAC	No
Taryn Hurley taryn.hurley@deq.ok.gov		AB – OK DEQ	No
Paul Junio paul.junio@pacelabs.com		LAB – Pace Labs, Inc.	No
Carl Kircher, Chair carl_kircher@flhealth.gov		AB – Florida Department of Health	Yes
LeeAnn Kline lkline@mjreider.com		M J Reider Associates	Yes
Ryan Lerch Ryan.lerch@deq.ok.gov		AB – OK DEQ	Yes
Marlene Moore mmoore@advancedsys.com		Other – Advanced Systems, Inc., Newark, DE	No
Mei Beth Shepherd, Vice Chair mbshep@sheptechserv.com		Other – Shepherd Technical Services	No
Aurora Shields Aurora.Shields@kcmo.org		Lab – KC Water	No
Nicholas Slawson nslawson@a2la.org		AB – A2LA	No
Ilona Taunton Ilona.taunton@nelac-institute.org		Other – TNI Program Administrator	No
Cathy Westerman cathy.westerman@dgs.virginia.gov		AB – VA DCLS	Yes

Guests :			
Vanessa Soto-Contreras Vanessa.sotocontreras@flhealth.gov		FL DOH	

Attachment 2 – LAB Expert Committee Meeting Agenda, October 20, 2023

- Welcome and Roll Call
- Approval of Agenda
- Approval of Minutes (September minutes attached)
- Committee Internal Audit Results and Proposed Corrective Actions (see attached spreadsheet, FYI)
- Continue Review of Comments on DS Revision 1 (Vanessa Soto-Contreras and Paul Junio comments -- Response-to-Comments and annotated DS Rev 1 attached)
- New Business, if any
- Adjourn