SUMMARY OF THE
TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

FEBRUARY 26, 2016

The Committee met by teleconference on Friday, February 26, 2016, at 11:00 am EST. Chair Shawn Kassner led the meeting.

1 – Roll call

Fred Anderson, Advanced Analytical Solutions (Other)	Present
Nicole Cairns, NYSDOH (Other)	Present
Rachel Ellis, NJ DEP (AB)	Present
Patrick Garrity, KYDOW (AB)	Present
Scott Hoatson, Oregon DEQ (AB)	Present
Craig Huff, ERA (Other)	Present
Shawn Kassner, Phenova (Chair; Other)	Present
Stacie Metzler, Hampton Roads San. Distr. (Lab)	Present
Mitzi Miller, Dade Moeller Assocs. (Other)	Absent
Tim Miller, Phenova (Other)	Present
Judy Morgan, Pace (Lab)	Absent
Joe Pardue P2S (Vice-Chair; Other)	Present
Donna Ruokenen, Microbac (Lab)	Absent
Ken Jackson, Program Administrator	Absent

Associate Committee Members present: Amanda Bruggeman, Phenova; Dan Dickinson, NYSDOH; Shari Pfalmer, ESC Lab Services; Bob Shannon, Quality Radioanalytical Support.

2 – Previous Minutes

It was moved by Scott and seconded by Joe to approve the minutes of January 15, 2016. All were in favor. It was moved by Fred and seconded by Stacie to approve the minutes of February 12, 2016. All were in favor.

3 – Laboratory Uncertainty for Radiochemistry PT Results

Shawn had invited Bob Shannon and Dan Dickinson on the call to discuss this issue. He asked Dan if the NY PT program would insert a field for radiochemistry uncertainty reporting. The other PT Provider (ERA) was prepared to do this, and it would be useful to collect the data, because at some point uncertainty may be taken into account in the FoPT tables and then into the evaluation of laboratories. Dan said he would do it, and he could warn laboratories if their reported uncertainty was out of specifications. Bob Shannon said that would be good. Shawn said the requirement would therefore be left in the standard. Only drinking water radiochemistry PTs are provided by NY, and Bob confirmed the uncertainty would just be counting errors, unlike other matrices that require total uncertainty.

4 – V3 and V4

Several comments remained to be considered before the interim standards could be prepared.

V3 – 5.6.1.7 *"For aqueous chemistry analytes, the assigned value of an analyte is verified if the mean of the provider's verification analyses is within one-third of the laboratory acceptance limits, as calculated per Section 5.9.2, not to exceed a maximum of 10%. Comment: I realize that a subcommittee had convened on this issue of "the 10% rule" and concluded that is it relevant. However, I dissented at the time and continue to do so. This rule is not supported internationally as there is no statistical basis for it. It is not generally applicable to the majority validation methods employed by the PT Providers. To say that it provides added confidence to participants is misleading."* The subcommittee had found the comment Non-Persuasive, and the Committee had generally concurred that the 10% maximum should remain in the standard. Scott agreed it did not change anything, but for the uneducated it tells them that everything is going to be better than that, so he did not see the harm in it. Tim and Craig agreed with Scott. Stacie wondered why it should be dropped now when it had been in the standard for so long, but she could go either way. Rachel suggested, since the Committee members did not feel strongly either way, and Dan felt so strongly, then why not remove it? It was then moved by Scott and seconded by Fred to remove it. This was approved unanimously.

V3 – General *"Other comments have made reference to redundancies with ISO 17011 which is a standard for Accreditation Bodies. TNI EL V3 is a standard for Proficiency Testing Providers and not accreditation bodies. While it is a legitimate comment that there are redundancies with ISO 17011 I would not expect the PTP to be familiar with ISO 17011 and thus don't really have a problem with some things that could be considered redundant to requirements for an AB. It might actually be beneficial for EL V3 to have these "redundant" requirements as they are for the PTP and not the AB and the PTP is clear what requirements are "pushed down" on them from the AB who has to meet ISO 17011. I guess these items don't really give me heartburn unless they cause me as an AB to be in conflict with ISO 17011 and my MRA obligations. I tried to address those potential issues specifically in my comments above."* This had been discussed, but there had been no vote. It was moved by Nicole and seconded by Scott to find the comment Non-Persuasive. All were in favor.

V3 - 3.0 *"Intro wording in section 3.0 is confusing, it seems that the definitions are meant to "conform" to the ISO definitions but sometimes they are the same, sometimes they are different, sometimes they are new and distinct terms from the ISO definitions. Also, some definitions are from ISO Guide 30/34 and should be referenced in the document. It just seems very confusing and an organization having to conform to all standards might be pulling their hair out with terms that mean different things in different standards. Also, it seems like the definitions are meant to be in alphabetical order but they get random (or it appears) after 3.13. There are also numbering errors where some numbers are duplicated. Possible Resolution: Use the ISO definitions when possible and appropriate and clearly reference the applicable ISO standard. Perhaps even separate the ISO definitions from the unique TNI definitions so it is really clear. If alphabetical order is intended you'll want to rearrange the definitions. Also, renumber the definitions so there are no duplications."* Scott suggested the ISO definitions should be in italics for consistency elsewhere in the standard. It was also questioned if copyright issues would prevent the ISO definitions being reproduced in the standard. Shawn said he would check if this would be permissible. Several further comments also addressed this issue. Some of the definitions referred to "notes" and Nicole suggested the notes were not needed. Scott thought it should be sufficient to just refer to ISO without repeating the ISO definitions in the standard. However, Stacie cautioned that might not be

necessary if incorporation of ISO definitions was allowed. She said the committee should wait until those rules were known.

V3 - 5.4.3.1(a), 5.4.3.2, 5.4.3.3, 5.4.3.4 *"5.4.3.1(a): Since it uses "may," this should be deleted as a standard and added as a Note. 5.4.3.2, 5.4.3.3, 5.4.3.4: These paragraphs contain laboratory requirements, which should be reworded to be PT Provider requirements (e.g., "If the laboratory informs the PT Provider...") and restated in V1M1, if needed. EL-V1M1-2009 section 6.1(a) is sufficient for the latter: "The laboratory shall notify the PTP that the PT sample will be used for corrective action purposes so the PTP may ensure that the PT sample supplied meets the requirements for supplemental PT as defined in Volume 3 of this standard." The current wording seems to imply this was the intent; otherwise the sentence structure is incorrect."*. These sections were re-written, but the committee had neglected to vote on them. The same thing applied to four further comments: **5.4.3.2; 5.4.3.2, 5.4.3.3, 5.4.3.4; 5.4.3.3; and 5.4.3.4.** It was moved by Scott and seconded by Joe to approve those actions. All were in favor.

V3 – 5.6.1.5 *"Regarding "Analytical method used by the PT provider for assigned value verification shall have a repeatability relative standard deviation of not more than 1/6 of the acceptance limits for the participant laboratories.": Dropping this requirement disconnects the required precision of the verification method selected by PT providers for the products final intended use. Additional Comment: PT providers have been meeting this standard for years. Removing it serves no purpose other than to give more "wiggle" room to the verification process performed by the PT providers. It can introduce additional variability and adds no value to the accrediting authorities or participants. Possible Resolution: Add statement back to standard."* Nicole thought this was not needed, because if the RSD was too high, the subsequent validation would not work anyway. It was moved by Nicole and seconded by Scott to rule the comment Non-Persuasive. All were in favor.

V3 – 5.6.2.1 *"This whole section on homogeneity seems to be pretty empty compared to the assigned value verification and stability sections, particularly with no criteria spelled out here for acceptance. Add an additional sentence to Clause 5.6.2.1, to read as follows: <u>The PT provider shall document acceptance criteria for homogeneity (e.g., homogeneity of the base PT sample matrix, and/or homogeneity of the analytes spiked within this matrix) in its quality system."</u>* This requirement for documentation is already in ISO. Therefore, it was moved by Tim and seconded by Craig that the comment was Non-Persuasive because the requirement is already in ISO 17043. All were in favor.

V4 - 4.1c *"While this should be removed as stated above, Possible Resolution: A requirements document should state: "The PTPEC evaluates the PTPA at a minimum of every four (4) years."* Nicole reminded the committee this was left in because there was no requirements document. It was moved by Scott and seconded by Craig to rule the comment Non-Persuasive. All were in favor.

V4 – 4.2 *"This should be removed as stated above. Possible Resolution: Criteria can be placed in a requirements document."* For the same reason as the above comment, Scott moved and Fred seconded that the Comment was Non-Persuasive. All were in favor.

This completed the consideration of all comments, except Shawn need to check with Jerry whether the ISO definitions could be inserted. He indicated the committee may need to meet again to vote on the affected comments.

5 – Adjournment

The meeting was adjourned at 12:30 pm