SUMMARY OF THE TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

OCTOBER 9, 2015

The Committee met by teleconference on Friday, October 9, 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)	Absent
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)	Present
Judy Morgan, Pace (Lab)	Absent
Joe Pardue, P2S (Vice-Chair; Other)	Present
Jim Todaro, Alpha Analytical (Lab)	Absent
Lisa Touet, MA DEP (AB)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Mike Blades, ERA; Amanda Bruggeman, Phenova; Audrey Cornell, ERA; Maria Friedman, Testamerica; Rob Knake, A2LA; Tim Miller, Phenova; Shari Pfalmer; ESC Lab Services; Brian Stringer, ERA.

2 - Previous Minutes

It was moved by Fred and seconded by Kareen to approve the minutes of September 25, 2015. All were in favor.

3 – Comments on V3 Voting Draft Standard

The committee continued considering these comments, and first reopened the previously discussed comment on Section **5.10.4**, so that Maria Friedman could provide clarification on the issue. The comment read: "V4 adds requirements (Sections 5.4.3 and 5.4.4) for the PTPA to ensure the PTP is able to (and does) provide data upload to TNI per PTPEC request. There needs to be a corresponding requirement in V3 to require the PTPs to provide this data. Possible Resolution: Add Section 5.10.4 (after renumbering per my preceding comment), "PT Study Data Submission", and Section 5.10.4.1: "Upon request of the PTPEC, the PT Provider shall make available, via electronic upload to TNI, such PT Study data as PTPEC may require. The format and specifications of this electronic upload shall comply with requirements defined by PTPEC."" Shawn explained to Maria that the committee thought this would be too "open-ended", requiring the PTP to provide any data requested without restriction. Maria suggested amending the language to refer to an SOP that must be followed. This would address confidentiality and all PTPs would be welcome to assist in writing it. Shawn and Mitzi were both concerned this would refer to a document that does not exist, and the standard could not be written without the SOP first being available. Maria then suggested just putting in a description without referring to a specific SOP. She added there are only PT data that

are several years old, so the standard is needed to get more data. Nicole asked if it could be written that the PTPEC would only have access to the data provided to the PTPA, saying that would alleviate the confidentiality concerns. Shawn said there was a consensus to provide data, but not on what data to provide. Mitzi said a statement could be added that there will be additional information in future by mutual agreement, and asked if there are data the PTPEC wants that the PTPA does not have. However, Maria said that the PTPAs need PTP permission to release data, so it would be better for the PTPs to release the data. Shawn asked Maria to send the PTPEC minutes so the committee could see what was wanted. Scott suggested requesting the PTPs to authorize the PTPAs to release data to the PTPEC while maintaining confidentiality. Mitzi said the data requested had more detail than the data uploaded to the PTPAs, and that is what brought up the confidentiality issues. Shawn agreed to participate in meetings between the PTEC and the PTPAs. Nicole added she was also a member of the PTPEC, so she would also be involved. It was agreed to table this issue until the problems were resolved.

Comments considered by Scott.

- **4.7** "This is redundant to requirements of ISO/IEC 17011, the PTPA accreditation requirements documents rand the contractual obligations of the PTP with the PTPA, so it should be removed." Scott considered it acceptable to have some redundancy and believed it did not hurt to have it explicitly stated. Shawn agreed, saying PTPs need to follow that process, and that is emphasized by including it in the standard. It was moved by Scott and seconded by Fred to rule the comment Non-Persuasive. All were in favor.
- 5.9.3.1.2 :Up to now, it seemed clear that, without a clear conjunction, the subsections (a), (b), (c), etc. in the various clauses of this volume are connected by "and." In this clause, it is not clear at all and, in fact, any one case presented could and should cause the reported PT result to be scored "Not Acceptable." Recommended change: Insert the word "or" after Subsection (b) of this Clause." There was general agreement that the entire section should be made consistent with this comment. Shawn volunteered to draft language for consideration during the next call.
- **5.9.3.1.2.c** "Regarding "The result will be scored not acceptable if: the numeric value is reported with a > sign": The current design range listed on the NPW FoPT for Total, Fecal & E. coli is 20-2400 CFU or MPN/100mL. Several of the commonly used MPN methods have dynamic ranges that have a undiluted upper capacities of 1600 (9221, 15 tube, 1x:10x:100x) and 2420 (IDEXX QT). The 95% confidence intervals associated with each of these methods are 700-infinity and 1440-infinity respectively. Given such a high level of overlap between the TNI manufacturing range and the confidence levels associated with these methods, to evaluate >results as unacceptable would be technically inconsistent. It this standard was put in place all labs using QT2000 would need to run every WP study at a 50% dilution." Mike Blades added that it is difficult to keep diluting a micro PT, which they would have to do to be safe. He suggested, if a laboratory obtained a result of ">1600", the standard could require them to report "1600". Apparently, one provider already had it in their instructions for laboratories to do this. Scott suggested saying you can only report > the upper concentration of the method. Fred and Tim said they would check how they score now, and this would be re-visited during the next call. Shawn added that one chemistry PT (flashpoint) may have to be considered the same way.
- **5.9.3.2** "5.9.3.2.1 The result shall be scored "Acceptable" if: a) the numeric value reported is less than the PTRL or b) the numeric value is reported with a less than (<) sign. The use of the term

"or" at the end of clause a) segregates it from clause b) which means the clauses must be treated independently. If the committee had used the term "and" at the end of clause a) I would have agreed that in its entirety section 5.9.3.2.1 would have been correct and not in conflict with the New York regulation for PT scoring. If you change the "or" to "and" I will change my vote to "Yes". As a PT provider for the New York State Environmental Laboratory Approval Program, I am required to score analytes with assigned value less than (<) the PTRL in accordance with the New York Code of Rules and Regulations Title 10, Subpart 55-2.8. The regulation states; (c) Performance in examining an individual chemical or physical analyte shall be evaluated as follows, for a synthetic blank test sample: (1) Satisfactory performance shall be a result reported with the term "less than," and having a value less than or equal to the detection limit specified by the department, or, if no detection limit is specified, the method detection limit. (2) Unsatisfactory performance shall be a result reported with or without the term "less than," and having a value greater than the detection limit specified by the department, or, if no detection limit is specified, the method detection limit. The detection limit we specify is the PTRL. The TNI V3-VDS-2015 clause 5.9.3.2.1 is in conflict with NYCRR 55-2.8. The committee identified a "gray area" that the commenter may not have realized. Nicole offered to take this back to the commenter, and would report on this during the next call.

5.9.3.2.2 "As in the previous clause 5.9.3.1.2 above, any one of the subsections in this clause should cause the reported PT result to be scored "Not Acceptable." Recommended change: Insert the word "or" after Subsection (b) of this Clause." Shawn said he would add the language as recommended and it would be discussed during the next call.

3 – Standards Interpretation Requests

Shawn said he would circulate two SIRS for discussion.

Adjournment

The meeting was adjourned at 12:30 pm EDT.