Whole Effluent Toxicity Testing Expert Committee Meeting Summary June 15, 2016 1 pm Eastern

1. Welcome, Roll Call, Approval of Minutes and Announcements

Rami welcomed everyone to the meeting. Minutes of the May 18, 2016, meeting were approved, with Rami abstaining due to his absence from that session. Attendance is recorded in Attachment 1, below.

2. Assessment Forum Planning

The draft PowerPoint presentation was circulated before this meeting, with request for comments to be sent to Ginger. Also, <u>please send audit findings to her for the Assessment Forum discussions.</u>

Beth with Laura Davis are still gathering photos for use in the presentation. Several committee members indicated that they would send their comments directly to Ginger. The final PowerPoint will be reviewed at our July 20 committee meeting, and then turned over to the Assessment Forum group for final review before conference.

Ginger asked for someone to revise the state checklist from Virginia, to sanitize it so that it becomes more a "generic example." Pete and Rami agreed to work on this, with some help from Lynn. The other handout will be the WET Glossary, and Linda offered to provide additional comments on that, sent to Rami. Both of these documents are attached to the email delivering these minutes.

3. PTPEC Interactions

The "NOEC >100%" discussion continues (Footnote 6 in the WET FoPT table.) The PTPEC Chair seeks to resolve the issue before the July 31 publication date for the updated FoPT table, but EPA sources have not yet responded to Rami's inquiry about why this seemingly erroneous option might have been included in the original table, and there may be unexpected consequences from removing it, until thorough investigation has been performed. General consensus is that its use was to signify "no toxicity."

Participants indicated that multiple individuals within EPA have been contacted, and the DMRQA Coordinator, Brian Krausz, has asked for specific comments to address the criteria in updated EPA guidance.

Lynn explained that the possibility of the WET Expert Committee continuing to serve in an advisory capacity in place of the FoPT subcommittee of PTPEC gained TNI Board attention at the June 8 Board of Directors meeting. TNI's Policy Committee was charged with providing a recommendation to the Board about whether such cross-program activity can be allowed to continue, and that recommendation may reach the Board in time for its July meeting. The most likely outcome is that a separate FoPT subcommittee will be constituted within the PT program, under PTPEC.

4. WET as a Resource for Method Refinements and Recommendations

Shortly before this meeting, Rami provided draft responses to the submitted questions discussed over the past few committee meetings. (See Attachment

See Attachment 3 for the questions submitted. Rami asks for committee members to respond directly to him and address:

- 1) Personal comfort level with the concept of providing such a response, and
- 2) Specifics of the draft response, especially about implied mandatory or non-mandatory practices according to language in the chronic and acute manuals, and also to add material that may be appropriate.

5. Conference Agenda

The Assessment Forum presenters are planning to use any excess time in the afternoon committee session to continue the discussion of audit findings and appropriate corrective actions.

Very few committee members will be present at conference, but the Assessment Forum should have good attendance from labs and assessors as well as those generally interested in the topic.

Participants agreed that the afternoon committee session could begin with a 20-to-30 minute presentation about the WET Expert Committee and its activities, which Ginger will deliver, and then pick up with the audit findings from the morning's Forum session. Lynn will provide a draft presentation to Rami that will form the basis of the committee presentation.

6. Revising V1M7

It still looks like this activity may begin in the fall.

There was no new business. Ginger moved and Steve seconded that the meeting be adjourned. There were no objections.

7. Next Meeting

The WET Expert Committee will meet again on Wednesday, July 20, 2016, at 1 pm Eastern. Teleconference information and an agenda will be circulated in advance of the meeting. Materials for conference will get final reviews and the question responses will be discussed.

Attachment 1

Committee Membership

	Ter			Term		
Member	Affiliation	Email	Phone	Category	Expiration	Present
Rami Naddy (Chair)	TRE Env. Strat. LLC	naddyrb.tre@gmail.com	970-416-0916	Lab	Feb. 2018	Yes
Ginger Briggs	Bio-Analytical Laboratories	bioanalytical@wildblue.net	318-745-2772	Lab	Feb. 2018	Yes
Pete De Lisle (Vice Chair)	Coastal Bioanalysts Inc.	pfd@coastalbio.com	804-694-8285	Lab	Feb. 2018	Yes
Steven Rewa	Environmental Resources Management	steven.rewa@erm.com	616-738-7324	Lab	Feb. 2018	Yes
Chris Burbage	Hampton Roads Sanitation District	cburbage@hrsd.com	757-355-5013	Lab	Feb. 2018	No
Chris Pasch	Alan Plummer Associates, Inc.	cpasch@apaienv.com	512-687-2162	Other	Feb. 2018	No
Teresa Norberg-King	USEPA	norberg-king.teresa@epa.gov	218-529-5163	Other	Feb. 2018	Yes
Elizabeth West	LA DEQ LELAP	elizabeth.west@la.gov	318-676-7457	AB	Feb. 2018	No
Amy Hackman	Penn. Dept. Environ. Protection	ahackman@pa.gov	717-346-8209	АВ	Feb. 2018	No
Michele Potter	New Jersey Dept of Environ Protect.	Michele.Potter@dep.nj.gov	609 984-3870	АВ	Feb. 2018	No
Michael Pfeil	Texas Comm. Environ. Quality	Michael.pfeil@tceq.texas.gov	512-239-4592	АВ	Feb. 2018	Yes
Kari Fleming	WI DNR	kari.fleming@wisconsin.gov	608-267-7663	AB	Dec. 2017	Yes
Associate Members						
Kevin Dischler	Element Materials Technology	Kevin.dischler@element.com	337-443-4010	Lab (Assoc.)		Yes
Monica Eues	CK Associates	Monica.eues@c-ka.com	225-923-6946	Lab (Assoc.)		Yes
Barbara Escobar	Pima County RWRD, CRAO Laboratory	Barbara.escobar@pima.gov	520-724-6052	Lab (Assoc.)		No

Robert Kelley	ETT Environmental Inc	bobkelley@ettenvironmental.co m	864-877-6942	Lab (Assoc.)		No
Brian Krausz	USEPA	krausz.brian@epa.gov	202-564-3069	Other (EPA)		No
Jennifer Loudon	Raritan Township Municipal Utilities Authority	JLoudon@rtmua.com	908-787-7453 x 19	Lab (Assoc.)		No
Vel Rey Lozano	USEPA Region 8	Lozano.VelRey@epa.gov	303-312-6128	Other (EPA)		No
Robert Martino	QC Laboratories	rmartino@qclaboratories.com	267-699-0103	Lab (Assoc.)		No
Jamie Mitchell	Hampton Roads Sanitation District	jmitchell@hrsd.com	757-460-4220	Lab (Assoc.)		No
Linda Nemeth	Northwestern Aquatic Sciences	Inemeth@tds.net	541-265-7225	Lab (Assoc.)		Yes
Mark O'Neil	Environmental Enterprises USA, Inc.	moneil@eeusa.com	800-966-2788	Lab (Assoc.)		Yes
Marilyn O'Neill	Nautilus Environmental	Marilyn@ nautilusenvironmental.com)	858-587-7333	Lab (Assoc.)		No
John Overbey	American Interplex Corp.	joverbey@americaninterplex.co m	501-224-5060, ext. 209	Lab (Assoc.)		Yes
Joe Pardue	Pro2Serve	Parduegjjr@oro.doe.gov	423-404-4117	Other		No
Peter M Paulos	Atkins Environmental Toxicology Lab	Peter.Paulos@atkinsglobal.com	713-292-9023	Lab (Assoc.)		No
Katie Payne	Nautilus Environmental	katie@ nautilusenvironmental.com	858-587-7333 ext. 212	Lab (Assoc.)		No
Beth Thompson	Shealy Consulting	bthompson@ shealyconsulting.net	803-582-7996	Lab (Assoc.)		Yes
Tom Widera	ERA	twidera@eraqc.com	303-463-3536	Other		No
Program Administrator						
Lynn Bradley	TNI	Lynn.Bradley@nelac-institute.org	540-885-5736			Yes
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Attachment 2

Action Items

	Action/Activity	Responsible Person(s)	Anticipated Completion	Comments
1	WET session for Assessment Forum – determine content and presentation format for one 60- minute & one 90-minute block	Ginger/Elizabeth w/ Rami, Teresa & Katie/Marilyn to work w/ Barbara & LASEC	August 2016 conference in Orange County, CA	Draft powerpoint available for comments June 15. Still need audit findings for discussion
2	Review questions distributed with minutes, for discussion at April 20 meeting	All members	April 20 meeting	See discussion summarized in April 20 and May 18 minutes
3	Review V1M7 for needed revisions	Steve – DOC John – chemistry issues Beth, Linda, others	Ongoing	Formal revision cannot yet begin, likely until fall.
4	Develop checklist for WET assessors, possibly for use with Assessment Forum	Rami, Pete, Lynn	By July 20 committee meeting	Modify Virginia WET- specific checklist to become generic
5	Review discussion of questions, Item 6 in April 20 minutes	All members	May 18 meeting	Revision complete, minutes approved May 18, 2016
6	Review and provide comments on draft powerpoint presentation	All members	No later than July15 for 7/20 meeting and final version	
7	Review draft response to questions, as provided by Rami, and submit comments	All members	No later than July15 for 7/20 meeting and final version	
8	Submit audit findings for discussion at WET Assessment Forum	All members	No later than July15 for 7/20 meeting and final version	
9	Prepare draft presentation for WET committee session at conference	Lynn to prepare draft, Rami to finalize; Ginger will deliver at conference	By July 20 meeting	
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Attachment 3 - Draft Response to Questions (please send comments to Rami)

Questions

1) Is randomization necessary or can the lab justify conducting the test without randomization?

While there is nothing in the TNI Volume 1, Module 7 (Quality Systems for Toxicity Testing) to assist us in addressing this question, there are several instances in EPA's chronic WET guidance discussing the importance and requirement of randomizing both the addition of test organisms to test chambers and the placement of test chambers. The pertinent language describing this in the subsections are included below.

Per USEPA chronic WET guidance9.4.4.1: "Statistical independence among observations is a critical assumption in all statistical analysis of toxicity data. One of the best ways to insure independence is to properly follow rigorous randomization procedures. Randomization techniques should be employed at the start of the test, including the randomization of the placement of test organisms in the test chambers and randomization of the test chamber location within the array of chambers.

(FHM) 11.3.4.5.1 All test chambers must be randomized using a template for randomization or by using a table of random numbers. Test chambers are randomized once at the beginning of the test (see Subsection 11.10.2.3). When using templates, a number of different templates should be prepared, so that the same template is not used for every test. Randomization procedures must be documented with daily records.

11.10.2.3 Randomize the position of test chambers at the beginning of the test (see Appendix A). Maintain the chambers in this configuration throughout the test.

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13.10.2.2 the test chambers must be randomly assigned to a board using a template (Figure 1) or by using random numbers (see Appendix A). Randomizing the position of test chambers as described in figure 1 (or equivalent) will assist in assigning test organisms using blocking by known parentage (Subsection 13.102.4). A number of different templates should be prepared, and the template used for each test should be identified on the data sheet. The same template must not be used for every test.

2) Should passing or failing tests be considered invalid without demonstration of randomization or if they are not adhering to other items in the Method?

Specific questions like this are outside of the responsibility of the TNI WET expert committee and should be brought specifically to those State representatives that have jurisdiction (or in some cases clients) that are in a position to qualify the data. However, given that the specific wording in answering question #1 above includes 'must' phrases and not 'should' phrases, some individuals on this committee feel that WET tests that were not randomly set up are invalid for reporting purposes.

3) Should passing or failing tests be considered invalid without demonstration adherence to the specific items identified in the Summary of Test Conditions tables in the Method? [Randomization is not included the Summary of Test Conditions tables]

Again, specific questions like this are outside of the responsibility of the TNI WET expert committee and should be brought specifically to those State representatives that have jurisdiction (or the client's in question so they know what the testing lab is doing or not doing) that are in a position to qualify the data. However, some recommendations are to pay attention to the specific wording regarding what is required for not. For example using the summary of test conditions for the *C. dubia* chronic study below are the required conditions for this test (unless specified). Other items listed on the table are recommended.

- Static-renewal
- Test temperature of 25±1°C (<u>recommended</u>) with a maximum differential of 3°C (<u>required</u>)

- Daily renewal
- Age: <24-h old within an 8-h period
- 1 organism per test cup, placement assigned using blocking by known parentage
- 10 replicates
- 5 test concentrations & control (while this is required some states perform testing with only one
 effluent concentration and a control so this requirement is state specific)
- Test duration: when 60% or more of the surviving control females have had three broods (maximum test duration of 8 days)
- Endpoints: survival and reproduction
- Test acceptability criteria (TAC): ≥80% survival of control organisms, ≥ 15 average neonates per surviving control females, ≥60% of surviving control females have had three broods
- A minimum of 3 effluent samples per test with a maximum holding time of 36 h before first use, see Subsection 8.5.4 for more info.

While this committee cannot make a definitive ruling on whether a test should be considered valid or not, we do feel that tests should follow the specific requirements of the guidance.

4) The average reproduction in all passing tests in all dilutions and control water is always (observation in over 20 tests in over 3 years) between 22 neonates/adult and 25neonates/adult. Is that a concern and if so how should it be addressed?

Again, specific questions like this are outside of the responsibility of the TNI WET expert committee and should be brought specifically to those State representatives that have jurisdiction (or the client's in question so they know what the testing lab is doing or not doing) that are in a position to qualify the data. However, it does seem odd that the reproduction for 20 different tests over a three year period has average reproduction in all dilutions and control waters would be between 22 and 25 neonates. Some possible suggestions would be to perform a split test with an additional laboratory to compare results and to send blind (unknown) samples to the laboratory for testing in duplicate.

5) Should an official audit identify either 1) or 4) as a concern?

Again while this is outside of our specific jurisdiction we can only offer suggestions regarding any potential course of action. If there are specific things that make you wonder about the quality of the data being produced then you may first want to talk to the laboratory and raise those questions. If that does not resolve the issues and you feel like these are significant issues then bringing those issues to the client and state representatives would be a potential next step. If those do not result in addressing these issues to your satisfaction, then you may want to consider switching laboratories (or make a recommendation to switch laboratories) to one that follows the WET guidance for these specific tests.