

**Proficiency Testing (PT) Committee Meeting
January 13, 2009
Forum on Laboratory Accreditation
Miami, FL**

Committee members present:

Kirstin McCracken, Chair

Stacie Metzler

Dan Tholen

Jim Webber

Tom Mcaninch

Amy Doupe

Shawn Kassner

Stephen Arpie

Jane Wilson, Program Administrator

Kirstin welcomed the attendees and reviewed the agenda. Committee members made self introductions. Kirstin noted the contributions of the large number of associate members that also regularly participate in committee meetings.

Kirstin reviewed the recent activities of the committee. They have responded to 24 comments provided by LASC on the TNI PT standards. The PT Frequency sub-committee met frequently and has a progress report to present. Subcommittees were also formed for specific PT modules, but have not yet started their work.

PT Frequency Sub-Committee Report (Dan Tholen)

Dan reviewed a brief history of the sub-committee. It was chartered in April 2008 and provided a progress report in August 2008 at the Washington DC meeting. The sub-committee has also been monitoring other activities that are going on regarding the topic of PT frequency.

The August 2008 report focused on a study of New Jersey performance data of NELAP accredited labs (2 PTs/yr) versus state certified labs (1 PT/yr). Outcome statistics for each group were based on four end points. The conclusion was that lower unacceptable rates were observed for the 2 PTs/yr group, but the differences could be due to multiple factors – for example, quality management systems and lab size. The sub-committee is currently looking at results from other states – Maine and hopefully Wisconsin. Dan anticipates that by the next meeting in August 2009 those reports will be completed and the sub-committee will make a decision/recommendation to the PT Committee. Other potential data sources, such as USGS, were noted during discussion.

Judy Morgan briefed the participants on the survey of state accrediting bodies for PT requirements. Most states that responded require either one or two PTs a year. Most of the one PT states are drinking water only programs. It was discussed whether the PT

frequency sub-committee would be able to obtain data from all the responding states. PT providers may be another route, but not all would be willing or able to share data.

Participants discussed at what point will enough data evaluation have been performed to render a defensible decision. Again, the goal is to have this work wrapped up by August 2009. This data evaluation and the PT committee recommendation will be used to inform the standards development process to determine the persuasiveness of previously received comments on PT frequency. If the prior comments are found to be persuasive, the PT committee will initiate the next cycle of standards development to determine the appropriate frequency for TNI standards.

The following additional points were discussed:

- ABs use PTs to make accreditation decisions. The TNI Accrediting Bodies will need empirical evidence to change the required PT frequency. It was also noted that a variety of PT programs are required by different states.
- States use PTs as one component of assessing lab quality. The objective is to be able to distinguish the good labs from the bad labs. How do failed PT results correlate with denied accreditation?
- Some labs identified as performing one PT may actually be performing additional PT samples for internal purposes.
- The corrective action intent of PT samples should not be ignored.
- Analysts learn how to handle PTs, but it may not improve their day to day work. PT samples signify a break in routine.

The PT committee agrees the PT frequency subcommittee must proceed with its work. It was suggested that the model of “Investigate-Hypothesize-Test” be used by the subcommittee. The first two parts have been done. The subcommittee could design a controlled experiment in which one or more labs analyze the same sample and compare the results. The study could separate analyses over a period of several months. It was also suggested not to focus solely on PT success, but the subcommittee needs to look at the question of whether the data quality improved. Judy Morgan’s survey of NELAC labs included questions on PT cost. On average it was reported that the cost to run PTs is about 1.5x the cost of the PT itself.

Other federal agencies such as DOE, USGS and DOD were reviewed for their required PT frequencies. EPA Office of Water requires one PT by method for drinking water certification. Previous discussions with Office of Water have indicated they are willing to consider alternatives.

The committee should consider the economic impact for a potential change in frequency. It would be useful to know direct costs for labs and direct costs for the AB. Benefits are

speculative with regard to dollar value - internal checks, detected errors, customer confidence and access to markets are potential lab benefits. AB benefits are to mitigate the risk of bad testing and ongoing oversight.

International activity with respect to proficiency testing was reviewed. There are no definitive efforts, but TNI should benefit from the work of others rather than reinvent the wheel. One approach is the AB and lab working together to determine frequency based on scope and risk. Not much information is available in public studies. IUPAC has a specified frequency. TNI requirements are substantially greater than most of the world. ILAC has less stringent requirements that have resulted in lack of regulatory confidence in ILAC accreditation. Canada requires 8 PTs per year – may want to look at the decision process that supported that frequency.

Basic questions that need to be answered during this process include defining the purpose of PT samples for TNI's program. There are lots of reasons to run a PT sample, but TNI needs to define TNI's purpose. That is a question for the TNI Board/NELAP Board. Also the subcommittee needs to look at acceptance criteria, e.g. percent recovery requirements, and limitations on methods used by labs, etc. Analysis of the New Jersey data indicated two PTs didn't have much improved recoveries over 1 PT so there was a significant extra cost for a small increase in recovery.

Review of Major Changes and Implementation

Kirstin explained to attendees that the TNI Laboratory Accreditation System Committee (LASC) did a thorough review of the TNI standards as a whole, and performed a very valuable function. For PT, LASC identified some consistency issues across the different volumes. LASC provided 24 comments – some are editorial, some are more fundamental to the PT process. The PT committee has responded to each LASC comment. Some of the responses identified the need to develop either TIAs or implementation guidance.

Transition from PTRL to LOQ Reporting.

A PTRL workgroup was formed to address this issue. The workgroup reviewed requirements from each perspective – lab, provider, oversight body, and AB. TNI Volume 3 does need revisions. The workgroup is developing a guidance document to show examples of how scoring will be done. This will be done in the form of a comprehensive document that addresses all PT issues, not just PTRL. Experimental PTs and the TNI appeals process are two outstanding issues. TNI appeals process does not yet exist. The PT committee will incorporate “experimental” PTs into the FoPT tables so they won't be “experimental” anymore. The standard does not need to be revised since experimental PTs were written in as optional.

TIAs to be developed include issues related to PT scoring for PTRL to LOQ transition and lab requirement to purchase PTs from approved provider (need to revise volume 2).

Other very clear editorial changes are needed. Grammatical changes suggested by LASC need review by CSDB. The PT committee plans to start developing the TIAs after the Miami meeting. LASC does not have another report coming back to the PT committee as they have agreed with the PT committee's recommendations. Also, LASC does not know if it has a specific role in the development of the guidance document and TIAs but has offered any assistance that is needed. The PT committee expects to have draft changes by their February 2009 meeting.

The NELAP Board will receive the LASC recommendations on January 14th. It is anticipated that the NELAP Board will assume that the recommended revisions and documents will be put into place by the responsible committees, and vote to move forward with the standards adoption process.

The PTRL guidance document explains the background for the change in the new TNI PT standards. Some labs had to develop unique test methods for their PT samples, which is counter to the intent of processing them in same manner as routine samples. The document defines how terms are used for the new procedure. It also provides guidance to laboratories on the reporting of the samples. The PT committee will verify that "LOQ" is used the same way in the guidance document as in the PT standards.

Shawn Kassner presented the guidance that will be included for PT providers. Reported values up to the PTRL would be accepted, etc. Examples will be included in guidance document. It was asked whether there could be a scenario where acceptable results as defined by the standard come into ethical conflict with the PT provider and about providing that result to ABs when there is a concern. It puts PT providers in a position where they will not know if the lab is operating within its accredited range. That is not the PT providers' responsibility and the PT provider doesn't have enough information to say it is not acceptable. The purpose was to allow labs to handle samples in the same manner as environmental samples. The ultimate solution is to provide multi-level PT samples. But it makes no sense to continue to have labs analyze PTs in a manner unlike the routine samples.

The LASC comment was this change has complicated PT reporting so that ABs can't just look at PT reports to determine acceptance. There is a way to flag results to indicate it needs manual verification. ABs also need to verify on site during audits. The NELAP Board may need more guidance than what has been provided so far. If the TIA is not approved, is that a situation in which the TNI standard cannot be adopted. The score from PT provider is not the final score, only part of it. A lab can fail for not reporting on time while obtaining the correct value. The guidance will include recommendations on what documentation labs need to meet the new requirements. Labs are changing systems to conform to the new TNI standards as well. The standards can't be changed at this point other than to address the inconsistencies with TIAs. If NELAP won't adopt, it's back to the drawing board.

It is not known how many labs are currently operating under the issue of having to report PT samples differently than routine samples. It could become a bigger issue as TNI tries

to include wastewater labs and others within the TNI community. Ultimately the PT Board needs to look at multi-level PTs for technologies. There is no reason that this can't be done in terms of the PT providers. Providers even have these types of samples available for analytes not on the FoPT tables.

Other PT Subcommittees

Kirstin reported that three additional subcommittees had been formed for specific technical PT issues and the PT committee would like to recruit additional members for these subcommittees. The following are the subcommittees and their respective chairs:

Wet testing – Stacie Metzler

Air – Amy Doupe (have 2 AB reps, need labs or providers)

Radiochemistry – Shawn Kassner (need lab reps)

It was discussed whether purchasing custom PTs could be a solution – the number of labs is probably significant enough that routine samples should be available. Acceptance limits and consistency between ABs are issues that would have to be addressed. PT standards would have to provide the flexibility to use custom PT samples as well.

The PT committee will continue monthly meetings on the second Tuesday of the month, 1:00 pm -2:30 pm EST.