

**The NELAC Institute
Board of Directors Meeting
October 14, 2009**

1. Roll Call and Approval of September Minutes

Directors	Present
Joe Aiello	X
Aaren Alger	X
Steve Arms	X
Judith Duncan	X
Jack Farrell	
Ken Jackson	X
Tom McAninch	X
Sharon Mertens	X
Judy Morgan	X
Ken Olson	
Aurora Shields	X
Matt Sica	
Alfredo Sotomayor	X
Dave Speis	
Curtis Wood	
Bob Wyeth	X
Ex-Officio Directors	
Brenda Bettencourt	X
Brooke Connor	X
George Detsis	X
Edward Hartzog	X
Staff	
Carol Batterton	
Jerry Parr	X
Ilona Taunton	X
Jane Wilson	X
Janice Wlodarski	X

Approval of September Minutes: George Detsis
Second: Brooke Connor
Approved: Unanimous

1. Improving Audit Consistency

Changes to the Charter suggested include: adding the term “including causal factors” to the last bullet points of both goals B and C. Also for Goal B, add language that addresses preventative maintenance.

Motion to Approve Task Force Charter, including suggestions shown above: Judy Duncan
Second: Sharon Mertons
Approved: Unanimous

2. Seals

Three new seals have been designed and are presented for approval for use on certificates. These new seals would replace the current ones in use. These new seals are accurate and recognize TNI. For the labs, would not require new certificates.

Current Seals



Proposed New Seals



All TNI seals contain the same center graphic, but the ring is slightly different for NELAP, NEFAP and the accredited labs.

We do not issue accreditations for FSMO and so do not need a seal for that program. We will place an explanation in the newsletter as to when to use which seal. Brooke has provided EPS and other graphic versions of the seals to Jerry. Jerry will send them to all the ABs. Labs and ABs can continue to use the old ones until year 2011.

Question: Have we been giving ABs certificates? Many have run out and new ones have not been sent. Jerry will check with Carole.

Motion to Approve the 3 New Seals: Judy Duncan
Second: Aaren Alger
Approved: Unanimous

3. Information Technology Committee

The TNI website and national database committees met by teleconference on September 17 to discuss the possibility of combining the two committees into one new Information Technology committee. These reasons for this potential action include:

- The national database development effort has been completed and the Website committee needs to be involved in building the user interface on the TNI website.

- There are a number of spreadsheets and related documents that require management, including PT tables, method codes, analyte codes, and technology codes.

There was universal support for this proposed action and a proposed charter is attached to this agenda for approval by the TNI board. The new committee would be an administrative committee, is not a subcommittee under LASC, and does not require any change to the bylaws.

Motion to Approve Information Technology Committee and Charter: Ken Jackson

Second: George Detsis

Approved: Unanimous

4. NEFAP Board

The Field Activities committee is recommending a slate of 15 individuals to form the initial NEFAP Board. See the NEFAP report in Attachment 3. Note that this board includes one representative from every organization that wants to become a NEFAP AB plus enough other interests to ensure this group does not have dominance. Once formed, this board would then establish the policies and procedures for how changes to the board composition would be made.

Motion to Approve Establishment of NEFAP Board: Judy Duncan

Second: Brooke Connor

Approved: Unanimous

5. Program Reports

See Attachment 2.

6. TNI Organization

Group will meet on Friday, November 6 at 1pm EST.

Attachment 1
Consistency Improvement Task Force

A concerted effort to improve the consistency of TNI assessments and evaluations

I. Purpose

The Consistency Improvement Task Force (CITF) is charged with improving the consistency of TNI laboratory assessments and accreditation body (AB) evaluations.

The CTIF will promote systems and develop recommendations to achieve its purpose.

II. Members

Name	Affiliation
Alfredo Sotomayor, Chair	Wisconsin DNR
Jerry Parr, Ex Officio	TNI
Carol Batterton, Staff	TNI
James Broderick	New York City DEP
Jack Farrell	Analytical Excellence, Inc.
Ed Hartzog	US Navy NAVSEA Programs
Kevin Kubik	USEPA Region 2
Tom McAninch	Laboratory Consulting Services
Verl Preston	TestAmerica, Inc.
Stephen Stubbs	Texas Commission Env. Quality
Robert Wyeth	Columbia Analytical Services

III. Duration

The task force is chartered for a year, with an option for renewal at the conclusion of the term.

IV. Major Goals

To accomplish its purpose, the CITF has identified four major goals. Each of the goals will be supported by activities and tasks that will be developed during the initial CITF meetings. The CITF will assign priorities to the activities and tasks attempting to have a good mix of short term and long term assignments. The CITF may delegate some activities and tasks to other groups within TNI.

A. Establish Realistic Expectations about Consistency

Different people and organizations perceive and measure consistency in different ways. What may appear consistent to an individual may seem inconsistent to another. A set of deviations in a system may be labelled inconsistent by an organization, but not by another.

The CITF will

- Produce a document discussing attributes of consistent systems, sources of inconsistencies, and sensible means for determining and improving the degree of consistency of operations.

B. On-Site Assessments of Laboratories

Laboratory assessments are the most common and visible of TNI activities. The majority of the consistency concerns voiced by TNI members are associated with the on-site assessment of laboratories.

The CITF will

- Explore how assessor training can be used to improve the consistency of laboratory assessments.
- Develop a blueprint for conducting assessments that considers the emphasis given to different areas reviewed during assessments.
- Establish expectations for the communication of assessors within and between ABs.
- Investigate opportunities for having assessors observe other assessors performing laboratory assessments.
- Focus on the corrective action cycle of laboratory findings as an area in need of improved consistency.

C. Evaluations of Accreditation Bodies

Assessors, not ABs, are usually the focus of efforts to improve consistency of assessments. However, ABs employ assessors and therefore share responsibility for the consistency of assessments. TNI has made progress in standardizing the evaluation of ABs, but there is a need to review and evaluate systems that ABs establish to improve the consistency of operations associated with and beyond laboratory assessments.

The CITF will

- Explore how evaluator training can be used to improve the consistency of AB evaluations.
- Establish the elements of consistency plans to be used by ABs.
- Review how ABs use requests for interpretations of standards to promote consistency.
- Evaluate how ABs deal with political pressure in making accreditation decisions and the role that enforcement agents may have in shaping consistency efforts.
- Consider the role that third party ABs and reciprocal agreements may have in improving consistency.
- Focus on the corrective action cycle of evaluation findings as an area in need of improved consistency.

D. Laboratories and Users of Laboratory Services

It is logical to consider the regulated community and the users of their services in any efforts aimed at improving the consistency of assessments and evaluations. Developing clear and auditable accreditation standards is the first step in this process, but rarely does a standard alone, by itself ensure its own uniform implementation. The fresh start afforded by the upcoming implementation of the TNI Standards presents an opportunity to create systems to ensure the standards' consistent application.

The CITF will:

- Promote the development of tools to implement the TNI Standards
- Consider systems allowing ready access to decisions regarding interpretation of standards.

V. Deliverables

The CITF will issue a report at the conclusion of its term. The CITF envisions promoting or developing products that will be offered as they become available. The CITF will issue periodic progress reports to the TNI Board.

Attachment 2
INFORMATION TECHNOLOGY COMMITTEE CHARTER

1. Committee Name: Information Technology Committee	2. Version: Revision 2, <i>Draft</i>	3. Date: 10/1/2009
4. Mission Statement: To support the information technology needs of TNI members and programs through a user-friendly and attractive communications center and database.		
5. Program Administrator: Jerry Parr		
6. Committee Members: Art Clark, USEPA Region 1, Chair Dan Hickman Keith Ward, Wibby Environmental Robert Di Rienzo, ALS Laboratories Pam Varner, ASI Rip Starr, Alabama DEM Maria Friedman, Test America Irene Ronning, Oregon Public Health Lab Tim Fitzpatrick, LDC John Kuhn, JEA Judy Morgan, ESC David Caldwell, OK DEQ William Daystrom, TNI	7. Stakeholder Group: Other Other Other Accredited laboratory Accredited laboratory Accrediting organization Accredited laboratory Accrediting organization Other Accredited laboratory Accredited laboratory Accrediting organization Ex-officio (IT administrator)	
8. Objectives: ✓ Accurately and positively present TNI to the public in general and laboratories and data users in particular with a user-friendly, functional website. ✓ House TNI news, standards and information. ✓ Provide means of communication to and among members and to labs, governmental programs and the public. ✓ Provide member services (e.g., membership applications) ✓ Promote TNI events (e.g., electronic registration, posting agendas) ✓ Maintain the TNI Laboratory Accreditation Management System (LAMS) ✓ Maintain codes (methods, analytes, technologies)		
9. Success Measures: <ul style="list-style-type: none"> • Number of people accessing the site • Number of new members joining • Number of postings on forums • Optional survey on site (future) • Functional National Database 		
10. Key Milestones: <i>(significant events and corresponding dates)</i> <ul style="list-style-type: none"> • Design and implement web page for national database (LAMS) • Have a fully functional LAMS by January 2010. • Determine cost to maintain LAMS long-term 		
11. Considerations: <i>(assumptions/constraints/obstacles/risks)</i> Committee members are volunteers; typical database issues. AB limitations in uploading data to database		
12. Available Resources: reasonable funding		
13. Additional Resources Required:		
14. Anticipated Meeting Schedule: Conference call 3 rd Thursday of each month, 3 pm Eastern time		

Attachment 3
Program Reports

October 14, 2009

Consensus Standards Development

- The CSDB participated in a webinar demonstrating the capability of the Kavi workspace system, which is an on line collaboration system targeted to standards developers. Jerry will follow up with Kavi regarding pricing and have more internal TNI discussion about the tool.
- CSDB discussed the appeal being requested by Jeff Flowers. A detailed discussion indicated there are multiple topics under debate and there is concern that the subject of the appeal is different than the PT committee actions that are targeted by the appeal. Jerry is proceeding to nominate appeal panel candidates.
- Final standards with TIAs incorporated have been produced. The issue of how to cite the standards and track revision history was discussed. The standards will be cited by sector/volume-module/year on the front cover with the revision detail inside the front cover.
- SSAS is close to issuing final standards and the response to comments document (by end of October). Work will continue on the central database development.
- Other Expert Committees are either developing or evaluating the need for guidance to support implementation of the new TNI standard. Feedback on guidance issues (format, approval, etc.) has been requested from the Policy committee.

NELAP

- Based on feedback from the TNI board, the NELAP Board voted to modify the implementation date for the new standards to July 1, 2011. This change will establish a uniform date for all ABs and allow both labs and ABs time to prepare for the change.
- OR has sent a response to their final report which is under review by the evaluation team. LADEQ has submitted a modified response to their onsite evaluation report. IL's onsite report has been sent.
- For the new AB applicants, VA's onsite evaluation is scheduled for October 20-22. The MN application is in executive review. The OK application is tentatively scheduled for summer 2010.
- Paul Ellingson, QAO, has submitted follow up information on his report to the NELAP Board.
- The NELAP Board invited Eric Smith to talk about experimental PTs. Aaren will ask the LASC if labs would object to taking the experimental PT tables off of the website now while the PT Board is analyzing the data.
- The NELAP Board is developing a draft policy for secondary recognition.
- The NELAP Board will begin reviewing pending SIRs.
- Letters have been prepared to send to ABs advising of accreditation fee assessment beginning in July 2010. Each AB will be assessed a \$6,000 annual fee,

Technical Assistance

- The TAC subcommittee developing a guidance document for LOD/LOQ determination continues to meet. A draft document is expected by the time of the Chicago meeting. A subcommittee page has been set up on the TAC committee page.
- A draft schedule for delivery of regional training for the new TNI standards has been developed. The schedule will be finalized by the end of October.

Advocacy

- The next newsletter is scheduled for publication on November 1, 2009. Carl Craig is the editor.
- The newsletter schedule for 2010 has been developed.
- The Advocacy Committee is evaluating comments from Judy Morgan's survey to look for action items for TNI.

Laboratory Accreditation System Committee

- The review of seals is complete and recommendations are shown below. The group is recommending that all TNI seals contain the same center graphics, but that the ring around it be slightly different for NELAP, NEFAP and the accredited labs.
- Standards Interpretation Request process:
 - Five requests were received in September. The system has now been updated and all requests have been forwarded to the various committees and boards. The NELAP Board has also received an update on needed responses and Carol will work with the group to add these to the agenda until everything is current.
 - The LASC has asked that all DRAFT Final Letters be forwarded to them so they can add any comments for the NELAP Board's consideration when they review the response from the committee or board. This is not an additional approval step and it should not extend the response period.
 - Originally the goal for responses has been 60 days. This is being extended to 90 days so that we can work through the older requests and we will shorten the time frame as we become capable of quicker responses.
- Membership. To keep the LASC membership similar to where it has been, two new ABs are needed (to replace Jack McKenzie and Lew Denny) and one EPA representative (to replace Marvelyn Humphrey) and a lab representative (to replace Dale Piechocki) are needed.

PT Board

- Activities this month centered on working through the Experimental PT issue and finalizing the Limit Update SOP. The Board has been in communication with the NELAP Board and at this point it looks like Experimental PTs will be eliminated by July 1, 2010.
- The Chem FoPT Subcommittee is continuing to work on limit updates. The group has been refocused to specifically address Experimental PT analytes over the next couple of months so that recommendations can be made by late November/early December with an implementation date of July 1, 2010. The new format for the tables should be included in this update. This new format includes making it clear which analytes should be analyzed for which methods.
- The Board plans to review the Microbiology FoPT Subcommittee recommendations to see if any can now be implemented with the adoption of Volume 3 and 4 of the new standard. Many of the

recommendations of this subcommittee were originally tabled due to limitations of the 2003 NELAC Standard.

- Membership. The PT Board will have no vacancies.

National Database

- Committee has completed their work and will be merged into Website. Propose to change the name of committee to Information Technology.

NEFAP

- The NEFAP Board has been formed and the following recommendation is being forwarded to the TNI Board for approval:

NEFAP Board

CHAIR

1. Marlene Moore

AB

2. Scott Evans - STAC
3. Cheryl Morton - AIHA
4. Brian Connor - A2LA
5. Keith Greenway – ACLASS
6. Douglas Berg - PJLA

OTHER

7. Jan Wilson
8. Mike Miller
9. Patrick Conlon (ESI)
10. Michelle Henderson (EPA)

FSMO

11. Dane Wren
12. Kim Watson (Stone Environmental Inc)
13. Calista Daigle (Shaw - National Air Measurements Group)
14. Justin Brown (Wastewater)
15. John Moorman (Water Quality, South FL Water Management Dist)

- The subcommittee formed to prepare a Pros and Cons summary for lead accreditation has made significant progress. They have formulated a three tier approach involving personnel, FSMO and fixed lab certifications. It is being reviewed by the subcommittee and a DRAFT recommendation should be available at the next FAC meeting on the 29th of this month.
- The NEFAP Board will begin meeting after TNI Board approval. They have requested information from the NELAP Board to be used as a starting point for developing policies, procedures, etc.
- Membership. The FAC committee will be looking for three new members. They need FSMOs and at least on federal agency to maintain balance.
- Marlene received the following communication from Doug Leonard of L-A-B.

While I appreciate the nomination and the efforts in improving the quality of data for FSMO's in our country I must unfortunately decline the nomination to be on the NEFAP Board of Directors. My reason is two-fold: L-A-B's status as a signatory of the ILAC MRA for international recognition and L-A-B's membership commitment to NACLA's Objective,

Mission and Purpose and the hard earned National Recognition through NACLA. L-A-B believes the NEFAP objectives mirror those of NACLA with the addition of just an FSMO Technical Committee developed under the ACIL/NACLA MoU with a joint ACIL/NACLA/ TNI committee within ACIL. The committee under ACIL could establish all the technical requirements and TNI could publish those jointly with ACIL while NACLA utilizes them to recognize the AB's by adding the FSMO recognition to the scopes of the AB's. With the development of NEFAP unfortunately the company will create a redundancy in recognitions and potentially redundancy in accreditations. This will ultimately drive up costs well beyond what I believe to a bearable burden for the FSMO organizations. Additionally L-A-B is unclear on the FAC committee's (and it is ACIL member's and Federal Agency's) interpretation of 21 CFR 287 which provides clear guidance on these matters.

Conference Planning

- Contracts have been signed with Hyatt Regency for the 2011 meetings:
 - February 7-10, 2011, Savannah, GA
 - July 18-22, 2011, Seattle, WA

Membership

- Active Members: 605