

The Institute Review

The NELAC Institute

First Quarter 2008



Special topics of interest:

- *NELAC officially dissolved* (page 1)
- *Meeting dates set through 2010* (page 2)
- *Do you know what ACIL, CSDP, and NACWA stand for? Check out the list of frequently used acronyms* (page 4)
- *New Feature: Member Spotlight* (page 5)

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Jerry Parr
Editor, *The Institute Review*



TNI Newsletter Re-established

At the January meeting in Newport Beach, California, The NELAC Institute (TNI) decided to re-establish its newsletter. The TNI Advocacy Committee, whose purpose is to promote a national program for the accreditation of environmental laboratories, assumed the responsibility for setting the publication schedule and newsletter content. The committee will publish three newsletters each year. The newsletter will be distributed via email to TNI members. If you are not a TNI member and wish to view the newsletter, TNI posts a copy on the website (<http://www.nelac-institute.org/>) in the area called [News](#).

Anyone may submit an article or an idea for an article for inclusion in a future edition of the newsletter by contacting the Committee Chair, Aurora Shields. Submitted articles that advance or are consistent with the mission of TNI to foster the generation of environmental data of known and documented quality will be considered for publication. Articles should be approximately two paragraphs and no longer than one page in length. The deadline for submission of articles for the next edition is April 15, 2008.

Meeting Highlights

The Forum on Laboratory Accreditation, January 2008

By Jerry Parr

The 2008 winter meeting of The NELAC Institute (TNI) occurred in Newport Beach, California from January 14-17, 2008. Over 200 attendees enjoyed the warm weather of southern California, while working on a number of issues related to environmental laboratory accreditation. Updates of the key programs of TNI were provided in general sessions held throughout the week. In addition, TNI Chair Judy Duncan provided an update on the TNI strategic planning effort. These presentations have been posted on the TNI website in the area called [Presentations](#).

Sixteen TNI committees held public meetings during the week. In addition, a number of special sessions were held, including a session on air proficiency testing (PT), an assessment forum, and a mentoring session. Presentations from these sessions are also on the TNI website. Information about the other meetings will be contained in the minutes from those committees.

On January 18, the TNI Board of Directors and Committee Chairs met in a public meeting to continue the work on the TNI strategic plan. As a result of this effort, a draft operational plan was written during the meeting. Over the next few months, this plan will be finalized and made available to TNI members.

ANSI ACCREDITATION FINALIZED

On December 18, 2007, TNI was informed that the organization had been accredited by the American National Standards Institute (ANSI) as a consensus standards development organization, pending the resolution of any appeals. TNI is pleased to report that there were no appeals filed during the appeals period, which ended on February 19, 2008. Accordingly, standards development work performed by the TNI Expert Committees is recognized as compliant with OMB Circular A-119. All new TNI standards developed under the TNI Standards Development Policy are therefore defined as consensus standards. The National Technology Transfer and Advancement Act of 1995 directs EPA to use consensus standards in its regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Ken Jackson, Chair of the TNI Consensus Standards Development Board stated "Accreditation by ANSI puts TNI on a level with the most respected consensus standards development organizations nationally and internationally. With this timely recognition, the recently finalized TNI standards are endorsed as being truly representative of the consensus of all participating private sector and government stakeholders."

Meeting Highlights continued

The next TNI meeting will occur August 11-15, 2008 in Washington, DC at the Hyatt Regency Capital Hill. More details about this meeting will be posted on the website in early spring.



Dissolution of the National Environmental Laboratory Accreditation Conference (NELAC)

As TNI has taken over all activities previously performed by NELAC, those state and federal officials present in Newport Beach met once again as a body of representatives and delegates to perform one official piece of business, to dissolve the Constitution and Bylaws of NELAC. As the last Chair of NELAC, Judy Duncan said, "This is a bittersweet moment, one of some sadness because the organization that helped start this effort will now dissolve, but one of joy because we know we have a stronger organization to carry the effort forward where everyone can participate as equals."

Accreditation Body Recognition Renewals Begin

By Carol Batterton

The National Environmental Laboratory Accreditation Program (NELAP) Board has begun the process of renewing accreditation body (AB) recognitions for nine of the current thirteen state ABs. NELAP Board Chair, Dan Hickman, notified the ABs to submit their completed renewal applications by March 1, 2008. State programs up for renewal in this round include: California, Florida, Kansas, Louisiana Department of Health and Hospitals (DHH), New Hampshire, New Jersey, New York, Pennsylvania and Utah. Applications for AB recognition have been received by TNI from all nine of these state programs.

Following application completeness and technical reviews, onsite evaluations will be conducted by evaluation teams composed of Environmental Protection Agency (EPA) regional and state evaluators. Following the evaluations, the team will make a renewal recommendation to the NELAP Board. The NELAP Board anticipates that most renewals will be completed by the fall of 2008.

New to the process in this round of renewals are the Evaluation Coordinator and Quality Assurance Officer (QAO) positions. The Evaluation Coordinator position is being filled by EPA employee, Lynn Bradley, who will coordinate the process and facilitate timely completion of the evaluations in conformance with the NELAP Board's Evaluation Standard Operating Procedure (SOP). AQS, Inc. has been contracted to perform the QAO function. The QAO will participate in the evaluations as an observer and assure that all evaluations are performed in a consistent manner. The Evaluation SOP along with application forms and checklists for AB recognition and renewal have been posted on the NELAP Board page of the TNI website.

TNI Policies and Procedures Approved

By Alfredo Sotomayor

The Policy Committee finalized and the TNI Board of Directors has approved a set of policies and procedures that have wide applicability across TNI Programs. At the Newport meeting this January, the Policy Committee gave a brief presentation that highlighted the content of SOP 1-102, Decision-Making Rules for TNI Committees and Boards. All TNI groups must implement SOP 1-102 by May 1, 2008.

The SOP requires committees and boards to establish clear decision points and quorum requirements, to declare the type of rule they will use to make specific decisions, and to record in the meeting minutes all decisions made. It also provides guidance on different types of decision-making rules and how to reach closure on proposals. The following approved policies and SOPs created by the Policy Committee are available on the TNI website.



Future Meetings

Environmental Measurements Symposium

Forum on Laboratory Accreditation and National Environmental Monitoring Conference (NEMC)
August 11— 15, 2008
Hyatt Regency on Capital Hill
Washington, DC

Forum on Laboratory Accreditation

January 11— 16, 2009
Hyatt Regency Miami
Miami, FL

Environmental Measurements Symposium

Forum on Laboratory Accreditation and National Environmental Monitoring Conference (NEMC)
August 10 — 14, 2009
Hyatt Regency San Antonio
San Antonio, TX

Forum on Laboratory Accreditation

January 25 — 29, 2010
Hyatt Regency Chicago
Chicago, IL

Environmental Measurements Symposium

Forum on Laboratory Accreditation and National Environmental Monitoring Conference (NEMC)
August 9 — 13, 2010
Hyatt Regency on Capital Hill
Washington, DC



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TNI Policies and Procedures Approved continued

GENERAL POLICIES	
POL-100	Creating General Policies for TNI
POL-101	Conflicts of Interest
POL-102	Ethical Conduct of TNI Members
POL-103	Use of TNI Logos and Marks
POL-104	Management of Records

SOPS	
I-100	Format Guidelines for SOPs of TNI
I-101	Operations of TNI Committees and Program Boards
I-102	Decision-Making Rules for TNI Committee and Boards

The Policy Committee is responsible for generating general policies applicable across all of TNI and reviewing other policies for consistency and clarity. Other TNI programs have also created and approved policies and SOPs that are applicable to their program. As mentioned in the TNI Bylaws, the TNI Board of Directors reviews all policies and SOPs for fiscal impact to the organization and risk. After policies have been reviewed and approved, they are posted on the TNI website in the area called [About TNI](#).

The TNI Standards

By Ken Jackson

TNI has reached a major milestone by now having complete sets of new standards for the accreditation of environmental laboratories and for field sampling and measurement organizations. This article describes the organization's standards development process, the status of the new standards, and the next steps leading to adoption and implementation of the environmental standard by the NELAP ABs.

THE STANDARDS DEVELOPMENT PROCESS

Standards are developed by the TNI Consensus Standards Development Program (CSDP), in conformance with the "Procedures Governing Standards Development" that can be found on the TNI website. The American National Standards Institute (ANSI) recently approved the TNI process for standards development indicating that TNI meets the ANSI requirements. This means the TNI Standards are developed through an open consensus process in which all members and the public may provide input and have their position considered, preventing dominance by any one group of stakeholders by assuring a balance of interests among the committee members who develop the standards. The Expert Committees (Proficiency Testing; On-Site Assessment; Quality Systems; Accreditation Body; and Field Activities) each develop a **Working Draft Standard** that is presented to the membership and the public at the TNI Forum on Laboratory Accreditation. As a result of input received during and following that open meeting, the Expert Committees modify their Working Draft Standard to produce the **Voting Draft Standard**. All TNI members may then vote electronically, providing comments in support of their positive or negative votes. The Expert Committees must allow for public debate on every comment at the next Forum on Laboratory Accreditation. The Expert Committees hold meetings to rule each comment persuasive or non-persuasive. Committees must resolve every persuasive comment, which may require modification of the standard. Some comments may suggest major changes to the standard (e.g., reduce proficiency test frequency to once per year instead of twice per year), and they may be placed on hold until the next standards revision cycle to allow consideration and debate by the membership and the public. When persuasive comments are resolved and the standard modules are approved by a majority vote of the Committee Members, the standard then becomes final as the **TNI Standard**.



TNI Accreditation Standards

ENVIRONMENTAL LABORATORY SECTOR

Volume 1: Laboratory Requirements

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

Volume 2: Accreditation Body Requirements

- ◆ Module 1 — General Requirements
- ◆ Module 2 — Proficiency Testing
- ◆ Module 3 — On-Site Assessment

Volume 3: Proficiency Testing Provider Requirements

Volume 4: Proficiency Testing Oversight

FIELD SAMPLING AND MEASUREMENT ORGANIZATION (FSMO) SECTOR

Volume 1: General Requirements for Field Sampling and Measurement Organizations

Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations



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The TNI Standards (continued)

STATUS OF THE TNI STANDARDS

The TNI Standards are currently undergoing a final review stage for editorial clean-up. The TNI Standards conform to relevant international (ISO) standards and includes clauses from ISO 17011 and ISO 17025. Individuals or organizations may purchase the TNI Standard at a modest cost, which covers the licensing requirements TNI must pay to use these copyrighted international standards. Information about the purchase of these standards is on the TNI website.

After publication, TNI must allow thirty days for appeals (as described in the Procedures Governing Standards Development). The Standards will be available for adoption and implementation after resolving appeals.

ADOPTION AND IMPLEMENTATION OF THE TNI STANDARDS

The TNI Laboratory Accreditation System Committee (LASC) reviews the adopted TNI Standards and develops supplementary documents (guidance, SOPs, etc.), when needed. The LASC distributes the standards to the TNI NELAP and other interested standards-adoption organizations. TNI expects NELAP ABs will require a lead time of about two years to amend regulations and implement the standard. Because modifying regulations is restrictive and time-consuming, the current NELAP ABs may possibly continue to accredit laboratories to the 2003 NELAC Standards until the year 2010, when their proposed regulations are finalized to allow accreditation to the TNI Standards.

NEXT STEPS

Already, the Expert Committees are considering the comments that were put on-hold during the recent standards development cycle. If the committees decide, after receiving input from the membership, that any part of the standard can be improved, the next standards development cycle will begin.

OPPORTUNITY TO PROVIDE COMMENTS ON ISO STANDARDS

ANSI's International Conformity Assessment Committee (ICAC) is conducting periodic reviews on a couple ISO Standards and is also reviewing Committee Drafts of revisions to other ISO Standards. Carl Kircher of the Florida Department of Health represents TNI on the ICAC and solicits the Membership's comments on the following Standards:

- ISO 17020: General Criteria for the Various Types of Bodies Performing Inspection
- ISO 17021: Conformity Assessment – Requirements for Bodies Providing Audit & Certification of Management Systems
- ISO 17024: Conformity Assessment – General Requirements for Bodies Operating Certification of Persons
- ISO 17043 (proposed): Proficiency Testing by Interlaboratory Comparisons

The first and third items have a comment and ballot deadline of **April 25**; the other items have a longer timeframe for comments to be received. Due to ANSI copyright issues, TNI cannot provide the ISO documents directly to members, but members are free to purchase the ISO Standards from ANSI and then provide comments. All relevant comments, recommended revisions, and recommendations for voting may be submitted to **Carl at 904-791-1574** (leave message if necessary), or by **e-mail at carl_kircher@doh.state.fl.us**.

FREQUENTLY USED ACRONYMS

AB — Accreditation Body	NELAP — National Environmental Laboratory Accreditation Program
ACIL — American Council of Independent Laboratories	NEMC — National Environmental Monitoring Conference
ANSI — American National Standards Institute	NPW — Non-Potable Water
APHL — Association of Public Health Laboratories	PT — Proficiency Testing
AWWA — American Water Works Association	PTPA — Proficiency Test Provider Accreditor
CSDP — Consensus Standards Development Program	QS — Quality System
DW — Drinking Water	SCM — Solid and Chemical Materials
FoPT — Fields of Proficiency Testing	TAC — Technical Assistance Committee
FSMO — Field Sampling and Measurement Organization	TNI — The NELAC Institute
ISO — International Standards Organization	WEF — Water Environment Federation
LASP — Laboratory Accreditation System Program	
NACWA — National Association of Clean Water Agencies	

Note that in the context of TNI, the word NELAC is not an acronym; it is a contrived word.



More Meeting Highlights

Newport Beach, CA



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Frequency of Proficiency Testing Discussed

By the TNI Laboratory Accreditation System Committee

A White Paper on the frequency of proficiency testing was distributed by the TNI Laboratory Accreditation System Committee (LASC). In the paper, the LASC asks, "Should the current Proficiency Testing (PT) standard be changed from performing two PT samples per Field of Testing per NELAC matrix per year to a less frequent directive?" The paper discusses the current requirements, the historical basis for its adoption, and why some laboratories and accrediting bodies think the standard should be changed.

The LASC contends that reducing the frequency of PT analyses for accredited laboratories will harmonize the TNI Standards on PT frequency with EPA requirements. Further, the LASC believes that such harmonization has the potential to increase the number of accredited labs and remove some of the criticism associated with the 2003 NELAC standard. The LASC's paper is posted on the TNI webpage.

Assessment Survey Announced

By the TNI On-Site Assessment Committee

The TNI On-Site Assessment Committee developed two surveys. Both have been posted on the TNI website in the area called [News](#). The first is a survey for laboratory assessors. The committee hopes that the majority of assessors will participate in the survey to ensure that the data reflect the broad spectrum of current laboratory accreditation programs and assessor expertise. The second survey is designed to capture data from a laboratory perspective. The committee would like responses from analysts as well as laboratory management to achieve a data set representative of all requirements in the standard (e.g., management requirements, quality assurance requirements, and analytical systems requirements). The results of both surveys will be used to evaluate the effectiveness of the standards to generate environmental data of known and documented quality.

TNI "Small Laboratory" Subcommittee Status

By Brook Connor, Small Laboratory Subcommittee Chair

Ever since the national effort for a laboratory accreditation began, the impact of the accreditation requirements on small laboratories has been an issue of primary concern. Small laboratories have expressed concern that the costs and overhead of laboratory accreditation impact their operations disproportionately to large labs. Since TNI is a consensus-based standards setting organization, it seems natural that small labs could voice their concerns at the biannual conferences, by joining committees, or by attending conference calls, and be able to affect changes that remove those requirements that are not essential for data quality. Yet, rarely do small laboratory employees have permission or funding to attend TNI conferences. Even the long distance charges to participate on a TNI conference call can be a roadblock for some small labs.

Small laboratories need to be assured that their concerns about accreditation requirements are heard, addressed, and incorporated into the standards where appropriate. Having a committee of small laboratory representatives seemed to be a

Continued on next page



More Meeting Highlights

Newport Beach, CA



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TNI “Small Laboratory” Subcommittee Status (continued).

logical conduit between the members of the small laboratory community and TNI, but this approach has not been effective because of this very challenge — limited resources and funding.

The TNI Small Laboratory Subcommittee held its (potentially) last meeting in Newport Beach in January. The decision to disband the committee was due to the inability of small laboratories to participate and lack of a specific task. Out of nine or ten subcommittee members, only three were able to be present at the conference. During the meeting, several non-committee members offered to participate on the committee, even though they themselves may not be from small laboratories. It was also suggested that TNI should not break the only link for small laboratories to contribute to the standards creation process. So, how can TNI keep the voice of the small laboratory heard?

It was decided that the small laboratory community could be better served with an advocate who would function within the Technical Assistance Committee, which has a primary objective of providing assistance to laboratories of all sizes. This advocate would seek out opinions from small laboratories and route suggestions to the appropriate TNI committees. The advocate would also answer questions, and collect overall views and ideas to present to TNI for action. The announcement of this position and any contact information will be posted on the TNI website shortly.

Everyone agreed that the concerns of small laboratories need to be an integral part of every TNI meeting, thus the concept of a small laboratory forum — a dedicated meeting to bring forward the concerns of small laboratories — was discussed. TNI is committed to having a cost-effective accreditation program that addresses the needs of everyone — small laboratories, large laboratories, regulators, and data users.

Member Spotlight: Lee Friell

By Kirstin McCracken

This issue of the TNI Newsletter includes the first of what is hoped to be a regular feature — a spotlight on the background and activities of a TNI member.

The Member Spotlight for this issue is [Lee Friell](#). Lee has been an active participant in TNI (formerly NELAC) since the inception of the national organization and he has attended every annual meeting of the organization since the early 1990s! Let's get to know a little more about him...

Lee is a native of Bangor, Wisconsin. He earned his Master's degree in Analytical Chemistry from the University of Iowa and began his professional career with the University by teaching chemistry to nursing students. Lee has now been with the University Hygienic Laboratory (UHL) for more than 35 years and has been the manager of the Hygienic Laboratory's Des Moines branch, now located in Ankeny, Iowa, since 1991. The UHL is a full service testing laboratory that holds primary accreditation with the State of California and secondary accreditation with at least two other accrediting bodies. The UHL's sister laboratory in Iowa City also holds primary accreditation in California and secondary accreditation with at least 3 other accrediting bodies. Both University Hygienic Laboratories maintain certification with several non-NELAP state ABs in a variety of program areas associated with public and environmental health including radiological testing.

During his career, Lee helped develop environmental laboratory certification programs and became a leader in the analysis of wastewater, biochemicals and trace metals, and in industrial hygiene monitoring. Under his watch, UHL Ankeny added newborn screening for the states of South Dakota, North Dakota and, in emergency response to Hurricane Katrina, also for the state of Louisiana for more than two years. This is in addition to newborn screening that is performed by UHL for all



24th Annual National Environmental Monitoring Conference

The 24th Annual National Environmental Monitoring Conference will be held at the Hyatt Regency Capital Hill, Washington, DC, from August 11-15, 2008.

NEMC provides the principal forum for addressing policy and technical issues affecting monitoring in all environmental media (i.e., water, air, soil, and wastes) and across all environmental programs.

Organized jointly by the U.S. Environmental Protection Agency (EPA), The NELAC Institute (TNI) and the Independent Laboratories Institute (ILI), the focus of NEMC 2008 is on new approaches for analyzing conventional and emerging pollutants in water, soil, and air. NEMC brings together scientists and managers from federal and state agencies, the regulated community, and laboratory and engineering support communities. It includes a policy session, technical sessions, training courses, exhibits, and networking opportunities. For the second year, NEMC will be combined with the Forum on Laboratory Accreditation as the [Environmental Measurements Symposium](#).

TNI members are encouraged to submit an abstract by going to www.nemc.us.



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Member Spotlight: *Lee Friell continued*

babies born in Iowa. Lee was a leader in the recent addition of a Biosafety Level 3 facility in the Ankeny Lab, which increases the Lab's ability to test for infectious agents that could cause serious or potentially lethal diseases.

When I asked Lee how he thought TNI has influenced his organization and the work he does, he responded that TNI and its predecessors stepped up to fill in the gaps of the existing laboratory certification programs. Iowa is not a NELAP AB, but their state has tried to model its program to fit with TNI standards as best it can given available resources and needs of the program.

When the national organization for accreditation was formed in 1997, Lee began serving as the state representative at the annual meeting and continued to do so every year in the role of representative or alternate. Lee says that there are many benefits to attending the annual meetings — including professional dialog and exchange of ideas — but his primary interest at the meeting is participating in the committee sessions and special forums that allow him to keep current with issues related to lab assessments and the interpretation of analytical protocols found in the laboratory during those assessments.

Lee has spent many hours both at the bench and in the field conducting on-site visits to laboratories across Iowa and the country. Does Lee have any interesting audit stories? You bet! While performing an audit of a municipal laboratory located near a state prison, Lee found himself pulled into the search for prison escapees. On another occasion, Lee was to perform an audit in a federal government contract laboratory the day of the Oklahoma City bombing and was subsequently held in the laboratory under security controls until the government determined that the threat was not widespread. He says his military ID and clearance helped him through the ordeal. Lee served in Vietnam and served in the Army Reserves for 35 years until October 2006. His military career included two deployments overseas to the Middle East. Thank you Lee!

What has been Lee's favorite NELAC/TNI meeting location? Lee says there are many, but he especially enjoyed the 1998 meeting held in Dallas, Texas because of its location at the Anatole Hotel. The 1999 meeting in Saratoga Springs, New York and the 2000 meeting in Williamsburg, Virginia round out the top three. Lee mentions that he thought the Williamsburg meeting marked a transition point where the various groups in the organization really began to work together. The most recent meeting in Newport Beach also marked the official ending of NELAC, an event which Lee says was sad, but enlightening.

Lee is avid sports fan. He especially enjoys baseball and attended the World Series in Denver. Before this interview, I heard Lee had achieved the impossible — he scored a ticket to a sold-out Red Sox game in Fenway Park last summer during the August meeting in Boston. Rumor has it that Lee is friendly with many of the umpires of the major league, so I thought I would get a scoop on an inside lead. When I asked Lee how he managed to get into Fenway, [to get tickets to a sold out game] he quipped "I took a cab!", but then shared the real story. Lee took that cab to Fenway and he found a ticketholder not going to the game. As luck would have it, the ticket was in the Executive Level of the stadium where he comfortably enjoyed the game along with dinner and refreshments. Lucky fellow indeed! Lee confirmed that he knows many of the Major League umpires quite well, so next time you see Lee at a TNI meeting be sure to ask him about baseball.

I hope everyone has enjoyed getting to know Lee as much as I have. Lee is a role model to the TNI community and a friend to Iowa's public health and environment. Thank you, Lee, for sharing your thoughts about TNI and the interesting facts about your life!

Questions or comments regarding the content of this newsletter should be directed to Jerry Parr (jerry.parr@nelac-institute.org).



TNI MISSION

The NELAC Institute is a 501 (c) 3 non-profit organization whose mission is to foster the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community.



VISION

All entities generating environmental data in the United States will be accredited to consensus national standards.



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Organizational Members

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

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Stakeholder Group:
 A = Accreditation body
 L = Laboratory
 O = Other



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