TNI Microbiology FoPT Subcommittee
Minutes from March Conference Call - 03/12/14

Subcommittee members present on call:
Susan Butts - Chair (SCDHEC), Fred Anderson (Advanced Analytical Solutions), Jennifer Best (EPA - OGWDW), Mike Blades (ERA), Andy Lincoff (EPA – R9), Jeff Lowry (Phenova), Andy Valkenberg (Energy Lab), Viola Reynolds (EPA – R4), Carol Haines (EPA – R10), Bennie Cockerel (SCDHEC), Stacie Metzler (Hampton Roads Sanitation District– VA) - joined the call at 1:56 EDT)

Review of the minutes from 01/15/14

1. Jennifer B. requested clarity regarding the use of "best" and "worst" performing methods. (These terms were used when the group discussed the 20-200 organism range for qualitative PTs.) After some discussion Andy V. moved to strike the sentence with these references from the minutes. Fred A. seconded. Motion passed.

2. Jennifer B. referred to the discussion of background noise re: TNTC and how it might affect a laboratory PT report. She indicated that she offered it as side information but didn't believe it should be included in the minutes. Jennifer requested that the sentences be stricken from the minutes. Carol H. moved to remove the sentence. Fred A. seconded. Motion passed.

3. Susan B. suggested that the last line of page 1 (" She [Patsy Root] noticed some micro PTs that don't specify the method.") needed to be modified for clarity: "micro PTs" should be changed to "micro PT providers". Some discussion followed that concluded that this was Patsy's intent. (Patsy was not present on this call.)

4. **ACTION ITEM: Based on the number and substance of changes, Susan said that she would send out corrected minutes. These could be reviewed and voted on to accept or reject by email prior to the next conference call.**

Discussion of Minutes from the Micro FoPT Subcommittee Meeting at the TNI Forum on Lab Accreditation – January 2014

Susan stated that she wasn't physically present at the meeting and although she could hear the speakers at the table, she was unable to hear the comments from the audience. Below is a summary of the main topics with discussion of those topics.

1. If a change in requirements affecting PTs is going to be considered, the cost/method must be carefully considered. Factors affecting the cost included the amount of testing required of providers, whether or not extra stipulations on preparation ranges were

needed, whether or not PT providers needed to assess the efficacy of a PT sample with 10 samples or 1 sample (enumerative vs qualitative). Questions to ask:

- Does the cost outweigh the benefit?
- What is broken that should be fixed?
- Does current data support a need for change?

Susan indicated that in the opinion of the PT Executive Committee, the Subcommittee has collected and reviewed the data that it was charged with collecting.

2. With regard to Methodology questions, there was some confusion about whether this should be considered in the Microbiology PT Expert Committee or PT Executive Committee.

3. Jennifer B. referred to a document Michella Karapondo cited during the meeting. The document stated that all PT providers must confirm by all approved methods for each strain used in PT tests (DW F0PT Table, footnote 9). For P/A there are no enumeration criteria.
   Jeff L. stated that at certain levels, some methods will not detect certain strains.
   Jennifer responded that failure to respond to a specific strain doesn't mean that a method is flawed. Coliforms are not a group of taxonomically defined organisms. They are not as predictable as a chemical which is definable.
   Susan B. summarized these observations by saying that preparation ranges need to have enough organisms to make certain that the level can be detected.
   Mike B. added that due to the large variability of method response, organisms should not be present at such low levels that they can't be detected by approved methods.
   Susan restated the concern. "Procedures may not be in place to affect the preparation of PTs so that they can effectively provide a PT test experience for a lab. I know there is concern because of quantitation results. However, qualitative testing does not have a high failure rate."

4. Jennifer B.: The tasks this Subcommittee were given came out of the Phenova and ERA presentations to the PT Executive Committee meeting in January 2013 during the Annual Forum.
   Jeff L.: They asked us to 1.) address the question of strains and 2.) address quantitation ranges for P/A microbiology tests. We've deliberated and should record our conclusions and complete the job.
   Susan B. : In reviewing this data, the PT Executive Committee says that we can move forward with the recommendation that preparation ranges for P/A are not required.
   Mike B.: The data that we collected was from three (3) providers with three (3) ranges (30-500).

Stacie M.: No AB's are saying that there is a problem. PT Provider Accreditors at Louisville stated that there were no high failure rates for P/A (see powerpoint).
Andy V.: There is masking with high levels of organisms. The instructions also stipulate a single strain. In quantitation levels aren't as critical.
Carol H.: The statement to the PT Executive Committee should be precise regarding what we actually discussed and researched.
Susan B.: I agree. The statement should be precise regarding what we did and by implication should identify what we didn't research.
Andy V.: High level PTs don't evaluate incubation conditions. However, incubation conditions could cause someone not to pass a low level PT.
Jennifer B.: I agree.
Andy L.: When EPA ran the PT program, our PTs were 10^5 cells.
Andy V.: Yes, that was what was originally published.
Susan B.: Does the cost to PT providers outweigh the benefit?
Stacie M.: The guidance says, "Concentrations not to exceed method performance range."
Jennifer B.: EPA and PT manufacturers don't have these performance ranges.
Stacie Metzler: "TNI will have a hard time making a costly change based on preferences."
Susan B.: "I'm not sure the PT Executive Committee would even support a vote for preparation ranges even if we did give them a range."
Jennifer B.: Methods are tested at very low organism levels.
Andy V.: "We're trying to set performance criteria at the sensitivity of the method (20 cfu recommended). We need to be testing the method at the criteria of the method (1 cfu/100 ml) which is what the intent and regulations imply."
Jennifer B.: We need to indicate that our conclusions are based on a limited data set.
Stacie M.: Clearly document any conclusions.
Susan B.: At this time we could not support a specific data range.
Carol H.: I think we have evidence for a lower range of 20 if not for the upper range.
Susan B.: We have to make a decision regarding how we proceed.
Fred A.: **"I move that the Micro FoPT Subcommittee summarize the findings of these discussions in a form suitable to present to the PT Executive Committee with discoveries and scope of investigation documented." ACTION ITEM**
Jennifer B seconded. Motion passed.

Meeting was adjourned by Susan B.

Minutes approved by subcommittee on 4/14/14