SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

MARCH 1, 2013

The Committee held a conference call on Friday, March 1, 2013, at 1:00 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)	Present
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; Gale Warren; Charles Decker

2 – Previous Minutes

It was moved by John and seconded by Anand to approve the February 15 minutes as presented. All were in favor. The minutes were therefore approved.

3 – Calibration Modified Working Draft Standard

John had provided by e-mail the following proposed edits to the document.

1.7.1 – 1st paragraph; added "with second source verification" after "initial calibration".

1.7.1.1 l) moved to 1.7.1.1 e).

1.7.1.1 i) and 1.7.1.1 j) combined and moved to 1.7.1.1 f).

1.7.1.1 f) moved to 1.7.1.1 m).

1.7.1.1 n) i) reworded to read "The calibration criteria and/or initial verification criteria fails marginally and;"

1.7.1.1 n) ii) – added table of marginal exceedances.

1.7.2 f) ii) – 1st sentence reworded to "non-detected analytes that marginally fail the continuing calibration verification low may be reported without qualification…etc.". Also, on Francoise's suggestion this paragraph was preceded by "For methods with more than 10 analytes".

With these changes it was moved by Anand and seconded by Tim to approve the document as a Voting Draft Standard. Ken was tasked with formatting it to be suitable for voting.

4 – Method Detection Limit Procedure

Section 6b.

Dan was concerned that, on calculating the detection limit based on blanks, when only some blanks give a result the blank result might be lower than the lowest standard. On quantitation, this could introduce a large bias that might not also exist in the spiked samples. Richard suggested that bias would also exist sitting underneath the spike recovery. Dan said, when looking at individual REs for each calibrant, maybe it would be insignificant at the signal level of the spike blank. To account for that, he questioned if there should be language to address how high the highest blank can be. Nancy said if a laboratory is using a poor calibration model then it may be appropriate for the MDL to be high. Tim suggested if a laboratory has a negative bias on its calibration model and (say) 1 out of 7 values is non-numerical, the highest blank might not be representative of the MDL. Richard responded, if you are trying to achieve the level of 99% confidence in distinguishing something real from a blank, if blanks are negative then as long as the detection limit is positive it's not really an issue. Dan asked if laboratories should then make a distinction whether its MDL is based on spikes or blanks. Tim thought it did not matter, because sometimes bias comes in through preparation that calibration standards do not go through, and that is not correctable. This is an attempt to get at that contamination or artifacts that show up when you prepare your actual samples. Richard pointed out that EPA, in trying to defend the existing MDL procedure, had a laboratory do spikes at 10 – 12 levels above and below the MDL and then calculated that MDL. In some case the levels in blanks were more than 10 times the MDLs that EPA came up with. Nancy suggested a sentence somewhere saying laboratories should minimize rounding and censoring prior to calculation. Richard said there needs to be a definition of "numerical result", which can say it is what comes off the instrument before censoring or rounding. Francoise was concerned that the maximum number of blanks should be stated as well as the minimum of 7. Nancy asked what the t-value would be for 100 blanks, saying you could get a lower MDL if you have a larger n value. Richard suggested if you have a population with a large number of blanks, not many blanks will exceed the calculated MDL. Nancy suggested when t gets small, the mean + 2 sd does not give 99% coverage of even a normal distribution. Richard thought it did not take 3 sd to get out to

99% in a normal distribution, but it was agreed to look that up and come back to it next time .

Section 7a.

Anand and Nancy questioned if the 2 spikes could be run consecutively at any time during the 3 months, or if they should be separated by at least a month. Brooke said laboratories might be running a test seasonally. After some discussion it was agreed to change the text in the first sentence from "At least once every 3 months.." to "During any quarter in which samples are analyzed.." It was also agreed they should be in separate batches if available. There was also discussion on whether the batches should be on different days, since there was concern over spreading it out and not just running both batches close together. There was some concern over the remaining 10% of analytes that do not pass. It was questioned if 90% pass whether to just ignore the fact that the remaining 10% were not seen. Poor performing analytes (low recovery) are a concern, and after discussion the following comment added: "May need a footnote for very poor performing analytes -if mean recovery in the initial MDL is < 30% then allow spiking up to 10X MDL". Lee said it should be made clear that if you do another MDL determination, you have to meet the new MDL and not the one before you changed it last time. The language was changed to say the current MDL, rather than the initial one.

5 – Next Steps

Richard asked everyone to look at Sections 6 and 7 and distribute any comments before the next call on March 15 at 2:00 pm ET.

6 – Adjournment

The meeting was adjourned at 3:30 pm EST

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	Complete
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