SUMMARY OF THE TNI LABORATORY PROFICIENCY TESTING EXPERT COMMITTEE MEETING

JANUARY 25, 2016

The Committee met at the Forum on Environmental Accreditation, Tulsa OK on Monday, January 25, 2016, at 1:30 pm CST. 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)	Absent
Patrick Garrity, KYDOW (AB)	Absent
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)r	Absent
Tim Miller, Phenova (Other)	Present
Judy Morgan, Pace (Lab)	Present
Joe Pardue, P2S (Vice-Chair; Other)	Absent
Donna Ruokenen, Microbac (Lab)	Absent
Ken Jackson, Program Administrator	Present

2 - Introduction

Shawn welcomed the attendees and the Committee Members introduced themselves. A status update of the all the volumes and modules was presented. Shawn said Volumes 3 and 4 were now being readied for presentation as Interim Standards, and the main agenda item for this session would be the public presentation and consideration of voters' comments on the Volume 1 Module 1 and the Volume 2 Module 2 Interim Standards.

3 – Volume 1 Module 1 Comments

4.2.2 A commenter was concerned that the language requiring PT samples to be treated the same way as routine samples was now worded as follows: "PT samples shall be analyzed in accordance with the laboratory's established standard operating procedures (SOPs) using the same quality control, acceptance criteria, and staff as used for the analysis of routine environmental samples." The commenter argued this appeared less stringent than the language in the 2009 standard that read "The laboratory shall analyze PT samples in the same manner as used for routine environmental samples using the same staff, sample tracking, sample preparation and analysis methods, standard operating procedures, calibration techniques, quality control procedures, and acceptance criteria." This had been considered at length by the committee who did not consider this wording a diminution of the requirement, and it had received no comment when presented in the Voting Draft Standard. Thus, it had already passed the voting as written and could not be considered further.

- **4.2.3** "The new language in Volume 1, Module 1 sections 4.2.3 and 4.3.7 do not adequately address my concerns, specifically: Section 4.2.3 appears unchanged from the original balloted draft. I suggest the words "For chemistry" be added to the beginning of the second sentence. "4.2.3 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. For chemistry, if the laboratory's Limit of Quantitation (LOQ) is below the PTRL, they may evaluate results to their normal LOQ." There were two more similar voters' comments. The committee agreed with this concern. It was moved by Scott and seconded by Nicole to rule the comment Persuasive and to separate the requirements by re-writing 4.2.3 and creating a new 4.2.4. All were in favor.
- **4.3.2** A commenter suggested, for clarity, inserting a comma after the word "shall" on the first line. The committee agreed to make this editorial change.
- **4.3.6** "The acronym MDA appears, and there is no listing in the definitions section. Therefore, spell out the acronym on first usage, as follows, in the first sentence: "... whether above or below the <u>Minimum Detectable Activity</u> (MDA)."". The committee agreed to make an editorial change, spelling out Minimum Detectable Activity on its first usage. It was decided not to include it in the definitions, but the committee would ask for it to be in the glossary that is under preparation by the Consensus Standards Development Executive Committee.
- **4.3.6** "Similarly, 4.3.6 is too narrow and dances around what really needs saying. According to Volume 1, module 6, labs should not censor results (not just against an MDA), rather results should be reported "as measured". Suggest the following language: 4.3.6 Radiochemistry results shall be reported as measured, including zero, negative, and positive results, and shall not be censored or reported as "less than" values (e.g., < PTRL or < MDA). All radiochemistry PT study results shall be reported in association with the measurement uncertainty, as appropriate to the program (e.g., CSU is generally appropriate although counting uncertainty at the 95% confidence interval may be required for SDWA compliance measurements)." There were two more similar comments. Scott felt that "shall not be censored" was redundant, and Stacie suggested stating they must be reported per the PT Provider's instructions. However, it was pointed out by one PT Provider that they accept the reported uncertainty but do nothing with it. Stacie also said it should be specified which program is referred to in "as appropriate to the program". On Ken's suggestion it was agreed the committee would invite the commenters to the next conference call to discuss this before a decision was made.
- **4.3.7** "Section 4.3.7. may or may not be acceptable as written it is not currently limited to chemistry, but one might argue that since LOQs do not exist for radiochemistry, it does not apply. This fact would be much clearer, however, if the section specifically pointed at chemistry. In other words, "The laboratory shall evaluate and report each FoPT result for chemistry as follows:"" There were two more similar comments. It was moved by Scott and seconded by Nicole to rule the comment Persuasive and to add the word "chemistry". All were in favor.

4.3.7 (b) and (c). *RECOMMENDATION*:

- a. 4.3.7.c provides <u>three options</u> which the laboratory <u>SHALL choose from</u> if results are below the PTRL.
- b. 4.3.7.b provides, in the second sentence, a "SHALL" directive which is contradictory to the choices provided in 4.3.7.c.
- c. The first sentence of 4.3.7.b is "understood" by the options provided in 4.3.7.c.

This is unnecessarily "bulky" and confusing, and also contradictory. It seems that 4.3.7.b should be removed. This comment generated a protracted discussion, resulting in the following suggested new language.

- "4.3.7 The laboratory shall evaluate and report chemistry FoPT result to the PT Provider as follows:
 - a) If the analytical result is a numeric value above or equal to the PTRL, the lab shall report the value. If the PTRL is less than the laboratory's Limit of Quantitation (LOQ), the laboratory shall report the result without the qualification of result required in Volume 1, Module 4 of this Standard.
 - b) If the analytical result is a numeric value below the PTRL, the laboratory shall report one of the following;
 - i. < PTRL or,
 - ii. the obtained analytical result, if the result is between the LOQ and the PTRL or,
 - iii. < LOQ, if the LOQ is less than the PTRL.
 - c) If the analytical result is a non-detect the laboratory shall report one of the following;

<PTRL or,

< LOQ**

** Note: In the case where the laboratory LOQ is greater than the PTRL: If the laboratory chooses to report a value of < LOQ and the analyte is present above the PTRL, the result will be scored as "Not Acceptable" by the PT provider. "

It was moved by Scott and seconded by Fred to rule the comment Persuasive and to accept the above new language. All were in favor.

7.2 "This sentence may not be up for consideration in this IS stage, but the sentence does not read clearly to me. Does the insertion of this word capture the intent of the Expert Committee in writing this Standard? "Laboratories shall have to submit questions to their AB in regards to the AB's PT evaluation, if necessary."" This had been considered by the committee at length and received no comment when presented in the Voting Draft Standard. However, the Committee agreed with the comment and made the suggested change editorially.

This completed discussion of the comments on the module.

4 – Volume 2 Module 2 Comments

General "There may be usage of "FoPT's" that should be "FoPTs". The apostrophe may not be needed." The Committee agreed to fix this editorially.

- General "The use of the word "shall" needs to be equally applied for both laboratory suspension for failing PTs as well as reinstatement in meeting the established criteria. Allowing ABs discretionary judgment on laboratory suspension with the use of the work "may" sets up inconsistent judgments/interpretation by each TNI AB. Allowing for AB discretionary decision-making does not foster a national, uniform and consistent standardized approach to applying suspension criteria across all ABs." The use of "may" was technically correct when it referred to States' needing to use their own processes for suspension. However, the language was reworded to keep that sense while avoiding the use of "may". It was move by Scott and seconded by Stacie to rule the comment Persuasive and to adopt the re-written language. All were in favor.
- **3.1.6** "Clause 3.1.6 had been modified in the IS to change the definition of Suspension to read "The temporary removal of a laboratory's accreditation for a defined period of time, which shall not exceed six (6) months or the period of accreditation, whichever is shorter, in order to allow the laboratory time to correct deficiencies or area of non-conformance with the Standard." Previously it had read "..whichever is longer..". In discussions at the Chicago meeting, we determined that the change would be inconsistent with other parts of the standard and that the definition of suspension cannot vary between modules. It was agreed this should be changed back to "longer"." It was moved by Fred and seconded by Judy to rule the comment Persuasive and to make the change requested by the commenter. All were in favor.
- **3.2** "Since this definition is being targeted for deletion and the other subsequent sections are not being renumbered, should Section 3.2 be left with a place-holder? If so, insert "<<u>Reserved></u>" in place of the deleted text for Section 3.2." The Committee agreed to make this proposed editorial change.
- **4.2.1** "In the VDS, Clause 4.2.1 states "The Secondary AB shall have procedures in place to evaluate and update a laboratory's accreditation status based on the accreditation granted by a Primary AB." On discussion in the Chicago meeting, it was agreed clause 4.2.1 is redundant, since it is covered in 4.2.2. It was agreed 4.2.1 should be removed, with its language being merged into 4.2.2." It was moved by Tim and seconded by Scott to rule the comment Persuasive and to delete 4.2.1 and merge the language into 4.2.2. All were in favor.
- **5.0** "Since Section 5.2 is being eliminated, the Section numbered as 5.1 is unnecessary. Renumber sections 5.1.1 5.1.4 as 5.1 5.4." The Committee made the suggested editorial change.
- **6.1 and 6.2** "I am voting Affirmative only with the assumption and condition that the changes in sections 6.1 and 6.2 agreed to by the Committee during the public meeting in Chicago in July are being made." This had already been ruled Persuasive (General comment above moved by Scott and seconded by Stacie).
- **6.1.1** and **6.2.1** "The numbering of sections 6.1.1 and 6.2.1 is unnecessary since there are no corresponding sections 6.1.2 and 6.2.2. Please delete." This proposed editorial change was accepted by the Committee.
- **6.1.1** (b) "Clause "6.1.1(b)" [should really be 6.1(b)]. There are two periods at the end of the sentence. One of them can be deleted." This proposed editorial change was accepted by the Committee.

6.3.1 If [comment regarding Clauses 6.1.1 and 6.2.1] above is persuasive, then change the reference to "section 6.1.1a" in the second line to "section 6.1a." If [comment regarding Clauses 6.1.1 and 6.2.1] above is persuasive, then change the reference to "section 6.1.1b" in the second line to "section 6.1b." This proposed editorial change was accepted by the Committee.

This completed discussion of the comments on the module.

5 – Committee Charter

The difficulty of maintaining balance on the committee was discussed. Ken suggested creating a new interest group of Proficiency Test Provider. This would not only help with balance, but it would avoid the possibility of a future committee with no PT Providers. On discussion it was moved by Fred and seconded by Stacie to request approval of the Consensus Standards Development Executive Committee Chair to allow the Committee to have the following four interest groups: Laboratory, Accreditation Body, Proficiency Test Provider, and Other. All were in favor. It was also move by Stacie and seconded by Nicole to appoint Fred and Rachel to a second term on the Committee. All were in favor. Shawn said the Committee would have a conference call to decide on appointment of new members.

6 – Adjournment

There being no further business, the meeting was adjourned at 4:30 pm CST.