**TNI FoPT Subcommittee for Protozoa**
7/18/11
Attendees:
*Leah Villegas, Carl Kircher, Lisa McDonald, Sue Boutros, Patricia Klonicki, Matt Sica, Po Chang, Carrie Miller, Jim Broderick, Becky Hoffman*

**Highlights of previous meeting and email correspondence:**

1.) We discussed that EPA has set PT limits for *Cryptosporidium*:
   a. *EPA has issued a Federal Register notice on Vol. 74, No. 36 Wednesday, February 25, 2009 in the Clarifications of Basis and Procedures for Downgrading/Suspending Approval of Laboratories for the Analysis of* Cryptosporidium *in Water Under the Long Term 2 Enhanced Surface Water Treatment Rule which maintains that for approval within the current PT program a laboratory must be within ±2 standard deviations of the round mean.*

> The acceptance limits are laboratory mean recovery between ±2 standard deviations (SD) of the mean recovery for all approved laboratories in a given test event. Recoveries below the mean recovery minus 2 SD will fail the PT test event. Recoveries higher than the mean recovery plus 2 SD trigger additional evaluation, which may include one or more of the following: (1) On-site evaluation; (2) presence of a proctor when processing PT samples during the next test event; and/or (3) submission of PT microscope slides to the Approval Authority before the expiration of holding time during the next test event

   *b. The TNI Standard Operating Procedure for the Calculation of Acceptance Limits states in section 3.0 that "For those fields of proficiency testing that have acceptance limits specified in the US EPA regulations, the acceptance limits used by the TNI program shall not be winder than the US EPA limits."*
   *c.* The question was raised to if the FR was binding since it is not the CFR. Matt Sica responded: "In my former position as the CO for ME, the State always treats FR notices as they would the CFR."

*2.)* The group discussed the that the current Cryptosporidium and Giardia PT are a partial process
   *a.* **Matt Sica**: Partial process PTs are fine. With current technology, it is probably the only way we can do this. But this again is different than what TNI standards are based upon. And that is why I specifically pointed it out. The TNI standards require you run and report the PT as you would treat normal samples. Labs currently do not report these PTs as they would the method. Again the remedy would be inclusions in the appropriate modules of the TNI standard.
   *b.* **James Broderick**: I like the idea of considering whether EPA is really getting the information they need out of the PT. There is concern that a lab may not be able to properly identify crypto, but this is not evaluated by the PT, which is only spiked with Crypto/Giardia. The PT does evaluate the quality of the protozoa to some degree. Only crypto/Giardia that are properly stained and of the correct size are counted and reported. As such, I don't see the need to consider the significant change to the PT scheme by considering a qualitative component. I am comfortable continuing to utilize only the quantitative aspect of the PT because I think the qualitative component is best considered during the on-site assessment.

*3.)* The group discussed the importance of working with the Standard Committee to set standards regarding the PTs—especially as more providers become available and that the PT limits could rely on the standard deviation of the mean of for all approved laboratories in a given test event.

*a.* **Matt Sica:** After sitting through the CO class, the crypto program itself operates much differently than the other microbiology under the SDWA. It clearly is looking to improve the laboratories and promotes consistency. While much of this is done through the method requirements, this may be lost if multiple ABs interpret the method. Carl pointed out the FLDOH accredits labs for crypto. This is not an EPA approved program. Has EPA evaluated the way FLDOH current assumes oversight for the labs for consistency with how EPA handles their current laboratories? I am sure there would significant differences. If EPA wants to divest the program, but maintain the standard of oversight of labs as in the past, I believe that we should be working on specific modules for the AB, Lab, as well as PT TNI standards. The stakeholders with EPA can develop the a program which can then be adopted and promoted for consistency. Currently, if we use the current standards as is, I fear that each state will implement and accredit labs as they see fit, by their interpretation of the method and not necessarily to the standard of care EPA has in the past. For instance, how does FL determine an analyst is seeing what they think they are seeing? Also, these labs are currently audited in deep detail, they would be lucky to spend an hour on the method with the current standard. After we have standards all stakeholders can live with, then we can focus on developing more stringent criteria. This is unlike other PTs for TNI, for example, I see no way of allowing quick turnaround PTs for something based on study mean. These issues should be addressed before we develop an FOPT, not after. I think this is the same for the next issue.

*4.)* The group accepted that the FoPT table is restricted to the EPA limits set in the FR with the following questions:

***a.*** **Do we want a laboratory to "fail" for having too high a recovery?**

*i.* The FR states that a laboratory would trigger additional evaluations. **James Broerick** states that I also believe that the upper limit should be established to always include 100%, in order to support labs with exceedingly good recovery now and into the future. Unlike the Federal Register, I believe that a high level failure should be considered a failure, but I understand this decision has to align with the accreditation procedure which is outside the scope of this group. I don't think TNI's set-up or the State AB's will can really support the text in the FR (it is unlikely and probably not necessary for States to visit a lab after a high PT failure). If a lab has really good technique, they should simply pass. If a lab has carryover or contamination, a high limit should identify a failure.

*ii.* **Carl Kircher**: described footnotes for PT acceptance for FoPT tables which can be utilized to set extreme bounds of PT acceptance criteria. For example:

> *4) If the lower acceptance limit generated using the criteria contained in this table is less than (<) 10% of the assigned value, the lower acceptance limits are set at 10% of the assigned value, with the exception of Microbiology analytes.*
>
> *5) If the lower acceptance limit generated using the criteria contained in this table is greater than (>) 90% of the assigned*

*value, the lower acceptance limits are set at 90% of the assigned value, with the exception of Microbiology analytes.*

*6) If the upper acceptance limit generated using the criteria contained in this table is less than (<) 110% of the assigned value, the upper acceptance limits are set at 110% of the assigned value, with the exception of Microbiology analytes.*

Carl continues: As Subcommittee, we can choose to keep the "exceptions" for Cryptosporidium & Giardia as is done for Total Coliform, Fecal Coliform, & E. coli. Based on the EPA reports I looked at and compiled, #4 has rarely happened for Cryptosporidium & Giardia, except for cases where the study relative standard deviation was large. Footnote #5 has never happened in the Cryptosporidium and Giardia proficiency rounds to date. Footnote #6 would be definitely worth considering. In just about all the EPA testing rounds, the mean+2 std. dev. value was below 100% of the verified Assigned Value. We could leave the EPA FR Notice alone and say +infinity is the upper acceptance limit (i.e., NO upper bound by which labs. could fail the PT). Or, we can add language to Footnote 6 saying that "This footnote applies, however, to Cryptosporidium and Giardia proficiency testing study rounds." My personal opinion is the latter choice.

**b. Do we want the FoPT for Drinking water and Source Water only?**

**i.** Overall thoughts are to focus on drinking water (including source water) matrix at this time as the regulation focuses on this matrix

**c. What about the QC Acceptance Criteria set in Method 1623 does that play a role in the FoPT table?**

The FR notice mentioned above also updates reagent water criteria to 22% for Cryptosporidium. The matrix level is 13% for Cryptosporidium and during past PT rounds ±2 standard deviations of the round mean has put the lower level below the Method 1623 criteria.

**d. Is 2 PT rounds a year enough?**

The NELAC standard is 2 times a year and the group did not object to this frequency.

**e. Do we set a table for Cryptosporidium and Giardia, the FR is just for Cryptosporidium.**

Overall thoughts were to develop the FoPT for both organisms.

5.) **James Broderick** sent the following FoPT submission starting point:

| Matrix | EPA Code | NELAC Code | Analyte | Conc Range | Acceptance Criteria | NELAC PTRL |
|---|---|---|---|---|---|---|
| Drinking Water | | | Cryptosporidium | 50-200 | Mean +/- 2SD (footnotes 17, 18, 19) | Not Applicable |
| Drinking Water | | | Giardia | 50-200 | Mean +/- 2SD (footnotes 17, 18, 19) | Not Applicable |

17) If the lower acceptance limit generated for Cryptosporidium or Giardia using the criteria contained in this table is less than (<) 10% of the assigned value, the lower acceptance limits are set at 10% of the assigned value.

18) If the lower acceptance limit generated for Cryptosporidium or Giardia using the criteria contained in this table is greater than (>) 60% of the assigned value, the lower acceptance limits are set at 60% of the assigned value.

19) If the upper acceptance limit generated for Cryptosporidium or Giardia using the criteria contained in this table is less than (<) 100% of the assigned value, the upper acceptance limits are set at 100% of the assigned value.