

**SUMMARY OF THE  
TNI CONSENSUS STANDARDS DEVELOPMENT  
EXECUTIVE COMMITTEE MEETING  
DECEMBER 10, 2020**

The Executive Committee held a conference call on Thursday, December 10 at 1:00 PM EST. Chair Paul Junio led the meeting. The conference call was recorded for the sole purpose of preparation of meeting minutes. The recording will be deleted immediately upon completion of the meeting minutes. The Agenda for the meeting is presented as Attachment 1. The agenda was modified to show the date as 12/10/2020.

**Agenda item 1 – Roll call**

Attendance:

Carl Kircher, LAB	Present
Kevin Holbrooks, At-Large Member	Present
Valerie Slaven, Chemistry	Present
Robin Cook, At Large Member	Present
Sheri Heldstab, Stationary Source Audit Sample	Present
Paul Junio, Chair, At Large Member	Present
Kirstin Daigle, Proficiency Testing	Absent
Jessica Jensen, Quality Systems	Absent
Rami Naddy, WET	Present
Kasey Raley, Microbiology	Present
Scott Haas, FAC	Present
Terry Romanko, Radiochemistry	Absent
Cathy Westerman, VA DCLS, Ex-Officio	Present
Michelle McGowan, Asbestos	Present
Ilona Taunton, TNI Staff	Present
Lynn Bradley, TNI Staff	Present
Robert Wyeth, Program Administrator	Present

A quorum was present and the meeting proceeded.

**Agenda item 2 - Review and approval of November 12, 2020 minutes**

The meeting minutes were reviewed. Minor editorial corrections were made. A final version is presented below. A motion to accept was made by Jessica and seconded by Sheri. The motion, after an abstention by Carl, passed unanimously. Minutes will be forwarded to William for posting.



### **Agenda item 3- Reminders – Committee Training**

Chair & Committee Member Training (<http://nelac-institute.org/eds/download/ChairTraining.php>) remains available to any interested party but as previously announced, is being revised. With the completion of SOP 2-100 and SOP 2-101 efforts to revise the training are nearly completion. A draft of the revised training has been prepared. Paul and Bob will work to prepare a final working draft for review by Program Administrators. A target of use by January of 2021 was established. The decision was made to focus on and prepare training for Expert Committees only and leave training of all other committees (which was previously being included) to another group (likely the Policy Committee) using the Expert Committee Training materials as a template, as these other committees are governed by a different SOP.

### **Agenda Item 4- Mandatory Requirement – Must v Shall**

As previously reported, the WET committee has been working to create an acceptable approach to analyst DOC. Currently significant differences exist within AB interpretations of the requirements. In their on-going discussions, a member brought to the WET Committee the FAA definition that “must” is the only legally acceptable and enforceable use of the Must vs. Shall question. This Must vs Shall discussion was ultimately raised to the BoD for consideration who suggested the term “must” should be used whenever possible for clarity and enforceability.

TNI’s glossary states that must and shall are equivalent but as the glossary is not now a part of the Standard, this is not enforceable by the ABs.

It was also pointed out that this use of “must” is not consistent with ISO language as “shall” is frequently used in ISO documents. The LAB DS recently presented for comment and ISO 17025-2017 both include the following:

- Shall a requirement
- Should a recommendation, not mandatory
- May reflects permission
- Can suggests a possibility

It was further pointed out that the EPA uses “shall and should” as being mandatory without the specific use of “must” in all cases.

CSDEC commentors suggested a universal change in the Standards and in SOPs and other TNI documents would be difficult and time consuming and not insignificant and maybe too aggressive an approach without fully considering each change being proposed. The AB representative to the CSDEC, offered that ultimately the inclusion of the glossary in the Standard would help eliminate this concern. It was further suggested that change should occur

as we move forward but that a universal change was not a recommended approach as this is currently not an issue for ABs. It was also suggested that we not make a big deal of this as we don't need to encourage people to challenge implementation of the standard through the use of the word "shall"

The consensus of the CSDEC, was that this is not currently an issue that requires immediate attention and that changes of "shall" to "must" should be made in the normal course of standards development and revisions to SOPs and other TNI documents.

Carl for the LAB committee will review this issue in their DS currently in a comment period.

One comment was that this issue may ultimately be more appropriately addressed by the Policy Committee and the BoD.

### **Agenda item 5- Delayed – Charter Reviews and Internal Audits**

Paul is working on revisions to the Internal Audit program for the CSDEC and the Expert Committees based upon changes in operational SOPs and had intended to have this task completed shortly. Committee Charters are to be reviewed annually.

Paul reported that the Internal Audit Schedule has been updated for this year as follows:

- Each Committee Update Internal Audit Checklist (as needed): Due January 5, 2021
- Policy Committee Review and Updated Checklists Sent to IT Administrator: Due February 5, 2021
- Internal Audit Data Base Updated: Due March 1, 2021
- Internal Audits Performed: Due April 30, 2021
- Corrective Action Process Completed: Due September 30, 2021

The Committee agreed that updated Committee Charters will be due March 30, 2020. This gives time for the TNI Board to review the 2021 Committee plans before Charters are prepared.

### **Agenda Item 6- ANSI Audit Status**

All required information has been provided to ANSI and we were awaiting the review of the Executive Standards Council as to our reaccreditation. Some additional questions/comments were received to which we have responded. The schedule for further consideration by the Executive Standards Council is unknown.

### **Agenda item 7- Standards Activity**

Activity is currently seen in the Asbestos, LAB and FSMO areas and other expert committee standards and/or Modules remain in the planning or pre-NOI stages. Bob will provide copies of the individual Standards and/or Module profiles to the PAs and committee chairs as soon as possible.

The list of recipients of TNI non-members and “interested parties” has been compiled and they have been notified of their future receipt of Standards Development Activities for comment to the relevant Expert Committees. Notifications of request for comments to this group on the Asbestos DS will be sent out this week. This list is available to PAs and being managed by Jan.

### **Agenda item 8- Glossary Update**

The Glossary work group has begun consideration of this document. A few versions of the glossary have been distributed. The version which displays all terms in the By-Laws and the Standard, will be the primary working document. As much agreement as possible is the goal. An additional glossary of terms not specifically included in the Standards (i.e., Policy documents, SOPs, etc.) will also be developed more in line with a guidance document in hopes that over time consistent use of terms can be accomplished.

The overriding guidance for the work group is that whatever is currently in the standard must be maintained to ensure AB acceptance. If changes are needed to resolve duplicity within these documents, committees will need to make the changes in the next revision of the Standard. The final concern is to ensure that ISO terms actually used are properly addressed. An unaddressed issue in the previous glossary was definitions in AB rules and regulations. Cathy has sent relevant definitions from her state as well as numerous other AB states and has request said information from remaining ABs. Bob has incorporated the various state definitions from these rules and regulations into their spreadsheet. Generally speaking, the definitions received to date have not indicated definitions that are inconsistent with TNI definitions.

### **Agenda item 9-Committee Reports**

Proficiency Testing –The committee continues developing the list of potential changes to be proposed for their volumes and modules of the standard and has developed a priority as well as a schedule to address these issues in 2021. The committee completed its 2021 roster with 14 voting members. The committee intends to actively solicit an AB for the 15<sup>th</sup> member of the committee.

Field Activities – Committee is continuing to work on changes to their standard. The committee has plans for a public webinar on February 4, 2021 to present their summary of changes. Standard changes will then be finalized and the process will proceed. The committee is also addressing membership for 2021.

Quality Systems – The committee recently completed their public webinar on proposed changes to their module. The committee will review and prepare responses to comments to the proposed changes to their module. Work will then commence on preparation of the DS. The committee also continues to address membership for 2021 including election of a new chairperson.

Laboratory Accreditation Body – The DS for EL V2M1 has been posted and is open for comment. Carl requested that CSDEC members please review and provide any appropriate comments to Carl/Lynn. The committee is finalizing plans for a public presentation of the DS at the January TNI Winter Meeting. The committee is also working to develop a technical checklist for evaluation of ABs.

Stationary Source Audit Sample – Committee is awaiting approval of SOP 6-100, Pilot Study Operations; Sheri was told that the BoD declined to review the SOP, thus the SOP is now official. Committee is continuing work on a revision to their draft of SOP 6-101, SSAS Table Management, which should be ready for Committee vote at the January meeting. A question was posed for consideration that the term “Matrix” in both the SSAS table and the FoPT table should be more accurately titled “Quality System Matrix”? In communications with EPA, it was asked if the definition of “Commercially Available” may be open for revision as this could potentially resolve the issue of only one provider and the resultant suspension of the program. Committee was advised to address this issue to the appropriate level in EPA after establishment of the new administration in Washington. The Committee re-elected its current leadership team for 2021.

Chemistry – Committee reviewed and responded to LASEC on a number of SIRs. The committee’s response to these SIRs was forwarded to Lynn on behalf of the LASEC. In closed session, the committee reviewed membership status and rotations of committee members and potential needs for additional member terms. The roster for 2021 was finalized. Unfortunately, one member elected to the committee had to decline the invitation. The January meeting will subsequently address one additional member as well as the committee leadership. The committee will then return to continuing efforts to develop items for consideration for changes to Module 4, including issues around laboratory and individual initial and continuing DOC.

Microbiology – Committee has been developing guidance on incubator equilibrium testing but has tabled this activity until 2021. The committee had their webinar regarding proposed changes to their module which was well attended and generated 70+ comments. Committee will be addressing all comments and preparing a R2C document. They are also working on their 2021 roster and plan to add 2 “lab” classified members and reaffirm leadership positions during their January meeting.

Whole Effluent Toxicity – Still attempting to resolve analyst IDOC amongst various ABs. Committee is also working on membership issues for 2021. Committee meeting later this month will reaffirm leadership and replace members rotating off the committee. Balance will be maintained.

Radiochemistry – Committee continuing to develop potential items requiring attention in the next version of their module but has yet to meet since the last CSDEC meeting. Committee is also working on membership issues for 2021 and should have membership status and roster finalized after their December meeting later this month.

Asbestos – The Asbestos DS successfully balloted and committee has preparing the required summary document, and current R2C document which were submitted to William for posting and opening of the 60-day comment period. The announcement to TNI non-members as required by SOP 2-100 will be distributed this week. 2021 roster has been established and leadership affirmations will be completed in January.

Accreditation Council – Only relevant information from the most recent meeting was discussion of the need for timely review of the DS from LAB.

### **Agenda Item 11 - New/Old Business**

During the January meeting, CSDEC will have to elect a new vice-chair as Jessica is rotating off the committee.

No additional new and/or old was presented for discussion.

### **Adjournment**

It was moved by Michelle and seconded by Kasey to adjourn at 2:40PM ET. All were in favor. The next meeting of the CSDEC is scheduled for January 14, 2020 at 1:00 PM ET.

Consensus Standard Development Executive Committee  
Action Items

Date	Action #	Description	Responsibility	Completion Date
2/19/2019	1	Contact Jerry reference ex-officio and/or associate representation from AB	Bob	Complete
2/19/2019	2	Vice Chair of CSDEC	Paul	Complete
2/19/2019	3	Reconstitute SRC	Paul	Complete
2/19/2019	4	Develop new Committee and committee chair training	Bob and Paul	On-going
2/19/2019	5	Communicate with each expert committee chair to update Standards Tracking form	Bob	Complete
2/19/2019	6	Ensure Radiochemistry Standard submitted to ANSI	Bob	Complete
2/19/2019	7	Post outline from LAB for comment	Bob	Complete
2/19/2019	8	Task Force for modification of SOP on Standard Development	Paul	Complete
3/14/2019	9	Complete SIR spreadsheet review and Summary by August, 2019	Committee Chairs	Complete
3/14/2019	10	Access to Internal Audit Database	Ilona	Complete
4/11/2019	11	Contact Jerry regarding reserving of module names based on consolidation of V2M1 and V2M3	Bob	Hold as "RESERVED" 5/10/2019
11/14/2019	12	Committee Membership /Newsletter	Bob/Paul	complete
11/14/2019	13	Ensure completion of Internal Audits of expert committee by 1/3/2020	Program Administrator/Chairs	Complete
4/9/2020	14	Complete Corrective Action response to internal audit findings	Program Administrator/Chairs	Complete

## ATTACHMENT 1

### Consensus Standard Development Executive Committee Conference Call

December 10, 2020; 1:00 PM ET

Dial-in-number: 1-712-832-8330; code 822174#

1. Roll Call
2. Review and approval of November 12, 2020 meeting minutes (attached)
3. Reminders - Committee Member Spreadsheet/Chair & Committee Member Training  
(<http://nelac-institute.org/eds/download/ChairTraining.php>)
4. Mandatory Requirement – Must v Shall
5. Delayed – Charter Reviews and Internal Audits
6. ANSI Audit Status
7. Standards Activity
8. Glossary Update
9. Committee Reports
  - a. Proficiency Testing
  - b. Field Activities
  - c. Quality Systems
  - d. Laboratory Accreditation Body
  - e. Stationary Source Audit Sample
  - f. Chemistry
  - g. Microbiology
  - h. Whole Effluent Toxicity
  - i. Radiochemistry
  - j. Asbestos
  - k. Accreditation Council
10. New/Old Business