

TNI Board of Directors Meeting Summary November 10, 2021

ROLL CALL

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

AGENDA

1. **Review of Consent Agenda – Approved 11/10/2021**
2. **Accreditation for Covid Testing (Attachment 1)**

Comments were submitted to the CDC on November 5, 2021. See Attachment 1.

3. **Committee Charters**

Based on a change to SOP 1-101 that was approved by the Board in May this year all committees have been working to update their committee Charters. SOP 101-1 requires the CSDP Executive Committee to approve all the Charters of the Expert Committees and the Board to approve all other Charters after a Policy Committee review. Compared to the previous (2017-19) versions, the following global changes were made:

- o Success Measures clearly written as such.
- o Decision Making section removed per changes to SOP 1-102 on Voting.
- o Teleconference and Fac-to-Face changed to Virtual and In-Person
- o Removal of name of Program Administrator
- o Added a new Objective for every committee relating to an Annual Report and annual Work Plan.

3.1 Expert Committee Charters

- All Charters have been revised and approved by the CSDP Executive Committee.

3.2 Other Committee Charters

- The Charters for the Advocacy, CSDP EC, and LASEC committees are ready for Board review. Changes from the previous Charters are summarized below. The other Charters should all be complete by December.

- Advocacy:

- Added review of documents prepared by other committees as required by SOP 1-104 to Objective 1.
- Added ASTM to Objective 2 and reworded success measures.
- Combined Objectives 3 and 4 into one objective related to outreach.
- Added a new objective related to the Mentor Initiative.
- Added Mentor/Mentee database to available resources.

Motion to Approve the Advocacy Committee Charter: Jack Farrell

Second: Patsy Root

Approved: Unanimous

- CSDP EC:

- Added ex-officio member from the NELAP AC to composition and added statement disallowing Associate Members.
- Added accreditation as a consensus standards body as a Success Measure to Objective 1.
- Significantly reworded the Success Measures for Objective 2 for clarity.
- Significantly reworded the Success Measures for Objective 3 for clarity.
- Added a new Objective 4 related to seeking feedback.

Motion to Approve the CSDP EC Committee Charter: Judy Morgan

Second: David Caldwell

Approved: Unanimous

- LASEC:

- Added Small Laboratory Advocate to committee composition.
- Added second Success Measure to the first goal in Objective 1 relating to review time for key documents.
- Revised the third goal in Objective 1 to avoid conflict with the TNI Mentor Initiative.
- Removed an objective relating to recognition of NGABs as that will not occur until after 2022.

Motion to Approve the LASEC Committee Charter: Stacie Crandall

Second: Patsy Root

Approved: Unanimous

4. Policy 2-100: Viewing TNI Standards Incorporated by Reference

- As part of the on-going effort in California to challenge the use of the TNI Standard in their accreditation regulations, TNI made a view only version of the standard available. However, there was no underlying policy or procedure to codify this action. Policy 2-100 was developed to remedy this action. As stated in the Policy:
 - TNI Standards Incorporated by Reference (IBR) into state or federal regulations may be accessed at no cost in a “read only” format upon request by the agency which is making the IBR. There are no print or download options. Any individual viewing the standards must register.
- This approach is virtually identical to what other ANSI accredited standard development bodies do and the Agreement in the appendix to this Sop was customized from the National Fire Protection Agency agreement.
- William has set this up so the standard can only be viewed in a web browser. It cannot be downloaded, text cannot be copy/pasted from it, and it cannot be printed (in any form other than badly formatted partial page fragments). Each page has an “Unlicensed Copy” watermark. The only “features” that are supported are that the viewer can go to a specific page, and the standard is searchable.
- This Policy requires Board approval.

Jerry will report back in December with a report from William that will help explain how this data is tracked.

Motion to Endorse Policy 2-100: Paul Junio

Second: Maria Friedman

Approved: Unanimous

5. EMC Letter on Instrument Calibration

The Environmental Monitoring Coalition prepared three letters that were sent to EPA, ASTM, and Standard Methods relative to the use of correlation coefficient and coefficient of determination in instrument calibration. The EPA letter was provided separately with this agenda.

The EMC would like for TNI to post the letter on the TNI website.

Motion to Approve Posting: Jack Farrell

Second: David Caldwell

Approved: Unanimous

Attachment 1 Comments on National Wastewater Surveillance System for COVID-19

November 5, 2021

Prepared by:
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CONTACT: Jerry Parr, Executive Director; 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.

TNI manages the National Environmental Laboratory Accreditation Program (NELAP). Currently, 14 state agencies are recognized by TNI as Accreditation Bodies. TNI's Accreditation Bodies are responsible for ensuring the competency of environmental testing laboratories, including those analyzing wastewater under the National Pollutant Discharge Elimination System (NPDES) program. Over 1400 laboratories are accredited under NELAP including over 800 municipal wastewater facilities. The state of California has adopted the TNI standard into their regulation for an additional 800 laboratories.

TNI also manages a Consensus Standards Development Program. TNI is accredited by the American National Standards Institute as a voluntary consensus standards organization and fully conforms to all requirements in OMB circular A-119.

In general, TNI applauds CDC for implementing a National Wastewater Surveillance System for COVID-19a to ensure a timely, actionable surveillance program to inform prevention and control activities. TNI's comments are focused on one aspect of this proposed rule, the competency of the laboratories performing the testing.

Background

The ability to rapidly and reliably detect and monitor the spread of pathogens in wastewater is vital for early intervention in preventing more widespread disease outbreaks. Current clinical-based surveillance methods have many limitations, such as the invasive nature of the testing and the challenges in testing large numbers of people. Wastewater surveillance is based on the analysis of wastewater to monitor the emergence and spread of infectious disease or contaminants of concern at a population level, has received renewed attention in light of the COVID pandemic.

Key advantages of wastewater surveillance include (1) it is a less resource-intensive way to gather information on large numbers of individuals, (2) it provides data on entire populations rather than just the subset of individuals who seek healthcare, and (3) it can serve as an early-warning system, given that fecal shedding of

pathogens such as SARS-CoV-2 typically precedes symptom onset. The quantitative Polymerase Chain Reaction (PCR) assay can be used to analyze wastewater to supplement clinical testing.

A July 2021 article in *Environmental Science and Technology*¹ stated: “Many researchers are not reporting necessary and sufficient controls and methods, which would serve to strengthen their study results and conclusions.” In this article, the authors indicated the following:

- Only 20% of the laboratories run negative controls,
- Only 38 % of the laboratories run positive controls,
- Only 25% of the laboratories evaluate calibration curves,
- Limit of Detection (LOD) and Limit of Quantitation (LOQ) concepts are mostly not appropriately applied, and
- Quality Control (QC) Results are mostly not reported.

A 2020 TNI White Paper², *Laboratory Accreditation Makes a Difference: Data You can Rely On*, clearly demonstrated that implementing a QMS “makes a difference in the quality of the data and laboratory performance.” This White Paper documented numerous instances of unreliable data because of factors such as:

- Measurement traceability,
- Inaccurate or incorrect result,
- Insufficient documentation,
- Non-conformance to method requirements,
- Diminished confidence in result,
- Not meeting customer requirements, and
- Lack of training.

A National Academy of Science³ report reviewing the U.S. Geological Survey Laboratories noted these advantages of an externally defined QMS:

- Compliance with an external standard allows a laboratory to conduct analyses that meet regulatory requirements to support high-risk applications and to demonstrate a high level of accountability through accreditation by independent and external assessors.
- Most formal consensus-based standards are written with the understanding that there are many ways to comply with a given requirement. Therefore, the laboratory can customize how it will meet the requirements.
- Accreditation provides external recognition that the measurement was made under conditions that optimize the likelihood that the measurement is verifiable.
- A laboratory may use both accredited and nonaccredited test methods. If so, the QMS put in place to support its accredited tests is likely to enhance the management of the nonaccredited tests as well.

¹ *Environmental Microbiology Minimum Information Guidelines: qPCR and dPCR Quality and Reporting for Environmental Microbiology*, July 21, 2021. <https://pubs.acs.org/doi/pdf/10.1021/acs.est.1c01767>

² <https://www.nelac-institute.org/news.php?id=4370>

³ National Academies of Sciences, Engineering, and Medicine. 2019. *Assuring Data Quality at U.S. Geological Survey Laboratories*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25524>.

Concepts for Demonstrating Competency

Accreditation has been used in a wide variety of industries to help laboratories standardize analytical methods, ensure valid results that can be compared, and in ensure competency amongst testing laboratories. The international standard ISO/IEC 17025, *General requirements for the competency of testing and calibration laboratories*, describes the requirements laboratories have to meet if they wish to demonstrate that they “operate a management system, are technically competent, and are able to generate technically valid results.” ISO/IEC 17025 indicates that accreditation bodies should use this standard as the basis for their accreditation. In the US, a number of non-governmental accreditation bodies have been recognized by the International Laboratory Accreditation Conference to accredit laboratories to ISO/IEC 17025.

In 2011, EPA issued a policy memo regarding organizations that have grants or contracts with EPA for testing to demonstrate competency. A copy of this memo is in Appendix 1. The Policy indicated that accreditation granted to a consensus standard, or by a state accreditation body, was one acceptable approach. Organizations have been able to use other options to demonstrate competency such as peer review, previous experience, or implementing a Quality Management System (QMS) without seeking accreditation. **CDC should explore publishing a similar competency policy.**

In 2019, the American Society of Crime Lab Directors (ASCLD) initiated a substantial effort to encourage crime laboratories to implement a Quality Management System and seek accreditation, with an emphasis on state crime laboratories. This effort had substantial funding from the FBI. <https://www.asclcd.org/accreditation-initiative/> The ASCLD process has 14 steps from an application for assistance, to a mentorship, to achieving accreditation. ASCLD uses ISO/IEC 17025 for its accreditation standard and utilizes non-governmental accreditation bodies such as the American Association for Laboratory Accreditation (A2LA) and ANSI National Accreditation Board (ANAB) to grant the accreditation.

State public health laboratories have a similar need and **CDC should explore developing a mentor program as was done with the crime laboratories.**

TNI has developed a standard based on ISO/IEC 17025, *TNI-EL-V1: Management and Technical Requirements for Laboratories performing Environmental Measurements*. This standard is used by state accreditation bodies recognized by TNI to accredit environmental laboratories that analyze drinking water, wastewater, soils, and other media. While there is no specific standard methodology for this testing, the laboratory assessment can be done under the TNI standard or the ISO/IEC 17025 standard. The American Council of Independent Laboratories (ACIL) has been leading a collaborative effort to develop a checklist that could be used by laboratory assessors specific for SARS-CoV-2 that could be easily adapted for other pathogens.

There are four major differences between 17025 and TNI’s NELAP standards. These are:

- TNI has added requirements for accreditation bodies, Proficiency Test (PT) providers, and PT provider accreditors. These requirements are found in Volumes 2, 3, and 4.
- TNI has added a module to Volume 1 describing laboratory requirements for proficiency testing.
- TNI has added much more detail and specificity to the 17025 requirements that focus on environmental testing. These details are essential to ensure that multiple accreditation bodies can assess laboratories consistently.
- TNI has added some additional requirements, such as a data integrity component, that are missing from 17025.

Accreditation to either ISO/IEC 17025 or to TNI's environmental laboratory standard is the clearest and most defensible approach to demonstrate competency. Laboratories such as university or public health laboratories that are not already accredited would likely choose the 17025 accreditation since it is a little easier to implement. Laboratories already accredited to the TNI standard, such as municipal wastewater laboratories, would most likely find adding SARS-CoV-2 to their existing scope of accreditation to be the easier path. A laboratory could also choose to implement a QMS based on either of these standards without seeking accreditation. **CDC should encourage, or even mandate, laboratories implement a Quality Management System based on ISO/IEC 17025 or the TNI standard.**

This approach has been used successfully for the accreditation of laboratories that test for *cryptosporidium*, *giardia*, and *Legionella pneumophilia* in water samples. See Appendix 2.

Additional Recommendation

The method checklist being developed by ACIL will be a useful tool for laboratory assessors. But more is needed. **Specifically, TNI recommends CDC develop a training course on the PCR assay.** This course should cover:

- a) Basic theoretical and operating principles of the technology and associated instrumentation and software.
- b) Critical steps and processes of the technology that must be executed to ensure quality data, including critical quality control (QC) measures and QC criteria based on the technology.
- c) Major sources of error, and how to control them, for the technology.
- d) Inappropriate procedures for the technology.
- e) Key information required to document completely the reported results.
- f) Essential elements for assessing data generated.
- g) Ways to detect improper practices.
- h) Traceability of raw data to reported results.

Appendix 1. FEM Competency Policy

March 28, 2011

MEMORANDUM

FROM: Paul Anastas
EPA Science Advisor

SUBJECT: Policy to Assure Competency of Laboratories, Field Sampling, and Other Organizations
Generating Environmental Measurement Data under Agency-Funded Acquisitions

Attached is a new Agency Policy Directive titled, *Policy to Assure Competency of Laboratories Field Sampling, and Other Organizations Generating Environmental Measurement Data under Agency-Funded Acquisitions*. This Policy Directive was developed by the Forum on Environmental Measurements (FEM) in consultation with the Office of Acquisition Management and the Office of General Counsel, and has cleared intra-agency review under the auspices of the FEM.

The purpose of this memorandum is to convey EPA policy requiring that organizations (e.g., laboratories, field sampling and measurement) generating environmental data under Agency-funded acquisitions submit documentation of their competency, which may include participation in applicable certification and/or accreditation programs. All organizations performing environmental analysis for the Agency shall demonstrate their qualifications in the field(s) of analyses to be conducted, prior to performing such analyses.

Please disseminate this information to your respective staff for immediate use. If you have any questions, please contact me or have your staff contact Lara Autry, FEM Executive Director, at (919) 541-5544.

POLICY TO ASSURE COMPETENCY OF ORGANIZATIONS GENERATING ENVIRONMENTAL MEASUREMENT DATA UNDER AGENCY-FUNDED ACQUISITIONS

Agency Policy Directive Number FEM-2011-01

PURPOSE

This document establishes the U.S. Environmental Protection Agency's (EPA's or the Agency's) policy requiring that organizations (e.g., laboratories, field sampling and measurement) generating environmental data⁴ through measurement under Agency-funded acquisitions must submit documentation of their competency, which may include participation in applicable certification and/or accreditation programs.

EFFECTIVE DATE

This Policy is effective for five years from February 22, 2011. The Policy shall be reviewed prior to its effective term, and will either be reissued without revision, reissued with revisions, or rescinded.

APPLICABILITY

This Policy applies to all EPA programs (e.g., Program Offices, Regional Offices, Laboratories) and their sub-programs responsible for evaluating, issuing, and/or managing Agency acquisitions such as purchases, contracts, and contract work assignments. This is an additional requirement to be implemented by the project officers across the Agency for acquisitions generating environmental data, but in no way does this policy prohibit an Agency program from placing additional requirements or stipulations to meet the needs of their work being performed.

The scope of this Policy encompasses organizations which shall generate environmental data under:

- New Agency acquisition requests for proposals (RFPs)
- New approved purchases, contracts, contract work assignments/task orders, etc.

BACKGROUND/AUTHORITY

The EPA Science Policy Council⁵ established the Forum on Environmental Measurements (FEM) as a standing committee of senior EPA managers who provide the Agency and the public with a focal point for addressing measurement, monitoring, and laboratory issues with multi-program impact. Since the FEM's inception in April 2004, it has been a primary goal of the Forum to promote national accreditation. Accreditation is a means to ensure that organizations performing environmental data operations are technically competent and have effective quality system management, enabling them to generate valid environmental measurement data. After years of working with communities that operate

⁴ As defined in the *EPA Quality Policy* (CIO 2106.0; 10/20/08), environmental data include any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology.

⁵ In July 2010, the Science Policy Council was reconstituted as the science and Technology Policy Council (STPC) to reflect Administrator Lisa Jackson's strong interest in promoting technology innovation to achieve environmental and public health goals.

accreditation programs and encouraging private, public, and State programs to be accredited, the Agency issued a policy to assure the competency of EPA laboratories in 2004
<http://www.epa.gov/fern/pdfs/labdirective.pdf>.

Another FEM goal is consistency with other federal agencies' accreditation practices. This policy has been developed to promote the use of accredited organizations, if available, for any applicable work performed. The project officer shall insert the appropriate level of quality standards, such as accreditation and/or certification for the Higher-Level Contract Quality Requirement (i.e., 48 CFR Parts 46 and 52) in solicitations and contracts when the inclusion of this policy is appropriate. Alternatively, the burden of demonstrating the qualifications of an organization shall fall on the Agency program responsible for funding the data generation. This policy also does not replace any requirements, such as general acquisition information or quality assurance documentation, nor does it prohibit an Agency program from placing additional requirements or stipulations on an organization to meet the needs of the work being sought.

POLICY or (REQUIREMENTS)

Organizations performing environmental analysis for the Agency shall demonstrate their qualifications in the fields of analyses to be conducted, prior to performing such analyses. Where accreditation or certification is available for those fields of analysis, organizations may submit documentation of existing accreditations or certifications. Accreditation/ certification granted by an organization that accredits environmental data operations to an international consensus standard, or a state accreditation or certification program acceptable to EPA, or the contracted laboratory's participation in the EPA Contract Laboratory Program for those fields of analyses, shall be valid at the time of award and must be sustained through the life of the period of performance. If accreditation/ certification is suspended or revoked at any time during the period of performance, the EPA project officer must be notified immediately to ensure any potential impact to the scope of work being performed is addressed accordingly.

REFERENCES

1. 48 CFR 46 Higher-level contract quality requirements, http://www.epa.gov/quality/qa_ctrs.html#4SPART46
2. Quality Specifications for Solicitations and Contracts <http://intranet.epa.gov/quality/contracts>
3. EPA Contract Management Manual <http://oamintra.epa.gov/files/OAM/cmin 0 0.pdf>
4. EPA CIO 2105.0 Policy and Program Requirements for the Mandatory Agency-wide Quality System, <http://www.epa.gov/irmpolifi/ciopolicy/21050.pdf>
5. FEM Lab Accreditation Policy, <http://www.epa.gov/fern/labcomp.htm>

Appendix 2: Laboratories Accredited to the TNI Standard for Selected Bacteria and Parasites

Name	City	State	Giardia	Crypto	Legionella
Access Analytical, Inc.	Irmo	SC			x
Accurate Laboratory - OKC	Oklahoma City	OK	x	x	
AG Environmental	Ferndale	NY			x
ANALYTICAL SERVICES INC	WILLISTON	VT	x	x	
BCS Laboratories, Inc. - Gainesville	Gainesville	FL	x	x	
CHARLOTTE WATER	CHARLOTTE	NC	x	x	
City of Tampa Water Quality Laboratory	Tampa	FL		x	
CWM Environmental, Inc. - Cleveland	Cleveland	OH			x
EMSL ANALYTICAL INC	CINNAMINSON	NJ	x	x	
Eurofins Eaton Analytical	Monrovia	CA	x	x	x
Eurofins Eaton Analytical	South Bend	IN	x	x	
Flowers Chemical Laboratories	Altamonte Springs	FL			x
Future Laboratories, Inc.	Milton	FL			x
Grants Pass Water Laboratory	Grants Pass	OR	x	x	
HGS Analytical Laboratory	Oxford	AL			x
J.L. Rogers and Callcott Engineers, Inc.	Greenville	SC			x
KINGSTON LABORATORY - NYC DEP	KINGSTON	NY	x	x	
LABCOR INC	SEATTLE	WA	x	x	x
MAINE ENVIRONMENTAL LABORATORY	YARMOUTH	ME			x
Meridian Analytical Laboratory - Wichita	Wichita	KS			x
Neilson Research Corporation	Medford	OR			x
Nova Biologicals, Inc	Conroe	TX			x
OKLAHOMA STATE ENVIRONMENTAL LABORATORY SERVICES	OKLAHOMA CITY	OK	x	x	
Orange County Utilities Central Laboratory	Orlando	FL	x	x	
PA DEP BUREAU OF LABORATORIES	HARRISBURG	PA	x	x	
Pinellas County Utilities Laboratory	Largo	FL			x
Portland Water Bureau Laboratory	Portland	OR	x	x	
Sanders Laboratories, Inc. - Nokomis	Nokomis	FL			x
SCIENTIFIC METHODS, INC.	GRANGER	IN	x	x	
State Hygienic Laboratory at The Univ. of Iowa	Coralville	IA		x	

CONSENT AGENDA Approved 11/10/2021

1. Approval of October Minutes

2. Board Election

Nominations for the 2022 Board began on November 8 and will run until December 31. Of the existing Board, terms that expire in 2022 include Alfredo, Judy, Stacie, and Steve. Sharon has sent them all a reminder that they are eligible to serve another term.

3. [Reserved]

4. [Reserved]

5. CONSENSUS STANDARDS DEVELOPMENT REPORT

5.1.1 CSDP Executive Committee

- Standard/Module review continues for virtually all Volumes and Modules of the TNI Standard. An NOI for EL-V1M1, V2M2, V3 and V4 concerning all aspects of Proficiency Testing are being prepared for submission to the CSDEC and subsequent notifications to all interested parties including ANSI. The PINS for Chemistry and Microbiology are both nearing the close of the comment periods and with the exception of one AB comment, none have been received.
- The TNI Glossary Work Group has to, a large degree, completed Work on the Glossary Annex (i.e., those definitions not in the Standards but in other TNI documents). Relevant ISO Standards definitions have also been considered in this review as have state specific definitions contained in laboratory accreditation regulations. The Work Group is now focusing on those terms/definitions in the Volumes and Modules of the Standard. As any changes proposed by the Work Group involving these terms/definitions must go through the entire Standard development process, initial efforts will be directed towards those Volumes and/or Modules that are currently under review and potential modification by the Expert Committees.
- A request of the authors of the documents in question to modify their language to utilize the harmonized definition will be made.
- Training for Expert Committee Chairs and Committee members is progressing well and documentation of said training for all Committee participants should be completed prior to year end.
- All Expert Committees are also beginning the process of Roster review for calendar year 2022. Numerous changes are anticipated, and publication of opening should occur within the next 30 days.

5.2 Asbestos Committee

- The Asbestos Expert Committee has completed all requirements for their modified Draft (DS). All notifications have been made and the comment period is closed. The Committee has prepared and published their Response to Comments (R2C) document consistent with SOP 2-100. A number of editorial (and clarifying), as well as persuasive comments were received, and the Committee has now prepared a revision to its Draft Standard which will be discussed and voted upon during the November meeting later this month.

5.3 Chemistry Committee

- The Chemistry Committee continues to seek resolution of SIRs from the LASEC. The primary focus of the Committee is now on development of proposed modifications to the language in V1M4 in preparation for a revised Draft Standard. While the entire Module will be examined as per SOP 2-100, at this point in time, principal issues facing the Committee relate to reconsideration of the language and/or clarification of the requirements for Initial and Continuing Demonstration of Capabilities for the laboratory and individual analysts, and detection limit and calibration language clarifications. Numerous other issues of a lesser nature are also being discovered as the Committee reviews the current Module.

5.4 Laboratory Accreditation Body Committee

- LAB members continue reviewing the comments submitted on the V2M1 Draft Standard. Decisions about replacement language for the assessor qualifications and training section of the Draft Standard are being postponed to the end of comments, as the committee still struggles with finding consensus on that portion of the module.
- In January 2022, LAB will lose at least half of its current membership due to term limits, and Carl's third term as Chair also expires. The committee is actively recruiting new members but does expect to have the minimum requirement (5 members) carrying over.

5.5 Microbiology Committee

- The Committee posted the DRAFT Standard on the TNI website for comment. The comment period just closed, and the Committee will start reviewing comments this month.
- Work on the implementation guidance for Equilibrium Testing (V1M5: 1.7.3.7.b.v.a) will continue after the comments to the DRAFT standard are reviewed.
- The Committee completed work on SIR 414 regarding DOCs and Variability/Reproducibility Testing. It has been posted to the NELAP AC voting site.
- The Committee worked on membership to ensure balance can be maintained since the Chair's Stakeholder Group will be changing to Lab. A lab just resigned this week and so the issue has been resolved.

5.6 Proficiency Testing Committee

- The PTEC Committee has completed its work plans focusing on needed changes to Module 1 including review of ISO 17011, 17025, 17034 and 17043 for consistency with the TNI Standard. The Committee is also beginning to look at EL V2M2, EL V3 and EL V4 for any needed updates or modifications to these Standards. These latter Standards will have to initiate the revision process or be reaffirmed through the ANSI process by 11/29/2021. The Committee is also addressing SIR 413 concerning Secondary Accreditation and its requirements in the PT Volumes and Modules. The Committee anticipates the presentation of an NOI for V1M1, V2M2, V3 and V4 within the next 30 days.

5.7 Quality Systems Committee

- The Committee did not have a working meeting in October because of lack of voting member participation. They did meet to start discussion on the SIR noted below, but no official business could be done.

- SIR 412 (dealing with solvent analysis and unique IDs) was completed during the November meeting, but the vote will be by email so a 2/3 vote can be attained.
- The Committee reviewed work being done by the ISO/IEC 17025 Crosswalk Workgroup.
- The Workgroups continued meeting this month to update parts of the Standard.

5.8 Radiochemistry Committee

- The DRAFT Standard is now ready to be posted as a DRAFT Standard for comment.
- The Committee discussed the topic mentioned in the PTPEC report. They feel it is important that uncertainty be reported, and a comment was made by the previous Committee Chair that he had understood that the PT Providers could handle this reporting. The Committee will help PT resolve this issue.

5.9 Stationary Source Audit Sample Committee

- Jerry received a response to the letter to the EPA to request that they reconsider their requirement for two providers. They do not intend to make a change.
- The Committee is working on the update to its three Standard modules.
- Updates were made to SOP 6-101 (SSAS Table Management).

5.10 Whole Effluent Toxicity Committee

- The WET Data Interpretation Training was rescheduled to October 27 after technical difficulties interfered with the originally planned presentation. The training was successful and well-attended. Review of draft revisions to various sections of the V1M7 module of the TNI Standard continues, with some progress in drafting people to work on the remaining sections.

6. NEFAP

6.1 NEFAP Executive Committee

- The Committee membership vote has been completed and they are awaiting final results from William. The new terms begin this month.
- The Committee finished their review of their Charter, and an update is being voted on to send to Policy.
- The Training Subcommittee is continuing working on the development of an Internal Audits course. Paul Bergeron is coordinating this effort with Adam Szafran. They should have a DRAFT for review later this month. Once they receive comments, they will plan a training date.
- The Marketing Subcommittee drafted a presentation to use to promote NEFAP. The next step is to start assigning members to promote NEFAP to their states. A request for website changes have been sent to Jerry to send to William.
- Justin and the Marketing Subcommittee will put a note together to get a better understanding about what needs to be reviewed by the Advocacy Committee before it is published.

6.2 Field Activities Expert Committee (FAC)

- The Committee has continued work on Volume 2 of the Field Standard – General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations. A new DRAFT has been sent out to Committee members and NGABs. Comments will be incorporated before the December meeting and a Summary of Changes document will also be reviewed.
- The FSMO Standard (Volume 1) was worked on this month. It has been a slow process because most of the work is occurring during meetings. Progress is being made.

7. NELAP

7.1 Accreditation Council

- Three AB renewals have now been approved, two years into the evaluation cycle. A fourth remote site visit was conducted last week after rescheduling due to an emergency. At present, two application reviews are well underway and two more beginning. Otherwise, there are two submitted applications awaiting review and two yet to be submitted with two more renewal letters yet to be send for the current cycle that ends in fall 2022.
- There are no changes to the implementation status of the 2016 TNI EL Standard since the September Board meeting.

7.2 Laboratory Accreditation Systems Executive Committee

- LASEC considered and rejected an appeal concerning the initial decision that an SIR was not valid, and instead, Implementation Guidance will be developed in conjunction with the Consumables Task Force, as the SIR related to documented procedures for reagent preparation.
- Planning for the Mentor Session and the Assessment Forum in San Antonio is now underway. Again, many thanks to Dorothy Love and Judy Morgan for spearheading these training events.

8. PROFICIENCY TESTING PROGRAM

- Work on SOP 4-107 (FoPT Table Management) has been completed by the SOP Subcommittee, but the Committee did not have time to review it. It will be reviewed in November.
- Work on metrics and the Charter continued. The Charter was voted on and will be sent to Policy for final review.
- The Committee was made aware of a conflict between Volume 1 and 3 of the Standard in regard to reporting uncertainty for Radiochemistry PTs. A subcommittee is being established to review the issue, whether there is value in reporting uncertainty, and how should it be evaluated.
- Ongoing items include review of the Voting SOP, PFAS ARA and the Radiochemistry Limits. The WET FoPT Subcommittee still needs to be formed.

9 ADMINISTRATION

9.1 Advocacy Committee

- Advocacy approved its updated Charter with an email vote and delivered the document to the Policy Committee. Shawn Kassner, Chair of PTPEC, joined the committee at its November meeting to discuss a new PT Initiative that will encourage non-NELAP state lab certification bodies to participate in TNI's PT Program activities beyond just requiring labs to purchase and perform PTs. This is a medium range project that Advocacy and PTPEC will share.

9.2 Policy Committee

- Review of SOP 3-105 (Standard Interpretation SOP) has been completed and Patsy is drafting an email to return this SOP for further updating.
- The Committee is continuing to review updated Charters. Final Charters will be submitted to the Board in December.
- Policy 2-100 (Viewing TNI Standards Incorporated by Reference) was reviewed by the Committee. Jerry shared the Policy with California and will finish up a final copy for the Policy Committee to vote on. *Policy Committee is done with 2-100.*
- The Committee is adding another voting member from the Administration side of TNI. Jerry will work with the Advocacy Committee to select a candidate.

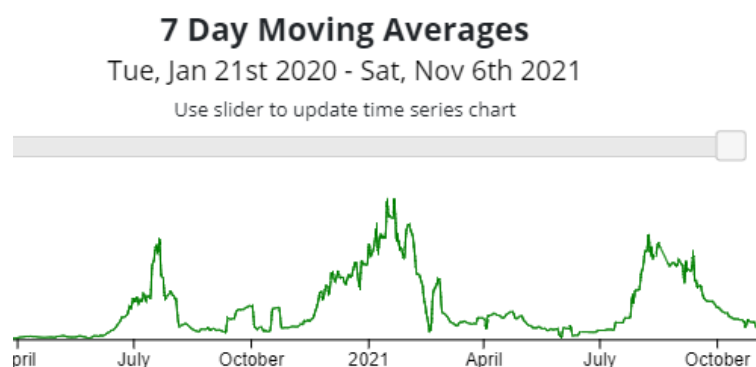
9.3 Training Committee

- Training Committee:
 - The Training Opportunities Workgroup has not met in November yet, but a meeting is planned.
 - The Credentialing Workgroup is being incorporated back into the Training Committee and meeting is being planned to discuss this topic next week.
 - Review on SOP 1-110 (Educational Delivery System) has been started and will be completed in November.
- Current Classes being worked on:
 - How to Properly and Scientifically Calibrate an Analytical System – Class has been completed and there were close to 60 participants.
 - Introduction to Proper and Scientific Integration Techniques for Chromatographic Systems – December 7 and 9th (4 hours). Registrations are very strong for this class and a need for a second class is being monitored.
 - WET Testing – Data Interpretation: This class has been completed. The original training date had to be scheduled for a week later due to some technical issues with Webex and two of the presenters. There were over 80 participants registered for the class between individual and group registrations.
- Good Laboratory Practice – Internal Audits – Part II (ANAB) – No additional update.
- ANAB's new course: Risk Based Thinking in the Environmental Laboratory. This will be a 10-hour class. People are asking about this type of class. They want to handle this class a little different. TNI will essentially be marketing the class on the website, but ANAB will be handling all the registration. They also signed up to do the class at the Winter meeting in person.

- Marlene and Ilona are still discussing evaluator training for the NEFAP/PTP Evaluations. It looks like this training will need to be completed during the summer.
- The NEFAP Training Subcommittee is developing an Internal Audit course for early 2022.

9.4 2022 Forum on Environmental Accreditation

- Registration has opened at <https://www.nelac-institute.org/forum/2022-winter/index.php> and a newsletter and email blast will go out soon to announce the winter Forum.
- We now have 18 Exhibitors.
- Bexar County is now at a substantial risk at 63 cases per 100K, but rapidly approaching a moderate risk of < 50. The positivity is down to 3.6% from a high of 20% in August.



9.5 2022 Environmental Measurement Symposium

- The Call for Abstracts is complete and should go out this week by mail and email.
- The Exhibit Program opened on November 1.
- A new domain was registered: envirosymposium.group. This domain will be the new home for consolidated information about the Environmental Measurement Symposium. Some pages have already been set up at the new website, however, note that if you go there now there are some pages that do not yet work.
- The Portal for the 2021 Symposium has closed and all presentations were converted to PDFs.

9.6 NGAB

- No activity.

9.7 Information Technology

- At the Advocacy Committee meeting in August, there was some discussion about how people find out about standards development activities, after a “Request for Comments” to a draft standard was posted on the website on August 9. To improve communication of these kinds of postings, William created a mailing list subscription for standards development activities. The list works in the same manner as the existing notification lists for Standard Interpretation and FoPT Table updates. In this

case, a signup form is on the [Standards home page](#) of the website. 86 individuals have signed up so far, and two notifications have already gone out as a result of news postings made last month.

10. TASK FORCES AND OTHER EFFORTS

10.1 Competency Task Force

- The Task Force received conflicting feedback from the NELAP Accreditation Council after presenting revised draft language to the NELAP ABs about updating the concept of “Technical Manager” (now renamed as Technical Expert). While there is general support for updating the concept, the Task Force will soon make a recommendation to Quality Systems Expert Committee, and that group will determine the fine details of language in the revised V1M2. The Task Force will now focus on the combined session with TNI’s Training Committee and Expert Committee Chairs at conference, where discussion will update participants on recent activities and then focus on components of a possible credentialing program, initially addressing Technical Experts and Quality Systems Management Experts.

10.2 Consumables Task Force

- The Task Force is continuing in the process of listing and classifying critical products, supplies and services. Meetings have resulted in further defining elements of the first area of concern, general products and supplies required for all laboratories. The Task Force nears completion on the topic of “General Laboratory Supplies and Services” and is developing the means by which laboratories can effectively utilize this data.
- The recent work of the Task Force has focused on how laboratories can ensure compliance with the TNI requirements and appropriate ISO/IEC requirements. The Task Force in response to this question, has and continues to investigate ISO Guide 31 and the necessary informational requirements of product “certificates”. The anticipated “checklist” for certificates for critical supplies and services has recently been presented in a final draft stage. A “decision tree” is also being developed for use in laboratory procurement efforts to ascertain which supplies and/or services are critical and subsequently require certificates to ensure compliance with TNI requirements.
- A Standard Interpretation Request from Scott Siders related to preparation of reagents was ruled an invalid request, but the topic merits resolution so it has been turned into an action item for this Task Force.

10.3 Mentor Initiative

- We now have 10 laboratories paired with 10 Mentors.

10.4 Environmental Monitoring Coalition

- [Reserved.]

11. MEMBERSHIP

- 1248 active members

11.1 Committee Applications

Sarah	Brown	Cove Environmental	WET (Associate)
Nwadiuto	Esiobu	Applied Biotech Inc	Microbiology
Helen	Conrad	North Water District Laboratory Services	WET (Associate)
Tiffany	Carey	New York City DEP	Microbiology
Yumi	Creason	Pennsylvania DEP	LAB

11.2 New and Renewed Members:

- Of the 21 expired memberships from September, 8 renewed or requested an invoice after contact, 8 did not respond, and 5 retired or had bad emails. Emails were sent to October expired members on November 6, 2021.
- 54 New and Renewed memberships in October 2021

11.3 Expired Memberships

- 28 Memberships expired in October.