SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

APRIL 10, 2015

The Committee held a conference call on Friday, April 10, 2015, at 12:00 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)	Absent
Gale Warren, NYSDOH (Accreditation Body)	Present
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	Present

Associate Committee Members present: Eric Davis; Arthur Denny; Tom Dziedzic; Reed Jeffery; Diana Shannon; Valerie Slaven

2 – Previous Minutes

It was moved by John and seconded by Francoise to approve the minutes of March 13, 2015. All were in favor. In discussing the minutes of April 2, Francoise asked for language clarification in the committee's discussion of a voter's comment on section 1.5.2.2 of the Interim Standard. With this change made, it was moved by Anand and seconded by John to approve those minutes. All were in favor.

3 – Introduction of New Committee Member

Richard welcomed Valerie Slaven as a new Committee Member. Ken said he would ask Bob Wyeth to officially appoint her. She would then be a voting member by the next call.

4- Comments on the MDL Procedure

During the March 20 conference call, the committee had been asked to vote by e-mail on 6 comments that had been proposed to be sent to EPA. The results of the vote from all 11 Committee Members were as follows:

Comment 1: 10 Yes; 1 Abstained

Comment 2: 9 yes; 2 Abstained
Comment 3: 7 Yes; 3 No; 1 Abstained
Comment 4: 11 Yes
Comment 5. 11 Yes

Richard said he had also incorporated editorial comments that had been circulated by Scott and Colin. Francoise pointed out a conflict in the section on quarterly verification. The first sentence specified two spiked blanks per instrument, and the second sentence said the minimum number of analyses per instrument would be one. Anand said it was important to stress in the comment to EPA that each instrument was being checked. A proposed wording change to clarify the requirement was discussed and agreed.

5 – Consideration of Comments on the Detection/QuantitationWorking Draft Standard

Richard had updated the language in the draft standard to incorporate some of the comments discussed during the previous call. He showed a bulleted list of requirements if a method of determining detection limit was used other than the EPA-proposed MDL in Part 136. Richard had also added language to **1.5.2.1 c** to clarify what types of test do not require a detection limit determination (based on the current LCS language).

Discussion continued on the comments considered by Valerie and John.

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". Otherwise he would consider this non-persuasive. On further review of this comment, the committee decided to leave the wording as it is.

1.5.2.2.2 *"The term "quarter" needs to be defined in section 1.5.2.2.2, such as at least once every 3 months. And, why per technology and not method and/or instrument?"* John felt "quarter" was good, allowing more flexibility in the timing. It was agreed the comment was non-persuasive.

1.5.2.2.2 *"The qualitative verification is not acceptable. And, I am not aware of any method requirements for verification of the LOQ, so why list that this must meet method criteria? The lab must be required to establish acceptance criteria that meets or exceeds the needs of the client (including regulatory requirements)."* It was decided to add wording to the initial verification section 1.5.2.2.1 that the LOQ is a spiking level and must all method, client and regulatory requirements. Then it would not need to be repeated in 1.5.2.2.2.

1.5.2.2.2 *"Continuing verification of the LOQ – again, without imposing recovery requirements I don't believe that the document truly addresses verification. Also, quarterly verification appears to be too infrequent. For both initial and continuing verification of the LOQ, I would suggest a 50-150% recovery limit be imposed on all analyte recoveries on a blank reagent sample spiked at the LOQ and carried through the entire analytical procedure with limited allowances made for a small percentage of poor performing compounds (up to a number or a percentage of analytes verified and only for those designated as poor performing compounds) Analysis should be more frequent that quarterly, perhaps at a minimum monthly or perhaps weekly to account for instrument changes over time. Failure of the LOQ*

standard would require maintenance and recalibration or an elevation of the LOQ to a value that meets verification requirements." This was similar to the preceding comment.

1.5.2.2.2 *"If a continuing LOQ verification test does not meet this requirement, the laboratory must take corrective action. Corrective action shall be either (i) raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study, or (ii) correcting method or instrument performance and repeating the verification test one time. In the event of second failure of a quarterly verification sample, the quantitation limit must be raised and the initial study repeated."* This was again a similar comment.

1.5.2.2.2. *"First sentence. Please include each method and instrument so it is clear that the verification is done by method and not just for each instrument. It is assumed that the verification must be done for each prep method as well as the instrumental method. Since the word technology is used in other parts of these sections, some may interpret this as only requiring verification for an analyte, by one technology (GC/MS) and not for each method (differing conditions, columns and preps). One statement in this section repated to the application may help to simply these statements. E.g; Application of verification or determination of LOD and LOQ is by quality system matrix, instrument, method (maybe better to say laboratory procedure), analyte."* Richard said separate methods may be required in many cases, but there may be two methods similar enough instrumentally that the same quantitation verification could be used. Richard inserted "method" in the place of "technology", with a note to check with existing standard language.

1.5.2.2.2 *"The text does not address the situation where only one of three instruments does not meet the qualitative identification criteria required. This may occur and requirements should be set if these circumstances (where one of several instruments does not perform similarly to the other instruments) occur."* It was agreed the text was satisfactory as written.

1.5.2.2.2 *"As stated above, delete the language regarding the use of data up to 2 years of age and provide text that will guide a lab on how to determine if data are representative of current conditions."* John suggested explaining why 2 years was chosen.

1.5.2.2.2 *"See the comment mentioned above. If the laboratory does not receive a sample to analyze in a given quality system matrix for years, what is the minimum frequency with which an initial LOQ should be verified? Rather than quarterly, I recommend annually in this case. Please consider adding an additional Section (e) to this section, to read as follows: "If samples are not being analyzed for each accredited quality system matrix, technology/method, and analyte quarterly, then perform the continuing LOQ verification at least annually for that matrix, technology/method, and analyte (on at least one instrument).""* Richard pointed out laboratories are not required to do verifications in any quarter they do not analyze any samples, but if just two per year, they must still do the minimum of 7. John suggested adding that if they stop dong the analysis and then start up again they must do the initial verification, and perhaps a statement to that effect should be added. It was agreed a minimum of 7 samples per year would be required.

1.5.2.2.3 *"Documentation: Same comment as above."* It was unclear which comment was being referred to.

1.5.2.2.3 *"This section requires the calculation of the percent recovery for each LOQ verification. The mean and standard deviation of the recoveries are also to be documented. There are no criteria on this or actions to take. This requirement appears to have no added value to the quality of the results produced. The section goes on to state that these data can be provided to clients upon request, used for project specific precision and bias determinations of measurement uncertainty statements. The laboratories are already generating measurement uncertainty values which serve this purpose. This should be listed as an item that labs need to have a process to generate the information if requested (it should be able to be compiled based on the data records) without making it a required piece of all documentation without clear expectations and value."* Richard disagreed that most laboratories are generating uncertainty data at the quantitation limit.

The remaining comments were deferred until the next call.

5 – Next Call

The committee would meet next on April 24.

5 – Adjournment

The meeting was adjourned at 1:00 pm EST.