**SUMMARY OF THE**
**TNI ENVIRONMENTAL MEASUREMENT METHODS EXPERT COMMITTEE MEETING**

**APRIL 6, 2012**

The Committee held a conference call on Friday, April 6, 2012, at 2:00 pm EDT.

**1 – Roll call**

| | |
|---|---|
| Richard Burrows, Test America (Lab) | Present |
| Francoise Chauvin, NYC DEP (Lab) | Present |
| Brooke Connor, USGS (Other) | Present |
| Dan Dickinson, NYSDOH (Accreditation Body) | Present |
| Tim Fitzpatrick, Florida DEP (Lab) | Absent |
| Nancy Grams, Advanced Earth Technologists, Inc. (Other) | Absent |
| 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 | Present |

**2 – Minutes from March 30, 2012**

It was moved by Lee and seconded by Anand to approve the minutes of March 30 as presented. All were in favor.

**3 – Continued discussion of Items to Include in the Calibration Section of the Standard**

Prior to the meeting, Richard had circulated an updated tracked version of Section 1.7 (Attached). This was discussed and edited.

Section 1.7.1, introductory paragraph. No further changes were proposed.

Section 1.7.1.1 (c). Brooke suggested, for consistency, adding "initial' before "calibration standards". Although the Section 1.7.1 header states initial calibration, it was noted the other subsections include "initial", so it was decided to put it into subsection (c).

Section 1.7.1.1 (g). Richard said he has done further work on the measure of relative error, but it is not yet in this document. He will send it to Ken who will incorporate it into the combined document.

Section 1.7.1.1 (j). Lee explained he has expanded this from specific one-point procedures such as those using ICPAES and ICPMS. Richard questioned, in 1.7.1.1 (j)

(i), whether it is necessary to establish linearity in this way. He said his labs would normally run higher standards until the returned value is off by 10% or so, but Lee suggested staying with the approach being used in this standard for a linear multipoint calibration. After further discussion it was agreed to leave Lee's sentence as-is. In response to a question by John, Lee said this would also include spectrophotometric methods. John questioned if annually is then frequent enough. Perhaps a high-level check should be done quarterly. Brooke said there could be push-back from the ICP people on that. Richard said some people (e.g., DOD) ask for quarterly ICP checks, and he suggested stating that linearity must be established annually and checked at least quarterly. There was general agreement on this. John asked what would be the consequence if the quarterly linearity check failed; i.e., if it would be necessary to re-analyze all samples tested during that quarter. Richard responded that you would just have to establish a new linear range if the quarterly check failed (if an MDL fails you don't have to go back and question all the data produced since the last check). Francoise questioned if stating "3 or more standards" is always sufficient for establishing linearity. Lee said the approach used in ICP by analyzing a series of standards until linearity is lost could be used, and perhaps the different approaches should just be in the guidance document, since they are range and technique dependent. Lee suggested taking out "3 or more" in that first sentence. John said perhaps the standard should say that one should be at or below the LOQ and one should be at the upper end of the linear range, but then there might be a danger of people only using a series of 2 standards. Dan pointed out that, later on in the section, it says a linear calibration requires 4 standards, so perhaps it should not be specified here how many standards are needed. The others agreed.

Richard suggested 1.7.1.1 (j) (ii) is not needed, since it is already implied in (i). Lee said it helps to define the established calibration range used in (iv). Richard suggested changing (iv) to the established linear range to tie it back to (i). Then (ii) can be removed. In the new (ii) (previously (iii)), Francoise asked if the standard corresponding to the LOQ is just a calibration check. Lee said the LOQ is just a check on sensitivity. It is not used to establish the slope. For clarification, Richard suggested amending the first sentence to read "The zero point and single calibration standard shall be analyzed with each analytical batch and establish the slope of the calibration". Then, the second sentence ("To verify…") should start a new subsection (iii). In the second sentence of (iv), Francoise suggested it should say linear calibration range, and this change was made.

Section 1.7.1.1 (l). Anand and Francoise explained the changes made in this subsection, including adding threshold testing rather than having a separate subsection on it. Dan suggested, since degrees of freedom are mentioned, perhaps the confidence interval around the slope should also be mentioned, since everyone may not know what is meant by degrees of freedom. He suggested perhaps this could be left for more discussion in the guidance document. Saying you need 4 standards for a linear fit is a different way of saying 2 degrees of freedom. Richard proposed leaving degrees of freedom in, since it explains why you have more standards as you have more coefficients in your curve. The others agreed to leave it in.

Section 1.7.1.1 (m). Anand said he and Francoise had discussed what constitutes a valid multipoint curve. They had been unsure whether to go into more detail; e.g., in the case of PCBs, if an Arochlor is detected that is different from the Arochlors used for calibration, what is then a valid multipoint curve? In subsection (ii) Richard said people are likely to think, in threshold testing, you have to run your single point at the LOQ. Brooke said maybe it should be stated that after you run the 1-point standard, you should then do what the method says you have to do. Anand conceded it is not being specified what that initial 1-point calibration is. Richard has the MICE hotline response and will send it to Anand and Francoise who will do more work on the subsection. In response to a question from John it was confirmed that "representative peaks" refers, in the case of PCBs, to congener peaks that can be used for both id and quantitation of the Arochlors. It was agreed this should be stated.

**4- Next steps**

At this point the discussion was curtailed. Richard announced, at the next meeting, the Committee will discuss Anand and Francoise's revised language and Richard's language on the RSE, relative error etc.

**5 – Adjournment**

The meeting was adjourned at 3:40 pm EST. The next meeting will be May 4, 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 | Committee | Ongoing |

| Item No. | Date Proposed | Action | Assigned to: | To be Completed by: |
|---|---|---|---|---|
| | | standards will be considered for the guidance document. | | |
| 5 | 2/17/12 | Draft language for items in the calibration standard | Richard (Items 1 and 2)<br>Anand (Item 3)<br>Nancy (Item 5)<br>Anand and Francoise (Item 6)<br>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 analysts using the most recent calibration rather than choosing which of 2 or more curves to use. | Committee | Complete (done in the 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 |

| Item No. | Date Proposed | Action | Assigned to: | To be Completed by: |
|---|---|---|---|---|
| 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 |

## ATTACHMENT

### 1.7 Technical Requirements

1.7.1 ~~Initial~~ Calibration

This module specifies the essential elements that shall define the procedures and documentation for initial calibration and continuing calibration verification to ensure that the data shall be of known quality for the intended use. This Standard does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which Standard is more stringent, then the requirements of the regulation or mandated method are to be followed.

Calibrations may be performed at the instrument level (analytical step only) or the method level (analytical plus preparation steps). For certain methods, such as purge & trap or head space analyses, it is not possible to not separate sample preparation from the analytical step. The elements presented in this section may be applied to either instrument or method calibrations.

1.7.1.1 ~~Instrument~~ Initial Calibration

~~This module specifies the essential elements that shall define the procedures and documentation for initial instrument calibration and continuing instrument calibration verification to ensure that the data shall be of known quality for the intended use. This Standard does not specify detailed procedural steps ("how to") for calibration, but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which Standard is more stringent, then the requirements of the regulation or mandated method are to be followed.~~

The following items are essential elements of initial instrument calibration:

a) the details of the initial instrument calibration procedures including calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the method SOP. When initial instrument calibration procedures are referenced in the method, then the referenced material shall be retained by the laboratory and be available for review;

b) sufficient raw data records shall be retained to permit reconstruction of the initial instrument calibration (e.g., calibration date, method, instrument, analysis date, each analyte name, analyst's initials or signature; concentration and response, calibration curve or response factor; or unique equation or coefficient used to reduce instrument responses to concentration);

c) the laboratory shall use the most recent calibration standard(s) analyzed prior to the analytical batch, unless otherwise specified by this standard;

d) criteria shall be established by the laboratory for the rejection of any calibration standards analyzed but not used to generate an initial calibration. The reason for the rejection of any calibration standard shall be documented and no data below the lowest or above the highest remaining calibration standard shall be quantitatively reported (see also h and i). The calibration generated from the remaining calibration standards shall satisfy all the requirements specified for initial calibrations.

~~c)~~e) sample results shall be quantitated from the initial instrument calibration and may not be quantitated from any continuing instrument calibration verification unless otherwise required by regulation, method, or program;

~~d~~f) all initial instrument calibrations shall be verified with a standard obtained from a second manufacturer or from a different lot. Traceability shall be to a national standard, when commercially available;

~~e~~g) criteria for the acceptance of an initial instrument calibration shall be established (e.g., correlation coefficient or relative percent difference). The criteria used shall be appropriate to the calibration technique employed;

a measure of relative error in the calibration shall be used (correlation coefficient or~~f~~ coefficient of determination alone ~~is~~are not sufficient). For all regression-type calibrations ~~T~~this evaluation may be performed by either:

i. Measurement of the residual error ~~at or near (within 10%) of~~closest to the mid-point ~~(continuing calibration level)~~ of the initial calibration and at the lowest point of the calibration. The error must be less than the maximum specified in the method. If no level is specified in the method, a level shall be specified in the laboratory SOP. HOW DOES ONE MEASURE THE ERROR? %DIFF %RECOVERY.CAN WE PUT A MAXIMUM VALUE ON THIS OR STRATEGICALLY WAIT UNTIL ANOTHER PASS?

ii. Measurement of the Relative Standard Error (RSE). The RSE shall be less than or equal to the level specified in the method or laboratory SOP. HOW DOES ONE DETERMINE THE RSE?

~~f~~h) the lowest calibration standard shall be at or below the LOQ. Any data reported below the LOQ shall be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or explained in the narrative;

~~g~~i) the highest calibration standard shall be at or above the highest concentration for which quantitative data are to be reported. Any data reported above the calibration range shall be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or explained in the narrative;

~~h~~j) When test procedures are employed that use calibration with a single calibration standard and a zero point (blank or zero, however defined by the method), the following shall occur:~~the following shall occur for instrument technology (such as ICP or ICP/MS) with validated techniques from manufacturers or methods employing standardization testing using calibration with a zero point and a single point calibration standard~~:

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**Comment [O1]:** Does TNI use the routine/standard reporting limit term or is there just LOQ?

**Comment [O2]:** Should this last statement be below the lowest calibration standard in order to be consistent with other uses? See i.

**Comment [O3]:** Would it not be worth considering a procedure whereby a lab could do a demonstration of linearity (e.g., once a year) and then for as ICP and ICPMS do if criteria for linearity are met? This would open up the potential for more methods with good calibration linearity to do two point calibrations. However, we should also have criteria for linearity – an dperhaps slop.

i. Prior to calibration, the linear range of the instrument shall be established by analyzing a series of three or more standards, one of which shall be at or below the LOQ. To establish linearity, the requirements for a linear fit multi-point calibration included in this section (specifically 1.7.1.x.x) shall be met. Linearity must be established annually, or at the frequency defined by the method. ~~Prior to the analysis of samples, the zero point and single point calibration standard shall be analyzed and T~~the linear range of the ~~instrument shall be established by analyzing a series of standards, one of which shall be at or below the LOQ. Sample results within the established linear range will not require data qualifiers.~~

*i.*

ii. The upper limit of the calibration range is defined as the concentration of the single calibration standard. The concentration of the standard may not exceed the linear range.~~A zero point and single point calibration standard shall be analyzed with each analytical batch~~.

iii. The zero point and single calibration standard shall be analyzed with each analytical batch. To verify adequate sensitivity a standard corresponding to the LOQ shall also be analyzed with each analytical batch and shall meet the criteria established by the method or laboratory. The calibration and sensitivity evaluation shall be performed prior to sample analysis.~~A standard corresponding to the limit of quantitation shall be analyzed with each analytical batch and shall meet established acceptance criteria~~.

iv. Sample results within the established calibration range will not require data qualifiers. Samples with results above the calibration range must be diluted, or the over-range results qualified as estimated values~~The linearity is verified at a frequency established by the method and/or the manufacturer~~.

v.

~~i)~~k) if the initial instrument calibration results are outside established acceptance criteria, corrective actions shall be performed and all associated samples re-analyzed. If re-analysis of the samples is not possible, data associated with an unacceptable initial instrument calibration shall be reported with appropriate data qualifiers; and

l) ~~l)~~j. ~~if a reference or mandated method does not specify~~ the minimum number of calibration standards for establishing the initial calibration shall be as specified in the reference or mandated method. If not specified in the method, ~~,~~ the minimum number of calibration points ~~for establishing the initial instrument calibration for common calibration types shall be three is given~~shall be per ~~in~~ the table below (for common calibration types). ~~For linear regression techniques the number of initial calibration standards must be sufficient for at least one two statistical degrees of~~ For regression type calibrations not ~~included in the table~~listed below, the number of initial calibration standards must be sufficient for at least two statistical degrees of freedom.

~~d. freedom.~~

~~e.~~

| Type of ~~Standard~~ Calibration ~~Curve~~ | Minimum number of calibration standards | Degrees of Freedom |
|---|---|---|
| ~~Pass/Fail~~ Threshold | 1 | Not Applicable |

**Comment [O4]:** Not sure why the discussion of sample analysis got mixed into this.

**Comment [O5]:** How many standards/? Should there be a minimum per order of magnitude? A TNI minimum? How is linearity established? What are the minimum criteria?

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**Comment [O6]:** Why is it zero point and some positive point. Could it not be reporting limit level or lower than zero?

**Comment [O7]:** This material is really material for the calibration verification

**Comment [O8]:** Why each batch? Is there any minimum criterion for acceptance?

**Comment [O9]:** TNI should establish a minimum

**Comment [O10]:** What about at the high end? We have not indicated that the positive standard has to be at the top of the calibration range. Should there not be some control on reporting above the positive standard or a QC sample to confirm continued linearity to the highest level the lab reports data without diluting?

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**Comment [BR11]:** Consider adding reference to guidance document for range of calibration

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| | | |
|---|---|---|
| Testing [a] | | |
| Average Response | 3 | ~~Not Applicable~~2 |
| Linear ~~Regression~~ fit | 4 | 2 |
| Quadratic fit | 5 | 2 |
| ~~(a)~~ | ~~(b)~~ | ~~(c)~~ |
| ~~(d)~~ | ~~(e)~~ | ~~(f)~~ |

[a] The initial one point calibration must be at the project specified threshold level.

~~f.~~

~~g.~~

~~k~~m)~~.~~ If~~Where specifi~~allowed by~~in~~ the method and for ~~For~~ multi-peak analytes (e.g, PCBs, technical chlordane, toxaphene), it is acceptable to perform an initial one point calibration, as long as it demonstrates that all representative peaks can be detected at the required reporting limit~~an initial one point calibration is allowed which ensures that all representative peaks can detected. In this case the working range is defined by the analyte(s) that do have multi-point calibrations~~.

i) Samples above the required reporting limit with hits shall be reanalyzed and quantitated on a valid multipoint curve.

ii) ~~. Exception:~~ Samples analyzed for ~~pass/fail~~threshold testing ~~(threshold testing)~~ do not need to be reanalyzed if the initial one point calibration is at the project specified ~~presence/absence (pass/fail or~~ threshold~~)~~ level.

~~h.~~

~~i.~~

~~j.~~

~~k.~~

n) Any analytes detected in samples associated with an initial calibration that does not meet the calibration criteria in the method or laboratory SOP shall, if reported by qualified ~~be flagged~~ as estimated. Non-detected analytes may be reported without qualification~~flagging~~ if the laboratory has performed a demonstration of adequate sensitivity. This demonstration shall consist of analysis of a standard at or below the reporting limit with each analytical batch, with~~and~~ detection of all analytes in compliance with all applicable criteria for detection.

~~j~~i)

1.7.2 Continuing Calibration

When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch. The following items are essential elements of continuing instrument calibration verification.

a) The details of the continuing instrument calibration procedure, calculations and associated statistics shall be included or referenced in the method SOP.

b) Calibration shall be verified for each compound, element, or other discrete chemical species, except for multi-component analytes such as aroclors,

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**Comment [BR12]:** Add definition for threshold testing

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**Comment [BR13]:** Maybe need to add something for methods like 1668

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**Comment [CF14]:** I believe this requires more specifics. How does the ug/L range for analytes with multi-point calibration relate to ug/L range for the single-point calibration analytes? Instrument sensitivity and other factors have to be considered. As suggested during the 3/30/2012 call, this sentence may not belong here.

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**Comment [BR15]:** Add definition for threshold testing

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chlordane, total petroleum hydrocarbons, or toxaphene, where a representative chemical, related substance or mixture can be used.

c) Instrument calibration verification shall be performed:

i. at a concentration equal to or less than the mid-point of the calibration range (as determined by the average of the highest and lowest calibration standard).

ii at the beginning and end of each analytical batch. If an internal standard is used, only one verification needs to be performed at the beginning of the analytical batch;

iii. if the time period for calibration or the most recent calibration verification has expired; or

iv~~ii~~. for analytical systems that contain a calibration verification requirement.

d) 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.

e) 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 flagged. 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. Otherwise the samples affected by the unacceptable calibration verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted; or

a. ~~ii.~~ when the acceptance criteria for the continuing calibration verification are exceeded low (i.e., low bias), those sample results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted (except see following paragraph).~~.~~

~~iv.~~b. Non-detected analytes that fail the calibration verification low may be reported without flagging if a demonstration of adequate sensitivity (see section k

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of the Initial Calibration section) has been performed within the same analytical batch.