Summary of the NELAP Accreditation Council Meeting January 4, 2021

1. Welcome and Introductions

Kristin welcomed everyone to the call. Attendance is noted in Attachment 1. Tom Weiss of Illinois introduced the new program manager at IL EPA, Susan Besaw. The minutes of November 2 were approved unanimously with David abstaining.

2. WET Analyst Demonstration of Competency Concept

In January of 2020, Rami Naddy. Chair of TNI's WET Expert Committee, discussed with the Council that committee's efforts to identify a concept for individual analyst Demonstrations of Competency (DOCs) in WET labs. He spoke about the current widely varying assessment requirements of the NELAP ABs for analyst DOCs, complicated by the fact that most WET analyses are performed by a team of analysts that varies, while noting that the laboratory DOCs (both initial and ongoing) are consistently assessed to the specifications in the WET Method Manuals. At that time, the WET committee was close to reaching agreement on the requirement for one or two Standard Reference Tests (SRTs) but felt it important to make certain that all NELAP ABs would find that acceptable. Rami was asked to present something in writing, and agreed to return with a concept paper, so that AB representatives would have something definitive to review and provide feedback about. See the minutes of January 6, 2020, posted on the NELAP AC web page for details of that meeting.

Rami brought that concept paper with its two attachments to this meeting and presented the concept to the Council verbally while referring to the documentation provided (see Attachment 2 below for the documents). Pete De Lisle, the WET Vice Chair, also participated in the discussion. The final concept as approved by the WET committee proposes one SRT plus documented training in the various tasks that comprise a WET test, and a table of potential test and species combinations that could substitute for other test/species combinations was created as well. This table shows how a chronic test would substitute for an acute test with most species, and that there are also certain organisms that are sufficiently similar to allow substitution for DOC purposes. Participants discussed some aspects of these attachments, and Rami requested feedback on the general concept of the analyst performing one SRT with documented training on individual tasks that would be performed by the analyst as well as how best to incorporate the information in the attachments into the standard – as examples or as prescriptive requirements or just suggestions, or other options. AB representatives agreed to take these documents back to the assessors and gather feedback which may be emailed or presented when the WET representatives return.

Looking ahead at the Council's schedule, Rami and Pete will be asked to return for the April 5 meeting to hopefully get general agreement and approval of the concept (ensuring that no veto vote would be cast on the revised standard module), and to discuss any revisions to improve the concept. Kristin thanked Rami and Pete for their efforts and their presentation.

3. Renewal Recommendation for New York

The NY Evaluation Team provided a recommendation for continued recognition for NY ELAP, with requested status updates on avoiding assessment backlogs after catching up from the pandemic suspension of assessments which nearly all ABs experienced. These updates will go to the Lead Evaluator for review with team members.

Carl moved and Cathy seconded that the recommendation be accepted, and with every AB present, approval was unanimous with NY abstaining.

4. Conference Attendance

For AB representatives and our EPA Liaison who will not be able to register for conference, a one-time access for the Council meeting on Thursday morning, January 28, will be arranged. Carl, Victoria and Kim requested phone-only access and Eric requested WebEx access. The conference organizer has been notified and will provide access information when the time comes.

5. V2M1 Draft Standard

Since there will be no meeting on February 1, the 90-day comment period for this module would expire before the Council actually has an opportunity to discuss it among themselves, so Kristin will request a 30-day extension, making formal comments due on March 30. AB representatives should review the module and comment individually, but there may be common issues where a comment from the Council itself would be more meaningful, so the March 1 meeting will be devoted to discussion of this Draft Standard.

6. SIR Discussions

Lynn asked that SIR voters please vote on the outstanding SIRs, especially the remaining "needs discussion" votes for SIR 387. Participants expressed concern about the lost-but-resurrected SIR 132 being outdated and no longer relevant, but upon learning that the SIR Subcommittee of LASEC determined that it is relevant, those objections were withdrawn. One SIR, number 378, needs longer discussion but the meeting time was expired, so that SIR will be discussed at the March meeting, after the Draft Standard discussion.

7. New Business

Travis noted that ORELAP has implemented the 2016 Standard effective January 1, 2021, and requested that the AB listing be revised to reflect this. An updated status report has been provided for the Board of Directors.

8. Next Meeting

The next meeting of the NELAP AC will be the conference session on Thursday, January 28, 2021, at 11:45 am Eastern. The designated AB representatives will be panelists for this virtual meeting (i.e., able to speak during the session) while all others will be muted but may ask questions or make comments using the Q&A feature of WebEx.

The regularly scheduled February 1, 2021 teleconference meeting will not be held. The next teleconference meeting is Monday, March 1, 2021 at 1:30 pm Eastern. The agenda and documents will be provided in advance; this meeting will address the V2M1 Draft Standard, SIR 378, and likely one renewal recommendation.

Attachment 1

STATE	REPRESENTATIVE	PRESENT
-L	Carl Kircher	Yes
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NELAP AC	Lynn Bradley	Yes
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California	Christine Sotelo Christine.Sotelo@waterboards.ca.gov	No
Guests:	Rami Naddy, TRE Environmental Strategies, Inc., Chair of WET Expert Committee, <u>naddyrb.tre@gmail.com</u> Pete De Lisle, Coastal Bioanalysts, Inc. Vice Chair of WET Expert	
	Committee, <u>pfd@coastalbio.com</u>	
	Daniel Vang and Amy Suggett, KDHE	

Attachment 2 - WET Concept Paper with two attachments

Analyst Demonstration of Competency (DOC) WETT

V1M7 1.6.2.2

Background (not in the standard)

Demonstration of competency for analysts (both initial and continuous) is a challenging topic for toxicity tests (including WETT) because of some of the inherent aspects of toxicity tests and how they are performed. This is specifically for <u>analyst</u> DOCs and not <u>Laboratory</u> DOCs which are in section prior to this section. Some of these challenges are listed below.

- Test durations for WET / toxicity methods are typically anywhere from 24 hours to 7 days (for typical WET studies; other toxicity tests can go even longer).
- Laboratory staff work as a team when performing tests, and therefore multiple analysts may work on a single test (i.e., one analyst does not typically conduct an entire test from start to finish but may work on it a few times while it is up).
- Many of the steps in toxicity tests are very similar / are almost exactly the same from test to test / day to day, with the main difference being the use of a different organism (i.e., detector) which can allow for cross-training as provided in Attachment #1.
- Some methods (e.g., sediment tests) allow for using a shorter standard reference toxicity (SRT) test (e.g., 96-hours) using water only exposures compared to the test method itself (e.g., 10-day sediment toxicity tests).
- Auditors typically have expertise in chemical but less so in biological test methods
- There are typically differences in requirements for WET / toxicity testing methods across the country by different accrediting/regulatory bodies.

Text below is to be incorporated into the draft standard

Because there are challenges that are inherent to toxicity / WET testing (different from chemistry), the WET Expert Committee is providing <u>minimum requirements</u> for analyst DOCs associated with individual WET / toxicity testing laboratories.

There are certain general concepts that will apply to any WET / toxicity testing laboratory training approach for analyst training:

- The laboratory must have a detailed written approach for analyst training including initial and continuing DOCs.
 - This approach must be well documented and must make it understandable for anyone that has to document the analyst training.
 - The laboratory can include how it handles cross-training between methods of similar technology.
- An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision as defined in the laboratory's training procedure until a satisfactory initial analyst DOC is completed.
- Where the analyst performs the toxicity test from start to finish, that analyst must perform and document all major tasks of the test method they perform
 - The WET Expert Committee has provided a list of tasks that may be included for analyst training (Attachment #2)
 - The WET Expert Committee has provided a table illustrating a list of tests that can be used in substitution of other tests (Attachment #1). For instance, training on a fathead minnow chronic WET test (primary test) should cover analyst training on a fathead minnow acute WET test (secondary test), a mysid chronic for a mysid acute, etc. because of the similar / same tasks conducted in each test.
 - Flow-through tests or other specialty tests would have to be documented separately due to differences in technology.
- Where the analyst does not perform the entire toxicity test, task-based performance must be demonstrated and documented for each step in the test they perform

- Cross-training of methods are allowable as long as the secondary method has the same tasks as the primary method (e.g., fathead chronic test training covering training for acute fathead tests with similar technology (static or static-renewal).
 - Training on acute tests cannot substitute for training on chronic tests
 - although similar steps / tasks within an acute test may be used for dual taskbased (cross) training purposes for a chronic test of similar technology e.g., prep of test solutions, sample renewal, etc., i.e., similar technology items.
- Each analyst must be involved in the performance of at least 1 acceptable SRT for each primary test method they have competency or for the specific tasks.
 - SRTs are likely to be performed as a team unless the analyst performs the entire test
 - Some DOCs may be performed prior to SRT documentation as defined by the laboratory (see note).
- iDOCs for sediment toxicity tests (or similar tests) where the SRT does not have a similar test duration (as defined by the method) must include acceptable performance on one SRT and assessment of laboratory controls, or simulated controls, as appropriate (e.g., ≥ 90% recovery of organisms after at least 1-h in sediment tests, measurement of weights or lengths, etc., that produce acceptable control performance criteria).

This section is intended to be a note in this section of the standard:

- While work on SRTs is the preferred approach when documenting analyst's DOCs, some analyst DOCs can be documented prior to working on SRTs for WET.
 - Most analyst training consists of training on cultures, demo tests, job shadowing, tests with constant supervision, etc. in which some aspects of tests may be documented quantitatively (e.g., counting of the number of *C. dubia* neonates). Therefore, laboratories may use these non-SRT situations to serve and document analyst training, especially for analyst iDOCs.

Attachment #1: Demonstration of Capability – Toxicity Testing Substitution List of Common WET tests

Primary methods listed below (more common methods) can substitute for secondary methods to the right because they include the same analyst skillset / similar technology, i.e., can satisfy DOC for secondary methods	1000.0 Chronic Fathead	1002.0 Chronic Ceriodaphnia	1003.0 Chronic Algae	1004.0 Chronic Sheepshead	1007.0 Chronic Mysid	2000.0 Acute Fathead	2002.0 Acute Ceriodaphnia	2004.0 Acute Sheepshead	2007.0 Acute Mysid	2019.0 Acute Trout	2021.0 Acute <i>D. pulex /</i> magna
1000.0 Chronic Fathead	Х					Х					
1002.0 Chronic Ceriodaphnia		Х									
1003.0 Chronic Algae			Х								
1004.0 Chronic Sheepshead				Х				Х			
1007.0 Chronic Mysid					х				Х		
2000.1 Acute Fathead						Х					
2002.0 Acute Ceriodaphnia							Х				Х
2004.0 Acute Sheepshead								Х			
2019.0 Acute Trout										Х	
2021.0 Acute <i>D.</i> pulex / magna							Х				Х

Note: For a freshwater method to satisfy a saltwater method the analyst must also work on at least one saltwater DOC (besides the initial freshwater DOC). Other less frequent test species (topsmelt, silversides, shiner, etc.) may also be substituted with a more common test method, as appropriate (i.e., similar method, species, etc.). Other experimental design differences (static vs static-renewal vs flow-through) should be taken into consideration when training. Additional training may also include reading SOPs, nuances of tests, publications, etc.

Attachment #2: Steps for Individual DOC for Revised WET Module

Sample handling

- Proper temp upon receipt
- Holding time criterion met
- Support chemistry measurements
 - Calibration and use of meters (as appropriate)
 - pH, DO, conductivity, alkalinity, total residual chlorine, hardness, and/or salinity measurements

Initiation of test

- acclimation
- randomization
- collection of organisms
- age of organisms
- handling of organisms
- organism acceptability/selection
- prep of test dilutions
- test temperature
- food prep and addition
- dilution water prep and use
- light cycle and intensity (appropriate for the test species)

Renewal of test dilutions (Maintenance phase)

- temperature
- counting organisms
- organism observations
- feeding
- transfer of organisms
- food prep and addition
- prep of test dilutions

Ending of test

- transfer and counting organisms
- observations of organisms
- drying and weighing (as appropriate)
- balance calibration and use
- data gathering (i.e., weights, neonate production, survival data, etc.)
- QC data / bench sheets
- test acceptability criteria

Statistical analyses of data

- Crunch data (survival data, reproduction data, weight data)
- Determine appropriate endpoints for method (e.g., LC50s, IC25s, NOEC, NOAEC, etc.)
- Confirm that study meets test acceptability criteria
- Reporting

Footnote: all the requirements in Module 2 apply to this section (i.e., reading of appropriate SOPs, test methods, and any other organism / test specific information