

**SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING**

APRIL 2, 2015

The Committee held a conference call on Thursday, April 2, 2015, at 2:00 pm EST. Chair Richard Burrows led the meeting.

1 – Roll call

Richard Burrows, Test America (Lab)	Present
Francoise Chauvin, NYC DEP (Lab)	Present
Brooke Connor (Other)	Present
Gale Warren, NYSDOH (Accreditation Body)	Absent
Colin Wright, Florida DEP (Lab)	Present
JD Gentry, ESC (Lab)	Present
Nancy Grams, Advanced Earth Technologists, Inc. (Other)	Absent
Anand Mudambi, USEPA (Other)	Present
John Phillips, Ford Motor Co. (Other)	Present
Scott Siders, IL DEP (Accreditation Body)	Absent
Gary Ward, OR DPH (Accreditation Body)	Absent
Ken Jackson, Program Administrator	Absent

Associate Committee Members present: Reed Jeffery; Valerie Slaven.

2 – Previous Minutes

It was moved by Francoise and seconded by Anand to approve the minutes of March 20, 2015. All were in favor.

3 – Calibration Interim Standard Editorial Changes

Reed had volunteered to go through the standard and had provided editorial changes. On Steve Arms recommendation he had removed the words “choose to” in several places. Steve had also questioned the use of “sequentially” in **1.7.1.1 d i**. Richard explained it meant removing the lowest level and then removing the next lowest level of calibration standards. After discussion, the committee decided to leave “sequentially” in, but clarify the sentence as follows: “The laboratory may sequentially remove standard concentrations from the lowest level and/or the highest level of the calibration curve...”. In **1.7.1.1 d ii**, the committee agreed with Steve’s suggestion and changed “concentration” to “calibration level”. Section **1.7.1.1 d v a**, on Steve’s suggestion, was re-worded to use the active voice, and on Anand’s suggestion a similar change was made in the following subsection **b**, as well as the addition of “and” as Steve had suggested. Further corrections to use the active voice were made in **1.7.1.1 j**, and **o**).

This finalized the Calibration Interim standard.

4 – Response to Comments on the Detection/Quantitation Working Draft Standard

The following were considered by Valerie.

1.5.2 *“The use and definition of the Limit of Detection (LOD) terminology in the TNI standard differs from the same terminology used in the Department of Defense Quality Systems Manual. While Limit of Detection (LOD) is used in both programs the meaning is very different. As used in the TNI Standard and since this section of the Standard refers to the EPA method for determining MDLs, we would like to recommend that TNI continue to use the MDL terminology in the Standard. Use of LOD with different meanings in two programs that are integral in many environmental laboratories will lead to a great deal of confusion in the laboratories and with their clients.”* The committee had already decided to adopt MDL or DL and Richard had already made the change to MDL.

1.5.2.1 *“The sentence of section 1.5.2.1, “if the protocol for determining the LOD is not specified the laboratory shall document how LODs are to be determined” is not appropriate. The laboratory is required to document how LODs are determined regardless of whether or not the protocol is required by the method.”* It was agreed to re-word this to state “the protocol for determining the MDL shall be documented by the laboratory”.

1.5.2.1 *“Statement from 2009 standard should be included specifying that if the lab is not reporting at levels below the LOQ then the LOD study is not required.”* The committee confirmed it was the intention to remove this statement, because an initial LOD was required.

1.5.2.1 *“If a mandated test method or applicable regulation includes protocols for determining detection limits, these shall be followed. The word “these” can imply “herein”, which would potentially cause a lab to do the opposite of what is being said. This needs clarification.”* Valerie recommended this should be reworded to say the method procedures shall be followed. It was agreed to change “these” to “they”.

1.5.2.1 *“If no grandfathering language is considered, then the language must be made CLEAR that all analyses must have an established LOD. Laboratories will read this from the perspective of the previous standard and will not realize that the sentence from 2009 is not in the Standard any more and therefore additional clarification is required.”* It was agreed there can be no grandfathering. The committee did not think additional clarification was required.

1.5.2.1 *“There are a number of requirements that apply to calculation of the LOQ that should apply to the calculation of the LOD. Text should be added to address these points:*

o Need to represent current operations

o Need to include the entire analytical process

o Minimum number of samples and batch

o Requirement to analyze samples over multiple days; and

o Requirement to analyze samples for multiple instruments and combine results to calculate one limit”

Richard agreed these could be added, but thought it would be simpler if the MDL procedure was required. Otherwise he agreed this list should be added. On discussion it was agreed to list the

minimum requirements, and it should be added that the procedure in CFR Part 136 is one way to meet the requirements.

1.5.2.1 d) *“Verification of the LOD should be performed more frequently than annually – perhaps quarterly as is already required in other programs (DOD, TRRP). Verification procedures should be addressed in the standard. A suggestion for verification would be the analysis of a spiked reagent blank for each matrix of interest quarterly at a level 2-3 times the LOD. Requirements for successful verification of the LOD would be all analytes detected (meeting all requirements for detection by the method) at a level greater than the LOD. It might be wise to impose an upper recover limit (200%, 300%?) as well.”* Valerie thought these were well-addressed in the LOQ section, but Francoise said people may be worried they will have to do something extra for the LOD requirements. On discussion it was agreed to make no changes.

1.5.2.1 d) *(This) “indicates the LOD is needed for both technology and method, but does not indicate instrument as it does now. Doing an LOD by instrument/ method is the most importance (method defines matrix and analytes)”*. There was reluctance to put “instrument” in, because people may misinterpret the requirement to be that they must do an LOD for each instrument.

1.5.2.1 b) *“Section 1.5.2.1.b says that the lab needs to use a quality system matrix. This means that the lab would need a separate LOD for Aqueous and Drinking Water matrices. Do you really mean this?”* Colin made the point it is permissible to use distilled water as either matrix.

1.5.2.1 d) *“In Section 1.5.2.1.d why are you requiring an LOD verification by both technology and method? Why not just by method? And what about by instrument?”* Valerie said it is because different technologies can be performed by the same method. Instrument is addressed in LOQ.

1.5.2.2 *“Section 1.5.2.2 is setting DW labs up to fail to require LOQs that are required to be at least 3X the LOD.”* Richard said it was decided to leave in the 3x requirement, because if you pass what is in the method you will not have a problem with this. Francoise agreed with the concern, because the current drinking water methods require the EPA MDL and MRL set by regulation. Then the LOQ has to be at the MRL. Laboratories are not free to “start from the MDL” and set the MRL at 3 times the MDL. The concern then is that the MDL will be too close to the MRL. Francoise felt this would come up for methods where regulation requires reporting down to a level that does not provide the quality we would like to see. She offered to look for a specific example and get back to the committee.

1.5.2.2 *“The second sentence of Section 1.5.2.2 should read “and LOQ study is required...” And the sentence should end at “analyte.” The sentence “except: An LOQ is not required...” should just be its own stand-alone sentence.”* The committee discussed this proposed editorial change. They reworded it but not as the commenter suggested.

1.5.2.2 *“The text does not address the implications of mandated methods and regulations similar to the approach used in section 1.5.2.1. Since mandated methods and regulations can impact the use and development of the LOQ the inclusion of such language will be important and is recommended.”* Richard added the language.

The following were considered by John

1.5.2.2.1.b) *“The section states that data up to 2 years old can be used in the calculation. This is arbitrary. The data used in the calculation needs to be representative of current operations. The text needs to provide a procedure for determining whether data is representative of current conditions and the text regarding data up to 2 years of age needs to be deleted.”* John agreed two years is arbitrary, but it is a time period which is reasonable and allows a sufficient amount of data to be accumulated to perform the assessment. This section also requires that the data used be compliant with requirements and representative of current operations.

1.5.2.2.1.c) The commenter suggested rearranging the text for clarity, and the committee agreed.

1.5.2.2.1.c) ii *“The section should be re-worded to read “The concentration of the LOQ must be at least 3X the established LOD.” Although I feel this requirement is not going to be able to be met for some DW methods.”* The committee agreed to the revised wording.

1.5.2.2.1.a) *“The second sentence should be re-worded to be “Both preparation and analysis of these samples must occur in at least 3 batches on 3 separate days on each instrument.” Are these separate batches and days preparation and analysis batches and days? See comment #17”* it was decided not to make the change. John agreed the intent is to have three separate preparations and analyses, but they did not need to be processed on different instruments on different days.

1.5.2.2.1.a) *“The intent of the “Notes” is unclear. It is suggested that the second note be revised (expanded) to state, “... to verify the LOQ, such as by evaluating the percent recovery of the same spiked blanks against established criteria.”, or add other clarifying language deemed appropriate by the committee.”* The committee clarified the language.

1.5.2.2.1.c) *“Section 1.5.2.2.1.c will not be approved if the LOQ only requires a qualitative verification. This is a show stopper for me as an AB. And, the only examples included in this section are organic examples. The committee needs to do a better job of including all analyses including metals, non-metals, etc.”* Satisfying this comment would involve a major change in the procedure, and the committee decided to see what happens in the voting stage.

1.5.2.2.2 *“The header of section 1.5.2.2.2 should be “Verification of the LOQ” not “Continuing Verification of the LOQ””.* John argued that “continuing” had been used throughout the document. He said the committee may want to change "continuing" to "on-going". But otherwise he would consider this non-persuasive.

The remaining comments were deferred until the next call.

5 – Next Call

The committee would meet next on April 10 at noon EDT.

5 – Adjournment

The meeting was adjourned at 3:30 pm EST.