SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

AUGUST 5, 2013

The Committee met on Monday, August 5, 2013, at 1:30 pm CDT at the Environmental Measurement Symposium, San Antonio, TX. Chair Mitzi Miller led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Present
Stephen Arpie, Absolute Standards (Other)	Present
Kareen Baker, Veolia Water N. American (Other)	Absent
Yumi Creason, PA DEP (AB)	Present
Rachel Ellis, NJ DEP (AB)	Present
Scott Hoatson, Oregon DEQ (AB)	Present
Shawn Kassner, Phenova (Other)	Present
Roger Kenton, Eastman Chemical Co. (Lab)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Present
Mitzi Miller, Dade Moeller Assocs. (Chair; Other)	Present
Judy Morgan, Env. Science Corp. (Lab)	Present
Virgene Mulligan, Amrad (Lab)	Present
Joe Pardue, P2S (Other)	Present
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Absent
Ken Jackson, Program Administrator	Present

Mitzi welcomed the attendees, and the Committee members introduced themselves.

2 – Standard Interpretation Requests (SIR)

Mitzi presented slides of 8 SIRs, and described the resolutions and responses on 6 of them. The remaining 2 outstanding SIRs were discussed.

The question on **SIR 184** (referring to V1M1 4.2.1) was: *"Is it the intent of the standard for ABs to continue treating a failure to meet the semiannual schedule as a failed study? This is a significant enforcement issue since a potential alternative seems to be in V2M2, 10.3: "The Primary AB shall revoke the accreditation of a laboratory for a FoPT when:(a) the laboratory does not participate in the PT program as required by this Standard." This penalty is too severe and problematic for what could be just a missed deadline. "*

The draft response stated: *"If a laboratory fails to report a single proficiency testing result it is evaluated as not acceptable per V2M2 7.3 part b. If the laboratory fails to*

report results for 2 out of 3 proficiency testing study time frames, then the laboratory's accreditation shall be revoked per V2M2 10.1 for failing to participate in the timeframes specified in the standard. The laboratory's accreditation would only be suspended once they were evaluated as not acceptable for 2 out 3 study timeframes for failing to report results."

Steve Arms explained that the FL Accreditation Body suspends and does not revoke a laboratory for failure to participate in 2 PTs. He suggested changed the wording in the standard to "can be" rather than "shall be" cause for revocation. Following discussion, it was moved by Joe and seconded by Virgene to make the change recommended by Steve Arms. All were in favor and the motion passed.

SIR 193 asked *"What are the proficiency testing requirements for the accreditation of preparatory methods?"* The draft response stated that preparation methods are not currently a part of the standard. It was discussed whether to add to the response *"..unless included as part of the determinative method"*. However, following further discussion it was moved by Scott and seconded by Fred to leave the response as drafted. All were in favor and the motion passed.

3 – Committee Membership

Judy, Mitzi and Scott had completed their 3-year membership on the committee. Judy and Mitzi declared they were prepared to serve a second term, and Scott said he would check whether he could. Mitzi elected to step down as Chair, and Joe thanked her on behalf of the committee for her hard work and leadership during a difficult time of standards development. It was then moved by Judy and seconded by Scott to elect Shawn as Committee Chair. All were in favor, except Shawn who abstained, and it was agreed that Shawn would take over the responsibilities of Chair after the day's meeting

4 – Resolution of comments on V1M1 and V2M2

Mitzi announced that over 90 comments had been received on the Working Draft standard (WDS) of V1M1 and V2M2. The committee had considered all comments, and had drafted a Modified WDS (MWDS) that was published on the TNI website. She explained that repetition had been avoided in V2M2 by referring readers to the language in V1M1. This was possible because V2 is the Accreditation Body (AB) volume, and all ABs would be required to have V1 (the laboratory volume). Discussion of the MWDS had already started during a webinar on July 18, 2013. This discussion would continue during the present meeting, when anyone present would be able to offer comments. Two TNI members had already submitted comments and they were discussed.

In **V1M1 Section 4.1.4**, Richard Sheibley had suggested deleting "Certification Manual" and inserting "by Federal Regulations, 40 CFR 140." The Certification Manual has no regulatory status unless a State has adopted it into law or regulation. Also, 40 CFR 141 covers testing of source water as well. His suggested wording was : *"Federal Regulations, 40 CFR 141, require annual successful analysis of PTs by test method*

rather than technology for laboratories testing drinking water samples." Scott commented that the EPAOW uses the certification manual as if it is regulatory. Cathy Westerman reminded everyone that laboratories can accommodate the EPA requirement by reporting one method for the first PT in a year and a second method for the second PT, provided both methods use the same technology. Steve Arms pointed out the EPA requirement applies only to regulated chemistry analytes, and not radiochemistry, microbiology etc. **Action Item**: Judy Morgan agreed to check the 40 CFR 140 requirements and to suggest appropriate wording for the standard.

The remaining comments were from Cathy Westerman.

In **V1M1 4.1.6**, she said "Will result in revocation " may not be enforceable by some states (if not in their own regulation), so this language could be cause for veto. She suggested replacing "will result in" with "is cause for". It was moved by Stacie and Seconded by Fred to make the change recommended by Cathy. All were in favor and the motion passed.

Cathy was concerned that **V1M1 4.2.2** stated only that PT samples shall be analyzed as routine samples using the same SOPs etc., and the detail provided in the previous standard had been omitted. She suggested including much of the language in the 2009 V2M2 6.1. Others, including an AB and a laboratory, agreed this level of detail should go back in the standard. There was a lot of discussion on whether the requirement should be included for PT samples to be tracked through the laboratory in the same manner as routine samples, and Cathy said "handled" might be better than "tracked". Following a recommendation by Scott, it was moved by Roger and seconded by Fred to insert the following bullets into V1M1 4.2.2:

- PT samples are handled in the same manner as routine samples;
- PT samples are analyzed under the same analytical conditions and instrument calibrations as used for routine samples;
- the type, composition, concentration, and frequency of quality control samples analyzed with the PT samples are the same as with routine samples; and
- PT samples are not analyzed multiple times unless routine samples are analyzed multiple times and results from multiple analyses are calculated in the same manner as routine samples;

An amendment was proposed by Virgene to replace V1M1 4.2.1 with *"PT samples are prepared according to the PT Provider's instructions and subsequently analyzed as routine samples."* The mover and seconder agreed to the amendment. All were in favor and the motion passed.

V1M1 4.2.3 states *"The laboratory shall evaluate the analytical result for each chemistry and radiochemistry field of accreditation to the PTRL as established by the TNI FoPT Tables, or if the laboratory's LOQ is below the PTRL, they may evaluate results to their normal LOQ."* Cathy said the Proficiency Test Providers will be given the directives on

how to score the PTs, and the laboratory just needs to know and understand what the rules are. When this section (4.2.3) and Section 4.3.7 are written as "shall", that puts the AB responsible for enforcement per V2M2 4.1.1, 4.1.2, and 4.1.3. The ABs can't possibly audit this for all PT reporting, and it is not necessary because if the lab is doing it acceptably they will be successful at PTs and if not, they will not be successful. She added that **Section 4.3.7** is also very hard to understand and examples are necessary for clear communication. She suggested this information be presented as notes in V1M1 so that laboratories have access to the information, and not written such that the AB is responsible to verify that the laboratory "did it right" so that the PT can be "accepted". Scott suggested stating that laboratories will be evaluated to the PTRL etc., and then leaving it to the laboratories how they want to report it. If they do it wrong they will fail. He agreed an example needs to be included in the note. **Action Item:** Scott was assigned to edit 4.2.3 and re-examine 4.3.7. Virgene added that 4.3.5 is redundant to 4.2.3. Scott agreed to remove reference to radiochemistry, and Virgene agreed to draft comparable wording applicable to radiochemistry.

V1M1 4.3.2 states *"The laboratory shall, before the closing date of the study, direct the PT Provider to report the PT study performance results directly to the selected AB(s). Alternatively for initial accreditation, the AB may request the most recent (up to 3) studies directly from the PT provider for the laboratory."* Cathy felt the second sentence put the burden on the AB to "complete" the application process which could be for several hundred analyses. She suggested rewording the second sentence to read *"For initial accreditation the laboratory may request the most recent (up to 3) studies be provided to the AB after the close of the study."* In response to a suggestion to just delete the second sentence, Nicole Cairns disagreed, saying the wording was put in to prevent a laboratory from selecting which PT results it would send to the AB (e.g., it could fail 3 and then pass to but only send the 2 successful ones to the AB). Mitzi thought here should be a separate requirement for initial and continuing accreditation. After further discussion it was moved by Scott and seconded by Judy to accept Cathy's proposed language. All were in favor and the motion passed.

Cathy was concerned that the requirement "The Primary AB shall not require calibration ranges that are not typically employed by the laboratory for the sole purpose of analyzing PTs." would not be in the standard. Scott said taking it out gives a laboratory choices on its course of action, and it does not say the laboratory does not have to run the PT. Mitzi pointed out that ISO 17025 allows laboratories the discretion to not require PTs if none are available in the appropriate concentration range, and said it is done all the time in non-environmental areas. **Action Item**: Stacie and Nicole agreed to draft wording that would allow ABs the flexibility to require or not require PTs by laboratories working at high concentration levels.

Time did not permit further discussion of the V1M1 and V2M2 MWDS.

5 – Volume 3

Mitzi explained that all PT providers will be expected to be accredited to ISO 17043/Guide 34, and the standard will specify only the additional requirements. Shawn presented the slides listed in Appendix 1. He said the committee will go through Guide 34 to determine which pertinent sections are applicable to PT provider accreditation. There were two comments from the floor: (1) it was suggested Section 8.2.2 should be presented in a positive sense; i.e., what shall be done rather than what shall not be done; (2) the reporting section of ISO should be reviewed with respect to promulgated method equivalency.

6 – Next Steps

The committee needs to discuss what should be included and what should be dropped. It was undecided whether this would be done section-by-section by the whole committee, or if the work would be broken down for handling by subcommittees.

The committee plans to put all 4 volumes out for vote at the same time, hopefully within a year.

6 – Adjournment

The meeting was adjourned at 5:00 pm CDT.

Appendix 1

TNI Volume 3 Next General Requirements for PT Providers
Laboratory Proficiency Testing Expert Committee
TNI August 2013 San Antonio

Goals
Review each of the 11 Volume 3 Sections
Begin to determine the places where to focus discussions on what are to be included in the Volume 3 as TNI requirements.
Not all sections will need to be changed.
Many sections will be extensively edited.

Review PTP Requirements
Review the requirements for PTP's with an eye to requiring the PTP's to be accredited to ISO 17043 and Guide 34.
Highlighted and documented where there are TNI specific requirements that need to be evaluated.

Section 1: The Intro

1.1 Introduction

This Volume specifies the requirements for proficiency testing (PT) providers conducting PT studies for the evaluation of environmental testing laboratories.

1.2 Scope The PT program includes the following elements:

a) The production and supply of PT samples that challenge the critical components of each analytical procedure, from initial sample preparation to final data analysis;

b) The yielding of PT data that are technically defensible on the basis of the type and quality of the PT samples provided; and

c) The preparation of PT samples which pose equivalent difficulty and challenge regardless of the manner in which the PT samples are designed and manufactured by the PT providers.

1.3 Applicability

This Volume does not purport to address issues of laboratory accreditation. The laboratory accreditation process is defined in Volumes 1 and 2 of this Standard.

Sections 2 and 3
Section 2 References
Section 3 Definitions
These will need to be reviewed once the changes to Volume 3 are complete.

Section 4 PT Provider Accreditor

No changes required for this section
BUT, let's review

Section 5 Management Requirements
5.1 Quality System Requirements
Most incorporated into ISO 17043 and Guide 34.
ISO 9001 mentioned *BUT NOT* related to PTP studies.
Need to retain?
5.15 – Specifics to PTPA
5.16 - Documents Retention
Section 5 Management Requirements

5.2 Provider Conflict of Interest and Confidentiality
Most incorporated into ISO 17043 and Guide 34.
Need to retain reporting requirements?
5.2 c
5.2 d
5.2 f
Section 5 Management Requirements

Section 5.3 Facilities and Personnel
All contained in ISO 17043 and Guide 34
Section 5.4 Complaints Handling
Most contained in ISO 17043 and Guide 34
Retain?
5.4.2 – Have records available to the PTPA
5.4.3 – Unresolved complaints over 90 days must be reported to the PTPA
Section 5 Management Requirements

5.5 Notification of Sample Integrity
Present in ISO 17043 and Guide 34.
Specific requirement of notification within 7 days.
This should be retained.

Section 6 PT Manufacture and Design
All of this section contains specifics to the TNI program.
Need to review the requirements and verify that these requirements add value and consistency to the TNI PT Program.
Review some examples -

Section 7 PT Sample Testing
7.1 Verification of the Assigned Value
Many TNI specific requirements
2nd source material for calibration
Criteria for the meeting verification for water and soil analyses
Setting AV of unspiked analytes to < PTRL

Section 7 PT Sample Testing

7.2 Homogeneity
Criteria to for meeting homogeneity
7.3 Stability Testing
Criteria to for meeting stability testing
7.4 VHS Reporting
All TNI specific requirements

Section 8 Provision of PT Samples
8.1 Study Duration
TNI 45 day study length, unless noted by the PTPEC
8.2 Study Instructions
List of "Shall not's"
Otherwise covered
Section 8 Provision of PT Samples

8.3 Regularly Scheduled PT's
Not from previous lots
8.4 Supplemental PT's
All TNI Specific

Section 9 System of Reporting
All covered in the ISO 17043.
No TNI specific criteria listed.

Section 10 PT Study Data Analysis
Mostly TNI specific requirements in each section.
Many are necessary to provide a consistent data evaluation, statistical approach, and laboratory scoring.
Review by Section….

Section 11 Generation of Study Reports
ISO 17043 much more extensive on reporting
TNI should review and take advantage of this section of ISO 17043
Some specific reporting requirements
All parties within 24 hrs.
21 day limit to issuing reports
Specifics on the reports
TNI analyte code
Lab EPA Id number
Etc…

Questions?