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

ROLL CALL

AGENDA

1. Review of Consent Agenda – Approved 10/13/2021

2. Accreditation for Covid Testing (Attachment 1)

As stated in this report, this Task Group is recommending only the following actions at this time:

- o Submit comments to CDC on a Federal Register notice;
- Share comments with APHL and seek their support for funding from HHS;
- Present this plan to our community at the upcoming San Antonio meeting and seek feedback, especially from laboratories that might consider this accreditation.

After the San Antonio meeting and depending on feedback, we will consider developing a training course on PCR technology.

Motion to Approve the Actions in the 3 Bullets above: Jack Farrell Second: Maria Friedman Approved: Unanimous

3. Third Quarterly Report to TNI Board of Directors on NEFAP Metrics

The training subcommittee has internalized development of the (paid) training program, which will benefit the program by keeping revenue generated internal to the program. Work has begun on course development, and we anticipate the course being offered late 2021/early 2022. The training component of our plan is still in development and is unlikely to meet the goals established.

Marketing efforts are in progress and we are seeing a small increase in interest from them. We anticipate this interest slowly increasing as our marketing efforts continue.

The metrics have not shown much growth in interest over the past few months, but the focus has still been in development of the components of the plan which should continue to progress and begin to see returns, especially in terms of interest once the marketing component reaches the wider marketplace.

Metric	Target by December 2021	Current	Priority
Increase number of FSMO applications	8	2	High

TNI Strategic Plan Objective #6: Develop revenue source via training or other streams to fully support this program and marketing activities needed for growth. (Medium Priority)

Develop revenue generating training sessions	3	1 in development	High
training clips or informational media to promote	2	1 in development	Low
paid sessions			
Increase in number of people completing NEFAP/Field training courses in TNI	10	0	High
Increase NEFAP related revenue	\$1,500 increase	0	High

TNI Strategic Plan Objective #2: Focus available resources and efforts towards marketing the program. (High Priority)

Increase in presentations given external to TNI	3	3	Medium
Increase in published promotions (articles/white paper)	1	1	Low
Increase in social media presence	20 posts on various formats	0	Medium

Additional indicators of program interest – not included in TNI strategic plan

Increase in participation in EC meetings	75% attendance 6 new	44% in 3Q	Medium
Increase in associate members (NEFAP EC & FAC)	associates (there are 12 existing)	4	Medium
Inquiries from stakeholders into program (NEFAP EC & FAC)	3	4	Medium

Comments:

- Strategic Plan Objective #3 for establishing subcommittee dedicated to evaluating training needs and developing classes related to field measurement and sampling is completed and their work is ongoing.
- Strategic plan Objective #4 of establishing metrics and timeline for evaluation of success measures and impact on the program has been initiated and is ongoing (this objective is the premise for this report).
- Strategic plan Objectives #1, #5, and #7 relate to the routine business operations of the program and committee and are not reflected on this report specifically.

10.1 Competency Task Force

• The Task Force representatives again met with the NELAP Accreditation Council on October 7, with a revised draft from the Council for the language intended to address the Council's concerns about updating the concept of "Technical Manager" (now renamed as Technical Expert).

Changes discussed:

- 1. Technical Manager to be redefined as Technical Expert.
- 2. Eliminate the requirement of so many hours of credit in a particular science and replace it with an associate degree or a 4-year degree or in some cases, just experience with certain tests.
- 3. Expand the section on exceptions to allow ABs to not require the educational experience for someone who has a lot of experience, like 5 or 6 years of experience. This would be at the AB's discretion.

With this task approaching completion, the Task Force will now focus on the combined session with TNI's Training Committee to discuss credentialing and training at conference.

Attachment 1: Concept for Ensuring the Competency of Laboratories Performing Wastewater Surveillance Testing

DRAFT 10/11/21

1.0 Purpose

This document describes options by which laboratories that use molecular detection methods to analyze wastewater for health-related contaminants, such as but not limited to, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) could demonstrate their competency for such testing.

2.0 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,
- LOD and LOQ concepts are mostly not appropriately applied, and
- QC Results are mostly not reported.

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

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

review, previous experience, or implementing a Quality Management System (QMS) without seeking accreditation.

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.

TNI has developed a standard based on ISO/IEC 17025, Management and Technical Requirements for Laboratories performing Environmental Measurements.

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.

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."

TNI manages a national environmental laboratory accreditation program, implemented by 14 state agencies that currently accredits over 1400 laboratories including over 800 municipal wastewater facilities. The state of California has adopted the TNI standard into their regulation for an additional 800 laboratories. The TNI could easily be adapted to accredit laboratories that perform wastewater surveillance. While there is no specific standard methodology for this testing, the tests themselves can be done under the TNI standard or the ISO/IEC 17025 standard. ACIL has been leading an 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. See Appendix 3.

The industry-accepted technique for this type of wastewater surveillance testing is quantitative Polymerase Chain Reaction(qPCR)³ including Real Time PCR, Reverse Transcription PCR, digital PCR, chipbased digital PCR, and digital drop PCR. TNI intends to use a generic PCR technology code for all of these.

This approach has been used successfully for the accreditation of laboratories that test for *cryptosporidium, giardia* and *Legionella pneumophilia* in water samples. See Appendix 4.

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

³ Polymerase chain reaction from Wikipedia. <u>https://en.wikipedia.org/wiki/Polymerase_chain_reaction</u>

3.0 Investigate Feasibility

TNI should reach out initially to three specific groups regarding the feasibility of this effort, APHL, CDC, and the TNI Accreditation Council.

3.1 APHL

On September 8, 2021, Jerry Parr requested feedback from APHL. APHL responded on September 23 indicating "it is too soon to develop an accreditation program without many resources that are standardized yet, including a method, proficiency tests, etc. There were some comments about the broad spectrum of labs that are performing this work and how educational step-wise resources to help improve the quality of testing could be very beneficial." The text of the request and response is in Appendix 2.

TNI could consider going back to APHL with the competency approach discussed below in Section 3.2.

3.2 CDC

CDC seeking public comments, open until Nov 8, 2021, on a proposed information collection project called National Wastewater Surveillance System for COVID-19.

Docket #: CDC–2021–0090; <u>https://www.federalregister.gov/documents/2021/09/07/2021-</u> 19160/proposed-data-collection-submitted-for-public-comment-and-recommendations

Federal register notice here: <u>https://www.govinfo.gov/content/pkg/FR-2021-09-07/pdf/2021-19160.pdf</u> In comments we provide to CDC we should encourage CDC to ask for funding from HHS to support a similar mentor effort, especially for state public health labs and to issue a competency policy that stresses the importance of a QMS. We could ask APHL to support this effort.

3.3 NELAP Accreditation Council

The Council discussed this topic on October 4 and concluded there is currently no regulatory requirement for this public health testing, not all ABs are expressing interest in accreditation, but those ABs that are associated with the public health labs in their state do seem interested, and many ABs expressed interest in obtaining training in the assessment of PCR technology. Several participants commented that EPA is developing a PCR method for coliforms and enterococcus in recreational waters, so providing training in the method/technology itself might also be valuable.

Five ABs expressed some interest which should be adequate at this time. The specific responses are summarized below.

FL	Florida is interested. Although pricey, Fl probably would have a handful of labs interested in
	this testing. I agree with Travis, it would be fantastic if TNI could offer training for the
	assessors.
IL	It appears that Illinois Department of Public Health is doing this, so I do not think we would be
	interested in the addition.
KS	
LA	
MN	Minnesota might consider offering this field of testing (SARS-CoV-2 by PCR in non-potable
	water) if there is a need or it becomes a field of testing requested by the Clean Water Act or
	other federal program. We would need training on PCR technology.
NH	Yes, if the demand was there. None at this time.
NJ	Unlikely unless SARS-CoV-2 becomes a regulated contaminant.
NY	We will not be adding this technology at this time. NYS has been handling this as part of PH
	emergency between clinical and environmental.
ОК	Oklahoma which is not directly connected to its public health is reviewing this topic and has
	not ruled out the possibility for accrediting laboratories. We would like to see the checklist and
	discussion lies around the quality controls for accreditation. Our group definitely does wish to
	have training.
OR	ORELAP would be interested in exploring this. The main issue on our end is most laboratories
	aren't getting a lot of demand for this type of testing in our neck of the woods. The PCR
	equipment can be too pricey. Could TNI provide training on PCR, it would be useful.
PA	DEP is not interested in adding this accreditation due to lack of regulations and enforcement
	concerns.
ТΧ	
UT	
VA	In VA, our accreditations are based on requirements specified in regulations or permits, so this
	is not something we anticipate adding in the near future. However, I certainly see the value in
	TNI being prepared for this addition of technology and serving those who need this
	accreditation. Having training available is certainly of interest.

4.0 Concepts for Demonstrating Competency

Accreditation to either ISO/IEC 17025 or to TNI's environmental laboratory standard is the clearest and most defendable approach to demonstrate competency. A laboratory could also choose to implement a QMS based on either of these standards without seeking accreditation. A National Academy of Sciences report⁴ indicated a QMS is a recognized and accepted method for assuring confidence in laboratory results, the use of a QMS should improve quality, reliability, work transparency, and consistency across the laboratory, and an effective QMS promotes opportunities for self-assessment and improvement of work habits through independent auditing and process review.

In 2019, the American Society of Crime Lab Directors (ASCLD) initiated a substantial mentor effort to encourage crime labs to get accredited. This effort had substantial funding from the FBI. WHO has a similar effort for clinical laboratories in Africa.

⁴ 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.

5.0 Benefits and Risks

5.1 Benefits

5.1.1 Benefits to TNI

If this program is implemented TNI would benefit both financially and from public perception. Although TNI would not receive any accreditation fees, TNI would accrue other revenue in terms of sale of standards, templates, and related documents and sale of training courses. The increase in revenue from California laboratories attests to this fact.

TNI's Strategic Plan has a key strategy to "promote TNI as the premier resource for all activities related to generating environmental measurement data." This effort would be very much aligned with this strategy.

5.1.2 Benefits to Laboratories

Those laboratories already accredited to either the TNI or ISO/IEC standard would have an easy path to accreditation as all they would need to do is expand their Fields of Accreditation. Conversely, those laboratories that are not accredited to any standard may face a harder path to accreditation.

5.1.3 Benefits to Public Health Agencies

This program when implemented will improve comparability and reproducibility in PCR assays, better inform public health agencies for preventing disease transmission, and ensure that credible and reliable data are used.

5.2 Risks

Since this testing does not fall under the purview of EPA, and since CDC has no authority to require accreditation, it would be a voluntary program like NEFAP with the same programmatic issues. Research by Sharon Mertens showed only two laboratories in Wisconsin are doing this testing, the State Lab of Hygiene and the UW Milwaukee School of Freshwater Sciences and they have funding from CDC, Alfred P. Sloan, and others.

If TNI were to aggressively implement the program as described in Section 6.0. we run the risk of expending financial resources needlessly and diverting several committees from their current priorities. Accordingly, this Task Group is recommending only the following actions at this time:

- Submit comments to CDC,
- Share comments with APHL and seek their support for funding from HHS,
- Present this plan to our community at the upcoming San Antonio meeting and seek feedback, especially from laboratories that might consider this accreditation.

Note: All efforts to date, including Staff labor, have been voluntary.

6.0 Approach (Tabled for now)

This Action Plan describes four specific activities to be undertaken by TNI, internal actions to support the program, publicity and outreach, education, and standards development.

TNI Internal Actions

As with all other tests and analytes, TNI relies on its Laboratory Accreditation Management System (LAMS) to document the accreditation status of laboratories. Laboratories are accredited for the analyte, the matrix, the technology used, and the specific method. Accordingly, TNI has added SARS-CoV-2 as an analyte (Analyte Code 2571) and Polymerase Chain Reaction (PCR) as the technology. Any laboratory can request a specific method, including a laboratory's internal SOP, to be added to LAMS. TNI should also post the method checklist developed by ACIL on its website for laboratory assessors to use.

TNI should task the Proficiency Testing Executive Committee to investigate the feasibility of creating a Field of Proficiency for SARS-CoV-2.

3.2 Publicity and Outreach

TNI should develop a "White Paper" or similar document providing background information on this topic indicating how Accreditation Bodies can use the TNI laboratory accreditation standard as the basis for adding SARS-CoV-2 to their Fields of Accreditation. This White Paper should discuss why the TNI standard is appropriate and how an AB could implement the program. The White Paper should be shared will all TNI accreditation bodies (government and non-government), other state accreditation/certification programs and other stakeholders including ACIL, APHL, and WEF. The document should be made available on the TNI website and an article written for the next Newsletter.

TNI should also support the efforts of other organizations such as ACIL and APHL to convince the CDC to encourage accreditation for this type of testing.

3.3 Education

The checklist being developed by ACIL will be a useful tool for laboratory assessors. But more is needed. Specifically, TNI needs to identify an individual or group of individuals that can provide a training course on PCR. This course will need to 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.
- 3.4 Standards Development

The Quality Systems module in the TNI laboratory accreditation standard should suffice as the framework for accrediting laboratories for SARS-CoV-2 just as it does for other emerging contaminants such as PFAS and microplastics. Nonetheless, TNI should task the Consensus Standards Development Executive Committee to investigate whether or not changes should be made to either Module 2 (Quality Systems) or Module 5 (Microbiology) to address specific issues related to this type of testing. In reviewing the checklist in Appendix 2 it appears PCR is more comparable to chemical testing with detection and quantitation limits, calibration curves, etc.

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 data ⁵through 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 Council ⁶established 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-

⁵ 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.

⁶ 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.

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 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.htm1#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, <u>http://www.epa.gov/irmpolifi/ciopolicy/21050.pdf</u>
- 5. FEM Lab Accreditation Policy, <u>http://www.epa.gov/fern/labcomp.htm</u>

Appendix 2. Outreach to APHL

September 8, 2021

From Jerry Parr to Sarah Wright

On the TNI Board call today we discussed a presentation I made at NEMC on August 2 and my subsequent recommendations for TNI to pursue an effort to develop a program for accreditation of laboratories performing Wastewater Based Epidemiology (WBE) testing. While my original presentation focused only on SARS-CoV-2, the Board thinks this should be a broader effort on any virus where WBE is important.

The Board did not act on my recommendations today but rather has formed a small group to look at the feasibility and benefits of such an effort. Part of the feasibility is to see what other groups might like TNI to pursue this effort. I will be reaching out to our state Accreditation Bodies to see if this is something they would like to offer. We already accredit laboratories for legionella so it should not be too much of a stretch, but the concern is that the data are not reported to an environmental agency but rather to a public health agency.

I will also be reaching out to the CDC to gauge their interest in either a voluntary or mandatory program. I am sending this to you to request you reach out to the appropriate APHL members to gauge their interest as well. Even if we do not take the route of developing an accreditation program, there may be value in some of the other planned activities such as training courses on PCR and proficiency testing. I have attached a summary of my presentation along with the recommendations made today.

September 23, 2021

From Sarah Wright to Jerry Parr

The APHL Environmental Laboratory Science Committee (ELSC) met yesterday.

The consensus as I heard it was that perhaps it is too soon to develop an accreditation program without many resources that are standardized yet, including a method, proficiency tests, etc. There were some comments about the broad spectrum of labs that are performing this work and how educational stepwise resources to help improve the quality of testing could be very beneficial. We didn't speak specifically about the checklist, but it seems like, absent standardized methods, PTs, etc., the checklist provides a good "what" as to what should be done to at least ensure quality data production surrounding your lab's SOP, and then an accompanying white paper or guidance document could provide more of the "why" behind the steps. As you mention in your summary proposal, another good step could be to update TNI's Module 4 to include the technical requirements for quantitative analysis.

I've copied our chair, Shane Olund of MN PHL, our vice-chair, Enoma Omoregie of the NY PHL, Julie Nassif, our EH director, and you know my colleague, Erin Morin. Those from APHL please respond if I have misrepresented anything or you'd like to add more.

ELSC would be happy to have subsequent conversations on this topic.

Quality Control Measure	Description	Frequency	Purpose	Control Limit	Corrective and Preventative Actions?
SAMPLE CHECKS					
Chain of Custody documentation describing at a minimum: Sample ID; Client ID; Time and Date; Custodian, Analysis required	Details to identify specific sample under analysis	Every sample	Sample traceability	Column A indicates minimum requirements	Do not initiate analysis without information required
Temperature of sample and subsamples	Temperature is measured upon receipt of sample; on initiation of analysis of sample/sub- sample (if >4h post-receipt)	See column B	Determine if there are significant temperature changes post- storage or subsampling	Temperature between samples should be within 5 C of each other	If >5C, discard sample/subsample and re-sample OR confirm sample use as agreed with client OR note deviation on report
pH of sample and subsamples	pH is measured upon receipt of sample and during the subsampling process if subsampling applied	At subsampling	Determine if there are significant pH changes during subsampling	pH of subsamples within ±1 of original sample pH	If >pH1, note on report
Sample volume	Measure actual sample volume using certified laboratory grade volumetrics. Sample and subsample weight can be used as an indirect measurement for sample volume	During all subsampling	Ensure recorded volume for all samples and individual sub- samples	The measured volume and/or weight of each sample/subsample is within ±3% of the target weight.	If outside of defined limits, re-combine, rehomogenize and re- sample.
Total Suspended Solids	Total suspended solids (TSS) determined of sample and subsamples as applicable to test/client need	For every sample and or subsample OR as required by client (NOTE: some utilities may report this data point to the lab with sample)	TSS verifies homogenization of aliquots	The TSS of the subsamples are within 10% of original TSS read	If outside of defined limits, re-combine, rehomogenize and re- sample.

Appendix 3: Draft Checklist for SARS-CoV-2 Testing in Wastewater

DRAFT

Sample Arrival and Holding	Samples to arrive		Detectable virus	2-5°C	If >5C. discard
temperature	on ice but not		genome copies can		sample/subsample and
I I	frozen		diminish at elevated		re-sample OR note
	Temperature upon		temperatures		deviation on report OR
	receipt to the lab		temperataree		as agreed with client
	and must be $1 -$				before processing
					before processing
	sample is taken				
	and immediately				
	processed Sample				
	is refrigerated at 2				
	1°C until				
	processing up to a				
	maximum hold				
	time of 21d				
Maximum hold time (prior to	Movimum timo		Dotoctable virue	Rogin processing	Store complex at <60
processing)	following resount of			immediately or within 2	and maggure pH ato
processing)	comple at lab prior		diminish with time	dave after receipt at lab	and measure price.
	sample at lab prior		diminish with time.		prior to analysis within
	to start of analysis.				2 Id of fecelpt. Record
Turne and time a			Encure times by	language)	on report.
i umaround ume	ASAP Iollowing		Ensure limely	Maximum analytical time	II analylical lime
	sample receipt or		analysis and data	consumed from sample	exceeds 48n, discard
	retrieval from		delivery of samples	to data generation is 48h	data OR confirm
	storage in		received		agreement with client
	accordance with				on use of sample OR
	client				process and note
	commitments.				deviation on report
STANDARD CURVE					
Has the Laboratory Established a Limit	Yes				
of Detection and Limit of					
Quantification?					
Has the laboratory established the	Yes	Is this necessary?	Measures		
linear dynamic range of the method?			Efficiency- Serial		
			dilution with 5-log		
			dilutions (Slope		
			~3.3; R2> 0.99)		
Low and high sample concentration					
ranges covered in the curve Does					
calibration range bracket expected low					
and high range samples					
Are at least 5 serial dilutions prepared	Yes				
to be used as standards?					

Are all standards analyzed in	Voc	How many replicatos are	3		
replicate? Number of replicates? 2, 3	103	needed?	5		
other?		needed !			
Deep the leberatery have defined	Vaa		SD 40 107		
Does the laboratory have defined	res	2- RPD. 3- RSD?	SD <0.167		
precision acceptance criteria for					
standard replicate analysis?					
Does the laboratory meet a correlation	Yes	r2 value? Is 0.990	≥0.98		
coefficient value of 0.980 For		reasonable?			
calibration curves?					
Does the laboratory meet acceptance		Is 20% reasonable ??	Yes, 20% for		
criteria for Relative Standard Error			positive control.		
(RSE)					
Is PCR amplification efficiency 90-	Yes				
110%					
Does the laboratory use RNA as	Ves		RNA during RNA		
standards source to ensure all	105		extraction and PCR		
standard go through RT step as			extraction and 1 Or		
proparation?					
Deep the leberatory remake standards	Voo				
if there is a C shift of 0.5 1.02	165				
If there is a Cq shift of 0.5-1.0?	NI-				
Does the laboratory use DNA as	NO				
standards source?					
Does the laboratory determine slope	Yes		(Slope ~3.3; R2>		
and y-intercept for calibrations and			0.99)		
have defined acceptance criteria?					
Slope >0.990					
Does the laboratory perform LOQ	Yes	Annually			
Verification and meet acceptance					
criteria of <u>+</u> 35%?					
Frequency of calibration is established		Per Instrument run		what should the	
and documented				minimum frequency be?	
				Public feedback	
Sub-Sampling					
Homogenization	sonication, or	determined by SOP	ensure that	replicate precision is	Consider revising
5	similar mixing	,	subsamples are	within predetermined	subsampling
			representative of	limit: visual inspection	procedure or report
			the larger sample	innit, fieddi niepeeden	data with deviation
					noted
Quality Control Measure	Description	Frequency	Purpose	Control Limit/Point	Corrective and
	Description				Preventative Actions?
Burnasa of Concentration: To improve	l o concitivity of the c	esav (o a to detect lower o	ncontrations of terms	t: tochnically ontional as t	his stop may not be
recipose of Concentration: To Improv	e sensitivity of the a	assay (e.g. to detect lower c	oncentrations of targe	i, technically optional as t	nis step may not be
needed due to case rate)					

SOLIDS REMOVAL - PRE-CONCENTR	ATION STEP				
"Slow" Centrifugation	~4000xG or per SOP	per sample or at a frequency as stated in SOP	solids removal	per SOP (which can include a TSS or Turbidity measurement limit below X)	Revise SOP; report data with deviation noted
Membrane Filtration	0.2 - 0.5 micron or pore size as described in the lab SOP	per sample or at a frequency as stated in SOP	solids removal	per SOP (which can include a TSS or Turbidity measurement limit below X)	Revise SOP; report data with deviation noted
Electro Negative Membranes			I		
Sample pH range adjusted	PH is adjusted to level in SOP	Per sample	ensure pH allows to electronegative membrane to work properly	pH to be XX	discard sample/subsample and re-sample OR note deviation on report OR as agreed upon with client before processing
Magnesium Chloride treatment			Enhance particle attachment to membrane		
Acidification of membranes	HCI titration to specific pH		Enhance particle attachment to membrane (Mia to check)		
Process controls, blanks, rinsing checks (di water, PBS)			determine cross contamination	blanks and controls present appropriate data	
Membrane Lot #, CoA, exp date	material control tracking	per lot or batch	Can help with tracing assay issues	data retained in LIMS or other tracking system	
Polyethylene glycol (PEG) precipitation	on				
Matrix Spike	used Y/N per SOP	per sample	determining target loss due to refrigeration and heat inactive on the matrix of the sample	verify sufficient material added to run the test	reprepare sample
Heat inactivation	used Y/N	per sample	to handle sample in BLS2+ vs BLS3		also in Safety section
Volume processed documented	per SOP	each sample		Standardize sample volume processed	
Supernatant volume (after Solids Removal)	per SOP	each sample	helps determine amount of NaCl and PEG to use;	volume needed to assay and calculation used is documented	reprepare sample

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			ensures complete		
Incubation time & temperature	per SOP	per batch	ensures complete precipitation	records	reprepare sample
PEG Pellet Resuspended	per SOP	each sample	resuspend precipitate	volume needed and/or calculation used is documented	
Take Aliquots	per SOP	# per sample	Used for Extraction	depends on Extraction SOP; record volume	
PEG pellet and/or Supernatant and/or Aliquot storage temp	per SOP	each sample	preserves target	sample maintains defined temperature	Note deviation on report OR as agreed with client before processing
spike material checks: lot/prep #, storage conditions, date of preparation	per SOP	per lot		records	
spike measurement, Ct value	per SOP	per sample run of samples			
concentrate measurement, Ct value	per SOP	per sample run of samples			
efficiency calculation, determination of acceptability	per SOP	per sample run of samples			
Skim milk flocculation			·	-	
volume, pH, concentration of flocculated skimmed milk solution	per SOP	per lot	optimized precipitation	controls are recovered per SOP	reprepare skim milk solution
Sample volume	per SOP	per sample		laboratory established would work for the control limits.	
Sample incubation time		per batch			
Sample incubation temperature		per batch			
Sample continuously agitated during incubation		per batch			
volume of sample, incubation time, temp, and agitation					
centrifugation time, temp					
Pellet resuspension volume					
Time/Temp of concentrate during storage until RNA extraction.					
spike material checks: lot/prep #, storage conditions, date of preparation.					
EXTRACTION					
Product kit, part number, lot #, exp, storage conditions recorded				information documented	

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Lysing Type (Chemical, Physical, heat)	per SOP	per Sample	release of RNA from sample		
Time	per SOP	per Sample		time stays within range per SOP	Note deviation on report OR as agreed with client before processing
Temperature	per SOP	per Sample		temperature stays within range per SOP	Note deviation on report OR as agreed with client before processing
Extraction Blank Control (reagent only, no WW)	Yes/No	per batch	to determine or identify cross contamination	Evaluate specificity, non- target interference reference	Note deviation on report OR as agreed with client before processing
Internal Extraction Control (Murine virus etc.)	Yes/No	per SOP (typically annual)	iDOC and/or during method validation	ensure successful/complete extraction of target RNA	Retraining
Inhibitor Removal	Chemical, Spike, or dilutions may be used or may be part of a kit and not treated separately	per sample	remove inhibitors from sample	Test for inhibition	Inhibition present after PCR; Note deviation on report OR as agreed with client before reporting
Eluate Volume	measure eluate volume vs. original volume per SOP	per column run	Helps determine if column may have clogged	volumes documented	Rerun sample, Note deviation on report OR as agreed with client before processing
RT-PCR			-		
Thermocycler equipment and calibration	per SOP, based on manufacturer's specifications	per manufacturer specification or as needed	ensure performance per manual	temperature, calibration are documented	equipment not used if fails pre-check process; change frequency as needed
Inhibition assessment and determination	per SOP	per sample	Difference of signal can mean inhibition present		Proceed per SOP or as agreed upon with client
Standard Curve	per SOP	per batch/plate/machine run	positive control	see Standard Curve section	Rerun sample, or note deviation on report OR proceed as agreed upon with client
Negative control, no template control	per SOP	per batch/plate/machine run	no template contamination	no amplification	Rerun sample, or note deviation on report OR proceed as agreed upon with client

Reagent checks	per Sop	per Sop	reagents are kept at appropriate temperature in storage and during use and used prior to expiration date	Rerun sample, or note deviation on report OR proceed as agreed upon with client
Sample rejection criteria are in place	per Sop	per Sop		Rerun sample, or note deviation on report OR proceed as agreed upon with client
Materials are assessed to be nuclease free	per Sop	per Sop		Rerun sample, or note deviation on report OR proceed as agreed upon with client
SOP describes data evaluation	per Sop	per Sop		
Calculation documented to convert Ct to viral copies	per Sop	per Sop		

General Report Criteria:

- Report title (example "Test Report", Report of Analysis", etc.)
- Name and address of reporting laboratory
- Location where analyses were performed If different from reporting laboratory
- Customer contact information
- Unique identification of all components (sample ID, sample type, analysis type, spike ID, etc.)
- Sample description
- Sampled date, received date; filtered date, preparation date, extraction date, analyzed date, reported date (if applicable)
- Sample condition, chlorination status, container type/volume and temperature upon laboratory receipt
- Reference to sub-sampling plan or sampling method if applicable
- a statement that results relate only to the samples tested
- Identification of person authorizing the report
- Clear identification when results are from external providers.
- If lab does not do sampling, then include a statement that results relate only to the samples as received
- Case Narrative (or similar sections) where appropriate (includes opinions, interpretations, explanations of method modifications/deviations/additions and qualifiers
- Report labeled as Amended when amendments are made to the original report. Includes traceability to the original report.

- Identification of the method used
- Results and units where applicable
- Analyte RL/LOQ
- Dilution Factor if applicable

Batch Extraction Blank and Units:

- Batch extraction blank spike recovery as applicable
- Batch extraction matrix spike recovery as applicable
- Sample RPD/RSD
- Internal control recovery per sample
- measurement uncertainty in the same units as the analyte or in a term relative to the analyte results (example: percent) where applicable
- Acceptance criteria listed for each quality parameter
- Method or Analyte qualifiers

Data Interpretation:

- Were holding times met for filtration, analysis
- Are results reported to method significant figures
- Were extraction blank spike results acceptable
- Were extraction matrix spike results acceptable
- Were uncertainty measurement results acceptable
- Were sample RPD/RSD results acceptable
- Were unacceptable results qualified.

Appendix 4: Laboratories Accredited to the TNI Standard for Selected Bacteria and Parasites

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

DRAFT

CONSENT AGENDA Approved 10/13/2021

1. Approval of July 2021 Minutes

2. Transfer of Banking Account

Our current bank, BBVA, has been bought out by PNC and our routing number and account number changed over this weekend. Suzanne has updated the system that captures credit card transactions (Authorize.net) and is in the process of notifying about 50 organizations that pay by direct deposit (ACH) of this change.

3. Staff Training Procedures

Suzanne and Jerry have been working on 20 or so internal administrative procedures. We are calling these STPs based on a recommendation by the Policy Committee, so they do not have to go thru the same approval process. This effort was done to assist Paul in transitioning to the EA position as well as have all of these activities well described. Here is a partial list:

- o Quarterly Account Receivables Report
- o American Express Reports
- o Bank Statements and Bank Activity
- o TNI Contact Database
- o Creating Training Courses
- Credit Card Transactions Using Authorize.Net
- Weekly, Monthly, and Quarterly Deposit Report
- E-commerce Transactions (Mals E-commerce or eMals)
- o The Environmental Measurement Symposium
- Monthly and Quarterly Financial Reports
- o The Forum
- o TNI Membership
- Tracking Standard Sales
- Training Course Spreadsheet

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 Chemistry has been approved by the CSDEC and all appropriate notification made including the filing of a Project Initiation Notification (PINS) with ANSI. An ANSI PINS was also re-submitted for Module 5 (Microbiology). ANSI acceptance of this PINS was delayed due to TNI's suspension of accreditation. The public comment period regarding the BSR-8 for EL-V2-M1 (General Requirements for Accrediting Bodies) remains open. An NOI is also under development from the PTEC for Module 1 and potentially for other Volumes related to proficiency testing.
- 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 will now focus 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.

- Revised training materials for Expert Committee members and Chairs has been completed and made available for all Expert Committee members. Committee members have been actively participating in this training and recording of said training presented to Expert Committee Chairs who are responsible for tracking participation. While not required, Committee associates are also being encouraged to participate in the training.
- The CSDEC Charter was approved by the Executive Committee and submitted to the Policy Committee. The Policy Committee however has returned the Charter to the CSDEC with questions and suggested changes. The requested CSDEC Charter changes continue being addressed by the Executive Committee.

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 is now
preparing a second draft of their Standard for publication and comment.

5.3 Chemistry Committee

- The Chemistry Committee continues to seek resolution of SIRs from the LASEC. The Committee prepared and submitted an NOI for Module 4 to the CSDEC which has been approved. All notifications, including ANSI have been completed. 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.
- One new application for associate membership on the CEC was processed in September.

5.4 Laboratory Accreditation Body Committee

 LAB members continue reviewing the comments submitted on the V2M1 Draft Standard. Commenters on the assessor qualifications and training section of the Draft Standard were invited to meet with the committee on September 21, and good progress was made in understanding the ABs' concerns and in drafting replacement language.

5.5 Microbiology Committee

- The Committee posted the DRAFT Standard on the TNI website for comment. It was posted on August 9, 2021 and comments are due in 90 days.
- Language was developed for the Abstract of Project needed for Bob to submit a BSR-8 to ANSI.
- The Committee reviewed comments received at the summer conference meeting.
- Work was started on the new implementation guidance for Equilibrium Testing (V1M5: 1.7.3.7.b.v.a).
- The Committee is starting work on SIR 414 regarding DOCs and Variability/ Reproducibility Testing.

5.6 **Proficiency Testing Committee**

The PTEC Committee continues to develop 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 Module 1 and potentially other Volumes and Modules prior to the end of the calendar year.

5.7 Quality Systems Committee

- The Committee did not have a working meeting in September because of lack of voting member participation. The group did do some voting on minutes and an SIR.
- SIR 412 (dealing with solvent analysis and unique IDs) was completed again and sent back to LASEC.
- The Workgroups continued meeting this month to update parts of the Standard.

5.8 Radiochemistry Committee

- The DRAFT Standard is being reviewed by Jan for some glitches and then it will be posted as a DRAFT Standard for comment. This should happen within the next week. The Committee also finalized the list of changes and the justification that will be posted with the Standard.
- The Committee did not meet in September.

5.9 Stationary Source Audit Sample Committee

- A response to the letter to the EPA to request that they reconsider their requirement for two providers has been acknowledged and a response is expected in the next 3 weeks.
- The Committee is working on the update to its three Standard modules.
- Updates were made to SOP 6-101 (SSAS Table Management). Committee members will review the updates for finalization and then it will be sent back to Policy Committee.

5.10 Whole Effluent Toxicity Committee

• The WET Data Interpretation Training will be presented at 2 pm Eastern on October 19. 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 Metrics report did not make it onto the September Board Agenda. It will be reviewed in October. From Justin:

6.2 Field Activities Expert Committee (FAC)

 The Committee worked Volume 2 of the Field Standard – General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations. There was a lot of discussion surrounding whether the Standard needs to be "friendly" to government ABs. Right now there are only NGABs, but Oklahoma has expressed some interest in becoming a NEFAP AB. Concerns were expressed that a state AB cannot meet ISO/IEC 17011 and NEFAP would have to review these concerns just as was done in the LAB Expert Committee. The Committee will continue on this update, but will reach out to some State ABs and NGABs to make sure they look at the DRAFT language and comment. Scott will also invite someone from Oklahoma to join the Committee.

7. NELAP

7.1 Accreditation Council

- Two AB renewals have been approved and a third was presented to the Council on September 7. A
 Three AB renewals have now been approved, two years into the evaluation cycle. A fourth remote
 site visit will need to be rescheduled as an emergency forced its cancellation. At present, one
 application review is well underway, and another is beginning. The EPA Region 2 evaluator has
 changed plans and does intend to complete the evaluator training in time to participate in New
 Jersey's review but does plan to observe the remote site visit. Otherwise, there are four submitted
 applications awaiting review and one yet to be submitted; another renewal request will go out in
 October.
- The Policy Committee's requested revisions to the NELAP Evaluation SOP 3-102 were approved by the Council at its September 7 meeting and have been transmitted to Policy Committee for final approval.
- Jerry met with the Council on October 7 to discuss and fine-tune "Option 3" for what we hope will become qualifications and role of the now-renamed Technical Expert (formerly Technical Manager). This information will be handed off to Quality Systems for its consideration as it revises V1M2.
- There are no changes to the implementation status of the 2016 TNI EL Standard since the September Board meeting.
- The committee charter was revised as requested by Policy Committee and returned for final approval.
- LASEC and CSDEC have agreed to distribute a memo to expert committee chairs advising the use of disclaimer language when discussing SIR responses, and in committee minutes containing "approved" SIR responses, as there are additional steps after expert committee that must be completed before an SIR response is final. As the SIR Management SOP 3-105 with multiple changes is currently undergoing Policy Committee review, this tweak to the language will be added once the feedback from Policy is received on the existing revision.
- 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.

7.2 Laboratory Accreditation Systems Executive Committee

- The committee charter was revised as requested by Policy Committee and returned for final approval.
- LASEC and CSDEC have agreed to distribute a memo to expert committee chairs advising the use of disclaimer language when discussing SIR responses, and in committee minutes containing

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"approved" SIR responses, as there are additional steps after expert committee that must be completed before an SIR response is final. As the SIR Management SOP 3-105 with multiple changes is currently undergoing Policy Committee review, this tweak to the language will be added once the feedback from Policy is received on the existing revision.

• 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**

- The Committee did not meet in September.
- Work on SOP 4-107 (FoPT Table Management) has been completed by the SOP Subcommittee and PTPEC will be looking at it during their October meeting.
- Work on metrics and the Charter has continued. The Committee is hoping to finish up the Charter and vote on it in October.
- 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

- In addressing the comments on its Charter from Policy Committee, Advocacy realized that it needs to become the "umbrella" coordinating group for the outreach efforts of all TNI programs, even as its primary focus is on sustaining and expanding NELAP. Additional revisions to the Charter are being drafted for committee consideration and eventual approval.
- The State of National Accreditation report was sent to all state contacts. This report was sent directly to EPA several months ago, and the state contact list is now available.
- The Fall newsletter should in a week or so, but needs to be timed to coincide with actions for upcoming conferences as discussed in 9.4 and 9.5.

9.2 Policy Committee

• The Internal Audit schedule was finalized for 2022 and a note was sent to Program Administrators to share with their Committees.

Action	Due Date
Update audit checklists	November 15, 2021
Policy review checklists	January 15, 2022
IT posts updated checklists to database	Due March 1, 2022
Internal Audits complete	May 15, 2022
Corrective Action Complete	October 1, 2022

• Review of SOP 3-105 (Standard Interpretation SOP) has been completed and Patsy is drafting an email to return this SOP for further updating. Still needs completion.

- The Committee is continuing to review updated Charters. Many Charters are being returned to the groups to ensure they are specifying Success Measures and not tasks/action items. Most of the Charters are expected back in October, so Policy should be able to finish this process by early November 2021.
- The Committee discussed whether the procedure for how Program Chairs are selected should be consistent between all TNI Programs. For example, the CSDEC Chair is supposed to be appointed by the TNI Board. The NEFAP EC and PTPEC chairs are selected by the Committee members. The Committee is leaning towards making this consistent. Jerry is working on language to describe how Executive Committee Chairs are selected.
- The Committee is continuing review of SOP 1-110 (Educational Delivery System).
- 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 later in October.

9.3 Training Committee

- Training Committee:
 - The Training Opportunities Workgroup has started working on a list of courses for the next RFP expected to go out late November for classes in early Spring.
 - The Credentialing Workgroup made great progress, but it is a small group with limited time to meet. The work of this group will now be incorporated into regular Training meetings.
 - The first monthly training flyer went out in September and there was an increase in registration for training classes.
 - o The Committee completed its Charter, and it will go to the Policy Committee for review.
 - SOP 1-110 (Educational Delivery System) is being reviewed by the Committee.
- Current Classes being worked on:
 - The 8 hour "Basic Statistics for Environmental Laboratories" course has been completed. 34 students attended.
 - How to Properly and Scientifically Calibrate an Analytical System Class dates were switched to October 26th and 28th. Response after the monthly flyer has registrations over 40. A second class on November 3rd and 4th is being discussed and a decision will be made when registrations are at 45. Any further registrations will be for the November class only and people currently signed up in October will have the option to switch to the November class.
 - 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 is scheduled for October 19, 2021. There at least 35 students already fully registered. There are also some 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

• The program is pretty well finalized as shown in the table below. More details are in the draft program provided separately.

Time	Monday: 1/17	Tuesday: 1/18	Wednesday: 1/19	Thursday: 1/20	Friday: 1/21
8-12	Training Courses - Risk-Based - QA Manager	- Mentor Initiative - Asbestos (1/4) - Microbiology (1/4) - FAC	- Assessment Forum: Writing Findings - QS - LAB	- Special Session on Experts*	- Advocacy Committee
12-1	Lunch on Own	Lunch on Own	Lunch Provided	Lunch Provided	
1-5	Training Courses - Risk-Based - QA Manager	1:00 TNI Annual Meeting 3:00 BREAK 3:30 New Initiatives Consumables Wastewater Surveillance	 Mentor Session: Responding to Findings NELAP AC (1/4) LASEC (1/4) Chemistry 	- (PT (1/4) / PTP(1/4) - Training Committee - Committee Reports 4 pm	
5-7		Reception			

*TNI Special Session: Quality and Technical Experts

A Joint Meeting of the Competency Task Force, Training Committee, and Expert Committee Chairs

- 8:00 8:15 Background on the Task Force, Training Committee, and Credentials Subcommittee
- 8:15 8:45 Work by the TNI Competency Task Force on Redefining the Technical Manager
- 8:45 9:15 Work by the Credentials Subcommittee on a Quality Management Systems Expert
- 9:15 10:00 The Concepts of "Credentialed" Experts and Digital Badges
- 10:00 10:15 Break

10:15 – 11:00 Open Discussion of Credentialling Program

- 11:00 12:00 Knowledge, Skills, and Attributes (KSAs) of Assessor, Quality and Technical Experts
- Registration for the Exhibit program has opened up but is going very slowly with only three exhibitors so far.
- Bexar County is still at a high risk, but the positivity is down to 5.6% and the number of cases has dropped to 161/100K down from around 2K in mid-August.



- Registration is schedule to open on October 27 to coincide with newsletter.
- The conference brochure will be emailed and mailed to over 6000 individuals in mid-October.

9.5 2022 Environmental Measurement Symposium

- The Call for Abstracts is complete and should go out late October.
- The Exhibit Program will open on November 1.

9.6 NGAB

• No activity.

9.7 Information Technology

The new on-line system for managing committee membership and applications is now active. The
most visible change to TNI members is that it only allows a member to apply to one committee at a
time. Behind the scenes, it will be used to more effectively manage committee memberships as
described in SOP 1-125 (<u>https://nelac-institute.org/docs/sop-policy/SOP-1-125-Rev0-PolicyCommitteeApp-4-17-20-FINAL.pdf</u>) It will also be used to manage the TNI Internal Audit process.

10. TASK FORCES AND OTHER EFFORTS

10.1 Competency Task Force – Moved to main Agenda

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". A spreadsheet of issues and areas of interest/concern for laboratories regarding the appropriate content of these product certificates is the most recent focus of the Task Force.

Environmental Monitoring Coalition

- EMC received a response from the letter sent to EPA that indicated we would be added to the schedule to meet with Rosemary Enobakhare, Associate Administrator with the Office of Public Engagement and Environmental Education.
- The EMC has received feedback from the NELAP AC on Initial Demonstration of Capability for drinking water methods which suggests the guidance from the drinking water program is not appropriate for any analyte in a laboratory's certificate. EMC will start work on a guidance document on this topic.
- The effort to revise the language in Method 200.8 to allow the use of collision cell technology has evolved to developing a QC specification that could be approved through the Alternate Test Procedure process.
- EMC is very close to finalizing a letter to EPA regarding the use of correlation coefficient in instrument calibration. When finalized, the letter will recommend the approach in the Chemistry Module of the 2016 TNI Standard.

11. MEMBERSHIP

10.3

• 1230 active members

11.1 Committee Applications

• Anagha Chitre; Metropolitan Water District of So.CA – Microbiology (Associate)

11.2 New and Renewed Members:

- Of the 36 expired memberships in July and August, 7 renewed after contact, 21 did not respond, and 8 were no longer at the company and/or the email did not exist. Emails were sent to September expired members on September 7.
- 54 New and Renewed memberships in September

11.3 Expired Memberships

• 21 Memberships Expired in September