SUMMARYOF THE

TNI ENVIRONMENTAL MEASUREMENT METHODS EXPERT COMMITTEE MEETING

JANUARY 31, 2012

The Committee held a meeting at the Forum on Laboratory Accreditation, January 31, 2012, at 8:30 am EST.

1 – Roll call

Richard Burrows, Test America (Lab)	Present
Francoise Chauvin (Lab)	Present
Brooke Connor, USGS (Other)	Present
Dan Dickinson, NYSDOH (Accreditation Body)	Present
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, TNI administrative support staff	Present

2 – Minutes from January 6, 2011

The minutes were approved unanimously, after making changes proposed by Tim.

3 – Introduction

Richard said the purpose of the meeting was to discuss a list of potential items to be included in the standard. He explained this was for the chemistry module only (V1M4), and that the Committee had not reached consensus on all the items. The objective was to define which items should be included. Then the next task of the Committee would be to write the language. He showed slide 1 of a PowerPoint presentation (Attachment 1) outlining the decision criteria. He reminded the Committee Members they must keep these points in mind when voting on the items. Earlier voting on these items had been conducted by e-mail in December 2011, and Attachment 2 shows the results of this voting. Richard briefly showed the rest of the slides, which were color-coded to identify: those on which consensus had been obtained for inclusion in the standard (items 1,2,3,5,11,13); those on which the Committee Members were undecided (items 4,6,7,8,10,12); and one item which the Committee Members had reached consensus to not include in the standard (item 9). Each point would, however, be open for public discussion.

4 - Discussion of items

Item 1. Use of alternative or additional metrics for acceptance of a curve (rather than just correlation coefficient). (Slide 6).

The Committee had voted 7 yes and 2 maybe. Dan opened the discussion by stating Method 8000c is for organics, and he was not sure how this would be related to inorganics. Richard saw no reason to distinguish between organics and inorganics, but Anand pointed out that some inorganic methods have just 1 or 2 calibration points. Richard said if it is a single-point calibration there would be no correlation coefficient or RSE anyway. Tim said the 2009 TNI standard already allows more than correlation coefficient, and asked if this would just add to that language, or if there would be a requirement for certain types of calibration. Richard suggested it should be a requirement. It was pointed out from the floor that pH uses just 3 standards, so this cannot apply, and several other lower-end analyses should not have to follow this new requirement. Residual chlorine has surrogate standards. Richard responded that it would only apply when a regression curve is used, and language to that effect needs to be in the standard. Silky Labie asked if method requirements would prevail if they are different. Richard said the new requirements would be additional requirements. Bob DiRienzo pointed out there are RLs and QLs that may not be valid based on this requirement. Nancy responded that the Committee decided to focus first on calibration, and agreed RL/QL needs to be taken into consideration. Tim asked what you would do if the method requires correlation coefficient. Richard responded the analyst would then need to meet both the method and the new requirements, but he said fewer methods will require correlation coefficient. Nancy said there will need to some control over the minimum number of points, or the analyst could just use a higher order curve to connect the dots and pass (say) the RSE. It was asked how you would interpret the TNI standard if its requirements exceed the method requirements, but Richard pointed out that we already have requirements over and above the method requirements; i.e., this standard requirement would be in addition to the method requirements.

Richard presented Slide 7, with possible language.

No vote was necessary, since the Committee had previously approved inclusion of this item in the standard.

Item 2. Different calibration requirements for detected and non-detected analytes. (Slide 8).

The Committee had voted 8 yes and 1 leaning no. Richard said this would be optional for a laboratory. John asked if it could be in conflict with a method's requirements, and Richard replied the method would then take priority. Method 8000 will allow it, though the current standard does not. Dan cautioned that this allowance would not show if the preparation method has worked. Richard agreed an extracted standard is more stringent, but even a non-extracted standard is more than we have now. A comment from the floor said supposing 19 analytes are non-detects and then number 20 shows the analyte. Then

you would need to pass the calibration criteria for the method, and probably all 20 will fail. Richard disagreed, and Nancy said it would only be a problem if the laboratory is reporting to its DL rather than the QL. In slide 9 (possible language), Bob DiRienzo thought "demonstration of adequate sensitivity" would not be auditable. Richard disagreed, saying the criterion is there by stating "detection of all analytes". It was suggested from the floor that guidance would be needed for non-linear curve fits. Perhaps a table should be provided of the method with a check-box stating whether it applies to that method. Ed Askew will send the methods he has done so far. Silky Labie said it is not always right that you don't always have to flag analytes. Richard replied it would still be flagged if between the LOD and LOQ and this criterion would not apply. If not detected and below the LOD it would not have to be reported as an estimate. Silky suggested adding a definition of "reporting limit". Richard agreed, but said maybe "quantitation limit" is the term to use to avoid very high reporting limits. Paul Junio thought the low-level check would not pass anyway if it failed calibration. Tim said a few examples will be needed to make it clear what the intent would be. Silky suggested the laboratory should have to try to get a successful initial calibration curve before doing this. However, Tim said a calibration curve is not being used here (it's not quantitative).

No vote was necessary, since the Committee had previously approved inclusion of this item in the standard.

Item 3. Minimum number of standards. (Slide 10).

The Committee had voted 8 yes, and one concerned about difficulties with the criteria. Anand said while some methods specify a minimum number of standards, a lot of methods do not. Nancy added it only applies to regressions so not to a lot of methods that have 1-3 calibration points. Some concern on cost was expressed from the floor.

No vote was necessary, since the Committee had previously approved inclusion of this item in the standard.

Item 4. A standard at the quantitation limit in each analytical batch. (Slide 11).

The Committee had voted 4 yes, 3 no, 2 maybe. Richard went through slides 12 through 16. Bob DiRienzo said he likes this a lot, and it should be done in every batch. Ed Askew asked if it would apply to an extracted or non-extracted standard. Richard responded it would be just like you do for LCS. It would make every batch defensible. However, Richard was opposed to it, saying it would be extraordinarily expensive and would double the rate of batch failure. Silky Labie said if you just say the LCS must be at the decision level, then you would not need an extra LCS. Anand responded that many methods might preclude it replacing the existing LCS requirement. Tim said he has done this for inorganics, but it has proved too costly for organics. He was not sure the compromises would add a lot of value. The topic of whether this would be an instrument calibration (non-extracted) or an extracted QC sample (e.g., like a low level LCS was extensively discussed. The relative merits and added laboratory burden were discussed.

It was agreed that the topic being worked on by the committee at this time is calibration and that therefore the concept being discussed is a non-extracted (low-level CCV).]

At this point the Committee voted whether to include this item in the calibration section of the standard:

In favor 0
Opposed: 7 (Dan, Richard, Brooke, Anand, John, Lee and Tim)
Abstentions: 2 (Nancy and Francoise).

The item failed.

It was suggested, however, that the committee continue to consider this concept (routine low-level QC), with regard to the qualifiers: per batch; at the QL; with or without control criteria that would be wider than the LCS; extracted standard; in addition to the low-level LCS; for all analytes or surrogates. Lee said this would not fall under calibration so it is not applicable at this time. Therefore, the committee voted to reconsider the concept in the future when it discusses detection/quantitation.

In favor: 9
Opposed: 0
Abstentions: 0

The vote passed.

Item 5. Calibration verification shall be performed at or below the mid-point of the calibration curve. (Slide 17)

The Committee had voted 7 yes, 2 maybe. In response to a question from Paul Junio, it was explained the mid-point is the mid-concentration and not the middle number of standards. There was no further discussion.

No vote was necessary, since the Committee had previously approved inclusion of this item in the standard.

Item 6. Improve clarity on acceptance criteria for multi-peak analytes, eg PCBs, technical chlordane, toxaphene. (Slide 18)

The Committee had voted 5 yes, 4 no (who suggested a guidance document instead). Richard presented slides 18 and 19 and explained the 3 options. Tim said at least one method allows a single-point calibration unless there is a detect, when you have to calibrate. This suggested requirement would eliminate that option. Anand said most laboratories follow option 2 (slide 19), so this is a good compromise. However, he questioned if it should be a standard or just guidance.

The Committee voted whether to include this item in the calibration section of the standard:

In favor: 5 (Francoise, Dan, Nancy, Anand, and John)
Opposed: 4 (Richard, Brooke, Tim and Lee)
Absentions: 0

The vote passed.

Item 7. Remove the requirement that analytes must be quantitated from the initial calibration, rather than the continuing. (Slide 20).

The Committee had voted 3 yes, 4 no, and 2 wanted to discuss further. Richard said a lot of methods would not allow this change, but that would be an unnecessary statement to put in the standard. Tim said there would be a lot of uncertainty in how this might be applied, and it may only be good for a linear fit. Anand said the CCV is always compared to the initial calibration curve.

The Committee voted whether to include this item in the calibration section of the standard:

In favor: 2 (Richard and Brooke)
Opposed; 7 (Francoise, Dan, Nancy, Anand, Lee, Tim and John)
Absentions: 0

The vote failed.

Item 8. Require a multi-replicate calibration study as part of the initial demonstration of capability at a laboratory. (e.g., at least 6 runs at each of 5 levels). (Slide 21)

The Committee had voted 5 yes, 4 no. Richard presented slides 23 and 24, showing data for hexachlorocyclopentadiene. The standards initially produced a curve which then became linear a month later. Nancy asked if this would just be applicable to a new method, and if so whether it would be appropriate to this standard. Richard suggested it would be better in guidance if it just applied to a new method. A comment from the floor said it would be appropriate for validating an instrument, but not the initial demonstration of capability for a particular analyst. Ed Askew asked if it only applied to a major change to an instrument; it would not be feasible for something minor such as just cleaning the source. A commenter pointed out that the current standard addresses laboratory-developed methods in Section 1.5 of the technical modules, and Nancy said the Committee should check if calibration is adequately addressed in those sections, and if this belongs there. Dan said the AB would have to look in advance to see if the requirement would be allowable. John believed this should be done, because improved technology may have affected older methods. Anand said it does not belong in this part of the standard, which is for established methods, and perhaps it belongs in guidance.

The Committee voted whether to include this item in the calibration section of the standard.

In favor: 0
Opposed: 8 (Dan, Brooke, Richard, Nancy, Anand, Lee, Tim and John)
Abstained: 1 (Francoise)

The vote failed.

It was moved by Nancy and seconded by Lee that the Committee should review sections 1.5 and 1.6 of the 2009 standard's chemistry module to determine if the current calibration requirements are adequate. Richard spoke against the motion, saying that the Committee has too much going on at this time. It was agreed that since the scope of the committee includes a review of the flexible approach if time allows, that if and when we get to the flexible approach calibration will be evaluated.

Voting on the motion was as follows:

In favor: 8 (Dan, Brooke, Nancy, Anand, Lee, Francoise, Tim and John)
Opposed: 1 (Richard)
Abstentions: 0

Item 9. Require a multi-replicate calibration for each calibration.

The Committee had previously voted unanimously against this item, and it was not discussed further.

No vote was necessary, since the Committee had previously agreed not to include this item in the calibration section of the standard.

Item 10. Some requirement regarding spacing of calibration standards. (Slide 25).

The Committee had previously voted 3 yes, 6 no. Richard offered the opposing view that there is too much variability in deciding how to do this. Nancy asked if laboratories should have a policy to address this. This was discussed and it was concluded that NELAP frequently uses the approach of placing a requirement in the standards that a laboratory have minimum standards on a particular topic and that they describe those minimum standards in their quality manual. While the content of the QA manual is then not auditable, the requirement to have text in the manual is auditable. Brooke suggested there should be something saying what they should not do; e.g., do not have several zero points to weight the curve. John said this needs to be in guidance only. Nancy said it would not be appropriate to consider this until to the minimum number of calibration points has been considered, since they are linked.

The Committee voted whether to include this item in the calibration section.

In favor: 0
Opposed: 9 (Dan, Francoise, Brooke, Richard, Nancy, Anand, Lee, Tim and John)
Abstained: 0

The vote failed.

Item 11. Controls over what points or levels may be excluded from a calibration, and in what circumstances. (Slide 26).

The Committee had voted 8 yes, 1 maybe, so there was already consensus. It was pointed out there has to be a reason for removing a point. Anand questioned how the requirement would be auditable. Brooke said it might also apply to replacement of points.

Item 12. Control over the intercept. (Slide 27).

The Committee had previously voted 5 yes, 3 no, 1 maybe. Suggested language and counter arguments were presented in slides 28 and 29. Francoise said there needs to be a distinction between intercept and "offset", and this presents a quick test to look at the systematic error associated with that part of the curve. John said a further look is needed with some data sets to see if this is needed. Brooke said one analyst may report detected and another may not because calibration is different at the low end. Tim said it is difficult to evaluate the intercept because there may be a systematic error causing an offset. Nancy believed something is needed at the low end, and nothing else has been suggested. Ed Askew asked what you would do if the laboratory is not reporting below its lowest standard. Francoise said it is a mathematical test to say what your bias is at your reporting level, not a change to the reporting range.

The Committee voted whether to include this item in the calibration section of the standard.

In favor: 1 (Francoise)
Opposed: 5 (Anand, Dan, Richard, Lee and Tim)
Abstained: 3 (Nancy, Brooke and John)

The vote failed.

Item 13. Definition of "independently prepared second source standard" (Slide 30)

The Committee had previously voted 4 yes, with 5 votes not in because this was added later. Discussion of this item was deferred, since this would be considered during a special session on Wednesday February 1.

5 – Adjournment

The meeting adjourned at 12:00 noon, with next meeting, by teleconference, scheduled for Friday February 17, 2012 at 2:00 pm

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	Not determined
2	1/31/12	Continue to consider the concept of routine low-level QC in the standard.	Committee	Not determined
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	Not determined

Attachment 1

Items to Include in the Calibration Section of the TNI Chemistry Module

Decision criteria

- 1) Include only things in the standard that are known to address issues that lead to inaccuracies and that are practical for implementation on a routine basis
  - 2) standards under consideration must be practical and able to be implemented cost-effectively during routine operations
  - 3) proposed standards must be auditable – that is, what is required to comply must be clearly defined for both labs and assessors

Item #	Description	Summary
1	Use of alternative or additional metrics for acceptance of a curve (rather than just correlation coefficient)	7 yes, 2 maybe
2	Different calibration requirements for detected and non-detected analytes	8 yes, one leaning no
3	Minimum number of standards	8 yes, one concerned about difficulties with criteria
4	A standard at the quantitation limit in each analytical batch	4 yes, 3 no, 2 maybe

Item #	Description	Summary
5	Calibration verification shall be performed at or below the mid-point of the calibration curve	7 yes, 2 maybe
6	Improve clarity on acceptance criteria for multi-peak analytes, eg PCBs, technical chlordane, toxaphene	5 yes, 4 no (guidance document instead
7	Remove the requirement that analytes must be quantitated from the initial calibration, rather than the continuing	3 yes, 4 no, 2 want to discuss further
8	Require a multi replicate calibration study as part of the initial demonstration of capability at a laboratory. (eg at least 6 runs at each of 5 levels)	5 yes, 4 no

Item #	Description	Summary
9	Require a multi-replicate calibration for each calibration	9 no
10	Some requirement regarding spacing of calibration standards	3 yes, 6 no
11	Controls over what points or levels may be excluded from a calibration, and in what circumstances	8 yes, 1 maybe
12	Control over the intercept	5 yes, 3 no, 1 maybe
13	definition of "independently prepared second source standard"	4 yes, 5 votes not in because this was added later

Use of alternative or additional metrics for acceptance of a curve

- WHY
  - Correlation coefficient allows very large error at low end of curve
  - Correlation coefficient is not helpful in choosing between different curve options
- WHAT
  - Relative Standard Error (SW-846, CFR40, Part 136)
  - Assessment of residuals at low point or all points of the curve (SW-846, Drinking water)

Possible language

- a measure of relative error in the calibration shall be used. This evaluation may be performed by either:
    - Measurement of the error at 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.
    - 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.

Different calibration criteria for non-detected analytes

- WHAT
  - Allow reporting of non-detected analytes with a demonstration of sensitivity, even if initial or continuing calibration criteria fail
- WHY
  - Allows tighter calibration criteria for detected analytes (eg, SW-846 20%D for all analytes vs. CCC criteria, grand mean, etc)

Possible language

Any analytes detected in samples associated with an initial calibration that do not meet the calibration criteria in the method or laboratory SOP shall be flagged as estimated.

Non-detected analytes may be reported without 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, and detection of all analytes.

Minimum Number of standards

- WHAT
  - Establish a minimum number of calibration levels, based on considerations of curve type and calibration range
- WHY
  - Some method have insufficient control of the number of levels

Possible language

A minimum of 6 calibration levels shall be used for any quadratic calibration.

Standard at QL in each batch

- WHAT
  - Require an extracted calibration standard at the QL in each analytical batch
- WHY
  - Currently there is very little assessment of accuracy or precision around the QL

Possible language

A Laboratory Control Standard corresponding to the limit of quantitation shall be analyzed with each analytical batch and shall meet established acceptance criteria.

Discussion on QL LCS in Each Batch

1. It is important to verify both the calibration and the performance of the method across the entire calibration range, however the lower concentrations are more susceptible to poor performance.
2. Could optionally or additionally run a non-extracted QL CCV in each batch.
3. Concern that QL LCS will greatly increase cost, especially for multi-analyte methods.

Discussion on QL LCS in Each Batch

4. Options to reduce cost of QL LCS for multi-analyte methods include:
   a. Run QL LCS less frequently (daily, weekly, monthly, or quarterly)
   b. Run only shorter list of surrogate compounds
   c. Relax the QL spike level to say 0.5-2x the QL
   d. Raise the lab QL for some analytes to reduce the number of standard mixes required to cover all of the QLs

Discussion on QL LCS in Each Batch

5. If too many analytes to be able to fit a sufficient number of method QC samples in a single analytical batch then perhaps the analyte list should be split into multiple sub-methods – Considered out of scope
6. It is recommended to use similar performance measures as the Mid-Level LCS.
7. Failed QL LCS Responses:
   a. Qualify data (only data below mid-level LCS if pass)
   b. Re-extract and re-analyze batch

Discussion on QL LCS in Each Batch

- Draft EPA language for method 8000

"LLOQ verification is recommended for each project application to validate quantitation capability at low analyte concentration levels."

"Until the laboratory has sufficient data to determine acceptance limits, the LCS criteria +/- 20% may be used for LLOQ acceptance criteria."

Discussion on QL LCS in Each Batch

- Possible compromise
  - At least Quarterly, using SW-846 criteria

Calibration verification at or below the mid-point of the curve

- WHAT
  - Calibration verification standard concentration must be at or below the concentration half way between the low point and the high point.
- WHY
  - Encourages more realistic calibration verification

Possible language

Calibration verification shall be performed at or below the mid-point of the calibration curve.

Improve clarity of requirement for multi-peak analyte calibration

- WHAT
  - Set minimum specifications for calibration of analytes such as Aroclors, technical chlordane and toxaphene
- WHY
  - Currently a wide variety of interpretations

Improve clarity of requirement for multi-peak analyte calibration

1. Require a full multipoint calibration for every analyte, and require a CCV for every analyte
   a. There may be 5 or 6 different PCB mixes, technical chlordane, toxaphene and 2 different individual pesticide mixes in a Pest/PCB analysis. This means 50 or more analytical runs to establish an initial calibration, and up to 10 CCVs per 10 samples.
2. Require a full multi point for the individual pesticides, technical chlordane and toxaphene, and for 1016/1260, allow single points for the other PCBs unless there is a hit in a sample for a single point PCB, then require reananysis on a multipoint curve.
3. Same as #2, but allow quantitation of the PCBs from single points (except 1016/1260) – also allow just the single component pesticides, and 1016/1260 as CCVs, unless there is a hit.

Remove requirement that analytes cannot be quantitated from the continuing

- WHAT
  - Currently, TNI standard prohibits quantitation from the continuing standard – remove this requirement
- WHY
  - For average response factor methods, quantitation is probably more accurate if done from the continuing, since current conditions are reflected

Multi-replicate Calibration study as part of IDOC

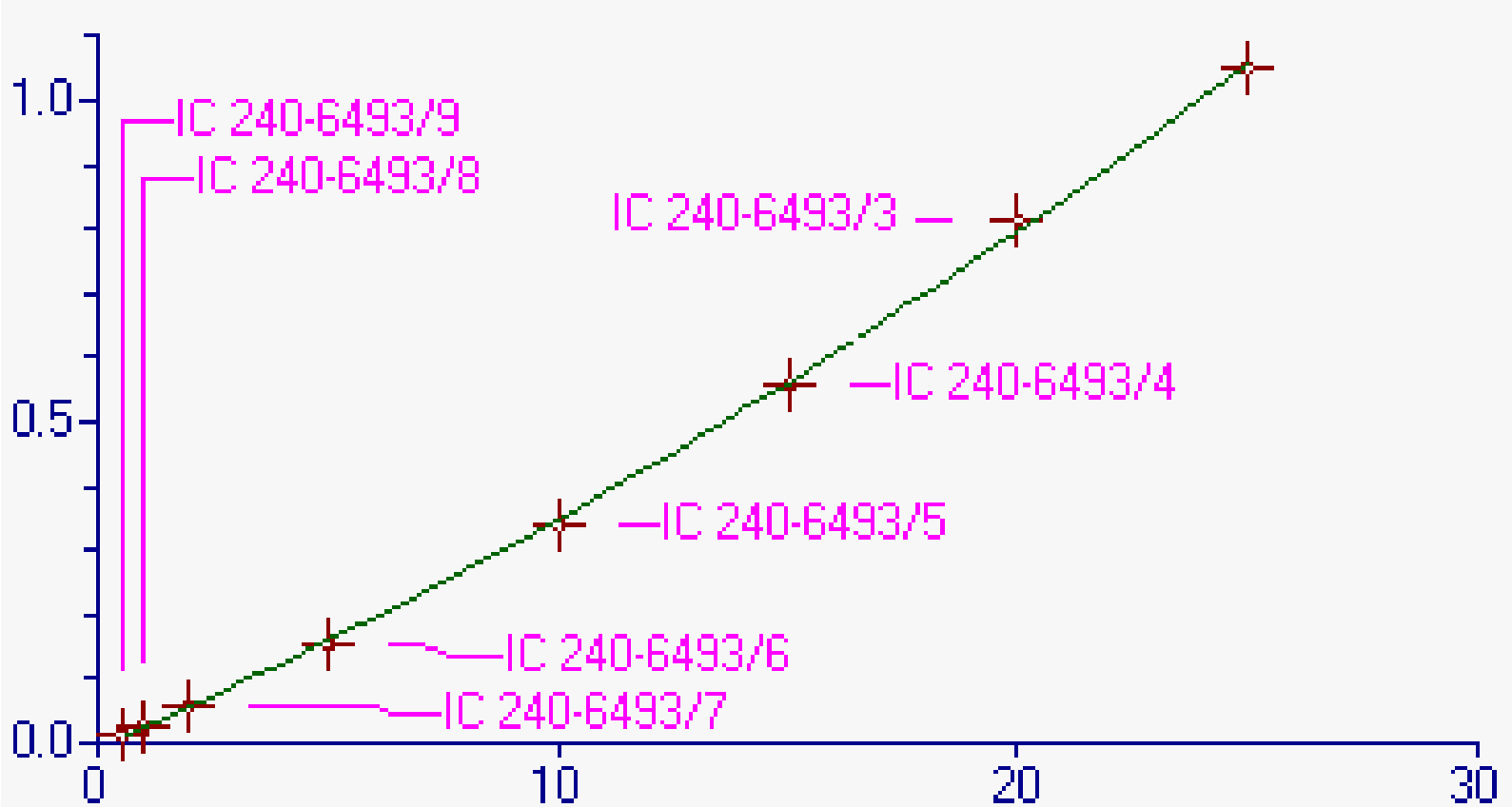
- WHAT
  - Require a multi-replicate (eg 6 points at each of 5 levels) calibration study as part of the initial demonstration of capability
- WHY
  - To scientifically determine the appropriate model for calibration over the range of interest
  - To evaluate the limitations of a specific model (e.g. where linear model ends)
  - To determine the precision and thus the uncertainty in the calibration and calibration model
  - To select and determine confidence in one model of calibration over other models
  - To produce scientifically and legally defensible documentation of method choices as regards calibration
  - To establish sound basis for the range, calibration model, calibrants, n, and calibration QC.
  - To estimate the best-possible quantitation limit (for use in initial QL determination)
  - To estimate the best-possible detection limit (for use in initial DL determination)

Multi replicate standard discussion

- Arguments against
  - Limiting the ability of the analyst to choose the best calibration fit for a specific data type may reduce, rather than improve, data quality
  - Best calibration curve type choice and calibration range is not necessarily constant – it depends, for example on the specific instrument, condition of the column, age of the multiplier, the specific trap, the condition of the source, and dozens of other variables

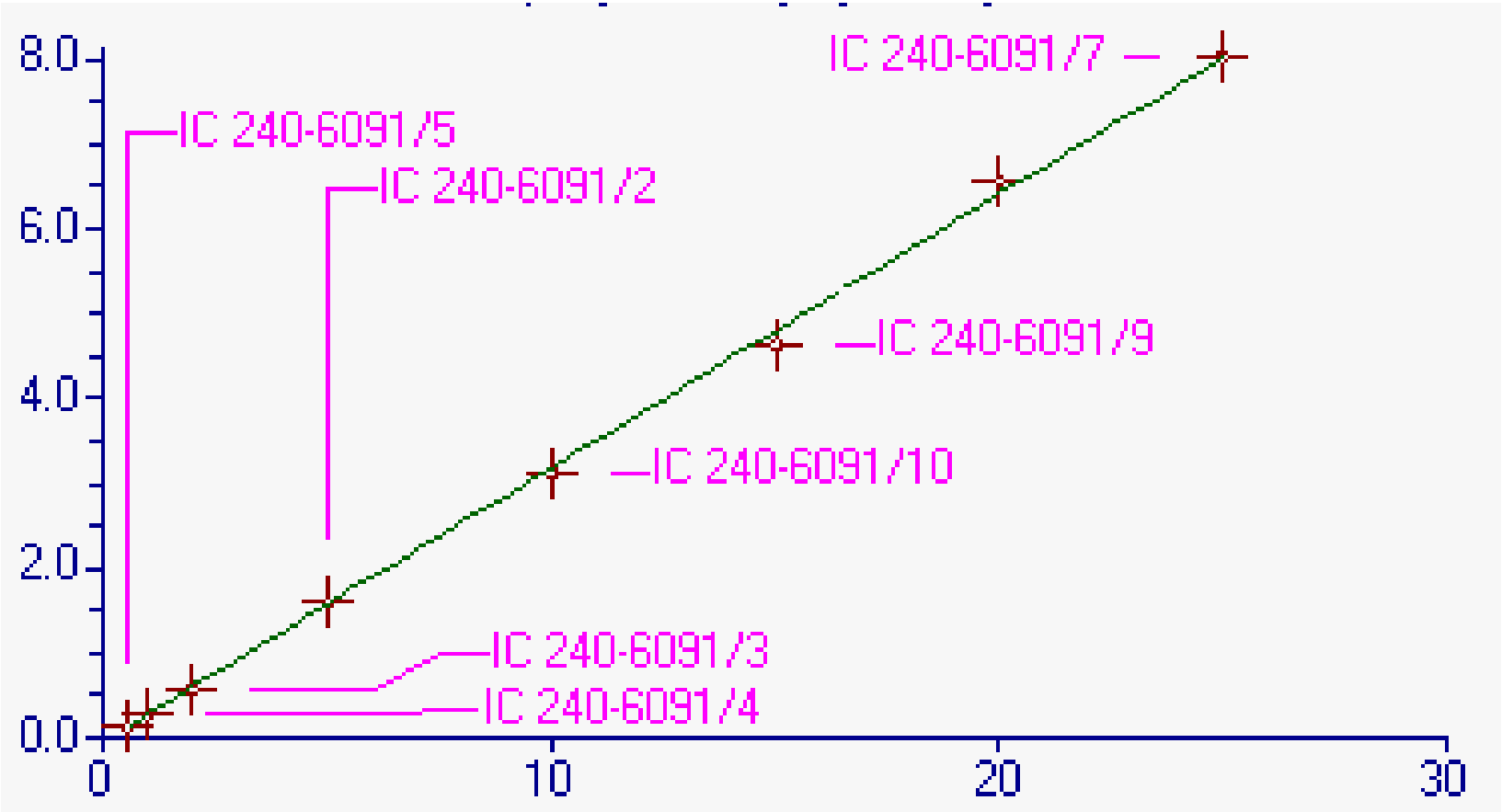
Hexachlorocyclopentadiene

Quadratic, 10% RSE, r^2 = 0.999



Hexachlorocyclopentadiene

One month later, Linear weighted, 3% RSE, $r^2 = 0.999$



Control of spacing of calibration standards

- WHAT
  - Some sort of specification regarding how calibration standards should be spaced
- WHY
- Inappropriate spacing can lead to poor calibrations
  - affect on curve fitting
  - expected sample response,
  - intended use of the data.

Removal of Calibration points

- WHAT
  - Specifications on the circumstances under which calibration points and/or levels may or may not be removed from a calibration
- WHY
  - Controversial issue with several different interpretations

Control of the intercept

- WHAT
  - Specification regarding how far from the intercept the calibration line may be and still be acceptable
- WHY
  - Calibrations that stray far from the intercept may lead to inaccurate low level data, and problems with detection and quantitation limits

Suggested language for intercept test

- Perform an intercept test (relative bias at the Limit of Quantitation) for each new calibration:
  - Divide the y intercept by the slope of the calibration = I
- Acceptance criteria: absolute value of I to be within laboratory established acceptance criteria or client data quality objectives for allowed uncertainty at the LOQ.

Counter arguments for control of intercept

- Important, but may not need to be directly addressed if additional metrics for calibration curve are adopted (eg RSE or % error of low point)
- Large intercept can coexist with accurate data at the QL for certain methods

Definition of “Independent standard”

- WHAT
  - Clear definition of what an independent standard is (as used for initial calibration verification)
- WHY
  - Different interpretations exist

Attachment 2

Item #	Description	Summary	TIM	LEE	NANCY	BROOKE	DAN	FRANCOISE	JOHN	ANAND	RICHARD
1	Use of alternative or additional metrics for acceptance of a curve (rather than just correlation coefficient)	7 yes, 2 maybe	Maybe - 1.7.1.1(e) only states that acceptance criteria shall be established and currently allows metrics other than the correlation coefficient. Are you proposing we add numeric values for specific metrics? (RB - No to numeric values, yes to specific techniques)	Y	If it is a standard, we would have to decide that it is a requirement. If RSE is the requirement, then RSE will be 'perfect' by default unless three point calibration is required with linear regression and more points of each 'curving' allowed. We seem to be as a group suggesting that all sort of curving is going to be allowed which becomes just connecting the dots calibration. Connecting the dots calibration, again leads to perfect RSE.	Yes. Never just correlation coefficient. The standards should be able to be back calibrated to within X% of expected; maybe residuals;	Yes - However, the standard currently does not have restrictive language for curve acceptance.	Yes - Correlation coefficient is very insufficient to determine goodness of fit and should not be the only criterion to use to choose between models.	Yes - Correlation coefficient could be used as well, but I think we need to also specify RSE as a requirement as appropriate.	Yes- RSE as an additional metric	Yes
2	Different calibration requirements for detected and non-detected analytes	8 yes, one leaning no	Y	Y	If we do this it will become a complex requirement as it is not cut and dry. What if a detection occurs in a non-detection type calibration. Do they have to reanalyze under different calibration.	Yes but 1.) how well do they know their detection probability? 2.) and how would you pass CCV or DL check samples or blanks to prove your detection capabilities. 3.) So this implies only if you fail the curve by overestimation only? Or what? 4.) Would we require a sensivity check to pass for that analyte then? Do we keep or remove the data from our databases for long term analysis of performance and control limit setting? Because if we keep it, the limits will get wider until we pass when we shouldn't (right????)	Yes - is this limited to single component methods?	Absolutely yes	Yes, but we will need to think through the requirements.	Yes - need to think about requriements e.g., running one level first (low?) with samples and then all levels for detected analytes like PCBs.	yes
3	Minimum number of standards	8 yes, one concerned about difficulties with criteria	Y	Y	When we tried to get to this answer before, one was the minimum. Unless we are willing to go down the method-by-method approach, what are the categories.	Yes if we can find a nice generalization that will work for most classes of analyses or something.	Yes	Yes - using the text of TNI 2009, Mod 4, 1.7.1.1.j as a starting point and not requiring less. The current text of TNI 2009, Mod 4, 1.7.1.1.h (Re: case of ICP instruments) being addressed (or not) sepaprately.	Yes, but this will also need some well thought out and clear requirments.	Yes	Yes
4	A standard at the quantitation limit in each analytical batch	4 yes, 3 no, 2 maybe	Maybe - do you mean a CCV or an LCS? A calibration standard is already required at the LOQ. (RB - I don't think that there is currently a requirement in TNI standards for a LOQ standard in each batch)	N	I would like to have a discussion about the relative merits of what ever this is. Historically there has been much push back on an LCS in each batch. I believe that for detection and quantitation it is much more important to have a LCS in each batch than it is to have a CCV in each batch for quantitation. So I would vote no, unless this is on top of agreeing to an LCS in each batch.	Need a sensitivity check if you are going to say that ND means you don't have to have a passing initial calibration.	Yes	Yes	Yes, I would prefer and LCS and one at the QL in every batch would be prefered over one in the mid range. I also think that we need some checks throughout the concentration range, but it does not have to be with every batch.	Yes	No
5	Calibration verification shall be performed at or below the mid-point of the calibration curve	7 yes, 2 maybe	Y - or varied throughtout the run as was in the first NELAC standard. I'd like to hear the rationale for removing that requirement in 2003.	Y	I believe that were NELAC tried to go then backed off of is still where it needs to go. Three levels low, mid, high and different criteria for each. In the long run measurement uncertainty should be the goal and you cannot get there with one level.	Should be verified within the environmental sample concentrations per run? .	Yes for verification - debateable as to midpoint or otherwise.	Yes to cal checks at several levels. Perhaps there should be flexibility in the actual levels to be checked? Actual levels to be determined by the labs, depending on the levels of analytes found in their samples. Standard to specify criteria to set these levels	Yes, varied throught the run.	Yes - need to look at methods that already require variation in levels	Yes
6	Improve clarity on acceptance criteria for multi-peak analytes, eg PCBs, technical chlordane, toxaphene	5 yes, 4 no (guidance document instead	Y - bear in mind that some methods allow single point calibration for screening multi-peak analytes (e.g., 8081)	N	No, this is too big a chunk to bite of in the standard. You can talk about it in guidance, but unless someone has some specific text in mind, this is a quagmire.	Guidance document.	Yes	Yes it is important. but it would be difficult to address. This issue should definitely be addressed in the guidance document; it might be realistic to start there.	No, I would rather this be in the guidance document, but we couldn't we refer to the guidance document in the standard for this.	Yes	Yes
7	Remove the requirement that analytes must be quantitated from the initial calibration, rather than the continuing	3 yes, 4 no, 2 want to discuss further	Maybe not - I'd like to hear discussion on this issu.e.	Y	NO. This just uses a lower n to lower the quality. Unless there is some specific reason under very limited circumstances, another quagmire.	Yes. In volatiles especially, it is not the initial calibration that starts to fail, it is that the calibration verification sample is run when instrument conditions have changed. The CCV tells us the conditions have changed. The response of the instrument to that CCV is REAL and is representative of how the instrument is behaving at that time. I wouldn't make it a standard that a single pt calibration be used from the CCV, but it certainly can be used to say that response has changed. We would then need to determine if it is guidance or a standard on what to do. The requirement to not be able to use the CCV is restrictive.	No	No	I would need to be convinced on this one as more data points are better statistically.	No	Yes
8	Require a multi replicate calibration study as part of the initial demonstration of capability at a laboratory. (eg at least 6 runs at each of 5 levels)	5 yes, 4 no	N - not sure what this gets us if we want the latitude to adjust our calibration model to fit the detector response during a particular day of operation	N	YES - As a one time demonstration. I disagree that the real model based on the physics of the analysis is SO variable. I think it is mostly bad chemistry chasing the model of the day and we should be pushing for linear calibration unless there is positive evidence of some other 'demonstrated through scientific method' of some other model being appropriate.	I don't see how this would improve the current situation because it is not the within run variability of consecutive clean injections that will better define our problems. We have problems knowing the quality of our low concentrations and we have problems knowing enough about mid to end run variability with only a single CCV concentration. There are opinions out there that multipoint multiple concentration calibrations are the best way to determine detection levels. If this is so, I can see where I'd want to consider this.(PS - Can you use multiple previous calibrations to accomplish the same thing rather than within run variability of 6 injections per concentration?? This way there are no additional costs of prep and running the samples - just data crunching.)	Yes, but only in cases of significant method modification	Yes - Also, there should also be instructions on when/how the labs would be allowed to switch calibration models and the experimental and documentation requirements when doing so should be specified.	This needs to be done when the method is first developed, thereafter, only when "significant" (need to define) method modifications are made. If this was not done when the method was first developed we should generate this data in a small interlaboratory study. If you don't modify the method a minimum of 3 replicates at each of 4 levels should be sufficient as an initial demonstration of capability.	Only for methods developed in-house by the laboratory or for standard methods altered "significantly" - of course would need to define "signficantly"!	No
9	Require a multi-replicate calibration for each calibration	9 no	N	N	no	no	No	No	No	No	No
10	Some requirement regarding spacing of calibration standards	3 yes, 6 no	N - don't know how we'd construct the language to cover all cases of operations - best left to guidance in my opinion.	N	NO - While I think it should be, it is to complex with multianalyte methods for a NELAC standard to handle.	guidance	Yes	This should definitely be addressed in the guidance document. I would prefer seeing it in the standard as well	Include in Guidance Document	Yes	No
11	Controls over what points or levels may be excluded from a calibration, and in what circumstances	8 yes, 1 maybe	Y - at a minimum establish a requirement to document the reason for removing a calibration point, which should adhere to some set of conditions.	Y	YES	Yes, in the broadest sense.	Yes	My opinion is that this should not be allowed. If it is, there are serious implications on the items listed above, number of calibration levels and spacing	Maybe, if it can be done sucinctly, but should refer to the Guidance Document for a complete discussion.	Yes	Yes
12	Control over the intercept	5 yes, 3 no, 1 maybe	N	N	YES - Abuse of intercepts is a major problem in the industry.	Yes if this is where we are blowing it!	Yes if not part of Item 1, above. Or No if included there either as limits on LOQ level std residual or some other related parameter.	Yes - Could be part of # 1 above. Related to # 2 above as well.	Yes, this is important for Detection and near the Quantitation Limit.	Yes	No
13	definition of "independently prepared second source standard"	4 yes, 5 votes not in because this was added later						Yes	Sounds reasonable, if we want it something that is clearly auditable.	Yes - (but I think we already have definitions for it)	Yes