

THE INSTITUTE REVIEW A publication of The NELAC-Institute

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Steve Arms, Florida DOH (Retired) Editor in Chief



Article	Page
2022 Environmental Measurement Symposium	3
Summary of the 2022 Forum on Environmental Accreditation	5
2021 Annual Report	8
Meet the 2022 TNI Board of Directors	9
Conceptual Overview and Current Status of the TNI Credentialing Initiative	
Update on Environmental Monitoring Coalition Activities	
Standard Interpretations, Implementation Guidance, and Guidance Documents	14
FDA's Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF) under Food Safety and Modernization Act (FSMA)	
The TNI Laboratory Accreditation Management System (LAMS)	19
TNI Committee Openings	20
Social Media—TNI on LinkedIn	21
Member Spotlight—Catherine Katsikis	22
ChairSpeaks — "Musings from the TNI Chair"	24
TNI Organizational Members	



2022 Environmental Measurement Symposium

By Lara Phelps, USEPA and Jerry Parr, TNI

For the sixteenth year, the Environmental Measurement Symposium (the Symposium), which represents the combined meetings of the National Environmental Monitoring Conference (NEMC) and the Forum on Environmental Accreditation (the Forum), will be meeting at the Hyatt Regency in Crystal City, VA from August 1 - 5, 2022. This year, the Symposium's theme is "Where Do We Go from Here?"

Special advance hotel registration rates of \$159 per night (single or double) can be obtained before July 11, 2022 using our secure on-line registration system.

Some of the highlights for the Symposium are:

- A special half-day general session focused on the conference theme;
- Over 170 oral and poster presentations in the NEMC portion of the Symposium on a variety of cutting-edge environmental monitoring issues;
- Meetings of TNI Committees to further TNI efforts on environmental laboratory accreditation, proficiency testing, and accreditation of field sampling and measurement organizations;
- An exhibit program showcasing the latest innovations in environmental monitoring;
- An Innovative New Technology Showcase;
- Five virtual vendor lunch presentations; and
- Three special keynote presentations on topics of general interest.

All NEMC sessions and TNI meetings are open to all attendees according to your registration. Attendees have the ability to participate in person at the Symposium or to view a recorded version of each session that will be made available shortly after the presentation.

NEMC Technical Program

The NEMC Technical Program is organized into 20 breakout sessions containing 117 oral presentations. There will also be 20 poster presentations. The titles of the presentations, abstracts, and authors can be found on the <u>Symposium website</u>.

- Air Monitoring Methods & Technology
- Analyzing Microplastics in the Environment: Striving to Better Assess Occurrence, Fate and Effects
- Best Management Practices for Environmental Laboratories
- Collaborative Efforts to Improve Environmental Monitoring (Two Sessions)
- Community Based Monitoring and the Role of Citizen Science



Use the blue button below to register your hotel room for \$159/night before **July 11, 2022**.

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2022 Environmental Measurement Symposium cont.



4

- Drinking Water (Two Sessions)
- Environmental Forensics
- High Resolution Mass Spectrometry
- Instrumentation Focus: Reducing Interferences in ICP/MS
- Laboratory Informatics
- Metals Analysis and Remediation
- New Organic Monitoring Techniques (Two Sessions)
- Operational Issues Impacting the Environmental Laboratory Industry (Two Sessions)
- Polyfluoroalkyl Substances (PFAS) in the Environment (Two Sessions)
 - Shale Oil and Gas
 - Wastewater Surveillance State of the Science and Its Uses for Monitoring Public Health

TNI Program

The TNI sessions are meetings of TNI committees and an Assessment Forum and Mentor Session. Details of the TNI meetings can be found at the <u>Symposium website</u>.

- Advocacy Committee
- Asbestos Expert Committee
- Assessment Forum Internal Audits: Bringing Together Assessor Expectations and Perspectives
- Chemistry Expert Committee
- Field Activities Committee
- Laboratory Accreditation Body Committee
- Laboratory Accreditation System Executive Committee (LASEC)
- Laboratory Quality Systems Committee
- Mentor Session The Incredible Journey of Internal Audits Episode 1 How much ground do you need to cover and how?
- Microbiology Expert Committee
- NELAP Accreditation Council
- Proficiency Testing Program Executive Committee
- Training Committee



Summary of the 2022 Forum on Environmental Accreditation By Lynn Bradley, TNI

The 2022 Winter Forum on Environmental Accreditation was held January 17, 2022 in San Antonio, TX. In addition to TNI committee meetings, the following other sessions were held:

- Special session on Proficiency Testing (PT) for Radiochemistry
- TNI Annual Report
- Update on Consumables Task Force
- Update on TNI Mentor Initiative
- Update on the Environmental Monitoring Coalition
- Mentor session "Writing Audit Responses to be Acceptable First Time Through!"
- Assessment Forum "Writing Assessment Findings"
- Special session on Quality and Technical Experts

The presentations from all of these sessions are on the TNI website under <u>Training and Meetings/Past</u> <u>Conferences</u>. Below is a summary of committee activities that took place during the public meeting sessions.

Asbestos Expert Committee

The Response to Comments document for the Draft Standard was reviewed during the meeting. Feedback was received from the audience on two items which were shared with the Chair and Program Administrator for their follow-up. Persuasive comments will result in a next revision of the Draft Standard.

Chemistry Expert Committee

The Committee reviewed many Standard Interpretation Requests (SIRs), and there were problems in completing the process with some of them. Module 4 was reviewed, and items that may need modifying were identified for possible update. Audience feedback was invaluable during the session for such items.

Laboratory Accreditation Body Expert Committee

The Response to Comments document for Volume 2 Module 1 was reviewed, specifically looking at comments that have not yet been determined to be persuasive or non-persuasive. Comments have been received, including some that are global, editorial changes. There will be an additional revision to the Draft Standard, which will result in an additional posting and public comment period. Aaren Alger is the incoming Chair of the Committee. The goal is to have the revision of the Standard ready by the time of the Crystal City conference. Assessor training comments (i.e., education/experience, additional training, Basic Assessor Training, written exams) are among the items requiring resolution.

Quality Management Systems Expert Committee

A summary of the three Work Groups' work was discussed. The Definitions Work Group has updated definitions of terms to be included in the Standard (i.e., annual, quarterly) as well as some that may not be included. This Work Group is also cognizant of additional work being done on the Glossary. The Language Work Group was assigned certain portions of the Standard that may be more problematic. They are working on language in a smaller group that will then come back to the whole Committee for consideration. The ISO 17025 Work Group compared language found in ISO 17025:2005 to ISO 17025:2017. While certain requirements are

Summary of the 2022 Forum on Environmental Accreditation cont.



no longer stated in the 2017 version, the group is verifying whether or not there is any language in the 2005 version that we may want to keep. One SIR was also reviewed, and a response prepared.

Radiochemistry / Special Session

There was a good turnout Tuesday morning. The consensus is that there isn't a concern about reporting uncertainty on PT samples. ABs would not need to score the results, and everyone seems to be agreeable to that plan. There needs to be a discussion with the Accreditation Council (especially those with radiochemistry interests) to be certain that there is no concern.

LASEC

The committee reviewed its 2021 results and 2022 goals. They talked about tracking for SIRs including using the SIR number online to make things easier to track. They are prepared for any SIRs related to ISO 17025 (it shouldn't be an issue since there have been such requests previously). They're streamlining their SOP, focusing especially where interpretations relate to disputes. Previous discussions have indicated that SIRs resulting from disputes would be rejected. This has been clarified on the website; the timeline for the process isn't fast enough to resolve a dispute. The committee is interested in clarifying the timeline on SIR responses. They want a streamlined approval process for the SIRs that seem to result in more back and forth discussion among the various committees. This needs to be reflected in the SOP.

Accreditation Council

The Council members each reviewed their (1) current operational status related to the pandemic; (2) their implementation status for the 2016 TNI Standard; and (3) their status related to the 2021 EPA Method Update Rule. The Council also discussed updates to LAMS, especially as it relates to the timeframe for updates. They would like a combined meeting with LASEC to discuss SIRs in Crystal City. Kristin Brown, Chair, offered a thank you to all who participated - this was a good job, as always. This is a great chance to learn and share knowledge among all.

Proficiency Testing Program Executive Committee

Subcommittee reports were provided as well as a review of the SOP.

Proficiency Testing

The committee recapped its 2021 accomplishments and discussed its 2022 goals. The Notice of Intent to modify their Standards has been approved. They offered their proposed changes for the PT standard and sought feedback. The chief complaint among both the laboratories and the accreditation bodies is that confusion over the method codes causes issues with reporting data, choosing the correct method, and uploading data.

Summary of the 2022 Forum on Environmental Accreditation cont.



7

Microbiology

The committee presented the formal comments on the revised standard. They went through the work that has been done so far on addressing those comments. They sought additional feedback for later work on the draft standard. They also had audience input on microbiology training that they would like to see or have the committee address. The commitment worked on an SIR response and finalized it via e-mail the next day. The committee needs AB members especially. The meeting in Crystal City would be dealing with comments from the draft standard as well as possible training ideas. Jerry asked if the training would be ready for August. Cody replied that it might be – that is the goal. Feedback from participants was for more in-depth training at shorter session-length.

Assessment Forum

The forum went incredibly well. Similar good feedback was received using the findings, the severity and the terminology differentiations that were described. There was great audience participation. If we could to keep the ABs in the room, it would give even better participation in the forum and add credence to the responses provided. The forum organizers would like their session to not be scheduled at the same time as Quality Systems, Chemistry, or Microbiology to aid in that possibility. Pairing the Assessment Forum with the mentor session went really well.

Mentor Session

There was an intentional pairing of the assessment forum and mentor session to tie the two sessions together. That obviously went very well. Approximately 40 were in attendance for the mentor session. As mentioned with the Assessment Forum, the Mentor Session needs AB participation. We would fill whatever time is available.

Training Committee

The committee presented its 2021 accomplishments and 2022 goals. Discussion revolved around the concepts of digital badges or credentialing. Both were considered useful, and there was agreement among the attendees that the committee should pursue both options. Additional discussions revolved around possible training courses. Specific Knowledge, Skills, and Abilities were discussed and what training might fall underneath each type. There was also a discussion of what courses may be needed for future goals of the organization.

Competency Task Force

There was a clear directive to move toward the technical expert concept and away from the technical manager concept. Requirements for credit hours of courses would be removed and this would be turned over to the Quality Systems committee. The task force is finished with this issue. Credentialing and digital badges also met with approval and needs to be presented to the TNI Board for funding approval.



2021 Annual Report

By Jerry Parr, TNI

In December each year, every TNI committee is requested to prepare a brief summary of Accomplishments from the current year and Objectives for the next year. The TNI Executive Director combines these summaries into one PowerPoint presentation and then adds in other significant accomplishments.

This presentation is presented to the Forum on Environmental Accreditation attendees during a general session at the conference. A copy of this presentation is also made available to the public on the Previous Conferences webpage.

Subsequently, the TNI Executive Director combines all of the Monthly Program Administrator Reports into one document and then edits this to prepare a summary of activities. The Objectives from the annual meeting presentation are then added in. Additionally, the following items are included:

- A listing of all Policies and SOPs developed and approved.
- A listing of all Training Courses developed.
- A Laboratory Accreditation Management System (LAMS) report containing demographics including the number of accredited laboratories and Field Sampling and Measurement Organizations (FSMOs), the number of analytes and method codes, and an appendix listing all new analyte and method codes generated during the year.
- A list of all individuals who rotated off as Committee Chairs and a list of new Committee Chairs.
- A membership report showing the total number of members and the number of committee applications.
- A financial report (Statement of Activities).
- An appendix containing a roster for every committee and task force.

The 2021 report was provided to the Board for its review and approval to empower each committee's Work Plan for the upcoming year. Click here for the TNI 2021 Annual Report.



Meet the 2022 TNI Board of Directors

By Sharon Mertens, TNI Past-Chair

As reported to you in the last newsletter, elections took place in January and February. The newly elected directors assumed office on March 9 during the Board's regularly scheduled monthly teleconference.

The Nominating Committee, which this year consisted of Sharon Mertens, Catherine Katsikis, and Aurora Shields, reviewed the qualifications of each nominee and assembled the ballot for voting by the TNI membership. In addition to reviewing qualifications, the Nominating Committee must ensure that the board retains balance and representation from all recognized stakeholder groups.

This year's ballot contained eight candidates. This included four returning Board members – Steve Arms, Stacie Crandall, Judy Morgan, and Alfredo Sotomayor, who were willing to serve another term. The other four positions have been filled by new directors – Caitlin Brice from SGS North America, Robin Cook from the City of Daytona Beach, Harold Longbaugh from the City of Houston Drinking Water Operations, and Valerie Slavin from Pace Analytical.

Eighty-four of our approximately 1100 members cast votes, and all the candidates were elected by at least 90% affirmatives.

The collective length and breadth of experience of the members of the current TNI Board is impressive and should serve us well as we go forward as an organization. Follow the link below, click on the Members section, and hover over each name to read a brief bio on each of the directors.

After the introduction of the new Board members at the March meeting, the Board also held its annual election of officers, which include the Chair, Vice-Chair, Secretary, and Treasurer. These were all filled by the incumbents – Alfredo Sotomayor as Chair, Kristin Brown as Vice-Chair, Justin Brown as Treasurer, and Patsy Root as Secretary.

TNI Board of Directors Committee/Bios



Conceptual Overview and Current Status of the TNI Credentialing Initiative

By Ken Brown; City of Escondido, CA

In April 2020, the TNI Board of Directors chartered a Competency	In the November 2021 issue of <i>The</i>
Task Force to "Explore and make recommendations regarding	<i>Institute Review</i> , Aaren Alger wrote an
programs to document competencies for Quality Managers,	article on <i>Reimaging the Technical</i>
Technical Managers, Assessors, Samplers, and others as appropriate.	<i>Director/Manager Position</i> . This was a
Note: Such documentation could involve credentialing and/or digital	result of a separate activity of the
badges."	Competency Task Force.
Conceptually, TNI would set up credentialing programs to certify	This topic was further deliberated at
individuals for key functions such as a Quality Manager, a Laboratory	the San Antonio meeting and minor
Assessor, or a Technical Expert. In all cases the program would	adjustments were made to the
contain these key elements:	proposed changes.
 Awarding the Certificate with minimum requirements for	The Task Force has handed this issue
education and/or experience and passing a comprehensive	off to the Quality Management System
exam.	Committee to finalize for the next
 Derivative recordification based on continued employment in 	version of Volume 1, Module 2 of the

Periodic recertification based on continued employment in the field and some minimum number of professional development hours annually.

S TNI Standard.

Training courses made available to assist with the initial certification and/or recertification, but not required.

Professional development hours would be awarded for such activities as participation in a professional society, preparing publications and/or presentations, attending training courses, or attending meetings.

An alternative pathway for credentialling could be the "digital badge" approach. Under this option, individuals would take specific courses and then earn a digital badge after passing an exam. An example might be a Data Integrity Specialist who would be awarded the badge after taking TNI's course, "Ethics Training for the Environmental Professional." If the individual then earns enough digital badges, the individual could be credentialled as a Quality Management Systems Expert.

Currently, the Task Force has identified 13 potential digital badges that could lead to this credential:

- 1. Proficiency Testing (PT) Specialist
- 2. Data Integrity Specialist
- 3. Document Control Specialist
- 4. Customer Service Specialist
- 5. Measurement Traceability Specialist
- 6. Corrective Action Specialist
- 7. Records Specialist
- 8. Internal Audit Specialist

THE INSTITUTE REVIEW May 2022 TNI Credentialing Initiative cont.



- - 9. Method Validation Specialist
 - 10. Calibration of Support Equipment Specialist
 - 11. Sample Handling Specialist
 - 12. Quality Control Specialist
 - 13. Data Handling and Management Specialist

The Task Force is working to develop this concept into a plan to present to the TNI Board of Directors later this year. If you are interested in participating, please contact the Task Force Chair, Ken Brown at <u>kbrown@escondido.org</u> or Lynn Bradley at <u>lynn.bradley@nelac-institute.org</u>.

2



Update on Environmental Monitoring Coalition Activities

By Jerry Parr, TNI

The Environmental Laboratory Advisory Board (ELAB) was established in 1995 by EPA to provide advice, information, and recommendations on enhancing EPA's measurement programs and facilitating the operation and expansion of a national environmental accreditation program. Over the time of its operation, ELAB produced over 30 reports on a variety of topics relating to environmental measurements. ELAB was disbanded on October 17, 2019, as part of the Trump administration's Executive Order 13875, Evaluating and Improving the Utility of Federal Advisory Committees.

To address this void, the four organizations listed below agreed to form the Environmental Monitoring Council (EMC) to continue the mission of ELAB and to expand its outreach to states as well as to EPA.

- American Council of Independent Laboratories
- Association of Public Health Laboratories
- The NELAC Institute
- Water Environment Federation

The mission of this new organization is to *"work cooperatively on environmental monitoring issues."* More details can be found on the <u>EMC website</u>. This article was written to highlight some of the accomplishments of EMC over the last 6 months. The three documents discussed below are all on the EMC website.

Guidance on the Initial Demonstration of Capability for Drinking Water Methods

Most EPA drinking water methods require that laboratories conduct an Initial Demonstration of Capability which includes verifying that the Half Range Prediction Interval of Results (HR_{PIR}) for all analytes is within limits published in the method. This requirement has proven difficult to meet for methods which contain many analytes. EMC discussed this issue with the EPA drinking water program and EPA indicated the requirement should only be only required for *regulated* drinking water analytes, not all analytes in the method.

EMC then reached out to all state accreditation/certification bodies to see if this would be an acceptable approach. The states strongly disagreed indication that any analyte on the laboratory's scope of accreditation must meet method requirements. EMC agreed with this conclusion and developed a guidance document on the topic.

The guidance document recommends laboratories who fail to meet the criteria follow the corrective action and root cause analysis as described in the TNI standard.

Guidance on Instrument Calibration

Many environmental test methods allow for the use of correlation coefficient (r) and/or coefficient of determination (r^2) even though this has been proven to be inappropriate. EMC developed a guidance document on this topic which contained data showing calibration curves with a R² of 0.999 could have calibration errors s high as 11,260%. The guidance recommends all method developers cease using R or R² to evaluation calibration curves and instead use the relative error or relative standard error as described in the 2016 TNI Standard.

THE INSTITUTE REVIEW May 2022 Environmental Monitoring Coalition Activities cont.



This guidance document was provided to EPA's Environmental Methods Forum, Standard Methods, and ASTM International. A meeting was then held with EPA to discuss removing R and R² from all EPA methods, especially SW-946 and the wastewater methods promulgated in 40 CFR Part 136. Although EPA supports this change generally, they indicated it could take time to make these changes due to their regulatory processes.

Evaluating Preservation and Holding Times for Acrolein and Acrylonitrile in Aqueous Matrices

In 40 CFR 136, Table II and Table 4-1 in SW-846, the EPA established aqueous sample preservation and holding time requirements for acrolein and acrylonitrile that differ significantly from those of other volatile organic compounds that are measured by the same EPA method, either Method 624.1 or 8260D.

The need to employ different sample preservation methods for these analytes results in a significant reduction in productivity for the laboratory community. It requires that samplers and laboratories collect and handle separate samples for these two analytes rather than being able to use the same sample for all the needed method 624.1 and Method 8260 analytes. Current regulatory requirements for acrolein and acrylonitrile specify that samples be preserved to a pH of between 4 and 5 and be analyzed within 14 days. For most volatile organic compounds in water, samples are preserved to pH \leq 2 and analyzed within 14 days. In addition, preserving samples to a pH between 4 and 5 is virtually impossible to achieve in the field without compromising the sample volatiles so samples are commonly over or under preserved.

The EMC designed a study to evaluate both preservation and holding times. Samples were collected from six (6) sources representing matrices of interest in the Clean Water Act (CWA) and Resource Conservation and Recovery Act (RCRA) programs. Three laboratories were involved in performing the testing. Upon arriving at the laboratory, an aliquot of each sample was analyzed to determine the "native" level of acrolein and of acrylonitrile and to determine other chemical and physical properties of the water samples.

The remaining samples of each matrix were then split into three 2-Liter aliquots. One aliquot was immediately preserved with 1:1 HCl to pH \leq 2.; one preserved with 1:1 HCl to a pH of 4.0 – 5.0; and one aliquot was left unpreserved. Each type of preservation was then analyzed in quintuplicate (number of replicates = 5) on Days 0, 3, 7, 10 and 14 using EPA Method 624.1.

The report published by the EMC demonstrated that using pH \leq 2 preservation for samples to be analyzed for acrolein and acrylonitrile is clearly better than the currently required pH 4 – 5 preservation, and that there is no need to have different requirements for these two analytes. This report also shows that samples that are not acidified can provide unacceptable results for acrolein much shorter than the current 3-day holding time.



Standard Interpretations, Implementation Guidance, and Guidance Documents

By Maria Friedman, Chair, LASEC

TNI committees strive to create standards that are clear and unambiguous. Even so, in a field as complex as ours, there may still be requirements that are not easily understood or that could be interpreted in different ways.

To address those situations, TNI has long maintained a process whereby questions about a standard can be submitted to TNI to obtain an official interpretation. In addition, for questions that may not be suitable for the interpretation process, TNI provides two additional resources: Implementation Guidance and Guidance Documents.

Standard Interpretations

A Standard Interpretation is an official explanation of specific questions related to a section or provision in a standard, where the language of the standard is not clear. Standard Interpretations are created in response to a Standard Interpretation Request (SIR), which is generated when a stakeholder submits a request via the TNI website for TNI to interpret a specific section of a standard.

After an SIR has been submitted, the LASEC Program Administrator receives the submission and forwards it to the LASEC Chair and NELAP Accreditation Council Chair to determine whether it is appropriate to be processed as an SIR. Due to the time and effort required by committees to evaluate and respond to an SIR, several factors are considered to ensure that the issue raised in the SIR is valid for interpretation. Among these factors are the following:

- 1. The SIR should contain only one question;
- 2. The SIR should apply directly and clearly to a cited section of the Standard;
- 3. The SIR can be understood without supposition;
- 4. The SIR is compelling, i.e., the language used in the Standard(s) section cited is not clear or might have more than one interpretation; and
- 5. The SIR is not a "how to" question or a request for a method interpretation.

Standard Interpretations Published To Date

> 2003 NELAC Standard: 67 2009 TNI Standard: 45 2016 TNI Standard: 20

It is important to note that SIRs may not be submitted to resolve a dispute between a laboratory and their Accreditation Body (AB) regarding accreditation issues. Such disputes must be resolved through the appropriate appeals process established by applicable state laws and regulations.

Standard Interpretations are written and approved by the expert committee responsible for the module of the standard in question and subsequently undergo review and approval of the SIR Subcommittee of LASEC and then the NELAP Accreditation Council before they are published on the TNI website.

THE INSTITUTE REVIEW May 2022 Standard Interpretations, Implementation Guidance, and Guidance Documents cont.



SIR submissions that are not valid for interpretation may instead be treated as clarification requests. Such submissions may be addressed with "Implementation Guidance" as discussed below. Whether processed as an SIR or not, the LASEC Program Administrator notifies the submitter of the outcome of their request.

Where to Find Standard Interpretations

Standard Interpretations are available on the <u>TNI website</u>, and TNI membership is not required in order to view. Standard Interpretations are organized by applicable Standard, with the top-most folder containing a combined list of interpretations from the 2003, 2009, and 2016 TNI Standard. The combined list applies to the 2016 TNI Standard.

In addition, you may subscribe to a mailing list to receive an email whenever a new Standard Interpretation is made available. Add your name to the list and stay informed!

Implementation Guidance

Implementation Guidance (IG) are documents approved by the LASEC to explain best practices for problemsolving or basic laboratory activities typically in response to questions submitted for interpretations that cannot be addressed adequately by that route. IG documents are brief, address one relatively small topic, and are entirely separate from Guidance Documents (see below) that are typically prepared for broader issues related to understanding the actions required by the Standard.

There are currently 37 topics addressed by IG, ranging from the simple to the complex. Here are some examples of the questions answered by IG:

- 1. For microbiology, if purchased vessels are used which contain the required amount of sodium thiosulfate, is a test for chlorine residual done in the field sufficient?
- 2. During data review (or internal audit) it is found that analysts have been utilizing an expired standard. What responses are needed?
- 3. What approach is acceptable to demonstrate matrix effects on field samples when the laboratory is not provided with sufficient sample volume to perform an MS/MSD with the sample batch?
- 4. The weekend staff recalibrated an instrument on Saturday and ran samples following the calibration curve. Weekday staff came in on Monday and loaded the prior calibration to process Friday's samples. They failed to reload the Saturday calibration curve back to the instrument, and all subsequent data for the next month was processed and reported with the old calibration curve. How could this have been discovered? What course should the investigation take? What should be done to correct the situation?

Where to Find Implementation Guidance

IG is available as a benefit to TNI members only. To view, log in to the TNI website with an active TNI Member account. Go to the <u>Standard Interpretations, Implementation Guidance, and Guidance Documents</u> page and look for the folder labeled "Implementation Guidance."

THE INSTITUTE REVIEW May 2022 Standard Interpretations, Implementation Guidance, and Guidance Documents cont.



Guidance Documents

Guidance Documents are prepared by TNI committees to help users of the standard better understand and implement a standard in their laboratory. These documents are neither intended to be an official interpretation of a standard nor are they to be used in place of a standard.

Three Guidance Documents are currently available:

1) TNI V1M1 2016 Standard Update Guidance on Proficiency Testing Reporting Limit (PTRL)

This document provides guidance on the evaluation and reporting of proficiency test sample results to the PTRL for conformance with the 2016 TNI Standard Volume 1 Module 1 (V1M1), Proficiency Testing. This document does not discuss all sections of V1M1, only those pertinent to PTRL.

2) TNI Guidance on Instrument Calibration

This document provides guidance on the instrument calibration section (1.7) of the 2016 TNI Standard Volume 1 Module 4 (V1M4), Quality Systems for Chemical Testing. This document focuses primarily on those parts of Section 1.7 which have changed substantially with the 2016 TNI Standard.

3) TNI V1M4 2016 Standard Update Guidance on Detection and Quantitation

This document provides guidance on the detection and quantitation section (1.5.2) of the 2016 TNI Standard Volume 1 Module 4 (V1M4), Quality Systems for Chemical Testing. This guidance is written as a set of procedural recommendations that will allow the requirements of the Standard to be met in a relatively productive and efficient manner.

Where to Find Guidance Documents

Guidance Documents are available as free PDF downloads; TNI membership is not required. . Go to the <u>Standard Interpretations, Implementation Guidance, and Guidance Documents</u> page and look for the folder labeled "Guidance Documents."



FDA's Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF) under Food Safety and Modernization Act (FSMA)

By Patsy Root, IDEXX Laboratories

On December 1, 2021, the FDA published the final Food Safety Modernization Act (FSMA) rule on Laboratory Accreditation for Analyses of Foods (LAAF) that establishes a laboratory accreditation program for the testing of food under specific circumstances. LAAF does not pertain to routine testing under FSMA and is a voluntary program for accreditation bodies (ABs) and laboratories. Under the LAAF program, the FDA will recognize ABs that will accredit laboratories to the standards established in the final rule (to be called LAAF-accredited laboratories).

The goal for the LAAF program is to improve the FDA's capacity to protect U.S. citizens from unsafe food by improving the accuracy and reliability of certain food testing, by creating uniformity of standards, and through enhanced oversight of participating testing laboratories.

The final LAAF rule does not apply to all food testing. Food testing, including environmental testing, is required to be conducted by a LAAF-accredited laboratory and will only occur under certain circumstances that are specified in the rule.

The requirements for an AB that wants to participate in the LAAF program are not overly extraordinary. An AB seeking to participate in the LAAF program must be a full member of the International Laboratory Accreditation Cooperative (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA). The AB must demonstrate competency to ISO/IEC 17011:2017(E) with the scope of "Testing: ISO/IEC 17025." The LAAF final rule also includes certain conflict of interest requirements beyond what is included in ISO 17011, e.g., generally an accreditation body may not own or have a financial interest in, manage, or otherwise control any laboratory (or any affiliate, parent, or subsidiary) that it may accredit to LAAF.

The LAAF program does not apply to routine testing under FSMA or the Produce Safety Rule. When the LAAF rule is implemented, owners and consignees will be required to use a LAAF-accredited laboratory for testing under these conditions:

- To support removal of a food from an import alert through successful consecutive testing requirements.
- To support admission of an imported food detained at the border because it is or appears to be in violation of the Federal Food, Drug, and Cosmetic Act.
- Required by existing FDA food safety regulations, when applied to address an identified or suspected food safety problem (i.e., certain tests of shell eggs, sprouts, and bottled drinking water).
- Required by a directed food laboratory order, a new procedure being implemented in this final rule that will allow FDA to require use of a LAAF-accredited laboratory to address an identified or suspected food safety problem in certain, rare circumstances.
- Conducted in connection with certain administrative processes such as testing submitted in connection with an appeal of an administrative detention order.

THE INSTITUTE REVIEW May 2022 FDA's Final Rule cont.



On February 11, 2022, the FDA launched the <u>LAAF application portal</u> and <u>User Guide</u> where accreditation bodies can apply for recognition under this program. Once the FDA has recognized a sufficient number of accreditation bodies (TBD), the Agency will announce that laboratories may apply LAAF recognition using the recognized ABs. When there is sufficient LAAF-accredited laboratory capacity for the food testing covered by the final rule, the agency will publish a document in the Federal Register giving owners and consignees 6 months' notice that they will be required to use a LAAF-accredited laboratory for such food testing.



For more information you can visit SMA Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF).

You may contact FDA directly with questions about the LAAF program at this email address: <u>Questions about LAAF Program</u>.



The TNI Laboratory Accreditation Management System (LAMS)

By Mei Beth Shepherd, Shepherd Technical Services and Dan Hickman, TNI

The Laboratory Accreditation Management System (LAMS) is a powerful tool that you should know about so that you can more easily get the information you need. If you need to know which laboratories analyze for PFOA/PFAS in a certain state, look no further than the LAMS.

This database contains laboratory and field of accreditation data from all of the state and non-governmental Accreditation Bodies (ABs). Anyone can query the database to get information about laboratories and the method/matrix/analytes for which they are accredited. The ABs are required to update their information regularly, so be assured you are getting current listings.

The LAMS also contains lots of information on matrices, technologies, methods, and analytes. The database provides links to the actual method documentation as long as it isn't proprietary (ASTM/Standard Methods). TNI has worked hard to include as much metadata about each method as possible, such as the date of approval and whether the methods are approved for use in certain EPA programs like drinking water and wastewater. If you want to update your LIMS with the most current method and analyte codes, LAMS allows you to download these tables as CSV files.

If the method or analyte code that you want/need is not currently available, you can request one using the links found on the bottom of the left sidebar. Our LAMS team is typically able to respond to these requests in just a few days.

Take some time to get familiar with the LAMS database by clicking the large brown button on the <u>TNI home</u> page at or by following this link to the <u>TNI LAMS webpage</u>. You'll be glad you did!



TNI Committee Openings

By Paul Junio, TNI

TNI is composed of an awesome group of volunteers. Among the things we do as volunteers is to serve on committees. Some of these committees are Standards Development committees. Others are Administrative committees. All are important to the overall success of the organization.

All TNI members are welcome and encouraged to apply to join a committee. The application is found on the TNI Member Page (that little button in the upper right corner of the <u>TNI website's homepage</u>). From there, there is a link to 'Join a Committee' under the Member Benefits listing. In order to help us track our associate committee members (since Associate Members are frequently asked to become voting committee members), we have added the ability to choose to be an Associate Member at that link. If you are interested, but still have questions, feel free to contact me by email at <u>paul.junio@pacelabs.com</u>, and I will help where I can.

TNI is actively working to make sure that committee openings are adequately publicized and as attractive as possible, and the Advocacy Committee is considering several concepts. In terms of publicizing, we already often talk about committee openings at our semi-annual conferences, and this might be re-emphasized. Since many of our volunteers appear at other conferences around the country, it may be advantageous to publicize these opportunities. We might be able to add incentives to becoming a committee member by offering things like an extension of the volunteer's membership term in TNI. We also may help new TNI members find volunteer opportunities by asking in which committee(s) they might have an interest or by assigning a mentor/buddy to new members who have expressed an interest.

TNI thrives only through its volunteers. If you have suggestions about how we might improve our recruitment and retention processes, please contact Steve Arms, the Advocacy Committee chair, at arms.steve@comcast.net.



Social Media—TNI on LinkedIn

By Jerry Thao, Pace Analytical Services

TNI is now live on LinkedIn!

Through the use of a social media platform like LinkedIn, TNI can stay connected with members, as well as share updates with the environmental community on a global scale. Content that can be shared on LinkedIn include, but are not limited to:

- Committees (ex: mission of a Committee, how to join a Committee, and new projects or initiatives);
- Conferences (ex: registration information, program details, highlights from a conference and future conferences);
- Personnel (ex: new chair elected to serve in a Committee or on the Board of Directors, along with a brief biography);
- Training (ex: new training events, types of trainings, and training opportunities, including RFPs); and



• TNI Standards (ex: proposed changes, public comment periods, how to submit requests for Standards interpretation, and when a new Standard is finalized).

The amount and type of content that TNI can share is immeasurable—these are just a few examples.

If your Committee would like to share content (information/news/events/updates) through TNI's LinkedIn page, please send it my way! At minimum, please include the following information when submitting a post request:

- Committee Name
- Information for the post
- If available and/or applicable:
 - Photo(s)
 - Video clip(s)
 - External link(s)

Requests can be submitted to me via e-mail at <u>Jerry.H.Thao@outlook.com</u>, referencing "TNI – LinkedIn" in the subject line. Please don't hesitate to reach out with any questions.

Go like, share, and follow TNI on LinkedIn at: <u>https://www.linkedin.com/company/the-nelac-institute</u>!



Member Spotlight—Catherine Katsikis

Catherine graduated from Teachers Training Institute, Athens, Greece, with studies in Chemistry/Laboratory Supervision. She was interested in photography and worked in photo shops throughout her education beginning in high school. She began her chemistry career in Brooklyn, New York, where she worked at Argus Chemical Corp (a WITCO Division) as the Physical Testing Lab and Plastisol/Polymer/Stabilizers Supervisor for eight years.

Catherine was born in New Jersey and lived most of her early life in the New York area. Her family moved to Ft. Lauderdale in 1989 to open an art gallery. Unfortunately the tourist-based economy was affected by the Gulf War and Catherine returned to her passion, the laboratory.

Catherine found employment in Savannah Laboratories and Environmental Services, Inc. where she eventually became the Metals/Inorganics and Microbiology Supervisor. She continued her career at VOC Analytical Laboratories, Inc., ultimately being offered the QA Director's position for the national-based lab. The lab later became US Biosystems, Inc. where Catherine remained the QA Director managing six QA Officers until 2006. During this time, she, like most others in the industry sought out opportunities to further her knowledge and education regarding QA practices, while also promoting quality in both the lab and the field in private and public organizations.

In 2007, Catherine was approached by Rich Amano and Julio Paredes to join their team in Florida supporting the Everglades Restoration Project. This was a turning point in her life and career; she joined Laboratory Data Consultants FL, Inc. (LDCFL, Inc.) as a Senior Scientist. When Julio Paredes retired in 2017, he offered the company to Catherine. She is presently the President and Principal Scientist for LDCFL-NAOS Consulting, LLC.

Through the years Catherine has been a speaker, officer, and member of several professional organizations. Catherine considers herself lucky that early in her QA role she encountered Dr. Carl Kircher, Silky Labie, and Alfredo Sotomayor, of whom impressed on her the importance of Quality Management.

Why do you support a National Environmental Laboratory Accreditation Program?

"During a conference in Tampa there was talk in the hallways about the Institute for National Environmental Laboratory Accreditation (INELA). I signed up on the spot and have not stopped promoting the National Environmental Laboratory Accreditation Program since.

As QA Director of a national lab with multiple state and federal certifications the idea of reducing the number of audits every year was extremely appealing. Consistency in auditing, even within the same organization, was another issue the labs were facing at the time.

As a consultant, auditor, and a data validator I saw the importance of consistency in data quality when making data usability decisions. Basing the TNI Standard on the ISO Standard also enables the data and metadata to be comparable and usable at an international level.

Finally, I can say that in my experience I have seen a significant improvement for the labs that are under the program not only at the analytical level, but also in the understanding and accountability of the analysts and management."

THE INSTITUTE REVIEW May 2022 Member Spotlight—Catherine Katsikis cont.



Catherine is currently a Florida Society of Environmental Analysts (FSEA) Professional Relations Committee chair as well as member of the Host and Program Committee. She is a Board member in the Florida Section of the American Water Resources Association and a member of the TNI Training and Nominating committees. She recently rotated off the TNI Laboratory Accreditation Body Expert Committee where she remains an associate member. She enjoys traveling, history, genealogy, art, music, theater, movies, architecture, reading, and Disney.

She remarked, "Being part of TNI has been a valuable professional and personal experience. Every conference brings innovative ideas and education along with fun excursions in the area where we are meeting. (Shout out to Michael Michaud!) The last few years during my health challenges, the outreach from colleagues has been remarkable, and I am humbled and grateful for their prayers and support. This year I am slowing down to work on a testimonial book, starting a Ministry, and, God willing, happily expecting to be a first-time grandmother in April!"



Dream come true of hugging a Scottish cottage 2014



ChairSpeaks: "Musings from the TNI Chair"

Authenticity or To Be Real

You are, or you are not. You are one of us, or you are not with us. I am with you now because of what it may get me in the short term, or I am not with you because of the long-term consequences. This is so antithetical to the way we operate.

The search for authenticity...Anatomized, that pursuit strives for harmony, aligning one's principles with those of a stable construct, or in contrast, when bastardized, an all-out fight to get others to believe baseless alternatives.

These times demand a critical understanding of what is and what is not. When "fake" becomes a broad label for an enticing "not real", "not true", or when universally held truths are questioned for the sake of ideological convictions, the world becomes too faceted to make sense of the everyday, an excuse, or a directed attempt to make us doubt gravity.

And this is where our core values, our mission, come so critically into play. When in doubt, go back, openmindedly, to the founding principles.

Mission

This is the core of our mission, without the legalese, and with some emphasis of my own.

TNI is a 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.

And these words, quoted on our website, complement our stated mission:

"TNI has a clearly stated mission and purpose, approved by the Board of Directors, **in pursuit** of the public good. All of its programs support that mission and all who work for or on behalf of the organization understand and are loyal to that mission and purpose. The mission is responsive to the constituency and communities served by the organization and of value to the society at large." [Emphasis is mine again.]

True to the Cause

This is how we can remain authentic, by constantly referring back to our mission.

We are open because we welcome wide-range participation from the environmental community. We facilitate all viewpoints and styles, and actively communicate about our proceedings and decisions, so that TNI's

THE INSTITUTE REVIEW May 2022 ChairSpeaks — "Musings from the TNI Chair" cont.



operations can be pieced intelligibly by all, not just our members.

Check out, for corroboration, our website for records of what our committees discuss and decide.

Is TNI an Authentic Organization?

Authenticity may exist without transparency, but transparency documents whether an organization can truly claim to be authentic. Sincerity is just not enough. Intentions are not sufficient when authenticity is demanded. Transparency transcends executive privilege and convenience.

Yes, TNI is an authentic organization. We believe in transparency. Our consensus model for developing standards favors disclosure. Consensus implies that no one faction can derail legitimate opposition, or that a loud voice in the steppes can collapse years of convivial compromise. It is not that we go with the flow all the time. It is that as we evolve we consider all views, and as we move with the changing times, we consistently remain cognizant of our mission and core values.

What Now, My Love?

We must continue to refine our modes of operation, and our means for sustainability, so that we do not end up catacombic, artifacts in the present, or quaint historic references in the future. As we do that, we must continue to remain true to our mission, for only that desire to accomplish what may always be one inch away from being completely achievable, is what gets us motivated, chugging along. It is that sustained effort that is the best measure of our authenticity.

Only connect.

Alfredo

Alfredo Sotomayor TNI Chair



26

TNI Organizational Members

We are grateful for the generosity of the organizations that have joined us as members:

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A2LA WorkPlace Training Advanced Systems, Inc. Analytical Excellence, Inc. CHEMTECHNIQ, LLC ChemVal Consulting ddms, Inc. **Environmental Laboratory Consulting and** Technology Labtopia Solutions, Inc. LDCFL-NAOS Consulting, LLC Meadows Lab Fundamentals Miller Quality Consulting NV5/Dade Moeller Quality Assurance Solutions, LLC SAW Environmental Shepherd Technical Services, LLC The Markay Consulting Group LLC William Ray Consulting LLC

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THE INSTITUTE REVIEW May 2022 Organizational Members cont.



PATRONS

A2LA

ANSI National Accreditation Board (ANAB) City of Phoenix Lab Services Div. City of Santa Cruz Florida Dept of Health ELAP Illinois EPA International Accreditation Service Kansas Department of Health and Environment Louisiana DEQ / OES Minnesota DOH New Hampshire ELAP New Jersey DEP - OQA New York City DEP New York State DOH Oklahoma DEQ **Oregon Health Authority** Pennsylvania DEP Perry Johnson Texas Commission on Environmental Quality Utah Dept. of Health Virginia DCLS

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