

## **TNI PT Program Executive Committee Meeting Summary**

**October 16, 2014**

### 1. Roll call and approval of minutes:

Chair, Maria Friedman, called the TNI PT Program Executive Committee (PTPEC) meeting to order on October 16, 2014, at 1 PM Eastern. Attendance is recorded in Attachment A – there were 8 Executive Committee members present. Affiliates Present: Rob Knake, Dixie Marlin, and Shawn Kassner.

Maria reviewed the handouts everyone should have received for today's meeting.

A motion was made by Joe to approve the August 4, 2014 minutes with the addition of Nicole's new email address and a correction to Matt's attendance after the break. The motion was seconded by Nicole. The motion was unanimously approved and the minutes will be prepared for posting on the TNI website.

A motion was made by Joe to approve the August 21, 2014 minutes with the following corrections – remove reference to Washington, DC in section 1 and add Nicole's new email address. The motion was seconded by Susan. The motion was approved and the minutes will be prepared for posting on the TNI website (6 – For, 0 – Against, 2 - Abstain: Patrick and Matt. They were not in attendance).

A motion was made by Joe to approve the September 18, 2014 minutes with the addition of Nicole's email address. The motion was seconded by Susan. The motion was unanimously approved and the minutes will be prepared for posting on the TNI website.

### 2. Chair Update

- Action items will be reviewed even though some of the items are not on the agenda.
- Our charter will need to be updated based on the Strategic Planning meeting held in Milwaukee last week. We will receive action items after the TNI Board finalizes the Strategic Plan in November.

### 3. PT Expert Committee Comments

There were 3 comments sent by the PT Expert Committee. The first two deal with FoPT Table concerns and the third is from Volume 4. The comments are included in

Attachment D. These comments came in in response to the PT Expert Committee Working Draft Standard.

Maria suggested that these comments be initially reviewed and worked on by subcommittees. She thinks the first two can likely be addressed by the new FoPT Table Update Subcommittee.

Shawn Kassner reviewed each of the comments with the PTPEC. He noted that the third comment will need a subcommittee that includes PTPAs.

Matt does not think a subcommittee is needed for Comment 3. He thinks the PTPEC chair should be able to meet with the PTPAs to find out if there are still issues with sharing data. Matt agrees data should be more available and this will help with comments 1 and 2. If there are still issues after meeting with the PTPAs – then it would be appropriate to pull a subcommittee together.

Rob Knake agreed that a subcommittee is not needed yet. He thinks the PTPAs should be checking with the PT Providers to find out if there are issues with sharing the data. He would like answers to questions about how the data needs to be provided if it needs to be provided by the PTPAs. Patrick commented that this is provided in SOP 4-101 (FoPT Limits Update SOP). There is a list of what PT Providers have been asked for historically.

Andy noted that he feels that the PT Providers and PTPA's need to start collecting data by method.

Shawn would like a response to the three comments before the TNI conference in early February. He requested that the PTPEC let him know if an extension is needed. If the timeframe cannot be met – the Expert Committee may still need to move forward with the information they have.

Maria will contact Stacie about expediting the update on SOP 4-101 so that PT Providers and PTPA's know what data is needed by the PTPEC for FoPT updates and to periodically address complaints. The SOP should also address the format of the data. She will also request that the SOP Subcommittee consider including prep methods in the SOP.

Matt made an additional comment – for Comments 1 and 2 there is going to need to be a real evaluation of the commutability of the materials based on the technologies that are now available. The different digestions in metals have a great affect on analysis results. This will be a long term issue. Need to start looking at prep methods with the better technologies that are now available. Shawn agreed and noted that this will change the format of the FoPT tables.

Andy noted that we need to start encouraging PT Providers to collect information on the prep methods if there will be a need to start including prep methods in limit development.

Shawn commented that there will need to be a requirement for PT Providers to collect the data or it will likely not happen. A number of stakeholders need to be talked to before the SOP Subcommittee completes the FoPT Limit Update SOP they are working on – PTPs, PTPAs, etc. They should also informally make recommendations on how the standard should be updated to address some of the concerns surrounding the effect of prep methods. Maria will include this in her correspondence with Stacie.

Ilona will plan to post FoPT Table Format Subcommittee meetings on the TNI website. Not all subcommittee meetings are posted on the website, but there will likely be people that have an interest in this topic and may want to join in.

#### 4. WET Testing FoPT Table Update

Maria asked people to open the file she forwarded regarding Footnote 3. The NELAP AC expressed concern and said they don't look at the footnotes on the FoPT tables during their assessments. They would prefer that this type of information to be in the PT Provider instructions. There is some question as to whether the new standard requires information like this to be in the PT Provider instructions.

Shawn thinks the first part of the footnote is actually in the PT Provider instructions currently. He is concerned about the last sentence – “must be provided ...”. He thinks it should be changed to “must be ordered ...”. This would mean that the PT Providers would have to change their PT designs. Pat does not like the specificity of what the PT Provider has to provide. It is not consistent with other PT instructions. Shawn also asked if this is a problem because too much assistance is being given to the laboratories – an issue for PTPAs in the past (Volume 3 issue). Matt and Rob did not think this would be a problem if it was a requirement. Matt's bigger concern is whether the PT Providers are being asked to do more regulatory oversight instead of the ABs looking at this when they do the onsite assessments of the laboratory.

Joe Pardue thinks the PTPEC needs to provide direct guidance to the WET Testing FoPT Subcommittee on this topic. Joe does not think the subcommittee has been comfortable with the process. They need more understanding of what the issues are. There is a lot of confusion. Rami needs to be on the next call or a special call needs to be planned to provide more guidance or it will be difficult to work through the obstacle of the footnotes. Joe will reach out to Rami and Maria will follow-up. The subcommittee does not have all the historical knowledge they should have to work through this and the PTPEC can help in this area.

Andy noted that the permits are very specific with regards to limits, methods and how the tests should be run. Andy thinks the type of dilution water and temperature should be included in the PT instructions too. The idea behind the footnote was to mimic how the permits provide direction to the labs and build consistency in how the PT is analyzed.

Patrick bigger concern is specifying exactly what needs to be in the instructions the PT Provider sends when the PT goes to the lab. It has never been done this way in the past. He would prefer the labs follow the FoPT tables.

## 5. Subcommittee Updates

### FoPT Table Format Subcommittee

Iлона noted that not enough people are responding to the Doodle requests for the first meeting. Maria asked that a note be sent to everyone not responding to see if they still want to be on the subcommittee and then send out one more Doodle request to setup a meeting.

Andy noted that the Scope for this committee will likely need to be updated when this committee has their first meeting.

### WET Testing FoPT Subcommittee

Maria will reach out to subcommittee. See above.

### Chem FoPT Subcommittee:

The Chemistry FoPT Subcommittee is continuing to review SCM analytes. The group is still finishing up Metals and will begin some General Chemistry analytes on their next call.

### SOP Subcommittee

They are still working on the FoPT Limit Update SOP. The next meeting will be in November.

## 6. New Business

SIRs will be distributed for an updated response at next months meeting.

## 7. Action Items

- See Attachment B.
- Complaints are still being addressed.

## 8. Next Meeting

The next teleconference will be November 20, 2014 at 1pm ET.

Action Items are included in Attachment B and Attachment C includes a listing of reminders.

The meeting was adjourned at 2:26pm EDT. Matt motioned, Andy seconded. Unanimously approved.

## Attachment A

### Participants TNI

#### Proficiency Testing Program Executive Committee

Members	Affiliation	Contact Information
Stacie Metzler (2009) <b>Absent</b>	HRSD	757-460-4217 <a href="mailto:smetzler@hrsd.com">smetzler@hrsd.com</a>
Maria Friedman (2014) - <b>Present</b>	TestAmerica	949-260-3201 <a href="mailto:maria.friedman@testamericainc.com">maria.friedman@testamericainc.com</a>
Ilona Taunton, Program Administrator <b>Present</b>	TNI	828-712-9242 <a href="mailto:tauntoni@msn.com">tauntoni@msn.com</a>
Eric Smith (2010) <b>Absent</b>	ALS Environmental	904-394-4415 <a href="mailto:eric.smith@alsglobal.com">eric.smith@alsglobal.com</a>
Justin Brown (2011) <b>Present – Arrived 2:06</b>	Environmental Monitoring and Technologies, Inc.	847-875-2271 <a href="mailto:jbrown@emt.com">jbrown@emt.com</a>
Susan Butts (2012) <b>Present</b>	South Carolina DHEC	(803)896-0978 <a href="mailto:buttsse@dhec.sc.gov">buttsse@dhec.sc.gov</a>
Patrick Brumfield (2012) <b>Present</b>	Sigma-Aldrich RTC	(307) 721-5488 <a href="mailto:Pat.Brumfield@sial.com">Pat.Brumfield@sial.com</a>
Michella Karapondo (2011) <b>Absent</b>	USEPA	513-569-7141 <a href="mailto:karapondo.michella@epa.gov">karapondo.michella@epa.gov</a>
Nicole Cairns (2012) <b>Present</b>	NY State DOH	(518) 473-0323 <a href="mailto:nicole.cairns@health.ny.gov">nicole.cairns@health.ny.gov</a>
Joe Pardue (2011) <b>Present</b>	Pro2Serve, Inc.	423-337-3121 <a href="mailto:joe_pardue@charter.net">joe_pardue@charter.net</a>
Dr. Andy Valkenburg_(2011) <b>Present</b>	Energy Laboratories, Inc.	406-869-6254 <a href="mailto:avalkenburg@energylab.com">avalkenburg@energylab.com</a>
Ron Houck <b>Present</b>	PA DEP	<a href="mailto:rhouck@pa.gov">rhouck@pa.gov</a>
Matt Sica <b>Present</b>	ACLASS	<a href="mailto:msica@anab-aclass.org">msica@anab-aclass.org</a>

## Attachment B

### Action Items – TNI PT Executive Committee

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
185	Send updated DW table with Footnote 15 to NELAP AC for approval.	Stacie	4/1/12	Stacie submitted this. Need to confirm approval.
214	Update Tin, Total Xylene and Total Cyanide on FoPT tables and submit for approval.	Carl Stacie	Next Meeting	In Progress
231	Meet to discuss how information is requested from PTPAs and how it relates to PT Providers.	Ilona Maria	4/15/14	See Action Item #249
233	Review complaint process.	Maria Ilona	5/14/14	In Progress
238	Contact AIHA regarding Asbestos.	Ilona	7/16/14	10/16:Dixie suggested contacts. Maria to follow-up with Jerry to see if need is still there.
242	Find out if all volatiles need to be spiked.	Michella	9/18/14	Complete
244	Draft response to complainant for 3051A complaint and distribute to committee for review.	Maria	9/11/14	
245	Forward TDS complaint to Chem FoPT with request to review data and respond.	Maria	8/31/14	
246	Rewrite request to the Chemistry FoPT subcommittee and send to Ilona for distribution.	Maria	10/6/14	
247	Request that Chem FoPT Subcommittee review DW footnotes and ensure they are consistent with the Criteria Document.	Maria	10/6/14	

	<b>Action Item</b>	<b>Who</b>	<b>Expected Completion</b>	<b>Actual Completion</b>
248	Contact Stacie to check on status of the SOP Subcommittee.	Maria	10/6/14	
249	Meet with PTPAs to discuss issues surrounding receiving data for FoPT Limit Updates and complaints. Determine if issue exists and whether subcommittee is needed to address this issue.	Maria	11/13/14	
250	Contact Stacie about expediting work in SOP Subcommittee so the PTPEC can respond to PT Expert Committee comments. Also provide feedback about looking at prep methods and collecting information on methods.	Maria	10/30/14	
251	Follow-up with Rami to provide support to solve footnote issue on WET FoPT Table.	Maria	10/30/14	

**Attachment C**

**Backburner / Reminders – TNI PT Executive Committee**

	<b>Item</b>	<b>Meeting Reference</b>	<b>Comments</b>
7	Add the Field PT Subcommittee to the limit update SOP during its next update.	3/4/10	
11	Evaluate how labs are accredited for analytes that co-elute.	5-19-11	
12	PTPA Evaluation Checklist needs to be updated prior to next round of evaluations.	8-6-13	
13	Charter needs to be updated in November.	Ongoing	
14	<p>When new limits are established for the FoPTs, what is considered to be a statistically significant change to the old rates? At what point is it appropriate to question new limits? This lends to the TSS discussion a few months ago.</p> <p>Patrick commented that it would make sense to look at changes to pass/fail rates 6 months after new limits are effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP.</p> <p>3/20/14: Eric noted that there are some logistics with doing a 6 month review. This may need to be a separate committee so it does not hamper the progress of the Chemistry FoPT Subcommittee.</p>	2/20/14	

**For Discussion on PTPEC Teleconference, 10-16-2014: Comment #1****Comment on V3 WDS that acceptance rates based on study mean are biased against new, more accurate technologies**

Recent advances in analytical instrumentation, especially the availability of more sensitive mass selective (MS) detectors have allowed some environmental labs to transition from older, non-selective technologies such as GC-ECD and GC-NPD to more selective MS based methods (GC/MS, GC/MS/MS, HPLC-MS and HPLC/MS/MS).

The newer MS based technologies often match or exceed the sensitivity of the methods they replace. They also display less systemic bias and are more capable in terms of both the accuracy and precision of the data they report. In contrast, many of the older non-selective detection methods such as GC-ECD tend to have a low bias and greater variance in the data they report.

**Table 1** below, displays data from a recent PT study for chlorinated acid herbicides in Soil. The acceptance limits in **Table 1** are statistically derived, and based on pooled data reported by all technologies used by participants in the PT study. As seen from the acceptance limits, the data for most analytes is highly skewed with a bias toward lower recoveries. It is noteworthy that with the exception of Acifluofen and Bentazon all the other analytes had Lower Acceptance Limits (LAL) of 10% or below (0% for Dichlorprop & Picloram).

**Table 1**

Analyte Name	Reported Value	Assigned Value	LAL	UAL	LAL(%)	UAL(%)	Reported Value (%)
Acifluorfen	490	577	182	696	32%	121%	85%
Bentazon	467	359	163	421	45%	117%	130%
2,4-D	620	688	68.8	1170	10%	170%	90%
2,4-DB	710	734	73.4	1130	10%	154%	97%
Dicamba	453	469	46.9	734	10%	157%	97%
Dichlorprop	957	973	0	1410	0%	145%	98%
Dinoseb	373	457	45.7	658	10%	144%	82%
MCPA	<13.0	<1000	0	1000			
MCPP	<13.0	<1000	0	1000			
Picloram	227	336	0	520	0%	155%	68%
2,4,5-T	337	368	36.8	616	10%	167%	92%
2,4,5-TP (Silvex)	292	302	30.2	451	10%	149%	97%

LAL: Lower Acceptance Limit ; UAL: Upper Acceptance Limit

We checked with the PT provider and learned that the assigned values are determined gravimetrically, and are based on weights and volumes recorded during the manufacturing of the PT standard. These values are independent of the analytical methods used by labs to measure (and report) data.

We also know that all the labs except one, used GC-ECD to report data for this PT sample. The data in the “Reported Values” column in Table 1 are data reported by our lab using EPA method 8321 (HPLC/TSMS). The GC-ECD method (EPA 8151) used to report most of the data for this PT standard is known to have a bias for low recoveries.

The recoveries reported by HPLC/MS display better accuracy than the GC-ECD data, with recoveries ranging between 68% and 130% of the true values. The skew in the pooled data for some analytes is so severe that more accurate data reported by a different technology (HPLC/MS in this case) is penalized simply by virtue of being in the upper portion of the distribution. This was the case for Bentazon with upper and lower limits of 117% and 45% respectively. We also know that only nine labs reported data for this parameter. This combination of small sample size and skewed data resulted in Bentazon failing the PT despite being closer to the assigned value than other results for the same parameter,

This example suggests that data reported by diverse technologies such as GC/ECD and HPLC/MS are sufficiently different in their analytical characteristics that data from these technologies come from separate (statistical) distributions. More data comparing results from the two technologies will very likely show a bi-modal distribution with distinct means and variances for the two technologies.

We believe that the current procedure for assigning acceptance limits to PT samples based on pooled data from a small number of labs unfairly penalizes participants that may be reporting more accurate data - simply because the majority of labs in the sample are using a method that has an inherently low bias (GC-ECD in this case). Data accuracy should also be an important consideration in evaluating laboratory performance, not merely the (relative) position of the reported data in the sample distribution, especially one with highly asymmetric acceptance limits.

We hope the TNI PT committee will revisit current policies used to set acceptance limits to take into account data accuracy as well as differences in technology used to report data. Thank you.

### **Summary:**

- 1) Commenter provided an example regarding soil herbicides PT. Their lab analyzed the sample by Method 8321 (HPLC/TSMS), while most other labs used Method 8151 (GC-FID). The commenter said 8321 is more accurate than 8151, and that 8151 is known to have a low bias.
- 2) The acceptance limits for soil herbicides are set to study mean +/- 3SD

### **Maria's comments:**

- 1) If most labs use a technology that has a low bias, then the study mean will also have a low bias, resulting in acceptance limits that are on the low side. A lab that uses a technology with higher

recoveries will therefore have a harder time being within limits since their method does not have a low bias.

- 2) Unless the number of labs using the two technologies is about even, a bimodal distribution would not become apparent in the results. In other words, if there are 10 participating labs, and 9 of them use GC-FID, and 1 uses HPLC/TSMS, then you would not see a bimodal distribution in the results, since only 1 lab used the HPLC/TSMS. If 5 labs uses HPLC/TSMS and 5 labs used GC-FID, then a bimodal distribution would be expected.
- 3) The preceding point would discourage labs from using new or better technology to analyze PTs. When acceptance limits are based on study mean, the "smart" lab will use the technology that most other labs also use. If you run a lab and find out about a new method that is 100% accurate, as opposed to the old, less accurate method, you can't use the new method for the PT and be sure to pass.

## **For Discussion on PTPEC Teleconference, 10-16-2014: Comment #2**

### **Comment on V3 WDS that a PTP used data with a bimodal distribution to calculate acceptance limits**

Several EPA regions have concern regarding the evaluation of Proficiency Test (PT) results/evaluations for some methods, particularly SM 9221 (Multiple Tube Fermentation) and 9223 (Colilert using Quantitray). Specifically, the EPA Region 10 Laboratory recently failed a PT using the Multiple Tube Fermentation Method (SM (9221B) after having been certified (and as such, successfully completing PTs) for this method for many years. Upon notification of failure, EPA Region 10 contacted <the PT provider>, and was told that for this study <they> considered all methods as equivalent for E. coli and combined the results from all methods for the statistical analyses. Because in this study, there were a small number of data points for SM 9221F, the results from 9221 were combined with the results from laboratories utilizing SM 9223B, even though contacted <the PT provider> acknowledged a low bias for this test and a bi-modal distribution of results.

Upon discussion of this matter with other EPA regional personnel and staff in the Office of Water, we discovered that EPA Region 10 is not alone in having failed this <specific> PT and others for this reason. We respectfully request this matter be reviewed by the TNI PT Executive Committee.

The 2009 TNI Standard, Volume 3, Sections 10.1.1-3, states the following.

#### 10.0 PT STUDY DATA ANALYSIS

##### 10.1 Data Review

10.1.1 PT providers shall review all PT study data sets for bimodal or multi-modal distributions and/or situations where results from a given method have disproportionately large failure rates or reporting anomalies.

10.1.2 If a multi-modal distribution is found related to analytical method and acceptance criteria are

calculated using robust statistical analysis of participant data, results shall be evaluated on a method-specific basis.

10.1.3 PT providers shall review all PT study data sets for disproportionately high or low failure rates compared to historical norms.

Please consider clarifying the Standard (Section 10.1) to require the PT provider, if they offer a PT for a particular method, to evaluate data separately when the data are produced by different methodologies. Combining methodologies calculation of acceptance criteria may be the source of disproportionately high failure rates when methods differ.

**Summary:**

- 1) PT was for E. Coli (not mentioned if DW or NPW; E. Coli is on both FoPTs). Some labs analyzed using Method SM9221F, while others used Method SM9223B. Commenter says that one of those methods (not clear which) has a low bias and there is a bimodal distribution of results.
- 2) Commenter noted that the current TNI Standard V3 Section 10.1 requires PTPs to review PT study data for bimodal or multimodal distributions.
- 3) Commenter requests TNI Standard be changed to say that PTPs evaluate data separately when the data are produced by different technologies, because "combining methodologies calculation of acceptance criteria may be the source of disproportionately high failure rates when methods differ."

**Maria's comments:**

- 1) TNI Standard does tell PTPs to review PT data for bimodal or multimodal distributions and or disproportionately large failure rates, but it does not seem to say what the PTPs are supposed to do about it ("OK, we reviewed the data. We see a bimodal distribution. So now what?")
- 2) Note the similarity of this issue to Comment #1.

**For Discussion on PTPEC Teleconference, 10-16-2014: Comment #3**

**Comment on V4 WDS that proposed change to TNI Standard, in which PTPA is supposed to provide data to PTPEC, requires more detail about how exactly the data would be provided, and how to avoid confidentiality concerns**

The criteria established by the PTPEC have to come from the data from the PTPA. Therefore, I strongly request you add a statement that the PTPA must provide the data to establish the pass/fail rates criteria to the PTPEC upon request. The committee may want to add other data and leave it more open such that the PTPEC can request any data from the PTPA and they must provide it. Maybe ask the PTPEC how to word it.

As stated in your web seminar by another participant, the data to establish FoPT tables has come from PT Providers volunteering the data not the PTPA Data Management System (formally Database). PTPEC needs full access to this data being stored by "their" PTPAs.

Change proposed to TNI Standard V4 in recent WDS:

Original language:

6.3.2. The PTPA shall investigate any situation where a PT Provider's pass/fail rate for any analyte or overall is statistically different from the national average at a 95% level, as determined by appropriate statistical techniques.

Proposed language:

6.3.2. The PTPA shall monitor pass/fail rates per the PTPEC. The PTPA shall investigate pass/fail rates that deviate from criteria established by the PTPEC. The PTPA shall notify the PT Provider of pass/fail rate deviations and monitor associated corrective actions taken by the PT provider.

A PTP representative commented that the language should be changed to require the PTPA to provide, upon request, the data to establish pass/fail criteria to the PTPEC. A PTPA representative wondered if legal issues should be considered. Another PTPA representative thinks the requirements should be more specific, e.g. every 3 months.

#### **Maria's comments:**

- 1) The proposed 6.3.2 introduces a new concept to the PT Program: pass/fail criteria established by the PTPEC. FoPTs set acceptance criteria per analyte, but do not set pass/fail rate criteria. The current TNI Standard says that PTPAs investigate situations where the pass/fail rate is "statistically different from the national average."
- 2) Presumably, the "national average" is whatever the PTPA's own data tells them it is (in other words, A2LA has their own "national average" and ACLASS has their own, perhaps different, "national average"). Example: if A2LA's historical data says that a 50% pass rate for Benzene is the "national average," and ACLASS's historical data says that a 80% pass rate for Benzene is the "national average," then the PT Providers are being held to different standards, depending on which PTPA they have. A PTPEC-established pass/fail criteria would presumably eliminate this problem by taking data from all PTPs, regardless of PTPA, and setting the same pass/fail rate criteria for all.
- 3) The current setup does not encourage PT performance to be better; it encourages PT performance to be consistent.
- 4) Are pass/fail rates intended to measure the performance of labs, or the performance of PTPs? If there is an unusual pass/fail rate for a particular study, it probably isn't because a bunch of labs suddenly started failing their PTs, it's probably because the PTP did something wrong in creating the PT samples or verifying the assigned value)

#### **Questions this raises:**

- 1) Are PTPEC-established pass/fail rate criteria needed?
- 2) How would the PTPEC establish pass/fail rate criteria?
- 3) Do the PTPAs have "national averages" available for the PTPEC to review?
- 4) How would the PTPEC publish pass/fail rate criteria? If added to FoPT Tables, they are subject to NELAP AC approval. If published some other way, would they still be subject to NELAP AC approval (ABs may demand it)?
- 5) Assuming PTPEC establishes pass/fail rate criteria, what is the corrective action when that rate is not met? Example: PTPEC establishes requirement of 80% pass rate for NPW Benzene. If the pass rate of a given PT study is 78%, what is supposed to happen? Does that bring into question the PTP's samples? Does it invalidate the whole PT Study data for Benzene (so the 78% labs who passed don't get "credit" for passing)? Is it left up to the PTPA to decide on their own whether a PTP's compliance to the PTPEC's pass/fail criteria requires corrective action (to be determined and reviewed by the PTPA, not the PTPEC)?
- 6) What would PTPEC-established pass/fail criteria accomplish? The current standard requires PTPAs to investigate when the pass/fail rate deviates from the "national average," i.e., the historical pass/fail rate. If PTPA data shows the historical pass rate for Benzene to be 80%, what criteria would the PTPEC establish? 80%? What rationale would there be to use a different criteria? If A2LA's rate is 80%, and ACLASS is 50%, do you just take the average and make the criteria 65%? Keep in mind that if you set a higher pass rate as the criteria (e.g., 90%), the surest way for more labs to pass is to widen the FoPT acceptance criteria, not tighten it.
- 7) Assuming that the PTPEC *should* establish pass/fail criteria, what data does the PTPEC need to do this? Presumably, all you need would be the pass rates of past PT studies for each analyte.
- 8) If the PTPEC would establish pass/fail criteria, presumably the most efficient process for this would be for the FoPT subcommittees to review and establish pass/fail rate criteria at the same time that they are reviewing FoPTs. If that is true, then data would be needed by the subcommittees to evaluate FoPTs, too. How do they obtain that data now? If from PTPAs, then they can get the pass/fail rates from the PTPAs at the same time they get the PT recovery data. If from PTPs, then PTP data should also be able to provide pass/fail rates.
- 9) Note that the V4 WDS, Section 5.5.1, has the following proposed language: PT providers shall demonstrate to the satisfaction of the PTPA that their PT sample designs and manufacturing processes result in laboratory pass/fail rates that are consistent with historical norms. The underlined (added) language seems consistent with the way the old V4 6.3.2 was written but is not consistent with the WDS proposed 6.3.2 quoted above.
- 10) Finally, is there reason to believe that PT pass/fail rates from PTPs accredited by A2LA are statistically different from PTPs accredited by ACLASS? Perhaps this should just be a review done by PTPEC when reviewing PTPA accreditation renewal. If PTPs accredited by different PTPAs did have statistically different pass/fail rates, then that may suggest different approval and review criteria or processes by the PTPAs are holding PTPs to different standards.

11) To reiterate: what are we trying to accomplish with pass/fail rate criteria, and what corrective action is required when the criteria are not met?