SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

FEBRUARY 27, 2015

The Committee held a conference call on Friday, February 27, 2015, at 2:00 pm EST. Chair Richard Burrows led the meeting.

1 – Roll call

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)	Present
Anand Mudambi, USEPA (Other)	Present
John Phillips, Ford Motor Co. (Other)	Present
Scott Siders, IL DEP (Accreditation Body)	Absent
Gary Ward, OR DPH (Accreditation Body)	Absent
Ken Jackson, Program Administrator	Absent

Associate Committee Members present: Tom Dziedzic; Ricky Lopez; Diana Shannon; Marilyn Slaven.

2 – Previous Minutes

It was moved by Anand and seconded by Brooke to approve the minutes of February 13, 2015. All were in favor.

3 – Calibration Interim Standard

The Committee continued working through the voters' comments

1.7.1.1 (d) ii *"I believe that for tests with a large number of analytes the requirement to always remove an entire calibration level(all analytes) from the interior of a calibration curve is excessive. To me it makes more sense for you to remove all potentially effected analytes. To better clarify, an example that we have at our lab would be our standard 8260 list which contains 105 analytes. A calibration curve contains 11 points and each point is spiked with five standards. That is 55 individual spikes per curve. It does happen where only one of the five standards was spiked incorrectly or a spiking error occurred in one of the calibration points. In this case currently we would document that all compounds from standard "X" were removed due to spiking error. There is absolutely nothing wrong with all the other compounds in the calibration level, and when an incident like this occurs it is clearly identifiable. In my*

opinion the above stated practice with the proper documentation should not be excluded from the standard. We should not be required to remove data points that are clearly acceptable due to the failure of one spike mix or any other clearly identifiable cause for specific compound/compound group failure. An error of this nature is bound to happen from time to time due to the high number of analytes and individual spikes required.

To take it a step further I believe similar logic could be used here as is used for the marginal exceedence rule. A certain number of failures should be understood if not expected when you are working with this number of analytes and standards. In the case of the 8260 curve listed above the instrument would be generating 1155 individual data points. It is completely understandable that everything will not function perfectly for each data point."

Richard explained to the commenter (Marilyn Slaven), who was present on the call, that this had been a controversial section. Some Accreditation Bodies had a problem with the original language and the resulting verbiage represented a negotiated settlement. Marilyn understood it may be hard to change the language so there would be no loophole anyone could use to do something improper. She withdrew the comment. However Gale said she agreed with Marilyn and she wanted it changed. She added it would be difficult for a laboratory if just the gases fail and the liquid analytes are satisfactory. Richard said there was nothing in the language to stop a laboratory just re-running the gases, and said it would be difficult to draft it so there are no loopholes. It was moved by Gale to revisit the calibration language to allow laboratories to justify and document why they might want to discard a specific point in a calibration standard. There was no second so the motion failed. Brooke and John did not disagree with the motion, but worried about the ramifications if it was passed. Richard suggested tabling the comment for consideration with the next standard update.

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."*

The Committee had changed the standard to say the laboratory shall have a written procedure.

1.7.11 (e) *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.*

Anand wrote a response to this and 5 similar comments. There were no comments on the response, but it was agreed to change "standards" to "calibration standards" in the document to avoid confusion with TNI standard.

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."*

The Committee had agreed, since this is a new concept, it would be tabled and that was explained in the response to the comment.

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.*

Method 524.3, rev 1.0 June 2009 –

10.1.10 CALIBRATION ACCEPTANCE CRITERIA – The initial calibration is validated by calculating the concentration of the analytes for each of the analyses used to generate the calibration curve by use of the regression equations. Calibration points that are ≤MRL must calculate to be within +50% of their true value. All other calibration points must calculate to be within +30% of their true value. If these criteria cannot be met, the analyst will have difficulty meeting ongoing QC criteria. In this case, corrective action is recommended such as reanalyzing the calibration standards, restricting the range of calibration, or performing instrument maintenance."

John explained the responses he had written to this and 5 similar comments. He also added a definition for RE, relating it to % Drift. Gale suggested it should be clarified in the definition that RE is a concrete number and %RE is not.

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."*"

and

"ISO17025 already requires initial calibration standards that are traceable to a national standard. There is added cost to purchasing these standards. Adding it as an ICV requirement in the TNI Standard is not necessary since the calibration standards are already traceable and the ICV is checked against those. It would be a redundant check with increased cost to the laboratories."

Richard said the committee had made a mistake by making it a requirement for the ICV to be traceable to a national standard instead of the calibration standard. That had now been changed.

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?"*

It had been decided on the previous call this would be a controversial issue, and Richard outlined a response, saying it could not be changed because it is controversial and might cause individuals that had voted positively to modify their vote. However, it would be acceptable to use project or method specific criteria that specify CCV levels. The committee agreed with the 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):"* (Suggested language was provided).

The proposed language was not used, but Richard made a minor change to the existing language to clarify it is the ICV rather than the CCV.

1.7.2 (f) "*1. It is not TNI's right or obligation to determine what data is "valid" for individual laboratory, industry, or regulatory use. This section implies that if a continuing calibration verification fails during an analysis the data is not reported unless it meets the special conditions in 1.7.2.f.iii.a and 1.7.2.f.iii.b. This section should be modified to allow for reporting the data with qualification unless the special conditions in these 2 sections are met. Let the end-user determine if the data is "valid" for their purposes.*

2. Most instruments are automated in today's society and these sections do not give options for the course of action to take once the analysts determines what occurred during an automated analytical run where the samples and other QC have already been run before the analyst was aware of the failing continuing calibration verification. 1.7.2.f.i refers to running a second calibration verification sample immediately, but that is not realistic for automated analyses. And especially for a "missed autosampler injection", at least one sample would be in the process of being analyzed prior to the analyst discovering that an injection was missed."

Although the language says a laboratory cannot report data if the CCV fails, that was not intended. Richard had re-drafted the section and had sent it to LASEC. He was waiting to hear back from them.

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."*

Richard outlined his proposed response that the allowance for running two CCVs after a failing CCV was controversial and cannot be added at this stage of the standard. He did note, however, that it is acceptable to run a passing CCV after corrective action. The laboratory SOP should define what constitutes corrective action for individual methods. Gale added that the new 624 and 625 methods suggest 2 CCVs because some compounds might fail. She was concerned the language might conflict with it. Anand said he would ask Adrian at EPA. Richard thought the standard would not prohibit this for a method where it is specified, but it should not be encouraged for all methods.

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."

The commenter proposed revised language.

Richard modified the language and explained it to the committee

This concluded the committee's consideration of the comments.

4 – Standards Interpretation Request

The committee had previously responded to SIR 277, but it had been returned to the committee. It concerned the exception to run an LCS for those analytes for which no spiking solutions are available. The committee had responded that, although whole volume QC samples might be available they are not spiking solutions and should not be classified as LCS. The SIR subcommittee was concerned with the committee's interpretation of the intent of the standard, saying it should be re-phrased or moved to the comment section of the response. They were also concerned about distinguishing between spiking solutions and QC samples. This was discussed and Gale pointed out, as an AB, she did not require a laboratory to run an LCS for solids tests. The committee agreed that is not required by the standard. Richard said he would draft a modified response.

5 – ELAB Comments on the Published Modified MDL Procedure

Richard emphasized that the committee also needed to make comments, and it would be very valuable if everyone on the committee submitted comments individually. He suggested looking at the ELAB comments and deciding if something similar would be appropriate from the committee. Nancy asked if they should comment that a laboratory could still do an MDL_b even if it could not do an MDL_s. Richard asked her to suggest wording. John said he would draft something on his comment during the last call that 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. John added that ELAB also addressed the issue about additional instruments.

5 – Next Call

During the next call, on March 13, Richard wanted to discuss appointing a vice-chair to the committee. He added that his term would expire at the end of 2016, and he would like to hand over to a new chair at the end of 2015.

6 – Adjournment

The meeting was adjourned at 3:30 pm EST.