**SUMMARY OF THE**
# TNI CHEMISTRY EXPERT COMMITTEE MEETING

## FEBRUARY 13, 2015

The Committee held a conference call on Friday, February 13, 2015, at 2:00 pm EST. Chair Richard Burrows led the meeting.

### 1 – Roll call

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| Richard Burrows, Test America (Lab) | Present |
| Francoise Chauvin, NYC DEP (Lab) | Absent |
| Brooke Connor (Other) | Present |
| Gale Warren, NYSDOH (Accreditation Body) | Present |
| Colin Wright, Florida DEP (Lab) | Present |
| JD Gentry, ESC (Lab) | Present |
| Nancy Grams, Advanced Earth Technologists, Inc. (Other) | Absent |
| Anand Mudambi, USEPA (Other) | Present |
| John Phillips, Ford Motor Co. (Other) | Present |
| Scott Siders, IL DEP (AB) | Absent |
| Gary Ward, OR DPH (AB) | Absent |
| Ken Jackson, Program Administrator | Present |

Associate Committee member present: Arthur Denny.

### 2 – Previous Minutes

It was moved by Anand and seconded by John to approve the minutes of January 23, 2015. All were in favor. It was moved by John and seconded by Anand to approve the minutes of February 3, 2015. All were in favor.

### 3 – Calibration Interim Standard

All voters' comments had been presented, discussed, and resolved during the Forum on laboratory Accreditation in Crystal City (see the minutes of February 3, 2015). The committee now discussed the action being taken on resolution of specific comments. Richard said volunteers would be needed to write responses to the Non-persuasive comments.

**1.7.1.1 (d).** *"As an assessor, we must have written procedures when removal or replacement of points occur. This should not have been removed - having this allows assessors to clearly write this as a finding."*

**1.7.1.1 (d).** *"This section has been revised to remove the requirement for a laboratory to have a written procedure to address removal/replacement of calibration standards. Even though the standard is more clear regarding removal/replacement, a written procedure is still necessary so that the laboratory can define its actual procedures and address how and where the required documentation will take place. The procedure is also essential to staff training and consistent application of the use of removal/replacement."*

These two comments had been ruled Persuasive, and Richard said he would put the language back in the standard.

**1.7.1.1 (e).** *"It is our opinion that it is not necessary to increase the minimum number of calibration standards. Since the degrees of freedom portion of the table is deleted there is no need for Note (b). Delete Note (b)."*

This and five similar comments were considered together. Richard reminded the committee that this increase in the number of calibration standards came about to satisfy several persuasive comments at the Voting Draft Standard stage, so the committee had ruled the comments Non-Persuasive in Crystal City. He added, besides satisfying those persuasive comments, it was also more consistent with new EPA methods. Anand volunteered to draft a response to be considered during the next conference call.

**1.7.1.1 (g)** *"Add an allowance to report results that are within +10% of the highest calibration level without qualification. For example, if the high standard is 300 and you obtain a result of 301 you would need to qualify and/or dilute the sample before reporting. Dilution would introduce more error than reporting at the original 301 concentration."*

This would be a new requirement that had not been discussed previously and would be controversial. Consequently, it was placed on hold until the next revision of the standard.

**1.7.1.1 (j).** *"It is our opinion that calculating a %RE or %RSE as a means of assessing the acceptability of calibration curves would not be cost effective and as an alternative, we suggest using similar language as used in UCMR3 Methods. As an example Method 524.3, rev 1.0, June 2009. This procedure is easily implemented offers EPA acceptance, and consistency with acceptance criteria across all laboratories."*

The next eight comments were considered together with this one. Richard said this was one of the most important changes to the standard for improving data quality, so the committee had ruled the comments Non-Persuasive. It was agreed not to make the change to %Difference as one of the commenters had suggested; %Difference is usually associated with continuing calibration and not initial calibration. An action item was to modify the definition. John said he would draft a response and fix the definition.

**1.7.1.1 (m).** *"The intent of the statement that "...all initial calibrations shall be verified with a standard obtained from a second independently prepared lot or from a second manufacturer" needs clarification. To avoid the possible interpretation by an auditor that someone other than the analyst who prepared the calibration standards must prepare the ICV, I suggest that the clause should be revised to read "...all initial calibrations shall be verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the manufacturer.""*

This was considered together with a similar comment. It had been ruled persuasive in Crystal City, and the language would be modified. Richard also added that initial calibration standards need to be traceable.

**1.7.2 (c) and (d).** *"We often receive client requirements in QAPPs that stipulate the concentration range for the CCV that differ from the </= ½ the high cal std requirement stated in c). There are also some methods and client requirements for a low and high level LCS. Would d) iii. allow using these LCS standards for the CCV when the processes are the same for the two standards? Is it acceptable to use project specific criteria for the CCV levels if it differs from the range stipulated in the TNI standard?"*

Having been ruled Non-persuasive, Richard volunteered to draft a response.

**1.7.2 (d).** *"This whole section is confusing to me. Any clause that contains the word "except" tends to invite further thought or scrutiny. If the Committee would please consider and use the following revisions, this section would read much more clearly (at least to me) on what the laboratory is required to do (changes and additions underlined):*

*d) Instrument continuing calibration verification shall be performed at the beginning and end of each analytical batch, normally with the same standard source as used for the initial calibration, and at the frequency defined in the method except:*

*i. if an internal standard calibration procedure is used, calibration verification needs only to be performed at the beginning of each analytical batch, and at the frequency defined in the method;*

*ii. a calibration verification with a second source standard that passes the continuing calibration verification criteria may be used in place of a continuing calibration verification made with the same initial calibration standard source.*

*iii. a laboratory control sample (LCS) may be used in place of a continuing calibration verification (but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS and the LCS results pass the continuing calibration verification acceptance criteria."*

The committee discussed language suggested by Richard.

**1.7.2 (f) (ii).** *"The allowance to run two passing CCVs after a failed CCV and then continuing with analysis has been removed. This should be added back in."*

The committee felt it was inappropriate to routinely run 2 CCVs and accept the second one if the first failed. Richard would draft a response.

**1.7.2 (f) (iii).** *"The current language reads: "if samples are analyzed using a system on which the calibration has not been verified, the results shall be qualified. Data associated with an unacceptable*

*calibration verification may be reported under the following special conditions, unless "prohibited by the client, a regulatory program or regulation". The language needs to be more clear that in such circumstances, if data are to be reported they must also be qualified.*

*Proposed revised language:*

*"if samples are analyzed using a system on which the calibration has not been verified, the results shall be qualified. Data associated with an unacceptable calibration verification may be reported with qualifiers under the following special conditions, unless prohibited by the client, a regulatory program or regulation. ""*

The committee discussed language suggested by Richard.

**4 – Revised MDL Procedure**

The committee considered EPA's edits of the procedure, which was about to be published for comments by EPA in the Federal Register. Richard asked if the committee should make any comments. John remarked that the following two sentences had been removed from the first paragraph of the scope and application, and he believed they were important for saying what the use of the MDL is: *"The MDL obtained by this procedure is used to judge the significance of a single measurement of a future sample. A result below the MDL is judged to be qualitatively unreliable while a result at or above the MDL is judged to be qualitatively reliable"*. Richard suggested John might want to recommend to EPA that those sentences go back in. John also noted changes in the procedure from days to calendar days, and a re-wording of a sentence in the on-going analytical verification section, but he had no problem with those minor changes.

Richard said EPA was asking for comments on whether to accept the changes to the MDL procedure in part or in whole, and he stressed the importance of each committee member individually saying EPA should accept the changes in whole. Other people should also be persuaded to submit supporting comments.

John wondered if they should make a comment to improve what might have been an oversight in the $MDL_b$ calculation. He said it would be better, if over 100 data points, that the 99-percentile non-parametric approach was used as a superior approach to calculating the interval that assumes a normal distribution of the data which may not be normally distributed. Richard suggested the committee talk about that later.

Richard had already received a few comments saying it was not clear what to do when a new instrument was introduced with an existing method. He thought it was reasonable, at a minimum, to run 2 spikes and 2 blanks on that instrument and recalculate the $MDL_b$ and $MDL_s$ to make sure it is still within the allowable range of the existing MDL. John said another option would be to determine an MDL on the new instrument. Richard discussed whether 1 spiked blank on each instrument could be enough, saying if several instruments are multiplied by several different preparative methods with different matrices and several iterations of different concentrations of spiking standards, that can lead to a remarkably large number. Richard said the committee needed to think about whether a change should be suggested.

**5 – Next Steps**

Richard suggested, at the next meeting the committee should spend time considering the comments received in Crystal City on the detection/quantitation language. A Voting Draft Standard needed to be put out for voting as soon as possible, with votes and comments received before the July meeting in Chicago.

**4 – Adjournment**

The meeting was adjourned at 3:25 pm EST.