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The **2016** TNI Standard V1 M4

GUIDANCE ON THE MAJOR CHANGES TO THE 2009 TNI STANDARD V1M4

Quality Systems for Chemical Testing

Presenting Changes to:

Limits

- 1.5.2.1 LOD requirements
- 1.5.2.2 LOQ requirements

Calibration

- 1.7.1.1e Removal and replacement
- 1.7.1.1.f Minimum number of standards
- 1.7.1.1.k Relative Error
- 1.7.1.1.l Single point calibration
- 1.7.1.1.p Linear range calibrations
- 1.7.2.f Continuing calibration

2016 V1M4 1.5.2.1
Method Detection Limit

(no longer using the term LOD)

Richard Burrows, Ph.D.
TestAmerica Inc.

Good News

- The revised MDL and TNI Chemistry standards are fully compatible
- If you are compliant with the revised EPA MDL then you are also compliant with the current MDL
  - One exception, discussed later
- If you are compliant with the revised TNI Chemistry standard then you are compliant with the current TNI Chemistry standard

First, what stays the same?

- Fundamental concept is unchanged
  - What is the lowest result that is qualitatively reliable, i.e., the lowest result that reliably indicates the analyte is in the sample?
- Fundamental approach is unchanged
  - Describe the distribution as Student's t times the standard deviation of results

What is different?

- Requires calculation of a MDL based on blanks as well as an MDL based on spikes (the higher of the two becomes the MDL)
- Incorporates longer term variance
- Includes checks for reasonableness
- Works effectively with various quantitation limit concepts and procedures

Details, details

- Spiking level
  - 2-10 times estimated MDL
- Run spiked replicates in at least 3 separate preparation and analysis batches
- Multiple instruments
  - At least 2 spike replicates on each instrument
- If blanks give ND, MDL_B does not apply
- Addendum for MDL determined on a specific matrix
- No 10X rule
- Use all method blanks unless batch was rejected

2016 TNI standard requirements for detection limit

2016
“reflect current operating conditions”
“entire analytical process”
“analytes of interest in each test method in quality systems matrix of interest”
“Include data from low level spikes and routine method blanks”
“Include evaluation of false positive rates”
Verification includes a minimum of one low level spike and one blank per quarter per instrument
Verification is only required if reporting below the LOQ
One option is to follow the EPA MDL procedure

MDL - Ongoing verification

V1M4 1.5.2.1.2 – new section

Richard Burrows, Ph.D.
TestAmerica Inc.

MDL on-going verification

- Collect data quarterly
  - One spike per instrument (two if only one instrument)
  - Requirement is detection
- Analyze data annually
  - Recalculate MDL based on last two years spike and blank data
  - If within factor of 3 (possibly 2) then lab option to leave unchanged or update
  - If outside that range then update

What does this mean regarding verification?

- MDL can be verified by examining blank results
- MDL cannot be verified with spiked samples
  - (Curries L_D could be verified with spiked samples)

Why do we need an MDL and an LOQ?

Richard Burrows, Ph.D.
TestAmerica Inc.

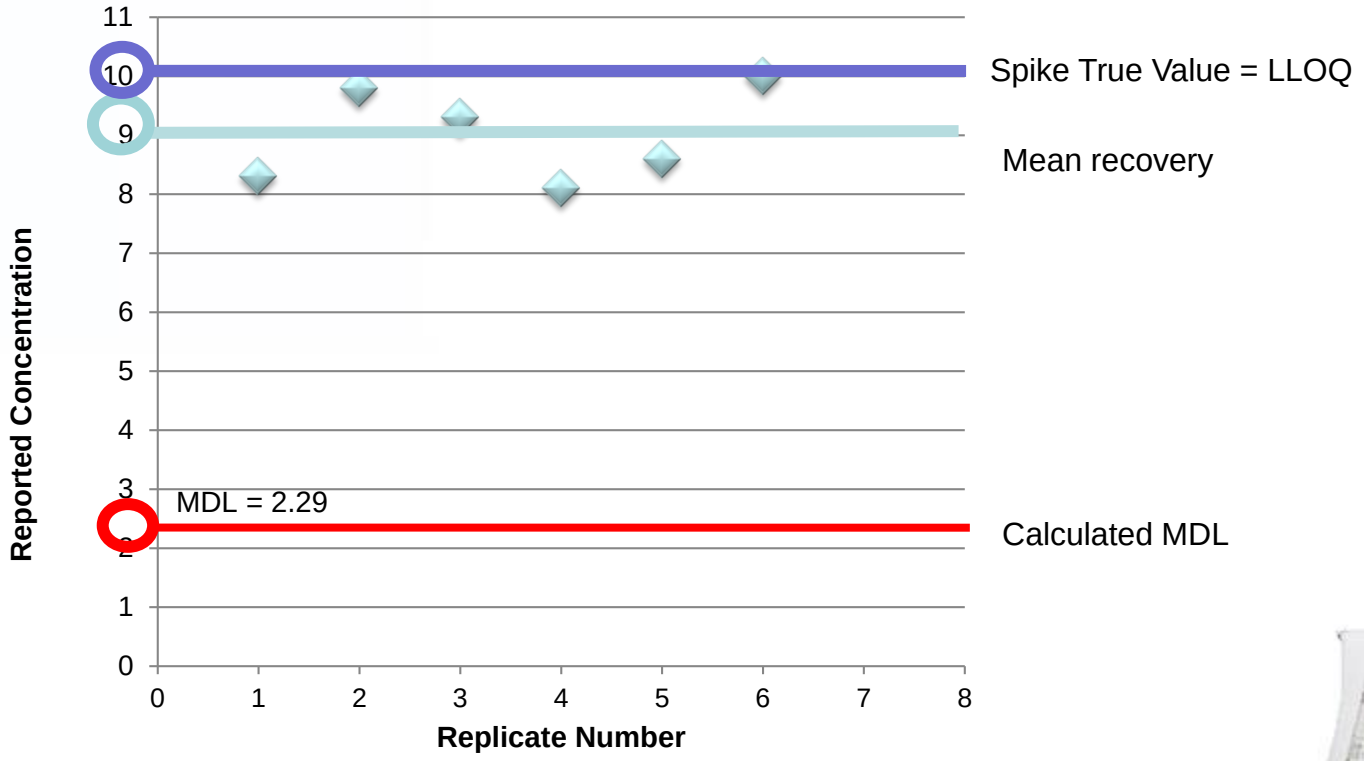
Reason #1 that we need MDLs

- We need to make the Quantitation limit meaningful
- Applies to MRL, LLOQ, or any quantitation limit
  - Without a MDL, a true concentration at or close to the LOQ is probably going to be reported as a false negative

In other words, without a MDL, our quantitation limit is not only not quantitatively reliable, it is not qualitatively reliable either

90% recovery, 9% RSD

Spike	#1	#2	#3	#4	#5	#6	#7	Mean	MDL
10	9	8.3	9.8	9.3	8.1	8.6	10.0	9.0	2.29



Reported results (without MDL)	ND	ND	ND	ND	ND	ND	10

Bottom Line

If you don't report below the LOQ you have a lot of false negatives.

You can't minimize false negatives and false positives at the same level.

With the LOQ and the MDL, false negatives are controlled at the LOQ and false positives are controlled at the MDL.

Reason #2 that we need MDLs

- MDLs are needed in risk assessment
  - Handling non-detects
    - Substitute a value such as ½ detection limit or detection limit
    - More sophisticated methods such as Maximum Likelihood estimation and Regression on Order statistics
      - These still benefit from a detection limit as low as possible

If we do not have a detection limit, the Quantitation limit will become the new Detection limit

Limit of Quantitation

V1M4 1.5.2.2, 1.5.2.3 and 1.5.2.4

Richard Burrows, Ph.D.
TestAmerica Inc.

2009 TNI Standard V1M4 1.5.2.2 - LOQ

- 2009 standard
  - Include all sample processing and analysis steps
  - Verify with analysis of a standard at 1-2 times LOQ
  - Verify annually, but not required if the LOD was determined or verified on that instrument

No way to determine precision and accuracy

2016 LOQ requirements

- 1.5.2.2 - LOQ
  - At least 3X the MDL
  - All processing steps
  - Above lowest calibration standard
- 1.5.2.2.1 - LOQ Verification (initial)
  - At least 7 spikes at of below the LOQ
  - 3 batches on 3 separate days
  - Distribute across instruments, at least 2 per instrument
  - Results must meet identification criteria and be above zero and within the laboratory established recovery criteria

2016 LOQ requirements

- 1.5.2.2.2 – Ongoing LOQ Verification
  - One verification sample on each instrument each quarter
  - Must meet identification criteria and be above zero
  - Once per year compile the data and create a statement of precision and accuracy

LOQ - New Section 1.5.2.3

- 1.5.2.3 - If no analysis was performed in a given year, the verification of the MDL/LOQ is not required, but a new initial MDL/LOQ verification shall be performed prior to analysis of client samples.

LOQ Documentation- New Section 1.5.2.4

At least once per year tabulate all results of the ongoing verification sample testing. Record the analytical and preparation methods used, dates of preparation and testing, the batch identifiers, the testing instrument, quality system matrix, technology, analyte, concentration in the spiked sample with units, and the test result (if any) for each LOQ and/or MDL verification test.

LOQ Documentation – 1.5.2.4 continued

For each analyte, the laboratory shall record the percent recovery, the number of results (n), the mean and standard deviation of the percent recovery, and the spiking concentration of the spiked samples with units. These data shall be provided to clients upon request.

Questions?

2016 TNI Standard

Chemistry Expert Committee

Calibration, Section 1.7.1.1.e - Removal and Replacement of Calibration Standards

Scott D. Siders
Director of Quality Assurance
PDC Laboratories, Inc.

Section 1.7.1.1.e
Removal and Replacement of Calibration Standards

- Background
  - Section 1.7.1.1.e was written to introduce language that reflected current industry data integrity practices relating to dropping calibration standard.
  - Multiple drafts based on CEC members and comments received were made prior to final language.

CEC: Chemistry Expert Committee

Basic Breakdown of 1.7.1.1.e

- Need a Written Procedure
- Procedure shall comply with 1.7.1.1.e
- Removal of Calibration Standards
- Replacement of Calibration Standards
- Technically Valid Reason for Removal or Replacement of any Interior Calibration Standard (standard, level or point)

Written Procedure

- Procedure must comply with all requirements in 1.7.1.1.e
- Can be in:
  - SOP (test method or non-test method), or
  - Quality Manual
- Recommend incorporate language into Data Integrity program and training (if not already done)

Removal

"the action of taking away or abolishing something unwanted"

e) i. The laboratory may remove individual analyte calibration levels from the lowest and/or highest levels of the curve. Multiple levels may be removed, but removal of interior levels is not permitted.

- Whether a single analyte curve (e.g., NO_3) or a multi-analyte curve (e.g., VOA) you can remove the lowest and/or highest calibration standard and do it multiple times.
- You can not remove (drop) an interior (e.g., mid-level) calibration standard that is between the lowest and highest calibration standards. Can't selectively drop interior standards so as to appear and pass calibration criteria! Helps prevent "cherry-picking" of calibration standard.

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*RESPONSE FACTOR REPORT GC MS #2

Method Path : C:\MSDchem\1\METHODS\
Method File : 032702.M
Title : method 525
Last Update : Wed Mar 27 14:03:40 2002
Response Via : *INITIAL CALIBRATION

* CALIBRATION FILES
1 =CAL1.D 2 =CAL2.D 3 =CAL3.D 4 =CAL4.D 5 =CAL5.D 6 =CAL6.D

*		COMPOUND	1	2	3	4	5	6	* AVG	%RSD
1)	I	p-Terphenyl-d14	----------ISTD----------							
2)		Acenapthene-d10	----------ISTD----------							
3)		Hexachlorocycl...	0.331		0.267	0.248	0.242	0.226	0.263	15.56
4)		Propachlor	0.623	0.559	0.510	0.462	0.454	0.528	0.523	12.12
5)		Hexachlorobenzene	0.510	0.493	0.501	0.507	0.494	0.546	0.509	3.87
6)	I	Chrysene-d10	----------ISTD----------							
7)		Simazine	0.285	0.277		0.140	0.153	0.113	0.194	42.01
8)		Atrazine	0.418	0.446	0.299	0.292	0.359	0.282	0.349	20.01
9)		Pentachlorophenol	0.202	0.164	0.078	0.040	0.037	0.028	0.092	80.85
10)		Lindane	0.250	0.272	0.208	0.211	0.292	0.256	0.248	13.51
11)		Metribuzin	0.261	0.278	0.176	0.128	0.141	0.101	0.181	40.35
12)		Alachlor	0.209		0.177	0.172	0.209	0.166	0.187	11.18
13)		Heptachlor	0.120		0.097	0.097	0.127	0.107	0.110	12.31
14)		Metalochlor	0.618	0.680	0.504	0.468	0.549	0.489	0.552	14.97
15)		Aldrin	0.122	0.146	0.119	0.125	0.171	0.142	0.137	14.45
16)		Heptachlor Epo...	0.087		0.084	0.089	0.116	0.114	0.098	15.76
17)		Butachlor	0.273	0.286	0.207	0.190	0.200	0.161	0.219	22.48
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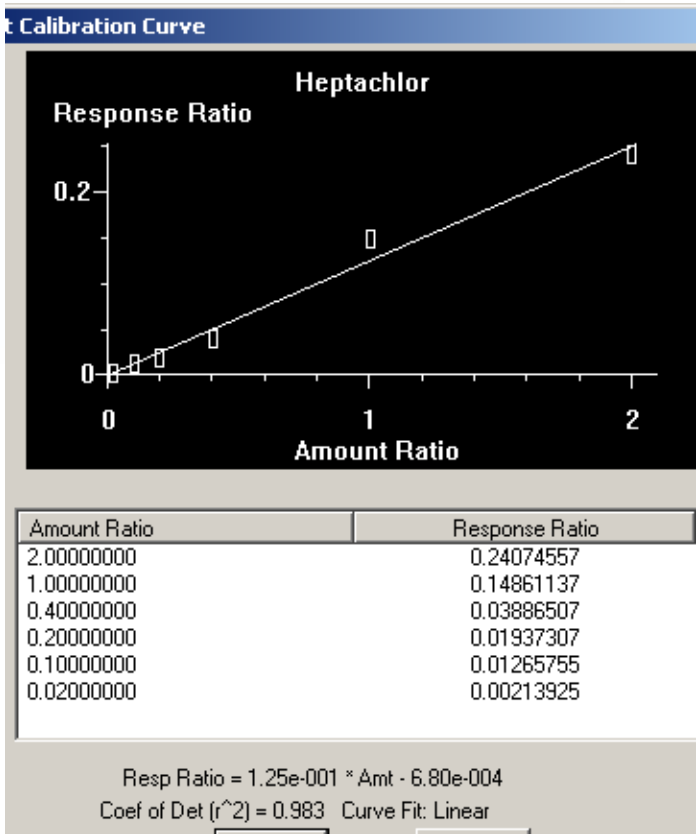
19)		4,4-DDE	0.234	0.257	0.221	0.222	0.285	0.315	0.256	14.84
20)		Dieldrin	0.140	0.150	0.143	0.148	0.190	0.202	0.162	16.49
21)		Endrin	0.042		0.034	0.032	0.039	0.037	0.037	10.53

Removal of Interior Level To Pass Calibration Criteria

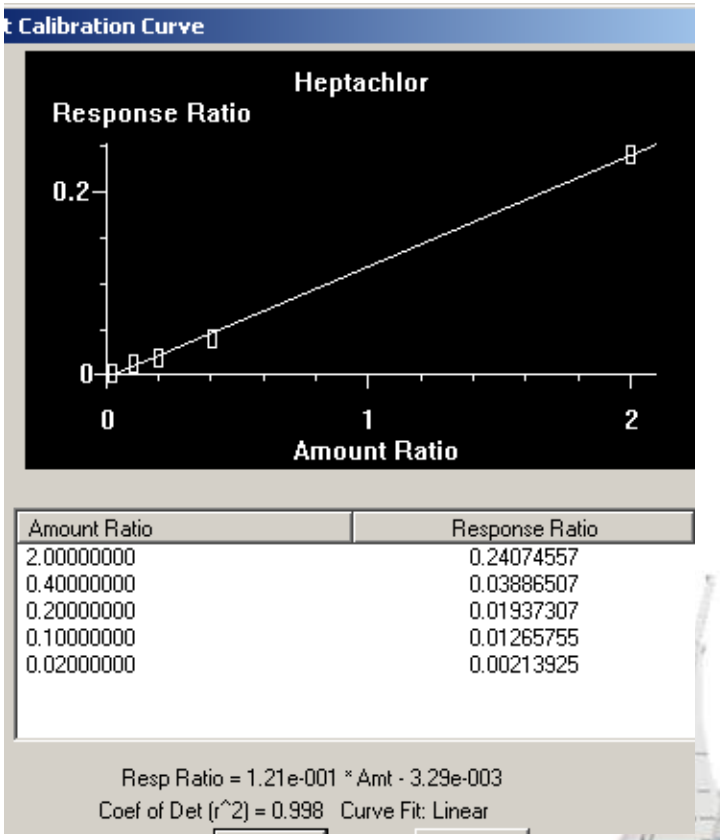
With 1.0 level standard



Amount Ratio	Response Ratio
2.00000000	0.24074557
1.00000000	0.14861137
0.40000000	0.03886507
0.20000000	0.01937307
0.10000000	0.01265755
0.02000000	0.00213925

Resp Ratio = 1.25e-001 * Amt - 6.80e-004
Coef of Det (r^2) = 0.983 Curve Fit: Linear

Drop 1.0 level standard



Amount Ratio	Response Ratio
2.00000000	0.24074557
0.40000000	0.03886507
0.20000000	0.01937307
0.10000000	0.01265755
0.02000000	0.00213925

Resp Ratio = 1.21e-001 * Amt - 3.29e-003
Coef of Det (r^2) = 0.998 Curve Fit: Linear

Important to Understand

- What is a “individual analyte calibration levels” versus an “entire single standard calibration level?”

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21)		Endrin	0.042		0.034	0.032	0.039	0.037	0.037	10.53

Removal

"the action of taking away or abolishing something unwanted"

- *e) ii. The laboratory may remove an entire single standard calibration level from the interior of the calibration curve when the instrument response demonstrates that the standard was not properly introduced to the instrument, or an incorrect standard was analyzed. A laboratory that chooses to remove a calibration standard from the interior of the calibration shall remove that particular standard calibration level for all analytes. Removal of calibration points from the interior of the curve is not to be used to compensate for lack of maintenance or repair to the instrument.*
- not properly introduced e.g.,"…bent injection needle on an auto-injector that yields very low responses for all the compound because the injection was not completed…" Ref: EHSG MICE, Email, April 2000

Incorrect

- **Simple Definition of *incorrect:***
  - not true or accurate
  - having errors or mistakes
  - not proper or appropriate in a particular situation
- incorrect e.g., "…single standard that has gone so bad that the difference is obvious to the naked eye…" Ref: EHSG MICE, Email, April 2000
- The intent is to allow a laboratory to provide a good and sound documented technical reason for the rare instance of removal of a standard from a curve. For example, there was no standard solution added; the extract spilled; the bottle number was transcribed wrong. Only gross technical errors are to be allowed. It is not intended to allow substitution to improve curve fitting.

Adjust LOQ/RL and Quantitation Range

- *e) iii. The laboratory shall adjust the LOQ/reporting limit and quantitation range of the calibration based on the concentration of the remaining high and low calibration standards.*

- If you drop the lowest calibration standard your LOQ or reporting level goes up. Data reported below lowest calibration standard concentration must be qualified.
- If you drop the highest calibration standard then your quantitation range goes down. Possible more dilutions and or qualified data if reported above quantitation range.

Minimum Number of Calibration Standards

- *e) iv. The laboratory shall ensure that the remaining initial calibration standards are sufficient to meet the minimum requirements for number of initial calibration points as mandated by this standard, the method, or regulatory requirements.*
- For example in 1.7.1.1

Type of Calibration Curve	Minimum number of calibration standards[b]
Threshold Testing[a]	1
Average Response	4
Linear Fit	5
Quadratic Fit	6

Replace

"to put something new in the place or position of something"

e) v. The laboratory may replace a calibration standard provided that

a. *the laboratory analyzes the replacement standard within 24 hours of the original calibration standard analysis for that particular calibration level;*

b. *the laboratory replaces all analytes of the replacement calibration standard if a standard within the interior of the calibration is replaced; and*

c. *the laboratory limits the replacement of calibration standards to one calibration standard concentration.*

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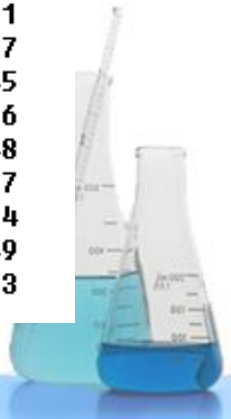
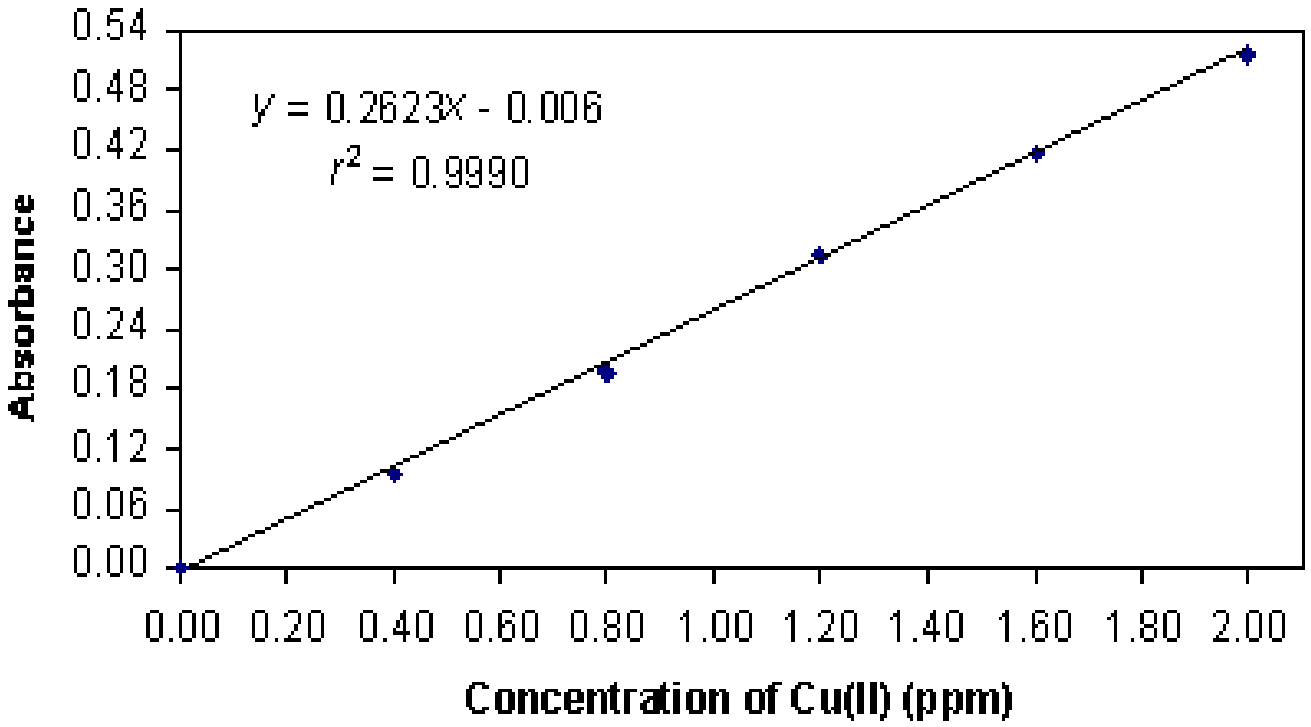


Single analyte calibration curve



The BIG Caveat

- *e) vi. The laboratory shall document a technically valid reason for either removal or replacement of any interior calibration point.*

- You must have a documented technically valid (sound) reason to either remove or replace any interior standard!
- Not to just pass calibration criteria, calibration verification or quality control criteria!, or
- Not to compensate for lack of maintenance or repair to the instrument.
- You better address this in your procedure!

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Questions?

2016 TNI Standard

Chemistry Expert Committee

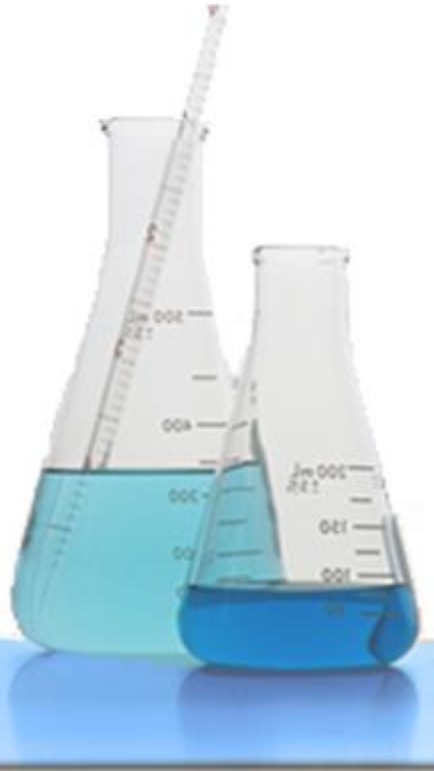
Calibration, Section 1.7.1.1.f

1.7.1.1.g

1.7.1.1.h

Colin Wright. Ph.D.

Florida Department of Environmental Protection



Writing the 2016 Standards: Chemistry Committee Goals

Limit any NEW requirements to those where there are clearly demonstrable weakness that result in inaccurate quantitation.

Must be:

Practical

Cost effective

Auditable

Technical Requirements: Initial and Continuing Calibration

Background:

- Sections 1.7.1 and 1.7.2 were re-written to introduce language that reflected current industry data integrity practices relating to the calibration of an analytical method.
- Multiple drafts based on CEC members and comments received were made prior to final language.

Minimum Number of Standards

TNI 2009 Standard:

1.7.1.1 j) if a reference or mandated method does not specify the number of calibration standards, the minimum number of points for establishing the initial instrument calibration shall be three.

Minimum Number of Standards

TNI 2009 Standard Weaknesses:

- Too high a bar - Threshold testing.
- Too low a bar - One size does not fit all - Linear v Quadratic v Response Factors

Minimum Number of Standards

TNI 2016 Standard:

1.7.1.1 f) for regression or average response/calibration factor calibrations the minimum number of non-zero calibration standards shall be as specified in the table below.

Type of Calibration Curve	Minimum Number of Calibration Standards[b]
Threshold Testing[a]	1
Average Response	4
Linear Fit	5
Quadratic Fit	6

Minimum Number of Standards

TNI 2016 Standard:

a - The initial one point calibration shall be at the project specified threshold level.

b - Fewer calibration standards may be used only if equipment firmware or software cannot accommodate the specified number of standards. Documentation detailing that limitation shall be maintained by the laboratory.

Minimum Number of Standards

1.7.1.1 g) the lowest calibration standard shall be at or below the lowest concentration for which quantitative data are to be reported without qualification;

1.7.1.1 h) the highest calibration standard shall be at or above the highest concentration for which quantitative data are to be reported without qualification;

Number of calibration standards

* Ensures a Minimum of 3 degrees of freedom *

Type of Calibration Curve	Minimum number of calibration standards	Degrees of Freedom
Threshold Testing [a]	1	Not Applicable
Average Response	4	3
Linear Fit	5	3
Quadratic Fit	6	3

The degrees of freedom in the equation scientifically justifies the minimum number of calibrants for all curve fitting routines.

Minimum Number of Standards

TNI 2016 Standard:

- Now has a statistical basis for the minimum number of standards required for each type of calibration
- Is now consistent with the requirements specified in the current EPA SW-846 methods and updates to the EPA 600 series methods for the minimum number of initial calibration standards for the different calibration types.

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Questions?

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2016 TNI Standard

V1M4, Section 1.7.1.1.k

RELATIVE ERROR

Requirement to measure Relative Error

What is Relative Error?

Error measured as a percentage rather than an absolute value.

If the true value is 20 and the measured result is 22:

- Absolute Error is 2
- *Relative error* is 10%

Is Relative Error currently used in Environmental Testing?

Yes:

Most methods express CCV (Continuing Calibration Verification) limits as *relative error*:

True value +/- 20%

Standard Language for Relative Error

j) the laboratory shall use and document a measure of relative error in the calibration.

i. for calibrations evaluated using an average response factor, the determination of the relative standard deviation (RSD) is the measure of the relative error;

If your calibration is evaluated by RSD then no further relative error evaluation is needed

ii. for calibrations evaluated using correlation coefficient or coefficient of determination, the laboratory shall evaluate relative error by either:

Option 1: Relative Error

a. Measurement of the Relative Error (%RE).
Relative error is calculated using the following equation:

$$\%\ Relative\ Error = \frac{x'_i - x_i}{x_i} \times 100$$

x_i = True value for the calibration standard
x'_i = Measured concentration of the calibration standard

Does that look familiar? **CCV % drift**

$$\%\ Drift = \frac{x'_i - x_i}{x_i} \times 100$$

Same formula, but used with an initial calibration standard rather than a continuing calibration standard

Option 1: Relative Error

This calculation shall be performed for two calibration levels: the standard at or near the mid-point of the initial calibration and the standard at the lowest level.

The Relative Error at both of these levels must meet the criteria specified in the method. If no criterion for the lowest calibration level is specified in the method, the criterion and the procedure for deriving the criterion shall be specified in the laboratory SOP.

Essentially, measure the error at the low point and mid-point of the calibration using the same calculation as for a CCV

Option 2: Relative Standard Error, RSE

$$\%\ RSE = 100 \times \sqrt{\sum_{i=1}^{n} \left[\frac{x_i' - x_i}{x_i}\right]^2 \Big/ (n-p)}$$

Looks complicated but just like RSD for an average curve

- Provides one number to evaluate the curve (like RSD)
- Not required if relative error has been evaluated using option 1 (also not required if the curve is assessed using RSD)

The Relative Standard Error must meet the criterion specified in the method. If no criterion is specified in the method, the maximum allowable RSE shall be numerically identical to the requirement for RSD in the method. If there is no specification for RSE or RSD in the method, then the RSE shall be specified in the laboratory SOP.

Why do we need to evaluate relative error in a curve?

- Correlation coefficient and coefficient of determination do not effectively control relative error
- Without an evaluation of relative error, results, especially towards the low end of the calibration can be meaningless.

Examples

Which curve type would you have selected based on "r^2" ???

Fluoride Method 300.0		Relative Error		
			Weighted Curves	
Conc.	**Response**	**Linear**	**Linear 1/x**	**Linear $1/X^2$**
0.05	**1497075**			
0.5	**12858983**			
2.5	**67621646**			
5	**1.43E+08**			
10	**3.02E+08**			
	r^2	**0.9994**	**0.9990**	**0.9979**

Which Curve Type??

Propachlor Method 8081		Relative Error		
			Weighted Curves	
Conc.	**Response**	**Linear**	**Linear 1/x**	**Linear $1/X^2$**
5	**$2.67X10^6$**			
25	**$9.99X10^6$**			
50	**$1.74X10^7$**			
125	**$3.86C10^8$**			
175	**$5.21X10^8$**			
250	**$7.18X10^8$**			
500	**$1.37X10^9$**			
	r2	**0.999**	**0.997**	**0.991**

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Questions?

2016 TNI Standard

Chemistry

1.7.1.1.l and 1.7.1.1.p

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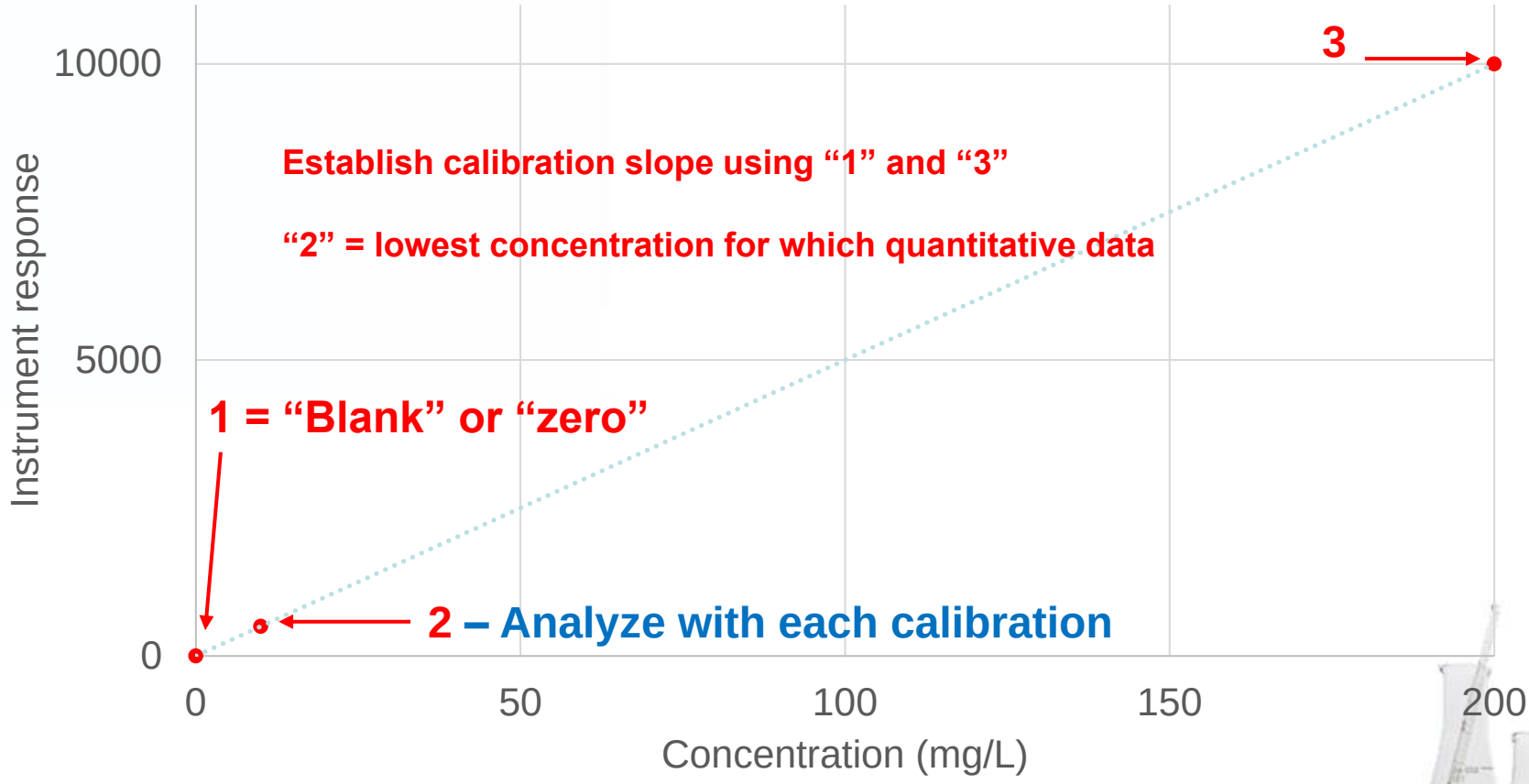
New York City DEP

Single point calibration and linear range methods

- Some methods allow calibration with only a blank (or “zero”) and a single calibration standard
- for example ICP technology
- Number of Calibration standards is per 1.7.1.1.l and 1.7.1.1.p, not per 1.7.1.1.f

Required at least daily:



No change from 2009 Standard

Sensitivity check ("2" in previous slide)

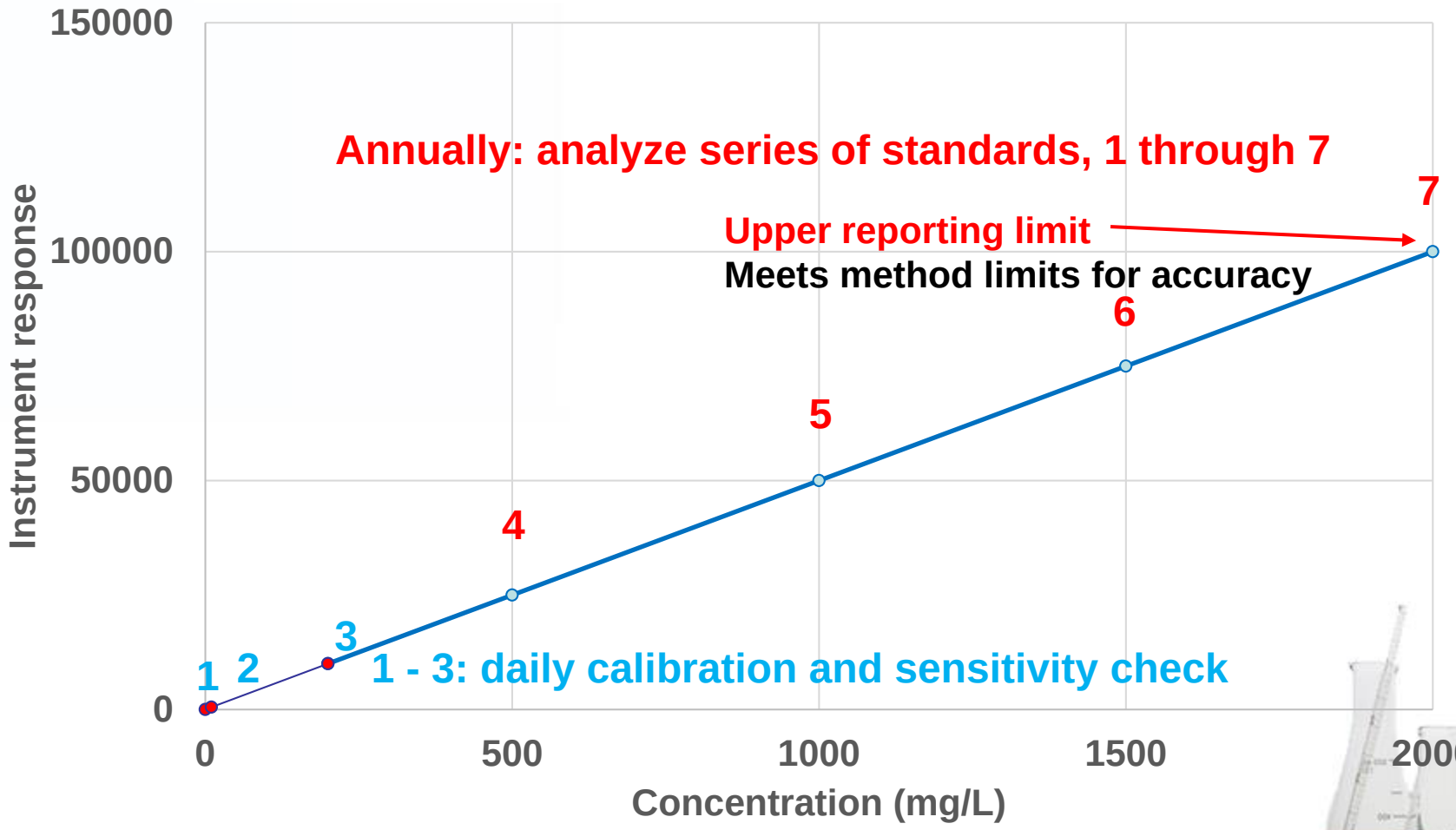
- Standard at the lowest concentration for which quantitative data may be reported without qualification
- Analyze (at least daily):
  - With each calibration (i.e., at least daily)
  - Prior to sample analysis
- Compare against acceptance criteria
  - Per method (if provided)
  - Per SOP (if not provided in method)

If method allows…

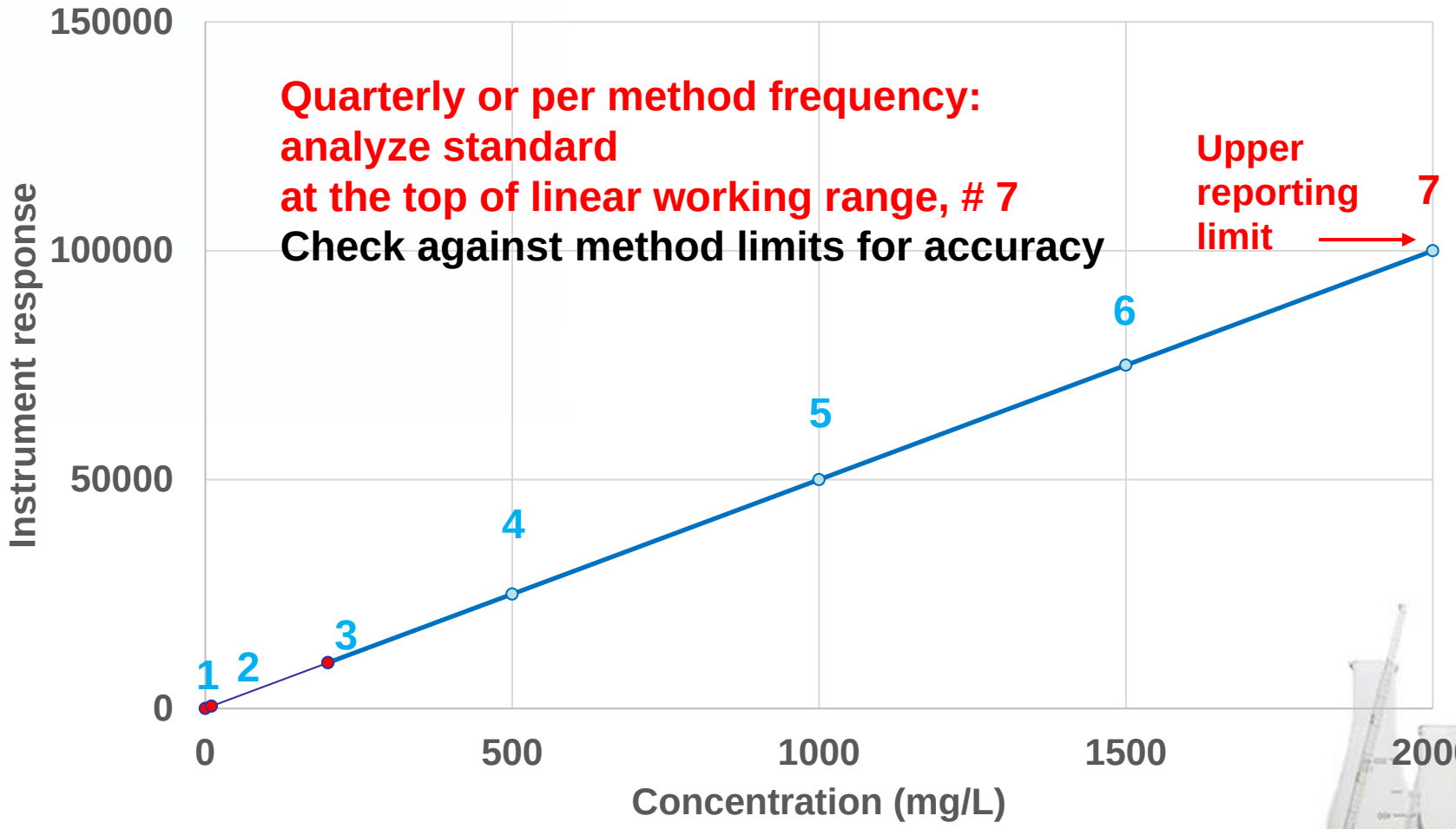
… Data above daily calibration to be reported without qualification:

- Unqualified data must be within the linear range
- Linear range to be established and checked per next slide.

Linear range
Annual requirement



Linear range
Quarterly requirement



Result above linear range

- Sample to be diluted and reanalyzed, or
- Over range result qualified as estimated value

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Questions?

2016 TNI Standard

V1M4 1.7.2. f

Continuing Calibration Verification (CCV)

Valerie Slaven

Teklab Inc

Eric Davis

2016 - 1.7.2 f)

- Criteria for the acceptance of the continuing calibration verification shall be established. If the continuing instrument calibration verification results obtained are outside the established acceptance criteria, the following steps shall be taken:

2016 - 1.7.2 f) i

- if an **obvious** cause for the calibration verification failure is identified that impacts **only** the calibration verification sample (e.g. a missed autosampler injection), then analysis may proceed if a second calibration verification sample is analyzed immediately and the result is within acceptance criteria. Samples analyzed previously shall be considered valid if bracketed by a passing calibration verification sample (refer to 1.7.2(d)). The cause for the failure of the first calibration verification result shall be documented

2016 - 1.7.2 f) i

- CCV fails and only impacts the CCV
  - Missed autosampler injection
  - Low/no Internal standard in the CCV
  - CCV spiked at incorrect concentration(1/2)
  - Instrument error on CCV

- Document cause of failure and immediately reanalyze a second CCV

2016 - 1.7.2.f) i

- if the cause for the calibration verification failure is **not obvious** and/or has the **potential** to have identifiable or has **impacted other samples**, then corrective action shall be performed and documented. Prior to analyzing samples, the laboratory shall demonstrate acceptable performance after corrective action with calibration verification or a new initial calibration shall be performed. Samples analyzed prior to the calibration verification failure shall be **reanalyzed** or the results **qualified** if calibration verification bracketing is required (refer to 1.7.2(d))

2016 - 1.7.2 f) ii

- CCV fails and impacts other samples or cause is unknown
  - Just fails
  - Poor Peak shape
  - Poor response
  - Incorrect IS concentration
- Perform Corrective Action
  - Replace Reagent
  - Replace Internal Standard valve
  - Clean needle
  - Replace injection port liner
  - Replace tubing

2016 - 1.7.2 f) ii

- Document the corrective action
- Demonstrate acceptable performance with new CCV or recalibration

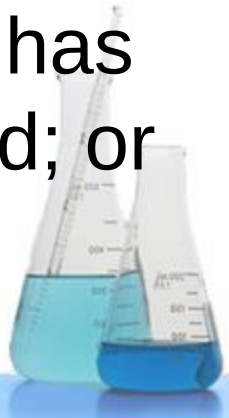
- Don’t forget samples before a failing CCV will also need to be reanalyzed if bracketing is required, or qualified as listed in the next section.

2016 - 1.7.2 f) iii

- 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 fully useable reported under the following special conditions, unless prohibited by the client, a regulatory program or regulation:

2016 - 1.7.2 f) iii. a

- when the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are nondetects, 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



2016 - 1.7.2 f) iii. b

- 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.

2016 - 1.7.2 f) iii

- CCV is out high and samples are non detect
- CCV is out low and samples exceed the maximum regulatory/decision level
- Reanalyze

2009 vs 2016

- 2016
  - Requires identifiable cause for CCV failure for second CCV to be acceptable. If cause is not identifiable requires corrective action
  - Requires only one passing CCV after corrective action.
  - States data may be reported un the special conditions unless prohibited by the client, regulatory program or regulation.

- 2009
  - Does not require identifiable cause for CCV failure before analysis of second CCV
  - Requires two passing CCVs after corrective action
  - States data is fully useable under the special conditions

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??QUESTIONS??