TNI Board of Directors Meeting Summary September 14, 2022

ROLL CALL

Directors	Present	Staff	Present
Jordan Adelson	X	Lynn Bradley	X
Aaren Alger	X	Paul Junio	X
Steve Arms	X	Jerry Parr	X
Caitlin Brice	X	Ilona Taunton	X
Justin Brown		Janice Wlodarski	X
Kristin Brown	X	Bob Wyeth	X
David Caldwell			
Robin Cook	X		
Stacie Crandall			
Jack Farrell	X		
Maria Friedman	X		
Myron Gunsalus	X		
Jessica Jensen	X		
Harold Longbaugh	X		
Judy Morgan	X		
Patsy Root	X		
Debbie Rosano			
Valerie Slaven	X		
Nick Slawson	X		
Alfredo Sotomayor	X		
Lem Walker			
Past Chair			
Sharon Mertens			

AGENDA

1. Review of Consent Agenda – Approved 9/14/2022

2. Status of Stationary Source Audit Sample Program

On July 25, Sheri Heldstab, Jerry Parr, and Ilona Taunton had a conference call with several individuals from the EPA Office of Air regarding a letter we had sent them on options for continuing this effort. EPA informed us they would not consider having a single provider of audit samples and have no other options for us to consider. Thus, this program is now effectively dead.

Sheri has retired, but before she did, she sent an email to all the committee members letting them know the program is inactive and the committee is dissolved. We will continue to keep the SSAS webpage active, at least until the end of the year, when ERA also ceases inputting laboratory data into the SSAs central database.

3. 2024 Meeting Locations

Based on two Request for Proposals for the winter and summer meeting in 2024, we received proposals from Anaheim, Chicago, Columbus, Denver, and Newport Beach for the winter 2024 meeting. (We did not receive proposals from several other locations including Sarasota, Savannah, and Nashville.) After reviewing a summary of the proposals, the Advocacy Committee recommended we go with Columbus based on pricing, meeting space, and the fact the summer meeting will likely be in Anaheim. We received proposals from Anaheim, Atlanta, Chicago, and Denver. The Symposium Steering Committee has recommended we go back to Anaheim as the other proposals all had major issues with the meeting space or costs.

4. Third Quarter Financial Report

The 3rd Quarter Financial Report was reviewed during this meeting.

CONSENT AGENDA Approved 9/14/2022

1. Approval of July Minutes

2. Rebuttal of LC/GC article

As discussed in the June minutes, the Advocacy Committee developed a rebuttal to an article published in LC/GC North America. A summary of the rebuttal is provided below. The entire article is appended to this agenda as Attachment 1.

The NELAC Institute (TNI) agrees with many of the statements contained in the article <u>Laboratory Accreditation is Not a Cloak of Infallibility</u> published in LC/GC North America in March 2022 but believes the authors have overlooked other critical areas and, in some cases, have conclusions that are not supportable. A robust laboratory accreditation program can ensure the competency of laboratories and help ensure reliable data.

Jerry heard back and they will share TNI response with the authors of the article so they can review and publish a reply if necessary.

3. Comments on Ohio Proposed Regulation

Ohio EPA published a proposed rule relative to the use of accredited/certified laboratories for their Voluntary Action Program (VAP). The VAP is for clean-up of brownfield sites. This is a revision to a 2018 rule that started the process of eliminating their certification program which was found to be duplicative to TNI. This 2022 rule would begin the process to completely phase out the Ohio program.

TNI provided comments to clarify the name of our organization and the two laboratory accreditation programs that are part of TNI, emphasizing the use of NGABs for Ohio laboratories. These comments are shown in Attachment 2.

4. 2022 Environmental Measurement Symposium

The Symposium was successful with 487 attendees of which 458 attended in person. Attachment 3 contains a summary of the TNI closing session. Additional information is contained in the various committee reports.

5. CONSENSUS STANDARDS DEVELOPMENT REPORT

5.1 Consensus Standard Development Program Executive Committee

2022 Objectives	Status
Develop policies and procedures that guide standards development	All Volumes and Modules of the TNI Standard are currently under review. The EC approved SOP 2-102 (Conflict of Interest) and has finalized changes to SOP 2-101 (Committee Operations) to include voting requirements. Internal Audits will begin upon directions from the Policy Committee.
Ensure consistency and uniformity between Volumes and Modules of the Standard	Nothing to report.

Provide technical and administrative assistance in developing tools to facilitate the implementation of the Standard

Provide opportunities for stakeholder involvement throughout the development process and assist Expert Committees in dissemination of pertinent information and responses to comments.

Prepare and deliver an Annual Report for the previous year and Work Plan for the coming year for the annual meeting or whenever requested by the Executive Director.

Submit one of the revised Modules (including the entire Development Process) to ANSI to finalize TNI's re-accreditation.

Additional Comments/Concerns:

Nothing to report.

All internal and public information for each Volume and/or Module of the Standard are being completed consistent with SOP and ANSI requirements.

Accomplished at TNI Winter Meeting.

PINS for EL V4 and BSR-8 filed for Radiochemistry and Microbiology.

Awaiting closure of ANSI public comment period for PINS on EL V4 and BSR-8 for Radiochemistry and Microbiology. Expert committee progress continuing.

5.2 Asbestos Testing Expert Committee

2022 Objectives	Status
Develop and maintain consensus standards for asbestos testing (AT) that are practical, implementable, and meet the needs of the environmental testing community while providing data of known and documented quality.	The second revision of the modified EL V1M3 has been approved by committee and posted on the TNI website. Public comment closed, one minor (non-substantive editorial comment) to be addressed. Committee concluded responses to comments on revised DS, R2C to be posted and next revision of DS to be published and re-opened for any additional comments.
Seek American National Standard status from ANSI and pursue adoption of Module 3 in NELAP.	Nothing to report.
Serve as a technical resource regarding AT to TNI members and other interested parties.	Nothing to report.
Provide technical assistance in developing tools to facilitate the implementation of the Standard.	Nothing to report.
Prepare and deliver an Annual Report for the previous year and Work Plan for the coming year for the annual meeting or whenever requested by the Executive Director.	Accomplished at TNI Winter Meeting.
Additional Comments/Concerns:	2022 Leadership and membership established. All training completed.

5.3 Chemistry Expert Committee

2022 Objectives Status

Evaluate and improve as needed the TNI Chemical Testing Standard:

- Demonstration of Capability
- Calibration
- MDL/LOQ

Develop chemical testing standards that are usable across various environmental accreditation programs.

Provide technical assistance in implementation of the Standard.

Provide technical assistance in interpretation of the Standard.

Continue to contribute to resolution of the Technical Manager issue.

Prepare and deliver an Annual Report for the previous year and Work Plan for the coming year for the annual meeting or whenever requested by the Executive Director.

Additional Comments/Concerns:

Module/section specific work groups established for calibration, demonstration of capabilities, validation/verification, and QC; work groups meeting. Work groups continue in their efforts. Continuing to develop revised language of M4 for consideration.

All SIRs and public comments are being addressed.

Nothing to report.

Continuing to work with LASEC/AC on outstanding SIRs.

Accomplished at the TNI Winter Meeting.

2022 Committee leadership and membership completed. Two full members and 4 new Associates joined the Committee. All training completed.

5.4 Laboratory Accreditation Body Committee

2022 Objectives

Revise and maintain the TNI Standards for Laboratory Accreditation Bodies (Volume 2 Module 1 of the TNI Environmental Laboratory Standard.)

 Finish review of comments received on Revision 0 Status

Currently reviewing comments – ruling them persuasive or non-persuasive and deciding upon revised language for those comments deemed persuasive. Requested specific feedback from NELAP AC about whether to authorize continuing remote assessments in the Revised Draft Standard.

Four especially complex issues were discussed at the August 2 conference session, and two were resolved. LAB is meeting with the NELAP AC in September to further explore possible ways to address the remaining two issues – assessor training and remote assessments.

- 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

NA

NA

NA

receive/review comments again

Committee vote for Final Standard.

Prepare draft Compliance Checklist.

Support the NELAP Accreditation Council (AC) and the Laboratory Accreditation Systems Executive Committee (LASEC) in reviewing draft policies and procedures to ensure consistent standard implementation and in gathering and disseminating information on accreditation body activities, as requested.

Provide information on developing and recommending training and guidance materials as appropriate.

Review and respond to Standards Interpretation Requests, as referred.

Monitor and report on ISO Conformity Assessment Committee (CASCO) Work Group revisions to ISO/IEC 17011. Support TNI by completing any tasks assigned by the Board or required by the AC or LASEC.

NA

Draft checklist awaits final standard for review.

None at present. Anticipate reviewing and revising the Application Form for NELAP Recognition that is used for both new and renewing ABs.

NA

The NELAP AC has a protected website where AB representatives review and vote on proposed responses to SIRs.

Carl Kircher, LAB Past-Chair and current Associate member, monitors CASCO activities. No other tasks assigned to LAB at present.

5.5 Microbiology Committee

2022 Objectives	Status
Complete Volume 1 Module 5 DRAFT Standard.	Committee is working through comments received on posted DRAFT Standard. Review continued. The Committee hopes to complete vote on final responses to comments in September.
Develop "Understanding Microbiology" Webinar course(s).	Committee has started discussing possible content and turning the training into a series of courses instead of one class. Workgroup has been formed and course is being developed. First class of series was held live in Virginia and then will be done as a Webinar. Committee is working on a schedule for remaining webinars.
Continue to respond to Standard Interpretation Requests.	Sent response to SIR 425 (regarding quality control checks) to LASEC. Completed new responses to SIRs 425 and 423 (positive and negative culture controls) and sent them to back to LASEC.
Prepare Implementation Guidance regarding Incubator Equilibrium checks.	
Support Quality Management System's efforts to finalize language for Technical Expert.	Comments sent to Quality Management Systems.

5.6 Proficiency Testing Committee

2022 Objectives

Develop and maintain consensus standards for proficiency testing (PT) that are practical, implementable, and meet the needs of the environmental community.

Develop and maintain consensus standards for the manufacture of PT samples that ensures PT samples provide equal challenge to participants regardless of manufacturer.

Develop and maintain consensus standards that support PT sample design and scoring criteria (analyte, matrix, concentration, and acceptance criteria) appropriate to evaluate a participant's competency in the field(s) of accreditation for which the PT sample was manufactured.

Serve as a technical resource to TNI membership and the environmental testing community regarding PT performance.

Prepare and deliver an Annual Report for the previous year and Work Plan for the coming year for the annual meeting or whenever requested by the Executive Director.

Additional Comments/Concerns:

Status

Review of existing Volumes and Modules complete and modification for each being developed by work groups. Volume specific work groups established. Work groups continuing in efforts to develop modifications to PTEC related Volumes and Modules. C comments received at the Symposium for consideration.

Review of existing Volumes and Modules complete and modification for each being developed by work groups. Work groups continuing in efforts to develop modifications to PTEC related Volumes and Modules.

Review of existing Volumes and Modules complete and modification for each being developed by work groups. Work groups continuing in efforts to develop modifications to PTEC related Volumes and Modules.

All SIRs and public comments are being addressed.

Accomplished at the TNI Winter Meeting.

Committee roster completed with 4 new full voting members (Mike Delaney, Danielle Pearman, Brian Stringer, and Ryan Pangelian) to replace those rotating off the committee; 3 new Associates as well.

Agenda and materials for face-to-face meeting at August EMS developed.

Voting member of PTEC resigned her position and has left the industry. Seeking replacement for vacancy in order to maintain 15-member committee.

5.7 Quality Management Systems Committee

2022 Objectives

Status

Complete Volume 1 Module 2 DRAFT Standard.

Language is now being inserted into Section 5 the DRAFT Standard.

Continue to respond to Standard Interpretation Requests.

Discussion on SIR 412 dealing with uniquely identifying solvents is continuing. Kristin Brown is discussing this with LASEC.

SIR 422 (deals with documentation for purchase, receipt, and storage of consumables for technical operations) was completed and sent back to LASEC.

The Committee is working on SIR 433 that deals with when SOPs are sufficient verses records and documents. Response finalized and sent to LASEC.

Continue working through controversial topics:

- Internal Audits
- Document/Record Retention
- Quality Manual

Define "Appropriate QC" in Section 7.7 (ISO/IEC 17025:2017)

Work on Technical Expert.

Progress has been made on language for the Quality Manual. Topic for September meeting: How to define Technology or how to specify internal auditing frequency without technology.

The Committee received the formal hand-off of the Technical Expert Concept from the Competency Task Force. Finalize comments in May to send to Quality Management Systems Committee.

The Committee had a special meeting at the end of June to start discussing language. Comments were received from all expert committees except Asbestos. Significant comments and agreement at conference:

- Looking at whether list of degrees could be changed to "scientific discipline".
- Specific questions have been formulated for expert committees to make changes to their recommendations.
- Investigate working with universities/colleges on internships.
- Look at possible language being added for all regarding adding accreditation for new technologies.

Work on language from Sections 4.2 and 4.1.3 from ISO/IEC 17011:2017. LAB noted that lab requirements are included in these sections and should be added to Module 2.

Committee has drafted language for review.

5.8 Radiochemistry Committee

2022 Objectives Status

Complete Volume 1 Module 6 Standard.

The DRAFT Standard is currently posted for comment. Comments are due by April 6, 2022.

Delayed review to May meeting. There were no comments received on the Standard, so the Standard is final. An email was received with some suggestions. The Committee voted that the suggestions/comments were non-persuasive and the information is being placed into the comment table and the commenter will be notified as soon as the table is complete. The Standard is final.

Resolve reporting uncertainty with PT results.

A workgroup has been formed to prepare a recommendation on how to resolve this issue based on the combined meeting in San Antonio. Language has been sent to PTPEC and PT Expert.

Explore options for FoPT tables for non-DW matrices.

On hold until the uncertainty issue above is resolved and the new DW FoPT limits are approved by the PTPEC. Discussed 4/27/22 and workgroup will be developed.

Support Quality Management System's efforts to finalize language for Technical Expert.

The Committee had extensive discussion and formulated a recommendation that has been sent to Quality Management Systems. In addition to their recommendation, they sent the following comment: The Committee understands the definition of "equivalent technical course" may not be perfectly clear and up to subjective decisions. However, we feel that opening things up to types of training other than just college/university is important and well past due. Initially it will likely be up to the laboratory to convince an AB that the instruction received at a particular course meets the intended need. This may not be all that hard if, for example, the laboratory can compare the topics covered at a non-university training class to the syllabus of a published university class. It may be more difficult in other situations. Ultimately, it may be that there is a need for definition by TNI (i.e. the REC) as to what constitutes appropriate training. However, this would take quite a bit of time, and itself will likely be somewhat "controversial".

Responded to QMS Expert Committee with additional comments and participated in special meeting to discuss technical manager/expert language.

Continue to respond to Standard Interpretation Requests.

Other

The Committee Vice Chair (Robert Aullman) resigned due to a new job. They are looking for a Vice-Chair. Patrick Garrity has been added to the Committee as a voting member.

5.9 Stationary Source Audit Sample Committee

2022 Objectives	
•	Status
Complete Volume 1 Modules 1, 2 and 3 update.	Effort terminated.
Establish path to achieve data comparability for WET PT data, working with PTPEC and PTEC to add language to either the Standard or the WET FoPT tables (yet to be determined).	Effort terminated.
Respond to recent notification that ERA will no	The Committee met with Jerry Parr and Craig Huff

longer be providing Audit Samples.

(ERA) and discussed the impact of ERA's decision. There are now no audit sample providers. The Committee prepared a letter to EPA with Jerry and Craig's assistance that Jerry will send from TNI. Committee operations are suspended pending any response from EPA that might change this decision.

Sheri, Jerry, and Ilona met with the EPA to see if any changes to the current requirements could be made. No changes are possible, so Committee operations are now terminated.

5.10 Whole Effluent Toxicity Committee

2022 Objectives	Status
Revise and maintain the WET module of the TNI standard.	
Complete review and revision of updated language for each section of revised V1M7.	Currently underway.
Publish Draft Standard EL Volume 2, Module 1, Revision 1.	NA
Discuss and rule on any comments, Persuasive or Non-persuasive.	NA
Revise language of Revision 0 as warranted by comments.	NA
Publish Draft Standard EL V1M7 Revision 1 if controversies identified during review of comments.	NA
Committee vote for Final Standard.	NA
Establish path to achieve data comparability for WET PT data, working with PTPEC and PTEC to add language to either the Standard or the WET FoPT tables, as determined by PT Program.	Ongoing activity. The WET Chair met with the new PTPEC Chair on September 1 to discuss the current status of WET's efforts.
 Provide volunteer committee members to serve on PTPEC's WET FoPT Subcommittee. 	During that meeting, the Chairs finalized membership of a WET FoPT Subcommittee for PTPEC to seek possible ways to resolve the complex issues currently interfering with this data comparability.
 Standardize Proficiency Testing conditions and endpoints. 	Delivered an approved table of standard PT conditions that will support data comparability among PT results to PTPEC and PTEC for use in upgrading WET PT instructions to provide consistent testing for PT samples. Awaiting response from recipients.
Offer expert assistance to TNI on WET testing methods, quality control and data interpretation.	No activity at present.

6. NEFAP

2022 Objectives	Status
Support standard revision process by providing comments and suggested changes to improve the TNI Field Activities Standards.	Members of NEFAP EC attended special meeting with FAC to help develop language for Volume 1 (FSMO).
NEFAP AB re-evaluation process.	The final checklist is being worked on by Shawn Kassner and Ilona. Work on the SSAS portion of the checklist will cease.
	Application has been reviewed with both the PTPEC and NEFAP EC. SOP 7-101 (x) has been updated and both Expert Committees have been given copies for final voting in July. Remote procedures needed to be added. Also starting to look for members for the evaluation teams. NEFAP approved SOP 7-101 by email vote. It was approved by the PTPEC and forwarded to the Policy Committee for finalization.
Continue to develop training courses and implement strategic plan as it relates to training.	A DRAFT presentation for an Internal Audit class for FSMO's is complete and being finalized. The course anticipated for late Spring.
	The first half of the course is developed and second half will be complete in time for a September/October offering of the class.
Aggressively market the Program utilizing the strategies outlined in the strategic plan.	The Marketing Subcommittee is working with Jerry Thao to include a NEFAP presence on
 Expand online presence. 	LinkedIn. They are also working on the Ambassador program.
 Update and develop FSMO application tools. 	
 Market program to state agencies – NEFAP Ambassador Program. 	
 Open dialog with EPA on agency efforts related to field sampling quality. 	
Generate more awareness of the program and drive growth and interest in participation.	Tracy attended FSEA late May and spoke about the program and shared NEFAP brochures. She has some leads to follow-up on.
Streamline Program/EC operations to minimize resources required to maintain program based on size and need.	
Establish and monitor success measures.	Report submitted by Justin for May Board meeting.
Determine a path forward regarding its interaction with NELAP.	
Committee Management	The Committee voted in a new Chair – Tracy Szerszen (AB). She was the former Vice Chair. Paul Bergeron has been voted in as Vice-Chair. Justin Brown will continue as a committee member, but other obligations prevent him from

continuing in the Chair role.

The Committee is re-writing their membership procedures and it looks like there is support to begin voting in members similarly to other TNI committees instead of the formal process of a nomination committee and voting by the entire TNI membership. The update should be complete within the next month.

6.2 Field Activities Expert Committee (FAC)

2022 Objectives **Status** Complete Volume 1 and Volume 2 DRAFT A public meeting is scheduled for Volume 2 (AB) Standard. on March 15, 2022 at 11am Eastern. Volume 2 is being reviewed post public meeting for any additional updates to be discussed in May. Additional language originally in the 2014 version of the FSMO Standard was removed because it duplicated language in the new ISO/IEC 17025:2017 standard. The Committee is working on value added sections in Volume 1 (FSMO Standard). A number of sampling documents will be reviewed as "homework" for the June meeting so the Committee can continue work on Section 7. Example documents include: Guidance for Quality Assurance Project Plans - EPA QA/G-5 and EPA Requirements for Quality Assurance Project Plans -EPA QA/R-5. Continue to respond to Standard Interpretation

7. NELAP

Requests.

7.1 Accreditation Council

2022 Objectives	Status
Sustain governance role for the program and promoting consistency in AB operations.	Modified NELAP Mutual Recognition Policy POL 3-100 to require reporting of both primary and secondary accreditations into LAMS at least monthly. Discussed why and how to manage PT Providers qualified results for supplemental PTs. Also discussed language in Volume 3 that is not contained in state regulations, e.g., 45-day time frame for supplemental PTs. Members of the AC will be reaching out to the PT executive and Expert committees to discuss these issues further.
	Michella Karapondo of EPA OGWDW's Technical Support Center is the new EPA Liaison to the Council.
Review and comment on Draft Standards as	An additional NELAP AB representative is now an

offered for comment.

associate on LAB Expert Committee to monitor the development of V2M1 Draft Standard Version 1.

Received LASEC recommendation that the Radiochemistry Draft Standard V1M6 meets suitability criteria.

Received LASEC recommendation that the Asbestos Revised Draft Standard V1M3 meets suitability criteria

The Council is meeting with LAB Expert Committee on September 12 to discuss possible ways to address the remaining complex comments on the V2M1 Draft Standard – assessor training and remote assessments. An off-agenda meeting with the EPA Drinking Water team at conference in Crystal City provided insight into what that program might accept.

Review and approve existing and prospective ABs to become or remain NELAP-recognized.

All renewal letters have been issued for the evaluation cycle ending this calendar year. Each of the three Lead Evaluators (Steve, Aaren, and Ilona/Alternate) is working on at least one active evaluation. Approved renewal of recognition for PA and KS. Invited Nevada representatives to join in the NELAP AC calls, as NV is currently deciding whether to apply for NELAP recognition. Six renewals have been approved thus far.

Tentative assignments for evaluation teams are being reviewed by the evaluators and Lead Evaluators, and will be presented to the NELAP AC for acceptance no later than its October meeting.

Work with LASEC to include new standards into the NELAP program, provide interpretations and clarification of the TNI Environmental Laboratory Sector standards, and adopt policies and procedures prepared for use within the AC.

Voting to approve new SIR responses as implementable (the final approval step) is being done in timely fashion by most ABs.

Review and comment on relevant acceptance limits for proficiency testing in FoPT tables developed by the PTPEC.

None offered at present.

Implement a national program for the uniform and consistent accreditation of environmental laboratories.

The Accreditation Council meets monthly to address administrative issues and to provide a forum for discussion among AB representatives. Addressed LAB committee's request for feedback on continued use of remote assessments.

A list of issues that AB representatives wish to discuss has been created since conference, and these will be addressed in the coming months according to the Chair's prioritization.

Implementation Plans for 2016 TNI ELS Standard – 1/5/2021			
Stat	Process for Implementing the New Standard	Anticipated	
е		Implementation Date	
FL	FL adopted the TNI 2016 Standards by regulation on	Fully implemented on	
	September 26, 2018. Laboratories were granted a grace	April 1, 2019	
	period until April 1, 2019, to implement the new standards		
IL	Full implementation on January 31, 2020	January 31, 2020	
KS	Rulemaking will require another 6-12 months, and then 6	2023	
	more months from final rule to implementation date. Is		
	allowing labs to upgrade now and is assessing to 2016		
	Standard even though 2003 NELAC standard is still the		
	official version		
LA	May be able to avoid rulemaking, decisions being made by	Unknown	
	departmental management.		
MN	Full implementation of 2016 Standard accomplished.	January 2021	
NH	Is encouraging labs to upgrade now, working with counsel	Unknown	
	about how and when they can proceed with rulemaking		
NJ	Incorporated into regulation by reference	January 31, 2020	
NY	Adopts by reference; unable to obtain permission to complete	PT changes	
	rulemaking to update other aspects on separate timeline.	implemented; other	
	Implemented PT modules of 2016 Standard immediately but modules await		
	not able to use the updated/2016 checklist yet. Encouraging	rulemaking to revise	
	labs to upgrade now NYS certification		
	manual. Unknown		
		date for completion	
OK	Proposed rulemaking published to adopt 2016 Standard.	Likely September 1,	
	Approval by state legislature expected.	2022	
OR	Implemented 2016 Standard effective January 1, 2021	January 1, 2021	
PA	Incorporated into regulation by reference, all labs are	January 31, 2020	
	required to have the 2016 standard implemented by July		
	2020.		
TX	Incorporated into regulation by reference. Implementation has	January 31, 2020	
	gone well.		
UT	Rulemaking complete, 2016 standard implemented.	June 11, 2021	
VA	Regulation change effective April 1, 2022.	November 1, 2022	

7.2 Laboratory Accreditation Systems Executive Committee

2022 Objectives Status

fanage the Standards Interpretation Request (SIR) rocess to ensure that all SIRs meeting the requirements of iOP 3-105 are successfully addressed. The SIR subcommittee will initially review all SIR activities, making ecommendations to LASEC for action once the SIR esponse is ready for final approval to post it for vote on the iC voting site. Engage the assistance of Expert and executive Committees as appropriate for standards interpretations, guidance documents and related tools.

lanage development of Implementation Guidance (IG) in ccordance with SOP 3-114, as needed.

Ongoing.

The SIR Management SOP 3-105 is being updated to reflect removal of SIR Subcommittee's delegated authority to manage SIRs.

Discussions about implementation of SIRs will continue after conference.

No new Implementation Guidance requested; one in development.

Approved revisions of IG SOP 3-114 to address Policy Committee concerns, but rejected request to have full committee

approve IGs. As the SIR Subcommittee had delegated authority to approve SIR responses, LASEC proposes to modify its charter to include SIR Subcommittee approval of IGs.

The Implementation Guidance SOP 3-114 is being updated to reflect removal of SIR Subcommittee's delegated authority to oversee and approve IG development.

Although LASEC had voted to rename IGs, Policy Committee determined that the name "Implementation Guidance" would be acceptable, so LASEC quickly approved a return to the original IG nomenclature.

Review Voting Draft Standards as they are developed to ensure they are suitable for use by considering AB and laboratory needs early in the development process. Voting on Recommendation about Radiochemistry Draft Standard V1M6 completed and recommendation delivered to NELAP AC.

Voted approval of Recommendation about Asbestos Revised Draft Standard V1M3 for delivery to NELAP AC. LASEC recommendation is conditioned on addressing two specific and needed technical edits.

Ensure that laboratory assessors, regulators, QA managers and technical managers have an organized forum at every TNI conference to discuss common issues (Assessment Forum).

Sessions at EMS in Crystal City

 Internal Audits: Bringing Together Assessor Expectations and Perspectives.

Planning for the winter conference in San Antonio will soon begin.

Assume Role as Recognition Body for NGAB status (parallel to NEFAP and PTPEC recognitions).

Ensure that laboratory representatives and other stakeholders have an organized session at every TNI conference to discuss common issues (Mentor Session).

Session at NEMC in Crystal City – The Incredible Journey of Internal Audits – Episode 1 How much ground do you need to cover and how?

Planning for the winter conference in San Antonio will soon begin.

None active at present.

Develop Draft Policies and SOPs for NELAP as requested.

Added new member, Patty Carvajal, San Antonio River Authority.

8. PROFICIENCY TESTING PROGRAM

2022 Objectives	Status
Address WET EC requests to standardize WET PT program.	A meeting was held on February 24, 2022 with the Chairs of PTPEC and WET, Program Administrators and Paul Junio to determine next steps to make progress on this activity.
	Members of the WET Expert Committee attended March PTPEC meeting. A last call for WET FoPT Subcommittee members will go out and subcommittee will be developed by end of month.
	The Chair of the PTPEC and WET Expert Committee met with the program administrators to discuss how to move forward. Stacie will initially Chair the WET FoPT Subcommittee and they will begin meeting in September.
Proficiency Testing Provider Accreditor (PTPA) evaluations.	The final checklist is being worked on by Shawn Kassner and Ilona. Work on the SSAS portion of the checklist has ceased.
	Application has been reviewed with both the PTPEC and NEFAP EC. SOP 7-101 (TNI Accreditation Body Evaluation and Recognition Procedure used by the PT Program Executive Committee and NEFAP Executive Committee) has been updated and both Expert Committees have been given copies for final voting in July. Remote procedures needed to be added. Also starting to look for members for the evaluation teams. The update to SOP 7-101 (TNI Accreditation Body Evaluation and Recognition Procedure used by the PT Program Executive Committee and NEFAP Executive Committee) has been approved by the PTPEC and forwarded to the Policy Committee for finalization.
Develop resolution for reporting uncertainty with Radiochemistry PT results.	In progress. Waiting for report from Radiochemistry Expert Committee and reaching out to NELAP AC with questions about collecting information on PT reports that will not be evaluated. The Committee received the recommendation from the Radiochemistry Expert Committee.
Complete and gather information on PT Program metrics.	A workgroup will work on the position poper for
Continue working to be inclusive of non-TNI ABs.	A workgroup will work on the position paper for Advocacy that will help with this activity.
	Fred will contact Advocacy to see if information can be funneled to states through the Ambassador program for non-TNI states. Fred is also hoping to encourage non-TNI states to

Address issue of method codes in LAMS for TPH/Oil and Grease/HEM

Method Codes

Perform feasibility studies to explore adding the following to the TNI PT Program.

- Perfluoroalkyl substances in drinking water
- Radiochemistry Uncertainty to PT evaluations
- Technology based PTs
- Adding preparation methods to the FoPT tables.
- Development of PT Program metrics
- Air and Emissions FoPT tables

Ensure that fields of Proficiency Testing (FoPTs) are appropriate for their intended use.

Develop a better process for setting PT acceptance limits.

PT SOP Subcommittee

Committee Management

TNI members).

Fred will be attending the special meeting in Crystal City to discuss issues with method codes. Jennifer Best (EPA) offered to reach out to someone who is working on method codes for SDWIS (Safe Drinking Water Information System) to see if they can attend the meeting also. Stacie will investigate how PTPEC needs to be involved moving forward.

Fred and Shawn are working on fixing footnotes on the Radiochemistry FOPT Table update so it can be finalized and sent to the NELAP AC for comment. These limits were developed with new procedures that are described in SOP 4-101.

Stacie is working with Shawn on this effort.

SOP 4-101 has been sent to the Chemistry FoPT Subcommittee for final comments and examples so this SOP with new improved procedures can be finalized.

The PT limit setting SOP (SOP 4-101) just needs examples added by the Chemistry FoPT Subcommittee and then it will be sent to Policy.

The Committee voted in a new Chair – Fred Anderson (Other-PT Provider). He was the former Vice Chair. Fred will be talking to people this month to help choose a Vice Chair. Shawn Kassner will continue as a committee member, but other obligations prevent him from continuing in the Chair role.

Tim Miller and Eric Smith have been added to the Committee and Rachel Ellis has been voted into a second term. Stacie Crandall has been added to the Committee and has been voted in as the new Chair of the PTPEC. Susan Jackson was voted in as the new Vice-Chair. Fred Anderson will continue as a Voting member.

9 ADMINISTRATION

9.1 Advocacy Committee

Create and sustain a systematic approach for encouraging volunteers to become involved in TNI activities and ensure a pool of volunteers is available for all types of committees.

2022 Objectives

Create a plan for systematic outreach to data users to explain and promote the benefits of a quality management system.

Revise and update the "Introduction to TNI" presentation to create a webinar for new members.

Monitor EPA/federal activities for opportunities to share TNI's activities and promote national accreditation.

Expand TNI Ambassador activity into additional non-NELAP states.

Sustain oversight of the Mentor Initiative. This will no longer be an Advocacy Committee responsibility, as it is now a staff function.

Sustain organizing newsletter publication.

Publish Spring Newsletter.

Publish Summer Newsletter.

Publish Fall/Winter Newsletter.

Sustain assistance to Executive Director for the winter Forum.

Sustain assistance to Executive Director for the summer Environmental Measurement Symposium.

Sustain support for Small Laboratory Advocate role

Develop a "State of National Accreditation" report every two years and offer briefings to interested stakeholders. Workgroup volunteers identified, will begin once volunteer recruitment and "pipeline" plan is in place. One step, preparation of a mass mailer to all accredited labs that are NOT TNI members, is underway.

Status

Workgroup volunteers identified, will begin once volunteer recruitment and "pipeline" plan is in place.

TBD

Ongoing

Ongoing volunteer Ambassadors are being identified. Ambassador activities will be incorporated into the Advocacy Charter. Discussed what information might be useful for Ambassadors to share with state contacts. Discussed a draft SOP for the Ambassador program (SOP 1-126).

The Mentor Steering Committee has dissolved. Acceptance of mentor and mentee applications and the pairing needed will become a staff function (Jerry and Paul). The draft Mentor SOP 1-127 will not be finalized but will be replaced by a Standard Training Procedure for future staff use. The activity itself will continue, although interest has dropped off dramatically since the first few months with only one application received since August 2021.

Email publication sent May 5, 2022.

NA

Planning is complete and articles are due October 3.

No activity until after summer conference.

See 9.5 for more details.

Ongoing

May use Annual Report in place of this document; decision by end of calendar year, as State of National Accreditation was issued

in 2021.

Work with other trade associations to develop National program at the Federal level.

TBD

Maintain relationships with other organizations (WEF, AWWA, ACIL, ASTM, etc.), EPA program offices, other federal agencies, and non-NELAP state agencies that have an interest in accreditation issues.

Ongoing.

Provide outreach (e.g., presentations and papers) to promote The NELAC Institute and TNI's programs.

Ongoing. Recommendation provided to Board about how TNI might respond to EPA's Environmental Justice Initiative.

Jerry will be presenting at the Texas Trade Fair on May 10, the Virginia WaterJAM conference on September 12, the Oregon Environmental Laboratory Association on October 18, and the Gulf Coast Conference on October 12. Draft response to published article about shortcomings of accreditation (LC/GC North America, March 2022, Volume 18, Issue 3, Pages 30-32) was reviewed by Advocacy at its September meeting and submitted to the journal's editor. Comments on a draft rule from Ohio concerning acceptance of labs accredited to the TNI ELS Standard for its hazardous waste program were discussed at the September meeting and then submitted to the rule managers. These comments were intended to correct misunderstandings of TNI's accreditation programs and the use of spelled-out NELAC in our name, errors that would have made a final rule exceedingly confusing upon implementation.

NEW: Perform 5-year review of Advocacy SOPs.

Updated SOPs 1-115 (Newsletter) and 1-118 (Position Statements) have been approved and sent to Policy Committee for review.
SOP 1-122 (Advocacy Documents) awaits approval and revised Presentations POL 1-115 is pending review. New Ambassador SOP 1-126 awaits review and comment by committee. Updated draft of Mentor Steering Committee SOP 1-127 awaits committee discussion.

9.2 Policy Committee

2022 Activities Status

Review Internal Audit Checklists.

Working on top portion of the checklist for all Committees. Completion delayed until mid-March as two critical SOPs are being updated that need to be included in the checklist (see below).

Internal Audit Checklists are now being reviewed and should be ready for use after first Policy meeting in

May. A missing file will be duplicated for the master checklist and internal audits should be available before the end of July. Top half of checklists finished for all committees except CSDP/Expert. Updates needed from CSDP to finalize their checklists.

Continue to Review SOPs and Policies.

Completed update of SOP 1-101 (Operation of TNI Committees) and approved by the Board on March 9.

SOP 1-125 (Committee Applications) has been updated and approved by the Board on April 13.

SOP 1-101 (Operation of TNI Committees): Update made to eliminate option for subcommittees to make final decisions. New SOP being submitted for Board approval on 7/13/22.

SOP 3-102 (Evaluation of Accreditation Bodies): Review completed and finalized by Policy.

SOP 2-101 (Procedures for Expert Committee Operation): CSDP has decided to have their own and it has been submitted to Policy for review.

SOP -101 (Voting Procedure for General Business and Laboratory Accreditation Matters): Policy is working on incorporating procedures into SOP 1-102.

SOP 1-118 (Development of Position Statements): Policy approved 4/22/22.

SOP 1-115 (TNI Newsletter Preparation and Distribution): Policy approved 4/22/22.

SOP 6-100 (Conducting Pilot Studies for New Concentration Ranges and Acceptance Limits for Source Sampling Audit Samples): Met with EPA 7-25-22 – SSAS Expert Committee suspended – no need to compete review.

SOP 6-101 (SSAS Table Management): Review started (5/5/22). Met with EPA 7-25-22 – SSAS Expert Committee suspended – no need to compete review.

SOP 1-102 (Voting Rules for TNI Committees): SOP being updated to incorporate differences between program voting SOPs so there can be one SOP on voting instead of multiple SOPs. CSDP has decided to have their own. Updates were made to the SOP to include unanimous consent procedures. Needs review by LASEC on exception wording in Appendix.

SOP 1-110 (Educational Delivery System) Updated staff responsibilities, tracking procedures and training categories. Submitting for Board review on 7-13-22.

SOP 3-105 (Standard Interpretation SOP): Sent back to LASEC to update voting procedures prior to Policy completing review.

SOP 3-114 (Preparation and Approval of Implementation Guidance for the Laboratory Standards): Sent back to LASEC to update term/title, development process and voting procedures.

SOP 2-100 (Procedures Governing Standards Development): needs some language changes to address the review of a new Standard by the CSDP.

SOP 4-107 (FoPT Table Management): Review completed and being sent back to PTPEC for consideration and update.

Begin Maintaining Glossary.

No activity

9.3 Training Committee

2022 Activities	Status
Implement and expand Linked-In page.	LinkedIn page is now available and Jerry Thao is starting to work with other committees for content.
Work with Competency Task Force to develop Credentialing Program.	Requested preliminary course listings to help Training Opportunities Workgroup develop ideas for next RFP. Included in presentation made during conference.
	Jerry to request NELAP AC discussion on whether states can require credentialling or badges. People are concerned that the ABs may do this if program is developed.
Work with Competency Task Force to develop Digital Badge Program.	In progress.
Look for opportunities to collaborate with other training providers.	Collaborating on another class with ANAB – see below. This time they are handling registration.
Continue to develop ideas for training courses.	
Evaluate ways to automate certificates so cost can be reduced.	
Prepare and issue RFPs to meet Credentialing Program needs.	RFPs were received from 5 trainers that were developed into 11 classes. Classes included:
	<u>July 14</u> – Applying Data Integrity to Field Activities (Silky)
	<u>July 22</u> – Beyond the Demonstration of Capability (Tony)
	<u>August 16</u> – Managing Laboratory Support Equipment – Calibration, Verification and Maintenance (Tony)
	<u>August 30</u> – Brown Bag 13: Handling Samples and Sample Integrity (Tony)
	<u>September 8</u> – Managing Your Proficiency Testing Program (Tony).
	August 2022 – Keeping the Chain of

Measurement Traceability Intact to Ensure Reliable Data (ANAB – Self-Paced Class)

Essential Water Analyses – 4 Class Series (Mary Johnson)

<u>July 12, 2022</u> - Session 1: Sampling, Safety, Quality Control, pH, fecal coliform, chlorine residual

<u>July 26, 2022</u> - Session 2: Residues – TSS, TS, TVS, TVS, TDS

August 9, 2022 - Session 3: BOD, COD, TOC

<u>August 23, 2022</u> - Session 4: Nutrients – ammonia, TKN, phosphorus, nitrate, nitrite.

<u>September 23, 2022</u> Choosing the Correct Analytical Protocol (Jerry, Judy, and Kristen)

The Microbiology Expert Committee has finalized the outline/content for their 5-part series of classes — Understanding Microbiology. The first class was taught live in Crystal City and then will be offered as a webinar after the conference. The Committee will be determining a date for the other classes.

Work is beginning on the next RFP.

The Training Review Workgroup is making progress on course reviews, 11 courses have been reviewed as of this month. These courses were developed before the 2016 Standard became effective. Ilona will be reaching out to appropriate trainers with recommended plans for updates. In most cases the references are the same between the 2009 and 2016 Standard, but course descriptions will note this and the month and year the material was reviewed will be included. In other cases, a summary of changes (e.g., references, regulatory updates, items to be aware of while taking class, etc.) will be included with the course handout. The update completed for the Asbestos assessor course and wording update to be sent to IT for update on website. Course participants to use 2009 Standard to take course, but updates to 2016 Standard are described. New assignments for course reviews made.

Template has been developed. Need to look at ways to standardize course

Review training to ensure it is not obsolete.

Development of Course Catalog

9.4 2023 Forum on Environmental Accreditation

- January 9-12, 2023 in San Antonio.
- Preliminary Schedule below:

Time		Monday: 1/9	Tuesday: 1/10	Wednesday: 1/11	Thursday: 1/12
8-12 AM		General Session 8:00 Introduction to TNI 10:30 Annual Meeting	1. Assessment/M entor Forum 2. Chemistry 3. PT Executive	1. Qualit y Syste ms 2. LAB/M icro 3. Advoc acy	Training Courses - Cause Analysis - MDL/LOD/LOQ TNI Staff mtg
12-1		Lunch on Own	Lunch Provided	Lunch Provided	
1-5 PM	1.	Assessment/Mentor Forum NEFAP/FAC PT Expert	1. Assessment/Mento r Forum 2. NELAP/LASEC 3. Training	1:00 Special Session on Credentials 4:15 Committee Reports	
Evening		Reception		Committee member reception	

Exhibit program runs from 12:00 noon on Monday to 3:30 pm on Tuesday Advocacy will meet the week on 1/15

- Recommending a ~10% increase in registration fees to reflect inflation. Basic full conference registration fee for a TNI member will be \$575 vs \$525 for this year.
- Note the two training courses on Friday

9.5 2023 Environmental Measurement Symposium

The 2023 Symposium will be in Minneapolis, MN from July 31-August 4. The Call for Abstracts will go out in October. The Steering Committee is considering a session on "Ensuring Reliable Data" with a session Chair or Chairs from TNI.

Reliable data is much more than the analytical process. We are seeking abstracts on how implementing a Quality Management System improves data reliability by activities such as measurement traceability, records management, corrective action, purchasing, method validation, and sample handling to demonstrate these activities are equally important in ensuring data quality.

NGAB

• No activity.

9.7 Information Technology

2022 Objectives	Status
Continue to support the website and LAMS.	Ongoing; Dan Hickman created a new AB category in LAMs, Supplemental Primary AB, to address situations where a laboratory has two primary ABs.
Continue to support the Mentor initiative.	Ongoing
Support the credential initiative.	No activity
Expand LAMS into non-NELAP states.	No activity

10. TASK FORCES AND OTHER EFFORTS

10.1 Competency Task Force

2022 Objectivities	Status
Transfer Technical Expert concept to Quality Systems Expert Committee for final clarification and definition of role.	Completed February 2022.
Engage Credentialing Subcommittee and Expert Committees to create proposed structure for credentialing of defined roles.	Preparing business plan for potential credentialing program for presentation to TNI Board of Directors.
If decision to proceed, transform Task Force into a Committee and undertake pilot credentialing program for Quality Manager role, in accordance with approved business plan.	Review of Knowledge, Skills, and Abilities (KSAs) and training courses needed for various badges that will comprise the QM credential is completed. The KSAs needed (and corresponding test) for the full QM credential are next, then comparison of needed KSAs with content (learning objectives) of existing training courses will be addressed.
	A special session is being planned for conference in San Antonio to present the preliminary plan for rolling out the badges and full credential.
Coordinate with TNI Training Committee in developing courses.	Once QM KSAs are identified, the needed courses and their content can be defined.
If pilot is successful, replicate with additional roles.	
Define the types of professional positions to which this program would apply.	NA
Prepare KSAs for roles in ways that enable course and exam creation for credentialing of individuals for those positions (voluntary use of credentials).	NA
Establish generic competencies for each group.	NA

10.2 Consumables Task Force

2022 Objectives	Status
Explore the feasibility of developing implementation guidance, an ultimately a standard for laboratory consumables.	Ultimate implementation will be ascertained as work progresses.
Understand and identify the use of the term "critical consumable, services and supplies;" categorize as appropriate.	Critical consumables, services and supplies has been defined and items categorized.
Provide expanded and detailed information related to documentation for meeting requirements of the Standard.	Work in process.
Define evaluation criteria necessary for laboratories to meet the requirements of the Standard.	The TF has further developed the certificates content checklist and is in the process of validating the list against items/certificates currently in laboratories. The decision tree remains a work in progress.
Prepare and deliver an Annual Report for the previous year and Work Plan for the coming year for the annual meeting or whenever requested by the Executive Director.	Accomplished at the TNI Winter Meeting.
Additional Comments/Concerns:	Three (3) new members joining the Task Force. Task Force membership at 13 participants (down from 17). Materials produced to date provided to new roster members and Phase 2 of CTF to begin in June 2022.

10.3 Mentor Initiative

No applications since June 2022.

10.4 Environmental Monitoring Coalition

A very controversial subject developed the last week in July surrounding prewarming samples in a water bath for Colilert and Colisure as described in Standard Methods 9223. EMC prepared a draft letter to appeal the decision made by Standard Methods point out they did not follow consensus procedures as described in OMB Circular A-119. This topic was part of a very contentious discussion at the EMC Open Forum on August 2. EMC planned to revise the letter at the August 23 meeting, however in the interim, Standard Methods withdrew the requirement and indicated they would revise their procedures for standards development. EMC plans to continue to monitor this effort.

11. MEMBERSHIP

• 1174 active members

11.1 Committee Applications – Voting/Associate

First	Last	Organization	Committee Interest	Committee
Alexande	Chieh	City of San Jose	Associate Member	Laboratory Quality Systems
r				
Ron	Eidson	Pace Analytical	Voting Member	Radiochemistry
Nick	Slawson	A2LA	Associate Member	Proficiency Testing Program

11.2 New and Renewed Members:

- Of the 45 expired memberships from July, 13 renewed or requested an invoice after contact. Emails were sent to August expired members on September 2, 2022.
- 68 New and Renewed memberships in August, 2022

11.3 Expired Memberships

• 32 Memberships Expired in August

Attachment 1 A Robust Laboratory Accreditation Program Can Ensure Reliable Data September 9, 2022

By: Jerry Parr, Executive Director, The NELAC Institute

Executive Summary

The NELAC Institute (TNI) agrees with many of the statements contained in the article <u>Laboratory Accreditation is Not a Cloak of Infallibility</u> published in LC/GC North America in March 2022 but believes the authors have overlooked other critical areas and, in some cases, have conclusions that are not supportable. A robust laboratory accreditation program can ensure the competency of laboratories and help ensure reliable data.

Background

The NELAC Institute (TNI) is a non-profit organization that among other activities manages the National Environmental Laboratory Accreditation Program (NELAP). NELAP has 14 state agencies such as the Texas Commission on Environmental Quality (TCEQ) and four non-governmental accreditation bodies such as the American Association for Laboratory Accreditation that accredit over 1000 laboratories in the United States.

Like many other organizations, TNI uses the 2005 version of ISO/IEC Standard 17025, *General Requirements for the Competence of Testing and Calibration Laboratories*, as the basis for its accreditation program. However, TNI has extensively added language to address many of the concerns in this article. As shown in the table below, the TNI standard is organized into 7 different modules, one for proficiency testing, one for quality system requirements, and then 5 for different types of testing. By comparison, ISO/IEC 17025 is 28 pages; the TNI laboratory standard is 180 pages with specific language appropriate for environmental testing and client contract review.

Table 1. Organization of the TNI Laboratory Standard

Module 1	Proficiency Testing
Module 2	Quality Systems General Requirements
Module 3	Asbestos Testing
Module 4	Chemical Testing
Module 5	Microbiological Testing
Module 6	Radiochemical Testing
Module 7	Toxicity Testing

Note: TNI has also developed standards for Accreditation Bodies and Proficiency Test Providers and a separate standard for Field Sampling and Measurement Organizations.

As one example of the differences between ISO/IEC 17025 and the TNI standard, see the language below from ISO 17025:2005 Section 5.6

By comparison, The TNI requirements for instrument calibration in Module 4, Section 1.7 is 6 pages and addresses initial and continuing calibration, number of calibration points, removal and replacement of calibration standards, acceptance criteria, and corrective actions.

Quality Control Measures

TNI agrees with the statements made by the authors on the quality control (QC) measures. The article listed four major areas of focus: control and surrogate measurement, calibrations, validations, and instrumental upkeep. TNI has developed specific detailed language to address these issues as shown below:

Control and Surrogate Measurements	Module 2, 5.9.3 Module 4, 1.7.2 and 1.7.3
Calibrations	Module 4, 1.7.1
Validations	Module 2, 5.4.5.4
	Module 4, 1.5
Instrumental Upkeep	Module 2, 5.5

In addition, TNI would add:

- Calibration and maintenance of support equipment, including volumetric devices (Module 2, 5.5.13.1),
- Measurement Traceability (Module 2, 5.6.4),
- Sample Handling (Module 2, 5.8.5 5.8.7),
- Limits of Detection and Quantitation (Module 4, Section 1.5.2)
- Demonstration of Capability (Module 4, 1.6)

QC Limits for Surface Water Samples

The article discussed a QC limit of 50-200% for the analysis of benzene. The TNI standard is very specific on this issue in Module 2, Section 5.9(c) stating:

The laboratory shall ensure that the essential standards outlined in Technical Modules or mandated methods or regulations (whichever are more stringent) are incorporated into their method manuals. When it is not apparent which is more stringent, the QC in the mandated method or regulations is to be followed.

EPA requires laboratories to follow the methods they promulgate as written. The accreditation process works by ensuring that laboratories follow the method. If the method has wide acceptance limits, such as the 50 - 200% example provided and the laboratory meets these limits, the laboratory is following the method. Therefore there is no violation of the method or the accreditation.

For example, EPA Method 624.1, published in 2014 and promulgated by EPA in 2017 has QC limits of 37-151%, comparable to what the laboratory reported. Those numbers date back to an interlaboratory study conducted in 1984. Method 624.1 is promulgated for wastewater analyses but is frequently used for surface water. TNI agrees that limits of 50-200% can yield data with higher imprecision, but if the method is required by EPA, and the laboratory is not allowed to modify the method to improve its accuracy, the laboratory is not at fault for providing data of that quality. Thus, this would not be an assessment finding from an Accreditation Body.

As stated in ISO/IEC 17025, Section 5.4.2:

The laboratory shall use test methods which meet the needs of the customer and which are appropriate for the tests it undertakes.

If the customer does not clearly state data quality objectives (e.g., methods, matrices, QC limits, etc.) then the laboratory nor the assessment process of these laboratories is at fault.

Calibrations

Most EPA methods and the TNI standard require measurement results to be reported within the calibration range of the method and TNI requires at least 5 calibration points. The TNI standard requires samples to be diluted if they are outside the calibration range and a failure to perform this dilution would be an assessment finding.

The article stated: "If performed correctly, a multipoint calibration curve of five to seven points should yield a linear correlation value (r-value) >0.99." TNI, the Environmental Monitoring Coalition (EMC), https://envmoncoalition.org, and many others believe linear correlation values have no place in instrument calibration. An October 2020 article in LC/GC, *Evaluating the Goodness of Instrument Calibration for Chromatography Procedures*, showed curves with a perfect coefficient of determination (1.000) can have errors of over 1000% at low concentrations while calibration curves with r² as low as 0.958 can have a Relative Standard Error (RSE) of < 20%. "For almost any calibration, the correlation coefficient and coefficient of determination lead us in the direction of choosing the wrong calibration." TNI recommends the use of relative error or relative standard error to evaluate calibration curves and section 1.7 in Module 4 describes both approaches.

The example of the 104.5% THC value is exactly the kind of thing a TNI accreditation solves. TNI requires the analysis of independent standards to check the accuracy of a calibration and also the analysis of control samples taken through the entire method. If these controls were run, the laboratory would have immediately recognized their error and fixed the problem. That said, nothing can make up for the necessity of having people with enough knowledge of the testing that would have immediately noted that 104.5% THC is not possible.

TNI agrees that the calibration of the instrument must be verified daily and the TNI standard requires a calibration verification be performed any day samples are analyzed.

The Value of a Robust Accreditation Program

There is no doubt that accreditation to the TNI standard makes a difference in the quality of the data and in laboratory performance. TNI's National Environmental Laboratory Accreditation Program has been shown to improve laboratory data quality, laboratory performance, and the reliability of the data. Accreditation is not just about a quantitative improvement in data quality and a Quality Management System (QMS) that is committed to the maintenance of quality but about generating data that can be relied on for use in decision making.

Providing quality data is much more than getting the right answer and being able to reconstruct the result. Quality includes confidence in the data as well as better laboratory operations. The laboratory QMS in and of itself does not generate better quality data, but if followed, ensures that the data will be of documented quality and that the laboratory management is committed to fostering a culture of quality. Laboratories accredited to the TNI standard have documented significant improvements which include efficiency, additional capability, and quicker reports. Traceability, training, sample tracking, and documentation all contribute to better decisions and contribute to laboratories with TNI accreditation having more confidence in their data.

Attachment 2 Comment on Proposed Changes to the Ohio Voluntary Action Program Rules September 7, 2022

Comments provided by:

The NELAC Institute (TNI)

Contact: Jerry Parr Phone: 817-308-0449

Email: jerry.parr@nelac-institute.org

The NELAC Institute (TNI) is a 501(c)3 non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community. Among other activities, TNI manages the National Environmental Laboratory Accreditation Program (NELAP) and is accredited by the American National Standards Institute as a consensus standards development organization.

The comments below are primarily editorial in nature, clarifying the name of our organization and our laboratory accreditation programs.

Definitions - Section A(2)

The National Environmental Laboratory Accreditation Conference (NELAC) was an unincorporated organization of state and federal officials that was dissolved in 2007. As stated above, The NELAC Institute (TNI) is an IRS recognized 501(c)3 non-profit organization that was formed in 2006. TNI retained the word "NELAC" in its name to reflect this heritage but NELAC is not used as an acronym.

TNI administers the National Environmental Laboratory Accreditation Program (NELAP), which consists of state agencies (NELAP Accreditation Bodies or ABs) recognized to accredit laboratories to the TNI Environmental Laboratory Standard, and a Non-Governmental Accreditation Body (NGAB) program, which consists of non-governmental organizations recognized by TNI as ABs as qualified to accredit laboratories to that same standard. These two laboratory accreditation programs currently have 18 recognized Accreditation Bodies (ABs). Our NGAB ABs can assist the Ohio certified laboratories to make the transition to becoming accredited laboratories without increasing the workload of our state ABs. Any Ohio laboratory can choose which AB from which to seek accreditation. Accordingly, we recommend revising this section as shown below.

- (2) "Accredited laboratory" means a laboratory that is accredited as follows: (a) For analysis of asbestos, valid accreditation by one of the following:
 - (i) The American industrial hygiene association, asbestos analyst's registry;
 - (ii) The national institute of standards technology, national voluntary laboratory accreditation program for asbestos fiber analysis;
 - (iii) An accreditation body recognized by The .
- (b) For analysis of any constituent other than asbestos, valid accreditation by one of the following:
 - (i) T

TNI proposes comparable editorial changes to this section as shown below.

(e) A laboratory that holds certification for analysis of any constituent other than asbestos may rely on current accreditation from an accreditation body that is recognized by TNI.

Attachment 3 TNI Closing Meeting – 8/4

PT Executive – Bob Wyeth - this was a very superficial meeting with no real proposed actions or detailed information provided. Half day

PT Expert – Bob Wyeth - two work groups working on Volume 1/Volume 2 and the other work group on Volume 3/Volume 4. They went over their proposed and planned changes. They took public comment on the concepts. Their intent is to propose all four volumes in January. Half day

Assessment Forum – Dorothy Love – assessment forum was very well attended. It covered internal audits from the Accrediting Body perspective. We need to define technologies. Although they appear in LAMS are we sure that is the list that we want to use? Jerry said while the list is in LAMS it is fairly buried. There could be consequences with trying to use a different list.

Mentor Session – Dorothy Love - also very well attended. It covered internal audits from the laboratory's perspective. There is much more information available based on the survey that was sent out and returned by respondents from within TNI. That data can be mined in many different ways, and will be forwarded to Jerry, Alfredo, and Paul. They already have ideas for next year's session and would make it complementary with the assessment forum. Along those lines is it possible to have three half day sessions divided among the assessment forum and the mentor session?

Jerry added that the prior assessor's call which were attended by state assessors is the subject of an EMC topic that was started with Lem Walker. The assessors call has been cancelled due to a lack of funding. There is a proposal to get funding from the EPA for these calls and again have a literal assessor forum as had been held in the past by NELAC.

Laboratory Accreditation Body – Kristin Brown - they discussed elements of the standard that are being worked on at the moment. Chief among them were the frequency and components of internal audits. There were also questions regarding remote onsite assessments and issues with how to handle suspension and/or revocation, especially as it relates to secondary accreditation, quarter day

Quality Systems – Paul Junio - the Quality Systems committee has rolled TNI language into ISO 17025:2017. In conjunction with this they reviewed ISO 17025:2005 for any language that we would like to keep. TNI language that was added to the 2016 standard has been placed in this framework. Duplicate language between TNI and ISO 17025 has been eliminated. Two work groups are also working on the standard. One has taken specific sticking points in the standard and is working at getting those clarified in a small work group. The other is working on definitions, both those that already exist in the standard and revisions to some that have been requested. Jerry Parr - the technical specialist groups are also busy with that language. They've reached consensus and are almost done. It is possible that there is one Accrediting Body hold out. EPA's Drinking Water group is good with the language. Radiochemistry had language that is great for how to handle new methods and Jerry recommended that it be used across the board. Half day

Microbiology – Cody Danielson - the committee reviewed the training series – part one of five will be given Friday August 5. It was created by a work group of eight people. The other parts are not yet finished but they hope to be done by November. All would be offered as webinars. The first session is offered from a non-microbiology background, and then the parts build from there so that part five will be very detailed. Part one should run about three others the others are likely shorter. They haven't selected which methods they will address. Sections 2 to 4 are likely to be an hour long while part five could be two to three hours long. Hoping to finish the standard and get feedback in San Antonio. Quarter day

Chemistry – Michelle Wade - the committee discussed SIR requests and reviewed them. There are four work groups working on revising the standard. They reviewed the content of three of those work groups. Half day

Accreditation Council - Kristin Brown - the AC offered status updates and they are closer to fully implementing

the 2016 standard. Two action items for the AC are working with Dan Hickman on method codes and SIR consistency. Quarter day

LASEC – Maria Friedman - the committee offered their background and how to find what exists regarding SIRs. They received feedback for the assessment form and the mentor session. They discussed the revised SIR approval process. They're proposing a change in the SOP requiring two-thirds approval from the subcommittee, but working on making it easier to return to the expert committee if it is not OK. They will also begin to look into policies as well as the standard when reviewing SIRs. quarter day

Training – Calista Daigle - there are lots of new faces at the training and assessment sessions. Jerry indicated around 100 new attendees this year. They talked about their usage of LinkedIn. They discussed the catalog for training, trying to make it more intuitive and interactive and yet still something that could be printed. Ken Brown talked about credentialing and that it might be a secondary path for the technical specialist. One suggested topic would be EPA method 537.1 for a lab trying to start up that method. Jerry indicated that EPA drinking water office ordinarily wouldn't do training such as this, but that they are considering it due to it being a new technology and a very high priority. This might be better than if it were vendor driven. Due to a special session in San Antonio on credentialing, training may get about a 30 minute portion of that session. Jerry indicated we could have half day long session on credentialing focusing on the talking points for implementation. Still needing to be worked out are how exams will be proctored, who could write test questions, and a business plan. We think this would be a good draw to keep people there.

NEFAP/Field – Tracy Szerszen - there was only a sidebar here at lunch regarding NEFAP. It could be the same in San Antonio. Possibly a sidebar, and possibly a joint meeting with Field. Scott Haas wasn't here so we don't have his input. Hoping to have a workshop next August. quarter day

Not present were Asbestos and Radiochemistry. It's possible that each would have a webinar for presenting their standards.

San Antonio Forum

San Antonio is shaping up to be three days and these meetings fit that schedule. The meeting will be January 9 through 11. It will be our typical approach to the winter meeting. [insert calendar from NEMC Steering Committee?]

Dorothy Love asked if we could have new attendee questions, potentially Monday morning like we have had in the past.

Jerry indicated that we will be changing how we record the sessions due to feedback.

Environmental Monitoring Coalition and Sidebar Meetings

EMC met with the EPA at lunch on Monday and there is a commitment to continue working together.

Jerry met with the EPA Drinking Water group and it was mostly a good meeting. We may begin doing certification officer training in conjunction with these meetings. Specifically it would be the regulation training.

EMC open forum was controversial. EMC is working on an issue relative to Standard Methods 9020 and 9223. Kristin and Cody knew of the issue prior to the meeting. EMC will be taking the lead on it. Note: This issue was resolved by Standard Methods the week following the Symposium