SUMMARY OF THE
TNI CHEMISTRY EXPERT COMMITTEE MEETING

SEPTEMBER 19, 2013

The Committee held a conference call on Thursday, September 19, 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)	Absent
Dan Dickinson, NYSDOH (Accreditation Body)	Absent
Mandi Edwards, Envirochem (Lab)	Absent
Tim Fitzpatrick, Florida DEP (Lab)	Present
Andrew Friedrich, Chevron (Lab)	Present
Nancy Grams, Advanced Earth Technologists, Inc. (Other)	Absent
Anand Mudambi, USEPA (Other)	Absent
John Phillips, Ford Motor Co., (Other)	Present
Scott Siders, IL DEP (AB)	Present
Gary Ward, OR DPH (AB)	Absent
Ken Jackson, Program Administrator	Present

Associate Committee member present: Arthur Denny

2 – Previous Minutes

In the absence of a quorum these were deferred.

3 – Calibration Voting Draft Standard

The committee continued working through the voters' comments on the VDS. Line numbers refer to the comments spreadsheet the committee was working from. The comments are in italics.

Line 90: Bob DiRienzo, Section 1.7.2.1 f. [NOTE: this is 1.7.2 f (ii)*]*. *Standard Language: "for methods with more than 10 analytes, non-detected analytes that marginally fail the continuing calibration verification low may be reported without qualification for a continuing calibration verification failure 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 qualified or re-analyzed." Comment: This concept was introduced for LCS in the NELAC 2003 standard. The one difference is the marginal exceedences for LCS must be RANDOM. Can the same analyte always fail? Suggestion: Remove or changed to random events.

Tim had sent in a proposed revision to this section, which Richard suggested reviewing later.

Line 91: Nicole Cairns, Section 1.7.2 a. *The details of the continuing instrument calibration procedure, calculations and associated statistics shall be included or referenced in the method SOP. Proposed Language - The details of the continuing ~~instrument~~ calibration procedure, calculations and associated statistics shall be included or referenced in the method SOP. Same as comment 1.*

This point was already dealt with.

Line 92/93: Dorothy Love/Amy Doupe, Section 1.7.2 b. *Regarding chlordane, does this section allow alpha and gamma chlordane as a "related substance"?*

This was done in the initial calibration section. Anand was drafting language and a note was made to look at his language.

Line 94: Andrew Friedrich, Section 1.7.2. c. *why is 1.7.2 c. not defined for ICV in an ICV section rather than as a CCV as it is? and I think that is a main point of mine, ICV criteria is mixed into the CCV sections, making it difficult to sort out for the author and reader. I would clarify such by sorting into the following 4 sections and define criteria for each seperately:*

Andrew agreed this had already been addressed and he withdrew his comment.

Line 95: Dixie Marlin, Section 1.7.2. c. *Section 1.7.2 c – VERY prescriptive. This requires the determination of the mid-point of the calibration curve being mathematically determined and not simply using the mid-level calibration point for daily verification.*

Richard suggested this should not be an issue, but it was agreed it is persuasive. John suggested saying "approximately the mid-point or below". Francoise cautioned against saying "approximately" in a standard, and Richard proposed "equal to or less than half".

Line 96/97: Judy Morgan/Aaron Alger, Section 1.7.2. c. *too prescriptive/This whole section is confusing and difficult to understand.*

These were similar comments to Line 95.

Line 98: Dixie Marlin, Section 1.7.2. d. *This whole section is so poorly worded that it's confusing. The inclusion of ". . .at the beginning and end of each analytical batch,. . ." in the first sentence puts the reader on the defensive when considering the totality of the*

methods analyzed by the laboratory. Even though in subsequent sections, there are exceptions listed, the initial statement would be a much stronger lead by just saying that "Instrument continuing calibration verification shall be performed using the process and at the frequency defined in the method". In that case, the exceptions are not needed.

This was discussed in San Antonio, when Anand was assigned to re-word the section for clarity. John volunteered to do this if Anand was not doing it. It was agreed the meaning of the language should not be changed.

Line 99 through line 107. Re-wording section 1.7.2. d would address all these comments.

Line 108: Nicole Cairns, Section 1.7.2. e. *Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification (e.g., method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing verification data to the initial instrument calibration. Proposed Language - Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification (e.g., method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing calibration verification data to the initial instrument calibration.*
Remove the word "instrument" for the same reason as stated in comment 1 and add the word calibration for consistency in terminology.

Persuasive. The committee agreed with Nicole's suggestion.

Line 109: Judy Morgan, Section 1.7.2. f. *What was the purpose for changing this? The ability to run a second CCV after a failure is key where performance has been affected by carryover, a mis-injection, a syringe issue, etc. Where GC and GCMS is concerned, surrogate and IS performance indicate where those failures occur. Laboratories following this practice have solid documentation to justify a 2nd analysis/injection. The section goes on to talk about "data associated with an unacceptable calibration".....this is why we have SOPs and an accepted data qualifier system, which is based from EPA CLP. This document should not be intended to deal with issues at this level.*

Richard said this is where there was an update to the previous standard that the committee had not considered. The change was "If that calibration verification analysis is not within acceptance criteria, the laboratory shall demonstrate acceptable performance after additional corrective action measures with two consecutive calibration verifications or a new instrument calibration." Richard pointed out that the path Judy wanted to follow would not be allowed by this language that is in the 2012 standard. A discussion followed on the wording of the 2009 standard that explicitly stated that this situation of

running a second CCV could only apply for instruments not calibrated that day, but the committee wondered if that was really the intent. This was struck out in the proposed standard, so now it can be for any CCV. Richard clarified the difference between the language in the proposed standard and that in the 2012 version. The proposed standard requires only a single CCV after corrective action, whereas the 2012 standard requires 2 consecutive CCVs. Tim reminded the committee that it was agreed in San Antonio to revise the language and he had sent out a proposed revision. Richard said Tim's language just needed expanding to add the action that had to be taken on samples prior to the failed CCV. Tim volunteered to further amend his language.

Line 110: Shari Prestanski, Section 1.7.2.f. *This section removes the ability to perform a second injection of a continuing calibration verification standard when an initial injection fails. This is problematic in instances where, for example, an instrument may be exhibiting lingering carryover, but an analyst unaware of the problem, injects the standard and a failure results. Corrective action (per this section) is then required, when a second injection may have resulted in an acceptable performance following the cleanup of the analytical system with the first attempt to perform calibration verification. This section also contradicts itself. Initially, it states that "if continuing instrument calibration verification results are outside the established acceptance range, corrective actions shall be performed", but then goes further in the latter part of the paragraph to state that "Data associated with an unacceptable calibration verification may be fully useable under the following conditions:"*

This would also be addressed with Tim's re-wording.

Line 111: Steve Arms, Section 1.7.2.f. *This section has always been problematic and misleading for laboratories. An accreditation standard has no place giving laboratories discretion to decide if results are useable. All results associated with any QC failure must be clearly qualified if reported. Then the data user has the opportunity to make a sound decision as to the usability of the data. Delete ALL text starting with "Data associated" and to the end.*

Richard posed the question what you would do if the CCV failed high and you got a non-detect. Should you have to qualify that result? Andrew said "no" and contrary to Steve he finds this section useful. There was a general opinion that in such a case it would be reasonable for the laboratory to decide on the usability of the data. Andrew added that the current standard allows reporting of a sample that is over the regulatory limit when a CCV is low without qualification. The proposed standard does not include this allowance, and he wondered why. Richard suggested saying "may be reportable", rather than "may be fully usable". Andrew questioned the sentence "If samples are analyzed using a system on which the calibration has not yet been verified the results shall be qualified." He asked if that meant a verification attempt had been made and had failed, or if no attempt at verification had been made. On Richard's suggestion, "yet" was taken out of the sentence. Tim read back his note from the San Antonio meeting that the preceding sentence could read "Data qualified with an unacceptable calibration verification may be reportable: (i) when the acceptance criteria for a CCV are exceeded high bias and there are associated samples that are non-detects then those non-detects

may be reported with qualification." Richard therefore suggested the following wording: "If samples are analyzed using an instrument with a failing CCV the results shall be qualified. Data associated with an unacceptable calibration verification may be reportable under the following special condition: when the acceptance criteria for the CCV are exceeded high and there are associated samples that are non-detects then those non-detects may be reported with qualification." For 1.7.2.f (ii), Richard had edited both the initial and continuing parts. He said he struck everything and just stated: "For methods where reporting non-detected analytes, completion of a sensitivity check is allowed (similar to threshold testing, but only for non-detects). The requirements of this standard shall not prohibit the practice."

The next call was scheduled for October 3, 2:00 – 3:30 pm Eastern Time.

5 – Adjournment

The call was adjourned at 2:30 pm EDT