TNI PT Board Meeting Summary
January 14, 2009

1. Roll call and approval of minutes:

   Chairman Carl Kircher called the TNI PT Board to order on January 14, 2009, at 1:30 PM EST. Attendance is recorded in Attachment A. Associate members Dan Tholan and Randy Querry were also present. The meeting was adjourned at 5 PM EST.

   Minutes from the December 18, 2008 meeting were approved for posting on the TNI website (Motion: Gary Second: Eric). Ilona will have minutes posted.

2. PT Board Membership and Chair Election

   Stacie and Amy were welcomed as new PT Board members.

   Curtis nominated Eric Smith to become the PT Board Chair for 2009. Gary seconded the nomination. Eric expressed his willingness to serve in this role.

   Carl moved to accept Eric Smith as the new PT Board Chair for 2009. Gary seconded the motion and the Board unanimously voted to accept Eric into this position.

3. A2LA Review

   Gary and Kirstin McCracken noted the review was performed against the 2003 NELAC Standard. It was conducted in two parts – they attended an audit A2LA performed on a PT Provider and they did an on-site review.

   The final report was submitted to A2LA. There were five findings. The major finding was that the database has not been fully implemented. A2LA has already responded to this with an action plan that Gary and Kirstin are reviewing. Most of the other findings dealt with the PT Board's overview of the PTPA review process. The checklists need to be reviewed and updated.

   Gary and Kirstin recommend that A2LA be approved with the understanding that the database must be operational.

   Additional observations:
   - There were three Board members (Carl, Kirstin, Gary) present for the A2LA audit of a PT Provider. In the future, one Board member would likely be sufficient.

- The PTPA review process needs to be updated. SOPs need to be reviewed and updated as appropriate. Items to consider include: Final report format, time frame, who approves, where maintained, who approves the corrective action plan, who evaluates the corrective action has been completed, etc … A step-wise procedure is needed instead of a general description. Gary agreed to work on updating the SOP. A couple of issues to look for include:
    - There is a requirement that implies that A2LA has to make PTs. A2LA does not intend to do this.
    - The standard states that the NELAP Director will approve a PT Provider. At this point it appears that the PTPA is approving the provider. Perhaps the NELAP Director designates the PTPA and then they approve the PT Provider?
    - There is an issue with the title of the NELAP Director. NELAC may have designated where different responsibilities within NELAC went after TNI was formed. Ilona will confirm.
    - Conflict of Interest policies. It may not be appropriate for a lab person to review some PT Provider records.
- Next steps should be discussed during the February teleconference.
- A2LA commented that they gained a significant amount of information during the review process. They appreciated the thoroughness when records were reviewed.
- Need to determine whether the review should be posted or only archived. Ilona will follow-up on this.

4. Experimental PTs

Carl notified the membership that the PT Board decided to choose the following option regarding Experimental PTs:

Discontinue the use of Experimental Analyte Tables. Each new analyte would now be added directly to the accreditation tables and a default study mean of +/- 3 standard deviations would be applied to that parameter until sufficient data is generated to determine better analyte specific acceptance criteria.

Some members of the audience stated that they preferred to see fixed limits on Experimental PTs rather than a default study mean of +/- 3 standard deviations. Carl addressed the concern: Historically, this is a common value. The thought was that labs would not be negatively impacted and data could be received to update in the future. Where analytes are listed in CFR, a +/- 2 standard deviations will need to be used.

Carl will notify the Chemistry FoPT Subcommittee and NELAP Board of this decision.

Implementation of this change was discussed with the following comments:

- Curtis noted that an implementation time period will need to be established. Concern has been raised in the lab community, so perhaps change needs to happen sooner rather than waiting for an update from the Chemistry FoPT Subcommittee.

- Kirstin noted there is a sense of urgency. This was the number one issue from labs and ABs when the PT Expert Committee received comments on the new TNI Standard. A lead time will need to be considered for labs and ABs that have not been analyzing them. Labs that are not being required to run them have a competitive advantage.

- Eric noted that he felt the Chemistry FoPT Subcommittee could finalize changes to the tables within the next 2-3 months. PT Providers at the meeting did not have a problem with this. The Board would like to post new tables in March with implementation in July. A member of the audience asked if updated tables could distinguish new analytes with color or bolding.

- A discussion is needed with the NELAP Board to answer the following questions:
    - How much lead time is needed for the change? Is March to July enough time?
    - When should notification be posted?
    - What do labs need to run now? There needs to be consistency.

5. SOP from Chemistry FoPT Subcommittee

   The limits update SOP (TNI #4-001) was approved by the PT Board before Curtis had a chance to comment. He reviewed the SOP after the vote regarding the Experimental PTs and had concerns that part of the SOP needs to be updated based on this decision.

   The Board agreed that the SOP should be reviewed for additional revisions. Board members should send comments to Curtis before the next teleconference so that Curtis can provide language for any changes at the 2/19/09 meeting. If this update is not completed by 3/09, we should finalize the version the Board voted on electronically and continue with the update as a newer revision.

6. Open Comments

   - Gary stated that the PT Board needs to look at their function and get a better feel for what it should be doing.

   - Is it OK for the PTPA to share PT Provider data to help the PT Board determine limits, etc ...? It was requested that Dan Tholan make this request to each PT

Provider. He requested that the PT Board send him a formal request to do this. This needs to be done by 8/09.

- Carl gave a quick update on Subcommittee activities:
  - WET: They are very close to having new FoPTs.
  - Air & Emissions: The SSAS table is very close to completion. This table will go to the SSAS Committee for their consideration. Any additional changes will be made by the SSAS Committee. After the SSAS Table is recommended to the PT Board, the Subcommittee will work on the proposed NELAP AE FoPT Table.
  - Chemistry FoPT: They are working on clarifications to the Tables, and are in the process of receiving PT summary data from providers with which to do the evaluations of the existing acceptance limits.

7. Next Meeting

The next meeting of the PT Board will be Thursday, February 19, 2009, at 1pm EST.

Action Items are included in Attachment D and Attachment E includes a listing of reminders.

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8. PT Caucus

- <u>PTPA Presentation – Randy Querry</u>

  - All assessments are now done. They are going through the corrective actions and then it will go through the Accreditation Council for accreditations.
  - A2LA has committed that more staff will be provided to handle this process in the future and that anniversary dates will be staggered for renewals.
  - A2LA is continuing to work with Neptune to complete the database. All data should be collected by March 2009. They will be ready for the PT Board to review their corrective action regarding the database by summer.
  - Need to look at whether the implementation of the new TNI standard will require another assessment. Assessments are normally on a 2 year cycle.
  - Dan Tholan will plan to provide a database presentation in San Antonio.
  - A number of PT Providers in the audience raised an issue regarding a large fee increase. They asked that A2LA provide a fee breakdown and provide a copy of what the final reports are going to look like before they pay any fees to A2LA. It was questioned whether the PT Board should be given a copy of the fee structure. Gary mentioned that the assessment of the database in the summer will include assurance that the

database is doing what it was supposed to do. They will also validate that it was developed as stated and that calculations are correct.

- Acceptance Limits – Carl Kircher

  Carl's presentation can be found in Attachment B.

- ISO/IEC 17043 – Dan Tholan

  Dan's presentation can be found in Attachment C. It should be noted that the comment period ends 3/16/09. Comments should go to Carl. If successful, this could be finalized by the end of 2009.

Attachment A

Participants
TNI
Proficiency Testing Board

Members	Affiliation	Contact Information
Carl Kircher, Chair (2008) **Present**	Florida DOH	904-791-1574 carl_kircher@doh.state.fl.us
Ilona Taunton, Program Administrator **Present**	TNI	828-712-9242 tauntoni@msn.com
Gary Dechant **Present**	Analytical Quality Associates, Inc.	970-434-4875 gldechant@aol.com
Amy Doupe **Absent**	Lancaster Laboratories, Inc.	717-656-2300 x1812 aldoupe@lancasterlabs.com
Steve Gibson **Absent**	Texas Comm. on Env. Quality	512-239-1518 jgibson@tceq.state.tx.us
Svetlana Isozamova **Present**	Accutest Laboratories – Southeast Division	407-425-6700 svetlani@accutest.com
Michella Karapondo **Absent**	USEPA	513-569-7141 karapondo.michella@epa.gov
Stacie Metzler **Present**	HRSD	757-460-4217 smetzler@hrsd.com
Matt Sica **Absent**	State of Maine	207-287-1929 matthew.sica@maine.gov
Eric Smith (New Chair - 2009) **Present**	TestAmerica	615-726-0177 x1238 eric.smith@testamericainc.com
Curtis Wood **Present**	Environmental Resource Associates	303-431-8454 cwood@eraqc.com

Attachment B

(Presentation can also be viewed on the TNI Website.)

Evaluating PT Sample Acceptance Limits

Carl C. Kircher, FL Dept. of Health
P.O. Box 210, Jacksonville, FL 32231
904-791-1574
Carl_kircher@doh.state.fl.us

Input from:

- Two State Representatives (both are NELAP AB's
- Three PT Providers
- Two Commercial Laboratories
- One Statistician
- **Any volunteers??**

Current Situation for Chemistry FoPTs

- Acceptance criteria last established in 2006
- Acceptance criteria are based on limits fixed in regulations (e.g., SDWA), regression equations (per NELAC), or generic "mean - +/2,3 std.dev."
- There are both Accreditation and Experimental FoPTs
- Some acceptance limits are based on made-to Assigned Value while others are based on robust study participant mean (average)

Current Situation for Air & Emissions FoPTs

- **No** FoPTs posted on TNI website; therefore, NOT AVAILABLE under NELAP auspices in order to get laboratory accreditation

Evaluation of PT Data

For each analyte where there are at least 10 PT studies with 20 participants per study,

Plot the following parameters:

Assigned value vs Participant Mean
Assigned value vs (participant) Std. Dev.
Assigned value vs Mean Recovery

Initial Screening of PT Data for Anomalies

Number of PT Studies < 10
Mean Recovery <10% or >200% of AV
Relative Std Dev >50%

- Contact PT providers to correct for errors & attempt to resolve anomalies
- Record reasons not to consider particular PT data
- Retain data that cannot be justified for non-consideration

Evaluation of PT Data

- Linear Regressions are conducted for each analyte
  - Participant Mean = a (AV) + b
  - Participant Std. Dev. = c (AV) + d
- Calculate correlation coefficients ^{2}(R) & Standard Error of the Estimate (SER) for each regression
- Acceptance criteria:
  - R^2 value must be > 0.90 for PM vs. AV
  - R^2 value must be > 0.75 for SD vs. AV

Data Outlier Removal Criteria (in order of increasing censoring aggressiveness)

- Level 1: Data points above & below the regression line by over - +/2 SER
  - Both PM vs. AV and SD vs. AV
- Re-evaluate regression coefficients, R^2's, SER's, & acceptance criteria

Data Outlier Removal Criteria (in order of increasing censoring aggressiveness)

- Level 2: Data points above the regression line by over - +/1 SER
  - SD vs. AV
- Re-evaluate regression coefficients, R^2's, SER's, & acceptance criteria

Data Outlier Removal Criteria (in order of increasing censoring aggressiveness)

Level 3 manual procedures: Visual examinations

- Omit lower concentration ranges where convergence is evident (%RSD decreases with decreasing concentration)
- Single points at high end of the concentration range that bias the regression results
- Individual data points that, when removed, eliminate low-end convergence and high-end bias.

Evaluation of PT Data

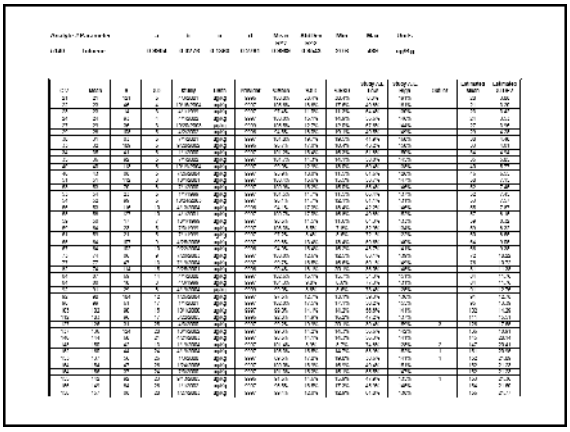
- If too many outliers, or correlation coefficients are too low, perform linear regression of participant standard deviations vs. participant means
  - SD = c (PM) + d
  - R^2 value must be > 0.75 for SD vs. PM
- The percentage of retained data points should be statistically reasonable & defensible
- Minimum # of data points needed to meet the NELAC Standards

Laboratory Analytical Considerations

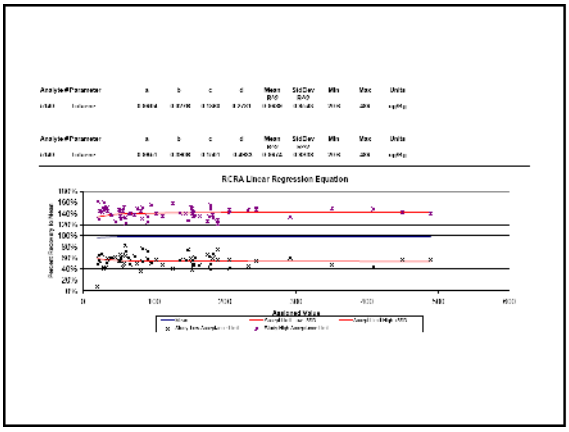
- Resultant PT acceptance criteria are consistent with test method performance for laboratory control standards
- PTRL (derived from lower acceptance limit at the lowest AV) is consistent with test method capability for LOD's & LOQ's

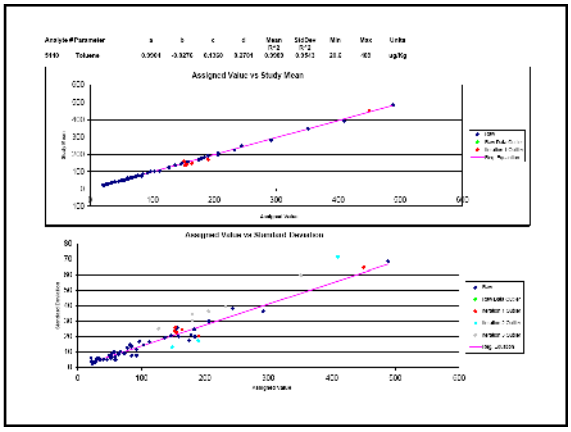
Laboratory Analytical Considerations

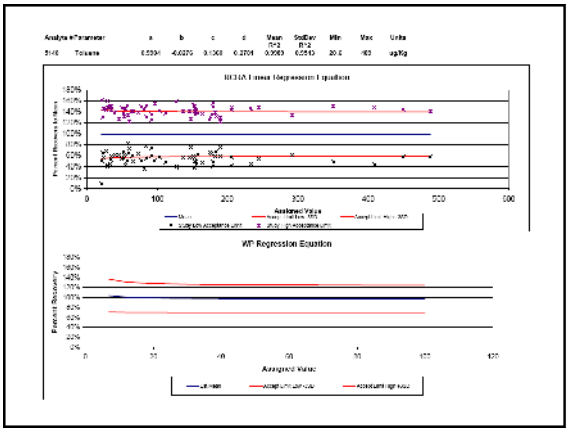
- Resultant PT acceptance criteria for soil matrix are consistent with corresponding wastewater & drinking water PT acceptance criteria for the same analyte

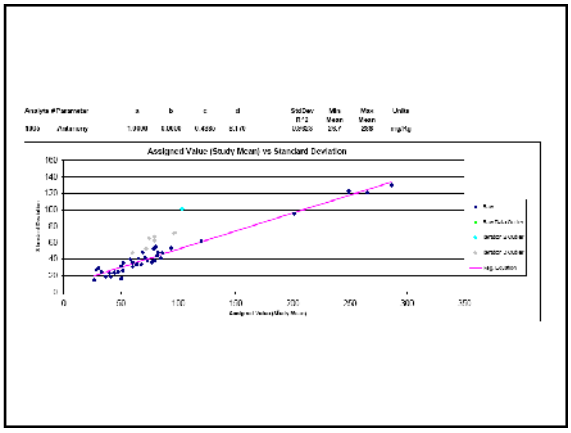


- PT concentration ranges are consistent with the applicability of different analysis technologies









Assumptions

- All participant laboratories deliver statistically identical testing performance
  - i.e., variances due to random error
- All test methods used by laboratories in analyzing 'PTs produce the same data quality performance for a given analyte
  - i.e., different analysis technologies produce results for bias & precision that are not statistically different
- Laboratory chemistry data variances follow Gaussian statistical distribution

Assumptions

- PT samples meet requirements for Homogeneity and Stability
- All PT samples are manufactured with consistent quality where differences are statistically indistinguishable
  - e.g., choice of soil or water type does not influence results

Comments Requested for DIS ISO 17043

Attachment C
(Presentation can also be viewed on the TNI Website.)

ISO/IEC 17043
Conformity assessment – General requirements for proficiency testing

TNI PT Board
January 14, 2009
Daniel Tholen, M.S.
A2LA

Background: ISO/IEC 17043

- Work Proposal from ILAC, 2006 to revise ISO/IEC Guide 43-1 and 43-2
  - In addition to Guide 43, use ILAC G13 and IUPAC as base documents.
  - Approved by CASCO; solicited experts for Working Group 28 (WG28)
  - 60 experts on WG28, 31 CASCO member countries and 6 liaison organizations

WG28 – Americas, Asia and Africa

- Argentina
- Brazil
- Canada
- Columbia
- Mexico
- Peru
- South Africa
- Trinidad and Tobago
- United States
- Australia
- China
- India
- Indonesia
- Japan
- Malaysia
- Pakistan
- Singapore
- Thailand

WG28 – Europe & Liaisons

- Belarus
- Czech Republic
- Denmark
- France
- Germany
- Sweden
- Switzerland
- United Kingdom

Liaisons:
- BIPM
- Eurolab
- IEC
- ILAC

WG28 Progress

2 years, 4 meetings, 2 ballots:

1. December 2006 (WD1)
2. May, 2007 (WD2)
   - WD3 sent to WG for comment
   - 211 comments, no serious objections
3. January, 2008 (CD)
   - CASCO CD ballot March-June, 2008
   - 49-0-6 ballot, 484 comments
4. September, 2008 (DIS)

ISO/IEC DIS 17043

Released 13 Nov 2008, 5 month ballot
ISO/IEC Ballot closes April 13
US comment closes March 16
5th meeting 30 June – 1 July, 2009, USA

- If ballot is successful and all comments are resolved successfully...
  - FDIS ballot (2 months)
  - Final standard released late 2009, early 2010

Else re-ballot DIS

ISO/IEC DIS 17043

Comments to Carl Kircher

- (TNI representative on ANSI ICAC)
- ISO Format needed for comments

Questions to Dan Tholen

- Copies of DIS and comment form are available from Carl, Dan, A2LA, ANSI

Structural changes from G1 3 and Guide 43 parts 1 and 2

- Technical Requirements come before Management Requirements
- One part with 3 Informative Annexes rather than two parts

A: Types of proficiency testing

B: Statistical methods for proficiency testing

C: Selection and use of proficiency testing

Differences between DIS 17043 and NELACCh.2&TNIVol.3

- NELAC Ch. 2 and TNI Vol. 3 requirements are "program requirements" and do not need to change to accommodate 17043:
  - FoPT tables
  - Study content and timing
  - Sample preparation
  - VHS testing
  - Oversight
  - other

17043 General Format

- Language and requirements in alignment with ISO/IEC 17025
- Management System Requirements conform with ISO PAS 17005 for content (ISO 9001)
- Structure not consistent with ISO 17005
- No reference to a particular means of recognition of competence of providers, laboratories and subcontractors:

"This International Standard has been prepared to provide a consistent basis for all interested parties to determine the competence of organizations that provide proficiency testing."

17043 Coverage

- Intended to apply to traditional PT (interlaboratory comparisons) and non-traditional settings:
  - Sampling
  - Inspection
  - Sensory evaluation
  - Personnel certification

ISO/IEC 17043 Scope

This International Standard specifies general requirements for the competence of providers of proficiency testing schemes and for the development and operation of proficiency testing schemes. These requirements are intended to be general for all types of proficiency testing schemes, and they can be used as a basis for specific technical requirements for particular fields of application.

Definitions – what it is

- **proficiency testing** – evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

– Quantitative & qualitative
– Single item (sequential) & bulk interlaboratory
– Single occasion & continuous
– Sampling
– Data transformation and interpretation

Definitions – what is provided

proficiency testing scheme - proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection

- **proficiency test item -** sample, product, artefact, reference material, piece of equipment, measurement standard, data set or other information used for proficiency testing

Definitions – who is involved

- **proficiency testing provider** – organization which takes responsibility for all tasks in the development and operation of a proficiency testing scheme
- **participant** – laboratory, organization or individual, that receives proficiency test items and submits results for review by the proficiency testing provider
  NOTE In some cases the participant may be an inspection body

Definitions – other parties

- **coordinator -** one or more individuals with responsibility for organizing and managing all of the activities involved in the operation of a proficiency testing scheme
- **customer -** organization or individual for which a proficiency testing scheme is provided through a contractual arrangement
- **subcontractor** – organization or individual engaged by the proficiency testing provider to perform activities specified in this International Standard and that affects the quality of a proficiency testing scheme

Definitions – statistical terms

- **assigned value** – value attributed to a particular property of a proficiency test item.
- **outlier** - observation in a set of data that appears to be inconsistent with the remainder of that set
  NOTE - An outlier can originate from a different population or be the result of incorrect recording or other gross error.
  ... this makes it inappropriate to use the term outlier" for a result outside the acceptance limit (e.g., z score >3); ... we eliminated the term extreme result" (Guide 43)

Definitions – from VIM, with Notes

metrological traceability - property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty (+8 Notes)

- **measurement uncertainty -** non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used (+4 Notes)

Differences between DIS 17043 and NELACCh.2&TNIVol.3

- Changes are same as changes from Guide 43, since Chapter 2 and Vol 3 include ISO Guide 43 (ILAC G13) and ISO 9001 as necessary requirements.
- Management Requirements in 17043 are consistent with ISO 9001:2008, edited for application specifically to PT providers
- Confusion over term “assigned value”

Content changes from Guide 43-1 and ILAC G13 -2007

- Added text to cover PT for Inspection Bodies (non-destructive testing)
- Enhanced requirements to promote educational potential of PT.

Content changes from Guide 43-1 and ILAC G13 - 2007

- Added requirements that some tasks *shall not* be subcontracted (5.5.2)
  - Planning PT scheme (4.4.1.2)
  - Evaluating performance (4.7.2.1)
  - Authorizing final reports (4.8.1)
- Add requirements for equipment in 4.3, similar to1 7025

Changes – Choice of method

4.5.2 Where participants are permitted to use a method of their choice, the proficiency testing provider shall have a policy and follow a documented procedure regarding comparison of results obtained by different test or measurement methods.

The proficiency testing provider shall be aware of which different test or measurement methods for any measurand are technically equivalent, and take steps to assess participants’ results using these methods accordingly.

Changes – 4.8 Reports

4.8.2 Reports shall include the following unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:

- o) assigned values and summary statistics for methods/procedures used by each group of participants
- p) comments on participants’ performance
- t) comments or recommendations, based upon the outcomes of the proficiency testing round

Traceability and Uncertainty

4.4.1.3 The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that shall address the following information and, where appropriate, reasons for its selection or exclusion:
q) the origin, *metrological traceability and measurement uncertainty* of any assigned values;

- **4.4.5.1** The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme. This procedure shall take into account the *metrological traceability and measurement uncertainty* required to demonstrate that the proficiency testing scheme is fit for its purpose.

Traceability and Uncertainty

- **4.7.2.2** Where appropriate for the purpose of the proficiency testing scheme, the proficiency testing provider shall provide expert commentary on the performance of participants with regard to the following:

  a) overall performance against prior expectations taking *measurement uncertainties* into account;

- **4.8.2** Reports shall include the following unless it is not applicable or the proficiency testing provider has valid reasons for not doing so:

  – m) details of the metrological *traceability and measurement uncertainty* of any assigned value

Changes - Assigned Value (all)

4.4.5.1 The proficiency testing provider shall document the procedure for determining the assigned values for the measurands or characteristics in a particular proficiency testing scheme.

This procedure shall take into account the metrological traceability and measurement uncertainty required to demonstrate that the proficiency testing scheme is fit for its purpose.

Changes - Assigned Value (calibration)

- **4.4.5.2** Proficiency testing schemes in the area of calibration shall have assigned values with metrological traceability, including measurement uncertainty.

Changes - Assigned Value (testing)

- **4.4.5.3** For proficiency testing schemes in areas other than calibration, the relevance, needs and feasibility for metrological traceability and associated measurement uncertainty of the assigned value shall be determined by taking into account specified requirements of participants or other interested parties, or by the design of the proficiency testing scheme.

Changes - Assigned Value (consensus values)

- **4.4.5.4** When a consensus value is used as the assigned value, the proficiency testing provider shall document the reason for that selection and shall estimate the uncertainty of the assigned value as described in the plan for the proficiency testing scheme.

Changes – 4.9 Communications

- **4.9.5.** If the proficiency testing provider issues statements of participation or performance, they shall contain sufficient information to not be misleading.

…based on a comment and confirmed by several WG members' experiences.

Annex A: Types of proficiency testing

- Revised from introductory language in ISO/IEC Guide 43-1
- Provides further explanation of NOTES in the definition of PT
  - Sequential schemes
  - Simultaneous schemes
    - EQA
    - Split level
    - Split sample
    - Partial process
    - Blind ←

Annex B: Statistical methods for proficiency testing

- Reference ISO 13528 and 2006 IUPAC Harmonized Protocol
- *Provide further discussion of statistical methods for qualitative and ordinal results*
  - *Simple listing of categorical responses*
  - *Don't take average of numeric ordinal data*

D, D%, Z score, E_n, *zeta*

ISO TC69/SC6 consulted

Annex C: Selection and Use of Proficiency Testing

- Based on Guide 43-2.
- Separate sections for laboratories and for "interested parties"
  - Accreditation bodies
  - Regulatory agencies
  - Laboratory Customers
- Very general guidance on recognition of competence and use of results
- Considerations for accreditation bodies to be addressed by revised ILAC P9

Thank you

Attachment D

Action Items – TNI PT Board

	Action Item	Who	Expected Completion	Actual Completion
8.	Gather additional names for newly formed Chemistry FoPT Subcommittee.	Carl	On-going until membership is about 14.	
10.	Let the new Chemistry FoPT Subcommittee know that information is available from NY regarding extraction/prep methods and PT results.	Carl	When Chemistry FoPT Subcommittee is formed.	
17.	Work on language for new TNI policy based on NELAC Policy #16 and EPA Criteria Document.	Chuck	~~11/17/08~~ ~~Next Meeting~~ Wk of 1/12/09	
31	Update PTPA Review SOP.	Gary	Discussion: 2/09	
32	Confirm that NELAC designated where different responsibilities within NELAC went after TNI formed.	Ilona	2/19/09	
33	Distribute final A2LA report and pertinent documentation to the PT Board members. This will be an agenda item in Feb 09.	Gary	2/19/09	
34	Check to see if review needs to be posted on website or only archived.	Ilona	2/19/09	
35	Notify Chemistry FoPT Subcommittee and NELAP Board of Experimental PT decision.	Carl	2/19/09	
36	Review and propose update of Limits Update SOP.	Board Members Curtis	Review: 2/19/09 Update: 3/09	

Attachment E

Backburner / Reminders – TNI PT Board

	Item	Meeting Reference	Comments
2	Finalize the SOP for Evaluating Updated Limits. The Board will work on an update based on the Experimental PT decision. If this update is not completed by 3/09, go ahead and finalize the version the Board voted on electronically.	1/14/09	
3	Send A2LA a formal request to ask PT Providers if PT data can be shared with the Board. Needs to be done before 8/09.	1/14/09	
4			
5			