

The Institute Review

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First Quarter 2011

Recap of Savannah Meeting, and On to Seattle!

By Carol Batterton, TNI

Over 200 people attended the Forum on Laboratory Accreditation in Savannah, which was packed full of meetings and information for attendees. There were a number of regular committee meetings, as well as several special focus groups. This article summarizes several meetings that are not otherwise discussed in this issue of *The Institute Review*.

One of the highlights of the Savannah conference was the US Environmental Protection Agency's (EPA's) special presentation on *Flexible Approaches to Environmental Measurements*. EPA program staff presented updates on how their respective program office has been flexible approaches to environmental measurements. The EPA also provided a series of free webinars in February and March for those not in attendance at the conference. A copy of the presentation is available at <http://www.epa.gov/fem>.

Representatives of TNI met with the EPA Office of Pesticides and Programs staff to discuss requirements for labs involved in efficacy testing of antimicrobial disinfectants. TNI may be able to assist the EPA in accrediting these labs.

The Stationary Source Audit Sampling (SSAS) expert committee met and Maria Friedman, Chair, reported that the TNI Standard for SSAS was complete. EPA regulations have been changed and the committee is answering some final questions from the EPA about the TNI program before implementation begins.

Discussions continued with the EPA regarding the *Cryptosporidium* program. This was primarily an information sharing meeting. The EPA has indicated it would like to pursue discussion with TNI about providing assistance with the Proficiency Testing (PT) portion of the program.

The Advocacy Committee held a joint meeting with representatives of the Association of Public Health Laboratories (APHL) to begin discussions on options to accredit state environmental labs. Advocacy will appoint a sub-committee, chaired by Ken Jackson, to work on this with APHL.

Now, it is time to think about the *Environmental Measurement Symposium* to be held in Bellevue, WA, on Seattle's eastside, from August 15 – 18, 2010! The combined meeting of the National Environmental Monitoring Conference (NEMC) and the Forum on Laboratory Accreditation (Forum) is in its fifth year and has been hailed as "...a meeting anyone in this business cannot afford to miss..." by many attendees from the past symposiums. As part of the Symposium, the EPA's Environmental Laboratory Advisory Board will also meet. This is 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, with a focus this year for the NEMC portion of the meeting being *Environmental Monitoring Community Response to Environmental Disasters*.

Concurrent technical sessions will be held on Monday, Tuesday, Wednesday, and Thursday. Wednesday morning will be a general session on the conference theme of responding to disasters. The NEMC technical sessions will be announced soon on the NEMC website at <http://www.nemc.us>. The Forum portion of the meeting will consist of committee meetings, an assessment forum, mentoring sessions, and training courses and workshops. Watch for registration details on the new Environmental Measurement Symposium website (<http://www.envmeasym.org>) and be sure to make your reservations soon. This will be one meeting this year that you do not want to miss!!!



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A Tale of Two Committees

By Shawn Kassner, Environmental Resource Associates

Charles Dickens wrote in a "Tale of Two Cities", "It was the best of times and it was the worst of times..." So goes this tale of these two committees.

The implementation of new standards is never an easy undertaking nor are these implementations ever smoothly done. As we move in time further away from last the standards' implementation, the memory of the difficulties experienced and the hard work required to implement the standards fades. The 2009 TNI Standards are no different nor are they strangers to implementation issues. The 2009 TNI Standards were voted on and approved by the TNI membership and the Accreditation Council (AC). However, at the time of implementation, the AC began to re-examine the standards and noted issues with the Proficiency Testing (PT) sections of each of the modules. The AC began debating and meeting over these issues and became very concerned that the standards were not implementable due to several concerns the AC had with the PT sections in each of the volumes.

In mid-November, the Laboratory PT Expert Committee had received news that the AC was indeed looking at a possible veto of the standards due to their implementation concerns. The Laboratory PT Expert committee had not heard directly from the AC, but through the TNI communication channels (i.e., Jerry Parr). To be honest, each of the committees felt a degree of frustration with one another over the concerns. The AC felt that their concerns were not sufficiently heard during the comment period for the 2009 TNI Standards development, while the Laboratory PT Expert Committee felt that the AC had not fully read the standards with an eye toward implementation. Regardless, the issues remained and the two committees were at odds as to how to resolve them.

The Laboratory PT Expert Committee had received documentation from the AC noting the issues discovered during their review of the 2009 TNI Standards for implementation and rule-making. The document was reviewed during the Laboratory PT Expert Committee call on November 30, 2010. Also during this timeframe, Aaren Alger, AC Chair, and Kirstin McCracken, Laboratory PT Expert Committee Chair, had each attended several meetings together where the view points of both committees had been voiced. It became apparent that the implementation issues needed to be addressed by members of both committees. The Laboratory PT Expert Committee determined that a small group made up from each of the committees should be gathered to begin communicating and understanding the issues. The Laboratory PT Expert Committee reached out to the AC and a group was quickly formed.

Early December 2010, members of the Laboratory PT Expert Committee — Shawn Kassner, Stacie Metzler, and Scott Hoatson — arranged to meet with members of the AC — Aaren Alger and Susan Wyatt — to review the implementation concerns of the AC. The issues that Aaren and Susan brought forth were boiled down to four main concerns.

The first concern was the use of analysis dates versus study close dates for tracking PT sample results for laboratories. The AC concern was that this placed a heavy burden on the Accreditation Bodies (ABs) to track each analyte/technology/matrix combination for laboratory accreditation by the dates of analysis, especially with many ABs still tracking PT data manually. Even those ABs with database reporting systems would have to make programmatic changes. The AC also felt that this requirement would be difficult for laboratories in tracking their own PT results and could result in unintended certification issues for the laboratories.

The second issue the AC raised dealt with the change to Limit of Quantitation (LOQ) reporting and the evaluation of less than (<) values. The 2009 TNI Standard changes the evaluation of < values when the analyte has been added to the PT sample. The 2003 standards evaluated all < values as "Not Acceptable", when the analyte was added to the sample and the lower acceptance limit was greater than zero. This requirement forced many laboratories to consider a "PT Reporting Limit" published on the TNI website, and report values to a LOQ that was comparable to how all other sample results were reported. The 2009 TNI Standard evaluates all results as "Acceptable", when analytes added to the sample have a < value reported that is greater than the lower acceptance limit, thus allowing laboratories to report PT results just like their normal sample results. The AC agreed that laboratories should be following their same procedures for reporting PT data just as they follow their normal procedures in analyzing their PT samples.



Newly Directors Elected

The NELAC Institute held an election for individuals to serve as members of the TNI Board of Directors for three-year terms, beginning on April 13, 2011. The individuals listed below were elected by the membership:

Keith Greenaway

ANSI/ASQ Nat'l Accreditation Board;
Alexandria, VA
Accreditation Body

Patsy Root

IDEXX Laboratories; Westbrook, ME
Other

Matt Sica

Maine CDC DEH DWP; Augusta, ME
Accreditation Body



EPA Publishes Proposed Rule: "Improving EPA Regulations"

On February 23, EPA published a proposed rule entitled "Improving EPA Regulations", whose stated goal was to "conduct a retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome and to modify, streamline, expand, or repeal them in accordance with what has been learned."

TNI submitted comments on the proposed rule supporting TNI efforts on accreditation. A copy of TNI's comment is now available on the TNI website under News.



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A Tale of Two Committees (cont.)

The third issue raised by the AC was the clause allowing the use of unaccredited PT Providers in the case where a Fields of Proficiency Testing (FoPT) Table existed with analytes and there were no accredited providers to supply the laboratories a sample for the analytes.

The last issue the group discussed was the dreaded experimental analytes. For many reasons, members of the AC could never come to terms as to how to implement experimental analytes, including legislation within each state. The group came to the conclusion that language concerning experimental PT's should be removed from the 2009 Standards. Especially, since the PT Executive Committee was already working to remove the experimental analytes from the TNI FoPT tables. However, the group felt that language and procedures had to be adopted for the addition and the removal of analytes from the FoPT tables.

Scott, Shawn, and Stacie agreed to take these concerns and their possible solutions back to the Laboratory PT Expert Committee for their review and further discussion. The issues were discussed for the next few meetings leading to the Savannah Forum in January.

Throughout the discussions, the two committees were always in communication concerning the possible solutions being developed and the language being proposed. Scott Hoatson, who serves on both committees, was instrumental in playing liaison, carrying communications back and forth between the groups and providing each group with insight into the substance of other groups' communication. Although differences between the two groups arose, there was never frustration over a lack of communication or cooperation.

The Laboratory PT Expert Committee is currently working to draft language to resolve these issues for the upcoming Working Draft Standard and continues to work with the AC to find solutions to the implementation concerns.

In Savannah, the Laboratory PT Expert Committee met with members of the AC and had one of the best working sessions in recent memory, according to Kirstin McCracken. Members of the Laboratory PT Expert Committee also attended the AC session and were there to support the solutions provided. Now, the tale does not end here, and as noted, solutions are still being decided upon for a couple of the AC concerns for the Working Draft Standard. The moral of the story is this...communication, which is open and honest, and met with professional, solution-focused individuals will always lead to the best of times, even when it is during the worst of times.

National Accreditation Program for Field Activities

By Marlene Moore, Advanced Systems

The National Environmental Field Accreditation Program (NEFAP) program is ready for implementation! The NEFAP Executive Committee has established and approved Standard Operating Procedures (SOP's) for organization and operation of the program. The Executive Committee is in the process of evaluating applications from Accreditation Bodies (ABs).

ABs with acceptable documentation of implementation of the TNI Field Sampling and Measurement Organization (FSMO) Standards will be announced on the TNI website in May/June 2011.

Field Sampling and Measurement Organizations (FSMOs) should apply to the ABs. The ABs will be witnessed as part of the TNI evaluation process. Following the witnessing and completion of the evaluation process, the ABs will be recognized by TNI as NEFAP ABs. This announcement is expected in January 2012. Accreditation can be used as a marketing tool and a competitive advantage in the sampling and data collection field. FSMOs can establish themselves as a leaders in the industry by becoming one of the first organizations to obtain national accreditation

Data users should start to specify the need for accreditation of FSMOs when performing sampling and testing for any environmental project. Placing the requirement for accreditation in contracts helps the data user know that the field sampling and measurements are coming from technically competent organizations.

The purpose of the TNI FSMO Standard is to establish a uniform standard for ABs and FSMOs to improve the quality and consistency of environmental data collected in the field. The Standard establishes quality systems and procedures for FSMOs aligned with the practical



Upcoming Meetings of Interest to Members

TCEQ Trade Fair

May 3-4
Austin, TX

<http://www.tceq.state.tx.us/>

Oregon Environmental Laboratory Association

May 12
Salem, OR

<http://www.oelaonline.com/index.php>

Florida Society of Environmental Analysts

May 25-27

Clearwater Beach, FL
<http://www.fsea.net>

American Public Health Laboratories Annual Conference

June 5-8
Omaha, NE

<http://www.aphl.org>



If you know of any upcoming meetings of interest to environmental laboratory professionals, please contact Jerry Parr at

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National Accreditation Program for Field Activities (cont.)

constraints of sample collection and field measurement as well as regulatory and industry specific requirements. The Standards are based on an ISO foundation; ISO/IEC 17025 for FSMOs and ISO/IEC 17011 for ABs.

A committee of industry experts representing interested stakeholders (i.e., regulatory agencies, accreditation bodies, field sampling and measurement companies, laboratories, and other interests) developed the Standard with the intention of setting standards that establish criteria. As the Standard is implemented, improvements are expected, so the committee is starting to work on changes to the Standard. The Field Activities Expert Committee of TNI is seeking members to assist with the task of updating and improving the Standard.

Keep current with program status and updates on the TNI website at <http://www.nelac-institute.org/newnefap.php>.

Looking for a Few Good Volunteers

By Judy Duncan, Oklahoma DEQ

"Most of the work of TNI is done by volunteers working on committees tasked with specific functions." This quote comes directly from the TNI website and truer words were never spoken. TNI is an organization of volunteers who devote their time and effort to furtherance of the organization's mission of *"fostering the generation of environmental data of known and documented quality through an open, inclusive, and transparent process that is responsive to the needs of the community."* TNI is always looking for ways to increase participation in our activities, and committee membership is an opportunity that is open to all members.

Most TNI committees may have both full and associate members. A "committee member" has full voting privileges. An "associate member" may participate on the committee, but does not have voting privileges. The normal cycle of committee appointments starts in January and ends in December of the same year. TNI members interested in becoming committee members may nominate themselves or can be nominated by another TNI member by completing the nomination form available on the TNI website.

If you are interested in actively helping our organization, please complete a [TNI Committee Application](#). Participation on TNI committees is described in ["Operations of TNI Committees."](#)

I made a decision to serve on a committee with TNI's predecessor organization over 15 years ago and it is a decision that has enriched my life in many ways. Not only have I had an opportunity for input into the way that the national environmental accreditation program has developed, I have formed friendships with many of my colleagues across the country! This is an opportunity that is open to any TNI member and I hope that many of you will consider becoming active in this manner.

Website Redesign

By William Daystrom, TNI

A number of recent changes to the TNI website (<http://www.nelac-institute.org>) have improved its functionality and appearance. The recent changes are summarized below.

New presentations page for past meetings. The new page provides a much easier way to locate and download presentations from past TNI Forums and Symposiums. It is a simplified subset of the Document Library with the added ability to filter presentations by the meeting where they were given. (<http://www.nelac-institute.org/meeting-presentations.php>)

New page for the Environmental Measurement Methods Expert Committee. A page was created for this new expert committee. (<http://www.nelac-institute.org/cms/posts/1299053623.php>)

New Education Delivery System page. A Training Needs and Opportunities survey has been underway for the past couple of weeks, collecting information for Ilona to use with the new Education system. Development is continuing on pages dedicated to this. The goal is to provide a searchable listing of live and pre-recorded training presentations that can be registered or purchased. (<http://www.nelac-institute.org/eds-home.php>)



National Environmental Monitoring Conference

The National Environmental Monitoring Conference (NEMC) provides the principal forum for addressing policy and technical issues affecting monitoring in all environmental media (i.e., water, air, soil, and waste) and across all environmental programs. Since 2007, NEMC has been combined with TNI's Forum on Laboratory Accreditation under the auspices of the Environmental Measurement Symposium to allow many attendees to minimize travel costs.

The 2011 Environmental Measurement Symposium will be held in Seattle, WA from August 15–19, 2011. For more information, visit the NEMC website at <http://www.nemc.us>.



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Website Redesign (cont.)

Change the main menu design to a horizontal menu. The new design has the following features and benefits:

- ◆ This layout allows full page width to be used for content.
- ◆ Menus and command buttons (e.g., Search, Contact TNI) are grouped together, so the visitor need not scan the page looking for the menu option or button they need.
- ◆ Rotating slides on home page are wider and not as tall as the previous slides. This provides for better presentation of information.
- ◆ The wider layout also provides room on the home page for a Resources section, next to the existing Quick Links. This section has buttons for the new Education page and the Document Library. When ready, buttons will be added for the Stationary Source Audit Sampling (SSAS) Central Database and the Laboratory Accreditation Management System (LAMS) to this space.

In addition, some pages built for the website in the past have gone without TNI menus at all due to problems encountered incorporating their content into the current layout; among these are the various ballots TNI has conducted, the Standards Interpretation Request voting pages, the SSAS Central Database, and the new training survey. The new layout largely eliminates this issue.

Consistency is Like a Box of Chocolates...

By Alfredo Sotomayor, Wisconsin DNR

The Consistency Improvement Task Force (CITF) held a half-day session at the Forum on Laboratory Accreditation in Savannah. The CITF was chartered by the TNI Board of Directors to improve the consistency of TNI assessments and evaluations. To accomplish its mission, the CITF set itself four main goals:

- ◆ Establishing realistic expectations about consistency.
- ◆ Improving the consistency of laboratory assessments.
- ◆ Improving the consistency of accreditation body evaluations.
- ◆ Engaging laboratories and users of data to improve consistency.

The CITF has identified specific tasks to support each of the goals. During the first part of the Savannah session, CITF leaders offered progress reports on those tasks.

Another Look at Consistency

The CITF Chair, Mr. Alfredo Sotomayor, opened the session challenging attendees to take another look at the nature of consistency. Mr. Sotomayor reiterated that consistency is not treating all in identical fashion or a “one-size fits all approach”. “Consistency is contextual”, he stated. Achieving and evaluating consistency requires different actions in different settings. He said the CITF is exploring how risk and cost can be used to decide where to focus consistency improvement efforts.

During his presentation, Mr. Sotomayor explored how the “decline effect” could help us understand consistency. The term, as discussed by Jonah Leher (i.e., The New Yorker, December 13, 2010), describes how, as experiments are repeated, results that were well established and documented diminish progressively and at times drastically. Even after controlling variables, experimenters find that what were strong findings and correlations weaken noticeably with each replication attempt. He cautioned that successful attempts at improving consistency may suffer from the decline effect as they get repeated in and among laboratories, and in and between ABs. Randomness cannot be ignored in diagnosing inconsistency and evaluating correctives to improve it.

True Blue

Dr. Thomas McAninch leads the CITF group exploring means to improve the consistency of assessments. His group has focused efforts in developing an assessment blueprint. When



Accreditation Body Task Force

Judy Duncan, Oklahoma DEQ

What is the Accreditation Body (AB) Task Force? A group commissioned by the TNI Board of Directors to explore ways to assist ABs in dealing with problems caused by today's economic downturn.

How can I find out what they are doing? Preliminary findings and recommendations were presented to the TNI membership at Savannah and may be viewed on the website at <http://www.nelac-institute.org/docs/meetings/savannah2011/AB%20task%20force%20-%20savannah%20-%20notes.pdf>.

What happens next? The AB Task Force has consulted with the Laboratory Accreditation System Executive Committee (LASEC) and the NELAP AC and plans to present a report to the TNI Board in April.



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Consistency is Like a Box of Chocolates... (cont.)

completed, the blueprint will provide, in a step-wise process, a tool to focus on major and secondary steps in the assessment process that are most prone to inconsistency.

Dr. McAninch's group has identified 17 major assessment components that are potential sources of inconsistency. Notable among those are the: length of routine assessments, selection of methods to review, assignment of assessment team, completeness of assessment, use of data review and staff interviews, citation of findings, definition of repeat findings, handling of disagreements between assessor and laboratory staff, and issuing of draft reports. Dr. McAninch reviewed recommendations reached by his group and mentioned they would be considered by the CITF for inclusion in a final report.

Planning Upfront for Consistency

The CITF had identified Consistency Plans as a tool that ABs should use to address and improve inconsistencies systematically. The CITF envisions that those plans would be reviewed during AB on-site evaluations. Ms. Susan Wyatt, a member of the CITF group addressing inconsistencies among ABs, offered an example of an AB's Consistency Plan. Her plan identified eight potential sources of major inconsistencies: interpretation of the Standard, accreditation decisions, scopes of accreditation, accreditation schedules, corrective action follow-ups, assessor training, assessor evaluation, and focus of assessments.

Ms. Wyatt's Consistency Plan identified the following prescriptives: aligning mission and goals, insisting on professional conduct, valuing education, reducing waste and inefficiency, communicating with customers, following established procedures, and understanding the AB's relationship with stakeholders. Ms. Wyatt gave examples of specific actions her AB would take to meet the plan's directives.

We, The Labs

Ms. Verl Preston presented the latest version of the "Laboratory Bill of Rights", one of the projects that her group, tasked with engaging laboratory and data users, has undertaken. Ms. Preston's group identified four general categories or articles for the bill: standard interpretation, proficiency testing, assessment, and laboratory management.

The four articles include 23 rights. Notably, the laboratory has a right to:

- ◆ a uniform interpretation of the TNI Standard;
- ◆ contest assessor interpretations;
- ◆ analyze the same PT sample for any accreditation by multiple methods, as long as those test methods are within the same field of accreditation matrix;
- ◆ submit questions about PT samples to the PT provider;
- ◆ expect trained, competent and qualified assessors that are free of conflicts of interest;
- ◆ provide an evaluation of the audit and audit team without fear of retaliation;
- ◆ designate individuals of laboratory staff to serve more than one management function; and
- ◆ inquire as to the end-use of data to determine applicability of the standards.

Ms. Preston emphasized that the "Laboratory Bill of Rights" did not absolve laboratories and data users from fulfilling their concomitant responsibilities.

Around the World in 80 Minutes

During the second part of the CITF, session attendees participated in an interactive exercise. Four stations, each decorated with elements of four different countries were set to correspond to each of the goals of the CITF. Attendees visited, at timed intervals, each of the World Cafes in groups and were asked to provide input to questions or concerns served by master waiters.

In Italy, guests rated the risks of five laboratory findings and the associated costs of correcting them or not resolving them. In Mexico, travelers mused that inconsistency was not as big a



Congratulations to John Grumpper!

He submitted the winning entry in the CITF meeting in Savannah when asked to complete the sentence "Life is like a..." by writing:

"Life is like the sample receiving area of an environmental laboratory..."

Please contact the [TNI Executive Director](#) for your box of chocolates.



TNI Participation in State Legislative and Regulatory Initiatives

Over the past few months, a number of states, including Florida, Kentucky, Maine, and New Jersey, have initiated actions to potentially revise the legislation or regulations concerning laboratory accreditation. TNI has been monitoring these activities to some degree and encouraging participation in the process by TNI members.

TNI's Advocacy Committee has also developed a White Paper in support of TNI's National Environmental Laboratory Accreditation Program. This White Paper is published on the TNI website under News. TNI encourages all members to contact TNI for assistance as needed to support state initiatives.



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Consistency is Like a Box of Chocolates... (cont.)

problem as in previous years because state programs had matured, and pondered, over chips and salsa, the usefulness of leaving draft reports at a laboratory after a closing conference.

In Greece, visitors consulted the olive oil oracle and found that the most critical areas of inconsistency were interpretation of the Standard, the frequency and depth of assessor training, and the scope and primary focus of assessments. In China, company realized that new method validation, method modifications, and limits of detection/limits of quantitation (LOD/LOQ) were the top three areas requiring more instruction and clarity for laboratories. And in China, a miracle of consistency occurred when all fortune cookies revealed the same message: "For assured accreditation success, communicate with your AB."

Next Steps

The CITF will continue to work on these and other projects. The tools developed by each of the work groups will be included in a report, along with a set of recommendations, for consideration and endorsement by the TNI Board of Directors. The CITF will provide a progress update at the Environmental Measurement Symposium this summer.

Update from the NELAP Accreditation Council

By Lynn Bradley, TNI

The renewal cycle for Accreditation Bodies (ABs) has begun again. Each AB's evaluation begins in time to allow completion 3 years after the previous cycle's renewal approval – a "rolling" schedule instead of "batches", as was done in the past. At press time, six evaluations are underway for KS, NH, LA DHH, PA, NY, and UT.

The Accreditation Council (AC) has modified its voting policy to accommodate electronic voting on Standards Interpretation Requests (SIRs), so that discussion in an AC meeting is only necessary if an AB specifically requests it or casts a "veto" vote. The policy itself awaits final approval from the Policy Committee, but has been implemented and is expected to substantially reduce the backlog of SIRs.

Some changes to the AC's implementation of the 2009 TNI Standard will be of utmost importance to laboratories participating in the NELAP Accreditation Program. Due to state governmental changes and political realities (e.g., such as a freeze on regulations by a new governor, for example), not all states will be able to implement the new Standard on July 1, 2011, as earlier agreed upon. The extent of such delays became obvious shortly before the conference in Savannah, as new governors were installed into office and began to make changes in state operations.

The AC and each of the 15 ABs fully commit to maintaining reciprocal recognition regardless of which standard is in use by any individual AB. As TNI's Chair of the Board stated, this is no different than when NELAC changed from the 2001 to the 2003 Standard, and TNI's Board of Directors has accepted the AC's proposal for a "rolling implementation." Expectations were that the change-over could be accomplished on a fixed date, but reality intervened and it is simply impossible.

The AC has asked the Laboratory Accreditation Systems Executive Committee (LAS EC) to speedily recommend an Implementation Policy to address this rolling implementation. Specifically, that policy will address general concepts for reciprocity, as well as how laboratories might juggle two primary ABs with different standards in use, plus as many of the details as can be foreseen and reasonably addressed in the time available for development of the policy.

The AC expects that the Implementation Policy will be completed and approved well before July 1, 2011, so that it will be available to the TNI community. This policy will address how the labs should proceed with changing over to the new Standard, in such a way that reciprocity continues to exist in all aspects. The AC has determined that all issued accreditation certificates will continue to be recognized as valid by all ABs, regardless of which standard is the basis for a particular AB's program at any given point in time.

For ease of reference, the status of each AB is listed on the next page, as discussed during that meeting.



Guidance on Implementing the New Standards for Laboratories

Over the past 15 months, TNI has held 22 regional workshops on implementing the new TNI Standard with 3 more planned for April of this year: Las Vegas, NV on April 14; Denver, CO on April 18; and Louisville, KY on April 21.

A detailed agenda for these workshops and registration information is available on the TNI website under News. A webinar will then be scheduled for May or June. This webinar will be recorded and converted to a downloadable webcast for those that cannot participate.

In addition, TNI has developed a companion guidance document, "Implementing the New TNI Standard", that provides a table summarizing all changes from the 2003 NELAC Standard to the 2009 TNI Standard. That document is now available on the TNI website.



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Update from the NELAP Accreditation Council (cont.)

State AB	Status
CA	No problem with reciprocity. Unknown when TNI Standard can be implemented, but is beginning the process.
FL	Essentially no impact, no problem with reciprocity. FL forms to implement new Standard are in rulemaking, held up by cessation of rule promulgation in FL.
IL	No problem with reciprocity. Expects to implement TNI Standard by the end of 2011.
KS	No problem with reciprocity. Due to change of administration, unclear when implementation of TNI Standard can begin.
LA DEQ	No problem with reciprocity. Will implement TNI Standard in August 2011
LA DHH	No problem with reciprocity. Moving to TNI Standard on July 1.
MN	No problem with reciprocity. Ready to implement TNI Standard on July 1.
NH	No problem with reciprocity. Rules are written, but now delayed one year. Will assess labs against whichever Standard the lab has in use.
NJ	No problem with reciprocity. Has a "name change" underway. Has not proposed rules for implementing TNI Standard, may delay.
NY	No problem with reciprocity. Rewriting regulations now, expects July 1 implementation of Modules 1 and 3; PT issues will delay implementation of PT module 2.
OR	No problem with reciprocity. Preparing now for July 1 implementation of TNI Standard.
PA	No problem with reciprocity. PA rules reference the AC adopted Standard.
TX	No problem with reciprocity. Preparing to transition to TNI Standard on July 1.
UT	No problem with reciprocity. On track for July 1 implementation of TNI Standard.
VA	No problem with reciprocity. Cannot adopt TNI Standard now, but can initiate new regulations in 2012.

EPA Issues Policy on Laboratory Competency

By Jerry Parr, TNI

On April 4, 2011, EPA published a policy, Policy Directive FEM-2011-1, requiring that organizations generating environmental data through measurement under Agency-funded acquisitions must submit documentation of their competency, which may include participation in applicable certification and/or accreditation programs. The policy states:

Organizations performing environmental analysis for the Agency shall demonstrate their qualifications in the fields of analyses to be conducted, prior to performing such analyses. Where accreditation or certification is available for those fields of analysis, organizations may submit documentation of existing accreditations or certifications. Accreditation/certification granted by an organization that accredits environmental data operations to an international consensus standard, or a state accreditation or certification program acceptable to EPA, or that the contracted laboratory is participating in the EPA Contract Laboratory Program for those fields of analyses, shall be valid at the time of award and must be sustained through the life of the period of performance.

A copy of the policy is available at: <http://www.epa.gov/osa/fem/pdfs/fem-lab-competency-policy.pdf>.



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Developed to address the laboratory industry's need to improve its focus on quality issues and recognize those laboratories with exemplary quality performance, the ACIL SOE Program costs \$500/site for ACIL members and \$1,200/site for non-members, complementing other means of quality assessment, while maintaining confidentiality.

To learn more or enroll in the program, [click here](#). We look forward to welcoming your participation!

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Partnering with the EPA

By Jerry Parr, TNI

In 2006, The NELAC Institute (TNI) began to manage the National Environmental Laboratory Accreditation Program (NELAP) that had largely been supported and managed by the US Environmental Protection Agency (EPA) beginning in 1994. Since that time, the EPA has continued to be a strong partner in NELAP by providing EPA liaisons to the TNI Board of Directors and the NELAP Accreditation Council. TNI has expanded this successful partnership into several other areas, which is the focus of this article.

Partnership with the Office of Air

In 2007, after meeting with EPA staff from the Office of Air Quality Planning and Standards (OAQPS), TNI discovered that a key component for ensuring data quality in this program, the stationary source audit sample program, was in danger of ceasing operation due to funding issues. TNI immediately formed an expert committee to develop consensus standards for the operation of this program that could be adopted with an implementation plan and database to continue its operation. TNI anticipates EPA will recognize TNI's program later this year.

Partnerships with the Office of Water

After a Federal Register Notice (FRN) appeared on February 25, 2009 about EPA's laboratory approval program for laboratories analyzing drinking water for cryptosporidium oocysts, TNI contacted the Office of Water and requested EPA explore the feasibility of TNI operating this program. An initial meeting was held in January, 2010 to share information and a Cryptosporidium Working Group was formed with members representing both EPA and TNI. As a result of on-going discussions, TNI has now formed a Protozoa Proficiency Testing (PT) Subcommittee to establish Fields of Proficiency Testing tables for cryptosporidium and related analytes, as already exist for other fields of testing, and continues to discuss bringing the laboratory approval program into the scope of NELAP.

In 2009-2010, TNI and the Office of Water worked together to harmonize the requirements of TNI's proficiency testing program with EPA's Discharge Monitoring Report Quality Assurance (DMRQA) program. That effort culminated in a policy memo issued by EPA allowing TNI's PT results to be used to satisfy DMRQA requirements.

"There is much work still to be done and we hope that by working together we will accomplish great things. TNI continues to be committed to a national accreditation effort, one that may in the future align and meet the needs of the EPA Programs."

~Steve Arms, TNI Board Chair

For the last two years, TNI has worked with EPA's Water Laboratory Alliance (WLA), promoting the program in The Institute Review and hosting WLA meetings at TNI's semi-annual meetings.

Partnership with the Office of Pollution Prevention and Toxic Substances

Recent changes to EPA's National Lead Laboratory Accreditation Program (NLLAP) indicated a need for Field Sampling and Measurement Organizations (FSMOs) to become accredited. TNI's National Environmental Field Activities Program (NEFAP) was formed for the specific purpose of accrediting FSMOs. On April 5, 2010, TNI entered into a Memorandum of Understanding with the Office of Pollution Prevention and Toxic Substances (OPPTS) to:

- ◆ document that the Office of Pollution Prevention and Toxics (OPPT) formally recognizes that NEFAP meets the goals and standards of the NLLAP;
- ◆ establish that TNI's NEFAP is qualified to evaluate, recognize, and perform oversight of the FSMO Abs; and
- ◆ establish that TNI's FSMO accreditation standards will be used by NEFAP ABs to assess and accredit FSMOs to perform analyses of lead in paint films, dust, and soil samples collected and measured on-site using portable field testing technologies.

Partnerships with the Office of Resource Conservation and Recovery

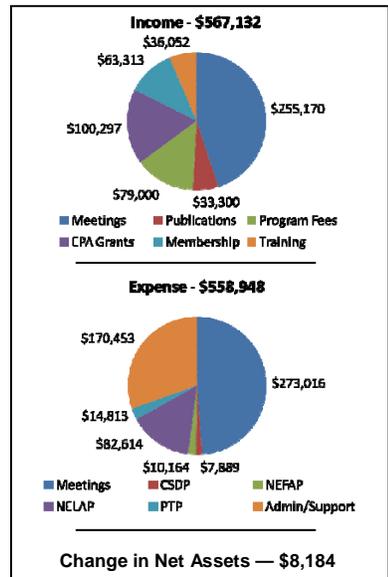
Numerous issues have been identified by the laboratory community on how revisions to the SW-846 methods compendium should be released and used. TNI has been working with EPA's Environmental Laboratory Advisory Board (ELAB) and the Office of Resource Conservation and Recovery (ORCR) to generate a policy on the release of revised SW-846



TNI's 2010 Financial Performance

David Speis, Accutest Laboratories, TNI Treasurer

The pie charts below summarize income and expense for each of TNI's major programs and categories for 2010. Later this year, when TNI files its annual Form 990 with the Internal Revenue Service, that document will be posted on the website in accordance with IRS guidelines for non-profit organizations.



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Partnering with the EPA (cont.)

methods. The goal of the policy is to eliminate confusion about which method version to use when multiple versions of the same method are published.

EPA has developed a process for reporting electronic data that was originally housed by the Contract Laboratory Program (CLP) called the Staged Electronic Data Deliverable (SEDD) system and TNI has encouraged EPA to provide training on this system at TNI meetings. Given SEDD is a tool with broader applicability than the CLP, it is now managed by the Forum on Environmental Measurements (FEM) and resides on their website.

“EPA looks forward to collaborating with TNI, building upon the collaboration over the past 10+ years, as TNI seeks to further develop and expand the accreditation program.”
 ~Michael Shapiro, EPA Office of Water

Partnership with the Forum on Environmental Measurements

EPA’s Forum on Environmental Measurements (FEM) is a standing committee of senior EPA managers formed under the Agency’s Science Policy Council (i.e., now the Science and Technology Policy Council [STPC]). The FEM was established to develop policies to guide the Agency’s measurement community in: validating and disseminating methods for sample collection and analysis; for ensuring that monitoring studies are scientifically rigorous, statistically sound, and yield representative measurements; and for employing a quality systems approach that ensures that the data gathered and used by the Agency is of known and documented quality. Because this group’s mission is so closely allied with that of TNI, TNI provides FEM periodic updates on the progress TNI is making.

Environmental Measurement Methods Expert Committee Holds Inaugural Meeting in Savannah

By Richard Burrows, TestAmerica

The Environmental Measurement Methods Expert Committee (EMMEC) held its inaugural face to face meeting at the Winter TNI conference in Savannah. We spent some time reviewing current options for detection, quantitation and calibration, and then moved on to work on mission and objectives. The Mission Statement was finalized as:

To improve the technical quality of environmental testing methodologies by providing tools (e.g., detection, quantitation and calibration) that assure the quality of data, which may be adopted by federal and state regulatory agencies. It is important that a balance between impact on laboratories and improvement in technical quality be maintained during this process.

We expanded on the Mission Statement with four objectives:

- ◆ Create and adopt standards to support a strong technical approach to quantitation.
- ◆ Create and adopt standards to support a strong technical approach to detection.
- ◆ Create and adopt standards to support a strong technical approach to calibration.
- ◆ Develop standards that are useable across various EPA and state programs.

Finally, we adopted three considerations that we need to take into account as we work towards the objectives:

- ◆ Developed tools should address: data comparability, flexible methods assessment, statistical assessment, and uncertainty.
- ◆ Any standard developed should incorporate data quality objectives.
- ◆ Effective communication of standards and tools.

The name of the subcommittee has led some to believe that we would be working on issues pertaining to specific EPA methods. While that would be a worthy task, it is not the task of this committee, at least initially. Instead, we will be working to develop standards that bring a better understanding and use of the fundamental concepts of detection, quantitation, and calibration that apply to all analytical methods.



EMMEC Committee Members

Member	Interest Category & Stakeholder Group
Richard Burrows TestAmerica Arvada, CO (Chair)	Laboratory
Brooke Connor USGS Denver, CO	Other
Dan Dickinson NYSDOH Albany, NY	Accreditation Body
Tim Fitzpatrick Florida DEP Tallahassee, FL	Laboratory
Nancy Grams Advanced Earth Technologies, Inc. Cocoa Beach, FL	Other
Anand Mudambi USEPA Washington, DC	Other
John Philips Ford Motor Co. Dearborn, MI	Other
Lee Wolf Columbia Analytical Services Kelso, WA	Laboratory



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Environmental Measurement Methods Expert Committee (cont.)

The committee decided to start with calibration in the hope that this might be a less controversial and difficult topic than detection or quantitation (i.e., it remains to be seen if this is, in fact, the case). We have created two subcommittees that are presently considering questions related to calibration curve development and calibration assessment respectively.

While analytical methods have advanced considerably in the last 30 years, our application and use of the fundamental parameters translating an instrument response in to a concentration, a result of "known and documented quality" have remained static. This needs to change and I firmly believe that the work of this committee can result in a major improvement in our use of measurement technologies. We have highly energetic and knowledgeable committee members, listed on page 10, and also several active associate members making valuable contributions.

New TNI Training — Educational Delivery System

By Ilona Taunton, TNI

If you have been on the TNI website, you will have seen a new tab called "Education". This is where you will find information about TNI's new training system. Currently, there is an application for providing training and a survey to give us information about training needs and training interests. When you click on the Application, you will find a link to the Draft Standard Operating Procedure (SOP) that describes the program in more detail. The electronic survey will be up until mid-April.

The training system is part of the Administration and Support arm of TNI, but each program has a committee or subcommittee designated with the responsibility to evaluate the training needs of the program and its users. NELAP has designated the Technical Assistance Committee (TAC), and NEFAP is developing a new subcommittee called the NEFAP Training Oversight Subcommittee, for this purpose.

This comprehensive training system utilizes various face-to-face and web-based types of training. Training courses, workshops, forums, seminars, and on-demand education materials are being developed by TNI and trainers. The material is reviewed and approved by TNI and then made available on the TNI website to its members and the environmental community. TNI held their first webinars in February for AB Evaluation training.

Trainers are offered various services that TNI provides to help them expand their training options. Trainers can develop proposals to partner with TNI or take advantage of specific services such as posting of courses they are teaching outside of TNI or the use of the TNI logo. There are also vendor opportunities to sponsor training and options for TNI training at regional meetings.

The site should be complete by mid-April. Upcoming training events include Quality Manual Template Workshops and Webinars; NELAP and NEFAP AB Evaluator Training Webcasts; NEFAP Assessor Training Webinar; and a few regional workshops for laboratories on the new TNI Standard.

Contact Ilona Taunton (Ilona.taunton@nelac-institute.org) or Jerry Parr (jerry.parr@nelac-institute.org) with any questions.

Member Spotlight

Due to unforeseen issues, the Member Spotlight is not included in this issue of *The Institute Review*, but will reappear in the next issue scheduled for early July.



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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