SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

OCTOBER 5, 2012

The Committee held a conference call on Friday, October 5, 2012, 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)	Absent
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, TNI administrative support staff	Absent

Associate Committee members present: Arthur Denny; Dianna Shannon.

2 – Minutes from September 21

It was moved by Anand and seconded by Tim to approve the minutes as presented. All were in favor except Nancy who abstained.

3 – Working Draft Standard on Calibration

The rest of the conference call was devoted to discussing Section 1.7.1.1 n of the WDS. Brooke had suggested, by e-mail, the following language.

"Non-detected analytes associated with an initial calibration failing any criterion from 1.7.1 of this standard for that analyte may be reported without further qualification if the laboratory has performed a successful demonstration of adequate sensitivity. The demonstration of sensitivity shall be the successful detection (meeting all identification criteria specified in the method or the SOP) of the analyte in a Sensitivity Check Standard. The concentration at which non-detected analytes are reported (e.g., the censoring level) shall be no lower than the concentration of the Sensitivity Check Standard. The Sensitivity Check Standard must be analyzed after the last sample for which this option for reporting non-detects is implemented."

Richard felt the language as it stands would require the sensitivity check to be at or below the level of the MDL if the laboratory is reporting any results down to the MDL. For multi-analyte methods where this allowance could be useful, the MDLs will cover a fair

range, and since making up a spike to match the MDLs is not practical most of the levels would have to be below the MDL. The problem with that is the MDL is not a level at which reliable detection is even expected. In fact, you could say that if a spike at the MDL is reliably detected, it is an indication that the MDL is too high. He said the verification level needs to be at the quantitation limit, regardless of whether or not the lab is reporting to the MDL. Richard had offered, by e-mail, the following revised language.

"Non-detected analytes associated with an initial calibration failing % RSD/E criteria by $\leq$10% or correlation coefficient/coefficient of determination criteria by $\leq$ 0.1 for that analyte may be reported without further qualification if the laboratory has performed a successful demonstration of adequate sensitivity. The demonstration of sensitivity shall be the successful detection (meeting all identification criteria specified in the method or the SOP) of the analyte in a Sensitivity Check Standard. The sensitivity check standard shall be at or below the quantitation limit reported by the laboratory."

Richard explained that the intent of his edit was to relieve some concern by limiting this to relatively marginal failure of the instrument calibration and through that limitation hopefully make people more comfortable with the sensitivity check only being provided at the LOQ. A lengthy discussion followed. Nancy was concerned that some methods don't have any qualitative identification criteria, and you might be using a numeric value that has been converted through a failed calibration to make this presence/absence determination. She would be more comfortable if an initial calibration was required to pass, and non-detects could be reported only if subsequently continuing calibration verification failed marginally and there was a sensitivity check at the end. There was concern that a laboratory could have a lot of such failures and report them all as non-detects. Anand suggested maybe limiting the number of analytes that can be reported as non-detects.

Following further discussion, the following language was drafted.

"A non-detected analyte with a failing initial calibration may be reported without further qualification if the laboratory has performed a successful demonstration of adequate sensitivity. The demonstration of sensitivity shall be the successful detection (meeting all identification criteria specified in the method or the SOP and results above the LOD) of the analyte in a sensitivity check standard. The concentration of the sensitivity check standard shall be at or below the LOQ and shall be analyzed in each analytical batch. This allowance is limited to initial calibrations where no more than 10% of the analytes fail."

Richard then outlined three options: remove the section from the standard; continue working on it; or accept it as it is. Several committee members wanted to remove the clause unless the sensitivity check was required to be at the end of the batch. However, that raised the concern that the option would not be exercised if a laboratory had to run an entire batch before knowing if the result can be used. Nancy said similar language will be needed in the continuing calibration section, and suggested leaving Richard's language as it is with a note to return to it after the language has been finalized for continuing

calibration. There was general agreement on this course of action and Anand volunteered to work on the continuing calibration verification language before the next call, with help from Brooke.

4 – Adjournment

The meeting was adjourned at 3:30 pm EDT. The next conference call will be on October 19, 2012 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)	Ongoing
6	2/17/12	Review Volume 1 Module 4 of the 2009 standard to identify any inconsistencies with the new language	All Committee Members	Not determined
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	6/18/12
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	10/19/12