



THE INSTITUTE REVIEW

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Assessors Reveal the Top 10 Common Onsite Assessment Findings

By Stephanie Drier, Minnesota DOH, J. Steven Gibson, TCEQ,
and Carl Kircher, Florida DOH

Two out of three accredited laboratories do not demonstrate compliance with the requirements contained in the management standards for quality systems (i.e. management system). The laboratory must review the lab's management system, documentation, and records to ensure continual improvements as similarly done with the technical aspects of a laboratory. Below, the references to the 2003 NELAC and 2009 TNI Standard citations create a list of common findings made during onsite laboratory assessments:

1. Control of Records (NELAC 5.4.12; TNI V1M2 4.13)

The laboratory must establish and maintain procedures to control quality and technical system records. Records are information that are created or received by the laboratory. Most findings for the control of records did not affect the data generated; however, the laboratory's record is the objective evidence that the activity occurred and as a result provides the client with data of a known and documented quality. Common citations for control of records are:

- traceability of observations and derived data must be performed and recorded in accordance with NELAC 5.4.12.2.1 and TNI V1M2 4.13.2.1. As an example, the laboratory must record the originally observed incubator and the derived temperature data after thermometer correction factor was applied;
- standard and reagent origin, receipt, preparation and use with analytical run logs, bench sheets, and notebooks must be maintained by the laboratory (NELAC 5.4.12.2.5.3. i and TNI V1M2 4.13.3.xi); and
- equipment used in analytical testing is incorrectly identified or not identified in the analytical records. The laboratory must track the equipment used to produce the data and allow for historical reconstruction of the lab activities used to produce the analytical data (NELAC 5.4.12.1.5 b and TNI V1M2 4.13.3.f).

2. Equipment (NELAC 5.5.5; TNI V1M2 5.5)

The laboratory must maintain support equipment in working order and must calibrate or verify the equipment annually for the entire range for which the equipment is used. The lab must also ensure to calibrate support equipment used to weigh media and soil samples, infrared temperature measuring devices, and non-class A volumetric glassware at the required frequencies. Here are two additional areas of concern for equipment and support equipment:

- all support equipment shall be calibrated or verified annually bracketing the range of use (NELAC 5.5.5.2.1.b; TNI V1M2 5.5.13.1.b.); and
- initial calibrations must be verified with a second source material or independently prepared lot from the same manufacturer (NELAC 5.5.5.2.2.1.d and TNI V1M4 1.7.1.1d).

3. Quality System/Management System (NELAC 5.4.2; TNI V1M2 4.2)

The quality and management system requirements are defined in the Standards, and TNI offers quality system manual templates (<http://www.nelac-institute.org>). However, the laboratory must review and incorporate the requirements and revise the templates to reflect the actual laboratory practice. Specifically, laboratories do not define in detail the data integrity policies and procedures (NELAC 5.4.2.6; TNI V1M2 4.2.8.1), internal audits, and management review procedures. The laboratory must define within the management procedures the frequency of data integrity training for current and newly hired laboratorians, the covered topics, and training documentation. In addition, the laboratory's management system must use internal audits (see below) and management reviews (see below) to assess and improve the implemented system to ensure compliance with the requirements, such as the periodic in-depth data integrity monitoring and other laboratory policies, procedures, and processes.



Assessors Reveal the Top 10 Common Onsite Assessment Findings cont.

4. Handling of Samples (NELAC 5.5.8; TNI V1M2 5.8)

The procedure for handling samples must clearly describe the process used to uniquely label all sample containers to ensure sample bottles cannot be confused physically or when referred to in records or other documents (NELAC 5.5.8.2 a; TNI V1M2 5.8.5 a).

5. Personnel (NELAC 5.5.2; TNI V1M2 5.2)

The laboratory's personnel records do not include or meet standard requirements as commonly observed in the following ways:

- initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff has participated and understand their obligations related to data integrity (NELAC 5.5.2.7; TNI VIM2 5.2.7); and
- technical manager designations must meet requirements for both bench and academic credentials (NELAC 4.1.1.1; TNI V1M2 5.2.6.1).

6. Management Reviews (NELAC 5.4.14; TNI V1M2 4.15)

- The annual review of the quality system must ensure effectiveness of the system for the size and scope of the laboratory. The laboratory management review must also assess any evidence of inappropriate actions or vulnerabilities related to data integrity (NELAC 5.4.14.1 and TNI 4.15.1);
- The laboratory must have a predetermined schedule or maintain a procedure for the management review process (NELAC 5.4.14.2 and TNI V1M2 4.15.2); and
- Several accredited labs conduct internal management reviews; however, the scope of the management review and required actions resulting from the review are not documented (NELAC 5.4.14.2; TNI V1M2 4.15.2).

7. Standard Operating Procedures (NELAC 5.5.4.1.1 and 5.5.4.1.2; TNI V1M2 4.2.8.5)

The laboratory must provide sufficient detail within the procedures to allow someone similarly qualified, other than the analyst, to perform the test procedures and must contain information for all the laboratory activities as listed (e.g. waste management and pollution prevention) by topic in the requirements per NELAC 5.5.4.1.2 b; TNI V1M2 4.2.8.5.f.

8. Document Control (NELAC 5.4.3; TNI V1M2 4.3)

The laboratory must establish and maintain procedures for approval, issuance, and change to all documents that form part of the laboratory's quality system. The laboratory must also ensure the adopted document control procedures address the following items:

- retained obsolete documents marking process (NELAC 5.4.3.2.2 d; TNI 4.3.2.2d); and
- control of internally generated and external source documents (e.g. regulations, standards, software specification, instruction manuals and etc.) per NELAC 5.4.3.1; TNI V1M2 4.3.1.

9. Internal Audits (NELAC 5.4.13; TNI V1M2 4.14)

The laboratory's internal audit procedure must address all elements of the lab's quality system and testing activities. The quality manager must:

- conduct internal audits of its all its activities to verify that its operations continue to comply with the requirements of the quality system and the standard requirements;



Assessors Reveal the Top 10 Common Onsite Assessment Findings cont.

- ensure that the internal audit is annually planned and conducted to adequately review all technical and **management** systems within the laboratory (NELAC 5.4.13.1; TNI V1M2 4.14.1).

10. Review of Requests, Tenders, and Contracts (NELAC 5.4.4.; TNI V1M2 4.4)

The contract review procedure must include the process the lab will follow to ensure that client requirements, including the method to be used, are defined, the laboratory has the resources to perform the work, and the appropriate test method is selected to meet the clients' needs.

The laboratory's contract review procedure must include a plan for subcontracting samples in case of unforeseen circumstances. The lab must maintain a register of all subcontractors that it uses and a record of their certificates/scopes of accreditation (NELAC 5.4.5.4; TNI V1M2 4.5.4).

Please review the common findings and observations to determine if your laboratory is in compliance with the standard requirements and use the listed items to evaluate and improve the health of your lab's management system.

Note: The information was compiled based on common assessment finding presentation and materials presented by the Minnesota Department of Health Environmental Laboratory Accreditation Program, the Florida Department of Health Environmental Laboratory Accreditation Program, Texas Commission on Environmental Quality, and the New York Department of Health. Finding information based on observations and findings cited from 2010 through early 2013.



Member Profile—Gary Dechant

By Stephanie Drier, Minnesota Department of Health

Early Life and Career

Gerald (Gary) Dechant has been involved with science and the art of observation for the majority of his life. He is a native of Kansas, but has spent most of his life and career in and around the city of Grand Junction, Colorado. Gary obtained his Bachelor of Arts degree in chemistry from the University of Northern Colorado, and then embarked on a career in the agricultural industry. After a short time in the agricultural industry, he made the shift to the Department of Energy (DOE), where he was a chemist for eighteen years.



Gary Dechant

During his career, Gary performed radiochemical experiments, worked in research and development, and co-authored and published technical papers on radiochemical calibration and spectrometry. In the early 1980's, he worked on a team developing and experimenting with new techniques to identify high levels of radioactivity from vehicles positioned miles away. The work and scientific process, at that time, was cutting edge and spurred new thoughts and technological advancement in the area of radioactive material detection. Gary stated that the projects were exciting and impressive at the time and he enjoyed seeing others on the project team take his ideas and projects and turn them into their life long careers. However, he stated that his greatest achievement was working with a team on cleaning up uranium weapon production waste contaminated sites throughout the Western United States. The team was the first federal clean-up site to obtain Environmental Protection Agency (EPA) signature for deletion from the National Priority List (NPL) and the site was transferred to the Department of Energy for long term management. He recently retired from his role as Quality Engineer at Laboratory Quality Systems, a consulting firm that he established in 2010. The firm is an environmental service consulting company, built on 35 years of analytical chemistry and quality auditor experience, which specializes in quality engineering and laboratory quality systems.

TNI Involvement and Participation

Also, while employed for DOE, Gary became involved in radiochemistry and chemistry data validations and performed laboratory audits in accordance with the DOE's Quality Systems for Analytical Services, which is the equivalent to the TNI Standard. This work and involvement with quality systems, was the lead-in for him becoming an active participant in the TNI (formerly INELA/NELAC) organization around 1999. Over the years, his involvement within the TNI organization has increased and his contributions to committees and appointments is immeasurable. Over the years, he has been involved with the Proficiency Testing, Policy, National Database, and Quality Systems (Radiochemistry), and Technical Assistance committees. Gary has attended several TNI forums on laboratory accreditation and has presented information about standards development and changes, implementation of Federal EPA requirements, control charting, and mentoring sessions. He also represented data users on the Environmental Laboratory Advisory Board (ELAB); which seeks advice from the environmental laboratory community on the NELAC/TNI standards development process.

Gary stated that his largest contribution of time and energy to the organization is through his involvement and work within the Small Lab Advocacy Group (SLAG). In working with this group, Gary has contributed a lot of his time and efforts in applying the standard to the environmental field within a small laboratory setting. He was instrumental in reviewing, drafting, and re-organizing the 'Guidance for Small Labs' handbook to ensure the contents aligned with the 2009 TNI Standard requirements. Today, the handbook content provides compliance assistance to laboratories of all sizes and scope of accreditation.

As a result of his vast involvement with the TNI organization and the knowledge within the scientific community, Gary shared some concerns about the 2009 TNI Standard and the standards development process. He compared himself to the little boy that blurts out that the Emperor is not wearing any clothes, in Hans Christian Andersen's short tale "The Emperor's New Clothes". Gary, like the boy in the tale, urges the standards



Member Profile—Gary Dechant cont.

development community to go through the adopted standard and actually apply the requirements to laboratory environment. He believes this practice will reveal that several requirements of the standard are not applicable, are inconsistently applied through the different parts of the standard, or are no longer applicable (e.g. references to obsolete technology or laboratory practices). He urges all members to continue to consider, apply, and revise the standard language requirements to ensure they truly apply to the environmental field and laboratory.

Other Activities

Gary also maintains membership and actively participates in several other environmental organizations, which include the American Society for Quality (ASQ) and American Water Works Association (AWWA). Gary was the Western Colorado ASQ Section Committee chair and is an ASQ certified Quality Engineer and Quality Auditor. Recently, Gary has been working with an AWWA committee to draft recommendations for recycled and replaced water for the [EPA's Guidelines for Water Reuse, September 2012](#).

Author's Note: At the time of the interview, Gary was speaking with me from the intensive care unit. His stay in the ICU is a result of his battle with pneumonia, which is a complication of his underlying health condition. Even with the need for a constant supply of oxygen and his fatigue, he agreed to my interview and responded to all of my questions with great enthusiasm, love, and passion for his profession. Many thanks go to Gary and his wife for coordinating and allowing me to conduct the interview during this time.

Gary passed away on Saturday, March 9, 2013. For those interested, memorial contributions can be made to the American Cancer Society (2754 Compass Drive, Suite 100, Grand Junction 81506); Trout Unlimited (1536 Wynkoop Street, Suite 100, Denver, CO 80202); or the Veterans Administration Hospital, Volunteer Program (2121 North Avenue, Grand Junction 81501).



National Environmental Field Activities Program (NEFAP) Update

By Kim Watson, Stone Environmental

NEFAP Program Structure

NEFAP is **not** part of the National Environmental Laboratory Accreditation Program (NELAP). While both programs are based on similar ISO/IEC foundations and both have similarities, there are distinct differences between the two programs and they are operated independently of each other. The NEFAP program is designed and developed specifically for those organizations performing field activities.

A “field” organization is one which collects data, whether physical samples or measurements. A frequent question is whether mobile laboratories belong to NELAP or NEFAP. The answer depends on what the data are used for and how they are collected. A subcommittee has been formed to review this and prepare a document to clear up any areas of confusion.

NEFAP operates as an independent program under the TNI Board of Directors. The NEFAP Executive Committee (NEFAP EC) is elected by the general membership of TNI to oversee the program. The NEFAP EC is responsible for policy coordination and approval, development of Standard Operating Procedures (SOPs) for NEFAP operation, and recognition of ABs under Volume II of the NEFAP Standard. NEFAP EC members represent all stakeholder groups to maintain a balance for fair and open decision-making. The NEFAP EC has recognized the first group of ABs and is working diligently to facilitate program implementation.

The Field Activities Committee (FAC) operates as an expert committee within the TNI structure. The FAC is responsible for the consensus standard development as well as standard interpretation requests. The FAC is currently working on developing a Voting Draft Standard (VDS), which will contain the first proposed changes to the Standard itself. The FAC is also getting started on the development of tools to assist FSMOs in the accreditation process. The first tool will be a guidance document/template for developing a Quality Manual.

Is this program required?

NEFAP is a voluntary program and is not required by regulation. The program may be required in contractual agreements or for work under programs or contracts in which the contracting organizations want to assure there is documented competency to a known Standard.

In 2011, the US EPA issued an Agency Policy Directive Number FEM-20-11-01 promoting the use of accreditation, by requiring organizations performing sampling and environmental analysis for the US EPA, to demonstrate their qualifications in the fields of analyses to be conducted, prior to performing the analyses. Where accreditation is available for those fields of analyses organizations may submit documentation of existing accreditations.

In December 2012, the US EPA issued Agency Policy Directive Number FEM-0212-02, “Policy To Assure The Competency Of Organizations Generating Environmental Measurement Data Under Agency-Funded Assistance Agreements Or Interagency Agreements” which again promotes the need for technical competence when generating data for the agency. Data generation is from organizations performing field sampling, field measurements, and laboratory analysis. The policy identifies accreditation as one of the mechanisms to achieve this demonstration of competence.

While voluntary, the benefits of this program, as outlined, demonstrate the value to all who participate. Arguably the greatest benefactor stakeholders are the FSMOs themselves. Accreditation assures a quality management system is in place and demonstrates the high level of quality and technical competency of the organization.

The TNI Standard

Representatives of various stakeholder groups developed the Standard through an open, consensus-based building process. The current TNI FSMO Standard was approved and formally adopted by the TNI Board of Directors in May 2007. The Standard is divided into two volumes:



NELAP Update

By Lynn Bradley, TNI

The final four NELAP Accreditation Body (AB) evaluations are underway, with only two site visits remaining. For the next round of evaluations that begins in December 2013, the evaluation process will be slightly modified as recommended by the NELAP QA Officer. The revised evaluation SOP and checklists are moving through the approval process now.

The NELAP Accreditation Council (AC) has updated its Implementation Status table. Several ABs had planned to revise their regulations to adopt the revised TNI Environmental Laboratory Sector Standard (ELSS) — since revisions were initially expected to be complete within a few months — but due to the delay in finalizing the revised modules, those ABs face either two sets of regulatory changes or further postponement of transitioning away from the 2003 NELAC Standard. Every NELAP AB continues to encourage laboratories to move to the 2009 TNI ELSS, and every NELAP AB continues to recognize accreditations to either Standard, regardless of which one the AB maintains for its accreditations.

Implementation Status of 2009 TNI Standard for NELAP ABs		
AB	Standard in Effect Now	Status/Progress
CA	2003 NELAC	Will change to 2009 TNI Standard once AB evaluation is completed.
FL	2003 NELAC	Laboratories may implement 2009 TNI if desired. Accepting PT reports per 2009 TNI Standard.
IL	2003 NELAC	Regulations cite 2003 NELAC Standard, but are encouraging labs to move to the 2009 TNI Standard. Had intended to skip 2009 TNI Standard and adopt its first revision as 2012 TNI Standard; delays in revising the standard mean that rulemaking to adopt 2009 TNI Standard will be undertaken instead.
KS	2003 NELAC	Will publish regulations to adopt 2009 TNI Standard. Currently allows 2009 Standard where it is more stringent than 2003 NELAC.
LA DEQ	2003 NELAC	Regulations to adopt 2009 TNI Standard should be completed by August 2013. Currently allows 2009 TNI Standard without penalty.
LA DHH	2009 TNI Standard	Changed in December 2012.
MN	2003 NELAC	MN statute allows either standard, but certificates show 2003 NELAC. Unable to change completely until database modifications can be completed, but allows 2009 TNI Standard where more stringent.
NH	2003 NELAC	Moving towards 2009 TNI Standard and encouraging labs to implement 2009 TNI.
NJ	2003 NELAC	Regulation cites 2003 NELAC. Assessing to both 2003 NELAC and 2009 TNI Standards and providing findings to both.
NY	2003 NELAC	Implementing and enforcing 2003 NELAC. Accepting secondary accreditations from labs with primary accreditations to 2009 TNI Standard and encouraging labs to move to 2009 TNI Standard.
OR	2009 TNI	Assessing labs to 2009 TNI Standard.
PA	2009 TNI	Assessing and enforcing to 2009 TNI Standard.
TX	2009 TNI	2009 TNI Standard in place.
UT	2009 TNI	2009 TNI Standard in place.
VA	2003 NELAC	Regulation development underway, completion date uncertain.

At its February meeting, TNI's Board of Directors has approved merging the Technical Assistance Committee (TAC) into the Laboratory Accreditation Systems Executive Committee (LAS EC). Everyone who wishes to remain involved with activities originating in either committee is welcome to continue, either as a member of the parent committee (which will retain the LAS EC name) or on one of several subcommittees that will address ongoing activities such as the Assessment Forum, the Mentor Sessions, Standards Interpretation Requests, and Standards Review. If you are not already involved, but wish to participate in one of those areas, please fill out the Committee Application and indicate which of the LAS EC subcommittee areas you prefer.



NEW Small Laboratory Advocate!

By Keith Chapman and Elizabeth Turner, SLAG Advocates

Addressing the concerns of small laboratories is integral to accomplishing TNI's vision. In 2008, TNI created the position of Small Lab Advocate to address the challenges of the small laboratory community. The role of the Small Lab Advocate is to seek input from the small laboratory communities, elevate concerns of the small lab community to TNI, and to facilitate the Small Laboratory Advocacy Group (SLAG). The Small Lab Advocate also brings TNI information to the small laboratory community. The position promotes resources for small labs through the Advocacy and Technical Assistance Committees.

Keith Chapman is retiring as TNI Small Laboratory Advocate. Keith, who succeeded Len Schantz in 2010, was previously employed as the Laboratory Manager for the City of Salem, Oregon (Keith is now retired). He has facilitated monthly conference calls for SLAG, provided numerous presentations, facilitated the SLAG discussion Board, and written the SLAG song (<http://nelac-institute.org/small-lab-song.mpg>). He was instrumental in the development of the Small Laboratory Handbook.

Keith has decided that it is time to pass the torch. His daughter is getting married and Keith would like to focus his energy on the wedding and other commitments. But Keith is not abandoning SLAG. He will still participate in SLAG calls and events. **Elizabeth Turner** will assume the duties of the Small Lab Advocate. Elizabeth, Laboratory Manager for the North Texas Municipal Water District, has been an active member of SLAG and is active in the water and wastewater laboratory communities. She worked in small utility laboratories for over fifteen years and understands the concerns of the small laboratory. Per Elizabeth, *"Keith has left some pretty big shoes to fill, but I will do my best to serve the small lab community."*



Newly Formed Radiochemistry Expert Committee Holds Face-to-face Meeting in Denver

By Bob Shannon, Quality Radioanalytical Support, LLC

Ten members of the Radiochemistry Expert Committee met for a working meeting at the TNI conference in Denver. Although we have been working together since last summer, first as a sub-committee of the Quality Systems Expert Committee, and since then as the newly formed Radiochemistry Expert Committee, the opportunity to gather around a table and work in person was an excellent launch for our new committee. The committee membership is as follows:

Members	Affiliation	Balance
Bob Shannon (Chair)	Quality Radioanalytical Support, LLC	Other
Tom Semkow (Vice Chair)	NY State DOH	AB
Dave Fauth	Consultant	Other
Todd Hardt	Pro2Serve, Inc.	Other
Marty Johnson	US Army Aviation and Missile Command	Lab
Sreenivas Komanduri	NJ Department of Environmental Protection	AB
Nile Ludtke	Dade-Moeller and Associates	Other
Larry Penfold	TestAmerica Laboratories, Inc.	Lab
Richard Sheibley	Sheibley Consulting, LLC	Other
Carolyn Wong	Lawrence Livermore National Laboratory	Lab

The committee charter officially approved at the end of 2012 states that the committee will maintain the radiochemistry standard (TNI Volume 1, Module 6) based on public input; provide technical assistance on issues related to radiochemistry; and, develop tools that facilitate the implementation of the standard. It outlines specific objectives:

- Reviewing and revising standards based on input from all stakeholder groups;
- Ensuring that the Standard will produce data of known and documented quality;
- Providing technical assistance such as responding to Standard Interpretation Requests (SIRs);
- Providing technical assistance in developing tools to facilitate the implementation of the standard, and
- Ensuring continuity with TNI Volume 1 Modules

Our first task will be to conduct a complete review of the current Module 6. Based on this review, we will prepare an updated working draft standard that addresses identified technical needs and concerns specific to radiochemistry. We expect to address weaknesses in several areas where radiochemistry differs from the other technical areas addressed by the TNI Standard. For example, outside of Drinking and Clean Water testing, there are no promulgated methods used at radiochemistry laboratories. Lab-developed/lab-modified (i.e., performance-based) methods are the rule. While performance-based methods are not new to NELAC, the radiochemistry community relies on them quite heavily. Confusion about this has led to significant confusion among labs, assessors, and customers about what must be done, or what has been done, to ensure the quality of data produced. We will also focus attention on the area of detection and reporting of results, and hope to provide clearer direction on making defensible detection decisions, estimating uncertainty, and consistent and defensible reporting of results. Once we have finished our initial work on the Standard, we will begin to prepare tools such as a radiochemistry assessment checklist, and white papers clarifying technical issues addressed in the standard, among others.



**Newly Formed Radiochemistry Expert
Committee Holds Face-to-face Meeting in
Denver cont.**

We are all excited at the opportunity to provide input into the standard and hope that our collective perspectives and efforts will result in improvements to Module Six that will improve the effectiveness, the ease of implementation and oversight, and that it will be welcomed across the Radiochemistry community. We have established 2 PM ET on the third Wednesday of each month as a standing meeting time. While the committee membership is currently full, we welcome persons interested in participating in the process as associate members. If interested, please contact Bob Shannon at BobShannon@boreal.org, or Ilona Taunton at ilona.taunton@nelac-institute.org.



Re-cap of Denver Meeting and Plans for San Antonio

By Carol Batterton and Jerry Parr, TNI

More than 200 individuals attended the Forum on Laboratory Accreditation in Denver, CO, which was packed full of meetings and information for attendees.

Highlights of the meeting included the formation of two new committees, Microbiology, chaired by Robin Cook, and Radiochemistry chaired by Bob Shannon. The Microbiology Committee reviewed their charter and expectations, and also discussed Cryptosporidium Fields of Proficiency Testing (FoPT) and EPA Cryptosporidium methods and how to include these in the standard or guidance. The Radiochemistry Committee focused on how to re-write the radiochemistry portion of the Standard to make it more suitable for regulatory use.

The Expert Committees in the Consensus Standards Development Program, including Quality Systems, Proficiency Testing, and Field Activities, focused on receiving and responding to comments on their working draft standards. The Chemistry Committee announced they were working on the calibration piece of their standard, and they will be proposing a working draft standard soon. Following up on a recommendation from the Accreditation Body Task Force, the Laboratory Accreditation Body Committee worked on their third-party assessor proposal to the Board, along with a generic application for laboratory accreditation.

The Laboratory Accreditation System Executive Committee (LASEC) reviewed the Standards Interpretation Request (SIR) SOP and discussed draft language to make the process more timely and efficient. The NELAP Accreditation Council discussed the Laboratory Accreditation Management System (LAMS) and reported that over half of the data from the states is now in the database. They will also be responding to a request to put information on the website about which version of the standards that the various ABs are using.

The National Environmental Field Activities Program (NEFAP) reported that they have approved an Accreditation Body and accreditation of FSMOs is in progress. They also focused the need for increased advocacy for NEFAP.

The Stationary Source Audit Sample (SSAS) Committee announced that a second PT provider has applied to the SSAS program and is going through the approval process.

The Advocacy Committee discussed a complete re-design of the newsletter format for the March edition. They will also be focusing on more outreach for NEFAP, which may include a special session at the San Antonio meeting.

The Assessment Forum session on the laboratory audit process had 35-40 participants in the morning; the discussion on SIRs in the afternoon was also well attended.

Upcoming Environmental Measurement Symposium, San Antonio, TX

Now it is time to think about the Environmental Measurement Symposium to be held in San Antonio, TX, on the Riverwalk, from August 5 – 9, 2013! The combined meeting of the National Environmental Monitoring Conference (NEMC) and the Forum on Laboratory Accreditation (Forum) is in its seventh 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 (ELAB) 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. This focus of the NEMC portion of the meeting for this year will be *Protecting Human Health through Environmental Measurement and Monitoring*.



Re-cap of Denver Meeting and Plans for San Antonio cont.

Concurrent technical sessions will be held on Monday, Tuesday, Wednesday, and Thursday. Wednesday morning will be a general session on the timely topic of hydraulic fracturing. 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, and will go through Friday.

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!!!

Preliminary Schedule for TNI Meetings at the Environmental Measurement Symposium

Monday, August 5

- 8:00 a.m. — 9:00 a.m. Keynote Address
9:00 a.m. — 12:00 p.m. Assessment Forum
1:30 p.m.—5:00 p.m.
- Proficiency Testing (PT) Program Executive Committee
 - Information Technology Committee
 - SSAS Committee
 - Assessment Forum (continued)

Tuesday, August 6

- 8:00 a.m. — 9:00 a.m. Keynote Address
9:00 a.m. — 12:00 p.m.
- Chemistry Expert Committee
 - Laboratory Accreditation Body Expert Committee
 - Radiochemistry Expert Committee
- 1:00 p.m. — 5:00 p.m.
- Chemistry (continued)
 - PT Expert Committee
 - Radiochemistry (continued)

Wednesday, August 7

- 8:15 a.m. — 12:00 p.m. General Session
1:00 p.m. — 5:00 p.m.
- Advocacy Special Session

- Laboratory Accreditation System Executive Committee
- Quality Systems Expert Committee

Thursday, August 8

- 8:00 a.m. — 9:00 a.m. Keynote Address
9:00 a.m. — 12:00 p.m.
- Field Activities Expert Committee
 - Conference Planning Committee
 - Non-Governmental Accreditation Body Working Group
- 1:30 p.m. — 5:00 p.m.
- Microbiology Expert Committee
 - NEFAP Executive Committee
 - Mentor Session

Friday, August 9

- 8:00 a.m.— 11:00 a.m.
- NELAP Accreditation Council
 - Consensus Standards Development Program Executive Committee
 - Advocacy Committee
- 11:00 a.m. — 12:00 p.m.
- General Session (Chairs report)

Training Courses at the Environmental Measurement Symposium

Powerful Communications – Public Speaking for Scientists
Implementing the 2009 TNI Standard
NEFAP as Seen through the FOG



Regulatory Update

By Jerry Parr, Catalyst Information Resources

This article was prepared to provide TNI members information about events at the national level that may be of some interest. This information covers the period of September 24, 2012 through March 1, 2013.

Two New SW-846 Methods Published

Method 1316 (Liquid-Solid Partitioning as a Function of Liquid-Solid Ratio using a Parallel Batch Extraction Procedure) describes a leaching extraction procedure for a granular solid material at five specified liquid-to-solid ratio (L/S) values used to assess how constituent leaching varies with the relative leachant volume in contact with a solid material under equilibrium conditions, and at the pH generated by the test material. Method 1313 (Liquid-Solid Partitioning as a Function of Extract pH using a Parallel Batch Extraction Procedure) describes a leaching extraction procedure for a granular solid material at nine specified pH values used to assess how constituent leaching varies with leachant pH under equilibrium conditions. This test provides information on the intrinsic leaching potential at different pH values, and allows evaluation of leaching potential over the range of plausible field pH values. http://www.epa.gov/epawaste/hazard/testmethods/sw846/new_meth.htm#1316

EPA Publishes Method 1611 for Enterococci

EPA has published a method that uses a genetic quantitative polymerase chain reaction (qPCR) approach to detect enterococci in ambient waters. The method will be updated following multi-laboratory validation in marine and fresh ambient waters. <http://water.epa.gov/scitech/methods/cwa/bioindicators/upload/Method-1611-Enterococci-in-Water-by-TaqMan-Quantitative-Polymerase-Chain-Reaction-qPCR-Assay.pdf>

EPA Issues Competency Policy for Organizations Providing Measurement Data

A policy titled, Policy to Assure the Competency Agreements of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance or Interagency Agreements, was approved by the Science Technology Policy Council (STPC) on December 12, 2012. All organizations performing environmental analysis for the Agency shall demonstrate their qualifications in the field(s) of analyses to be conducted, prior to performing such analyses, under Agency-funded assistance agreements or interagency agreements. http://www.epa.gov/fem/lab_comp.htm

Changes to the EPA Certification Manual for Drinking Water Laboratories

The Long Term 2 Enhanced Surface Water Treatment Rule (LT2 Rule) requires public water systems that use surface water or ground water under the direct influence of surface water to monitor their source water for Cryptosporidium and E. coli and turbidity. The LT2 Rule specifies the methods, approval criteria, and quality assurance practices to be used. The LT2 Rule also requires public water systems to have Cryptosporidium samples analyzed by a laboratory approved under EPA's Laboratory Quality Assurance Evaluation Program for analysis of Cryptosporidium or a laboratory that has been certified by an equivalent State laboratory certification program. EPA has revised their certification manual to include technical requirements for the analysis of Cryptosporidium. <http://water.epa.gov/scitech/drinkingwater/labcert/upload/epa815f12006.pdf>

Total Coliform Rule Revised

On February 13, 2013, EPA finalized revisions to the 1989 Total Coliform Rule (TCR). There is no longer a monthly maximum contaminant level (MCL) violation for multiple total coliform detections. Instead, the revisions require systems that have an indication of coliform contamination in the distribution system to assess the problem and take corrective action that may reduce cases of illnesses and deaths due to potential fecal contamination and waterborne pathogen exposure. The rule also updated provisions in other rules that reference analytical methods and other requirements. Among the changes noted to the analytical requirements were:



Regulatory Update cont.

- The 18th and 19th editions of Standard Methods are no longer approved.
- References to Standard Methods 9221A and 9222A are removed.
- The reference to Standard Methods 9221B is changed to 9221B.1, B.2.
- The reference to Standard Methods 9221D is changed to 9221D.1, D.2.
- The citation for MI agar is changed to Method 1604.
- The table clarifies that Standard Methods 9221 F.1 and 9222 G.1 may be used for E. coli.
- The table clarifies the correct formulation for E. coli medium with 4-methylumbelliferyl-Beta-D-glucuronide (EC-MUG) broth.
- The table reflects the approval of a modified Colitag method for the simultaneous detection of E. coli and other total coliforms.

In the proposed rule, the Agency requested comment as to whether the RTCR should require the samples to be held at 10 degrees C or less during transit. Several commenters expressed support for this provision stating that it would improve the integrity of the data collected under this rule. However, many commenters expressed concern that the addition of this provision would cause a hardship, especially to small systems, as it would increase the cost of the sample shipment. Additionally, concern was expressed that this provision would increase the number of violations, thereby imposing an enforcement burden on the States.

EPA has determined that the provision in the 1989 rule will stay as is: "Systems are encouraged but not required to hold samples below 10 C during transit." <http://www.gpo.gov/fdsys/pkg/FR-2013-02-13/pdf/2012-31205.pdf>



Status of Progress on Standards

By Ken Jackson, TNI

Environmental Laboratory Sector

During the recent Forum on Laboratory Accreditation in Denver, the Quality Systems Expert Committee presented its proposed changes to Modules 2 through 7 of Volume 1: Management and Technical Requirements for Laboratories Performing Environmental Analysis. These were mostly clarification changes resulting from persuasive comments received on its Voting Draft Standard. Before the amended standard becomes final, the committee will publish a detailed response-to-comments document. This is the last time the Quality Systems Expert Committee will be responsible for all those modules. Under the revised committee structure, it will retain responsibility for Modules 2 (Quality Systems: General Requirements), Module 3 (Asbestos Testing), and Module 7 (Toxicity Testing). The Chemistry Expert Committee (formerly the Environmental Measurement Methods Expert Committee) is now responsible for all of Module 4 (Chemical testing). In Denver they presented a Modified Working Draft Standard detailing proposed improvements to the calibration sections of Module 4. This has been modified further as a result of the discussion, and has now been published as a Voting Draft Standard, to be voted on in April. The committee has also worked on edits to the method detection limit language in 40 CFR Part 136 Appendix B. This revised language will be available for review at the summer meeting in San Antonio.

The remaining two modules, Module 5 (Microbiological Testing) and Module 6 (Radiochemical Testing) will now be the responsibility of the new Microbiology and Radiochemistry Expert Committees respectively. An article on the Radiochemistry Committee is in this issue of The Institute Review. The Microbiology Committee has established goals to review the current standard in light of addressing the issues with Parasitology and Virology and some of the emerging technologies such as qPCR, to review the relevant sections of Module 2 for these same issues, and then work with the QS Expert Committee to revise the standard. The Committee also plans to work with Dan Hickman and others to try and pare down the method code list and finally to assess the need for a guidance document for labs and assessors that would incorporate the TNI Standard and the specific method requirements.

Field Sampling and Measurement Organization (FSMO) Sector

Voting Draft Standards of both volumes (Volume 1: General Requirements for FSMOs; and Volume 2: General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement) have undergone voting and the Field Activities Expert Committee is currently making changes resulting from persuasive comments received. The committee will follow the revised standards development process (soon to be published), by issuing a response-to-comments document together with an Interim Standard that will be subjected to a final voting process.

As a reminder, any TNI member can participate in Expert Committee conference calls by registering as active Associate Committee Members. This requires registering with the chair of the Expert Committee of interest.



Summary of January 15, 2013 Meeting with EPA OGWDW TSC About Crypto Certification

By Carrie Miller, U.S. EPA

On Tuesday, January 15, the NELAP Accreditation Council (AC) met with EPA's Technical Support Center (TSC, in the Drinking Water program) representatives to discuss changes to certification processes for laboratories monitoring for Cryptosporidium. A document of "Frequently Asked Questions" was distributed prior to the meeting, the contents of which have posted on the TNI website. What follows is a summary from the meeting.

Having a crypto certification program is not a condition of primacy for state drinking water programs. Ten state assessors have thus far taken the TSC coordinated crypto certification course, for which the chemistry and microbiology courses are prerequisite.

Labs that were approved by EPA for the first round of monitoring under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2 rule) are not grandfathered into the second round. The second round begins in 2015. There is an updated version of Method 1623, known as Method 1623.1, as well as molecular methodologies available now that were not available for the first round. The molecular methodologies are not considered suitable at the 1-2 oocyst level. For Methods 1623 and 1623.1, the QA/QC acceptance criteria are more stringent in the revision (1623.1) than in 1623.

Initially, for the Information Collection Rule (pre-LT2), EPA approved individual analysts for EPA's ICR Method. Now the LT2 Rule specifies certification by laboratory, per the new Chapter 7 of the Drinking Water Certification Manual that has requirements for technicians performing the analyses.

EPA's intent to partner with states to approve labs for crypto testing is not limited to NELAP states. The EPA Regions will judge state equivalence based on substantial conformity to Chapter 7 of the Certification Manual, and a use of Certification Officers (COs), who passed the TSC coordinated training course for crypto CO's.

The TSC intends to maintain a list of approved labs. When asked how it will obtain this information, Carrie Miller indicated personal communication followed by laboratory certificates. If a lab is needed in a particular region, that EPA Region will refer to the list of approved labs.

Carrie Miller has posted two videos on YouTube.com about "How to Interpret a Crypto Report", and on the elution step of analysis. She has a proposal in progress for videos performing immunomagnetic separations. She says there is also an "Adobe Connect" course on how an analyst identifies crypto, as well as, four training modules for the detection method on EPA's website.

Six of the ten EPA Regions have COs trained in crypto. Carrie says that about fifty labs nationally may be seeking certification.

There was some discussion about the feasibility of producing a TNI standard for crypto accreditation and there were many concerns about why a separate standard would even be needed. Because a lab is NELAP-accredited to the standard, not the Certification Manual, at most, a new appendix might be needed, but not all states have regulations about crypto. After the meeting, Carrie re-submitted her notes and comments that were originally provided to TNI in 2012 after TNI's adoption of crypto as a FOPT.

The PT Executive Committee has a subcommittee that has completed a FoPT table for crypto.

The Certification Manual recommends observation of blind samples being analyzed. Concerns were expressed that this would take more than one person and more than one full day just to witness the analysis, and that this is excessive for just a single method. *Note: The manual is guidance and not a requirement. Equivalence of certification/accreditation will be based on demonstration of substantial conformity to procedures described in Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water* <http://water.epa.gov/scitech/drinkingwater/labcert/index.cfm#two>.

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Summary of January 15, 2013 Meeting with EPA OGWDW TSC About Crypto Certification cont.

Other concerns expressed were the need to train third-party assessors that could be used by NELAP ABs, and also that the current PT provider, Wisconsin Department of Health, is not a TNI-approved provider. However, the PT provider has been certified by ACLASS. It may be that one of the approved PTPs does offer crypto PT samples



TNI Board Election Begins

By Steve Arms, Florida DOH

Elections for the 2013 Board of Directors began on March 18 with the announcement of a slate of candidates on the TNI [website](#). Nominations opened on February 4 to receive applications for potential candidates. Applicants were able to use a handy new online nominations form, simplifying and streamlining the process. This year the Board has nine vacancies, with terms expiring for Directors in each of the general stakeholder groups, Accreditation Body, Accredited Laboratory, and Other. The By-Laws allocate a Board of ten to eighteen members, so not all slots need to be filled. Balloting will continue until April 1, and newly elected Directors will assume office on April 10 during the Board's regularly scheduled monthly teleconference.

The Nominating Committee, which consists of Lara Phelps, Aurora Shields, and Steve Arms, has painstakingly reviewed the qualifications of the nominees and has assembled a ballot to present for voting by the TNI membership. Each individual nominated is eminently qualified to serve and willing to give of their time and talents to the further the mission of TNI.

Directors need a broad understanding of issues facing TNI and must uphold the Institute's mission, goals, priorities, and Code of Ethical Conduct. Each must demonstrate a commitment to TNI's priority to be a highly functioning organization committed to balance and inclusion. Directors must have strong interpersonal skills and be able objectively to consider various perspectives in making major policy decisions.

Having these qualifications helps to ensure that elected Directors are prepared to fulfill their designated responsibilities, which include

- exercising fiduciary responsibilities and stewardship with regard to TNI's goals, policies, and resources;
- contributing to a policy governance model that provides leadership for TNI with a focus on mission; and
- identifying and cultivating future leaders.

All TNI members are encouraged to take advantage of this opportunity to vote for the candidates of their choice!



TNI Educational Delivery System Update

By Ilona Taunton, TNI

In 2011, TNI started a new process for providing training called the Educational Delivery System. Training may be provided by TNI or TNI contractors at TNI meetings in the form of webinars or webcasts, or in conjunction with regional meetings with TNI partners such as the Florida Society of Environmental Analysts (FSEA) or the Water Environment Federation (WEF) of Texas. In 2012, TNI provided twenty-seven training events that reached over 1300 individuals:

- 9 courses held at TNI's annual meetings,
- 5 courses held at regional meetings,
- 7 assessor training courses held throughout the country, and
- 6 webinars.

The webinars have all been recorded and are available for viewing as downloadable webcasts.

A number of additional training courses are in development and/or scheduled to be offered in 2013 and two webinars have already been held this year. To see the current list of courses being provided, go to the TNI Educational Delivery System webpage (<http://www.nelac-institute.org/edshome.php>). You can also access an application form from this webpage, if you would like to provide a training course.

Want to Hold A Training Event?

TNI is building a curriculum of training courses that can be provided by various trainers at meetings such as those described above. If you have any interest in having TNI work with your organization to put on such training, please contact Ilona Taunton at ilona.taunton@nelac-institute.org.

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TNI Third Party Assessors

By Jeff Flowers, Flowers Chemical Labs and Chair, Laboratory Accreditation Body Expert Committee

The AB Assistance Task Force tasked the Laboratory Accreditation Body Expert Committee (LAB) with developing a process for TNI to qualify third-party assessors, along with a model solicitation template, a process for performance review, and a mechanism by which state ABs could contract with TNI to utilize third-party assessors. After exhaustive examination of the possibilities, LAB offered the TNI Board a four-phase proposal to develop the qualification process, as follows:

- I) Produce and publish on the TNI website names of individuals and/or organizations conducting on-site assessments.
- II) Using contact information from Phase I, collect information from potential assessors on criteria used by ABs to select assessors and produce a report of findings.
- III) Develop a program to verify the information found in Phase II.
- IV) Implement program based on information found in Phases I, II and III.

At its February meeting, the TNI Board approved the LAB committee to go forward with producing the initial listing of individuals and organizations, along with their resumes addressing the criteria identified for Phase II. LAB will work with the TNI webmaster and if necessary, TNI's Information Technology Committee, to publish a straightforward listing, including a disclaimer that TNI is providing the information as a service, but has not verified the information provided by potential assessors as correct, and that despite best efforts, the list may not be exhaustive.

Any individual or organization wishing to be included in this listing of third-party assessors should contact the LAB Expert Committee Chair, Jeff Flowers at jeff@flowerslabs.com.



Upcoming Meetings of Interest to Members

Texas Commission on Environmental Quality

Trade Fair

May 1–2; Austin, TX

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

Florida Society of Environmental Analysts

Spring Meeting

May 23–25;

Clearwater Beach, FL

<http://www.fsea.net>

The NELAC Institute

Environmental Measurement Symposium

August 5–9; Washington, DC

<http://www.envmeasym.org>

If you know of any upcoming meetings of interest to environmental laboratory professionals, please contact Jerry Parr at jerry.parr@nelac-institute.org.



Update on Approval of Non-Governmental Accreditation Bodies for Laboratory Accreditation

By Carol Batterton, TNI

At the Denver meeting, the Accreditation Body Task Force presented for discussion a concept paper and process for Non-Governmental Accreditation Bodies (NGABs) to grant laboratory accreditation. Following Denver, the TNI Board approved the formation of a working group to develop the evaluation SOP and other policies to be used by the Recognition Committee that will approve NGABs. The TNI Board chartered the working group to develop the SOPs and policies necessary for TNI to approve non-governmental accreditation bodies (NGAB) to grant laboratory accreditations in conformance with the applicable TNI standards, and to assure that the NGAB is capable of managing an accreditation program in a consistent, uniform manner.

The TNI Board appointed Alfredo Sotomayor to chair the working group. Additional members were also appointed:

- Steve Arms, Florida DOH, representing NELAP ABs
- Kristin Brown, Utah DOH, representing NELAP ABs
- Marlene Moore, Advanced Systems, representing NEFAP
- Cheryl Morton, AIHA, representing non-governmental ABs
- Jim Todaro, Alpha Analytical, Laboratories, representing laboratories

The draft evaluation SOP and policies will be presented in San Antonio for discussion.



WEF Lab Committee Conducts Survey on National Laboratory Accreditation

By Elizabeth Turner, North Texas Municipal Water District

During the time period of December 11, 2012 and January 31, 2013, the Water Environment Federation (WEF) Laboratory Practices Committee conducted a short survey targeted at laboratories that perform wastewater analysis. The survey focused on two subject areas: national laboratory accreditation for laboratories that analyze wastewater samples and certification/licensing of laboratory analysts. This article focuses on the national accreditation portion of the survey.

The survey had 162 respondents. Approximately 69% of the respondents were government labs, 31% were from private laboratories, plus a few additional respondents that included NELAP auditors, accreditation bodies and consultants. The WEF Laboratory Practices committee was pleased to discover that 68% of the respondents had either state laboratory certification or NELAP accreditation for non-potable water analyses.

The majority (81%) of laboratories that were not certified or accredited were government/municipal laboratories. The vast majority of respondents were familiar with the TNI National Environmental Laboratory Accreditation Program and 74% of the respondents were in favor of a national accreditation program for laboratories that analyze wastewater samples. A majority (61%) of the laboratories that are not currently certified or accredited supported the idea of a national laboratory accreditation program for laboratories that analyze wastewater samples. The respondents recognized that a single national environmental laboratory accreditation program could have multiple benefits including: a national set of standards, standardized quality control requirements, and documented data quality. As one respondent noted *"if all the laboratories adhere to a national standard based on a quality system that requires documented data quality helps to ensure reliable data regardless of what lab or part of the country it is generated. And, the decisions that are made about the cleanliness of our water, process controls and countless other environmental markers can only be as sound as the data that it is based on."*

There are concerns and obstacles to 100% support of a national accreditation program for laboratories involved with wastewater analyses. The top three concerns are cost, degree of documentation required, and auditor inconsistency. There is a concern that some accreditation bodies add their own requirements on top of the NELAP requirements, thus defeating a true national program. There appears to be no rules on the structure and extent of an audit. Labs A and B can be accredited for the same number and type of parameters. Lab A will have four auditors onsite for a week while Lab B has one auditor onsite for one day. While many labs see the benefit of accreditation to a national standard, some labs that are NELAP-accredited do not believe that the benefits have outweighed the cost and effort to maintain accreditation.

A goal of the WEF Laboratory Practices Committee was to determine if the wastewater laboratory community would approve of WEF supporting a national laboratory accreditation program for wastewater analyses. While 80% of the respondents were in favor of WEF supporting a national laboratory accreditation program, they want WEF to be actively engaged in the standard development process to champion the needs and concerns of wastewater laboratories – particularly the small laboratories that do not have the resources to obtain and maintain accreditation as the current program exists today.

In conclusion, the wastewater laboratory community is in favor of a national laboratory accreditation program, but believes that there are obstacles that need to be overcome before the wastewater laboratory community can fully embrace NELAP or any national laboratory accreditation program.