

**SUMMARY OF THE
TNI CONSENSUS STANDARDS DEVELOPMENT
EXECUTIVE COMMITTEE MEETING
JANUARY 14, 2021**

The Executive Committee held a conference call on Thursday, January 14, 2021 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. No changes to the agenda were proposed.

Agenda item 1 – Roll call

Attendance:

Carl Kircher, LAB	Present
Kevin Holbrooks, At-Large Member	Present
Michelle Wade, 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	Present
Jessica Jensen, Quality Systems	Present
Rami Naddy, WET	Absent
Kasey Raley, Microbiology	Present
Scott Haas, FAC	Present
Terry Romanko, Radiochemistry	Present
Cathy Westerman, VA DCLS, Ex-Officio	Present
Michelle McGowan, Asbestos	Absent
Ilona Taunton, TNI Staff	Absent
Lynn Bradley, TNI Staff	Present
Robert Wyeth, Program Administrator	Present

Robert Aullman, Vice-Chair of the Radiochemistry committee represented Terry Romanko for this meeting. A quorum was present and the meeting proceeded.

Agenda item 2 - Review and approval of December 10, 2020 minutes

The meeting minutes were reviewed. Minor editorial corrections were made as was a revision to the SSAS monthly program report. A final version is presented below. A motion to accept was made by Kevin and seconded by Jessica. The motion, after an abstention by Michelle Wade, 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 completed. 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 early 2021 is anticipated.

Agenda Item 4- CSDEC Vice-Chair person

Jessica is rotating off the Quality Systems committee and will no longer be available to serve as Vice-Chair of the CSDEC. Kasey Raley was nominated for this role by Kirstin, seconded by Jessica and elected by unanimous vote of the committee members present. Debbie Bond is the new Chair of the Quality Systems Committee and will be assuming a position on the CSDEC.

Agenda Item 5- ANSI Audit Status

The Executive Standards Council of ANSI, who is responsible for our reaccreditation has submitted some final comments for TNI consideration. One is reference reaffirmation of standards which is virtually editorial and simply clarified. The more substantive comment is a request for SOP 2-100 to include “recirculation” of negative votes and public comments deemed non-persuasive by an Expert committee. If after a negative vote or non-persuasive comment, despite efforts to be resolved, is again considered non-persuasive, the Expert Committee members are to “recirculate” the issue and be given the opportunity to affirm or change their previous vote/decision. If 2/3 of the Expert Committee still considers the vote to be non-persuasive, the commenter may then appeal the decision as per Section 6 of the SOP.

The draft of SOP 2-100, Rev. 3.4 was presented and discussed. The language as presented was deemed confusing and efforts to re-write the modified section (i.e., 5.3.1 and 5.4.4) will be under taken. Due to the relative urgency of responding to ANSI, members of the CSDEC were aske to provide any suggestions for alternative language to Paul and Bob (with a cc to all CSDEC members) as soon as possible. Revised language will be shared with the committee in hopes of approval of this proposed modification to SOP 2-100 via an e-mail ballot.

The language in question can be found as tracked changes in section 5.3.1 and 5.4.4 in the attached.



SOP

2-100-Rev3.4_propos

Agenda item 6- Standards Activity

Recent standards activity includes Posting of the Draft Standard (DS), Summary Document and Response to Comments Document (received to date) for both the Asbestos (EL V1 M3) and the Laboratory Accreditation Body (EL V2M1) Expert Committees on the TNI website. Comment periods are open for both DSs. Requests for comments have also been sent to TNI committee Chairs, Accreditation Council members and interested and/or potentially impacted non-TNI members.

As presented in Expert Committee program reports, numerous other committees are currently working on future standards activities.

Agenda item 7- Glossary Update

The Glossary Work Group, under the auspice of the CSDEC, continues to work on a revised version(s) of the glossary. Guidance for the work group is that whatever is currently in the standard must be maintained to ensure AB acceptance and enforceability. 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 requested 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.

The current work plan is to first consider only those definitions in the Standard and attempt to harmonize any discrepant definitions and advise Expert Committees to include the appropriate definition in their modification efforts. The other definitions will then be reviewed and again harmonization attempted. These definitions would then be appropriately changed in SOPs, guidance documents and other TNI materials either immediately or as said documents are revised.

Agenda item 8- Winter Meeting / Annual Report

The virtual Winter Meeting is being held January 25-29, 2021. Paul reminded folks to register if they already have not done so.

Bob, at Jerry's request, has prepared an annual report for the CSDEC. The report summarizes the committee activities. Included in the summary are discussions of the ANSI reaccreditation

effort, progress on the Glossary and Internal Audits as well as ensuring 2021 roster completions with efforts to bring all committees to a maximum number (15) of voting members.

An additional topic during this discussion was that of the status of revisions to the Committee Charters. Lynn said that this activity was required by the Quality Management Plan and scheduled upon changes in the TNI Strategic Plan and surmised that review of the Charters would likely be required in the spring of 2021.

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 is also working to assist in the Mentor session of the Winter Meeting on management of a PT program. The committee will also participate in a joint meeting with PTPEC and WET in attempts to resolve their PT and DOC issues.

Field Activities – Committee is continuing to work on changes to their standard. The committee has plans for a public webinar on February 4, 2021 at 1:00 PM CT to present their summary of changes. Standard changes will then be finalized and the process will proceed. During the virtual meeting, the committee will review the materials to be presented in their upcoming webinar.

Quality Systems – The committee recently completed their public webinar on proposed changes to their module. The committee has finalized responses to the questions and comments from the webinar as insufficient time was available after the heavily attended event. Questions and comments will be responded to each individual. Efforts to modify QS module consistent with changes in the DOD documents will continue to progress on a schedule more conducive to the more typical standard development process. The committee elected new leadership as Jessica is rotating off the QS committee. Debbie Bond was elected as Chair and Kathy Grumper will continue as Vice-Chair. Three new members were also introduced to the committee.

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 AC has requested an extension on the comment period which will now close on March 30, 2021. The committee is also working to develop a technical checklist for evaluation of ABs.

Stationary Source Audit Sample –Committee has finalized work on a revision to their draft of SOP 6-101, SSAS Table Management. The document has been distributed for both internal and external review. The committee also continues to work on further development of their Standard.

Chemistry – Committee reviewed a number of SIRs, including non-valid SIRs, that may need consideration in development of changes to be proposed to Module 4. Committee also reviewed their input to the TNI Annual Report and established goals and objectives for 2021. The Committee then elected Michelle Wade as the new Chair of the committee as Valerie is rotating off but will remain an associate member. Tony Francis was elected as the Vice-Chair for Chemistry. Two (2) members were also welcomed to the committee. The committee is continuing in its efforts to develop items for consideration for changes to Module 4, including issues around laboratory and individual initial and continuing DOC.

Microbiology –The committee had their webinar regarding proposed changes to their module. Essentially, 7 items will require the majority of attention. One item was the definition of “lot”. The concern is that the same lot received months apart are being “validated” by the initial determination which may no longer be relevant or accurate. Multiple committees’ involvement is likely to be required as is discussion by the Glossary Work Group. The Committee also worked on the development of their 2020 Accomplishments and 2021 Goals for input to the Annual report. The committee roster was affected by a number of changes but the leadership of the committee was re-elected for 2021.

Whole Effluent Toxicity –Committee worked on membership issues for 2021. Committee reaffirmed leadership and replaced numerous members rotating off the committee which have been replaced with new members, most of whom were associates already participating in committee activity. The committee also approved revised language relative to analyst Demonstration of Capabilities which has been a significant “roadblock” for some time. The language was presented to the AC, as ABs per the stakeholder group most concerned with changes in this element of the WET module. The discussion was believed to be received reasonably well and further communications are anticipated. The committee now intends to move to other topics in question for their module including method validation and quality control.

Radiochemistry – Robert Aullman, the Expert Committee Vice Chair attended the meeting for Terry and presented the following summary of recent activities. Committee continuing to develop potential items requiring attention in the next version of their module. Committee is also working on membership issues for 2021 and two new members have been introduced to the committee.

Asbestos – The Asbestos DS successfully balloted and committee has prepared the required summary document and current R2C document which have been posted by William on the TNI website. A 90-day comment period has begun. The announcement to TNI non-members as required by SOP 2-100 has also been distributed. The 2021 roster has been established and leadership re-affirmations completed with two new members added to the committee.

Accreditation Council – Nothing relevant to report as a result of AC activity this month.

Agenda Item 9 - New/Old Business

Internal audit- according to Paul nothing to report on the topic but an update may be forthcoming.

Adjournment

It was moved Kasey and seconded by Michelle Wade to adjourn at 2:20 PM ET. All were in favor. The next meeting of the CSDEC is scheduled for February 11, 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

January 14, 2021; 1:00 PM ET

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

1. Roll Call
2. Review and approval of December 10, 2020 meeting minutes (attached)
3. Reminders - Committee Member Spreadsheet/Chair & Committee Member Training
(<http://nelac-institute.org/eds/download/ChairTraining.php>)
4. CSDEC Vice Chair person
5. ANSI Audit Status
6. Standards Activity
7. Glossary
8. Winter Meeting / Annual Reports
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

New/Old Business