Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Vote	**Section/clause**	**Comment**	**Committee action**	**Committee comment**
Negative with com	1.7.1 m)	The requirement for second source verification is very confusing to many based on comments received by TNI through Standard Interpretation Request. Further, this is an outdated requirement that is not needed if standards are purchased from Certified Reference Material Manufacturers that use valid approaches for determining the identify of the material. suggest replacing this section with the language similar to that below, found in EPA's Contract Laboratory Program Statement of Work: Mis-identification of compounds occasionally occurs and it is possible that a mislabeled compound may be received from a chemical supply house. It is the laboratory's responsibility to have analytical documentation ascertaining that all compounds used in the preparation of solution standards are correctly identified. Identification confirmation, when performed, shall use gas chromatography/mass spectrometry analysis on at least two different analytical columns, or other appropriate techniques. A presentation on this topic will be made by Joe Konschnik at the NEMC conference in San Antonio in August.	**Withdrawn**	Language changed to "independently prepared or second manufacturer"
Negative with com	1.7.1	The additional paragraph in Section 1.7.1 stating that the calibration routines can include “method level” implies that the laboratory may choose to use procedural standards during the initial calibration of the instrument. Very, very few methods allow for procedural standards and to include this statement is misleading and dangerous.	**Non-persuasive**	Many methods allow procedural calibrations and the method should be followed
Negative with com	1.7.1	Contrary to the statement "This standard does not specify detailed procedural steps" it absolutely does specify detailed procedural steps and is a prescriptive procedure that contains requirements contrary to regulatory method procedures that currently serve as precedent for calibration and calibration verification. These procedures are also contrary to manufacturer's recommendations for calibration using many common analytical systems.	**Non-persuasive**	Opinion not supported by the majority of members commenting on the standard
Non-member com	1.7.1	Contrary to the statement "This standard does not specify detailed procedural steps" it absolutely does specify detailed procedural steps and is a prescriptive procedure that contains requirements contrary to regulatory method procedures that currently serve as precedent for calibration and calibration verification. These procedures are also contrary to manufacturer's recommendations for calibration using many common analytical systems.	**Non-persuasive**	Opinion not supported by the majority of members commenting on the standard
Negative with comment	1.7.1 Last paragraph	While this paragraph isn't inaccurate - I feel that it doesn't inherently add to the standard either. It will cause more problems and make people ask more questions about something that doesn't necessarily mean anything. If these terms had been tied into the new language below it would be different.	**Non-persuasive**	This is an opinion.
Negative with comment	1.7.1 Last paragraph	Isn't the calibration (instrumental or method) dictated by the method requirements???? I think it should be restated. It really is talking about how the standards are treated, right??	**Persuasive**	Some methods give the option. The language has been slightly re-worded
Negative with comment	1.7.1.1.	This allows reporting of data from a failed calibration. The data is unacceptable. There are no appropriate qualifiers and most clients do not even consider qualifiers. This reduces the method to a non-quantifiable screening method.	**Persuasive**	Addressed with new language

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Affirmative with comment	1.7.1.1. Second paragraph	In "The following items are essential elements of initial instrument calibration" remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also
Affirmative with comment	1.7.1.1. Initial Calibration - third sentence -	In "If re-analysis of the samples in not possible, data associated with an unacceptable initial instrument calibration shall only be reported with appropriate data qualifiers." remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.1.1 first paragraph	Does it matter if it's the most current initial calibration - because reading this the way it is written does not even imply that. So is it now acceptable for a laboratory to utilize a passing calibration from a month ago, since the calibration ran this morning failed? I see where it's at below - but a lab isn't going to read that far	**Persuasive**	Clarified language to state most recent calibration
Affirmative with comment	1.7.1.1.a)	In "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." remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.1.1.a)	When ....referenced in the method SOP (add SOP to sentence for clarity???)	**Persuasive**	Added "test" for clarity
Affirmative with comment	1.7.1.1.b)	Proposed language - "sufficient raw data records shall be retained to permit reconstruction of the initial calibration (e.g., calibration date, method, instrument, preparation date, analysis date, each analyte name, preparer's initials or signature, 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); Remove the word "instrument" for the same reason as stated in comment 1; and, since preparation may be a part of the calibration process, it might be useful to list preparation examples.	**Persuasive** in part	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified. Preparation not included.
Negative with comment	1.7.1.1.c	Standard Language: 1.7.1.1 c) the laboratory shall use the most recent initial calibration standard(s) analyzed prior to the analytical batch, unless otherwise specified by the method; Comment: Format Change Suggestion: When processing data, the laboratory shall use the most current calibration sequence, unless otherwise specified by the method	**Persuasive**	Language edited (though not exactly as suggested).
Negative with comment	1.7.1.1.c	Opens the door for misinterpretation by assessor where the same instrument is used for multiple methods (i.e. DRO/EPH/etc.). Should state that the most recent initial calibration standards "for the applicable method. . ." Also, I cannot think of a method that allows for the use of calibration curves other than the most recent so the "unless otherwise specified by the method" statement is unnecessary in this section.	**Persuasive**	Language edited.
Negative with comment	1.7.1.1.c	This allows using an earlier calibration so QC passes. This practice has been the subject of numerous IG investigations as earlier calibrations were chosen to allow QC to pass.	**Persuasive**	Language edited

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Negative with comment	1.7.1.1.c	I am unaware of any method that allows for the use of calibration curves older than the most recent. Also, since some instruments are capable of running more than one method, the most recent calibration may be for DRO, but the desired analysis is EPH, which is a different calibration. This could be interpreted as requiring that you recalibrate every time. If the statement must stay in the standard, then I recommend the following change: the laboratory shall use the most recent initial calibration standard(s), "for the applicable method", analyzed prior to the analytical batch;	**Persuasive**	Language edited
Affirmative with comment	1.7.1.1.c	Not sure why TNI would allow the use of a previous curve since I cannot think of any method that would allow any but the most recent curve be used. If the most recent curve fails, no lab should be able to go back and use a previous curve since something obviously is wrong with the instrument.	**Persuasive**	Language edited
Negative with comment	1.7.1.1.c	I would change the wording on this whole sentence: "the laboratory shall use the most recent initial calibration analyzed prior to the analytical batch for determining analytical results". When exactly would a method not specify this?	**Persuasive**	Language edited
Negative with comment	1.7.1.1.c	what do they mean "recent inittial calibration standard(s)"??? Should this just say "the… most recent initial calibration curve analyzed prior…"	**Persuasive**	Language edited
Negative with comment	1.7.1.1.d	The additional requirement in 1.7.1.1.d now appears to allow a lab to “drop” midpoint calibration standards for virtually any reason as long as it is documented. This is a huge departure from the current calibration expectations.	**Persuasive**	New language added
Negative with comment	1.7.1.1.d	Standard Language: 1.7.1.1 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 f and g). The calibration generated from the remaining calibration standards shall satisfy all the requirements specified for initial calibrations. Comment: This is bad science to allow any calibration standard to be rejected. If a midpoint standard is rejected from my established criteria and documented can I establish a criterion like “If the barometric pressure exceeds 30.02 the calibration point can be rejected and eliminated from the calibration - barometric pressure is recorded.” Suggestion: Remove completely – This is bad science	**Persuasive**	New language added
Negative with comment	1.7.1.1.d	“Permission” to drop calibration standards is too broad. If the Standard is going to provide this opportunity for the lab to establish criteria for calibration rejection then it needs to also provide language directing appropriate allowances for this rejection. From an enforcement perspective, I understand this language to be giving a lab carte blanche permission to pick and choose calibration points that are used to establish the calibration. An AB has no authority to reject the criteria established by the lab for data rejection based on the language given. We are concerned that this language opens the door for intentional or unintentional fraudulent data manipulation.	**Persuasive**	New language added

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Negative with comment	1.7.1.1.d	"…rejection of any calibration standards…" Does this allow for dropping points other than the high and low standards as long as the lab specifies the reason/criteria to do so? This seems contrary to general industry policies.	**Persuasive**	New language added
Negative with comment	1.7.1.1.d	Section 1.7.1.1 d - Opens the door for deleting mid-level calibration points to get the curve to pass method criteria. There is nothing limiting the laboratory rejecting a single point in a single target analyte, but leaving the point for other targets. This section also PROHIBITS reporting MDL/RDL or forces you to calibrate to the MDL. This statement is WAY WAY too prohibitive and is making the decision for the client regarding their ability to use the data. Qualified data should be considered appropriate as we are aware that it is necessary in some cases, especially where risk based assessments drive the required reporting limits below what can reasonably be achieved currently by a laboratory.	**Persuasive**	New language added
Negative with comment	1.7.1.1.d	1.7.1.1 d) This allows “any” calibration standard to be pulled out to make the calibration pass. This practice known as “cherry picking” is not allowable. The “criteria” established by the lab could be anything.	**Persuasive**	New language added
Negative with comment	1.7.1.1.d	1.7.1.1 d - Opens the door to delete calibration standards other than just the lowest or highest standard, meaning that you can delete points just to get a passing calibration. I do not agree with this practice. In addition, it appears to prohibit being able to report between the MDL and RDL unless you calibrate to the MDL. This goes against most QAPP's where the MDL/RDL information is requested, qualified and used accordingly for risk based assessments which usually have lower than normal action levels. The statement is too prohibitive to meet all client needs.	**Persuasive**	New language added
Affirmative with comment	1.7.1.1.d	Reading this it almost sounds like the laboratories would be able to drop a mid point of the curve. The only acceptable reason for dropping a mid point, in my estimation would be if the level mis-injected or was obviously prepped wrong.	**Persuasive**	New language added
Negative with comment	1.7.1.1.d	So are we allowing them to drop mid points of calibration curves now? The implications of this are HUGE.	**Persuasive**	New language added
Negative with com	1.7.1.1.d	this seems a little vague, it just seems like the lab can drop any point as long as they have documented criteria	**Persuasive**	New language added
Negative with comment	1.7.1.1.d & f	" . . . no data below the lowest or above the highest remaining calibration standard shall be quantitatively reported (see also f and g)." Detection monitoring and other regulatory programs require the reporting of quantitative data with J flags or qualification. J flagged results are between the LOD and LOQ.	**Persuasive**	New language added
Negative with comment	1.7.1.1.d & g	" . . . no data below the lowest or above the highest remaining calibration standard shall be quantitatively reported (see also f and g)."	**Persuasive**	New language added
Negative with comment	1.7.1.1.d)	"…rejection of any calibration standards…" Does this allow for dropping points other than the high and low standards as long as the lab specifies the reason/criteria to do so? This seems contrary to general industry policies.	**Persuasive**	New language added
Negative with comment	1.7.1.1.e	it adds regression or average response/calibration. I honestly don't know what you are talking about. Google doesn't help either.	**Non-persuasive**	Commonly used statistical terms

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Negative with comment	1.7.1.1.e	Why are the degrees of freedom included? Isn't this based upon the number of standards and therefore out of the analyst's control?	**Non-persuasive**	Number of standards is in the analysts control
Negative with comment	1.7.1.1.e	The chart requires a minimum of 4 calibration standards for linear regression, but this goes against multiple EPA methods (i.e. EPA 625 requires a minimum of 3 calibration standards, but allows for linear regression fits where RSD does not meet acceptance criteria and the same would hold true for multiple 600 series methods). The required number in this chart for Quadratic Fit is also diametrically opposed to SW846 EPA 8000C that states in Section 11.5.3.1, " . . .a quadratic (second order) model requires six standards, . . ." Five standards for a quadratic fit would not adequately model a curve with an inflection point and may cause gross errors in the quantitation of target analytes at a mid-level concentration.	**Persuasive**	New language added
Negative with comment	1.7.1.1.e	The chart requires a minimum of 4 calibration standards for linear regression, but this goes against multiple EPA methods (i.e. EPA 625 requires a minimum of 3 calibration standards, but allows for linear regression fits where RSD does not meet acceptance criteria and the same would hold true for multiple 600 series methods). The required number in this chart for Quadratic Fit is also in conflict with SW846 EPA 8000C that states in Section 11.5.3.1, " . . .a quadratic (second order) model requires six standards, . . ." Five standards for a quadratic fit would not adequately model a curve with an inflection point and may cause gross errors in the quantitation of target analytes at a mid-level concentration.	**Persuasive**	New language added
Negative with comment	1.7.1.1.e	We need definitions for: thresh hold testing, Degrees of Freedom. Not being a statistician I find this hard to follow - which means a lab will easily misinterpret this which can cause problems. EPA OGWDW has HUGE problems with things like cubic curves - why even open this up - it's like saying it's OK to have questionable data.	**Persuasive**	Will propose adding some definitions. Cubic is not mentioned, and will not be added
Negative with comment	1.7.1.1.f	Add "without qualification" to the end of the statement. With the current wording it does not allow for reporting to the MDL.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.f	Why was this removed? It is valid.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.f	Anytime the QC does not meet method requirements, the data must be qualified. Otherwise signing the report that the lab followed the method is fraudulent.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.f	What happened to having a requirement for defined qualifiers? Labs are still going to report data above and below their curves... the old section f was better in my opinion.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.f	This is prohibitive to client needs. It makes no allowance for qualified data between the MDL and RDL.	**Persuasive**	Added "without qualification"
Affirmative with comment	1.7.1.1.f	This then reads that if the State or client requires MDL/RDL reporting, the laboratory needs to calibrate down to the MDL. This could be difficult in many cases.	**Persuasive**	Added "without qualification"

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Negative with comment	1.7.1.1.f & g	(f) This again makes a laboratory unable to fulfill the needs of the client. It makes no allowance for qualified data below the low standard or MDL/RDL reporting. (g) does not make allowances for any of the methods that are limited in the ability to perform dilutions (i.e. TO-15) or even worse TO-1 (Thermal Desorption) when it's a one-time shot type of analysis. This results in qualified data routinely above the high end of the calibration curve because there is NO ability to dilute samples prior to the initial analysis.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.f and 1.7.1.1.g	Former language for these items is preferred. This reference is frequently used for findings and the former language is clearer regarding the lab's responsibility.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.f)	Add "without qualification" to the end of the statement. With the current wording it does not allow for reporting to the MDL.	**Persuasive**	Added "without qualification"
Negative with com	1.7.1.1.g	Add "without qualification" to the end of the statement.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.g	Why was this removed? It is valid.	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.g	Makes no allowances for samples associated with methods that are limited in the ability to perform dilutions. In this case of a single shot analysis, a qualifier for over range can be necessary.	**Persuasive**	Added "without qualification"
Affirmative with comment	1.7.1.1.g	What if there is only enough sample for one analytical run and the hit is above the high end of the curve?	**Persuasive**	Added "without qualification"
Negative with comment	1.7.1.1.g)	Add "without qualification" to the end of the statement.	**Persuasive**	Added "without qualification"
Negative with com	1.7.1.1.g	What happened to having a requirement for defined qualifiers? Labs are still going to report data above and below their curves... the old section g was better in my opinion	**Persuasive**	Added "without qualification"
Negative with com	1.7.1.1.g	What about when a dilution is performed. The reported concentration may be over the highest standard concentration. Needs clarification.	**Persuasive**	Added "without qualification"
Affirmative with comment	1.7.1.1.h	In "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", remove "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	Instrument removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.1.1.k.iv	add to the first sentence the phrase, "unless data qualifiers are required for other reasons described elsewhere in the TNI standards, the method, or the laboratory's SOP" or in some other way de-generalize this sentence.	**Persuasive**	Section has been re-written
Affirmative with comment	1.7.1.1.i	In "criteria for the acceptance of an initial instrument calibration shall be established (e.g., correlation coefficient or relative standard deviation). The criteria used shall be appropriate to the calibration technique employed, remove "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	Instrument removed from all calibration language. Language in 1.7.1 has also been modified.

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Negative with comment	1.7.1.1.i	Standard Language: 1.7.1.1 i) criteria for the acceptance of an initial instrument calibration shall be established (e.g., correlation coefficient or relative percent standard deviation). The criteria used shall be appropriate to the calibration technique employed; Comment: Un-auditable term – What is appropriate to one is not appropriate to another Suggestion: calibration acceptance criteria used shall be stated in the procedure or method	**Non-persuasive**	Language from the current standard
Negative with comment	1.7.1.1.i	Missing some definitions. RSD, RF and relative error should be defined somewhere.	**Persuasive**	Will propose adding some definitions.
Negative with comment	1.7.1.1.j) I	Where did this come from? I'm not saying that it's not valid - just that I have real reserves about pulling something out of nowhere. I can see a lot of labs going this route even if the method calls for an RSD because this passes... and j doesn't specifically require them to follow the method requirements.	**Non-persuasive**	Is now in Part 136 and SW-846
Negative with comment	1.7.1.1.j	The new stuff is 1.7.1.1 j) i and ii. I disagree with adding %residual error and relative standard error.	**Non-persuasive**	Critical to add because of the weakness of correlation coefficient with respect to relative error
Negative with comment	1.7.1.1.j	It isn't clear to me that the requirement for the measure of relative error is satisfied by the evaluation of the correlation coefficient or coefficient of determination. This section goes on to give two separate instructions for measuring residual error and I think that it's too statistical and that it's not explained clearly enough for the average analyst to comprehend.	**Non-persuasive**	This is an opinion
Negative with comment	1.7.1.1.j	Minor issues that should be corrected to improve the revisions made to this section and/or comments: 1.7.1.1.j Define RSD and RF	**Persuasive**	Spelt out the acronyms
Negative with comment	1.7.1.1.j	The requirement for RSE should not be applied across the board to all methods. This is currently being added to some newer methods (i.e. 8260C & 8270D) but those methods also have other criteria changes that make this more practical to meet. For example, in 8260C and 8270D it only needs to be determined for the low standard and the RSD criteria is wider than in the previous versions of these methods. Most methods that we currently reference do not include this as a requirement and I do not agree with adding it as an overall TNI requirement.	**Non-persuasive**	RSE is not required for all methods but measure of relative error is - if not RSE then error at low point and mid point
Negative with comment	1.7.1.1.j	This area is strewn with inconsistent terminologies (relative error, residual error, relative standard error, etc.). Not all analysts, quality assurance, or auditors using this standard would be well versed in statistics to be able to interpret the intent of this section. The requirement to interpret intent is what I believe ISO standards were trying to prevent by being “non-prescriptive” as initially intended and implemented!!!	**persuasive**	Will add some terms to definitions

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Negative with comment	1.7.1.1.j	This section has reference to some terms that are not yet common to all labs. It begins with "relative error", moves to "residual error" and goes on to talk about "relative standard error". There are a number of concepts that are introduced that will not be familiar or easily understood by all laboratories. Many laboratories are not familiar with the term RSE as it not mentioned in many of the current approved methods. In addition it isn't clear how these choices are to be used relative to method requirements or suggestions, nor is it clear that one type of error measurement may be more appropriate than another, depending on the technology or analytes of interest. This type of requirement is prescriptive, which goes against the purpost of being ISO based.	**persuasive**	Will add some terms to definitions
Affirmative with comment	1.7.1.1.j	This area is strewn with inconsistent terminologies (relative error, residual error, relative standard error, etc.). Not all analysts, quality assurance, or auditors using this standard would be well versed in statistics to be able to interpret the intent of this section. The requirement to interpret intent is what I believe ISO standards were trying to prevent by being “non-prescriptive” as initially intended and implemented.	**persuasive**	Will add some terms to definitions
Negative with comment	1.7.1.1.j (ii)	The formula provided for %RSE is USELESS for evaluating the initial instrument calibration. Consider a perfectly horizontal straight line of Y vs. X (i.e., Y stays the same as X increases). The r-squared correlation coefficient is close to 1.0000, and the % RSE (as presented) is close to zero, even though a horizontal straight line is useless for calibrating an instrument. Adopting the following formula will help change my vote to “Negative” to “Approve”: % RSE = 100 * SQRT (SUM ((Yi’ – Yi)**2) / (n-p)) / (Ymax – Ymin), where Yi’ = instrument response predicted by the calibration model at level i Yi = the actual measured instrument response at level i p = Number of terms in the fitting equation (average = 1, linear = 2, quadratic = 3, etc.) n = Number of calibration points Ymax = the highest measured instrument response recorded during the calibration process Ymin = the lowest measured instrument response recorded during the calibration process	**Non-persuasive**	Derived equation
Negative with comment	1.7.1.1.j)	The requirement for RSE should not be applied across the board to all methods. This is currently being added to some newer methods (i.e. 8260C & 8270D) but those methods also have other criteria changes that make this more practical to meet. For example, in 8260C and 8270D it only needs to be determined for the low standard and the RSD criteria is wider than in the previous versions of these methods. Most methods that we currently reference do not include this as a requirement and I do not agree with adding it as an overall TNI requirement.	**Non-persuasive**	RSE is not required for all methods but measure of relative error is - if not RSE then error at low point and mid point

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Negative with comment	1.7.1.1.j.i	This allows the lab to set any criteria it wants for the lowest calibration standard. How about + 1000%?	**Persuasive**	Drafted for RSE - added languare requiring that the lab specify how the relative error limit was derived. Will consider numerical limits in the future
Negative with com	1.7.1.1.j.i	Concern / Question – this language does not allow percent recovery (which is very similar in this application to percent residual error / provides the same information – 'how far am I off from the target?') and if labs are already evaluating data by percent recovery (and have SOPs, software programming, etc) it will be difficult to 'justify' the benefit of compliance and change on this issue. Was percent recovery intentionally omitted? Would like to see language permit this by being modified to allow some alternate / equivalent evaluation measures or specifically mentioning percent recovery.	**Non persuasive**	Percent recovery is numerically the same value as relative error
Negative with comment	1.7.1.1.j.ii	Standard Language: 1.7.1.1 j) ii) p = Number of terms in the fitting equation. (average = 1, linear = 2, quadratic = 3). Comment: What do you use in "Unique" under 1.7.1.1 b) unique equation or coefficient used to reduce instrument responses to concentration); Suggestion: Simplify Equation to RPD calculations $\|(x-y)\|/((x+y)/2)$	**Non-persuasive**	RSE is different concept than RPD
Negative with comment	1.7.1.1.j.ii	This allows a lab to report results below the LOQ without passing calibration and without qualification at any level the lab sets.	**Persuasive**	Language added
Negative with comment	1.7.1.1.k	This to me states that EPA Methods that allow for single point calibration (zero and non-zero point) are no longer acceptable methods of calibration. Section ki would require that multi-level calibration be performed (maybe not with EVERY calibration, but at least prior to initial calibration) that contains a series of standards to demonstrate linearity. This implies that the EPA determination of linearity is not adequate where instruments like ICP is concerned. Also, is this in addition to or instead of the dynamic linear range determination required by the method? If that is the case, then this is a redundant linearity determination on instrumentation that the EPA has already determined that linearity does not need to be demonstrated more extensively than the single point calibration model and the linear dynamic range studies as required by the published methods. Interestingly enough though, this section does allow for quantitation above the instrument linear range (prohibited by previous sections) is adequately qualified.	**Non-persuasive**	These type of calibrations are specifically allowed by sec k

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Negative with comment	1.7.1.1.k	Seems to imply that current EPA Methods that allow for single point calibration (zero and non-zero point) are not thorough methods of calibration. Section "i" would require that multi-level calibration be performed (maybe not with EVERY calibration, but at least prior to initial calibration) that contains a series of standards to demonstrate linearity. This implies that the EPA determination of linearity is not adequate where instruments like ICP are concerned. Also, is this in addition to or instead of the dynamic linear range determination required by the method? EPA has already determined that linearity does not need to be demonstrated more extensively than the single point calibration model and the linear dynamic range studies required by the published methods. Additionally, this section does allow for quantitation above the instrument linear range with appropriate qualification, which is in conflict with previous sections.	**Non-persuasive**	These type of calibrations are specifically allowed by sec k
Negative with comment	1.7.1.1.k	Deletion of ". . . the following shall occur for instrument technology (such as ICP or ICP/MS) . . . " and addition of "when test procedures are employed that specify calibration with a single calibration standard and a zero point . . . " The new language seems to indicate that a quantitative result cannot be reported without qualification for ICP or ICP/MS methods that utilize multiple calibration levels if the highest calibration standard is exceeded even if a linearity check sample is analyzed and meets acceptance criteria. The standard should clearly indicate that linearity check standards (if a linearity study has been previously performed) can be used to report quantitative values without qualification for multiple calibration level ICP and ICP/MS methods. If the use of an ICP or ICP/MS linearity check sample is acceptable for a single point calibration and a zero point, then the use of an ICP or ICP/MS linearity check sample should be acceptable too. (I understand that this change may affect other technologies.) I thank the Committee for all of their efforts and for considering my comments. I recognize that the standard revision process can be challenging.	**Persuasive**	Clarified language and intent

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment	1.7.1.1.k)i	1. The statement "Prior to calibration .... " would infer that linear dynamic range determination is performed before the analytical system is calibrated which is incorrect. Calibration must be performed prior to LDR detennination. 2. The procedure appears to require a multipoint calibration with standards all the way up to the upper linear range to be used continuously with only reslope required on a routine basis. First, the multi point calibration described would be used primarily for ICP-OES and ICP-MS systems. These systems have very wide linear dynamic ranges (several orders of magnitude) and including the high concentration standards in the actual calibration function would greatly bias the low end of the calibration ranges. The concentration levels of the standards would also mandate that individual or "short list" standard mixes be prepared due to the levels of dissolved solids and interelement effects that would be sufficient to bias raw values. This would result in a significant increase in the number of individual standards that would need to be prepared and analyzed for no improvement in the linear dynamic range definition. 3. Use of the new process as written would result in LDR determined using calibrations not consistent with that used for routine sample analysis. The system should be calibrated with the single standard and zero point exactly as it would be for routine analysis with LDR evaluation based on this function. Current industry standard, manufacturer's recommended and method specified means for LDR determination with single point calibrations are sufficient.	**Persuasive**	Clarified language and intent
Non-member commenter	1.7.1.1.k)i	1. The statement "Prior to calibration .... " would infer that linear dynamic range determination is performed before the analytical system is calibrated which is incorrect. Calibration must be performed prior to LDR detennination. 2. The procedure appears to require a multipoint calibration with standards all the way up to the upper linear range to be used continuously with only reslope required on a routine basis. First, the multi point calibration described would be used primarily for ICP-OES and ICP-MS systems. These systems have very wide linear dynamic ranges (several orders of magnitude) and including the high concentration standards in the actual calibration function would greatly bias the low end of the calibration ranges. The concentration levels of the standards would also mandate that individual or "short list" standard mixes be prepared due to the levels of dissolved solids and interelement effects that would be sufficient to bias raw values. This would result in a significant increase in the number of individual standards that would need to be prepared and analyzed for no improvement in the linear dynamic range definition. 3. Use of the new process as written would result in LDR determined using calibrations	**Persuasive**	Clarified language and intent
Negative with comment	1.7.1.1.k)ii	Resloping of a previously constructed calibration function usign a single standard has long been forbidden in most environmental reference methods. This practice will result in poorer accuracy than the current daily, single point calibration allowed in Method 6010 c.	**Persuasive**	New cal each day clarified language
Non-member commenter	1.7.1.1.k)ii	Resloping of a previously constructed calibration function usign a single standard has long been forbidden in most environmental reference methods. This practice will result in poorer accuracy than the current daily, single point calibration allowed in Method 6010 c.	**Persuasive**	New cal each day clarified language

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment	1.7.1.1.k.i	Section does not include any acceptance criterion to determine if linearity and verification of the standard at the top of the linear range. It just requires that the verification occur.	**Non-persuasive**	This section was removed
Negative with comment	1.7.1.1.k.iii	To adequately verify sensitivity, shouldn't the LOQ standard be analyzed at the end of the run as well, to account for drift or other loss of sensitivity?	**Non-persuasive**	Too far outside current typical requirements, will discuss in the LOQ part of the standard
Negative with comment	1.7.1.1.k.iii	This allows reporting below the LOQ without qualification and with criteria decided by the lab. The lab can set the criteria at any value to make everything acceptable.	**Non-perusasive**	See language for LOQ 1.5.2.2c
Negative with comment	1.7.1.1.k.iv	Section states "…will not require data qualifiers." This statement is misleading and does not accurately describe the situations when qualification is not required.	**Non-persuasive**	Statement must be read in context
Negative with comment	1.7.1.1.k.iv	The sentence "Sample results within the established linear calibration range will not require data qualifiers." is unnecessary and can potentially be mis-understood or mis-applied if taken as a stand alone sentence (out of context). Prefer the sentence be omitted.	**Non-persuasive**	Statement must be read in context
Negative with comment	1.7.1.1.k.iv	This is a dangerous blanket statement to make. There may be other REQUIRED reasons to flag the data besides an ICAL. I can see a lab saying "I didn't flag the data even if my LCS failed because the standard said if my ICAL was good I didn't have to flag.	**Persuasive**	New language added
Negative with comment	1.7.1.1.l	Section is not accurate because most methods require that each multi-peak analyte be quantitated from a multi-point ICAL. This statement implies that this is not required. Identification of the multi-peak analyte may occur without an ICAL.	**Non-persuasive**	Method would override standard in this case
Negative with comment	1.7.1.1.l	This section mixes two separate issues. One is how to handle calibrations for multiple multipeak analytes (Aroclors, which is misspelled in the draft standard), and the other is how to handle calibration for multipeak analytes (chlordane, toxaphene). This section addresses the former. Replace everything before "using" with "for Aroclors" unless there is some other class of analytes for which this issue exists. Another section would be needed to address the second issue, which appears to be a perceived need to allow using a subset of the multiple components of the "analyte" (e.g., alpha and gamma chlordane for Technical Chlordane and a subset of congeners for Toxaphene). I am not convinced the latter issue needs to be addressed, but this section needs to address only Aroclors. Finally, add "for chromatographic" after the last "and" and change the last "for" to "of".	**Persuasive**	New language added

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Affirmative with comment	1.7.1.1.m	In "initial calibration verification: 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" remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.1.1.m	I totally understand 1.7.1.1 m) initial calibration verification. This takes care of sytems that were just calibrated on the day of analysis-immediately and initally verify calibration with a second source prior to sample analysis is the intent that I understand. So there is no need then to state the same thing at 1.7.2.d) because that as an ICV is already stated at 1.7.1.1m.), this is not a CCV! unless, unless, and this is critical, if that first CCV of an analytical batch is indeed "for a system that has not been calibrated that day". Even if one wants to eliminate the corrective action criteria as stated at TNI2009 1.7.2.e),which is also proposed in this draft, one should still keep the initial sentence of ..."when instruments are not calibrated on the day of analysis". this is my understanding of a CCV, on day of calibration- CCV occurs after ICV and samples, then a CCV, if more samples, another CCV (except where internal stds are used then there need not even be a CCV, only an ICV!)..so: initial Calibration, ICV-2nd source, ICB, samples, CCV 2nd or 1st source,CCB, samples,CCV,CCB, and so on On days where calibrations are not performed-then indeed everything is a CCV, and that is why one needs to keep that sentence, and yes of course verify the system is working as it was when calibrated	**Withdrawn**	**See 1.7.2. d iii**
Negative with comment	1.7.1.1.m	This section requires that all initial calibration verification standards are second source and names it the initial calibration verification. That is in agreement with the terminology from ICP and ICPMS published methods; however the term as used in this document is not limited to those analyses. Initial calibration verification can also be known to be the initial calibration verification used when daily starting an analytical sequence and not performing a full initial calibration. Therefore the terminology in this section can cause some confusion. A better term for this standard would be SSCV (Second Source Calibration Verification) to provide more clarity and less confusion regarding daily calibration verification and calibration source adequacy determinations. SSCV is utilized in this document in section 1.7.2d (ii) This entire section is VERY prescriptive. In some cases (particularly Wet Lab), we utilize a spike mix (LCS/LCSD/MS/MSD/etc.) as a second source verification, but this section does not allow for that process and forces an additional standard analyzed following the calibration curve.	**Persuasive**	Language clarified
Negative with comment	1.7.1.1.m	Terminology in this section could cause confusion. ICV for approved ICP and ICPMS methods are second source, but that is not true for all other approved methods/technologies. Additionally, Init Calibration Verification, can be viewed as the standard at the beginning of an analytical sequence and does not necessarily mean full initial calibration. It is not clear how you define this term.	**Persuasive**	Language clarified

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Affirmative with comment	1.7.1.1.m	This section requires that all initial calibration verification standards are second source and names it the initial calibration verification. That is in agreement with the terminology from ICP and ICPMS published methods; however the term as used in this document is not limited to those analyses. Initial calibration verification can also be known to be the initial calibration verification used when daily starting an analytical sequence and not performing a full initial calibration. Therefore the terminology in this section can cause some confusion. A better term for this standard would be SSCV (Second Source Calibration Verification) to provide more clarity and less confusion regarding daily calibration verification and calibration source adequacy determinations. SSCV is utilized in this document in section 1.7.2d (ii) This entire section is VERY prescriptive. In some cases (particularly Wet Lab), we utilize a spike mix (LCS/LCSD/MS/MSD/etc.) as a second source verification, but this section does not allow for that process and forces an additional standard analyzed following the calibration curve.	**Persuasive**	Language clarified
Negative with comment	1.7.1.1.n	The proposed wording suggests that once the method has 10 or more target analytes, ALL of them can have calibration criteria or verification criteria that "fail marginally." Adding the Table in Section 1.7.4.2(b) on the maximum allowable number of marginal exceedences to this section might help change my vote from "Negative" to "Approve."	**Persuasive**	Base on LCS marginal exceedance number in section 1.7.4.2b. Mostly removed, edits done
Negative with comment	1.7.1.1.n	Section implies that the lab does not need to qualify results associated with a failed ICAL. This is contradictory to many, if not most, methods. To includes this in a standard is misleading and inaccurate. Section 1.7.2.f inaccurately instructs the user that they are not required to qualify results of failed CCVs. Most methods require qualification of all results that are not associated with an acceptable CCV.	**Persuasive**	Edited - only if specific in the method and with qualification.
Negative with comment	1.7.1.1.n	Standard Language: for those methods with more than 10 analytes where: i the calibration criteria and/or initial verification criteria fail marginally and; ii a successful calibration sensitivity check determination as described below has been performed; non-detect sample results may be reported without qualification for initial calibration failure. The demonstration of sensitivity shall be the successful detection of the analyte(s) in the lowest calibration standard (at or below the LOQ) and meeting all identification criteria specified in the method or the SOP. Marginal failure is defined as: Comment: This concept was introduced for LCS in the NELAC 2003 standard. The one BIG difference is the marginal exceedences for LCS must be RANDOM. Can the same analyte always fail for calibration? Suggestion: Remove or change to random events	**Persuasive**	Edits done
Negative with comment	1.7.1.1.n	Section 1.7.1.1 n – I find this entire section confusing and it seems to me to be diametrically opposed to the first statement in section 1.7.1.1.	**Persuasive**	Edits done

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment	1.7.1.1.n	This allows results with a failed calibration, and a failed initial cal verification to be reported “without qualification”. This is unacceptable and allows the reporting of any data whether valid or not. How can the lab still sign the report as meeting method requirements.	**Persuasive**	Edits done
Negative with comment	1.7.1.1.n	This section appears to be in conflict with the first statement in 1.7.1.1, which forbids any analyte failure. "n" addresses marginal failures in the calibration, but were prohibited previously. Should this actually be related to the calibration verification?	**Persuasive**	Edits done
Negative with comment	1.7.1.1.n)i	The terminology "fail marginally" is unacceptable and will result in data that cannot be defended at litigation. An opposing attorney would welcome the opportunity to stand in front of a jury of non-scientists and challenge them to consider data that "fails", marginally or otherwise. This wording should be removed.	**Persuasive**	Edits done
Non-member commenter	1.7.1.1.n).i	The terminology "fail marginally" is unacceptable and will result in data that cannot be defended at litigation. An opposing attorney would welcome the opportunity to stand in front of a jury of non-scientists and challenge them to consider data that "fails", marginally or otherwise. This wording should be removed.	**Persuasive**	Removed
Negative with comment	1.7.1.1.n)ii	1. The specific expanding of the recovery limits for I ev or eev to 30% for all analytes in a test group is directly contradictory to Method 8000B, Method 8000e and many other routinely cited methods and would result in rejected data if relied on for regulatory reporting. The Method 8000B process using the grand mean with any individual outlier to be evaluated relative to the effect on project specific data quality objectives is sufficient. With a properly calibrated and operating analytical system, most analytes will recover well within the method mandated recovery limits. The outliers will be the poor performing anlaytes included in the test lists. These poor performers often vary by more than the 10% variance allowed but still have no effect on the data usability. In effect, this standard would lessen the accuracy for all the normally performing analytes while not providing sufficient range for the known poor performers. 2. The specific expanding of the correlation coefficient or coefficient of determination is directly contradictory to many of the methods routinely cited and would result in rejected data if relied on for regulatory repOliing.	**Persuasive**	Edits done

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Non-member commenter		1. The specific expanding of the recovery limits for I ev or eev to 30% for all analytes in a test group is directly contradictory to Method 8000B, Method 8000e and many other routinely cited methods and would result in rejected data if relied on for regulatory reporting. The Method 8000B process using the grand mean with any individual outlier to be evaluated relative to the effect on project specific data quality objectives is sufficient. With a properly calibrated and operating analytical system, most analytes will recover well within the method mandated recovery limits. The outliers will be the poor performing anlaytes included in the test lists. These poor performers often vary by more than the 10% variance allowed but still have no effect on the data usability. In effect, this standard would lessen the accuracy for all the normally performing analytes while not providing sufficient range for the known poor performers. 2. The specific expanding of the correlation coefficient or coefficient of determination is directly contradictory to many of the methods routinely cited and would result in rejected data if relied on for regulatory repOliing.	**Persuasive**	Edits done
Negative with comment	1.7.1.1.n.i	Suggest rewording. “Criteria” do not “fail”. The laboratory’s evaluation of data generated may fail to meet criteria.	**Persuasive**	Edits done
Negative with comment	1.7.1.1.n.i	I truely hope criteria themselves don't fail! the calibration verification itself may though.	**Persuasive**	Edits done
Negative with comment	1.7.1.1.n.i	maybe you should add a "see below" comment??? (Referring to "fail marginally").	**Persuasive**	Removed
Negative with comment	1.7.1.1.n (last paragraph)	1.7.1.1 States clearly that data can not be reported if the initial calibration is not acceptable.. so which is it???	**Persuasive**	Removed
Negative with comment	1.7.1.1.n (last paragraph)	is this confusing?? so is this just saying non detects in methods with over 10 analytes can be reported if the demonstration of sensitivity is met, even if the calibration criteria fails marginally?	**Persuasive**	Removed
Negative with comment	1.7.1.1.n.ii	Since most methods have >10 analytes, this just changes the criteria across the board, so %RSD is 30%, not 20%; % difference, etc is 30%, not 20%, and correlation coefficient is now 0.980, instead of 0.990. By the way, 0.980 is a pretty bad curve, particularly if the lab can cherry-pick calibration results.	**Persuasive**	Edits done
Negative with comment	1.7.2	section should not eliminate that first sentence. It is critical to the actual understanding of the intent of a CCV..."when instruments are not calibrated on the day of analysis". It is critical to the currently stated actions at TNI 2009 1.7.2 e.)-which are being eliminated at the draft as well.	**Withdrawn**	
Negative with comment	1.7.2	There needs to be a clear difference in what you are calling initial and continuing calibration. Since no unique terms are being used, then the stricken sentence should be left in the first sentence of the first paragraph.	**Persuasive**	Edits done
Affirmative with comment	1.7.2 First paragraph	In "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." remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment	1.7.2. First paragraph	I feel for clarity the deleted sentence should remain in the standard. Otherwise I think it means a CCV must be done even if a initial calibration is performed	**Persuasive**	This is overed in diii
Negative with comment	1.7.2.1.c	Standard Language: The concentration of the calibration verification standard shall be equal to or less than the mid-point of the calibration range (as determined by the average of the highest and lowest calibration standard). Comment: If the laboratory is using a linear range on ICP and the range is 10 to 50000 is the CCV be at 25000 Suggestion: Make this a multiple of the reporting limits like not to exceed 20 to 100 times the reporting limit.	**Non-Persuasive**	Though generally non-persuasive, subsection k has been clarified.
Negative with comment	1.7.2.f ii	Standard Language: for methods with more than 10 analytes, non-detected analytes that marginally fail the continuing calibration verification low may be reported without qualification for a continuing calibration verification failure if a successful demonstration of adequate sensitivity (see section n of the Initial Calibration section for criteria and reporting) has been performed within the same analytical batch. For methods that require bracketing continuing calibration verification standards,successful bracketing demonstrations of sensitivity are also required. Otherwise the samples affected by the unacceptable continuing calibration verification shall be qualified or re-analyzed. Comment: This concept was introduced for LCS in the NELAC 2003 standard. The one difference is the marginal exceedences for LCS must be RANDOM. Can the same analyte always fail? Suggestion: Remove or changed to random events	**Persuasive**	Removed most
Affirmative with comment	1.7.2.a)	In "calibration can be at the instrument or method level.The details of the continuing instrument calibration procedure, calculations and associated statistics shall be included or referenced in the method SOP" remove the word "instrument" to be consistent with paragraph above in section 1.7.1	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.2.b)	1.7.2 b) Regarding chlordane, does this section allow alpha and gamma chlordane as a "related substance"?	**Persuasive**	Changed to just aroclors
Negative with comment	1.7.2.b)	1.7.2 b) Regarding chlordane, does this section allow alpha and gamma chlordane as a "related substance"?	**Persuasive**	Changed to just aroclors

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment	1.7.2.c	why is 1.7.2 c. not defined for ICV in an ICV section rather than as a CCV as it is? and I think that is a main point of mine, ICV criteria is mixed into the CCV sections, making it difficult to sort out for the author and reader. I would clarify such by sorting into the following 4 sections and define criteria for each seperately: -Initial Calibration, (very nice stuff you did!) -ICV, (so little talk it is amazing I believe, this is the only required second source, and this deserves its own section altogether,midpoint conc., etc.) -CCV for instruments calibrated that day (draft often confuses with ICV, why? no need for lumping together with ICV, no need for secondary source, create a seperate section) -CCV for instruments not calibrated that day (being wrongly eliminated I think, it is ok to change the previous corrective action as I know it leads folks to believe that running a second immediate CCV without CAs is ok in any situation- because few realized it was only intended for the start of the day to wake up an instrument, that is why that first sentence was there to begin with, but it leads the draft to wrongly state "every analytical batch starts with a CCV", which is true for "instruments not calibrated on that day", but is false for batches that have an ICV). Batches that have an initial calibration performed that day start with an ICV, not a CCV!.....making 1.7.2.d) incorrect, because; there is no need to run an ICV followed by a CCV prior to analysis, but that is what is being stated in this draft, if one does not distinctly seperate those sections.	**Withdrawn**	
Negative with comment	1.7.2.c	VERY prescriptive. This requires the determination of the mid-point of the calibration curve being mathematically determined and not simply using the mid-level calibration point for daily verification.	**Persuasive**	Change to less than or equal to half the top end of the calibration
Negative with comment	1.7.2.c	Too prescriptive	**Persuasive**	Change to less than or equal to half the top end of the calibration
Negative with comment	1.7.2.d	This whole section is confusing and difficult to understand.	**Persuasive**	Section was re-drafted for clarity
Negative with comment	1.7.2.d	This whole section is so poorly worded that it's confusing. The inclusion of ". . .at the beginning and end of each analytical batch,. . ." in the first sentence puts the reader on the defensive when considering the totality of the methods analyzed by the laboratory. Even though in subsequent sections, there are exceptions listed, the initial statement would be a much stronger lead by just saying that "Instrument continuing calibration verification shall be performed using the process and at the frequency defined in the method". In that case, the exceptions are not needed.	**Persuasive**	Section was re-drafted for clarity
Negative with comment	1.7.2.d	This is wordy and somewhat confusing.	**Persuasive**	Section was re-drafted for clarity

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Affirmative with comment	1.7.2.d)	In "Instrument continuing calibration verification shall be performed at the beginning and end of each analytical, and at the frequency defined in the method except: " remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Affirmative with comment	1.7.2.d)	Instrument continuing calibration verification shall be performed at the beginning and end of each analytical, and at the frequency defined in the method except: Proposed Language - Instrument continuing calibration verification shall be performed at the beginning and end of each analytical, and at the frequency defined in the method except with the following exceptions: The original use of the word "except" does not flow well with sections 1.7.2 d) iii. and iv.	**Persuasive**	Section was re-drafted for clarity
Affirmative with comment	1.7.2.d) i.	if an internal standard is used, calibration verification shall be performed at the beginning of each analytical batch, and at the frequency defined in the method; Proposed Language - if an internal standard is used, continuing calibration verification shall be performed at the beginning of each analytical batch, and at the frequency defined in the method; Add the word "continuing" to ensure there is no confusion between initial calibration verification and continuing calibration verification.	**Persuasive**	Section was re-drafted for clarity
Affirmative with comment	1.7.2.d) ii.	when the defined time period for calibration or the most recent calibration verification has expired; Proposed Language - when the defined time period for calibration or the most recent continuing calibration verification has expired, continuing calibration verification shall be performed prior to further analyses. Again add the word "continuing" to ensure there is no confusion between initial calibration verification and continuing calibration verification. Also add a clarifying statement at the end of this exception. Without the clarifying statement it could be interpreted that a CCV does not have to performed at all as it is an exception from the initial statement.	**Persuasive**	Section was re-drafted for clarity
Affirmative with comment	1.7.2.d) iii	In "an instrument calibration verification (second source calibration verification) that passes the continuing calibration verification criteria may be used in place of a continuing calibration verification standard." remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level.for the same reason as stated in comment 1 and add the word "initial" to be consistent with terminology.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.2.d)(ii)	The proposed wording implies that when a calibration or calibration verification has expired, I don't have to do a calibration verification at all. The following additional language will help me change my vote from "Negative" to "Approve": ii. when the defined time period for calibration or the most recent calibration has expired, in which case another initial instrument calibration shall be performed;	**Persuasive**	Section was re-drafted for clarity

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
	1.7.2.d)(iii)	is this saying "You can use a second source standard as a continuing calibration standard??	**Persuasive**	Section was re-drafted for clarity
Negative with comment	1.7.2.d)(iv)	The following additional language should be added to clarify the meaning and intent: iv. a laboratory control sample … calibration goes through the same process (analytical and preparation steps) as the LCS (using the continuing calibration verification acceptance criteria).	**Persuasive**	Section was re-drafted for clarity
Negative with comment	1.7.2.d.iii & iv	example at 1.7.2.d.iii &iv...this criteria is for an ICV or for the "initial CCV" "where calibration has not occured on that day"-that sentenc eis critical to have	**Persuasive**	Section was re-drafted for clarity
Affirmative with comment	1.7.2.e)	Sufficient raw data records shall be retained to permit reconstruction of the continuing instrument calibration verification (e.g., method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing verification data to the initial instrument calibration. Proposed Language - Sufficient raw data records shall be retained to permit reconstruction of the continuing calibration verification (e.g., method, instrument, analysis date, each analyte name, concentration and response, calibration curve or response factor, or unique equations or coefficients used to convert instrument responses into concentrations). Continuing calibration verification records shall explicitly connect the continuing calibration verification data to the initial calibration. Remove the word "instrument" to be consistent with paragraph above in section 1.7.1, which states that calibration can be at the instrument or method level, and add the word calibration for consistency in terminology.	**Persuasive**	"Instrument" removed from all calibration language. Language in 1.7.1 has also been modified.
Negative with comment	1.7.2.f	What was the purpose for changing this? The ability to run a second CCV after a failure is key where performance has been affected by carryover, a mis-injection, a syringe issue, etc. Where GC and GCMS is concerned, surrogate and IS performance indicate where those failures occur. Laboratories following this practice have solid documentation to justify a 2nd analysis/injection. The section goes on to talk about "data associated with an unacceptable calibration".....this is why we have SOPs and an accepted data qualifier system, which is based from EPA CLP. This document should not be intended to deal with issues at this level.	**Persuasive**	Redrafted

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Affirmative with comment	1.7.2.f	This section removes the ability to perform a second injection of a continuing calibration verification standard when an initial injection fails. This is problematic in instances where, for example, an instrument may be exhibiting lingering carryover, but an analyst unaware of the problem, injects the standard and a failure results. Corrective action (per this section) is then required, when a second injection may have resulted in an acceptable performance following the cleanup of the analytical system with the first attempt to perform calibration verification. This section also contradicts itself. Initially, it states that “if continuing instrument calibration verification results are outside the established acceptance range, corrective actions shall be performed”, but then goes further in the latter part of the paragraph to state that “Data associated with an unacceptable calibration verification may be fully useable under the following conditions:”	**Persuasive**	Redrafted
Negative with comment	1.7.2.f	This section has always been problematic and misleading for laboratories. An accreditation standard has no place giving laboratories discretion to decide if results are useable. All results associated with any QC failure must be clearly qualified if reported. Then the data user has the opportunity to make a sound decision as to the usabilty of the data. Delete ALL text starting with "Data associated" and to the end.	**Persuasive**	Redrafted
Negative with comment	1.7.2.f	This section removes the ability to perform a second injection of a continuing calibration verification standard when an initial injection fails. This is problematic in instances where, for example, an instrument may be exhibiting lingering carryover, but an analyst unaware of the problem, injects the standard and a failure results. Corrective action (per this section) is then required, when a second injection may have resulted in an acceptable performance following the cleanup of the analytical system with the first attempt to perform calibration verification. This section also contradicts itself. Initially, it states that “if continuing instrument calibration verification results are outside the established acceptance range, corrective actions shall be performed”, but then goes further in the latter part of the paragraph to state that “Data associated with an unacceptable calibration verification may be fully useable under the following conditions:”	**Persuasive**	Redrafted

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Affirmative with comment	1.7.2.f)	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, corrective actions shall be performed. The laboratory shall demonstrate acceptable performance after corrective action with a calibration verification, 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 qualified. Data associated with an unacceptable calibration verification may be fully useable under the following special conditions: Proposed Language - Criteria for the acceptance of a continuing calibration verification shall be established. If the continuing calibration verification results obtained are outside the established acceptance criteria, corrective actions shall be performed. The laboratory shall demonstrate acceptable performance after corrective action with a continuing calibration verification, or a new initial calibration shall be performed. If the laboratory has not verified the 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 qualified or all associated samples shall be re-analyzed once an acceptable calibration or continuing calibration verification has been established. Data associated with an unacceptable continuing calibration verification may be fully useable under the following special conditions: Remove the word "instrument". Add the word "continuing" where applicable for consistency in terminology. Also, add statement that provides the option for re-analysis of sample associated with failing continuing calibration verification, not just qualification.	**Persuasive**	Redrafted. "Instrument" removed from all calibration language
Negative with comment	1.7.2.f)(i)	The proposed changes (to existing 1.7.2(e)(i)) are TOTALLY UNACCEPTABLE. Please keep the original language. The idea of clients not getting data qualifiers when calibration verifications are unacceptable is abhorrent.	**Persuasive**	Redrafted
Negative with comment	1.7.2.f)(ii)	The proposed changes to make unacceptable calibration verifications usable without data qualifications are unacceptable. Incorporation of the following changes will help me change my vote from “Negative” to “Approve”: ii. for methods with more than 10 analytes, … verification low may be reported with data qualification for a continuing … unacceptable continuing calibration verification shall be qualified or re-analyzed.	**Persuasive**	Redrafted

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment	1.7.2.f)ii	1. The terminology "fail marginally" is unacceptable and will result in data that cannot be defended at litigation. An opposing attorney would welcome the opportunity to stand in front of a jury of non-scientists and challenge them to consider data that "fails", marginally or otherwise. This wording should be removed. 2. The standard is not workable as written. As many eev s are analyzed during automated, unattended sequences, the laboratory would have to predict before analysis which analytes would be outside the lower limit or, across the board, run the additional sensitivity check ecv s thereby doubling the standards required. Again, A Unit of American Analytical Services, Inc. the Method 8000B process using the grand mean with any individual outlier to be evaluated relative to the effect on project specific data quality objectives is sufficient.	**Persuasive**	Removed
Non-member commenter	1.7.2.f)ii	1. The terminology "fail marginally" is unacceptable and will result in data that cannot be defended at litigation. An opposing attorney would welcome the opportunity to stand in front of a jury of non-scientists and challenge them to consider data that "fails", marginally or otherwise. This wording should be removed. 2. The standard is not workable as written. As many CCV s are analyzed during automated, unattended sequences, the laboratory would have to predict before analysis which analytes would be outside the lower limit or, across the board, run the additional sensitivity check CCVs thereby doubling the standards required. Again, the Method 8000B process using the grand mean with any individual outlier to be evaluated relative to the effect on project specific data quality objectives is sufficient.	**Persuasive**	Removed
Negative with comment	1.7.2.f)ii	Please clarify what is acceptable as a "demonstration of adequate sensitivity" for a CCV. The ICAL section refers to the low standard, does the CCV need to be at a specific level to serve as a sensitivity check?	**Persuasive**	Redrafted
Negative with comment	1.7.2.f)ii	Please clarify the term "analytical batch". Is this essentially the same as a tune period or check standard bracket?	**Persuasive**	Removed
Negative with comment	1.7.2.f.ii	Please clarify what is acceptable as a "demonstration of adequate sensitivity" for a CCV. The ICAL section refers to the low standard, does the CCV need to be at a specific level to serve as a sensitivity check?	**Persuasive**	Redrafted
Negative with comment	1.7.2.f.ii	Please clarify the term "analytical batch". Is this essentially the same as a tune period or check standard bracket?	**Persuasive**	Removed
Negative with comment		Second source is not applicable to all calibrations. Include "second source where applicable"	**Persuasive**	Added option for independent lot
Negative with comment		If reanalysis of the samples is not possible, data associated with an unacceptable initial instrument calibration shall only be reported with appropriate data qualifiers. THIS SENTENCE SHOULD BE REMOVED! WHAT IN THE WORLD WOULD AN "UNACCEPTABLE INITIAL CALIBRATION" QUALIFIER MEAN? THIS LOWERS "ESTIMATED" TO A NEW HIGH IN LOW. ANALYTICALLY UNSOUND.	**Persuasive**	Added only as a nonconformance

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
Negative with comment		The proposed changes result in greater complexity that is not justified by gains in data quality. A number of terms are not defined such as degrees of freedom, threshold testing and %RSD.	**Persuasive** (partially)	Definitions will be proposed for addition to definitions section Otherwise opinion. In process
Negative with comment		I am from a small wastewater lab. From my perspective the new stuff added to this standard is not documented in known standards like standard methods. It's seems like TNI wants to break new ground. In that case these additions should be better explained. The new stuff is 1.7.1.1 j) i and ii. I disagree with adding %residual error and relative standard error. Also in 1.7.1.1 e) it adds regression or average response/calibration. I honestly don't know what you are talking about. Google doesn't help either. Also i am not sure why you don't want to allow qualified data below the calibration range.	**Non-persuasive**	Additions needed to improve calibration quality. Definitions will be added.
Negative with comment		Also i am not sure why you don't want to allow qualified data below the calibration range.	**Persuasive**	Clarified language- is allowed with qualification
Negative with comment		Standard wide use of the term "analytical batch": 1. The term "analytical batch" is used throughout this standard in a manner not consistant with definition used in other parts of the TNI standards. A different term should be selected, i.e. "analytical sequence", "analytical run", etc. Summary: In summary, this standard represents a detailed, prescriptive procedure that is not in keeping with TNI's mandate to provide "performance based" standards. The procedures described cannot be applied routinely without direct contradiction to current regulatory method and industry standard precedent.	**Non-persuasive**	In current standard with same usage
Non-member commenter		Standard wide use of the term "analytical batch": 1. The term "analytical batch" is used throughout this standard in a manner not consistant with definition used in other parts of the TNI standards. A different term should be selected, i.e. "analytical sequence", "analytical run", etc.	**Non-persuasive**	In current standard with same usage
Negative with comment		Summary: In summary, this standard represents a detailed, prescriptive procedure that is not in keeping with TNI's mandate to provide "performance based" standards. The procedures described cannot be applied routinely without direct contradiction to current regulatory method and industry standard precedent.	**Non-persuasive**	Opinion
Negative with comment		This section removes the allowance to use a linearity check sample to extend the calibration range for highly linear techniques such as ICP. Depending upon the project (especially for waste testing), little is gained by cutting an ICP sample and re-running if a linearity check sample was performed and acceptance criteria were met. (See discusion for Section 1.7.1.1.k below too.)	**Persuasive**	Clarified language, allowance is not removed

Voting Draft Standard. EL-V1M4; Sections 1.71 and 1.72, 2013. Response to Comments, December 2013				
		Votes cast: 47 Affirmative; 1 Affirmative with comment; 21 Negative with comment; 2 Abstentions		