**Standard Update - Summary of Suggested Changes and Justification**

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| **Original Text** | **Suggested Change** | **Justification** |
| *Include current reference and language. (If presented for public view, ISO language should only be referenced.)* | *Don't need to work on specific language - just summarize change needed.* | *Why does this need to be changed/updated?* |
| Document wide: “Shall” | “Must” | Clarity |
| Document wide numbering | Updated to new format | Policy change |
| Corrective action | Sometime changed to “action” | “Corrective action” seems to imply that cause analysis is needed. Committee updated document to adjust corrective action to just action if cause analysis was not expected but something needed to be done. |
| Document | Frequent changed to “record” | Clarified when a record was needed. |
| * 1. Introduction   This document contains detailed quality control (QC) requirements for environmental testing  activities involving chemical measurements. The evaluation of laboratories for this discipline is in  conjunction with a quality system as specified in the general requirements module. Adherence to  quality systems requirements will ensure that all QC procedures specified in this module are being  followed. | 1. Introduction   This document contains essential quality control (QC) requirements for environmental testing activities involving chemical measurements. Additional QC requirements specified by method, regulation or project must be met by laboratories. The evaluation of laboratories for this discipline is in conjunction with a quality system as specified in the general requirements module. Adherence to quality systems requirements will ensure that all QC procedures specified in this module are being followed. | * Clarification of language. * Addition of “Additional QC requirements specified by method, regulation or project must be met by laboratories” – added to intro to clearly indicate this requirement from the beginning |
| 1.2 Scope  The essential QC procedures applicable to chemistry measurements are included in this module.  Additional QC requirements that are either specified by method, regulation or project shall be met  by laboratories. | REMOVED | Language included in introduction. Allowed by SOP 2-103 |
|  | **2.0 Normative References**  **Reserved** | Added for consistency in numbering with SOP 2-103. “reserved” because ISO language was not used in this section |
| 1.3 Terms and Definitions  The relevant definitions from TNI, Volume 1, Module 2, Section 3.0 are the preferred references.  Definitions related to this document, which are used differently or do not exist in the above  references are defined below… | **3.0 Terms and Definitions**  The relevant definitions from TNI, Volume 1, Module 2, Section 3.0 are the preferred references. Definitions related to this document, which are used differently or do not exist in the above references are defined below.  **3.1 Additional Terms and Definitions**  **Calibration Standard:** A substance or reference material used for calibration.  **Internal Standard**: A known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.  **Limit(s) of Quantitation (LOQ)**: The minimum levels, concentrations, or quantities of a target variable (e.g., target analyte) that can be reported with a specified degree of confidence.  **Verification:** Confirmation by examination and objective evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification particular to the management of the measuring equipment.  **Matrix Spike:** Additional aliquot of a sample to which known concentration(s) of target analyte(s) is added. The spiked sample must then be handled exactly the same as the original sample though all analytical preparatory and analysis processes. The matrix spike is used to assess the effect of the sample’s matrix has on a method’s recovery efficiency.  **Matrix Spike Duplicate:** A replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.  **Limit of Detection (LOD)**: The minimum result which can be reliably discriminated from a blank with a predetermined confidence level.  **Measurement System**: A method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).  **3.2 Exclusions and Exceptions**  Reserved | Definitions added that were going to be removed from V1M2 where they were previously housed. |
| 4.0 Technical Specialist | Section Added | Technical specialist added to all technical modules. |
| **1.4 Method Selection** | **5.0 Selection, Verification and Validation of Methods** | Combine sections 1.4 method selection and 1.5 Method Validation into a single Section 5. Included Verification of methods for clarification on what was needed for Validation vs. Verification |
| 1.4 Method Selection  Refer to Volume 1, Module 2, Sections 5.4.2, 5.4.3, and 5.4.4. | Refer to Volume 1, Module 2, Section 7.2 for general requirements. | Updated references |
|  | In cases where the laboratory has been performing a method for at least one (1) year prior to applying for accreditation, previously generated method data may be used to meet the requirements for verification in Section 5.1 or validation in Section 5.2 as long as there have been no significant changes in instrument type or method since the data was generated. | Moved language from previous sections 1.4 and 1.5 up to be inclusive of all portions of the new section 5.0 |
| When adding a new analyte to a reference method, the inclusion of the analyte in the method shall  meet all required calibration requirements and the QC requirements of the method to which the  analyte is being added. If no QC exists in the method, the laboratory shall adhere to the  requirements outlined in a reference method of the same technology (when available). |  |  |
| For example, when adding acetone to EPA Method 624, the calibration and QC requirements shall follow EPA Method 624. A method that meets these requirements shall be identified in such a wayso that there is no confusion that the analyte list has been modified. | Removed example | Removed examples across the board. Examples to be included in follow up guidance document. |
| **1.5 Method Validation** | **5.0 Selection, Verification and Validation of Methods** | Same as above. |
|  | 5.1 Initial Verification of Methods  Prior to implementation of a published reference method, the laboratory’s capability and competency to perform the method must be verified for each analyte of interest in each quality system matrix for which accreditation is sought.  a) The laboratory must verify the performance of a reference method using the procedures in the reference method and, at a minimum, must include an initial determination of detection limits (Section 6.1.1), an initial selection and verification of limits of quantitation (Sections 6.2 and 6.2.1), an initial and continuing calibration (Section 8.1), and the required quality controls (Sections 8.2 and 8.3).  b) The laboratory must have an analyst with a successful demonstration of capability per Section 7.0.  c) The laboratory must obtain acceptable performance of proficiency testing samples as required in Volume 1 Module 1. | Verification of methods added for clarity on what a laboratory needs to do for a published reference method. |
| 1.5.1 Validation of Methods  Prior to acceptance and institution of any method for which data will be reported, all methods shall  be validated. a) The laboratory shall validate reference methods via the procedures specified in Sections  1.5.2 and 1.5.3. For reference methods, the procedures outlined in Section 1.6 can satisfy the  requirements of Section 1.5.3. |  | Now 5.1 Verification. For consistency with ISO |
| b) For all methods, except reference methods, the validation must comply with Volume 1,  Module 2, Sections 5.4.5.1, 5.4.5.2, and 5.4.5.3. This validation must include the minimum  requirements outlined in Sections 1.5.2, 1.5.3, and 1.5.4 of this module.  c) For both reference and non-standard methods, laboratories shall participate in proficiency  testing programs. The results of these analyses shall be used to evaluate the ability of the  laboratory to produce acceptable data. | 5.2 Initial Validation of Methods  Prior to implementation of a non-reference method, laboratory-developed method, or a reference method used outside its intended scope, the laboratory must validate the method for each analyte of interest in each quality system matrix for which accreditation is sought.  a) The method validation, at a minimum, must include all items in Sections 5.1.1 a) – c) and an evaluation of precision and bias (Section 5.3), an evaluation of selectivity (Section 5.4), the selection of appropriate method quality controls (Section 8.2), and the selection and determination of acceptance criteria (Section 8.3).  b) When a reference method is used outside of its intended scope, such as the addition of a new target analyte or the addition of a new quality system matrix, the scope change(s) and/or modification(s) must be clearly identified. | * Re-worded for clarity and detail. * Added language to clarify each analyte in each matrix. * Removed language about PTs, requirement is elsewhere. |
| 1.5.3 Evaluation of Precision and Bias  a) Reference Methods. The laboratory shall evaluate the precision and bias of a reference  method for each analyte of concern for each quality system matrix according to Section 1.6 or  alternate documented procedure when the analyte cannot be spiked into the sample matrix  and QC samples are not commercially available. | Language removed | Precision and bias for reference methods is included in the reference method. Or is otherwise covered in other sections of V1M4 |
| b) Non-Reference Methods. For laboratory-developed methods or non-reference methods that were not in use by the laboratory before July 2003, the laboratory shall have a documented  procedure to evaluate precision and bias. The laboratory shall also compare results of the  precision and bias measurements with criteria established by the client, by criteria given in  the reference method or criteria established by the laboratory.  Precision and bias measurements shall evaluate the method across the analytical calibration  range of the method. The laboratory shall also evaluate precision and bias in the relevant  quality system matrices and shall process the samples through the entire measurement  system for each analyte of interest.  Examples of a systematic approach to evaluate precision and bias could be the following:  i. Analyze QC samples in triplicate containing the analytes of concern at or near the  LOQ, at the upper-range of the calibration (upper 20%), and at a mid-range  concentration. Process these samples on different days as three (3) sets of samples  through the entire measurement system for each analyte of interest. Each day, one (1)  QC sample at each concentration is analyzed. A separate method blank shall be  subjected to the analytical method along with the QC samples on each of the three (3)  days. (Note that the three (3) samples at the LOQ concentration can demonstrate  sensitivity as well.)  For each analyte, calculate the mean recovery for each day, for each level over each  day, and for all nine (9) samples. Calculate the relative standard deviation for each of  the separate means obtained. Compare the standard deviations for the different days  and the standard deviations for the different concentrations. If the different standard  deviations are all statistically insignificant (e.g., F-test), then compare the overall mean  and standard deviation with the established criteria from above.  ii. A validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA  Office of Water’s Alternate Test Procedure (ATP) approval process. | 5.3 Evaluation of Precision and Bias  a) For non-reference methods, laboratory-developed methods, and reference methods used outside their intended scope, the laboratory must have a documented procedure to evaluate precision and bias.  b) Precision and bias must be evaluated across the analytical calibration range of the method. At a minimum the evaluation must include the low, middle and upper segments of the calibration range.  c) Samples used to generate precision and bias results must be processed through the entire measurement system for each analyte of interest in each quality system matrix.  d) The laboratory must compare the results of the precision and bias measurements with criteria established by the client, criteria given in the reference method or a comparable reference method, or criteria established by the laboratory. | * Removed grandfathering clause. Outdated. * Requirement to consider client requirements included in intro to V1M4 and in d. * Added language to clarify what “across the analytical calibration range “meant. * Language modified for clarity * Removed examples to be included in guidance document. |
| 1.5.4 Evaluation of Selectivity  The laboratory shall evaluate selectivity by following the checks established within the method,  which may include mass spectral tuning, second column confirmation, ICP inter-element  interference checks, chromatography retention time windows, sample blanks, spectrochemical  absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors. | 5.4 Evaluation of Selectivity  For non-reference methods, laboratory-developed methods, and reference methods used outside their intended scope, the laboratory must evaluate the method for selectivity of each analyte of interest in each quality system matrix. | * Removed examples; to be included in guidance document * Added language for clarity for what needs to be done for nonreference methods. Reference methods have this built in. |
|  | 5.5 Ongoing Method/Matrix/Analyte Verification  a) Laboratories must perform ongoing verification for each method/matrix/analyte combination annually for all methods, including reference, non-reference and laboratory developed methods. The results of these ongoing verifications must be used to evaluate the ability of the laboratory to produce acceptable data. The requirement for ongoing verification may be achieved by performing one or more of the following actions, where applicable, for each method/matrix/analyte combination:  i. Completion of ongoing verification of the DL or LOQ (Sections 6.1.2 or 6.2.2.  ii. Acceptable performance of a blind sample (single blind to the analyst) or successful analysis of a proficiency testing sample where the analyte has an assigned value above the DL.  iii. Completion of an Initial DOC -(Section 7.2).  iv. Completion of an ongoing DOC -(Section 7.3).  b) When a single action does not provide ongoing verification for each method/matrix/analyte combination (e.g., non-detects in PT samples), actions from above may be combined until a record of verification is available for each method/matrix/analyte combination. | Section added.  Clarification of what needs to be accomplished to do an ongoing verification for each method/matrix/analyte combination on an annual basis.  This was the consensus product to handle an “analyst DOC” vs. a “laboratory DOC” to ensure that all method/matrix/analyte combinations are verified on at least an annual basis for the laboratory but that an ongoing DOC for an analyst could still utilize a PT sample that may or may not include all of these requirements. |
| **1.5.2 Limit of Detection and Limit of Quantitation** | **6.0 Detection Limit and Limit of Quantitation (however named)** | Moved into it’s own section |
| **1.5.2 Limit of Detection and Limit of Quantitation** (however named)  Procedures used for determining limits of detection and quantitation shall be documented.  Documentation shall include the quality system matrix type. All supporting data shall be retained. | Procedures used for determining limits of detection and quantitation must be documented. Records must include the quality system matrix type. All supporting data must be retained. If a mandated test method or applicable regulation includes protocols for determining detection limits or limits of quantitation, they must be followed. If the method or regulation does not contain specific directions for determination of the detection limit or limit of quantitation, the requirements below in 6.1 and 6.2 apply. | * Re-worded for clarity. * Language added to clarify that method requirements must be met. * *May need to update guidance documents to assist laboratories with understanding when requirements in the method override regulatory requirements (ex. Drinking Water).* |
| 1.5.2.1 Detection Limit (DL)  If a mandated test method or applicable regulation includes protocols for determining detection  limits, they shall be followed. The laboratory shall document the procedure used for determining the  DL. If the method or regulation does not contain specific directions for determination of the  detection limit, the following requirements shall apply. DL determinations are not required for  methods/analytes for which a detection limit is not applicable such as pH, color, odor, temperature,  or dissolved oxygen. DL determinations based on low level spikes are not required for analytes for  which no spiking solutions are available. If results are not reported below the limit of quantitation  (LOQ), an initial DL determination is required, but ongoing verification is not. | Combined into intro above | * Removed list. * Moved into 6.1.2 below |
| 1.5.2.1.1 Initial determination of the DL  The laboratory DL procedure, unless following a mandated test method or procedure, at a  minimum, shall incorporate language addressing the following requirements:  a) the DL shall reflect current operating conditions;  b) the DL determination shall incorporate the entire analytical process;  c) the DL determination shall include data from low level spikes and routine method blanks  prepared and analyzed over multiple days; at least one low level spike and routine method  blank must be analyzed on each applicable instrument; a minimum of seven (7) replicates is  required for both low level spikes and routine method blanks;  d) results from low level spikes used in the DL determination shall meet qualitative identification  criteria in the method, and shall be above zero;  e) the DL procedure shall include criteria for and evaluation of false positive rates in routine  method blanks;  f) the DL shall be determined for the analytes of interest in each test method in the quality  system matrix of interest in which there are neither target analytes nor interferences at a  concentration that would impact the results, or the DL shall be performed in the sample  matrix of interest.  NOTE: One option is to follow the United States Environmental Protection Agency Method  Detection Limit (MDL) procedure, effective September 27, 2017. | 6.1.1 Initial determination of the DL  Initial determination of the DL is required and must follow the United States Environmental Protection Agency Method Detection Limit (MDL) procedure, effective September 27, 2017, 40 CFR 136 Appendix B. | Consensus decision to move to EPA procedure in 40 CFR 136 to avoid confusion and include clarity.  Much discussion on including full reference for EPA procedure in the standard in the off chance that EPA updates their procedure before the standard gets updated. However; if the regulations change the intro would cover the shift. |
| 1.5.2.1.2 Ongoing verification of the DL  At a minimum, ongoing verification of the DL shall include assessments of spikes at or below the  LOQ and of method blanks. A minimum of one (1) verification spike and one (1) blank shall be  analyzed on each instrument during each quarter in which samples are being analyzed and results  are being reported below the LOQ. The criteria listed in Section 1.5.2.1.1 shall be met for ongoing  verification over the course of a year.  If the method is altered in a way other than routine maintenance, and the change can be expected  to elevate the detection limit, then a spike at or below the LOQ concentration and a blank shall be  prepared and analyzed. If the spike at the LOQ concentration gives a result meeting qualitative  identification criteria above zero, and the blank gives a result below the DL, then the DL is verified.  If not, the DL shall be re-determined.  In the event that verification fails, the laboratory shall perform a new DL study within thirty (30)  calendar days.  1.5.2.1.3 When a new DL is determined, the laboratory shall verify that the LOQ value is greater than the DL.  If it is not, the laboratory shall raise the LOQ value to greater than the DL. | 6.1.2 Ongoing verification of the DL  Ongoing verification of the DL is only required when the laboratory reports results below their limit of quantitation (LOQ). If required, ongoing data collection and ongoing verification of the DL must follow the United States Environmental Protection Agency Method Detection Limit (MDL) procedure, 40 CFR 136 Appendix B effective September 27, 2017.  a) When a new DL study is required per the USEPA MDL procedure, it must be completed within thirty (30) calendar days, and the laboratory must not report to the DL until a new DL is established.  b) If a new instrument is added to a group of instruments sharing a single DL, analyze a minimum of two spiked replicates at the same concentration as the original spikes and 2 method blanks, and proceed as described in the USEPA MDL procedure.  c) When a new DL is determined, the laboratory must confirm that the LOQ remains greater than the DL. If it is not, the laboratory must raise the LOQ to be greater than the DL. | See above for inclusion of EPA reference.  a), b), and c) included for clarity on what is expected in addition to , or how to handle items that were not necessarily clear in the US EPA reference. |
| 1.5.2.2 Limit of Quantitation (LOQ)  If a mandated test method or applicable regulation includes protocols for determining quantitation  limits, they shall be followed. The procedure used for determining the LOQ shall be documented by  the laboratory. The laboratory shall select an LOQ for each analyte, consistent with the needs of its  clients, and greater than the DL. An LOQ is required for each quality system matrix of interest,  technology, method, and analyte, except for any component or property for which spiking solutions  are not available or a quantitation limit is not appropriate, such as pH, color, odor, temperature,  dissolved oxygen, or turbidity.  a) Each selected LOQ shall be verified through analysis of initial verification samples. An initial  verification sample consists of a spiked matrix blank at or below the selected LOQ.  b) All sample processing and analysis steps performed for routine sample analysis shall be  included in the LOQ verification testing.  c) The LOQ must be at or above the lowest corresponding calibration standard concentration  with the exception of methods using a single point calibration.  d) The laboratory shall establish acceptance criteria for accuracy for the LOQ verification spikes. | 6.2 Limit of Quantitation (LOQ)  The laboratory must select an LOQ for each method/matrix/analyte combination, consistent with the needs of its clients, and that is greater than the DL, except for any component or property for which spiking solutions are not available or a quantitation limit is not appropriate.  a) Each selected LOQ must be verified through analysis of initial verification samples. An initial verification sample consists of a quality system matrix blank spiked with the analytes of interest at or below the selected LOQ.  b) All sample processing and analysis steps performed for routine sample analysis must be included in the LOQ verification testing.  c) The LOQ must be at or above the lowest corresponding calibration standard concentration with the exception of methods using a single point calibration.  d) The laboratory must establish acceptance criteria for accuracy of the LOQ verification spikes. | * Included in intro to 6.0 * Re-worded for clarity * Removed list |
| 1.5.2.2.1 Initial verification of the LOQ  When first establishing an LOQ, or when an LOQ concentration has been selected that is lower  than the concentration of the LOQ verification spikes previously performed, an initial verification  shall be performed as follows:  a) A minimum of seven (7) low level spikes at or below the LOQ concentration shall be  processed through all steps of the method. Both preparation and analysis of these low level  spikes shall include at least three (3) batches on three (3) separate days.  NOTE 1: Spiking slightly below the LOQ may help ensure that the results are also suitable  for DL determination.  NOTE 2: If low level spikes have been analyzed in order to generate a DL, the results may  be used to perform the initial verification of the LOQ.  i. If there are multiple instruments that will be assigned the same LOQ, then these low  level spikes shall be distributed across all of the instruments.  ii. A minimum of two (2) low level spikes prepared and analyzed on different days shall be  tested on each instrument.  b) Existing data may be used if compliant with the requirements for at least three (3) batches,  generated within the last two (2) years and representative of current operations.  c) The LOQ is verified if the following criteria are met:  i. All results are quantitative (above zero and meet the qualitative identification criteria of  the method; e.g., recognizable spectra, signal to noise requirements, and presence of  qualifier ions).  If a result from an LOQ verification sample is not above zero and/or does not meet the  qualitative identification criteria in the method, the problem shall be corrected and the  verification repeated, or the LOQ verification shall be repeated at a higher concentration.  ii. Recovery of each analyte is within the laboratory established accuracy acceptance  criteria.  iii. The LOQ is greater than the established DL and at or above the spiking concentration.  If the LOQ is less than or equal to the DL, the LOQ shall be raised to greater than the DL.  NOTE: It is not necessary to repeat the LOQ verification at a higher concentration when it is  necessary to raise the LOQ to greater than the DL.  d) The laboratory shall document the results of the initial LOQ verification as described in  Section 1.5.2.4. | 6.2.1 Initial verification of the LOQ  When establishing a new LOQ that is below the concentration of the previous initial LOQ verification samples, an initial verification must be performed as follows:  a) A minimum of seven (7) initial verification samples at or below the LOQ concentration must be processed through all steps of the method. The initial verification samples must be prepared in at least three batches on three separate calendar dates and analyzed on three separate calendar dates.  NOTE 1: Spiking slightly below the LOQ may help ensure that the results are also suitable for DL determination.  NOTE 2: If initial verification samples have been analyzed in order to generate a DL, the results may be used to perform the initial verification of the LOQ.  b) If there are multiple instruments that will be assigned the same LOQ, then these initial verification samples must be distributed across all of the instruments. A minimum of two (2) initial verification samples prepared and analyzed on different days must be tested on each instrument.  c) Existing data may be used if compliant with the requirements for at least three (3) batches, generated within the last two (2) years and representative of current operations.  d) The LOQ is verified if the following criteria are met:  e) All results are quantitative (above zero and meet the qualitative identification criteria of the method, e.g., recognizable spectra, signal to noise requirements, and presence of qualifier ions).  i. If a result from an LOQ verification sample is not above zero and/or does not meet the qualitative identification criteria in the method, the problem must be corrected and the verification repeated, or the LOQ verification must be repeated at a higher concentration.  ii. The mean recovery of each analyte is within the laboratory established accuracy acceptance criteria.  iii. The LOQ is greater than the established DL and at or above the spiking concentration.  If the LOQ is less than or equal to the DL, the LOQ must be raised to greater than the DL.  NOTE: It is not necessary to repeat the LOQ verification at a higher concentration when it is necessary to raise the LOQ to greater than the DL.  f) The laboratory must record the results of the initial LOQ verification as described in Section 6.5. | Re-worded for clarity and consistency. Requirements unchanged. |
| 1.5.2.2.2 Ongoing verification of the LOQ  The laboratory shall prepare and analyze a minimum of one (1) LOQ verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are being analyzed for each quality system matrix, method, and analyte.  a) Results of each LOQ verification sample analysis shall be evaluated at the time of the testing and shall meet the qualitative identification criteria in the method and laboratory Standard Operating Procedure (SOP) and the quantitated result shall be greater than the DL and meet the laboratory established accuracy criteria as established by Section 1.5.2.2 d).  b) If a continuing LOQ verification test does not meet this requirement, the laboratory shall take  corrective action and document a technically valid reason for the corrective action.  Corrective action shall be one of the following: (i) correcting method or instrument performance and  repeating the verification test; (ii) evaluating the laboratory established control limits to ensure  they reflect current performance; or (iii) raising the spiking level (and the quantitation limit if  the spiking level is above it) and repeating the initial verification study within thirty (30)  calendar days of the initial failure. Any samples analyzed in a batch associated with a failing  LOQ verification shall be reanalyzed or reported with qualifiers. | 6.2.2 Ongoing verification of the LOQ  The laboratory must prepare and analyze a minimum of one (1) LOQ verification sample spiked at the same concentration as the initial LOQ verification on each instrument during each quarter in which samples are being analyzed for each quality system method/matrix/analyte.  a) Results of each LOQ verification sample analysis must be evaluated at the time of the testing and must meet the qualitative identification criteria in the method and laboratory Standard Operating Procedure (SOP). The quantitated result must be greater than the DL and meet the laboratory established accuracy criteria as established by Section 6.5.d).  If a continuing LOQ verification test does not meet this requirement, an action must be taken and record a technically valid reason for the action. The laboratory must also evaluate the impact to analyses on previously reported data back to the last passing LOQ verification. (See section V1M2 XXXX for nonconforming work).  b) Action must be one of the following:  i. correcting method or instrument performance and repeating the verification test;  ii. evaluating the laboratory established control limits to ensure they reflect current performance; or  iii. raising the spiking level (and the quantitation limit if the spiking level is above it) and repeating the initial verification study within thirty (30) calendar days of the initial failure.    c) Any samples analyzed in a batch associated with a failing LOQ verification must be reanalyzed or reported with appropriate qualifiers.  d) If no analysis was performed in a given year, the verification of the DL and LOQ is not required, but a new initial DL and LOQ verification must be performed prior to analysis of client samples. | Re-worded for clarity and consistency   * Language added to explain what is expected if an LOQ verification fails. (SIR) |
| 1.5.2.3 Verification of DL/LOQ  If no analysis was performed in a given year, the verification of the DL/LOQ is not required, but a  new initial DL/LOQ verification shall be performed prior to analysis of client samples. | Moved up to 6.2.2 d | No change to intent |
| 1.5.2.4 Documentation  At least once per year, the laboratory shall tabulate all results of the ongoing verification sample testing. All data representative of the current operations shall be used, if generated within the last two (2) years. A minimum of seven (7) samples is required.  a) The laboratory shall 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 DL verification test.  b) 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. | 6.3 Ongoing verification of the LOQ documentation  At least once per year, the laboratory must tabulate all results of the ongoing verification sample testing. All data representative of the current operations must be used, if generated within the last two (2) years. A minimum of seven (7) samples is required.  a) The laboratory must record the analytical and preparation methods used, dates of preparation and testing, the batch identifiers, the testing instrument, quality system matrix, analyte, concentration in the spiked sample with units, and the test result (if any) for each LOQ and/or DL verification test.  b) For each analyte, the laboratory must 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. This data must be provided to clients upon request. | Re-worded for clarity and consistency. Requirements unchanged. |
| 1.5.3 Evaluation of Precision and Bias  a) Reference Methods. The laboratory shall evaluate the precision and bias of a reference  method for each analyte of concern for each quality system matrix according to Section 1.6 or  alternate documented procedure when the analyte cannot be spiked into the sample matrix  and QC samples are not commercially available.  b) Non-Reference Methods. For laboratory-developed methods or non-reference methods that  were not in use by the laboratory before July 2003, the laboratory shall have a documented  procedure to evaluate precision and bias. The laboratory shall also compare results of the  precision and bias measurements with criteria established by the client, by criteria given in  the reference method or criteria established by the laboratory.  Precision and bias measurements shall evaluate the method across the analytical calibration  range of the method. The laboratory shall also evaluate precision and bias in the relevant  quality system matrices and shall process the samples through the entire measurement  system for each analyte of interest.  Examples of a systematic approach to evaluate precision and bias could be the following:  i. Analyze QC samples in triplicate containing the analytes of concern at or near the  LOQ, at the upper-range of the calibration (upper 20%), and at a mid-range  concentration. Process these samples on different days as three (3) sets of samples  through the entire measurement system for each analyte of interest. Each day, one (1)  QC sample at each concentration is analyzed. A separate method blank shall be  subjected to the analytical method along with the QC samples on each of the three (3)  days. (Note that the three (3) samples at the LOQ concentration can demonstrate  sensitivity as well.)  For each analyte, calculate the mean recovery for each day, for each level over each  day, and for all nine (9) samples. Calculate the relative standard deviation for each of  the separate means obtained. Compare the standard deviations for the different days  and the standard deviations for the different concentrations. If the different standard  deviations are all statistically insignificant (e.g., F-test), then compare the overall mean  and standard deviation with the established criteria from above.  ii. A validation protocol, such as the Tier I, Tier II, and Tier III requirements in US EPA  Office of Water’s Alternate Test Procedure (ATP) approval process. | MOVED UP | Included with new section 5 after making Detection Limit and Limit of Quantitation its own section. |
| 1.5.4 Evaluation of Selectivity  The laboratory shall evaluate selectivity by following the checks established within the method,  which may include mass spectral tuning, second column confirmation, ICP inter-element  interference checks, chromatography retention time windows, sample blanks, spectrochemical  absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors. | MOVED UP | Included with new section 5 after making Detection Limit and Limit of Quantitation its own section. |
| **1.6 Demonstration of Capability (DOC)** | **7.0 Analyst Demonstration of Capability (DOC)** | Renamed after adding 5.5 Ongoing Method/Matrix/Analyte Verification to clarify that this is analyst specific. 5.5 is Laboratory specific. |
| 1.6 Demonstration of Capability (DOC)  1.6.1 General  a) An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is completed (see Section 1.6.2). | 7.0Analyst Demonstration of Capability (DOC)  7.1 General  a) An individual who performs any activity involved with preparation and/or analysis of samples must have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is completed (see Section 7.2). All reported data must be generated by or under the supervision of an individual who has current DOCs as defined in Sections 7.2 and 7.3.  b) The laboratory must have documented procedures describing DOC requirements. The laboratory must identify and retain data associated with DOCs. | * Added to clarify expectations * Added to clarify that laboratory must specify what their specific procedures are for DOCs. |
| b) Thereafter, ongoing DOC (Section 1.6.3), as per the QC requirements in Section 1.7.2 (such  as laboratory control samples), is required. |  | * Removed – felt the intent of the standard to do ongoing DOCs was clear, addressed below. |
|  | c) For methods in which the laboratory routinely separates sample preparation (such as digestions, distillations, or extractions) and sample analysis into distinct processes performed by separate individuals, the Initial and/or ongoing DOC for sample preparation and analysis processes must be separated. In cases where the preparation and analysis processes are performed by separate individuals, each must demonstrate capability of their assigned process. | * Added for clarity that if multiple individuals perform distinct steps that they are each required to have a DOC for that specific step. |
| c) In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for accreditation, and  there have been no significant changes in instrument type or method, the ongoing DOC shall be acceptable as an initial DOC. The laboratory shall have records on file to demonstrate that an initial DOC is not required.  d) All demonstrations shall be documented. All data applicable to the demonstration shall be  retained and readily available at the laboratory. | d) In cases where an individual has prepared and/or analyzed samples using a method that has been in use by the laboratory for at least one (1) year prior to applying for initial laboratory accreditation, and there have been no significant changes in instrument type or method, and the individual has performed the method within the past twelve (12) months, the ongoing DOC will be acceptable as an initial DOC. The laboratory must have records on file to demonstrate that an initial DOC is not required.  e) All demonstrations must be recorded. | * Added for clarity * Simplified for clarity. |
| 1.6.2 Initial DOC  An individual must successfully perform an initial DOC prior to using any method (see Section  1.6.1.a above), and any time there is a change in instrument type, method, or any time that a  method has not been performed by the analyst in a twelve (12) month period. | 7.2 Initial DOC  An analyst new to a method must successfully perform an initial DOC for each method/matrix/analyte prior to independently generating reportable data for said method/matrix/analyte (see Section 7.1.a above). Additionally, an initial DOC must be performed any time there is a change in instrument type, method, or any time that a method has not been performed by the analyst in a twelve (12) month period. | Reworded for clarity. |
| 1.6.2.1 The laboratory shall document each initial DOC in a manner such that the following information is readily available for each affected employee:  a) analyst(s) involved in preparation and/or analysis;  b) matrix;  c) analyte(s), class of analyte(s);  d) identification of method(s) performed;  e) identification of laboratory-specific SOP used for analysis, including revision number;  f) date(s) of analysis; and  g) summary of analyses, including information outlined in Section 1.6.2.2.c. | 7.2.1 The laboratory must record each initial DOC in such a manner that the following information is readily available for each affected employee:  a) analyst(s) involved in preparation and/or analysis;  b) quality system matrix;  c) analyte(s), class of analyte(s);  d) identification of method(s) performed;  e) identification of laboratory-specific SOP used for analysis, including revision number;  f) date(s) of analysis; and  g) summary of analyses, including information outlined in Section 7.2.2.c. | “Matrix” changed to “Quality System Matrix” for consistency in other section revisions |
| 1.6.2.2 If the method or regulation does not specify an initial DOC, the following procedure is acceptable. It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.  a) The analyte(s) shall be diluted in a volume of clean quality system matrix (a sample in which  no target analytes or interferences are present at concentrations that will impact the results of  a specific method) sufficient to prepare four (4) aliquots at the concentration specified, or if  unspecified, to a concentration of one (1) to four (4) times the LOQ.  b) At least four (4) aliquots shall be prepared and analyzed according to the method(s) either  concurrently or over a period of days.  c) Using all of the results, calculate the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same units) for each analyte of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and  logarithmic values, the laboratory shall assess performance against established and  documented criteria.  d) Compare the information from (c) above to the corresponding acceptance criteria for  precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all analytes meet the acceptance criteria, the analysis of actual samples may begin. If any one of the analytes does not meet the acceptance criteria, the performance is unacceptable for that analyte.  e) When one or more of the tested analytes fail at least one (1) of the acceptance criteria, the  analyst shall proceed according to i) or ii) below.  i. Locate and correct the source of the problem and repeat the test for all analytes of  interest beginning with b) above.  ii. Beginning with b) above, repeat the test for all analytes that failed to meet criteria.  f) Repeated failure, however, confirms a general problem with the measurement system. If this  occurs, locate and correct the source of the problem and repeat the test for all analytes of  interest beginning with b).  g) When an analyte not currently found on the laboratory’s list of accredited analytes is added to an existing accredited method, an initial demonstration shall be performed for that analyte. | 7.2.2 If the method or regulation does not specify an initial DOC, complete the following procedure. If this is not applicable it is the responsibility of the laboratory to select and document another approach to the initial DOC which incorporates criteria for precision, accuracy and acceptance.    a) The analyte(s) must be diluted in a volume of clean matrix appropriate for use (a sample in which no target analytes or interferences are present at concentrations that will impact the results of a specific method) to a concentration of one (1) to four (4) times the LOQ.  b) At least four independently prepared LCSs must be analyzed according to the method(s) either concurrently or over a period of days and meet LCS acceptance criteria.  c) Using all the results, calculate the mean recovery in the appropriate reporting units and the relative standard deviations of the sample (in the same units) for each analyte of interest. When it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, the laboratory must assess performance against established and documented criteria.  d) Compare the information from (c) above to the corresponding acceptance criteria for precision and accuracy in the method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all analytes meet the acceptance criteria, the analysis of actual samples may begin. If any one of the analytes does not meet the acceptance criteria, the performance is unacceptable for that analyte.  e) When one or more of the tested analytes fail at least one (1) of the acceptance criteria, locate and correct the source of the problem and proceed according to i) or ii) below.  i. Beginning with a) above repeat the test for all analytes of interest  ii. Beginning with a) above, repeat the test for only analytes of interest that failed to meet criteria.  f) When an analyte not currently found on the laboratory’s list of accredited analytes is added to an existing accredited method, an initial demonstration must be performed for that analyte. | * Re-worded for clarity * Added language to incorporate requirements for precision, accuracy and acceptance into the procedure for DOCs if the laboratory is going to establish their own procedure * Added wording for clarity * Removed, felt this was not needed. This is a general requirement for laboratories. Under corrective actions and cause analysis. |
| 1.6.3 Ongoing DOC  1.6.3.1 The laboratory shall have a documented procedure describing ongoing DOC that includes  procedures for how the laboratory will identify data associated with ongoing DOCs. The analyst(s) shall demonstrate on-going capability by routinely meeting the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard. If the method has not been performed by the analyst in a twelve (12) month period, an initial DOC (Section 1.6.2) shall be performed. It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate. | 7.3 Ongoing DOC  7.3.1 An analyst must continue to demonstrate ongoing competence through completion of an ongoing DOC to continue to generate reportable data for said method. The laboratory must have a documented procedure describing ongoing DOC that includes procedures for how the laboratory will identify data associated with ongoing DOCs. The analyst(s) must demonstrate on-going capability by routinely meeting the QC requirements of the method, laboratory SOP, client specifications, and/or this Standard If an ongoing DOC has not been completed by the analyst annually, an initial DOC (Section 7.2) must be performed. It is the responsibility of the laboratory to document their approaches to ongoing DOCs which comply with their procedures for monitoring the competence of personnel (see V1M2 6.2.5.f). | 7.3.1 was rewritten to incorporate clarity and understanding with the intent of removing 1.6.3.2 from the Standard to allow for more flexibility in how a ongoing DOC was to be done. It is not the intent of the standard that the laboratory must define how they will do it. |
| 1.6.3.2 This on-going demonstration may be one of the following:  a) acceptable performance of a blind sample (single blind to the analyst) or successful analysis  of a blind performance sample on a similar method using the same technology (e.g., GC/MS  volatiles by purge and trap for Methods 524.2, 624 or 5030/8260);  b) another initial DOC;  c) at least four (4) consecutive laboratory control samples with acceptable levels of precision  and accuracy. The laboratory shall determine the acceptable limits for precision and accuracy  prior to analysis. The laboratory shall tabulate or be able to readily retrieve four (4)  consecutive passing LCSs or reference sample(s) for each method for each analyst each  year;  d) a documented process of reviewing QC samples performed by an analyst or groups of  analysts relative to the QC requirements of the method, laboratory SOP, client specifications,  and/or this Standard. This review can be used to identify patterns for individuals or groups of  analysts and determine if corrective action or retraining is necessary;  e) if a) through d) are not technically feasible, then analysis of real-world samples with results  within a pre-defined acceptance criterion (as defined by the laboratory or method) shall be  performed. | REMOVED |  |
| 1.7 Technical Requirements  1.7.1 Calibration  This module specifies the essential elements that shall define the procedures and documentation  for initial calibration with second source verification and continuing calibration verification for methods that use calibration models including, but not limited to, average response factor or linear or quadratic regression, to ensure that the data shall be of known quality for the intended use. Calibration requirements for analytical support equipment are specified in Module 2. This Standard does not specify detailed procedural steps (“how to”) for calibration but establishes the essential elements for selection of the appropriate technique(s). This approach allows flexibility and permits the employment of a wide variety of analytical procedures and statistical approaches currently applicable for calibration. If more stringent standards or requirements are included in a mandated  method or by regulation, the laboratory shall demonstrate that such requirements are met. If it is not apparent which Standard is more stringent, then the requirements of the regulation or mandated method are to be followed. | 8.0 Technical Requirements  8.1 Calibration  This section of the module specifies the essential elements that must define the procedures and documentation for initial calibration with second source verification and continuing calibration verification for methods that use calibration to ensure that the data is of known quality for the intended use. Calibration requirements for support equipment are specified in Module 2. | Simplified wording. |
| 1.7.1.1 Initial Calibration  Samples shall be associated with an acceptable initial calibration. If the initial calibration is not  acceptable, corrective actions shall be performed and all associated samples re-analyzed. If reanalysis of the samples is not possible, data associated with an unacceptable initial calibration shall only be reported with appropriate data qualifiers.  The following items are essential elements of initial calibration:  a) the details of the initial calibration procedures including calculations, integrations, acceptance  criteria, and associated statistics shall be included or referenced in the method SOP. When initial calibration procedures are referenced in the test method, then the referenced material shall be retained by the laboratory and be available for review.  b) sufficient raw data records shall be retained to permit reconstruction of the initial calibration  (e.g., calibration date, method, instrument, analysis date, each analyte name, and analyst’s  initials or signature; concentration and response, calibration curve or response factor; or  unique equation or coefficient used to reduce instrument responses to concentration);  c) the laboratory shall use the most recent initial calibration analyzed prior to the analytical  batch, unless otherwise specified by the method | 8.1.1 Initial Calibration  Sample results must be determined using an acceptable initial calibration, except as noted in 8.1.1.a below.  The following items are essential elements of initial calibration:   1. The most recent initial calibration analyzed from the instrument utilized, prior to the analytical batch must be used. If the most recent initial calibration is not acceptable, any affected samples must be reanalyzed once a compliant initial calibration is achieved. If re-analysis of the samples cannot be performed, data associated with an unacceptable initial calibration must only be reported with appropriate data qualifiers. 2. The details of the initial calibration procedures including calculations, integrations, acceptance criteria, and associated statistics must be included or referenced in the method SOP. When initial calibration procedures are referenced in the test method, then the referenced material must be retained by the laboratory and be available for review. 3. Raw data records must be retained to permit reconstruction of the initial calibration. In cases where raw data is unavailable due to a factory provided calibration the laboratory must use a documented procedure to verify the factory calibration. | Lots of clarification and cleaning up of language, renumbering due to rearrangement words. Specific changes and justifications below.   * Language from original standard was cleaned up and moved into a) Language also moved up from c). * Allows for use of manufacturer calibrated instrumentation when the raw data may not be available. |
| d) standards used for calibration shall be traceable to a national standard, when commercially available; |  | Language removed. Covered elsewhere. |
| e) the laboratory shall have a written procedure addressing removal and replacement of  calibration standards. The procedure shall comply with the following requirements:  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.  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.  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.  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.  v. The laboratory may replace a calibration standard provided that:  a. the laboratory analyzes the replacement standard within twenty-four (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.  vi. The laboratory shall document a technically valid reason for either removal or  replacement of any interior calibration point; | 1. If removal and replacement of calibration standards is necessary, the laboratory must comply with the following requirements: 2. The laboratory may remove individual analyte calibration levels from the lowest and/or highest levels of the calibration. Multiple levels may be removed, but removal of interior levels is not permitted except as noted below in 8.1.1.d.ii. 3. The laboratory may remove an entire single standard calibration level from the interior of the calibration 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 must remove that particular standard calibration level for all analytes. Removal of calibration points from the interior of the calibration is not to be used to compensate for poor or erratic instrument response. 4. The laboratory must adjust the LOQ and quantitation range of the calibration based on the concentration of the remaining high and low calibration standards. 5. The laboratory must ensure that the remaining initial calibration standards are sufficient to meet the minimum requirements for the number of initial calibration points as mandated by this Standard, the method, or regulatory requirements. 6. The laboratory may replace an initial calibration standard provided that: 7. The laboratory analyzes the replacement standard by the end of the next working day of the original calibration standard analysis for that particular calibration level. 8. The laboratory replaces all analytes of the replacement calibration standard if a standard within the interior of the calibration is replaced; and 9. The laboratory limits the replacement of calibration standards to one calibration standard.   vi. The laboratory must record a technically valid reason for either removal or replacement of any interior calibration point. | * Written pro   .   * Added for clarity * Adjusted wording to allow for running a calibration on a day before a day off with an autosampler and then coming in the following working day and not being able to make changes. |
| 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; | 1. for regression or average response/calibration factor calibrations, the minimum number of non-zero calibration standards must be as specified in the table below:  |  |  | | --- | --- | | **Type of Calibration** | **Minimum Number of Calibration Standards b, c** | | Threshold Testinga | 1 | | Average Response | 4 | | Linear Fit | 5 | | Quadratic Fit | 6 |   a *The initial one-point calibration must 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 must be maintained by the laboratory.*  *c Fewer calibration standards for ISE technologies are allowed based on manufacturer’s instructions.* | Added to allow for fewer points with an ISE based off of manufacturer’s instructions. (SIR) |
| g) the lowest calibration standard shall be at or below the lowest concentration for which  quantitative data are to be reported without qualification;  h) the highest calibration standard shall be at or above the highest concentration for which  quantitative data are to be reported without qualification;  i) sample results shall be quantitated from the initial calibration and may not be quantitated  from any continuing calibration verification unless otherwise required by regulation, method,  or program;  j) criteria for the acceptance of an initial calibration shall be established (e.g., correlation  coefficient or relative standard deviation); | 1. the lowest calibration standard must be at or below the lowest concentration for which quantitative data are to be reported without qualification; 2. the highest calibration standard must be at or above the highest concentration for which quantitative data are to be reported without qualification except as addressed in o below; 3. sample results must be quantitated from the initial calibration and may not be quantitated from any continuing calibration verification unless otherwise required by regulation, method, or program; 4. criteria for the acceptance of an initial calibration must be established and met; | Removed list, added requirement for criteria to be met and not just established. |
| k) 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;  ii. for calibrations evaluated using correlation coefficient or coefficient of determination,  the laboratory shall evaluate relative error by either:   1. measurement of the Relative Error (%RE)   Relative error is calculated using the following equation:  *xi* = True value for the calibration standard *x’i* = Measured concentration of the calibration standard  This calculation shall be performed for two (2) 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 shall 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.  or,  b. measurement of the Relative Standard Error (%RSE)  Relative Standard Error is calculated using the following equation:    *xi*= True value of the calibration level i  *x’i*= Measured concentration of calibration level i  *p* = Number of terms in the fitting equation  (average = 1, linear = 2, quadratic = 3)  *n* = Number of calibration points  The RSE shall 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 laboratorySOP.  . | 1. the laboratory must use and document a measure of relative error in the calibration;     * 1. for calibrations evaluated using an average response factor, the determination of the relative standard deviation (RSD) is the measure of the relative error;      2. for calibrations evaluated using correlation coefficient or coefficient of determination, the laboratory must evaluate relative error by either: 2. measurement of the Relative Error (%RE)   Relative error is calculated using the following equation:  *xi* = True value for the calibration standard *x’i* = Measured concentration of the calibration standard  Unless the method specifies more points to be evaluated, this calculation must be performed for two calibration levels: the standard at or near the middle of the initial calibration range 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 must be specified in the laboratory SOP.  or,   1. measurement of the Relative Standard Error (%RSE)   Relative Standard Error is calculated using the following equation:    *xi*= True value of the calibration level i  *x’i*= Measured concentration of calibration level i  *p* = Number of terms in the fitting equation  (average = 1, linear = 2, quadratic = 3)  *n* = Number of calibration points  The RSE must meet the criterion specified in the method. If no criterion is specified in the method, the maximum allowable RSE must 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 must be specified in the laboratory SOP.  iii. ISE calibrations and/or other point-to-point calibrations do not require a calculation of the measure of relative error. | Language edited for clarity and to address SIR regarding “mid-point” definition.   * Language added to remove requirements for relative error calculations for certain types of instrumentation (SIR). |
| l) when test procedures are employed that specify calibration with a single calibration standard  and a zero point (blank or zero, however specified by the method), the following shall occur:  i. The zero point and single calibration standard within the linear range shall be analyzed  at least daily and used to establish the slope of the calibration.  ii. To verify adequate sensitivity a standard shall be analyzed at or below the lowest concentration for which quantitative data are to be reported without qualification. This standard shall be analyzed prior to sample analysis with each calibration and shall  meet the quantitation limit criteria established by the method. If no criteria exist the laboratory shall specify criteria in the SOP;  m) for analysis of Aroclors which use a linear through origin model (or average response factor)  the minimum requirement is to perform an initial multi-point calibration for a subset of  Aroclors (e.g., a mixture of 1016/1260) and to use a one-point initial calibration to determine  the calibration factor and pattern recognition for the remaining Aroclors; | k) when test methods are employed that allow calibration with a single calibration standard and a zero point (blank or zero, however specified by the method), the following must occur:  i. The zero point and single calibration standard within the linear range must be analyzed at least daily and used to establish the slope of the calibration.  ii. To verify adequate sensitivity a standard must be analyzed at or below the lowest concentration for which quantitative data are to be reported without qualification. This standard must be analyzed prior to sample analysis with each calibration and must meet the quantitation limit criteria established by the method. If no criteria exist, the laboratory must specify criteria in the SOP.  l) for analysis of Aroclors follow method requirements for calibration. | * Specify changed to allow. Grammatical faux pas. * Simplified and just referenced method for this |
| n) Initial Calibration Verification (ICV): All initial calibrations shall be verified with a standard  obtained from a second manufacturer or a separate lot prepared independently by the same  manufacturer;  o) for those methods where reporting non-detected analytes based on successful completion of  a sensitivity check is allowed (similar to threshold testing but only for non-detects) the  requirements of this Standard shall not prohibit the practice;  p) some methods allow data within the linear range of the instrument, but above the daily  calibration, to be reported without qualification. For these methods, the laboratory shall establish the upper reporting limit through analysis of a series of standards. The upper reporting limit is equal to the concentration of the highest standard meeting the method limits for accuracy. The laboratory shall establish linearity annually and check it at least quarterly with a standard at the top of the linear working range, or at the frequency defined by the  method. The laboratory shall dilute samples with results above the linear calibration range, or  qualify the over-range results as estimated values | m) Initial Calibration Verification (ICV): All initial calibrations must be verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer when available. If the method does not specify acceptance criteria the laboratory must develop acceptance criteria.  n) for those methods where reporting non-detected analytes based on successful completion of a sensitivity check is allowed (similar to threshold testing but only for non-detects) the requirements of this Standard must not prohibit the practice;  o) some methods allow data within the linear range of the instrument, but above the daily calibration, to be reported without qualification. For these methods, the laboratory must establish the upper reporting limit through analysis of a series of standards. The upper reporting limit is equal to the concentration of the highest standard meeting the method limits for accuracy. The laboratory must establish linearity annually and check it at least quarterly with a standard at the top of the linear working range, or at the frequency defined by the method. The laboratory must dilute samples with results above the linear calibration range or qualify the over-range results as estimated values. | * Not always available. * Added language to require acceptance criteria |
| 1.7.1.2 Continuing Calibration Verification (CCV)  The validity of the initial calibration shall be verified prior to sample analyses by a continuing  calibration verification with each analytical batch. The following items are essential elements of  continuing calibration verification.  a) The details of the continuing calibration procedure, calculations and associated statistics shall be included or referenced in the method SOP.  b) Calibration shall be verified for each compound, element, or other discrete chemical species,  except for multi-component analytes such as Aroclors, chlordane, total petroleum hydrocarbons, or toxaphene, where a representative chemical, related substance or mixture can be used.  c) The concentration of the calibration verification standard shall be equal to or less than half  the highest level in the calibration.  d) Instrument continuing calibration verification shall be performed at the beginning and end of  each analytical batch, and at the frequency defined in the method except:  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;  ii. a second source initial calibration verification that passes the continuing calibration  verification criteria may be used in place of a continuing calibration verification  standard;  iii. a laboratory control sample (LCS) may be used in place of a continuing calibration  verification (CCV) (but not as a replacement for a failing CCV) for methods where the  calibration goes through the same process as the LCS (using the continuing calibration  verification acceptance criteria).  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 calibration verification  data to the initial calibration.  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, the following steps shall be taken:  i. if a 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 Section  1.7.1.2.d). The cause for the failure of the first calibration verification result shall be  documented;  ii. if the cause for the 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 Section 1.7.1.2.d);  iii. Data associated with an unacceptable calibration verification shall be qualified if  reported, and shall not be reported if prohibited by the client, a regulatory program or  regulation. Data associated with calibration verifications that fail under the following  special conditions shall still be qualified, but may use a different qualifier:  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  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. | 8.1.2 Continuing Calibration Verification (CCV)  The validity of the initial calibration must be verified prior to sample analyses by a continuing calibration verification with each analytical batch. The following items are essential elements of continuing calibration verification.  a) The details of the continuing calibration procedure, calculations and associated statistics must be included or referenced in the method SOP.  b) Calibration must be verified for each analyte, except for multi-component analytes such as Aroclors, chlordane, or total petroleum hydrocarbons, where a representative chemical, related substance or mixture can be used if the method allows.  c) The concentration of at least one calibration verification standard per analytical batch must be equal to or less than half the highest level in the calibration.  d) Instrument continuing calibration verification must be performed at the beginning and end of each analytical batch, and at the frequency defined in the method except:   1. if an internal standard is used, calibration verification must be performed at the beginning of each analytical batch, and at the frequency defined in the method; 2. a second source initial calibration verification that passes the continuing calibration verification criteria may be used in place of a continuing calibration verification standard; 3. a laboratory control sample (LCS) may be used in place of a continuing calibration verification (but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS (using the continuing calibration verification acceptance criteria).   e) Sufficient raw data records must be retained to permit reconstruction of the continuing instrument calibration verification. Continuing calibration verification records must explicitly connect the continuing calibration verification data to the initial calibration.  f) Criteria for the acceptance of a continuing instrument calibration verification must be established. If the continuing instrument calibration verification results obtained are outside the established acceptance criteria, the following steps must be taken:   1. if a 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 prior to analyzing additional samples and the result is within acceptance criteria. Samples analyzed previously are considered valid if bracketed by a passing calibration verification sample (refer to 1.7.1.2.d). The cause for the failure of the first calibration verification result must be recorded; 2. if the cause for the calibration verification failure is not identifiable or has impacted other samples, then action must be taken and recorded to address the issue. Prior to analyzing samples, the laboratory must demonstrate acceptable performance after action with calibration verification or a new initial calibration must be performed. Samples analyzed prior to the calibration verification failure must be reanalyzed or the results qualified if calibration verification bracketing is required (refer to 8.1.2.d); 3. Data associated with an unacceptable calibration verification must be qualified if reported, and must not be reported if prohibited by the client, a regulatory program or regulation. Data associated with calibration verifications that fail under the following special conditions must still be qualified, but may use a different qualifier:   g) when the acceptance criteria for the continuing calibration verification are exceeded high (i.e., high bias) and there are associated samples that are non-detects, then those non-detects may be reported. Otherwise, the samples affected by the unacceptable calibration verification must be re-analyzed after a new initial calibration has been established, evaluated and accepted; or  h) 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 must be re-analyzed after a new initial calibration has been established, evaluated and accepted. | Minor editorial changes and changes for clarification.   * Clarification * Removed list |
| 1.7.2 Quality Control (QC)  The laboratory shall have QC procedures for monitoring the validity of environmental tests  undertaken as specified in this Section. | 8.2 Quality Control (QC)  The laboratory must have QC procedures for monitoring method performance and evaluating the validity of environmental testing data. These procedures must include the quality control types as specified in this Section. If a method, regulation, program or client specify quality control requirements, those must be followed. | * Phrase added to reemphasize, and applies to all sections of section 8.2 |
| 1.7.2.1 Negative Control – Method Performance: Method Blank  a) The method blank is used to assess the samples in the preparation batch for possible  contamination during the preparation and processing steps. The method blank shall be  processed along with and under the same conditions as the associated samples to include all  steps of the analytical procedure. Procedures shall be in place to determine if a method blank  is contaminated. Any affected samples associated with a contaminated method blank shall be  reprocessed for analysis or the results reported with appropriate data qualifying codes.  b) The method blank shall be analyzed at a minimum of one (1) per preparation batch. In those  instances for which no separate preparation method is used (for example, volatiles in water),  the batch shall be defined as environmental samples that are analyzed together with the  same method and personnel, using the same lots of reagents, not to exceed the analysis of  twenty (20) environmental samples, not including method blanks, LCS, matrix spikes and  matrix duplicates.  c) The method blank shall consist of a quality system matrix that is similar to the associated  samples and is known to be free of the analytes of interest.  d) Method blanks are not applicable for certain analyses, such as pH, Conductivity, Flash Point,  and Temperature. | 8.2.1 Negative Control – Method Performance: Method Blank  a) The method blank must be analyzed at a minimum of one (1) per preparation batch. In those instances where no separate preparation method is required (for example, volatiles in water), the batch must be defined as environmental samples that are analyzed together with the same method and personnel, using the same lots of reagents and spiking standards, not to exceed the analysis of twenty (20) environmental samples, not including laboratory QC (method blanks, LCS, matrix spikes and matrix duplicates). Or at the frequency as described within a reference method.  b) Method blanks are not applicable for certain analyses, such as pH, Conductivity, Flash Point, and Temperature.  c) The method blank must be prepared and analyzed using all of the same lots of reagents, equipment, and analytical steps used for the associated samples.  d) Procedures must be in place to determine if a method blank is contaminated. See section 8.3.1. | * Removed definition * Language added to allow for reduced frequency if allowed by the method. * Re-worded for clarity. * Taken from original section a) which was removed. |
| 1.7.2.2 Positive Control – Method Performance: Laboratory Control Sample (LCS)  1.7.2.2.1 The LCS is used to evaluate the performance of the total analytical system, including all preparation  and analysis steps. Results of the LCS are compared to established criteria and, if found to be  outside of these criteria, indicates that the analytical system is “out of control.” Any affected  samples associated with an out of control LCS shall be reprocessed for re-analysis or the results  reported with appropriate data qualifying codes. | 8.2.2 Positive Control – Method Performance: Laboratory Control Sample (LCS) | * Moved and simplified to go with order of MB above |
| 1.7.2.2.2 The LCS shall be analyzed at a minimum of one (1) per preparation batch. Exceptions would be for those analytes for which no spiking solutions are available, such as total suspended solids, total  dissolved solids, total volatile solids, total solids, pH, color, odor, temperature, dissolved oxygen, or  turbidity. In those instances for which no separate preparation method is used (example: volatiles in  water), the batch shall be defined as environmental samples that are analyzed together with the  same method and personnel, using the same lots of reagents, not to exceed the analysis of twenty  (20) environmental samples, not including method blanks, LCS, matrix spikes and matrix  duplicates.  1.7.2.2.3 The LCS is a quality system matrix, known to be free of analytes of interest, spiked with known concentrations of analytes.  NOTE: The matrix spike may be used in place of this control as long as the acceptance criteria are  as stringent as for the LCS.  Alternatively, the LCS may consist of a media containing known and verified concentrations of  analytes or as Certified Reference Material (CRM). All analyte concentrations shall be within the  calibration range of the methods. The following shall be used in choosing components for the spike  mixtures. | a) The LCS must be prepared and analyzed at a minimum of one (1) per preparation batch. In those instances where no separate preparation method is required (example: volatiles in water), the batch must be defined as environmental samples that are analyzed together with the same method -, using the same lots of reagents and spiking standards, not to exceed the analysis of twenty (20) environmental samples, not including laboratory QC.  b) The LCS is used to evaluate the performance of the total analytical system, including all preparation, handling and analysis steps.  c) The LCS is applicable for all analyses where a material which provides known and verified analytical results is available. If a material becomes available for an analysis which historically has not required an LCS, the laboratory must incorporate that material into the QC requirements for the method as an LCS. | * Removed list, cleaned up language. * From the original 1.7.2.2.1 above * Replacement language., clarify without list. * Removed note |
|  | d) All analyte concentrations of the LCS must be within the calibration range of the method being performed. | Language added to clarify. |
| The components to be spiked shall be as specified by the mandated method or regulation or as  requested by the client. In the absence of specified spiking components, the laboratory shall spike  per the following:  a) for those components that interfere with an accurate assessment, such as spiking  simultaneously with technical chlordane, toxaphene and PCBs, the spike shall be chosen that  represents the chemistries and elution patterns of the components to be reported; and  b) for those methods that have extremely long lists of analytes, a representative number may be  chosen. The analytes selected shall be representative of all analytes reported. The following criteria shall be used for determining the minimum number of analytes to be  spiked. However, the laboratory shall insure that all targeted components are included in the  spike mixture over a two (2) year period:  i. for methods that include one (1) to ten (10) targets, spike all components;  ii. for methods that include eleven (11) to twenty (20) targets, spike at least ten (10)  components or 80%, whichever is greater;  iii. for methods with more than twenty (20) targets, spike at least sixteen (16) components. | e) Regardless of whether a spike or reference material is used, the components in the LCS must be selected as specified by the mandated method or regulation or as requested by the client. for those components that interfere with an accurate assessment, the spike must be chosen that represents the chemistries and elution patterns of the components to be reported  f) In the absence of specified spiking or reference components, the laboratory must use the following rules     1. for methods that include one (1) to ten (10) targets, spike all analytes 2. for those methods that have more than 10 analytes, a representative subset may be chosen. The components selected must be representative of all analytes reported. The following criteria must be used for determining the minimum number of analytes to be spiked. However, the laboratory must ensure that all targeted components are included in the spike mixture over a two (2) year period: 3. for methods that include eleven (11) to twenty (20) target, spike at least ten (10) analytes or 80%, whichever is greater. 4. for methods with more than twenty (20) target analytes, spike at least sixteen (16) analytes or 60%, whichever is greater. | * Language revised for clarity and to avoid list   Language revised but intent unchanged   * Added to follow PT program. |
| 1.7.2.3 Sample Specific Controls  The laboratory shall document procedures for determining the effect of the sample matrix on  method performance. These procedures relate to the analyses of quality system matrix specific QC  samples and are designed as data quality indicators for a specific sample using the designated  method. These controls alone are not used to judge laboratory performance.  Examples of matrix-specific QC include: Matrix Spike (MS), Matrix Spike Duplicate (MSD),  sample duplicates, and surrogate spikes. The laboratory shall have procedures in place for  tracking, managing, and handling matrix-specific QC criteria, including spiking appropriate  components at appropriate concentrations, calculating recoveries and relative percent  difference, and evaluating and reporting results based on performance of the QC samples. | 8.2.3 Sample Specific Controls  The laboratory must have procedures for determining the effect of sample matrix on method performance. These procedures must include:  a) a description of the matrix-specific quality controls used (e.g., matrix spike, matrix spike duplicate, sample duplicate, surrogates),  b) the design of the matrix-specific quality controls, including frequency, spiked components, and the spiked concentration of analytes,  c) a mechanism for developing, tracking, updating, and implementing matrix-specific quality control criteria,  d) the formulas used to measure matrix-specific quality control criteria, including percent recovery and relative percent difference, and  e) a process for evaluating and reporting results based on the performance of the matrix-specific quality controls.  Matrix-specific quality controls alone are not used to evaluate laboratory performance unless specified by the method, regulation, program, or client. | * Reworded and moved to a list format for clarity and ease of use. * Moved up from 1.7.2.3.1 below |
| 1.7.2.3.1 Matrix spike; matrix spike duplicates  a) Matrix-specific QC samples indicate the effect of the sample matrix on the precision and  accuracy of the results generated using the selected method. The information from these  controls is sample/matrix specific and would not normally be used to determine the validity of  the entire batch.  b) The frequency of the analysis of matrix spikes are as specified by the method or may be  determined as part of the contract review process.  c) The components to be spiked shall be as specified by the mandated method. Any permit specified analytes, as specified by regulation or client requested analytes, shall also be  included. If there are no specified components, the laboratory shall spike per the following:  i. For those components that interfere with an accurate assessment such as spiking  simultaneously with technical chlordane, toxaphene and PCBs, the spike shall be  chosen that represents the chemistries and elution patterns of the components to be  reported.  ii. For those methods that have extremely long lists of analytes, a representative number  may be chosen using the following criteria for choosing the number of analytes to be  spiked. However, the laboratory shall insure that all targeted components are included  in the spike mixture over a two (2) year period.  a. For methods that include one (1) to ten (10) targets, spike all components.  b. For methods that include eleven (11) to twenty (20) targets, spike at least ten  (10) components or 80%, whichever is greater.  c. For methods with more than twenty (20) targets, spike at least sixteen (16)  components. | 8.2.3.1 Matrix spike; matrix spike duplicates    a) The frequency of the analysis of matrix spikes is as specified by the method, or when the method does not specify, as specified by the client, project or program.  b) The components to be spiked must be as specified by the mandated method. Any permit- specified analytes, as specified by regulation or client requested analytes, must also be included. If there are no specified components, the laboratory must spike per the following:   1. For those components that interfere with an accurate assessment the spike must be chosen that represents the chemistries and elution patterns of the components to be reported. 2. The laboratory must ensure that all targeted components are included in the spike mixture over a two (2) year period. 3. For methods that include one (1) to ten (10) targets, spike all analytes. 4. For methods that include eleven (11) to twenty (20) targets, spike at least ten (10) analytes or 80%, whichever is greater. 5. For methods with more than twenty (20) targets, spike at least sixteen (16) analytes, or 60%, whichever is greater. | * Moved into 8.2.3 above * Removed list * Added to follow PT program. |
| 1.7.2.3.2 Matrix duplicates  a) Matrix duplicates are defined as replicate aliquots of the same sample taken through the  entire analytical procedure. The results from this analysis indicate the precision of the results  for the specific sample using the selected method. The matrix duplicate may provide a usable  measure of sample homogeneity. It may also provide a measure of precision when target  analytes are present.  b) The frequency of the analysis of matrix duplicates are as specified by the method or may be  determined as part of the contract review process.  c) Matrix duplicates are performed on replicate aliquots of actual samples. The composition is  usually not known. | 8.2.3.2 Matrix duplicates  a) Matrix duplicates are replicate aliquots of the same sample taken through the entire analytical procedure. The results from replicate sample(s) provide a measure of the precision of the results for the specific sample using the selected method. The matrix duplicate may provide a usable measure of sample homogeneity. It may also provide a measure of precision when target analytes are present.  b) The frequency of the analysis of matrix duplicates are as specified by the method or as specified by project, client or program. | * Removed language, definition |
| 1.7.2.3.3 Surrogate spikes  a) Surrogates, when required, are chosen to reflect the chemistries of the targeted components  of the method and are added prior to sample preparation/extraction.  b) Except where the matrix precludes its use or when not commercially available, surrogate  compounds shall be added to all samples, standards, and blanks for all appropriate methods.  c) Surrogate compounds are chosen to represent the various chemistries of the target analytes  in the method. They are often specified by the mandated method and are deliberately chosen  for their being unlikely to occur as an environmental contaminant. Often this is accomplished by using deuterated analogs of select compounds. | 8.2.3.3 Surrogate spikes  a) As specified in certain test methods, surrogates are spiked into environmental samples prior to preparation and analysis. They are used to evaluate extraction efficiency and matrix interference on a sample-specific basis.  b) Except where the matrix precludes its use or when not commercially available, surrogate compounds must be added to all samples, standards, and QC for all appropriate methods. | * Clarified, simplified and combined language. |
| 1.7.2.4 Data Reduction  The procedures for data reduction, such as use of linear regression, shall be documented. | Removed section | No added value |
| 1.7.2.5 Reagent Quality, Water Quality, and Checks  a) In methods where the purity of reagents is not specified, analytical reagent grade shall be  used. Reagents of lesser purity than those specified by the method shall not be used.  Documentation of purity shall be available.  b) The quality of water sources shall be monitored and documented and shall meet method  specified requirements.  c) The laboratory shall verify the concentration of titrants in accordance with written laboratory  procedures. | 8.2.4 Reagent Quality, Water Quality, and Checks  a) The quality of reagents must be defined in the laboratory’s analytical methods and must meet the requirements in the appropriate reference method. In methods where the purity of reagents is not specified, the grade of reagents must be suitable for its application and meet corresponding quality control objectives. Records of reagent purity must be maintained.  b) The quality of water sources must be monitored and recorded and must meet method specified requirements.  c) The laboratory must verify the concentration of titrants in accordance with method requirements and written laboratory procedures. | Clarified language |
| 1.7.2.6 Selectivity  The laboratory shall document selectivity by following the checks established within the method. | 8.2.5 Selectivity  The laboratory must evaluate and document selectivity by following the requirements established within each applicable method or based on regulation, program or project. |  |
| 1.7.3 Data Acceptance/Rejection Criteria | 8.3 Data Acceptance/Rejection Criteria  The laboratory must have procedures for evaluating quality controls. This evaluation must be against the established acceptance criteria within the mandated methods. Where there are no established criteria, the laboratory must determine internal criteria or utilize client specified criteria and document the method used to establish the limits. | Added intro moving some of the common components to the top. |
| 1.7.3.1 Negative Control – Method Performance: Method Blank  While the goal is to have no detectable contaminants, each method blank shall be critically  evaluated as to the nature of the interference and the effect on the analysis of each sample within  the batch. The source of contamination shall be investigated and measures taken to minimize or  eliminate the problem and affected samples reprocessed or data shall be appropriately qualified if:  a) the concentration of a targeted analyte in the blank is at or above the reporting limit as  established by the method or by regulation, AND is greater than 1/10 of the amount  measured in the sample;  b) the blank contamination otherwise affects the sample results as per the method requirements  or the individual project data quality objectives; and  c) a blank is determined to be contaminated. The cause shall be investigated and measures  taken to minimize or eliminate the problem. Samples associated with a contaminated blank  shall be evaluated as to the best corrective action for the samples (e.g., reprocessing or data  qualifying codes). In all cases, the corrective action shall be documented. | 8.3.1 Negative Control – Method Performance: Method Blank  Each method blank must be evaluated to determine any interference and the effect on the analysis of each sample within the batch. If contamination is present as described in a) and b) below, the source of contamination must be investigated, and measures taken to minimize or eliminate the problem. Any affected samples associated with a contaminated method blank must be reprocessed for analysis or the results must be reported with appropriate data qualifiers:  a) The concentration of a targeted analyte in the blank is at or above the specified LOQ or as established by the method, project or by regulation, and is greater than 1/10 of the amount measured in the sample.  b) The blank contamination otherwise affects the sample results as per the method requirements or the individual project data quality objectives.  c) If a blank is determined to be contaminated the laboratory must take appropriate action to address the issue. In all cases, the action must be recorded. | Clarified and simplified   * Replaced with LOQ, reporting limit not used anywhere else. |
| 1.7.3.2 Positive Control – Method Performance: Laboratory Control Sample (LCS)  a) The results of the individual batch LCS are calculated in percent recovery or other  appropriate statistical technique that allows comparison to established acceptance criteria.  The laboratory shall document the calculation.  The individual LCS is compared to the acceptance criteria as published in the mandated  method. Where there are no established criteria, the laboratory shall determine internal  criteria and document the method used to establish the limits or utilize client specified  assessment criteria.  An LCS that is determined to be within the criteria effectively establishes that the analytical  system is in control and validates system performance for the samples in the associated  batch. Samples analyzed along with an LCS determined to be “out of control” shall be  considered suspect and the samples reprocessed and re-analyzed or the data reported with  appropriate data qualifying codes.  This includes any allowable marginal exceedance as described in b) below.  i. when the acceptance criteria for the positive control are exceeded high (i.e., high bias)  and there are associated samples that are non-detects, then those non-detects may be  reported with data qualifying codes; or  ii. when the acceptance criteria for the positive control are exceeded low (i.e., low bias),  those sample results may be reported if they exceed a maximum regulatory  limit/decision level with data qualifying codes.  b) Allowable Marginal Exceedances. If a large number of analytes are in the LCS, it becomes  statistically likely that a few will be outside control limits. This may not indicate that the  system is out of control, therefore corrective action may not be necessary. Upper and lower  marginal exceedance (ME) limits can be established to determine when corrective action is  necessary. An ME is defined as being beyond the LCS control limit (three (3) standard  deviations), but within the ME limits. ME limits are between three (3) and four (4) standard  deviations around the mean. The number of allowable marginal exceedances is based on the  number of analytes in the LCS. If more analytes exceed the LCS control limits than is  allowed, or if any one analyte exceeds the ME limits, the LCS fails and corrective action is  necessary. This marginal exceedance approach is relevant for methods with long lists of  analytes. It will not apply to target analyte lists with fewer than eleven analytes.  The number of allowable marginal exceedances is as follows:  Number of Analytes in LCS  Number Allowed as follows:    If the same analyte exceeds the LCS control limit consecutively, it is an indication of a  systemic problem. The source of the error shall be located and corrective action taken.  Laboratories shall have a written procedure to monitor the application of marginal  exceedance allowance to the LCS. | 8.3.2 Positive Control – Method Performance: Laboratory Control Sample (LCS)  a) The results of the LCS must be calculated in percent recovery or other appropriate statistical techniques that allow comparison to established acceptance criteria. The laboratory must document the calculation.  If results are found to be outside of these criteria all affected samples must be reprocessed for reanalysis, or the results reported with appropriate data qualifiers  This includes any allowable marginal exceedance as described in b) below.   1. when the acceptance criteria for the positive control are exceeded high (i.e., high bias) associated samples below the DL, may be reported with appropriate data qualifiers; or 2. when the acceptance criteria for the positive control are exceeded low (i.e., low bias), associated samples may be reported if they exceed a maximum regulatory limit/decision level with appropriate data qualifiers.   b) Allowable Marginal Exceedances. If a large number of analytes are in the LCS, it becomes statistically likely that a few will be outside control limits. This may not indicate that the system is out of control, therefore action may not be necessary. Upper and lower marginal exceedance (ME) limits can be established to determine when action to address the issue is necessary. ME defined as slightly exceeds the established control limits ±3 standard deviations but within the ME limits which are between 3 and 4 standard deviations. The number of allowable marginal exceedances is based on the number of analytes in the LCS. If more analytes exceed the LCS control limits than is allowed, or if any one analyte exceeds the ME limits, the LCS fails and non-conforming work procedures are necessary.  The number of allowable marginal exceedances is as follows:    If the same analyte exceeds the LCS control limit in consecutive batches. The source of the issue must be located and action taken by the laboratory. Laboratories must have a written procedure to monitor the application of marginal exceedance allowance to the LCS. | Clarified and simplified. Some language moved into intro for 8.3 |
| 1.7.3.3 Sample Specific Controls  a) Matrix Spike; Matrix Spike Duplicates  The results from matrix spike/matrix spike duplicate are primarily designed to assess the  precision and accuracy of analytical results in a given matrix and are expressed as percent  recovery (%R), relative percent difference (RPD), or other appropriate statistical technique  that allows comparison to established acceptance criteria. The laboratory shall document the  calculation for %R, RPD or other statistical treatment used.  The results are compared to the acceptance criteria as published in the mandated method.  Where there are no established criteria, the laboratory shall determine internal criteria and  document the method used to establish the limits. For matrix spike results outside  established criteria, corrective action shall be documented or the data for that sample  reported with appropriate data qualifying codes. | 8.3.3 Sample Specific Controls  a) Matrix Spike; Matrix Spike Duplicates  The results from matrix spike/matrix spike duplicate must be expressed as percent recovery (%R), relative percent difference (RPD), or other appropriate statistical techniques that allow comparison to established acceptance criteria. The laboratory must document the calculation or other statistical technique used.  For matrix spike/matrix spike duplicate results outside established criteria, action to address the issue must be recorded or the data for that sample reported with appropriate data qualifiers. | Clarified and simplified. Some language moved into intro for 8.3 |
| b) Matrix Duplicates  The results from matrix duplicates are primarily designed to assess the homogeneity of the  particular sample chosen. If that sample is homogenous it may also describe the precision of  analytical results in a given matrix. These may be expressed as RPD or another statistical  treatment (e.g., absolute differences).  The laboratory shall document the calculation for RPD or other statistical treatments. Results are compared to the acceptance criteria as published in the mandated method.  Where there are no established criteria, the laboratory shall determine internal criteria and  document the method used to establish the limits. For matrix duplicates results outside  established criteria, corrective action shall be documented or the data for that sample  reported with appropriate data qualifying codes. | b) Matrix Duplicates  The results from matrix duplicates must be expressed as RPD or another statistical treatment (e.g., absolute differences).  The laboratory must document the calculation.  For matrix duplicates results outside established criteria, action to address the issue must be recorded or the data for that sample reported with appropriate data qualifiers. | Clarified and simplified. Some language moved into intro for 8.3 |
| c) Surrogate Spikes  The results are compared to the acceptance criteria as published in the mandated method.  Where there are no established criteria, the laboratory shall determine internal criteria and  document the method used to establish the limits. Surrogates outside the acceptance criteria  shall be evaluated for the effect indicated for the individual sample results. The appropriate  corrective action may be guided by the data quality objectives or other site-specific  requirements. Results reported from analyses with surrogate recoveries outside the  acceptance criteria shall include appropriate data qualifiers. | c) Surrogate Spikes  Surrogates outside the acceptance criteria must be evaluated for the effect indicated for the individual sample results, action toto address the issue must be recorded or the data for that sample or the data reported with appropriate data qualifiers. | Clarified and simplified. Some language moved into intro for 8.3 |
| 1.7.4 Sample Handling  a) All samples that require thermal preservation shall be considered acceptable if the arrival  temperature of a representative sample container is either within 2°C of the required  temperature or the method specified range. For samples with a specified temperature of 4°C,  samples with a temperature ranging from just above the freezing temperature of water to 6°C  shall be acceptable.  i. Samples that are delivered to the laboratory on the same day they are collected may  not meet the requirements of Section 1.7.4.a. In these cases, the samples shall be  considered acceptable if the samples were received on ice.  ii. If sample analysis is begun within fifteen (15) minutes of collection, thermal  preservation is not required.  iii. Thermal preservation is not required in the field if the laboratory receives and  refrigerates the sample within fifteen (15) minutes of collection.  b) The laboratory shall implement procedures for checking sample preservation using readily  available techniques, such as pH or chlorine, prior to or during sample preparation or  analysis. An exception is allowed for volatile organic analyte analyses; chemical preservation  may be checked after analysis. | 8.4 Sample Handling  a) All samples that require thermal preservation are acceptable if the temperature upon receipt of a representative sample container is within the regulation, method or project, specified range. The following exceptions are allowed:  i. Samples that are delivered to the laboratory on the same day they are collected may not meet the requirements of Section 8.4.a. In these cases, the samples are considered acceptable if received with evidence of cooling. If applicable, evidence must be recorded by the laboratory.  ii. Thermal preservation is not required in the field if the laboratory receives and refrigerates the sample or begins sample analysis within fifteen (15) minutes of collection.  b) The laboratory must implement procedures for checking sample preservation prior to or during sample preparation or analysis. An exception is allowed for volatile organic analyte analyses; chemical preservation is checked after analysis.  c) Samples that do not meet the above-mentioned criteria must include appropriate data qualifiers. | * Removed specific temperature requirements and just referred to regulation, method or project ranges. * Replaced “on ice” with “evidence of cooling”. Required record of observation. * Removed section ??? * Added requirement for data qualifiers to be consistent with sections above. |

*Note: This table can be used to prepare for a public meeting to seek stakeholder input.*

*Note: When the standard has been developed and is presented as a Draft Standard, a new version of this table is prepared noting the actual changes made to the standard. The “Suggested Change” column will include the actual language from the DS. The “Original Text” column will include the language from the previous (if any) standard. The “Justification” column states the reason for the change and provides any additional comments the expert committee thinks are pertinent.*