# Whole Effluent Toxicity Testing Expert Committee Meeting Summary December 18, 2019 1:00 pm Eastern

# 1. Welcome and Announcements

Rami welcomed everyone to the meeting. Attendance is recorded in Attachment 1, below. The minutes of November 20 were approved with Sarah and John abstaining due to their absence from the meeting.

The usual "updates" were skipped for this meeting, in order to continue with the momentum of discussions about the revised V1M7.

# 2. Revising the Standard

As promised in the November minutes, Rami, Pete and Lynn met by teleconference with Michele, Amy and also Dwayne Burkholder of PA to try to reach tentative agreement on a protocol to address initial demonstrations of competency for individual analysts. The first conversation resulted in bullets identifying the various tasks that would need to be demonstrated successfully once training is completed (see Attachment 2). This list was considered suitable for training purposes, but not really "auditable", so the second call focused on a prose version that can become the basis for the language of the standard. These drafts were shared with the announcement for this WET committee meeting.

After Rami's explanation of the process above, Pete noted that there remain three questions:

- 1. Task definition level -- general vs. specific list
- 2. Number of SRTs needed (1-2 instead of 5?)
- 3. Cross-applicability of SRTs

As a working reference, the edited version of the draft prose that is eventually intended to become part of the standard as it stood at the end of this meeting is in Attachment 3, below.

#### **Task Definition**

The broad question of how much detail to include in the standard and whether it should be a specific list within the module or an appendix to the module remains unsettled. An appendix would be enforceable, as part of the standard.

#### Number of SRTs

There was general acceptance of the proposal to have two SRTs as the baseline for IDOC. Discussion points around this were that "successful" IDOC would mean that the test was consistent with lab control charts, and that a second test is useful to show an additional event over time. Note that this number is for individual IDOC only, that the requirement for five SRTs for the laboratory IDOC is unchanged.

It was noted that an analyst may still work "under close supervision" before all SRT/DOC testing is completed, and that there is language in the Chemistry and Microbiology modules about this process that could be used for WET (V1M4 1.6.1 and 5.2.1). Exactly how to specify when the entire method must be completed or when only specific tasks within the method must be performed (e.g., for weekend staff) remains to be addressed as well as some way to distinguish tests performed "under close supervision" from those performed after acceptable IDOCs are

completed (perhaps requiring two sets of initials to signify supervision). These tests are in addition to the "normal" monthly SRTs performed by the lab.

# **Cross-applicability**

Participants easily reached consensus that a chronic method fulfills all task DOC requirements for an acute method with the same species. However, the possibility of cross-species applicability, and how various similar organisms might be grouped, remains unsettled. It seems that for methods which address more than one species, performing the method with one species should satisfy DOC requirements for all species to which the method applies.

Discussion noted that analysts are not required to be taxonomists, but typically use "what's in the tank". Perhaps the method as written will be adequate to determine cross-applicability in many cases. It was also noted that if the analyst mishandles the organisms (of whatever species), the controls will show errors in meeting test acceptability criteria.

#### Wrap-Up

Several more minor edits were made, that appear in the version in Attachment 3.

The revised chemistry QC language will be covered at the January meeting. The draft IDOC language in Attachment 3 refers to language in the Chemistry module (V1M4) for the chemistry support measurements, but that language is not applicable for items such as dissolved oxygen, temperature and pH. Rami had asked Michele and John to address this in an updated version of the chemistry QC language, and that draft is included as Attachment 4 below. This is the version to be discussed in January.

# 3. Next Meeting

The next teleconference meeting will be on Wednesday, January 15, 2020, at 1 pm Eastern. An agenda and any needed documents will be sent in advance. Rami will not be available so Pete will chair the meeting.

# **WET Expert Committee Membership**

				Term			
Member	Affiliation	Email		Category	Expiration	Present	
Ginger Briggs	Bio-Analytical Laboratories	bal@bioanalyticallabs.com		Lab	Dec. 2020 (2)	Yes	
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Lynn Bradley	TNI Program Administrator	Lynn.Bradley@nelac-institute.org			Yes

# Steps for Individual DOC for Revised WET Module -- Tentative draft of discussion, 12/4/19

<u>REQUIREMENT for Individual DOC</u>: Two observed and approved performances of each step for each analyst plus successfully completing at least one reference toxicity test or one DMRQA or PT study (discuss whether this is per method or whether this is per similar technology – i.e., the observations)

#### Sample handling

- Proper temp at test initiation
- Support chemistry measurements (see QC for these elsewhere)
- Calibration and use of meters (as appropriate, prefer 4 LCS each type of meter)
- pH, DO, Conductivity, Alkalinity, Total Residual Chlorine, and Hardness measurements

# Initiation of test

- acclimation
- randomization
- collection of organism
- age of organisms
- addition of organisms
- organism acceptability/selection
- prep of test dilutions
- temperature
- food prep and addition
- dilution water prep and use

### 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)
- QC data / bench sheets
- · test acceptability criteria

# Statistical analyses of data

- Performed for appropriate endpoints for method (e.g., LC50s, IC25s, NOEC, NOAEC, etc.)
- · Confirm that study meets test acceptability criteria

# Analyst Initial Demonstration of Capability (IDOC) WETT – draft as of end of 12/18/19 meeting

V1M7 1.6.2.2

Following an in-depth training program, analyst performance shall be demonstrated by performing at least 2 standard reference toxicant tests (SRT) for each method, species and endpoint. An IDOC using a chronic test can serve as an acute SRT with the same species but not vice versa.

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 DOC is completed.

Where the analyst performs the test from start to finish, that analyst must perform all tasks of the test method (e.g., test initiation, chemical analysis, daily transfers/renewals, endpoint determination and statistical analysis as appropriate).

Where the analyst does not perform the entire WET test from test initiation to test termination/ evaluation, including daily transfers/renewals, task-based performance must be demonstrated. For the tasks which each analyst performs, an initial demonstration of capability must include at least 2 standard reference toxicant tests (SRTs). Analysts must demonstrate capability by performing their assigned tasks during the analysis of at least 2 SRTs. Analyst specific tasks may include, but are not limited to: suitability selection of organisms, preparation of dilutions, test initiation, daily organism transfer and counting, sample renewal, feeding, test termination result determination and statistical evaluation.

# **IDOC for Chemical Analyses of WETT**

Take wording from V1M4 1.6.2.2 (chemistry IDOC)

#### Ongoing Demonstrations of Capability (CDOC) WETT

Section 1.6.3 (include wording from V1M4, section 1.6.3.1)

This ongoing demonstration may include one of the following:

- Where the analyst performs the test from start to finish, that analyst must perform all tasks of the test method (i.e.; test initiation, chemical analysis, daily transfers/renewals, endpoint determination and statistical analysis).
- 2. Where the analyst performs the test from start to finish, acceptable results for a blind proficiency test sample or sample set, as required by the program, for target organisms in each field of accreditation.
- 3. Where the analyst does not perform the entire WET test from test initiation to test termination/ evaluation, including daily transfers/renewals, task-based performance must be demonstrated. For the tasks which each analyst performs, an initial demonstration of capability must include at least 2 standard reference toxicant tests (SRTs). Analysts must demonstrate capability by performing their assigned tasks during the analysis of at least 2 SRTs. Analyst specific tasks include, but are not limited to: suitability of organism, preparation of dilutions, test initiation, daily organism transfer and counting, sample renewal, feeding, test termination result determination and statistical evaluation.

#### Ongoing Demonstrations of Capability for Chemical Analyses of WETT

Include wording from V1M4 1.6.3.1 and 1.6.3.2

# Amended Chemistry Language for V1M7 - December 18, 2019 (additional text in red, below)

Instruments used for routine measurements of chemical and physical parameters such as pH, DO, temperature, conductivity, salinity, alkalinity and hardness must be calibrated and verified according to the instrument manufacturer's procedures and/or as indicated in the general section on quality assurance of each referenced test method.

Unless otherwise noted by a mandated method or by regulation, chemical, and physical tests, in toxicity testing are supporting parameters to help aid in the interpretation of toxicity results. As these are support measurements, only the calibration requirements specified in the applicable reference methods apply. Performing matrix spiking, duplicate analysis, and quality control charting of such results is not required during the performance of these tests unless more stringent standards are mandated by a separate State or Federal program.

Documentation of the calibration is required for all support measurements. The preparation of calibration solutions and the identity of the solutions utilized shall also be recorded. The details of initial instrument calibration procedures shall be included the quality system documentation. Sufficient raw data records shall be retained to permit reconstruction of the initial instrument calibration (e. g. calibration date, method, instrument, analysis date, analyte name, analysts initial or signature, concentration and response, calibration curve or response factor, or unique equation or coefficient used to reduce instrument responses to concentration). Sample results shall be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program. All initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or from a different lot. Commercially prepared standards shall be traceable to a national standard when commercially available. Criteria for the acceptance of an initial instrument calibration shall be established (e.g. correlation coefficient or relative percent difference). The criteria used shall be appropriate to the calibration technique employed.

Separate Demonstration of Capabilities (DOCs) for the chemistry support measurements are not required when included with the overall training and WET DOC. Specific States may require accreditation for the support measurements. If accreditation is required for the chemistry support measurements, the laboratory must follow the requirements listed in the chemistry module.