SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

OCTOBER 19, 2012

The Committee held a conference call on Friday, October 19, 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, Program Administrator	Absent

2 – Minutes from October 5

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

3 – Working Draft Standard on Calibration

The following revised Section 1.7.1.1 n), tentatively adopted during the October 5 conference call was discussed:

> "Non-detected analytes associated with an initial calibration failing % RSD/E criteria by <10% or correlation coefficient/coefficient of determination criteria by < 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.

It was noted that the correlation coefficient of < 0.1 in the first sentence should be < 0.01, and this change was made.

It was discussed whether measurement of RSE in the initial calibration was done by individual standards or the whole set. Nancy suggested, if an analyst is using errors at individual points, only the lowest point should be used. She then questioned what would constitute a failure when errors at multiple points are measured; e.g., if it would be a failure if any one of them failed. Richard responded the criteria must be in the SOP and the points evaluated are the mid-point and the point closest to the LOQ. Lee agreed with Nancy's point that there is the option of using residual error in the initial calibration section of the document at the mid-point and the point closest to the LOQ or measurement of RSE. He added that the residual error option needs to be addressed. This led to consideration of further changes to initial calibration Section 1.7.1.1 h). Nancy questioned what would happen if the correlation coefficient passed, but the calibration failed because the residual error criterion failed. Richard said the RSD is numerically the same value as relative error, so RSD needs to be added somewhere in the section. Following further discussion, the first paragraph of the section was amended to read:

> "a measure of relative error in the calibration shall be used and documented ~~(~~for calibrations evaluated using correlation coefficient or coefficient of determination ~~alone are not sufficient) for all calibrations created using regression analysis or average response / calibration factor~~. (The RSD from an average RF calibration is a sufficient measure of relative error).This analysis may be performed by either:"

At this point, a typographical error in Section 1.7.1.1 g) was seen; "relative percent difference" was changed to "relative standard deviation"

Richard suggested the initial calibration section should state if you have a failure in your initial calibration, you must meet the criteria in the continuing calibration sensitivity check if you want to use it. It was agreed to go to the continuing calibration section and then come back and see if further changes are needed in initial calibration.

Anand had provided, by e-mail, the following suggested changes to continuing calibration verification Section 1.7.2 f):

> "Criteria for the acceptance of a continuing instrument calibration verification shall be established. If the continuing instrument calibration verification results obtained are outside the established acceptance criteria and analysis of a second consecutive (immediate) calibration verification fails to produce results within acceptance criteria, corrective actions shall be performed. The laboratory shall demonstrate acceptable performance after corrective action with two consecutive calibration verifications, or a new initial instrument calibration shall be performed. If the laboratory has not verified calibration, sample analyses may not occur until the analytical system is calibrated or calibration verified. If samples are analyzed using a system on which the calibration has not yet been verified the results shall be qualified. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions:

i. when the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported without qualification ; or

ii. when the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias), ~~those~~ sample results of positively detected analytes may be reported as estimated values if they exceed a maximum regulatory limit/decision level. or

iii. Non[BR1] -detected analytes that fail the continuing calibration verification low may be reported without further qualification if a successful demonstration of adequate sensitivity (see section n of the Initial Calibration section for criteria and reporting) has been performed within the same analytical batch. For methods that require bracketing continuing calibration verification standards, successful bracketing demonstrations of sensitivity are also required.

Otherwise the samples affected by the unacceptable continuing calibration verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted."

Discussion was centered on whether "further" was needed in the first sentence of (iii). It was thought to be confusing because it implies there was already some qualification of this result, which may or may not be true since a lot of people don't think a "<" or ND is a qualification. Nancy suggested deleting "without further qualification", and the others agreed.

At this point, the committee referred back to the initial calibration section and decided further changes were not necessary.

It was moved by Lee and seconded by Anand that, with the changes discussed today inserted into the WDS the committee will consider the WDS to be complete and ready to be presented at the next meeting to the community at large.

The motion passed, with all in favor except Brooke who abstained. She agreed with the basics, but wanted to see it written more clearly.

4 – Next Steps

Richard announced that, prior to the next meeting, he would make the agreed amendments and circulate to the committee. He would also circulate the two edited MDL documents, one having Nancy's suggested edits.

5 – Adjournment

The meeting was adjourned at3:15 pm EDT. The next conference call will be on November 2, 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