SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

APRIL 12, 2013

The Committee held a conference call on Friday, April 12, 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)	Present
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: Arthur Denny; Diana Shannon; Chung-Rei Mao

2 – Previous Minutes

It was moved by Brooke and seconded by Lee to approve the March 28 minutes. All were in favor, except Tim and Francoise who abstained. The minutes were therefore approved. Ken said the previous minutes (March 15) had completed approval by e-mail.

3 – Method Detection Limit Procedure

The committee worked through the following discussion points, previously raised by Committee Members, that Richard had circulated by e-mail.

Should we have a LOQ at all or should we call it something else?

Richard said the reason for having it is a level is needed that can be described as a spiking level where there is freedom from false negatives. John had said QL should never be set below the L_D, where false negatives are evaluated. Our procedure protects against false negatives by ensuring that the QL would be above the LOD. It does not really attempt to home in on exactly where the LOD is or try to predict that. It says you run some spikes and establish that you have a low false negative rate and therefore you are above the L_D. He did not think it stops the laboratories from setting a higher LOQ based on a higher needed level of precision and bias as needed. Lee said it is necessary to differentiate between LOQ related to MDL and LOQ related to calibration, though they should be the same. John thought it might be called the method LOQ, to differentiate it from the

Product LOQ. Dan remarked that step 1 of the procedure is an estimate of the spiking level, and although it will be near the LOQ, it should not be called the LOQ which should have precision and accuracy information associated with it. Nancy suggested naming it the lower LOQ (LLOQ), to make that difference clear and avoid it being used as the real LOQ. Other suggestions included initial LOQ and estimate of the LOQ (LOQ_E). Tim emphasized the need to call it other than LOQ in determinations where you are working at a high concentration level (such as calcium). The LOQ may be at the lowest calibration standard which is much higher than the MDL and much higher than the estimate done in this MDL procedure. After a protracted discussion it was agreed to call it the LLOQ. Richard emphasized this is consistent with what the EPA OW is using, so it should be less confusing for laboratories. Nancy pointed out it should also be stated the laboratory can then set a higher LOQ based on regulatory requirements for precision and accuracy.

Seven Replicates Discussion

Nancy had suggested preparing a standard and decanting it into 7 bottles, but Richard questioned if that level of detail would be needed. Brooke agreed with the meaning of the language, but felt it needed to be clarified. Richard said he would re-draft the language before the next call.

Procedural Questions

Brooke had asked, since replicates have to be run on different instruments; e.g., the 2 quarterly spikes that must be run on every instrument, does it mean you can prepare two spikes and run them on all the instruments, or if you have 10 instruments must you prepare 20 spikes and run 2 on each instrument? Richard felt it should be allowed, at a minimum, to prepare just 2 samples, extract them, and then run them on different instruments. There was general agreement on this, but it was emphasized to say "at a minimum", because volatiles would need 2 on each instrument Lee suggested the language should include requiring them to be run under routine operating conditions. Richard agreed, but said it should be stated earlier because that applied to the entire operation.

Brooke had asked, in quarterly verifications, is there an out for failure of a few analytes, or does the laboratory need to go into spiking levels and LLOQs? She added that some semi-volatiles have very variable MDLs. Nancy added that the MDL procedure often doesn't even work, because the RSD remains very high. Richard said it should at least be detected. Dan asked how to mesh requirements in Sections 7a and 7d. The former requires quarterly measurements of 2 spikes, and all analytes must meet the criteria and return a positive result, but the latter requires the LOQ to be re-evaluated at least once per year, and to be raised if more than 1-2% of the spike results are less than the MDL. Richard responded that the Committee is trying to be a bit more liberal with the quarterly ones to avoid a laboratory having to change its MDLs every quarter, but to be more stringent with the yearly evaluations. However, Nancy commented it might be better to be more stringent at the beginning to avoid more problems later. Dan thought, since

there is a 2% limit annually, this probably will not be exceeded quarterly. It was agreed analytes must at least have to be detected, and it should be specified what to do if not detected; i.e, –raise the spiking level and re-spike for that quarter to verify it can be seen at a higher level. A note will be added that additional spikes will need to be run to ensure at least 7 by the end of the year . The LLOQ will change and then the MDL will change with this re-evaluation.

The yearly criterion for when a laboratory has to adjust its MDL says if the calculated MDL is within a factor of 2 of the existing one the MDL can be left as it is. Brooke had reported her laboratory had data to show this requirement is too tight and will cause MDLs to be constantly changing. This was especially so for inorganics, where the MDLs fluctuate up and down due to the blanks. Brooke suggested as long as the MDL does not go up it could be left where it was. There would still be protection against false positives if it goes down. Richard questioned if EPA would find it acceptable to allow it to go up but not down. There was discussion of using a statistical test, but Richard suggested staying with a simple multiplier. Nancy pointed out that changing the MDL forces the LLOQ to change, emphasizing the importance of making sure the LLOQ is not interpreted as the LOQ. Richard agreed if the MDL goes up it may be necessary to change the spiking level to make sure the laboratory is getting results above the MDL. Brooke pointed out the excessive cost of chemicals if laboratories have to keep changing the concentrations of their spiking solutions. Some Committee Members still favored keeping the criterion as a factor of 2 until Brooke guided the Committee to her laboratory's web page. She showed a scatter plot of the MDLs, over 4 years, for lead in water by ECPMS. The MDL was constantly changing due to the blanks. Based on these data, Richard suggested changing the factor to 3, and there was general agreement on this.

Redefinition of the MDL

John had proposed language for this. Richard thought the new language was very good, but he cautioned against changing the definition, because EPA might reject it. The task of the Committee was just to modify the procedure for the existing MDL.

Comments on section 7

Tim had provided comments, but their consideration was deferred until the section has been considered. Richard though most of the section might be deleted anyway.

Comments on tolerance limit

These had been submitted by Chung –Rei and already discussed by e-mail. It was agreed no changes would be needed.

4 – Adjournment

Richard reminded Committee Members to vote on the calibration VDS.

The meeting was adjourned at 3:50 pm EST. The next call was scheduled on April 26 at 2:00 pm 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 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	Committee	Complete (done in the

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		analysts using the most recent calibration rather than choosing which of 2 or more curves to use.		standard)
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

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
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 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	12/14/12
26	2/1/13	In the calibration standard	Committee	Not determined

Item No.	Date Proposed	Action	Assigned to:	To be Completed by:
		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 reported”if LOQ is re-defined.		
27	2/15/13	Check on travel funding for face-to-face meeting	Ken	3/1/13