# TNI Board of Directors Meeting Summary October 13, 2010

## 1. Roll Call and Approval of September Minutes

Directors	Present
Joe Aiello	X
Aaren Alger	X
Steve Arms	X
Susan Boutros	X
Judith Duncan	X
Robert DiRienzo	
Zonetta English	Χ
Jack Farrell	X
Ken Jackson	Χ
Sharon Mertens	X
Judy Morgan	
Matt Sica	
Alfredo Sotomayor	X
Dave Speis	X
Elizabeth Turner	
Curtis Wood	X
Bob Wyeth	X
Ex-Officio Directors	
Brenda Bettencourt	X
Brooke Connor	Χ
George Detsis	
Edward Hartzog	X
Staff	
Carol Batterton	X
Jerry Parr	X
Ilona Taunton	X
Jane Wilson	X
Janice Wlodarski	X

Kristin McCracken -- guest

## 2. Approve minutes from 9/8/10:

Corrections: 1<sup>st</sup> item Aaren's name – "e" instead of "o"; 3<sup>rd</sup> item: Motion: Bob Wyeth, 2nd Jack Farrell.

Motion to approve with corrections: Ken Jackson

Second: Curtis Wood Approved: Unanimous

## 3. Implementing the New Standard for Laboratories

The NELAP AC has voted to re-visit their approval of the PT portion of the new standard. After considerable discussion as to whether the standard as written could be implemented consistently, the AC determined that they needed to consider rescinding approval of several sections. Sections under consideration are:

- o LOQ reporting (also includes secondary AB acceptance of primary AB decision),
- o experimental PTs,
- o use of unapproved PT providers, and
- o PT analysis date reporting.

If approval of any section of the new Standard is rescinded, the AC will work with the PT Expert Committee to develop TIAs.

See Attachment 1 for more information on this topic.

Aaren to lead discussion. Kristin McCracken guest online.

Aaren gave a brief summary of background surrounding the issues, how they came about, and who was involved.

The first PT issue came up while voting on the new Standard. Texas commented about experimental PTs being a problem for them. Other ABs (i.e., Florida) have issues with analysis dates, and New York would not be using the TNI Standard because of LOQ reporting. A poll of ABs on the August AC call showed that these were the main issues:

Experimental PTs
Analysis date tracking
Use of non-accredited PT providers
Reporting of LOQs with less than's

The AC assessed the situation and decided further investigation was necessary.

Discussion continues in detail, including the following comments/questions:

The AC does not have any solutions yet. The documents shown below were just sent to the AC yesterday and there has not yet been time to discuss them. The next call is Monday, October 18.

A mixed response to the issues: A number of states don't care; some states do – how do we handle these? Ok to use their state-specific rules or they are not allowed to be ABs?

The Standard was reviewed and language referring to a particular issue is highlighted in blue on the Attachments: Most of the problems are in the PT modules; some are not. Those highlighted not in the PT modules are only included for completeness. Some of these indicated editorial changes may be in order but not of a substantive in nature.

The LASEC had reviewed and presented to the Board some of these items as potential issues before approval of the Standard.

Are these PT issues the majority of the problem and otherwise the Standard could be implemented on time – Aaren is 95% sure the answer is yes. Some states (i.e., VA) will continue to use NELAC 2003 because it's in their regulations.

TNI Standard was written to address problems/issues with the 2003 NELAC Standard. Not written to address the exceptions, but to address problems with 2003 NELAC Standard. If you take these 4 items away, you have the 2003 Standard.

What is the real issue:

- These things absolutely can't be done?
- These things are difficult to do?
- We don't have a way to do these things?
- Or we just don't like it?

LOQ Reptg – (for PTs) NY -- in violation of their regulations – do not have stakeholder support to change the regulations. We would need to go through the standard development process to fix this issue.

Cannot implement TNI Standard and use the PT modules from NELAC Standard because you would have to use the 2003 Standard in its entirety.

We need to find solutions but are afraid of the precedent that will be set.

Were ABs going to use selective enforcement or did they sign up to use it consistently?

We had the same type of issues when we adopted the 2003 NELAC standard and tried to change it.

#### **NEXT STEPS:**

- The PT Committee to come up with solutions for the three smaller issues.
- Kristin (with Jerry in supporting role) to work with Stephanie/New York on the LOQ issue.
- The AC will delay any action until the PT Committee has time to do a little work.

## 4. Program Reports

See Attachment 2.

## Attachment 1

## **NELAP Accreditation Council Issues with the PT Requirements**

Note: Blue font highlights language related to a particular issue; red font highlights language that appears to be in conflict with other sections of the standards.

#### Issue 1: Analysis Date

## V1M1: 3.0 TERMS AND DEFINITIONS

3.3 Analysis Date: The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.

#### 4.0 REQUIREMENTS FOR ACCREDITATION

#### 4.1 Initial Accreditation

4.1.3 When the PT samples used for initial accreditation were analyzed by the laboratory prior to the date of application, the analysis dates of the PT samples for the same accreditation FoPT shall be no more than eighteen (18) months prior to the application date of accreditation, with the analysis date of the most recent PT sample having been no more than six (6) months prior to the application date for accreditation. Otherwise, there shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the same accreditation FoPT.

#### 4.2 Continued Accreditation

**4.2.1** To maintain accreditation the laboratory shall:

a) analyze at least two TNI-compliant PT samples per calendar year for each accreditation FoPT for which the laboratory is accredited unless TNI-compliant PT samples are not available from any PTPA approved PT provider at least twice per year, in which case the laboratory shall analyze the PT samples in the minimum time frame in which the PT samples are available . The analysis dates of successive PT samples for the same accreditation FoPT shall be at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation, or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart:

#### **6.0 REQUIREMENTS FOR CORRECTIVE ACTION**

6.1 When the laboratory receives a "not acceptable" performance score from a PTP or a Primary AB, the laboratory shall perform corrective action. The requirements for corrective action are described in Volume 1, Module 2.

When the laboratory receives an evaluation of not acceptable for an accreditation FoPT in any study, the laboratory may choose to re-establish successful history for the accreditation FoPT with a PT sample from any study. The following requirements shall apply to the PT sample used to reestablish successful history:

b) The laboratory shall ensure that there are at least fifteen calendar days between the analysis dates of successive PT samples for the same accreditation FoPT.

## V2M2:

## 3.0 TERMS AND DEFINITIONS

3.1 Analysis Date: The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.

#### 5.0 REQUIREMENTS FOR ACCREDITATION

5.1 Initial Accreditation

- **5.1.3** The analysis date of the PT samples for an accreditation FoPT shall be no more than eighteen (18) months prior to the application date for accreditation, with the analysis date of the most recent PT sample for an accreditation FoPT having been no more than six (6) months prior to the application date for accreditation.
- **5.1.4** There shall be at least fifteen (15) calendar days between the <u>analysis dates</u> of successive PT samples for the accreditation FoPT.

NOTE 1: The requirements for successful performance are described in Section 6.0.

NOTE 2: The requirements for supplemental PT samples are specified in Volume 3 of this Standard.

**NOTE 3:** The TNI PT Board maintains the official listing of FoPT and experimental FoPT on the TNI website.

#### 5.2 Continued Accreditation

- **5.2.1** In order to maintain accreditation, the Primary AB shall have procedures in place that track the following requirements:
  - **d)** Ensure that the <u>analysis dates</u> of successive PT samples for the same accreditation FoPT are at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation or is being used to reinstate accreditation after suspension, in which case the <u>analysis dates</u> of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart.

#### 8.0 REQUIREMENTS FOR ASSESSMENT OF CORRECTIVE ACTION

- **8.2** The Primary AB shall accept the results of a proficiency testing (PT) sample used for corrective action when the laboratory follows these requirements:
  - **c)** There shall be at least fifteen (15) calendar days between the **closing date** of a previous study and the analysis date of any subsequent study for the same FoPT.

#### V3:

#### 11.2 Final Evaluation Report

- 11.2.4 The following information shall be included for each PT sample/analyte in the final evaluation report:
  - e) assigned value;
  - f) acceptance limits:
  - g) laboratory value, as reported;
  - h) method description, as reported;
  - i) analysis dates as reported by the participating laboratory;
  - j) evaluation per Section 10.3;

## **Issue 2: LOQ Reporting**

#### V1M1:

#### 5.0 REQUIREMENTS FOR PT SAMPLE HANDLING, ANALYSIS & REPORTING

#### 5.1 PT Sample Analysis Requirements

**5.1.1** The laboratory shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures and acceptance criteria.

## 5.2 PT Sample Reporting Requirements

- **5.2.1** The laboratory shall evaluate and report the analytical result for accreditation or experimental FoPT as follows:
  - **a)** For instrument technology that employs a multi-point calibration, the laboratory shall evaluate the analytical result to the value of the lowest calibration standard established for the test method used to analyze the PT sample. The working range of the calibration under which the PT sample is analyzed shall be the same range as used for routine environmental samples.
    - i. A result for any FoPT at a concentration above or equal to the lowest calibration standard shall be reported as the resultant value.
    - **ii.** A result for any FoPT at a concentration less than the lowest calibration standard shall be reported as less than the value of the lowest calibration standard.
  - **b)** For instrument technology (such as ICP-AES or ICP-MS) that employ standardization with a zero point and a single point calibration standard, the laboratory shall evaluate the analytical result to the limit of quantitation (LOQ) established for the test method used to analyze the PT sample. The LOQ for the FoPT shall be the same as used for routine environmental samples.
    - i. A result for any FoPT at a concentration above or equal to the LOQ shall be reported as the resultant value.
    - ii. A result for any FoPT at a concentration less than the LOQ shall be reported as less than the value of the LOQ.

**Note:** The definitions and requirements for calibration and limit of quantitation are included in Volume 1, Module 2.

## 6.0 REQUIREMENTS FOR CORRECTIVE ACTION

**6.1** When the laboratory receives a "not acceptable" performance score from a PTP or a Primary AB, the laboratory shall perform corrective action. The requirements for corrective action are described in Volume 1, Module 2.

When the laboratory receives an evaluation of not acceptable for an accreditation FoPT in any study, the laboratory may choose to re-establish successful history for the accreditation FoPT with a PT sample from any study. The following requirements shall apply to the PT sample used to reestablish successful history:

**c)** The PT sample shall be analyzed and reported in accordance with the requirements described this Module.

#### V1M2:

**Limit(s) of Quantitation (LOQ):** The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.

## V1M4:

## 1.0 CHEMICAL TESTING

- 1.7 Technical Requirements
- 1.7.1 Initial Calibration
- 1.7.1.1 Instrument Calibration

f) the lowest calibration standard shall be at or below the LOQ. Any data reported below the LOQ shall be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or explained in the narrative;

### V2M2:

## 6.0 REQUIREMENTS FOR ASSESSMENT OF PT SAMPLE ANALYSIS

**6.1** The Primary AB shall assess the laboratory to ensure that PT samples are tracked, prepared, and analyzed in the same manner as routine samples.

The Primary AB shall require the laboratory demonstrate through their records that:

f) the laboratory has procedures in place for the analysis of environmental and PT samples when the concentration range of the samples is outside of its normal range of measurement;

## V3:

#### 3.0 TERMS AND DEFINITIONS

**3.9 Proficiency Testing Reporting Limit (PTRL):** The value that corresponds to the lowest acceptable result that could be obtained from the lowest spike level for each analyte in a PT sample. PTRLs are established and published by the TNI PT Board.

#### 6.0 PT SAMPLE DESIGN AND MANUFACTURE

## 6.3 Sample Analytes

**6.3.5** The assigned value for unspiked analytes shall be set to <PTRL.

#### 8.0 PROVISION OF PT SAMPLES

#### 8.2 Study Instructions

8.2.1 The PT provider shall provide instructions to each participant describing:

- a) how to dilute or otherwise prepare the PT samples;
- **b)** how to report their data to the PT provider;
- c) the close date of the PT study; and
- **d)** a warning that the TNI standard requires PT samples to be analyzed like "real" samples utilizing the same analysts, methods, and quality control procedures.

#### **10.0 PT STUDY DATA ANALYSIS**

#### 10.3 Evaluation of Individual Participant Results

**10.3.1** If the assigned value is greater than "0" the numerical value reported shall be evaluated "Acceptable" if it is within the established acceptance limits and evaluated "Not Acceptable" if the numerical value reported is outside the established acceptance limits or the numerical value is reported with a less than (<) sign and the numerical value is less than the lower acceptance limit.

## **Examples are as follows:**

If the Assigned Value is "10.0", the lower acceptance limit is "5.00" and the upper acceptance limit is "15.0".

- a) Any reported numeric value between 5.00 and 15.0 shall be evaluated "Acceptable"
- b) Any reported numeric value greater than 15.0 shall be evaluated "Not Acceptable".
- c) Any reported numeric value less than 5.00 shall be evaluated "Not Acceptable".
- **d)** Any numeric value reported with a less than sign (<) shall be evaluated "Acceptable" if the reported numeric value associated with the less than sign is equal to or greater than the lower acceptance limit. In this example, a reported value of '< 5.00' shall be evaluated as "Acceptable" because 5.00 is equal to the lower acceptance limit.
- **e)** Any numeric value reported with a less than sign (<) shall be evaluated "Not Acceptable" if the reported numeric values associated with the less than sign is less than the lower acceptance limit. In this example, a reported value of '< 4.99' shall be evaluated as "Not Acceptable" because 4.99 is less than the lower acceptance limit.
- **10.3.2** If the Assigned Value is set to the PTRL with a less than sign (<) or set to "0", any numeric value reported with a less than sign (<), a reported value of "0" or a reported numeric value less than the PTRL shall be scored "Acceptable".

For example, if the assigned value is set to "< 2.50" and 2.50 is the PTRL associated with a less than sign (<):

- a) Any reported numeric value reported with a less than (<) sign shall be evaluated "Acceptable".
- b) A reported value of zero "0" shall be evaluated "Acceptable".
- c) A reported numeric value between "0" and 2.50 shall be evaluated "Acceptable".
- d) A reported numeric value greater than 2.50 shall be evaluated "Not Acceptable".

## 11.0 GENERATION OF STUDY REPORTS

## 11.2 Final Evaluation Report

- **11.2.4** The following information shall be included for each PT sample/analyte in the final evaluation report:
  - e) assigned value;
  - f) acceptance limits;
  - g) laboratory value, as reported;
  - h) method description, as reported;
  - i) analysis dates as reported by the participating laboratory;
  - j) evaluation per Section 10.3;

## Issue 2 (Continued): Primary/Secondary AB Requirements Related to PTs

## V1M1:

#### 3.0 TERMS AND DEFINITIONS

**3.7 Primary Accreditation Body (Primary AB):** The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

#### **6.0 REQUIREMENTS FOR CORRECTIVE ACTION**

**6.1** When the laboratory receives a "not acceptable" performance score from a PTP or a Primary AB, the laboratory shall perform corrective action. The requirements for corrective action are described in Volume 1, Module 2.

### V2M2:

## 1.0 INTRODUCTION, SCOPE AND APPLICABILITY

#### 1.2 Scope

The TNI Proficiency Testing program (PT Program) is established to provide for a primary accreditation body (Primary AB) to evaluate a laboratory's performance under specified conditions relative to given set of criteria in a specific area of testing through analysis of samples provided by an external source yielding PT data that are technically defensible on the basis of the type and quality of the PT samples provided.

#### 3.0 TERMS AND DEFINITIONS

- **3.5 Primary Accreditation Body (Primary AB):** The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.
- **3.14 Secondary Accreditation Body (Secondary AB):** An accreditation body that grants laboratory accreditation for a field of accreditation based on recognition of accreditation from a Primary Accreditation Body for the same field of accreditation.

#### 4.0 ACCREDITATION BODY REQUIREMENTS

## 4.1 Primary Accreditation Body (Primary AB)

- **4.1.1** The Primary AB shall ensure the laboratory meets the proficiency testing requirements for initial and continued accreditation as specified in this Standard. In this capacity the Primary AB shall have procedures in place to: . . .
- 4.1.3 The Primary AB shall accept evaluation reports from any PTPA-accredited PT Provider.

#### 4.2 Secondary Accreditation Body (Secondary AB)

- **4.2.1** The Secondary AB shall accept the assessment decisions made by the Primary AB regarding a laboratory's performance and compliance with the proficiency testing requirements set forth in this Standard.
- **4.2.2** The Secondary AB shall not impose additional requirements for proficiency testing that are not included in this Standard as a requisite for initial or continued accreditation.

#### 7.0 REQUIREMENTS FOR ASSESSMENT OF FINAL EVALUATION REPORTS

- **7.2** The Primary AB shall consider the analytical result for a FoPT acceptable when the result reported by the laboratory for a FoPT is evaluated acceptable by the PT provider.
- **7.3** The Primary AB shall consider the analytical result for a FoPT not acceptable when:
- a) the result reported by the laboratory does not meet the criteria for "acceptable" as specified in V3, Section 10.3 and associated subsections of this Standard. If the criteria in V3, Section 10.3 are met, and the result for the FoPT was scored "not acceptable" by the PTP, the AB shall overturn the performance evaluation and score the analytical result "acceptable";

#### 9.0 REQUIREMENTS FOR COMPLAINT RESOLUTION

**9.2** The Primary AB shall have procedures to resolve a laboratory's question about the validity of a not acceptable evaluation made by the Primary AB for a FoPT in any PT sample or when the validity of an entire study from a PTP may be questionable based on complaints, failure rates or data provided by the PTP.

#### <u>V3:</u>

**3.4 Primary Accreditation Body (Primary AB):** The accreditation body responsible for assessing a laboratory's total quality system, on-site assessment, and PT performance tracking for fields of accreditation.

#### Issue 3: Non-Accredited PT Providers

## <u>V2M1</u>

- 4.1.2 The PT samples used for initial accreditation shall be obtained from any PTPA-accredited PTP as part of a TNI-compliant study. If a PT sample for an accreditation FoPT is not available from any accredited PTP, the laboratory shall obtain the PT sample from any non-PTPA-accredited PTP.
- 4.2.1 To maintain accreditation the laboratory shall:
  - a) analyze at least two TNI-compliant PT samples per calendar year for each accreditation FoPT for which the laboratory is accredited unless TNI-compliant PT samples are not available from any PTPA approved PT provider at least twice per year, in which case the laboratory shall analyze the PT samples in the minimum time frame in which the PT samples are available. The analysis dates of successive PT samples for the same accreditation FoPT shall be at least five (5) months apart and no longer than seven (7) months apart unless the PT sample is being used for corrective action to reestablish successful history in order to maintain continued accreditation, or is being used to reinstate accreditation after suspension, in which case the analysis dates of successive PT samples for the same accreditation FoPT shall be at least fifteen (15) days apart;
  - b) maintain a history of at least two (2) successful performances out of the most recent three (3) attempts; for each accreditation FoPT; and
  - c) obtain the PT samples from any PTPA-accredited PTP. If a PT sample for a FoPT is not available from any accredited PTP, the laboratory shall obtain the PT sample from any non- PTPA-accredited PTP.

#### 2003 NELAC Standard

#### 2.0 PROFICIENCY TESTING PROGRAM: INTERIM STANDARDS

For fields of accreditation for which proficiency testing (PT) samples are not available from a designated Proficiency Testing Oversight Body (PTOB)/Proficiency Test Provider Accreditor (PTPA) (e.g., National Institute of Standards and Technology (NIST)) accredited PT Provider, a Primary Accrediting Authority may accept PT results from non-accredited PT Providers. In these cases, the Secondary Accrediting Authority shall accept the decision of the Primary Accrediting Authority.

## **Issue 4: Experimental Analytes**

## <u>V1M1</u>

4.2.2 When a laboratory is accredited for a field of accreditation for which the FoPT is an experimental FoPT, the laboratory shall analyze two (2) PT samples for the experimental FoPT per year within the same time frames specified for accreditation FoPT. However, successful performance of the experimental PT is not a requisite for continued accreditation.

## **V2M2**

- **3.1 Analysis Date:** The calendar date of analysis associated with the analytical result reported for an accreditation or experimental field of proficiency testing.
- **3.2 Experimental Field of Proficiency Testing (Experimental FoPT):** Analytes for which a laboratory is required to analyze a PT sample if they seek or maintain accreditation for the field of accreditation, but for which successful analysis is not required in order to obtain or maintain accreditation.
- 5.1.4 There shall be at least fifteen (15) calendar days between the analysis dates of successive PT samples for the accreditation FoPT.
  - NOTE 1: The requirements for successful performance are described in Section 6.0.
  - NOTE 2: The requirements for supplemental PT samples are specified in Volume 3 of this Standard.
  - NOTE 3: The TNI PT Board maintains the official listing of FoPT and experimental FoPT on the TNI website.
- 5.2.3 If the laboratory holds accreditation that is designated an experimental FoPT, the primary AB shall require the laboratory to analyze two (2) PT samples for the experimental FoPT per year using the same time frames specified for accreditation FoPT. However, successful performance of the experimental PT is not a requisite for initial or continued accreditation.

#### 2003 NELAC Standard

## C.1.1.3 Experimental Data: Analytes without Promulgated Acceptance Limits or Established Regression Equations

For those analytes not included in categories C.1.1.1 or C.1.1.2, e.g., newly regulated analytes, or analytes in a matrix that have not been fully evaluated in interlaboratory studies, NELAC acceptance limits shall be established only after interlaboratory data has been collected for a minimum of one year unless the NELAC Standing Committee on Proficiency Testing determines that sufficient data have been collected in less time. The data obtained during the one-year period shall be referred to as "experimental data". The NELAC Standing Committee on Proficiency Testing shall derive regression equations to be used to establish acceptance limits for analytes in the experimental category after sufficient data have been collected. The laboratory shall receive a copy of its own experimental data from the PT Provider at the conclusion of the PT study.

## Attachment 2 PROGRAM REPORTS

## CONSENSUS STANDARDS DEVELOPMENT

- Stationary Source Audit Sample committee has been meeting to review the EPA final rule for the stationary source program. Review to date indicates a few TIAs are needed to bring the TNI SSAS standards in full alignment with the EPA rule. SSAS meets next on October 18th. TIAs could be drafted for CSD EC review at their November meeting.
- Quality Systems was voting this week on releasing a Voting Draft Standard containing the
  clarifications presented as a Working Draft Standard at the DC meeting. If endorsed for release, a
  TNI membership ballot will be initiated to review the Voting Draft Standard following the TNI
  standards development procedures. QS is also working on several Standards Interpretation
  Requests.
- Laboratory Accreditation Body has endorsed the SOPs for the Evaluation and Provisional Recognition for further review and forwarded to LAS EC for comment.
- Laboratory Proficiency Testing committee still working on implementation solutions regarding LOQ change in TNI standards.

## **NEFAP** (including Field Activities Committee)

## **NEFAP Executive Committee**

- The NEFAP Executive Committee received their first application from an AB.
- The AB application and completion checklist have been posted on the TNI website.
- The AB checklist is complete, but will need to be updated once the 15 corrections are made to the standard (see below FAC).
- Marlene is working on a webinar for AB Evaluators training in November.
- Standards Interpretation Requests (SIRs)
  - One standards' interpretation was received and forwarded to the FAC.
  - The NEFAP Executive Committee reviewed Standard's Interpretation Request #1 and agreed that it is ready for a vote at the next meeting.

#### FAC

- The committee finalized a response to one Standards Interpretation Request (SIR) and has prepared draft language for the remaining two.
- A subcommittee made up of individuals who originally voted on the current Standard was formed to
  review the current standard to ensure that all updates to the standard were made prior to finalization.
  There were 15 changes that were approved that did not make it into the final version of the standard.
  The list of needed changes has been forwarded to Jerry Parr and the CSDP Executive Committee.

 Ilona has started tables to begin tracking comments and suggestions for the update to the Field Standard.

## **NELAP**

## **Accreditation Council**

- Kevin Kubik has been replaced by Art Clark as the EPA liaison to the NELAP AC.
- An RFP has been posted for evaluator training in Savannah.

## **Status of AB Payments**

AB		Amount	Date
California	\$	6,000	17-Jun
Florida	\$	6,000	16-Aug
Kansas	\$	6,000	16-Aug
Illinois			
Louisiana DEQ			
Louisiana DHH	\$	6,000	23-Jul
Minnesota	NA		
New Hampshire			
New York			
New Jersey	\$	6,000	17-Jun
Oregon	\$	6,000	28-Jul
Pennsylvania	\$	6,000	12-Oct
Texas	\$	6,000	15-Aug
Utah	\$	6,000	7-Jul
Virginia	\$	6,000	14-Jun
Total	\$	60,000	

#### **Technical Assistance Committee**

- A revised draft of the educational delivery systems SOP has been forwarded to TAC for review and comment. This version emphasizes approval of training rather than training providers.
- TAC will continue to work with SLAG to finalize the "NELAP Simplified: A Handbook for Small Laboratories" which is in development to assist labs with implementation.
- The final draft of the quality manual template is complete and has been sent to the Quality Systems Expert committee for review. Ilona will also send the draft to Keith Chapman for SLAG review. The target completion date for the Quality Manual is still December 2010 with the goal of providing training on this tool in Savannah.
- The LOD/LOQ webinar is tentatively planned for December 9, 2010.
- Betsy Kent cannot attend the Savannah meeting. Gary Dechant will chair the mentoring session. Topics are still under discussion.
- Jack Farrell will chair the Assessment Forum. Lara Autry will do a performance approach presentation. One additional topic is needed for this session.
- 16 regional workshops have been completed. Upcoming regional workshops include:

Date/Location	Lead	Other Speakers	Lead organization
October 27: West Palm Beach, FL	Jack	Jerry, Silky	FSEA
Nov. 23: Baton Rouge, LA	Carol	Linda/Tom	TNI
December 3: Chicago, IL	Jerry		IAETL
February 3, 2011: Savannah, GA	TBD		TNI

- The first DRAFT of the Quality Manual Template has been completed. It has been sent out for review to the Quality Manual Template subcommittee and the Quality Systems Expert Committee. The subcommittee has begun meeting on Monday's again to discuss any review issues and to begin formal compilation of the supporting tools that will be available on the website. People have already begun sending in examples that will be posted on the website. The Template will also be distributed to SLAG and a few other people who have offered to help review the manual.
- Ilona has completed a DRAFT TNI Training Educational Delivery System SOP that will be distributed for discussion at the next TAC meeting. It provides procedures that place this system in the Administration and Support arm of TNI and then each program will designate a committee that will have the responsibility to evaluate the training needs of the program and its users. In NELAP the Laboratory Technical Assistance Committee has been designated. NEFAP currently has designated FAC to coordinate this effort. These procedures also provide opportunities for TNI to work with third party trainers and support their training efforts.

## **Laboratory Accreditation System Executive Committee**

- Standards Interpretation Request (SIR) process:
  - 3 requests were received in September. Two were forwarded to the Quality Systems Expert Committee and one was sent to the On-site Expert Committee. Status updates have been sent to the inquirers. All three requests were for interpretations on the new standard. One of them addressed a concern that was raised at the TNI Board meeting in DC regarding training requirements for assessors.
  - The system for on-line voting by the NELAP ACs is now functional. E-mails were sent to each AB making them aware of the process and to let them know that SIRs have been posted for them to look at. Ilona will be providing Carol with an update every Thursday to let them know whether any new SIRs have been posted and the status on any that are receiving requests for discussion. The NELAP AC will be approving the on-line votes during meeting time to accommodate requirements in their voting SOP.
  - June and Ilona have started meeting to review the older SIRs and get them up on the website for on-line voting. The review of 7 SIRs has resulted in a few SIRs requiring contact with the inquirer to make sure they still need a response, another was determined to not be a SIR and the inquirer is receiving notification, and a few have been sent to Silky for final review.
  - Reminders have gone out to committee chairs for SIRs that are still open.
- The DRAFT Implementation Project Summary and is posted on the website. It is an "Easy Link" on the NELAP home page "2009 TNI Standard Implementation Project". Updates will be added once a week unless none were received.

#### **Consistency Improvement Task Force**

 The CITF met to review their progress. They are planning to present draft work products at the Savannah meeting.

## **Accreditation Body Assistance Task Force**

- The AB task force invited David Epstein to share NFSTC's experiences with providing third party services to laboratories and accreditation bodies.
- The AB task force has finalized a survey to distribute to ABs to help in determining what services
  would be most helpful to ABs. Results of the survey will be used to help the task force develop a
  range of plans to assist ABs.

## **PROFICIENCY TESTING**

- The Chem FoPT Subcommittee is continuing to work on limit updates. The subcommittee completed
  updates for the Drinking Water FoPT table and is starting on the Non-Potable Water FoPT table. The
  expected implementation dates for these tables will be July 1, 2011.
- The Field PT Subcommittee met to discuss formulation of the lead PTs. There were concerns
  expressed about the need for real world samples and homogeneity requirements. Data has been
  requested from AIHA. Other subcommittee members are also compiling data that will help the group
  determine the feasibility of the lead source in the PTs being from lead in paint.
- FoPT Table Issue
  - The PT Executive Committee is reviewing all the DRAFT tables (DW, NPW and SCM) and removing headers and analytes that failed the number of studies criteria from the 2003 NELAC Standard. These tables will be reviewed by the PT Executive Committee and forwarded to the NELAP AC.
  - The PT Executive Committee would like to continue discussions with the NELAP AC regarding FoPT tables for future updates. It was commented that the international standards (ISO/IEC 17043) are considering the difference in technologies with regard to sample preparation procedures. There are different limits for the same analytes based on the technologies being used.
- PTPA Assessments: ACLASS has provided a response to their assessment that is now being reviewed. The PT Executive Committee is looking at whether ACLASS needs to be fully approved in order to start assessing PT Providers. A renewal request has not yet been received from A2LA.
- The committee discussed the PTPA database issue and some ideas will be forwarded to the TNI Board for consideration.
- TNI/EPA Joint Cryptosporidium Work Group: Carrie Miller (EPA) has developed a work group to look at Cryptosporidium. The Work Group's first meeting will be late October/early November depending on people's schedules. The work group's goal: To discuss possible vendors for PT samples and/or development of equivalent lab approval programs for Cryptosporidium to the program EPA currently maintains.

## **ADMINISTRATION**

## **Advocacy Committee**

 The Advocacy Committee received a briefing on actions by the APHL state environmental laboratory accreditation subcommittee. The subcommittee is working on revising their position paper regarding

- TNI accreditation. APHL would like to meet with TNI at the Savannah meeting to discuss ways that state environmental laboratories could become accredited to TNI standards.
- The next TNI newsletter will be published November 15. Zonetta English is the editor. Due date for articles is November 1.
- The response letter to Mike Shapiro signed by Steve Arms was sent September 28, 2010.
- Zonetta English and Sharon Mertens are coordinating follow up actions with NACWA on the new standards. Elizabeth Turner is organizing a follow up meeting with the AWWA lab practices committee.

## **Policy Committee**

- The Policy Committee is continuing to refine the working draft of the global TNI Complaint SOP. A
  Complaint Policy is in final draft form, but the committee has decided to wait and send both
  documents forward at the same time.
- At their next meeting, the Policy Committee will be reviewing the following SOPs from the PT Executive Committee: SOPs 4-101, 4-102, 4-103, 4-105, along with the NELAP AC's Mutual Recognition Policy.

Membership Report: September 2010

Active Members: 730