TNI PT Program Executive Committee
Meeting Summary

December 17, 2020

1. Roll call, approval of minutes and overview:

   Chair, Shawn Kassner, called the TNI PT Program Executive Committee (PTPEC) meeting to order at 1:05 pm Eastern on December 17, 2020 by teleconference. Attendance is recorded in Attachment A – there were eight (8) members present. Associate Members: Mike Blades, Tim Miller, Nicole Cairns, Reggie Morgan, Partick Selig, Jennifer Best and Amy DeMarco.

   Shawn asked for confirmation that everyone received the agenda and meeting information.

   A motion was made by Fred to accept the November 19, 2020 minutes as written. The motion was seconded by Jennifer D. and there was no further discussion. The motion was unanimously approved.

   There were no changes made to the agenda.

2. FoPT Tables

   Shawn asked about the status of the Xylene ARA from Pennsylvania. Carl reminded the Committee that the Chemistry FoPT Subcommittee did provide to a recommendation. Carl provided the following information in an email on June 30, 2020:

   By unanimous vote, the Chemistry FoPT Subcommittee that reports to the TNI PT Program Executive Committee recommends for approval the attached SCM FoPT Table with the additions of m/p-Xylenes and o-Xylene as FoPTs. Please note that these additions are for both concentration levels of Volatile Organics. Also, please note that the attached Table may not be complete with respect to other changes that may have been made to the FoPT Table, such as with analyte codes or footnotes.

   This action partially fulfills the Analyte Request Application (ARA) that was received from PA-DEP. I am in contact with the Accreditation Body there to determine if the ARA is still applicable and needs to be addressed for the Drinking Water FoPT Table.

   Ilona may have some additions to this e-mail in case I have omitted any important points.

   Ilona added on 7/1/20:
   Just a reminder that the table Carl attached may not be the most current SCM table.

Shawn – Can you insert the updated xylene info into the most current version of the SCM table before it is presented to the PTPEC?
The Chemistry FoPT Subcommittee still needs to follow-up on DW with Pennsylvania.

Shawn provided copies of the DW, NPW and SCM DRAFT FoPT tables with the agenda. Xylene's will need to be added to the SCM table and Shawn will confirm all other changes have been made to the tables (e.g., Aroclor footnote, effective dates). Shawn will provide updates before the December meeting.

3. PTRL Definition

There was a question about the PTRL definition. What is on the FoPT tables does not match the definition in the Standard. The definition in the PT Standard is consistent with the rest of the Standard.

Shawn pulled the definitions in the FoPT tables:

NPW FoPT Table
7) TNI Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing TNI PT samples. These levels are the lowest acceptable results that could be obtained from the lowest spike level for each analyte. The laboratory should report any positive result down to the PTRL.
It is recognized that in some cases (especially for analytes that typically exhibit low recovery) the PTRL may be below the standard laboratory reporting limit. However, the laboratory should use a method that is sensitive enough to generate results at the PTRL shown. TNI PTRLs are also provided as guidance to PT Providers. At a minimum for all analytes with an assigned value equal to "0", the PT Provider should verify that the sample does not contain the analyte at a concentration greater than or equal to the PTRL.

SCM FoPT Table
7) TNI Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing TNI PT samples. At a minimum, the laboratory should use a method that is sensitive enough to generate quantitative results at the PTRLs shown. TNI PTRLs are also provided as guidance to PT Providers. At a minimum for all analytes with an assigned value equal to <PTRL, the PT Provider should verify that the PT sample does not contain the analyte at a concentration greater than or equal to the PTRL.

DW FoPT Table
7) TNI Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing TNI PT samples. These levels are the lowest acceptable results that could be obtained from the lowest spike level for each analyte. The laboratory should report any positive result down to the PTRL.
It is recognized that in some cases (especially for analytes that typically exhibit low recovery) the PTRL may be below the standard laboratory reporting limit. However, the laboratory should use a method that is sensitive enough to generate results at the PTRL shown. TNI PTRLs are also provided as guidance to PT Providers. At a minimum for all

analytes with an assigned value equal to "0", the PT Provider should verify that the sample does not contain the analyte at a concentration greater than or equal to the PTRL.

DW RAD FoPT Table

5) TNI Proficiency Testing Reporting Limits (PTRLs) are provided as guidance to laboratories analyzing TNI PT samples. These levels are the lowest acceptable results that could be obtained from the lowest spike level for each analyte. The laboratory should report any positive result down to the PTRL.
It is recognized that in some cases (especially for analytes that typically exhibit low recovery) the PTRL may be below the standard laboratory reporting limit. However, the laboratory should use a method that is sensitive enough to generate results at the PTRL shown. TNI PTRLs are also provided as guidance to PT Providers. At a minimum for all analytes with an assigned value equal to "0", the PT Provider should verify that the sample does not contain the analyte at a concentration greater than or equal to the PTRL.

Nicole Cairns read the PTRL definition in the TNI Standards - Vo1ume 1 Module 1 and Volume 3:

Proficiency Testing Reporting Limit (PTRL): A statistically derived value that represents the lowest acceptable concentration for an analyte in a proficiency test sample, if the analyte is spiked into the proficiency test sample. The PTRLs are specified in the TNI Field of Proficiency Testing tables.

Nicole saw other issues with the language in the FoPT tables. This is old language now. They need to be made the same. The FoPT tables will need to looked at again. PTRL related language needs to be updated and then an implementation date will be determined.

Shawn will look at doing a joint call with Kirstin to see what the definitions should be. He would like to have a call between both committees.

4. Joint Meeting Agenda – WET, PT Expert and PTPEC

Shawn pulled up the summary document provided in Attachment D. It includes the WET Expert Committee's suggested changes and Shawn's thoughts.

Blue should be go intio Volume 1 module 1.
Green should go into WET Module 7.

Suggested steps include: These can be included in the FoPT table for requirements. (Volume 3Additions)

1. Standardize the required number of replicates per test.
2. Standardize the required number of organisms per replicate.
3. Standardize and reduce the age range of test organisms used in the following tests:

a. DMR-QA Test code 13 and 14 (EPA Method 2000): Pimephales acute tests reduce age range from 1 – 14 days down to 1 – 5 days with a 24 hr range in age.
b. DMR-QA Test code 46 (EPA Method 2004): Cyprinodon acute test reduce age range from 1 – 14 days down to 1 – 5 (or other such consensus range) days with a 24 hr range in age.

The following additional suggested steps may be best placed into the TNI standard as requirements for the labs to implement. (Volume 7 Additions)

1. Require labs to affirm that DMR-QA/PT tests were conducted according to the specified test conditions listed in the PT instructions.
2. Require labs to document if any deviations from required test conditions occurred and whether a deviation invalidated the test or not. Some deviations from test conditions would invalidate a test such as incorrect number of replicates used, incorrect number of test organisms per replicate, incorrect test organism age, etc. would not.
3. Require labs to document each test's test acceptability criteria data, for example:
   a. For the negative laboratory performance control in acute tests, document the % survival.
   b. For the negative laboratory performance control in chronic tests, document the % survival and the mean weight per surviving test organism or the mean 3rd-brood reproduction per surviving C. dubia.
4. Require labs to document the sublethal PMSD evaluation for tests where PMSD bounds are established in the EPA test method and when a chronic NOEC test endpoint was reported.
   a. If a test's PMSD is less than or equal to the lower PMSD bound for the test method reported, then the lab must document that the relative % difference from the control of each test concentration tested and that the % relative difference reported for the NOEC is greater than the lower PMSD bound.
   b. If a test's PMSD is above the maximum PMSD bound for the test method then the NOEC shall not be reported.
5. Require labs to document the evaluation of interrupted dose-response curves for tests where an interrupted dose-response occurs and an NOEC test endpoint is reported. The lab shall document the statistical significance or non-significance of every test concentration subsequently to the PMSD evaluation in #4 above
   a. Lab shall evaluation dose-response curves per EPA 821-B-00-004 Method Guidance and Recommendations for Whole Effluent (WET) Testing (40 CFR Part 136).
6. Require labs to document the source of test organisms used in a DMR-QA/PT test.

Shawn will send an agenda to Suzanne, Rami and Kirstin.

5. PTPEC Meeting Agenda for Virtual Conference

- Membership
- Talk about WET meeting.
- It will be a regular meeting.
- Tables

- FoPT subcommittee input

Memberhsip discussion of candidates and voting will need to be on a separate call.

We will be using Webex for the virtual conference. Everyone should be familiar with using Webex, but there will be some additional tools we will use like Chat and Q&A.

The Committee will also need to develop 2021 Goals that will be due in January before the virtual conference. *(Addition: They are due to Jerry by January 15, 2021.)*

Shawn asked the Committee to brainstorm some ideas:

- PTPA evaluations
- Uncertainty for Radiochemistry (There is not an evaluation process and PT Providers are not collecting the information. Should they? If so, what would it look like? How would it be added to the FoPT table?
- Develop processes to keep non-TNI states involved.
- Explore the feasibility of technology-based PTs. Report prep methods.

6. TNI Board of Director Report

The Board would like to know when the PFAS request expands to NPW and Solids. They also expressed some concerns about whether the new PCB footnote will cause problems for labs that do not want to be accredited for all PCBs. Ilona needs a written response by Monday, January 11th. Shawn will work on this with Ilona.

7. Subcommittee Updates

Chem FoPT Subcommittee – Carl need to set-up meeting. Andy will re-send info on PFAS acceptance criteria and the contact information he sent November 20th.

Shawn asked that Carl send him a data request letter once the Subcommittee meets. Carl will also request data for Residues - NPW.

Ilona thinks the TNI database only populates what is on the FoPT tables. Not all analytes a PT Provider runs are going into the database. Is this something we can ask for?

SOP Subcommittee: Continuing work on SOP 4-101. Making good progress.

Microbiology Subcommittee: Jennifer reported the Subcommittee is not working on anything currently. Shawn had suggested looking at Legionella. Jennifer commented that rules are now being revised. There was a stakeholder kick-off meeting in October 2020. Legionella was a part of that conversation. Its regulated if you disinfect your water following procedures because the rule presumes the Legionella was killed. Jennifer will

let Shawn know how to find out about the Stakeholder meetings. There should be another one in the Spring. She will send a link that can be distributed with the minutes.

8. New Business.

None

9. Action Items

The action items can be found in Attachment B.

10. Next Meeting

The next meeting will be by teleconference on January 21, 2020 at 1pm EDT.

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

Adjourned at 2:16pm Eastern. (Motion: Fred. Seconded: Carl – Unanimous).

Attachment A
Participants
TNI
Proficiency Testing Program Executive Committee

Members	Rep	Affiliation	Contact Information
Shawn Kassner (2023*) (Chair) **Present**	Lab	Pace	shawn.kassner@pacelabs.com
Dixie Marlin (2021) (Vice-Chair) **Present**	Other	Marlin Quality Management, LLC	marlinquality@gmail.com
Ilona Taunton, Program Administrator **Present**		TNI	tauntoni@msn.com
Carl Kircher (2021*) **Present**	AB	Florida Department of Health	Carl.Kircher@flhealth.gov
Andy Valkenburg (2021*) **Absent**	Other	QASE Inc.	cvalkenbur@aol.com
Jennifer Duhon (2022) **Present**	Other	Millipore Sigma	jennifer.duhon@sial.com
Patrick Garrity (2022) **Absent**	AB	Kentucky DEP	patrick.garrity@ky.gov
Michella Karapondo (2022) **Present**	Other	USEPA	karapondo.michella@epa.gov
Fred Anderson (2020*) **Present**	Other	Advanced Analytical Solutions, LLC	Fred@advancedqc.com
Jennifer Bordwell (2020*) **Present**	Lab	Upper Occoquan Service Authority	jennifer.bordwell@uosa.org
Scott Haas (2020*) **Present**	FSMO	Environmental Testing, Inc.	shaas@etilab.com
Rachel Ellis (2022*) **Absent**	AB	New Jersey DEP	rachel.ellis@dep.nj.gov

Attachment B

Action Items – TNI PT Executive Committee

	Action Item	Who	Date Added	Expected Completion	Comments/ Actual Completion
295	Moved from Backburner: PTPA Evaluation Checklist needs to be updated prior to next round of evaluations. (Originally discussed 8/6/13)	Shawn Ilona		New Date: 5/31/19	In Progress (will use 2016 TNI Standards and current SSAS Standards)
349	Review LAMS/FoPT Table Differences document. Provide comments by email and next meeting. Follow-up on subcommittee reports from WET and the FoPT Table Format Subcommittee.	ALL	4/20/17	4/25/17 2/28/18 – For WET? June 2018 for all tables. New target date: 4/30/19	In Progress WET is still being reviewed. Update 1/23/18: Subcommittee expects to have updated FoPT tables with CAS #'s and LAMS changes by 3/15/18. 2/22/19: Still in progress. 6/21/18: Still working with Rami. 3/21/19: Stacie asked if the group should be working on this while ELAB is working through this. 2/20/20- ONGOING - Waiting for WET.
352	Moved from Backburner (originally discussed 2/20/14) : When new limits are established for the	All	2/20/14	TBD ~~(see #350)~~ ~~*350: Prepare formal*	In Progress – Update of SOP 4-101

	Action Item	Who	Date Added	Expected Completion	Comments/ Actual Completion
	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. 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.			~~*request to SOP Subcommittee regarding updating FoPT tables and applicable backburner items just moved to the Action Items table (#352, 353)*~~	6/21/18: Gil noted that this SOP will be worked on again at the next meeting. An expected completion date will be given at July meeting.
361	Analyte Code changes needed in LAMS. (TKN)	Maria Dan Hickman	7/20/17	9/30/17	Still need to look into TKN issue. 2/22/18 – Maria will confirm. 10/18/18: Maria still needs to confirm. She just got something. 2/20/20 – Maria will report next meeting.
363	Discuss procedural change in how changes are made to LAMS. Consider notifying PTPEC before relevant changes are made and provide a summary of changes at some frequency.			1/31/17	Will talk to IT about getting this in an SOP. 12/21/17: Maria will follow-up on this. 3/20/18: Maria will check this week.

	Action Item	Who	Date Added	Expected Completion	Comments/ Actual Completion
					6/21/18 – still being worked on. 2/28/19 – Maria will follow-up. 2/20/19 – Maria will take care of.
368	Forward Jerry's question to Chemistry FoPT Subcommittee. (Analyte code change for the non-polar extractable materials.)	Maria	8/24/17	9/1/17	Maria will resend to Carl. 6/21/18 – Maria will send to Ilona. 10/18/18: Maria will send Dan's new info. 11/15/18 – Ilona received the info and needs to review it. (April PTPEC meeting.) 2/20/20- Maria working with Dan Hickman on this.
384	Meet with Dan Hickman to get Analyte Codes and then prepare final DRAFT of Micro DW and WW tables. Send to Jennifer for review.	Maria	4/19/18	5/15/18	MTF version of the analytes have been added to the NPW and DW tables.
389	Present recommended LAMS updates to Dan Hickman.	Maria	5/17/18	5/20/18	FoPT format subcommittee provided recommendations . In Progress. Maria sent him tables this month (2/20/20)
~~400~~	~~Follow-up on subcommittee reports from WET and the FoPT Table Format Subcommittee.~~	~~Maria~~	~~11/15/18~~	~~12/18/18~~	In Progress – combined with 349.

	Action Item	Who	Date Added	Expected Completion	Comments/ Actual Completion
422	Send Isomer ARA data to Carl so Chem FoPT Subcommittee can begin work on this.	Maria	6/20/19	7/17/19	2/20/20 -Pending Needs to still be sent to Subcommittee.
430	Review FoPT Table Titles and website headers to be consistent.	TBD	10/31/19	TBD	2/20/20 - Pending
431	Discuss with IT Committee the need for LAMS updates to be communicated to the PTPEC.	Maria	10/31/19	11/20/19	2/20/20 – Maria will talk to Dan Hickman.
432	DW FoPT Table – Lines 17-26 need to be reviewed with LAMS Administrator. PTPEC is going to use what was originally in the table instead of what is currently in LAMS.	Maria	10/31/19	11/20/19	2/20/20 – Pending. Maria will talk to Dan.
433	Send final version of SOPs 4-102, 4-105, 4-107 and 4-108 to Ilona for finalization and distribution to the Policy Committee.	Maria	1/23/20	2/19/20	2/20/20 – Maria will still do this.
437	Reach out to Sennet Kim and ANAB to confirm there is still an issue related to SCM FoPT table metals footnotes for fixed limits.	Shawn	3/26/20	4/15/20	

	Action Item	Who	Date Added	Expected Completion	Comments/ Actual Completion
438	Reach out to NELAP AC to see if any additional progress has been made in dealing the PCB ARA.	Shawn	3/26/20	4/15/20	Complete
439	Send committee applications to PTPEC Voting Members for review.	Shawn	3/26/20	4/15/20	
440	Invite Rami to next meeting to discuss WET Expert Committee data needs.	Shawn	5/28/20	6/16/20	Complete
441	Send formal requests to Chem FoPT Subcommittee: Xylenes ARA (#422) and Uranium Analyte Number	Shawn	5/28/20	6/6/20	9/17/20 – Carl sent FoPT update to Shawn. To be discussed at 10/15/20 meeting.
442	Send out PCB survey.	Shawn	5/28/20	6/17/20	See Item 445
443	Meet with Michelle Potter and Rachel Ellis to review option 2 language for PCB issue.	Shawn	5/28/20	6/17/20	Update: 6/18/20 - Met and new language was presented to the PTPEC. The PTPEC modified it and sent it back to the NELAP AC for consideration. 9/17/20: Shawn will meet again to discuss new language option. Complete

	Action Item	Who	Date Added	Expected Completion	Comments/ Actual Completion
445	Send PCB survey to Ilona so she can arrange to have it sent out.	Shawn/Ilona	6/18/20		9-17-20: Shawn is working on this and will get to Ilona.
446	Review WET information distributed by Shawn for October meeting.	All	9/17/20	10/15/20	
447	Update Xylenes in FoPT table.	Shawn	9/17/20	10/15/20	See 441.
448	Check in with the PT Providers and NELAP AC regarding effective date for PCB footnote update.	Shawn	11-19-20	12-16-20	
449	Send request to Chemistry FoPT Subcommittee to be working on PFAS ARA.	Shawn	11-19-20	12-16-20	
450	Meet with Kirstin regarding PTRL definition.	Shawn	12-17-20	1-18-21	
451	Send agenda for WET meeting to Suzanne, Kirstin and Rami.	Shawn	12-17-20	1-11-21	
452	Update FoPT tables with Xylenes, PCB footnote, etc …	Shawn	12-17-20	1-18-21	
453	Work on response to TNI Board.	Shawn Ilona	12-17-20	1-11-21	

Attachment C

Backburner / Reminders – TNI PT Executive Committee

	Item	Meeting Reference	Comments
7	Add the Field PT Subcommittee to the limit update SOP during its next update.	3/4/10	In Progress
11	Evaluate how labs are accredited for analytes that co-elute.	5-19-11	
13	Charter needs to be reviewed/updated in November.	Ongoing	
18	Shawn noted that PTPEC should have some specific measurements. This should be passed along to the PTP SOP Subcommittee. Nicole noted that we need to determine which items to measure.	6-29-17	

Attachment D. WETT Suggested Proficiency Testing (PT) Instructions for PT Providers

These are suggested steps to standardize PT instructions for Whole Effluent Toxicity DMR-QA/PT testing to assure and increase the comparability and usefulness of the data generated the studies.

Suggested steps include: These can be included in the FoPT table for requirements.

4. Standardize the required number of replicates per test.
5. Standardize the required number of organisms per replicate.
6. Standardize and reduce the age range of test organisms used in the following tests:
    a. DMR-QA Test code 13 and 14 (EPA Method 2000): Pimephales acute tests reduce age range from 1 – 14 days down to 1 – 5 days with a 24 hr range in age.
    b. DMR-QA Test code 46 (EPA Method 2004): Cyprinodon acute test reduce age range from 1 – 14 days down to 1 – 5 (or other such consensus range) days with a 24 hr range in age.

The following additional suggested steps may be best placed into the TNI standard as requirements for the labs to implement.

7. Require labs to affirm that DMR-QA/PT tests were conducted according to the specified test conditions listed in the PT instructions.
8. Require labs to document if any deviations from required test conditions occurred and whether a deviation invalidated the test or not. Some deviations from test conditions would invalidate a test such as incorrect number of replicates used, incorrect number of test organisms per replicate, incorrect test organism age, etc. would not.
9. Require labs to document each test's test acceptability criteria data, for example:
    a. For the negative laboratory performance control in acute tests, document the % survival.
    b. For the negative laboratory performance control in chronic tests, document the % survival and the mean weight per surviving test organism or the mean 3rd-brood reproduction per surviving C. dubia.
10. Require labs to document the sublethal PMSD evaluation for tests where PMSD bounds are established in the EPA test method and when a chronic NOEC test endpoint was reported.
    a. If a test's PMSD is less than or equal to the lower PMSD bound for the test method reported, then the lab must document that the relative % difference from the control of each test concentration tested and that the % relative difference reported for the NOEC is greater than the lower PMSD bound.
    b. If a test's PMSD is above the maximum PMSD bound for the test method then the NOEC shall not be reported.
11. Require labs to document the evaluation of interrupted dose-response curves for tests where an interrupted dose-response occurs and an NOEC test endpoint is reported. The lab shall document the statistical significance or non-significance of every test concentration subsequently to the PMSD evaluation in #4 above
    a. Lab shall evaluation dose-response curves per EPA 821-B-00-004 Method Guidance and Recommendations for Whole Effluent (WET) Testing (40 CFR Part 136).
12. Require labs to document the source of test organisms used in a DMR-QA/PT test.

SMK Response

I have read 2016 TNI Vol 1 Mod, Vol 1 Mod 7 and the proposed changes to the standard and the FoPT tables. A couple of things to note, the FoPT tables are not just for PTPs anymore. The 2016 Vol 1 Mod 1 references that laboratories shall use the tables for the purposes of reporting data multiple times. So, the 2016 TNI standard directs laboratories to the FoPT tables currently.

Historically, the ABs and the PTPAs (A2LA and ANAB) have frowned upon PTPs providing laboratories more guidance then they thought went beyond instructions; such as helpful hints etc. The items 1 – 3 as listed below are not helpful hints to perform the method, they are an attempt to standardize the test conditions for the sake of statistical evaluation. The WETT expert committee can work with the PTPEC to evaluate whether these should be added to the table. We will then seek the input from the AC, the understanding must be that these criteria are needed to develop study-based statistics that allow for comparability and appropriate evaluations for the WETT labs. I have specific questions surrounding these for statistical impact but will save those for the WETT committee. If these are added to the FOPT table TNI and the PTPs will need to direct people to the table for their review. The Vol 3 specifically allows for the table to supersede it for acceptance criteria determination in section 5.9.2.2 "Analyte- or study-specific evaluation criteria defined in the TNI FoPT Tables shall supersede the criteria in this Section." This was done purposely to allow for more rapid changes to the acceptance criteria.

1. Standardize the required number of replicates per test.
2. Standardize the required number of organisms per replicate.
3. Standardize and reduce the age range of test organisms used in the following tests:
    a. DMR-QA Test code 13 and 14 (EPA Method 2000): Pimephales acute tests reduce age range from 1 – 14 days down to 1 – 5 days with a 24 hr range in age.
    b. DMR-QA Test code 46 (EPA Method 2004): Cyprinodon acute test reduce age range from 1 – 14 days down to 1 – 5 (or other such consensus range) days with a 24 hr range in age.

The remaining standard changes are covered in Vol 1 Mod 1 and Mod 7 to some extent, but let's review. My initial comment is that if the labs are required to document this information for PTs, who is going to evaluate it, deem it acceptable or not, and to what criteria? So there are a few questions surrounding these additions. My presumption is that the ABs would review these as part of their normal assessment.

Item# 1 is in 2016 TNI Vol 1 Mod 1 section 4.2.1 and can be removed as redundant.

Item #2 The requirement to document deviations from a method is required in TNI 2016 Vol 1 Mod 2 section 5.4.1. "Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. "So this is also a redundant clause to the current standard. The other issue I have with this item is who is going to be the arbiter of what method deviations are technically acceptable or not to the test results for the PTs. This must fall to the ABs as the PTPs do not have the technical expertise to evaluate these deviations nor is this their role.

Items# 3 – 6 are somewhat addressed in Mod 7 but nowhere near as much as here. I do believe that these are great QC tacking and practices that labs should be performing all the time. And perhaps these should be amended into Mod 7!? Again, I am going to ask what is the purpose, evaluation criteria, and who is reviewing the data? It also appears to be a great place to start a corrective action for a PT failure. These in general are potentially great improvements to the WETT program and standard, I am not sure that Vol 1 Mod 1 is the place for these and just be used for PT.

The next steps should be for Kirstin and I to validate what our committees think if these changes and return that information to this group. Everyone took the time to ask good questions, provide good answers and it is important for Kirstin and I to review these between us and then with our individual committees.

Regardless, I would also like Rami and the WET Expert committee to evaluate whether the items 3 – 6 should be adopted as the normal QC practices for Mod 7 or for corrective action investigation for failed PTs.