SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

JUNE 28, 2013

The Committee held a conference call on Friday, June 28, 2013, at 2:00 pm EDT.

1 – Roll call

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

Associate Committee Members present: Lynn Boysen; Arthur Denny; Mandi Edwards; Andrew Friedrich; Diana Shannon; Elizabeth Turner; Gale Warren

2 – Previous Minutes

It was moved by John and seconded by Nancy to approve the June 14 minutes. The minutes were approved with all in favor except Tim who abstained.

3 – Method Detection Limit Procedure

The latest draft document (dated 6/14/13) was considered. In **Section** 8b (renumbered from 7c previously) it had been discussed if the requirement was too tight that if less than 2% of the method blank results were above the MDL it could be left unchanged. Brooke had provided data, and it was thought generally that 2% might be a little bit too tight. Richard suggested not going as high as 5%. John thought Brooke's data showed it to be pretty rare that 2% would be exceeded. However, Brooke said the data could be a bit misleading, since the MDL may be set at the higher value and the next year if it should be lower they do not necessarily lower it. Richard was concerned about the smaller laboratories with limited data; e.g., if you only have 50 method blanks, then 2% is just 1. John thought it interesting the statistically calculated limits were higher than the non-parametric approach when the 99 percentile was taken. Richard said the argument for not using 1% is that, if it is working perfectly, 50% would be greater than 1%. Therefore, it needs to be higher than that. John remarked that Brooke's data showed outlier blanks were discarded for the calculation, but not looking at the percentile which already eliminates the highest ones. After some discussion, it was agreed to use 3%.

Additional definitions were discussed next. Brooke and Tim volunteered to go through the document to see what definitions would be needed.

Footnote 4 defined what data should be included. Nancy's point was that you include everything unless you reject the samples that went along with it. It was agreed with Richard's suggested wording: *"All routine data should be included with the exception of batches that are rejected and the associated samples re-analyzed"*.

Under **Documentation** John had provided a list of items to be included. These were: number of method blanks; number of numeric blank results; value exceeded by 1% of blanks; standard deviation of blanks; spiking concentration; number of spikes; mean result for spikes; standard deviation of spike results; calculated MDL_b; calculated MDL_s; and MDL in use. Discussion followed on the difficulty of documenting all the values, especially for a multi-analyte method. Brooke questioned if all this needs to be documented in addition to the spreadsheet of results where the calculations are being done. Richard replied the list is what an auditor is going to want to look at. Although most laboratories may be able to recover all the data from their LIMS system, it could be very time-consuming for small laboratories without LIMS. Nancy argued that small laboratories have to get this information to make the calculation in the first place. Richard agreed, but thought it would be a lot of work for them to put in on a paper for an auditor to review. Brooke and John suggested getting rid of the list and just say they must be able to reconstruct the MDL. There was general agreement on this, and it would be stated *"Data and calculations used to establish the MDL must be able to be reconstructed upon request."*

This concluded editing the document. Richard said it would be presented in San Antonio. Meanwhile, he would send it out for final review, when comments from Chung-Rei and Nancy could be considered. The document could also be shown to some people who have not been involved in the process to get their comments. John had a final comment on Paragraph 6, which stated *"Evaluate the spiking level: If any result for any individual analyte from the spiked blank samples does not meet the method qualitative identification criteria and provide a positive numerical result, then the MDLs must be repeated at a higher spiking level."* He thought it should be moved earlier and Richard put it as a new paragraph 4.

4 – Calibration Standard Comments

The comments were in a spreadsheet that Richard had organized by section of the standard. This would facilitate grouping some of the similar comments and dealing with them together. Ken said the Procedures Governing Standards Development required every comment to be discussed publicly, and the best way to handle it in San Antonio might be to get public input on each comment or group of similar comments without taking the time to reach a decision; i.e., armed with this input, the committee could make the decision on a comment later. If there is not enough time in San Antonio to achieve this, a public webinar could follow to deal with the remainder. Brooke volunteered to make a start on further grouping comments that are the same or similar.

It was decided to make a start on looking at some of the comments. Jerry Parr had suggested verification with second source standards should be removed from the standard, but Richard thought there would then be complaints from others if that was done. There was a set of comments complaining about the requirement for measurement of relative error, but the committee felt strongly it needed to remain to avoid bad calibrations passing. A comment from Karl Kircher recommended changing the definition (formula) for %RSE, because it is not effective when the calibration does not increase markedly with increasing concentration. Tim pointed out in that case sensitivity is poor, and the quantitation test would probably fail. It was considered not feasible to just change the definition of RSE. Richard said perhaps an additional requirement could be inserted that instrument response must increase with changing concentration. Several commenters believed the standard was preventing the reporting of data between the MDL and RL. Tim pointed out, however, the standard only prevents reporting of quantitative data without qualification. It was agreed it needs to be re-worded. There were a number of comments objecting to the removal of standards from a calibration, even when the reasons are documented. The current TNI standard appears to be silent on this, so perhaps the proposed standard is more rigorous since it requires justification and documentation for dropped calibration points. Tim suggested it might be added that a laboratory's policy for dropping standards must comply with the data integrity section.

5 – Next Steps

Richard said at the next meeting the committee should discuss any final comments on the MDL document, so it can be completed ready for presentation in San Antonio. He asked Ken to send the remainder of the applications for committee membership to him, and then the present Committee Members could hold a separate meeting to discuss the applications.

6 – Adjournment

The meeting was adjourned at 3:20 pm EDT. The next call was scheduled on July 12, 2:00 – 3:30 EDT.

LIST OF ACTION ITEMS TO BE COMPLETED

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	Committee	Ongoing

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		concept of routine low-level QC in the standard.		
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 recent calibration rather than choosing which of 2 or more curves to use.	Committee	Complete (done in the standard)
11	3/2/12	Include a paragraph in the standard that addresses a	Committee	Complete

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		single-point calibration for P/A testing.		
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 document how to check quarterly (ref. Section 1.7.1.1 (j) (i).	Committee	Not determined
19	6/1/12	Bullet points will be drafted for a proposed	Brooke, Richard, Tim, Francoise, Anand	Complete

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		PowerPoint presentation		
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	12/14/12
26	2/1/13	In the calibration standard Sections 1.7.1.1 (h) i and 1.71.1 (k) i, revisit the suggestion to replace LOQ with "lowest concentration for which quantitative data are to be	Committee	Not determined

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		reported"if LOQ is re-defined.		
27	2/15/13	Check on travel funding for face-to-face meeting	Ken	Complete
28	6/14/13	Some existing data would be circulated to the committee to see if the 2% requirement in Section 7c of the MDL document was too tight.	Brooke	6/28/13
29	6/14/13	A list of items to be documented in the MDL procedure would be prepared.	John	6/28/13