SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

MAY 10, 2013

The Committee held a conference call on Friday, May 10, 2013, at 2:00 pm EDT.

1 – Roll call

Richard Burrows, Test America (Lab)	Present
Francoise Chauvin, NYC DEP (Lab)	Present
Brooke Connor, USGS (Other)	Present
Dan Dickinson, NYSDOH (Accreditation Body)	Present
Tim Fitzpatrick, Florida DEP (Lab)	Absent
Nancy Grams, Advanced Earth Technologists, Inc. (Other)	Present
Anand Mudambi, USEPA (Other)	Absent
John Phillips, Ford Motor Co., (Other)	Present
Lee Wolf, Columbia Analytical Services (Lab)	Present
Ken Jackson, Program Administrator	Present

Associate Committee Members present: Stephen Arpie; Lynn Boysen; Arthur Denny; Mandi Edwards; Chung-Rei Mao; Diana Shannon; Gary Ward

2 – Previous Minutes

It was moved by John and seconded by Brooke to approve the April 26 minutes. All were in favor except Francoise who abstained. The minutes were therefore approved.

3 – Proposed Webinar

Ken said Jerry Parr had suggested 2-3 webinars could be presented in June/July to help prepare people for the San Antonio meeting. It seemed most appropriate for those committees in the process of standards development to present them. The committee agreed to do this, and Brooke volunteered to take the lead. Richard offered to give her the slides he would be presenting at the upcoming FSEA meeting in Florida. Ken said he expected the Consensus Standards Development Executive Committee to be discussing this during its next conference call.

4 – Method Detection Limit Procedure

The Committee worked through the latest draft of the MDL document that Richard had edited after the last call.

Richard asked the committee to reconsider if the quantitation limit should be in the document, because EPA might find this controversial. He thought the MDL document need only address spiking levels. Then the quantitation limit concept could be reserved for the TNI standard, which would refer back to this MDL procedure. Tim had supported this by e-mail, and John agreed. He thought it would be good to get quantitation in earlier, but it complicated things in detection. It would not be possible in the standard to use solely the spike level used for the MDL for determining quantitation, so this would require more work. Brooke indicated she wanted to see false negative control addressed somewhere. Richard said if quantitation limit is removed, the control at the spike level would have to be able to qualitatively identify. Getting a control above the MDL would be part of the quantitation limit piece that would be taken out of this MDL procedure and put into the TNI standard later on. In response to a question by Nancy, Richard said the only criterion for the spike would be positive results you could qualitatively identify. Nancy said there are three criteria: the spike has to be at least twice the initial estimate of MDL; there must be qualitative identification criteria; and a positive number must be produced. She suggested it could be made a requirement that the spiking concentration must be above the calculated MDL. John said the lower you set the spike value, the greater is the chance that you will be unable to verify the MDL, especially if recoveries are low. Nancy was concerned that laboratories might use a spiking concentration that would be inappropriate for the LOQ. Richard presented the situation where a laboratory runs spikes and poor-performing analytes with high RSD (>30%) would give a calculated MDL that is higher than the spiking level. Dan said spiking level needs to have some variance; not too much and not too little. Users need to know when they have a spiking level that is relevant, and only some EPA methods address this. Richard suggested putting a range in, and 30% RSD would be where the MDL would go greater than the spiking level. Richard asked the rest of the Committee members if they also favored removing LLOQ. Dan said adding language for LLOQ complicates the method, it would be difficult to explain its inclusion to users of the method, and it might be a problem getting it accepted for CWA analytes. Francoise also agreed to remove it. This prompted the following motion proposed by Nancy and seconded by Francoise:

> "Completely remove the term LLOQ and all references to the term from the draft procedure ".

All were in favor and the motion was therefore approved. Richard added that the absent Committee Members, Tim and Anand, had already indicated by e-mail that they favored this LLOQ removal.

Richard then led the committee through his proposed edits resulting from discussion during the previous conference call.

Section 6d. Richard had removed elevation of the spiking level to get results below the MDL. Otherwise there was an infinite loop. In the constant RSD range of the method (especially for poor-performing analytes) raising the spiking level would give a higher MDL, resulting in some results below the MDL. This would prompt raising the spiking

level again, which would raise the MDL more etc. More changes would be needed to reflect removal of the LLOQ.

Section 7a. The following statement would remain: "If more than 5% of the analytes in any individual spiked blank do not return positive numerical results that meet all method qualitative identification criteria then the spiking level must be raised and the MDL re-determined following the procedure in Sections 3 through 6." In response to a question by Brooke, Richard suggested the clarification that it means 5% of the analytes within one individual sample, and proposed changing the language to read "If more than 5% of the analytes within any individual spiked blank…" It was also agreed to add footnote # 3 to read "If the same analytes repeatedly fail the qualitative identification criteria, then the spiking level may need to be raised prior to the annual reassessment."

Section 7c. Richard said the 99% confidence interval was not properly explained, so he just referred back to the description of what is required for blanks in 6b; i.e., saying the value at which 1% of the blank results exceed the MDL_b. Boooke suggested rewording the first sentence to read "At least once per year calculate MDL_s and MDL_b from the accumulated results of 7a above." John said a laboratory that only does 2 per quarter should also include its initial ones. Rich agreed, saying it should be 2 years worth. The language was changed to: "At least once per year, re-calculate MDL_s and MDL_b from the collected spiked blank and un-spiked blank results using the equations in section 6 (Include data generated within the last 2 years. Include the initial MDL spikes if within two years)." Brooke pointed out it said use only data associated with samples that had been reported, and that could mean the laboratory could report MDL test samples on a run all by themselves. She said it should refer to normal methods passing QC. It was agreed to re-word to read: "Use only data associated with acceptable calibrations and batch QC.". There was a question on whether this would be auditable, but that would not be necessary in the MDL procedure. If the revised MDL procedure is accepted by EPA, the TNI standard will then be revised to reflect this, and it will be written to be auditable.

Next Steps

Richard said he would circulate a new draft of the document out with all reference to LLOQ taken out.

4 – Adjournment

The meeting was adjourned at 3:30 pm EDT. The next call was scheduled on May 31, 2:00 – 3:30 EDT.

LIST OF ACTION ITEMS TO BE COMPLETED

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
1	1/31/12	Add a definition of Reporting Limit or Quantitation limit to the standard.	Committee	Defer to quantitation sections
2	1/31/12	Continue to consider the concept of routine low-level QC in the standard.	Committee	Ongoing
3	1/31/12	Review Sections 1.5 and 1.6 of the 2009 standard's chemistry module to determine if current calibration requirements are adequate.	Committee	Not determined
4	1/31/12	Spacing of calibration standards will be considered for the guidance document.	Committee	Ongoing
5	2/17/12	Draft language for items in the calibration standard	Richard (Items 1 and 2) Anand (Item 3) Nancy (Item 5) Anand and Francoise (Item 6) Tim (Item 11)	Complete
6	2/17/12	Review Volume 1 Module 4 of the 2009 standard to identify any inconsistencies with the new language	All Committee Members	Complete
7	3/2/12	Add 1-2 sentences under the header 1.7.1 to explain that method is also included in calibration.	John	Complete
8	3/2/12	Clean up the parts of Section 1.7.1 referring to initial calibration and the parts referring to continuing calibration.	Committee	Complete
9	3/2/12	Add criteria for rejection of calibration standards to the guidance document.	Committee	Not determined
10	3/2/12	Add to the guidance document discussion of analysts using the most	Committee	Complete (done in the standard)

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		recent calibration rather than choosing which of 2 or more curves to use.		
11	3/2/12	Include a paragraph in the standard that addresses a single-point calibration for P/A testing.	Committee	Complete
12	3/30/12	Check the language does not contradict the existing standard regarding meeting method requirements vs. standard requirements for calibration.	Committee	Not determined
13	3/30/12	Sections 1.7.1.1 j and k will be modified further as a result of the March 30 discussions.	Anand and Francoise	Complete
14	3/30/12	Have the guidance document consider orders of magnitude in deciding the minimum number of standards, and keep a placeholder in Section 1.7.1 to refer to it.	Committee	Not determined
15	3/30/12	Add a definition for threshold testing	Committee	Not determined
16	3/30/12	Richard's, John's and Anand's March 30 changes will be incorporated into a single document.	Ken	Complete
17	5/4/12	Add to the guidance document that Section 1.7.1.1 (g) requirements should also be applicable for average response, when you evaluate with the RSD, and that is numerically the same value as the RSE.	Committee	Not determined
18	5/4/12	Discuss in the guidance	Committee	Not

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		document how to check quarterly (ref. Section 1.7.1.1 (j) (i).		determined
19	6/1/12	Bullet points will be drafted for a proposed PowerPoint presentation	Brooke, Richard, Tim, Francoise, Anand	Complete
20	6/1/12	Bullet points will be drafted for a slide that will describe the items to be discussed in the guidance document.	John	Complete
21	7/20/12	Explain in the guidance document the difference between MDL and the true detection limit.	Committee	Not determined
22	10/5/12	A note will be appended to the draft language of Section 1.7.1.1 n until the CCV language has been written.	Anand	Complete
23	11/2/12	For the MDL document, language will be drafted in the scope to limit the use.	John	Complete
24	11/2/12	In the Scope and Application section of the edited MDL document, the sentence "To accomplish this, the procedure was made device- or instrument-independent." Will be re-worked.	John	Complete
25	11/30/12	A letter will be drafted to the EPA OW, asking what kind of stakeholder composition they want ELAB to put together for reviewing the modified MDL procedure.	John	Complete
26	2/1/13	In the calibration standard Sections 1.7.1.1 (h) i and	Committee	Not determined

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		1.71.1 (k) i, revisit the suggestion to replace LOQ with “lowest concentration for which quantitative data are to be reported”if LOQ is re-defined.		
27	2/15/13	Check on travel funding for face-to-face meeting	Ken	Complete