

TNI PT Program Executive Committee Meeting Summary

September 21, 2017

1. Roll call and approval of minutes:

Chair, Maria Friedman, called the TNI PT Program Executive Committee (PTPEC) meeting to order by teleconference on September 21, 2017, at 1pm Eastern. Attendance is recorded in Attachment A – there were 8 members present. Associate Members present: Shawn Kassner, Andy Valkenburg and Mike Blades (ERA).

Maria confirmed everyone received the agenda and supporting documents on September 19th.

Maria reviewed the late August minutes with the committee. Nicole motioned to approve the August 24, 2017 minutes as written. Fred seconded the motion and it was unanimously approved.

The August meeting in Washington, DC minutes were reviewed and approved by email after Maria had had a chance to review them. A motion was made by Nicole on 9/20/17 to approve the minutes as written. The motion was seconded by Gil Dichter. The vote was as follows: For – 7 (Susan, Matt, Jennifer, Eric, Scott, Dixie and Maria) Against – 0 Abstain – 0 The motion passed.

2. Chair Update

- The NELAP AC still needs to address the question of LAMS vs FoPT table updates. Their plate is full and this will be discussed in October.
- Maria will send a copy of the complaint to the committee and people are asked to respect confidentiality.
- Craig just sent PT Instructions for WET. Maria asked if Jennifer could send hers too.
- Nicole sent a reminder to vote on Volume 1, Module 4 of the TNI Standard.

3. Combined Evaluation SOP

Susan and Maria provided comments on the Combined Evaluation SOP. Last meeting, Eric noted that he likes the idea of consistency among the Executive Committees and would like to see PTPEC do something similar to the other Executive Committees when it comes to recognition. All the comments made were provided as preparation for this call and Ilona requested that the committee review those and make sure there is

consensus within the committee on the comments. She noted one area there appears to be disagreement is in the actual recognition process. Should the PTPEC vote or should the vote for recognition be handled by the TNRC (recognition committee)? The committee should discuss this and reach consensus.

Maria was concerned that not many comments were received and perhaps the holiday may have affected that.

Maria asked the committee for comments on the recognition process:

Susan commented that she thinks the decision should remain with the PTPEC to approve the PTPA. The PTPEC should receive a copy of the report and response to make this decision. The TNRC can make a recommendation, but the final decision would be with the PTPEC.

Nicole feels the decision should be left with TNRC so it can be consistent with the other programs.

Shawn noted that if this committee is only receiving a recommendation letter, why does the decision need to come back to the committee. Shouldn't the decision be made by the people actually reviewing the information?

Maria's concern is whether the PTP requirements were met.

Susan noted that the PTPEC charter states the PTPEC does the recognition and having the TNRC vote instead would require an update of the PTPEC charter.

Nicole commented that ISO 17011 is the same across all programs. What if there is a conflicting recommendation?

Maria has some reservations, but will go with the majority decision of the PTPEC.

Nicole has the opposite concern – she does not want it to come back to her as a vote. She has not seen the information and does not feel good about the vote coming back to the PTPEC. The charter should be updated.

Dixie tends to agree with Nicole. Not having the entirety of the information to base a second vote on, there's no benefit to a second vote.

Nicole asked what the PTPEC review would add to the process?

Patrick thinks Nicole and Dixie's argument is correct.

Jennifer D. agrees with Nicole.

Jennifer M agrees with Nicole.

After listening to the discussion, Susan is OK with the voting within the TNRC instead of the PTPEC.

Maria does not think more input is needed and that the committee will follow a process similar to the NEFAP EC where the vote for recognition will happen within the TNRC.

The committee reviewed the other comments received on the SOP and there were no disagreements or additional comments.

The Combined Evaluation Workgroup will begin work on incorporating comments from both executive committees.

4. Cyanide Footnote Request - Mike Delaney

Mike requested that the PTPEC clarify in the Drinking Water FoPT footnotes that the Cyanide PT is appropriate for all forms of Cyanide. He suggested a statement such as: *b) Design criteria for Cyanide (all forms) – uncomplexed, e.g., Potassium Cyanide*. He would like the PTPEC minutes to clearly reflect that the Cyanide PT can be used for free, available and total cyanide.

Andy commented that Total Cyanide cannot be done above the MCL level. You have to do a Free Cyanide analysis. Cyanide is regulated as Free Cyanide (Table in 40 CFR 141.62(b) defines MCL of 0.2 mg/L for Cyanide (as free cyanide)), but Total Cyanide methods are allowed for screening. He emailed the committee a copy of an EPA Cyanide Clarification memo dated 2/25/2015.

The footnote needs to match what is in the EPA clarification. The document Andy sent was provided by Region 8, but it is based on federal directive.

The committee will further discuss this after the committee has a chance to review the document sent by Andy.

5. WET

Maria provided a number of documents for review with the agenda regarding the WET PT issue. There was a white paper from the WET Expert Committee, a summary of the meeting in Washington, DC on 8/9/17 and a copy of an email from Maria.

The WET Expert Committee is recommending reporting the IC25 value only and not the NOEC value for chronic WET studies. They commented: Using point estimate endpoints for both the acute (i.e., LC50 values) and short-term chronic (i.e., IC25 values) test method in the DMR-QA / PT program is the most appropriate and consistent means for evaluating the results of toxicity tests in DMR-QA / PT studies when the test protocols

are standardized. If WET laboratories obtain acceptable results participating in the DMR-QA / PT tests under strictly controlled conditions, we are confident that the laboratory can also produce reliable data in whatever conditions their clients' permits require.

There is no consistency. There are concerns about the small statistical data sets affecting confidence in determining "true" or assigned value for a given WET PT/DMR-QA WET test. Toxicity endpoints can be greatly affected by test variable such as test organism age, test organism source and other test conditions. The WET Expert Committee provided options to deal with some of these issues in their white paper (see Attachment D).

One issue being discussed is making the instructions the same from each PT Provider - same toxicant and organism. They would also like to see the criteria changed.

The WET Expert Committee is coming to the PTPEC for help to make PT Provider instructions consistent.

Jennifer Duhon and Craig Huff will send instructions to Maria. Shawn suggested that Maria ask for instructions from all the providers.

Maria asked that everyone review what they are requesting – see Attachment D and the summary of the Washington, DC meeting provided with the agenda. The PTPEC does not have the authority to tell PT Provider what to do. Any changes would require a change in the Standard. Shawn asked if this should be handled by the PT Expert Committee instead of the PTPEC. Nicole (Chair, PT Expert Committee) agrees. The PTPEC can only change FoPT tables. This issue will be passed on to the PT Expert Committee.

Nicole noted this will need to be developed with a number of committees and there will need to be a meeting down the road of all these people to finalize any changes. Maria will let Rami know about decision made.

6. Subcommittee Update

Chemistry FoPT Subcommittee – The committee hasn't met yet. A meeting will be planned in October.

SOP Subcommittee – No update at this time. Planning to meet on 10/13/17.

FoPT Table Format Subcommittee – Mike Blades is sitting in for Craig. He is working on the WETT FoPT table comparison to LAMS.

Microbiology FoPT Subcommittee – Jennifer Best (Chair) has now gotten some data from the statisticians that needs to be reviewed. Jennifer and Michella have been involved in lab assessments. Maria will follow-up with Jennifer.

7. New Business.

- None.

8. Action Items

The action items can be found in Attachment B. Updates are added as notes in the table.

9. Next Meeting

The next meeting will be on 10/19/17. Ilona will send out Webex invitations the morning of the meeting. The committee should plan to review the Combined Evaluation SOP and get final comments back to Maria and Ilona. Next months agenda will include complaint and cyanide issues.

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

Maria adjourned the meeting at 2:28pm Eastern. Motion to adjourn – Fred. Second – Nicole. Unanimous.

Attachment A
Participants
TNI
Proficiency Testing Program Executive Committee

Members	Rep	Affiliation	Contact Information
Maria Friedman (2020) Present	AB	California Water Board	949-307-0949 Maria.Friedman@waterboards.ca.gov
Ilona Taunton, Program Administrator Present		TNI	828-712-9242 tauntoni@msn.com
Eric Smith (2019) Absent	Lab	ALS Environmental	904-394-4415 eric.smith@alsglobal.com
Susan Jackson (2018) Present	AB	South Carolina DHEC	(803)896-0978 jacksosb@dhec.sc.gov
Nicole Cairns (2018) Present	Lab	NY State DOH	(518) 473-0323 nicole.cairns@health.ny.gov
Jennifer Duhon (2019*) Present	Other	Millipore Sigma	307-3897218 jennifer.duhon@sial.com
Matt Sica (2020) Absent	AB	ANAB, ANSI-ASQ National Accreditation Board	msica@anab.org
Dixie Marlin (2018*) Present	Other	Marlin Quality Management, LLC	513-309-3593 marlinquality@gmail.com
Gil Dichter (2018*) Absent	Other	IDEXX Water	207-556-4687 gil-dichter@idexx.com
Patrick Garrity (2019*) Present	AB	Kentucky DEP	502-319-4040 patrick.garrity@ky.gov
Michella Karapondo (2019*) Absent	Other	USEPA	513-569-7141 karapondo.michella@epa.gov
Fred Anderson (2020*) Present	Other	Advanced Analytical Solutions, LLC	Fred@advancedqc.com
Jennifer Mullins (2020*) Present	Lab	Upper Occoquan Service Authority	jennifer.mullins@uosa.org
Scott Haas (2020*) Absent	FSMO	Environmental Testing, Inc.	405-401-7344 shaas@etilab.com

Attachment B

Action Items – TNI PT Executive Committee

	Action Item	Who	Date Added	Expected Completion	Actual Completion
257	Email to SOP Subcommittee regarding clarification on how limit updates due to issues should be addressed.	Maria		12/12/14	Maria prepared it, but is waiting for a chair for this subcommittee. 4/20/17: Ilona will look back in minutes to find the original issue and send to Maria.
295	Moved from Backburner: PTPA Evaluation Checklist needs to be updated prior to next round of evaluations. (Originally discussed 8/6/13)	Shawn Ilona		9/15/17	In Progress (will use 2009 TNI Standards and current SSAS Standards)
349	Review LAMS/FoPT Table Differences document. Provide comments by email and next meeting.	ALL	4/20/17	4/25/17	In Progress WET is still being reviewed.
352	Moved from Backburner (originally discussed 2/20/14) : 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. Patrick commented that it would make sense to look at changes to pass/fail rates 6 months after new limits are	All	2/20/14	TBD (see #350)	In Progress – Update of SOP 4-101

	Action Item	Who	Date Added	Expected Completion	Actual Completion
	effective. This possible addition to procedures should be evaluated when updating the limit acceptance SOP.				
353	Discuss possible procedural changes to how limits are updated. Maria talk to SOP Subcommittee. (Need to look at PT database implications.)	All		TBD	In Progress – Update of SOP 4-101
358	Send request to SOP subcommittee to consider what happens when ARA's are rescinded. There is no formal process.	Maria	6-29-17	7/19/17	
361	Analyte Code changes needed in LAMS. (TKN0	Maria Dan Hickman	7/20/17	9/30/17	Waiting for NELAP AC meeting.
362	Setup meeting with NELAP AC to discuss issue on differences between LAMS and the FoPT tables.	Maria	7/20/17	9/30/17	Waiting for NELAP AC 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.				
364	Review combined Evaluation SOP and send comments to Maria by 9/8/17.	All	8/24/17	9/8/17	Complete
365	Compile PTPEC's comments and send to Evaluation Workgroup by 9/12/17.	Maria	8/24/17	9/12/17	Complete
366	Discuss attending NEFAP AC meeting with Lynn to talk about procedures for	Maria	8/24/17	9/1/17	In Progress

	Action Item	Who	Date Added	Expected Completion	Actual Completion
	making changes to tables.				
367	Provide copy of Cyanide request from Mike Delaney to committee.	Maria	8/24/17	9/1/17	Complete
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	
369	Send copy of Combined Evaluation SOP and comments to committee remembers and request final comments.	Maria	9/21/17	9/22/17	
370	Inform Rami of decision to move WET PT issue to PT Expert Committee.	Maria	9/21/17	9/28/17	

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 updated in November.	Ongoing 2017	
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	

Concerns About the Evaluation of Whole Effluent Toxicity (WET) Data Sets in Proficiency Testing (PT) or Discharge Monitoring Report – Quality Assurance Testing (DMR-QA) Studies

Background of the Issue

A concern recently brought to the attention of the Whole Effluent Toxicity (WET) Expert Committee was regarding how Proficiency Testing Providers (PTPs) analyze WET DMR-QA / PT data given the limited number of WET labs in general compared to analytical labs, that the limited number of WET labs are divided further among three different PTPs, and that some WET tests are specialty tests with even fewer participants. The concern is that with limited datasets (e.g., ≤ 5 labs participating), how statistically reliable and robust are the final acceptable and out of range values. So the question is, can we improve the study process (i.e., the reporting, usage, and evaluation of statistical data in PT or DMR-QA studies) to increase comparability of, confidence in, and reliability of, the final study results?

The WET Expert Committee desires to work with the Proficiency Testing Provider Executive Committee (PTPEC) towards the goal of producing more statistically reliable, robust, and useful WET data in DMR-QA / PT studies for all the stakeholders involved.

The Primary Purpose of PT Testing with WET Test Methods

The TNI WET Expert Committee believes that the primary purpose of EPA's DMR-QA testing program (and potentially other PT testing programs) is to compare the WET toxicity testing results among laboratories as one way of demonstrating competency. Using this approach the results from one laboratory are assessed in comparison to the results of all the other participating laboratories. Therefore, given that all the data from participating laboratories will be combined and compared to each other, it is imperative that the WET test methods (and endpoints) are standardized among those laboratories to have the best and most useful data possible. There are some specific test method requirements associated with DMR-QA testing and there should be additional detail added to the WET methods which WET Expert Committee has identified and recommended in a white paper titled, "The Primary Purpose of Whole Effluent Toxicity (WET) Proficiency Testing (PT) or Discharge Monitoring Report – Quality Assurance Testing (DMR-QA)". In this document, we recommended reporting the IC25 value only, and not the NOEC value for chronic WET studies. Using point estimate endpoints for both the acute (i.e., LC50 values) and short-term chronic (i.e., IC25 values) test method in the DMR-QA / PT program is the most appropriate and consistent means for evaluating the results of toxicity tests in DMR-QA / PT studies when the test protocols are standardized. If WET laboratories obtain acceptable results participating in the DMR-QA / PT tests under strictly controlled conditions, we are confident that the laboratory can also produce reliable data in whatever conditions their clients' permits require.

Concerns about WET PT / DMR-QA Studies

- Accuracy does not apply to WET testing as it would apply to a solution of metals or pesticides for analytical chemistry testing. A unit of toxicity cannot be gravimetrically delivered to PT / DMR-QA sample vials. Study "true" or assigned values and acceptance limits are derived from participating laboratory data.
- There are small statistical data sets in PT / DMR-QA studies for some WET test methods due to 1) very few participating WET laboratories ($n \leq 5$) and 2) the number of participating WET laboratories being divided into still smaller data sets among multiple PT Providers. The smaller data sets could inadvertently result in less confidence in the statistical determination of the "true" or assigned value (and acceptance limits) for a given WET PT / DMR-QA WET test.
- Toxicity endpoints (i.e., LC50 & IC25) can be greatly affected by test variables such as test organism age, test organism source, and other test conditions as listed on the attached, "Table of Toxicity Test

Conditions for WET PTs (WET DMR-QAs)". While the published methods are often presumed to be standardized, variations of test conditions not addressed in the WET test method protocols among participating laboratories in PT / DMR-QA studies are not reported to PTPs so deviations from a standardized test design cannot be accounted for as a potential factor affecting study results. Such unaccounted for interlaboratory variability can impair the statistical assessment of study results and any resultant corrective. Below are two examples that could result in increased variability in WET PT / DMRQA study results:

- Test organism age: Participating labs in DMR-QA / PT studies conducting Method 2000 can use *Pimephales promelas* (fathead minnows) with an age range from 1 to 14 days old (per the EPA method). We are familiar with studies that showed fish age / size affected organism sensitivity to toxicants. Variability in PT / DMR-QA study results due to test organism age cannot be assessed because the age of test organisms is not required to be reported by participating labs. Other DMR-QA / PT test methods have test organism age requirements too, for example *C. dubia*, must be < 24-h old.
- Test organism source: Laboratories that do not culture their own test organisms purchase test organisms from one or more vendors. Other laboratories culture and use their own test organisms, but may occasionally supplement their test organisms from vendors. Because of inadequately understood natural selection pressures on test organisms cultured by vendors or laboratories, the robustness and response of test organisms cannot be entirely controlled by WET laboratories or vendors. Thus, this is another potential source of variability affecting organism response and sensitivity which cannot be assessed because labs are not required to report where they obtain their organisms.

The WET Expert Committee would like to work with the PTP Executive Committee and other interested stakeholders in formulating a solution to this problem as we understand it. Below are some potential options for consideration. Hopefully by working together, we can identify others options and settle on a preferred choice.

Suggested Solutions and Various Options for Consideration

- The WET Expert Committee has identified various options that the PTPs could implement as solutions for increasing the sample size and the confidence in study results. We recognize that there would be substantial challenges to implement some of these solutions / options; however, we feel that it is necessary to present all options. The options are as follows:
 - Option 1: Have PTPs cooperate to use the same toxicant at the same concentration for each study, in order to pool study results to increase the sample size that determines pass/fail for the study round.
 - Option 2: Have PTPs combine data across years for tests with the same toxicant to increase the sample size.
 - Option 3: PT / DMR-QA WET testing for some methods (those with limited participants) would only be available from one PT provider for that year (it could rotate each year among the PTPs). This would increase the size of the small WET data sets without compromising the integrity of the toxicants.
- The source of cultured test organisms used by laboratories should be reported for PT / DMR-QA studies so that both intra-laboratory and inter-laboratory variability can be accounted for during statistical evaluation of WET data sets. The identification of the source of cultured test organisms should be assigned a generic identification name so that the confidential business information of the vendor / test laboratory which cultured the test organisms will be protected from potential commercial harm.
- Eliminate completely or defer PT studies for methods with very small ($n \leq 5$) numbers of participating labs to other similar technology studies. The uncertainty of the "true" values and acceptance limits for such studies limit or negate their use in assessing a lab's ability to perform the method. Participation

in other PT studies using the same technology per TNI 2009 V1M1-2009, section 5.1.1 is one possible solution. Additionally, there are currently many other WET methods/species that are not included (e.g., Trout Method 2019.0 and the freshwater algal method, *Selenastrum* Method 1003.0) in which PT studies and laboratory performance are assessed through additional means (e.g., reference toxicant tests, on-site audits, etc.) Currently, the DMR-QA / PT study test methods for *C. variegatus* (sheepshead minnows) have a small number of participants and we recommend that PT studies for these methods be either eliminated or deferred to a DMR-QA / PT study test method which is a similar technology.

- Have PTPs normalize final study results so the study data is more useful for stakeholders in evaluating study results and for determining any resultant corrective actions. The PTPs should report the identity of the toxicant, toxicant concentration in mass per volume, and the nominal test concentrations on a mass per volume basis in addition to the current practice of reporting the nominal test concentrations as percent effluent.
- Require that the participants of WET PT / DMR-QA studies report the test conditions used in the study for each test method tested as identified on the attached, “Table of Toxicity Test Conditions for WET PTs (WET DMR-QAs)”, so that any deviations from a test method’s standardized DMR-QA / PT study test design can be identified as a test method deviation and as a source of variability.

In addition, please refer to the previous recommendations we identified in “*The Primary Purpose of Whole Effluent (WET) Proficiency Testing (PT) or Discharge Monitoring Report – Quality Assurance Testing (DMR-QA)*” on the importance of ensuring standardized test conditions among participating laboratories in PT / DMR-QA studies and on eliminating the NOEC value and reporting the IC25 value only for short-term chronic WET test methods. Using point estimate endpoints for both the acute (i.e., LC50 values) and short-term chronic (i.e., IC25 values) test methods in the DMR-QA / PT program is the most appropriate means for evaluating the results of toxicity tests in DMR-QA / PT studies when the test protocols are standardized. For the list of recommended standardized test conditions, see attached, “Table of Toxicity Test Conditions for WET PTs (WET DMR-QAs)” for list of standardized test conditions.

Summary

The WET Expert Committee desires to work with the PTPEC (and other interested stakeholders) towards the goal of producing more statistically reliable, robust, and useful WET data in DMR-QA / PT studies for all the stakeholders involved. The TNI WET Expert Committee believes that the options and suggestions above, along with other options that PTPEC might offer, provide various solutions for increasing the confidence in the determination of final results in WET PT / DMR-QA studies. If these options or suggestions are applied to WET PT / DMR-QA studies, the quality and usefulness of the data generated in PT / DMR-QA studies for WET testing will improve. In the future, as the quality and usefulness of the data generated in WET PT / DMR-QA studies improves, additional improvements to the WET PT / DMR-QA study process may be identified and recommended by the TNI WET Expert Committee (i.e., the adoption of variability limits).

Table of Toxicity Test Conditions for WET PTs (WET DMR-QAs)

Analyte Code	Test Code	EPA Test Mtd	Test Organism	Test Type / Duration	Chamber Size (minimum)	Solution Volume (minimum)	# Organisms per Chamber	# Reps (minimum)	Organism Age	Temp.
754, 755	13, 14	2000.0	<i>Pimephales promelas</i>	48-hr static non-renewal	250 ml	200 ml	10	2	1-14 days, 24 hr range in age	25°C
808, 810, 812, 814	15, 16	1000.0	<i>Pimephales promelas</i>	7-d static renewal (renew daily)	500 ml	250 ml	10	4	<24-h ^a	25°C
764, 765	19, 20	2002.0	<i>Ceriodaphnia dubia</i>	48-hr static non-renewal	30 ml	15 ml	5	4	< 24 hr	25°C
767, 768, 770, 771	21, 22	1002.0	<i>Ceriodaphnia dubia</i>	3-brood study (until ≥60% surviving control females have 3 broods, max 8 d)	30 ml	15 ml	1	10	<24-h, 8-hr range in age	25°C
788	32	2021.0	<i>Daphnia magna</i>	48-hr static non-renewal	30 ml	25 ml	5	4	< 24 hrs	25°C
794	38	2021.0	<i>Daphnia pulex</i>	48-hr static non-renewal	30 ml	25 ml	5	4	< 24 hrs	25°C
798	42	2007.0	<i>Mysidopsis bahia</i>	48-hr static non-renewal	250 ml	200 ml	10	2	1-5 days, 24 hr range in age	25°C
816, 818	43	1007.0	<i>Mysidopsis bahia</i>	7-d static renewal (renew daily)	8 oz / 400 ml	150 ml	5	8	7 days	26°C
803	44	2006.0	<i>Menidia beryllina</i>	48-h static non-renewal	250 ml	200 ml	10	2	9-14 days, 24 hr range in age	25°C
825, 826	45	1006.0	<i>Menidia beryllina</i>	7-d static renewal (renew daily)	600 – 1,000 ml	500-750 ml	10	4	7-11 days, 24 hr range in age	25°C
804	46	2004.0	<i>Cyprinodon variegatus</i>	48-h static non-renewal	250 ml	200 ml	10	2	1-14 days, 24 hr range in age	25°C
820, 822	47	1004.0	<i>Cyprinodon variegatus</i>	7-d static renewal (renew daily)	600 – 1,000 ml	500-750 ml	10	4	< 24-hrs	25°C

^aif shipped then < 48-h within a 24 hr range in age

NB: the dilution series for all tests should be 0, 6.25, 12.5, 25, 50, and 100%; the dilution water for the freshwater studies should be moderately hard water with a hardness range of 80-100 mg/L and an alkalinity range of 57-64 mg/L, while the dilution water for the saltwater studies should have a salinity of 25 ppt