SUMMARY OF THE TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

NOVEMBER 13, 2015

The Committee met by teleconference on Friday, November 13, 2015, at 11:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Present
Kareen Baker, Independent (Other)	Present
Nicole Cairns, NYSDOH (Other)	Present
Rachel Ellis, NJ DEP (AB)	Present
Scott Hoatson, Oregon DEQ (AB)	Present
Shawn Kassner, Phenova (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Absent
Mitzi Miller, Dade Moeller Assocs. (Other)	Absent
Judy Morgan, Pace (Lab)	Absent
Joe Pardue, P2S (Vice-Chair; Other)	Absent
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Steve Arpie, Absolute; Mike Blades, ERA; Amanda Bruggeman, Phenova; Chandra Thekkekalathil Chandrasekhar, FLDEP; Craig Huff, ERA; Lauren Smith, A2LA.

2 – Previous Minutes

It was moved by Fred and seconded by Scott to approve the minutes of October 30, 2015. All were in favor.

3 – Comments on V3 Voting Draft Standard

Comments considered by Shawn were considered.

- **5.5.2** "No big deal, but I expected to hear about matrices other than soil in this section. For example, what are the other matrices represented by the program, and what is the surrogate matrix used in PT preparation for each." Shawn pointed out no surrogates are used, and soil is the only solid matrix that is proficiency tested. It was agreed this would be ruled Non-Persuasive, and Shawn said he would prepare a short narrative response and circulate it to the committee for voting.
- **5.5.3.3** "Some additional wording may be needed to make the requirements unambiguously clear. Recommended language after changes are made: For those multi-analyte categories designated in the TNI FoPT tables as not requiring all analytes to be spiked the PT Provider shall determine the number of analytes <u>to be spiked</u> based on the following:" It was agreed to make the recommended change, and it would be an editorial change.
- **5.6.1** "Clauses 5.6.1.2 through 5.6.1.6 are redundant to the earlier reference of ISO 17025:2009(E) Clause 5.1.2 states that: 5.1.2 The testing facilities used to support the verification, homogeneity and

stability testing required in the Standard shall meet the requirements of ISO 17025:2009(E)-(General Requirements for the Competency of Testing and Calibration Laboratories). Specifically, ISO 17025 sections 5.4 and 5.6 address these clauses. Also, the added requirements in EL-V3-2015, clauses 5.6.1.3 and 5.6.1.4 to use ISO Guide 34 materials has not been adequately demonstrated as necessary for purpose. Likewise, Guide 34 materials may not be available for certain analytes and perhaps not available for emerging analytes of interest in the future. Some Guide 34 materials may be prohibitively expensive and unable to offer much more confidence to assay value compared to the highest non Guide 34 grade materials that are currently available. I realize the committee is attempting to raise the bar for assigned value verification by requiring ISO Guide 34 materials, but I think the language in ISO 17025 covers the selection of appropriate calibrants, reference materials, and method validations. If my comment is otherwise nonpersuasive, at least consider encouraging the use of ISO Guide 34 materials rather than requiring them by using a terms such as "where necessary" or "where applicable". Shawn had offered the response: "The comments in ISO 17025 are not detailed to enough to allow the flexibility for proficiency testing provider calibrations. The words "where available" will be added to 5.6.13 end of the first sentence to clarify the requirement." It was moved by Scott and seconded by Fred to rule the comment Persuasive, to accept Shawn's response, and to make the change recommended by Shawn. All were in favor.

5.6.1.1, 5.6.1.8, and 5.7.3 "5.6.1.1 PT Providers shall analytically verify the assigned value of all analytes in all PT samples prior to use in a PT study. And 5.6.1.8 For solid matrix, and microbiology, and protozoan analytes, the assigned value of an analyte is verified if the mean of the providers verification analytes is within one-half of the laboratory acceptance limits (C), as calculated per Section 5.9.2, of either: And 5.7.3 Assigned values for quantitative microbiology and protozoan analytes: 5.7.3 a) shall be equal to the study calculated mean as specified in sections 5.9.2.5 or 5.9.2.8 as appropriate. Comment: In the section 5.7.3, the assigned value for quantitative microbiology shall be equal to the study calculated mean. Since the assigned value is the study mean and the study mean is not known at the time of pre-shipment verification analyses, the assigned values for microbiology and protozoans cannot be verified until after the close of the study when the study mean is calculated. This conflicts with clause 5.6.1.1. The 2009 standard at clause 6.4.3 stated that the assigned value for quantitative microbiology analytes shall be equal to the mean of the assigned value verification and/or homogeneity testing conducted per section 7.1 and 7.2 and. I think the conundrum is solved by reverting 5.7.3.a to the 2009 clause at 6.4.3. Shawn had suggested the comment was Non-persuasive and had drafted the response: "The issue with using the study mean as the assigned value has to do with that a providers' VHS mean has nothing to do with the evaluation of the laboratories, whereas the study mean does impact the laboratories. The statement at the end of 5.6.1.8 states "For analytes that are based on the study mean and study standard deviation, the PT Provider shall establish criteria approved by the PTPA that demonstrate verification of the assigned value." provides sufficient evidence that the microbiology, protozoan and other standards are verified as was noted in the NELAC 2003 Chapter 2 and associated appendices. The issue with using the study mean as the assigned value has to do with that a providers VHS mean has nothing to do with the evaluation of the laboratories, whereas the study mean does impact the laboratories. The statement at the end of 5.6.1.8 states "For analytes that are based on the study mean and study standard deviation, the PT Provider shall establish criteria approved by the PTPA that demonstrate verification of the assigned value." provides sufficient evidence that the microbiology, protozoan and other standards are verified as was noted in the NELAC 2003 Chapter 2 and associated appendices." Scott pointed out confusion may occur because there are two "assigned values" in 5.6.1.1 and 5.7.3, and he suggested saying "initial" assigned value in 5.6.1.1. Nicole pointed out a similar situation with soil chemistry, having an

assigned value initially that is not the study mean. It was moved by Kareen and seconded by Fred to accept Shawn's recommendation and draft response. All were in favor.

- **5.6.1.10** "Some additional wording may be needed to make the requirements unambiguously clear. Recommended language after changes are made: Any PT sample that fails to meet the requirements of this Section for each analyte therein shall not be used in a PT study. The committee agreed this was Persuasive and the recommended change would be made as an editorial change.
- **5.6.1.7** Can we be clearer what are aqueous chemistry analytes? Possible Resolution: Perhaps cite an example or add definition in section 3. It was agreed this term is well known. Shawn would add a narrative that they are described in the FoPT tables. It was moved Kareen and seconded by Scott to rule the comment Non-Persuasive. All were in favor.
- **5.6.1.7** "This is the first occurrence of the use of "C;" the second occurrence was in section 5.9.2.1, where it was explained further. Possible Resolution: Perhaps, add the same explanation used in section 5.9.2.1 to state that C denotes acceptance interval." Scott suggested just using "acceptance interval" in 5.6.1.7 and 5.6.1.8 and not using "C". He suggested "C" could then be in 5.9.2.1. It was moved by Kareen and seconded by Scott to rule the comment persuasive and to make Scott's suggested changes. All were in favor.

This completed discussion of Shawn's assigned comments.

4 – Next Meeting

This would be in 1 week (November 20), when Joe's V3 comments and Nicole's V4 comments would be addressed.

Adjournment

The meeting was adjourned at 12:00 pm EST.