

The Institute Review

www.nelac-institute.org

Second Quarter 2009



Editor-In-Chief
Ken Jackson

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Topical Sessions at the TNI Meeting in San Antonio

By Jerry Parr, TNI

The NELAC Institute's (TNI's) semi-annual meeting will be held August 10 – 15, 2009 in San Antonio, Texas and is an integral part of the Environmental Measurement Symposium (Symposium).

Throughout this issue of The Institute Review, there are multiple articles provided to prepare you for the meeting: the mentoring sessions, the Assessment Forum, the Stationary Source Audit Sample (SSAS) committee meeting, training courses, and the National Environmental Monitoring Conference (NEMC) highlights, held jointly with the Forum on Laboratory Accreditation under the Symposium. This article summarizes five other major TNI sessions. As these sessions become further developed, additional details will be available on the TNI website at <http://www.nelac-institute.org>.

Proficiency Testing Program: Monday, August 10th

On Monday afternoon, members of the TNI Proficiency Testing (PT) Board and PT Expert Committee will lead a session devoted to PT issues. Some of the topics to be discussed include:

- ◆ New Fields of Proficiency Testing (FoPTs), including discussion on chemical, microbiological, whole effluent toxicity, and air and emission FoPTs;
- ◆ Frequency of PT;
- ◆ PT Oversight Statement of Work;
- ◆ Summary of PT Expert Committee Tentative Interim Amendments and Editorial Changes to the new TNI standards (see Ken Jackson's article on page 9 of this newsletter); and
- ◆ Status of Experimental PTs.

Consensus Standards Development Program: Tuesday, August 11th

On Tuesday afternoon, the TNI Consensus Standards Development Board will meet. Topics for this meeting include an open discussion on the use of guidance documents; the use of copyright protected language within the NELAP program; and activities and future plans of the Quality Systems, Accreditation Body, and On-Site Assessment Committees.

National Environmental Laboratory Accreditation Program (NELAP): Thursday, August 13th

On Thursday, a day long session is devoted to discussions surrounding NELAP. Topics will include:

- ◆ Implementation of the new TNI standards, including the implementation schedule, training workshops, and guidance documents.
- ◆ Building the program, including an update on New Accreditation Bodies (ABs), the new AB Evaluation Standard Operating Procedure, and an update on the on-going AB recognitions that are underway.
- ◆ Continued discussion on the use of copyright protected language in state regulations, including a presentation on the Fair Use doctrine and the Peter Veeck decision.
- ◆ An open discussion on the fields of accreditation, specifically addressing the adoption of new and/or revised EPA methods with consideration of the discussion that will occur on Monday, August 10th at the meeting of EPA's Environmental Laboratory Advisory Board (ELAB) relative to SW-846 methods.
- ◆ Training for state agencies on the new TNI National Database.

Continued on next page

Topical Sessions at the TNI Meeting in San Antonio

National Environmental Field Activities Program (NEFAP): Thursday, August 13th

On Thursday afternoon, there will be a session on TNI's new National Environmental Field Activities Program (NEFAP). The progress made to date to establish this program, the model for recognizing NEFAP ABs, and policies and procedures that will be needed to implement the program will all be discussed at this time.

TNI Board of Directors: Friday, August 14th

On Friday morning, the TNI Board of Directors will meet in an open session to hear reports from each of TNI's programs. This meeting will allow all attendees to hear what has transpired during the week and what plans are being made for moving forward.

Environmental Measurement Symposium: Highlights of the National Environmental Monitoring Conference

By Lara Autry, USEPA

For the third year, the Environmental Measurement Symposium, which represents the combined meetings of the National Environmental Monitoring Conference (NEMC) and the Forum on Laboratory Accreditation (the Forum), will be meeting at the Hyatt Regency San Antonio in San Antonio, Texas from August 10 – 15, 2009. NEMC is a technical conference sponsored by The NELAC Institute (TNI), the Independent Laboratories Institute (ILI), and the US Environmental Protection Agency (USEPA).

Highlights of the week for NEMC include:

- ◆ More than one hundred technical presentations and posters on a variety of cutting-edge environmental monitoring issues;
- ◆ An exhibit program showcasing the latest innovations for laboratory and monitoring needs;
- ◆ Six training courses on advanced monitoring techniques, data usability, and laboratory accreditation issues;
- ◆ Four special keynote presentations on topics of general interest;
- ◆ A special half-day session providing global perspectives on the environmental landscape;
- ◆ A special half-day session with presentations on the emerging environmental issues of climate change, green chemistry, and nanomaterials; and
- ◆ An open meeting of the EPA's Environmental Laboratory Advisory Board (ELAB).

The Symposium brings together many quality professionals, chemists, analysts, microbiologists, engineers, and managers from Federal and State agencies; commercial, municipal, state, and federal laboratories; laboratory accreditation professions; and many others who are actively involved and interested in environmental monitoring and accreditation. Please take a few minutes to look over the preliminary program and register today. To view abstracts and the preliminary program in addition to conference arrangement details, visit <http://www.nemc.us>. We look forward to seeing you in August!!!



New TNI Board Elects Officers

Joe Aiello, Judy Duncan, Jack Farrell, Ken Olsen, David Speis, and Curtis Wood were all re-elected by the membership to serve 3-year terms on the TNI Board of Directors. Aaren Alger of the Pennsylvania DEP was newly elected to serve a 3-year term. In the first meeting of the 2009 Board on April 7, the following officers were elected:

*Chair: Steve Arms
Vice-Chair: Sharon Mertens
Secretary: Alfredo Sotomayor
Treasurer: David Speis*

Judy Duncan agreed to accept the position of Past Chair. The 2009 Board of Directors is shown below.

2009 Board of Directors

Joe Aiello (A) New Jersey DEP	Judy Morgan (L) Environmental Science Corporation
Aaren Alger (A) Pennsylvania DEP	Ken Olson (O)
Steve Arms (A) Florida DOH	Aurora Shields (L) City of Lawrence
Judy Duncan (A) Oklahoma DEQ	Matt Sica (A) Maine CDC DEH DWP
John E. Farrell, III (O) Analytical Excellence	Alfredo Sotomayor (A) Wisconsin DNR
Ken Jackson (O)	David Speis (L) Accutest Laboratories
Tom McAninch (O) Laboratory Consulting Services	Curtis Wood (O) Environmental Resource Associates
Sharon Mertens (L) Milwaukee Metropolitan Sewerage District	Robert Wyeth (L) Columbia Analytical Services

Ex-Officio Directors

Brenda Bettencourt (O) US EPA Region 9	George Detsis (O) US DOE
Brooke Connor (O) US Geological Survey	Edward Hartzog (O) US Navy

Stakeholder Group

A = Accreditation Body L = Laboratory O = Other



Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086
Jerry Parr

Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org

URL: <http://www.nelac-institute.org>

Training Courses at the Environmental Measurement Symposium

By Jerry Parr, TNI

As part of the Environmental Measurement Symposium in San Antonio, Texas from August 10 – 15, 2009, six training courses on a variety of topics related to laboratory accreditation, quality assurance, environmental monitoring, and data review are being offered. A brief summary of each of the courses is provided below; however, more information about these courses can be found at: <http://www.nelac-institute.org/meetings.php>. Please remember to register for each course you wish to attend, as seating is limited and an additional charge from the general registration fee applies.

1. Testing Requirements of EPA Regulations

In response to laws passed by Congress, the US Environmental Protection Agency (EPA) has developed regulations that require the testing of environmental contaminants in virtually all environmental media (air, water, soil, wastes). This workshop will review the process by which a law leads to a regulation, examine the major statutes that require monitoring, and then provide an in-depth presentation of the specific testing requirements, including test methods and analytes, in each regulation.

2. How to Use Qualified Data

The objective of the course is to review how to use qualified data for making environmental decisions and to limit the amount of qualified data for future decisions. The course includes practical examples of reporting data with qualifiers based on federal, state and client specific specifications. At the end of the course, the student should understand (1) when to use qualified data for making decisions, (2) how to evaluate data for the intended use, and (3) be able to assess how “good” is the data reported to the client.

3. Gas Chromatography and Mass Spectrometry Analysis and Data Review

The objective of the 4-hour course is to review the analytical process for obtaining data of known and documented quality for Gas Chromatography (GC) and Gas Chromatography/Mass Spectrometry (GC/MS). The course includes practical examples of (1) performing testing using GC and GC/MS, (2) preparation techniques for organic analysis, (3) identifying and implementing corrective actions, and (4) performing the necessary laboratory data review. The course is designed to help laboratory personnel improve their understanding of the science and the regulated methods. Test methods include EPA 600 series, 3000, 5000 and 8000 series, Contract Laboratory Program (OLC, SOM, OLM) for analysis of water and solids.

4. Metal Speciation Analysis

This course will focus on the use of EPA Method 6800 for the determination of species of chromium and mercury and other species in environmental matrices. Fundamentals of sample handling, including extraction, stable isotopic spiking and species stabilization integrated with detection will be covered. The course will describe and compare Isotope Dilution Mass Spectrometry (IDMS) and Speciated Isotope Dilution Mass Spectrometry (SIDMS) as tools for elemental and molecular species analyses. The course provides support methods and materials for current available instrumentation, reagents and standards use in carrying out these analyses. Software for solving equations and implementation tools will be provided on CD as part of the course. Additional support materials and manuals in addition to what is currently available in the method will be provided.

5. Inductively Coupled Argon Plasma & Mass Spectrometric Analysis and Data Review

The objective of the 4-hour course is to review the analytical process for obtaining data of known and documented quality for Inductively Coupled Argon Plasma (ICP) and Inductively Argon Plasma/Mass



Optional Social Activity at the Environmental Measurement Symposium

On Thursday evening, the San Antonio River Authority is sponsoring a reception at the San Antonio Museum of Art (SAMA), in celebration of the newly expanded Riverwalk. *Waterflow*, a special exhibition of recent works with themes centering on the essence of nature, the passage of time, nature as metaphor, and the preservation of the environment will be on display. This optional event is limited to 250 attendees and you must register by July 18 to attend. For more information about the museum, go to: <http://www.samuseum.org>.



Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086
Jerry Parr
Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
URL: <http://www.nelac-institute.org>

Training Courses at the Environmental Measurement Symposium (cont.)

Spectrometry (ICP/MS). The course includes practical examples of (1) performing testing using ICP and ICP/MS, (2) preparation techniques for metals analysis, (3) identifying and implementing corrective actions, and (4) performing the necessary laboratory data review. The course is designed to help laboratory personnel improve their understanding of the science and the regulated methods. Test methods include EPA 200 series, 3000 and 6000 series, and Contract Laboratory Program (ILM series) for analysis of water and solids.

6. Electronic Delivery of Laboratory Data for the Next Generation

This training course will introduce and discuss the implementation of the Staged Electronic Data Deliverable (SEDD). Although the course will focus on implementing SEDD for the newly developed Inorganic Superfund Methods (ISM01.1) Statement of Work for EPA's Contract Laboratory Program (CLP), the course will also be applicable to anyone using SEDD, including organics and other programs. Laboratories, software vendors, and Architect-Engineer firms who have bid or are considering bidding on this contract in the future or have worked with SEDD files would be highly encouraged to attend. SEDD is a universal format that can deliver environmental testing data for any program in an XML format. The course will introduce SEDD and discuss the various Stages and what type of data each can deliver. The structure of SEDD will be discussed that will show the type of data that is reported in a Stage 2a, 2b, or 3 SEDD file and how the files are constructed. The course will focus on the reporting of the data for the Stage 2a and 2b along with some discussion on Stage 3. SEDD allows for the complete linking of all samples to their associated Quality Control samples, the complete linking of all samples to their associated continuing and initial calibration data, and the complete linking of all reported results to the specific analysis that was used to derive that specific result. Numerous real examples will be displayed and discussed. The various means for constructing these files along with the current tools that can assist the laboratories with the evaluation of their in-house created files will be demonstrated. Overall, in the data review process, a significant cost savings has been demonstrated in the CLP through the use of these deliverables and associated software tools.

Update on Accreditation Body Renewals and Applications

By Carol Batterton, TNI

The NELAP Board has completed the first round of accreditation body recognition renewals with the final approval of the California program. Paul Ellingson is the Quality Assurance Officer for the renewal process and will submit his findings on the first round of evaluations to the NELAP Board soon. Paul will also give a summary presentation of his findings during the Forum on Laboratory Accreditation in San Antonio, Texas during the NELAP session on Thursday.

In the second round of renewals, the Oregon on-site evaluation and laboratory assessment observation has been completed with the draft report in preparation. The Texas on-site evaluation and laboratory assessment observation has also been completed with the report expected shortly. The Louisiana Department of Environmental Quality on-site evaluation is scheduled for the week of July 13th. Illinois has requested and been granted an extension till July 24th to respond to comments on their technical review.

The technical review on the Virginia Department of Consolidated Laboratory Services application for accreditation body recognition has begun. The Minnesota Department of Health has received legislative authorization to have a NELAP accreditation program and is expected to submit an application by August 2009.



TNI Mentoring Workshop: The New TNI Laboratory Accreditation Standards

The NELAC Institute (TNI) has approved changes to the National Environmental Laboratory Accreditation Program (NELAP) that are expected to be fully implemented by 2010. These changes will replace the 2003 NELAC standard with four new TNI standards:

- ◆ Management and Technical Requirements for Laboratories Performing Environmental Analysis
- ◆ General Requirements for Accreditation Bodies Accrediting Environmental Laboratories
- ◆ General Requirements for Environmental Proficiency Test Providers
- ◆ General Requirements for an Accreditor of Environmental Proficiency Test Providers

A special workshop will be held in conjunction with the Environmental Measurement Symposium in San Antonio on August 10, from 9:00 am to 12:00 noon. While this workshop will briefly review the requirements in all four new standards, the primary focus will be to review in detail the changes to the requirements for laboratories. The workshop will have four major topics as discussed over the next four pages.

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Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086
Jerry Parr

Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
URL: <http://www.nelac-institute.org>

The Semi-Annual TNI Assessment Forum

By Jack Farrell, Analytical Excellence

The first “Assessor Forum” was conducted about three and a half years ago after a clamoring of requests from the assessor community to have a place where assessors could meet during the semi-annual Forum on Laboratory Accreditation meetings to discuss issues related to assessments and the NELAC Standard. The first Assessor Forum was three hours long and presented materials on a variety of Standard and test method topics with the focus of “How do I audit to...?” and “How do I interpret...?” The Forum had over sixty participants from not only the assessor community, but from regulators, data users, accredited laboratories, and vendors with session feedback indicating it was wildly successful!

Three major recommendations were made to the TNI Board of Directors based on the feedback from this session.

- ◆ *First and foremost*, the Assessor Forum should become a staple at each of the semi-annual meetings.
- ◆ *Second*, the Assessor Forum should be extended to a full day.
- ◆ *Third*, the Assessor Forum should be designed for a larger group of stakeholders, since it was very clear that the session held appeal and interest for a larger participation than just assessors.

The TNI Board accepted those recommendations. The name of the session was changed to reflect the wider interest becoming the “Assessment Forum” and it has been an integral part of each meeting’s agenda since then in addition to a formally chartered Assessment Forum subcommittee of the Technical Assistance Program (TAP).

Six Assessment Forums have been conducted to date with the next Assessment Forum scheduled for Tuesday, August 11, 2009 in San Antonio, Texas. The Assessment Forum development team has undertaken the issue of inconsistency in NELAP assessments, which is a tremendously complex and important undertaking. Inconsistency of assessments has been raised as an issue by states, federal agencies, laboratories, and third-party assessor bodies – not just regarding NELAP assessments – but accreditation assessments in general. Concerns regarding comparability and consistency of assessments have been an issue that has surfaced as critically important to the future of TNI and NELAP in the ability for these programs to expand.

The August session is four hours and will focus on discussions and information gathering of techniques, tools, management systems for fostering assessor, and assessment consistency. The agenda focuses on three areas:

1. A panel presentation and discussion by Data Users entitled “What do Data Users want and expect from on-site assessments to support their decision making?”
2. A panel presentation and discussion by ILAC Accreditation Bodies entitled “Mechanisms Used by ILAC/ISO ABs to Manage and Assure Assessment Consistency.”
3. Interspersed between these panels will be ample time for participants to voice their opinions, suggestions, and questions regarding how to foster assessment consistency.

The information gathered during this session will be used by the Development Team to put together the next two Assessment Forum programs focusing on tools, techniques, management systems, training, and other solution strategies for TNI programs to work on in the future.

Your interest and participation has made the Assessment Forum a successful and integral part of the TNI semi-annual meetings. Your continued participation in the development of future programs of interest will be key to future success. Please come to this session, participate and help define the solution strategy to foster stronger, more consistent, and valuable assessments for all stakeholders including accreditors, data users, and accredited laboratories. To get involved, please contact Jack Farrell at AEX@ix.netcom.com or Jerry Parr at jerry.parr@nelac-institute.org to let them know about your interest.



TNI Mentoring
Workshop cont.

Consensus Standards Development Program

The purpose of the Consensus Standards Development Program is to develop consensus standards for the accreditation of environmental laboratories and other organizations involved in the environmental measurement process. TNI is a voluntary consensus standards development organization that is committed to the development of standards for use by accreditation bodies. Standards have been developed that are widely applicable, and will therefore promote a uniform national program of environmental laboratory accreditation. These standards are modular, allowing their assembly into a series of volumes, each specifically designed for a stakeholder group (Laboratories; Accreditation Bodies; Proficiency Test Providers; and Proficiency Test Provider Oversight Bodies). The consensus process used by TNI in standards development will be described.

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Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086
Jerry Parr

Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
URL: <http://www.nelac-institute.org>

Interest in the Small Laboratory Advocacy Group Grows

By Len Schantz, City of Rochester, NY

The NELAC Institute (TNI) Small Laboratory Advocacy Group (SLAG) continues to expand its membership. Since its inception in February 2009, membership has grown from the original dozen to the current forty members. SLAG was formed because TNI recognizes the concerns of small laboratories need to be heard and accommodated for national laboratory accreditation to succeed.

With this growth, the diversity of SLAG membership has also increased. Geographically, the experiences from seven states (i.e., OR, TX, LA, AL, OK, VT, and NY) are represented by members. The types of laboratories represented are also diverse, including the small utility laboratory (i.e., both wastewater and drinking water); the one-person, one-analyte commercial laboratory; the small industrial support laboratory; and the multi-analyte, small commercial (<20 staff) laboratory. Finally, add to this mix a couple of consultants and an assessor and you can begin to imagine the healthy exchange of ideas and opinions that results.

SLAG members have two methods for sharing their ideas, concerns, and information with one another. First, members can meet by dialing in to a monthly SLAG conference call. A part of each call is dedicated to discussing one piece of the NELAC Standard with discussion focusing on its effect on the small lab community. Second, there is a SLAG webpage, <http://www.nelac-institute.org/board>, which provides an online opportunity for members to raise and discuss issues important to the small laboratory community. Ultimately, the fundamental goal for SLAG is to provide feedback to TNI on training needs for the small laboratory community, as well as feedback on the future direction of the TNI Environmental Sector Standard.

Membership in TNI is not required to participate in SLAG. TNI believes that members of the broader, small laboratory community, not just TNI members, need a forum for their voices to be heard; however, TNI membership does provide additional benefits including participation in any of TNI's expert committees. Joining TNI also allows you to vote and comment on proposed standards.

Finally, it is easy to participate in SLAG and have your voice heard. If you would like to join, or if you are just interested in more information, please contact TNI's Small Lab Advocate, Len Schantz, at lgs@cityofrochester.gov.

Requirements for Membership of the TNI Board of Directors

By Aurora Shields, City of Lawrence, KS

The NELAC Institute (TNI) is a nonprofit organization governed by a member elected Board of Directors (Board). The Board has significant responsibilities to fulfill. This article is an explanation of what it means to be a "member" of the Board.

The main and most important responsibility of the Board is governance. Governance is what supports and maintains the core programs within TNI by providing the organization with an infrastructure to carry out these programs. The first TNI Board provided continuity for the organization by establishing its legal existence as a 501(c)(3) corporation. Now, TNI core programs work in cooperation towards our common vision. Each core program was created to have the authority to establish policies and procedures for the program, make decisions, and operate independently.

Adoption and documentation of policies and decisions is also the responsibility of the Board. This helps in keeping the organization on track and maintains organizational memory. The Board is also responsible for proposing amendments, repealing, or altering the Bylaws. Members of TNI must be notified of such actions, as well.



**TNI Mentoring
Workshop cont.**

A National Approach for Proficiency Testing

Proficiency Testing (PT) is defined as a means of evaluating a laboratory's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by an external source. The TNI PT program consists of:

- ◆ *A PT Expert Committee that establishes the requirement for proficiency testing.*
- ◆ *A PT Board who manages the implementation of the program.*
- ◆ *A PT Provider Accreditor that accredits organizations as PT Providers.*
- ◆ *Private and public sector PT Providers that manufacture and provide PT samples and evaluate the results.*

The TNI PT Expert Committee has developed standards for laboratory proficiency testing and proficiency testing samples, including: criteria for selection of the providers of the samples; protocols for the use of proficiency test samples and data in the accreditation of laboratories; and criteria for Proficiency Test Provider Accreditors (PTPAs).

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TNI Small Laboratory Advocate

Leonard Schantz
City of Rochester
lgs@cityofrochester.gov
585-428-7378

Requirements for Membership of the TNI Board of Directors (cont)

The Board is required to maintain a link to the community, which includes TNI's members, users of TNI products and services, other organizations, the public, and the media. Outreach is an important strategy to articulate TNI's mission, accomplishments, and goals to the public and to gather support from important members of the community that can have significant impact in accomplishing our goals.

Board members must actively pursue TNI's mission and advocate its vision. The key to stay in focus is strategic planning, which is conducted by the Board on an annual and sometimes more frequent basis. During strategic planning, the Board often evaluates TNI's mission and vision statements, and how the existing core programs are achieving their goals in order to better identify the programs and services that TNI will offer.

Board members also have fiduciary responsibilities. The Board is not only responsible for making sure that there are sufficient resources available, but also for making sure that these resources are managed effectively. The Board must approve annual budgets, annual financial reports, contracts, and grants. This is important for the long term survival of the organization and the program and services we deliver to the community. The Board must be accountable to its members, financial supporters, and preserve its tax-exempt status by insuring financial control.

The Board is supported by the Executive Director and staff. The Board members must work closely with the Executive Director, offer administrative advice, evaluate his performance on the basis of a established job description, and determine whether to retain or dismiss the Executive Director at any time. It is important to note that the Board does not and should not be involved with the day-to-day management of the organization – that is the job of the Executive Director. Another thing that should be noted is that although the Board may take recommendations from the Director, staff, and members into consideration, the Board should never rush into making decisions without researching and discussing the issue. The Board is continuously striving to conduct TNI's business by reaching consensus in an open, inclusive, and transparent way.

For conducting the business of TNI, the Board meets by conference call once a month (more frequently as needed) and two face-to-face meetings per year. Board members must prepare for these meetings and must make a commitment to attend the meetings. A Board member must also be aware of any situation that may pose a conflict of interest. For these situations, the Board member must inform the Board of the situation and, in appropriate instances, recuse themselves from certain matters.

Being a TNI Board member is hard work with a wide range of responsibilities, but it is a very rewarding experience. It is also important for the TNI Board to have new members that can bring other points of view and experience to the Board. If you are interested in serving as a member of the Board, please send in your nomination form found at <http://www.nelac-institute.org/committees.php>.

Basic Assessor Training Course Curriculum Posted for Review and Comment

The TNI On-Site Assessment Committee has posted on the TNI website (<http://www.nelac-institute.org>) a guidance document that gives a recommended course outline designed to ensure consistency of the on-site assessment. TNI welcomes comments on this draft document. Comments should be sent to the committee chair, Denise Rice at rice.denise@epa.gov before August 6. The document will be discussed during the On-Site Assessment Committee meeting in San Antonio on August 11.



TNI Mentoring
Workshop cont.

Requirements for an Accreditation Body

Although the National Environmental Laboratory Accreditation Program (NELAP) is a national program, state governmental agencies serve as Accreditation Bodies. States, which apply to NELAP to become an accreditation body, may select to operate an accreditation program which covers all of the EPA regulatory programs or as few as one. For example, many states may select to only accredit laboratories for chemistry and microbiology under the drinking water program. Other states may select to operate a comprehensive program, which includes all types of analyses for all types of media (i.e., hazardous waste, waste water, drinking water, air, soil, etc.) under the five EPA regulatory programs [i.e., Clean Air Act (CAA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), and Safe Drinking Water Act (SDWA)]. There is no requirement that a state incorporate any particular portion of the possible scope into its program. The scope of accreditation, the type of laboratory included under the state's program, including the regulatory or voluntary nature of the program itself, the assessment of fees, and the use of third party assessors are all options of the state.

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Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086

Jerry Parr
Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
URL: <http://www.nelac-institute.org>

Minnesota Adopts National Standards for Accreditation

By Susan Wyatt, Minnesota Department of Health

The 2009 Minnesota legislature approved changes to Minnesota Statutes 144.97 and 144.98 regarding laboratory accreditation. Effective July 1, 2009, all laboratories accredited by the Minnesota Department of Health (i.e., MDH or Department) must meet national standards for accreditation. The current adopted standard is the 2003 NELAC Standard. With few exceptions, the NELAC Standard is comparable to the current Minnesota Rules (effective October 2006) in terms of the range and stringency of requirements for accreditation.

The statute change applies to all MDH-accredited laboratories, whether privately or publicly owned or operated. In addition to clean water, safe drinking water, solid and hazardous waste, and underground storage tank programs already offered for accreditation, the statute adds authority for accreditation of air and emissions testing. The statute also adds provisions for accreditation of whole effluent toxicity testing and physical characterization of hazardous wastes.

The Department intends to apply for recognition as a NELAP Accreditation Body (AB) in August 2009 with pending approval by late fall. By adoption of the Standard, Minnesota joins thirteen other NELAP ABs in implementing uniform standards for the accreditation of environmental laboratories.

MDH is committed to providing the necessary assistance to meet the accreditation needs of the laboratory community. The Department will work with laboratories via updates to the accreditation program webpage, informational web-conferences and, on a case-by-case basis, will assist laboratories in implementing the new requirements. With accreditation renewal announcements in mid-September, a crosswalk between the national standard and the current Minnesota rules will be supplied to laboratories accredited by MDH.

Method Modifications: "What do I record?"

By David Caldwell, Oklahoma Department of Environmental Quality

On Thursday morning, August 13, 2009 at the Environmental Measurement Symposium in San Antonio, Texas, the Method Modifications Mentor Session will provide an opportunity for discussion of how to document method modifications. The primary objective of method flexibility is to enhance precision and accuracy for analysis. Flexibility should not be permitted if the altered method creates a less precise or less accurate analysis than the approved standard analytical method. The lab should list any method modifications and demonstrate by supporting data the equivalent performance of the modified method over the reference method as written. This flexibility is available to all laboratories, regardless of size, but the key is to document the method modification.

When a laboratory modifies a method, the following criteria should be used as a guideline to document any method modifications.

- ◆ Method validation is the process by which a method developer substantiates the performance of the modification for the method. Modified methods must be validated to prove that they accurately measure the concentration of an analyte in an environmental sample. The information and supporting data required in the validation must be sufficient to allow an independent reviewer (e.g., EPA, state, contractor) to verify each determination and calculation performed by the laboratory.
- ◆ If a laboratory intends to modify a method for more than one matrix type (e.g., air, soil, water, sludge), the laboratory must validate the method on each matrix type.
- ◆ Validation of modifications should explain the procedure that will be followed for reporting and validating study data and address statistical analysis of study results. The



**TNI Mentoring
Workshop cont.**

Requirements for Quality Systems in Environmental Testing Laboratories

The TNI Quality Systems Committee has developed and approved a consensus quality systems standard for use by environmental testing laboratories. The standard is based on ISO 17025:2005, NELAC 2003 Chapter 5 and DoD QSM. This new standard starts with a general requirements module which outlines the management system requirements for all environmental testing laboratories. The standard then includes modules for technical areas, Asbestos, Chemistry, Microbiology, Radiochemistry and Toxicity, and additional modules can be added addressing new technologies, new programs (Drinking Water or Homeland Security) and possibly contract compliance (DoD, Superfund or DOE).



Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086
Jerry Parr
Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
URL: <http://www.nelac-institute.org>

Method Modifications: “What do I record?” (cont)

report of the validation study must include raw data that will allow an independent reviewer to verify each determination and calculation performed by the laboratory.

- ◆ The modified method should include a brief justification for why the modifications are needed. Examples might include the method successfully overcomes interferences or significantly improves the quality of the analyses or the cost of analysis is significantly reduced using the modified method.

The Method Modifications Mentor Session will include detailed discussion of quality control checks that are essential and must be included in documentation in addition to matrices for which the method is satisfactory; data for the modified method, as well as the original method; calibration; method detection limit; reagent blank; laboratory fortified blank; matrix spike and matrix spike duplicates; internal standards, surrogate standards or tracers; control charts or other trend analyses of quality control results; specific frequency of control checks; and quality control (QC) acceptance criteria. If these QC checks are not included, a written rationale that indicates why they are inappropriate must be provided.

Status of the New Environmental Sector Standards

By Ken Jackson, Independent

The TNI Consensus Standards Development Program (CSDP) is on the brink of reaching a major milestone, by finalizing the Environmental Sector Standards. These standards for environmental laboratory accreditation are designed to replace the 2003 NELAC Standards that are now in use by the NELAP Accreditation Bodies (ABs).

The CSDP is accredited by the American National Standard Institution (ANSI) as a consensus standards developer. The ANSI requirements are incorporated in the TNI Procedures Governing Standards Development, which can be found on the TNI website, <http://www.nelac-institute.org>.

The Environmental Sector Standards were developed by four Expert Committees (i.e., Accreditation Body, On-Site Assessment, Proficiency Testing, and Quality Systems). Each Expert Committee has balanced membership (i.e., an ANSI requirement), so that all government and private-sector stakeholders are represented without any interest group being in a dominant position.

The standards have several major advantages over the existing NELAC Standards. First, they are arranged into separate volumes for laboratories, accreditation bodies, proficiency test providers, and accreditors of proficiency test providers. This will make it especially easier for laboratories, who will find all their requirements in one volume, without having to search through the entire standard as they do now with the NELAC Standard.

Second, the standards are fully compliant with all applicable ISO requirements. This applies to the accreditation body volume (ISO 17011), and the quality system general requirements in the laboratory volume (ISO 17035). These volumes will be available with the ISO clauses included, and supplemented by additional TNI requirements.

Third, the accreditation body and laboratory volumes are further separated into modules for ease of use (e.g., the laboratory volume consists of a proficiency testing module, a quality systems general requirements module, and specific quality systems modules for asbestos, chemistry, microbiology, radiochemistry and toxicity). Although the new standards may look a lot different at first glance, a crosswalk shows few major changes in requirements from the old NELAC Standard (e.g., the NELAC



EPA's Office of Water Publishes Memo Clarifying EPA Role in NELAP

On April 29, 2009, Cynthia Dougherty, the Director of EPA's Office of Ground Water and Drinking Water (OGWDW) released a memo to clarify the roles and responsibilities for EPA's Regional Offices relative to the National Environmental Laboratory Accreditation Program (NELAP) in oversight and decision-making associated with state Accreditation Bodies (ABs) and NELAP-accredited State laboratories.

The memo indicates that EPA “values Regional participation in the NELAP-led evaluations of the State AB programs and encourages continued participation.” EPA believes their participation “promotes quality and consistency.”

A copy of this memo is on the TNI website under News.



Contact TNI

The NELAC Institute
P.O. Box 2439
Weatherford, TX 76086
Jerry Parr
Executive Director
Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
URL: <http://www.nelac-institute.org>

Status of the New Environmental Sector Standards (cont)

quality system requirements currently in use already incorporate the essential ISO requirements, but without the specific ISO language).

The standards development process, described in the Procedures Governing Standards Development, afforded all TNI members the opportunity to vote on the draft standard and provide comments. All persuasive comments were then considered by the Expert Committees, who modified the draft standard as appropriate to produce the final standard. However, the "final standard" was not quite final, since editorial changes are allowed and also Tentative Interim Amendments (TIAs).

An editorial change must be only grammatical or provide clarification and cannot change the intent of the standard. Any change to the standard must be made with a TIA, which also must just be a temporary change arising from an unforeseen circumstance, must be of an emergency nature, and must be non-controversial. A TIA can only remain as such until the next standards revision cycle when it must be presented for membership vote along with all other proposed changes.

The TNI Laboratory Accreditation System Committee (LASC) was charged with examining the standard to determine if it would be suitable for adoption and implementation by the state accreditation bodies that comprise the National Environmental Laboratory Accreditation Program (NELAP). A very thorough review by LASC has resulted in several recommendations for modification of the "final" standard. Fortunately, most of these are editorial; however, there are a small number of proposed TIAs that have been published on the TNI website to allow fifteen days for anyone to comment. This process is now complete with the only comments being suggestions for grammatical rewording or clarification. At the time of writing this article, the Expert Committees are in the process of voting on the final wording of the TIAs.

The next step will be to provide LASC with the amended standard showing all editorial and TIA changes. Provided LASC has no further comment, this will indeed be the final standard for submission to the NELAP Accreditation Bodies, who are scheduled to discuss their progress on acceptance of the standard at the August Forum on Laboratory Accreditation in San Antonio, Texas.

Anyone wanting more information on the TNI standards development process is encouraged to attend the special workshop on this topic Monday, August 10th during the San Antonio meeting. There is a sidebar topic in this newsletter that highlights further details of the session.

SSAS Committee: Review of Voting Draft Standards

By Maria Friedman, TestAmerica

In accordance with Section 5.3.7 of The NELAC Institute (TNI) Policies Governing Standards Development, the Stationary Source Audit Sample (SSAS) Expert Committee will publicly review comments received on the three Voting Draft Standards developed by the committee over the past years at the Environmental Measurement Symposium in San Antonio, Texas on Tuesday, August 11, 2009. The three Voting Draft Standards are titled: General Requirements for Stationary Source Audit Sample Providers (Volume I, Module 1); General Requirements for an Accreditor of Stationary Source Audit Sample Providers (Volume I, Module 2); and Requirements for Participation in the Stationary Source Audit Sample Program (Volume I, Module 3). These Standards are intended to enable the externalization of the EPA's Stationary Source Audit Program (SSAP).

The SSAS Committee will also provide an update on the development of a TNI database to capture audit sample information in support of the audit sample program.



Other Upcoming Meetings of Interest to Members

Virginia Water Environment Federation
Good Laboratory Practices Conference
 August 3-4
 Charlottesville, VA
<http://www.vwea.org>

New York and Pennsylvania Association of Accredited Environmental Laboratories
Annual Meeting
 July 19-21
 Lancaster, PA
<http://www.nyaael.org>

Department of Energy Consolidated Audit Program
Analytical Services Program (ASP) Workshop
 September 13-17
 Jackson Hole, WY
<https://doecap.oro.doe.gov/>



Contact TNI

The NELAC Institute
 P.O. Box 2439
 Weatherford, TX 76086
 Jerry Parr
 Executive Director
 Phone: 817.598.1624

Email: jerry.parr@nelac-institute.org
 URL: <http://www.nelac-institute.org>

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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.

Contact TNI

The NELAC Institute; P.O. Box 2439; Weatherford, TX 76086
 Jerry Parr, Executive Director
 Phone: 817.598.1624; Email: jerry.parr@nelac-institute.org; URL: <http://www.nelac-institute.org>

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