



DoD/DOE QSM 6.0 Module 4 Chemical Testing Checklist

Checklists used for this assessment activity:

- M1/M2 PT/QMS
- M3 Asbestos Testing
- M4 Chemical Testing
- M5 Microbiological Testing
- M6 Radiochemical Testing
- M7 Toxicity Testing
- M8 Industrial Hygiene Testing

This checklist is only a tool, and not considered as the requirements of the standard(s)!

If there is a disagreement between this checklist and the standard(s), the standard(s) shall prevail.

Identify conformity for each requirement along with comments/objective evidence for each clause assessed.

A *clarifying statement* provides additional information to help understand a requirement.

A *permission* is an approach that a conformity assessment body can use to achieve compliance.

Assessment Number:

CAB Name:

Physical Address:

Assessment Date(s):

Assessors(s):

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4	Quality Systems for Chemical Testing		
M4: 5.0	Method Validation		
M4: 5.1	Validation of Methods Before acceptance and institution of any method for which data will be reported, are all methods validated?		
M4: 5.1.1	Does method validation meet the requirements in the Module 2 section on "Selection, Verification, and Validation of Methods" as well as all criteria in this module?		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 5.1.2	Does the laboratory validate reference methods through the initial determinations of a detection limit (DL) if required, a limit of detection (LOD) if required, and a limit of quantitation (LOQ) as well as an Initial Demonstration of Capability (DOC)?		
M4: 5.1.2	Requirements for DL, LOD and LOQ are contained in this module's section on "Detection Limits, Limits of Detection, and Limits of Quantitation."		Clarifying Statement
M4: 5.1.3	In addition to the QC procedures for reference methods, does the laboratory validate modified reference methods and non-reference methods (including laboratory- developed methods) using QC procedures and acceptance criteria that are consistent with those of similar reference methods or technologies, and does the validation include the following:		
M4: 5.1.3.a	scope;		
M4: 5.1.3.b	calibration verification;		
M4: 5.1.3.c	interferences and cross-contamination;		
M4: 5.1.3.d	analyte identification;		
M4: 5.1.3.e	analyte quantitation;		
M4: 5.1.3.f	selectivity;		
M4: 5.1.3.g	sensitivity; and		
M4: 5.1.3.h	precision and bias?		
M4: 5.1.4	Is the use of any modified or non-reference method approved by the customer before use?		
M4: 5.1.5	Are methods validated when substantive modifications are made to reference methods (e.g., stoichiometry, technology, mass tuning acceptance criteria, quantitation ions, compressing digestion or extraction timeframes, reducing reagent or solvent volumes, or changing solvents)?		
M4: 5.1.6	When a modification of a method includes changes to sample preparation steps, does the validation process include analysis of field samples in the matrices of concern?		
	Do the field samples represent a range of characteristics encountered or expected in customer samples?		
	Does validation include parallel studies to compare performance of the reference method to the modified method, where possible?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 5.1.7	<p>Do the field samples contain target analytes either found natively in the samples or spiked into the sample?</p> <p>Does validation include multiple levels of target analyte concentration?</p> <p>Where the method includes more than 45 target analytes, is a representative subset of at least 45 analytes used?</p> <p>If a subset of analytes is used for validation, does the subset include all chemistries and target analytes that show the most bias when analyzed using the reference method?</p>		
M4: 5.1.8	<p>Where modifications to only the analytical portion of the method are planned, does the laboratory take into consideration any effects the matrix may have on the analysis as part of its risk assessment?</p>		
M4: 5.2	<p>Detection Limit, Limit of Detection, and Limit of Quantitation</p> <p>For each combination of analyte-matrix-method, does the laboratory have procedures for determining and verifying DL, LOD, and LOQ, as defined by the QSM, that reflect current operating conditions?</p> <p>For each preparation method listed on the scope of accreditation, does the laboratory determine a DL, LOD, and LOQ, unless it falls within one of the stated exceptions?</p> <p>Although the laboratory is not required to determine a separate DL, LOD and LOQ for all possible combinations of preparation and cleanup techniques in use, does the laboratory determine the DL, LOD, and LOQ using the combination of processes most likely to interfere with sensitivity (i.e., preparation method with all applicable cleanup steps including drying, grinding, and incremental sampling, where applicable)?</p> <p>Is the DL, LOD and LOQ reported for all analyte-matrix-method combinations unless it is not applicable to the test or specifically excluded by customer requirements?</p> <p>Are records of all supporting data for DL, LOD, and LOQ determinations and verifications maintained?</p>		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 5.2.1	<p>Determination of the Detection Limit</p> <p>Does the laboratory determine a DL using a procedure that is compliant with the requirements of the 40 CFR Part 136 Appendix B, Revision 2 for each combination of analyte-matrix-method?</p>		
M4: 5.2.2	<p>Initial Determination of the Limit of Detection</p> <p>Does the LOD determination procedure address the following requirements:</p>		
M4: 5.2.2.a	<p>After each DL determination, does the laboratory establish the LOD by spiking a quality system matrix at a concentration greater than or equal to the DL?</p> <p>Is the LOD equal to the concentration of this spike?</p>		
M4: 5.2.2.b	<p>Is the apparent signal to noise (S/N) ratio at the LOD at least three and do the results meet all method requirements for analyte identification (e.g., ion abundance, second column confirmation, or pattern recognition)?</p>		
M4: 5.2.2.c	<p>For data systems that do not provide a measure of noise, does the signal produced by the LOD spike produce a response that is at least three standard deviations greater than the mean Method Blank concentration?</p> <p>Is the mean Method Blank concentration and standard deviation initially estimated based on a minimum of four Method Blank results and later established with a minimum of 20 Method Blank results?</p>		
M4: 5.2.2.c.i	<p>Alternatively, does the signal produced by the LOD spike generate a result above the MDLb derived in accordance with EPA 821-R-16-006?</p>		
M4: 5.2.2.d	<p>If the LOD spike response does not meet the requirements, does the laboratory repeat the DL and/or LOD determination at a higher level, or implement its nonconforming work procedure, until the requirements are met?</p>		
M4: 5.2.3	<p>Ongoing Verification of the Limit of Detection</p> <p>Does the LOD verification procedure address the following requirements:</p>		
M4: 5.2.3.a	<p>Does the laboratory verify the LOD on a quarterly basis, at a minimum?</p> <p>Is the verification made by repeating the LOD spike process at a concentration that is greater than or equal to half the current LOD and less than or equal to</p>		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	<p>double the current LOD (i.e., $1/2x \text{ LOD} \leq \text{Ongoing LOD Spike} \leq 2x \text{ LOD}$) provided the ongoing spike concentration is greater than or equal to the DL?</p> <p>Does the Ongoing LOD verification meet the same acceptance criteria as the Initial LOD verification for signal-to-noise and analyte identification?</p>		
M4: 5.2.3.a	If the acceptance criteria are met, the Initial LOD is verified and may continue to be used.		Permission
M4: 5.2.3.b	In the event the verification fails, does the laboratory redetermine the LOD and, if necessary, the DL, or implement its nonconforming work procedure, until the requirements are met?		
M4: 5.2.3.c	If the method is altered in a way other than routine maintenance, and the change can be expected to elevate the detection limit, is the LOD reverified using the Ongoing LOD verification procedure?		
M4: 5.2.3.d	If there are multiple instruments that will be assigned the same LOD, does the LOD verification spike meet the requirements on each instrument?		
M4: 5.2.3.e	<p>In situations where methods are setup and used on an infrequent basis, does the laboratory choose to perform ongoing LOD verifications on a one-per-batch basis, before sample analysis, in lieu of quarterly verification?</p> <p>Does the verification data meet the requirements of this section and reported to the customer?</p> <p>Is whichever verification frequency is chosen continued for a minimum of 12 months?</p>		
M4: 5.2.4	<p>Initial and Ongoing Verification of the Limit of Quantitation</p> <p>Does the LOQ verification procedure address the following requirements:</p>		
M4: 5.2.4.a	<p>For methods using multi-level calibration, does the laboratory select an LOQ for each analyte that is greater than or equal to the LOD and greater than or equal to the lowest non-zero calibration standard?</p> <p>For methods using a single-point calibration, is the LOQ greater than or equal to the LOD and greater than or equal to the low-level calibration check standard?</p>		
M4: 5.2.4.b	Is the LOQ verified through analysis of verification samples?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	<p>Does the LOQ verification sample consist of a spiked quality system matrix greater than or equal to the LOD or one-half the LOQ, whichever is less, and less than or equal to double the LOQ (i.e., $LOD \text{ or } 1/2 \text{ LOQ} \leq LOQ \text{ spike} \leq 2x \text{ LOQ}$)?</p> <p>Does the LOQ verification meet the same criteria as the initial LOD verification for signal-to- noise and analyte identification and within the laboratory's stated acceptance criteria?</p> <p>Is the laboratory acceptance criteria determined based on a maximum of three standard deviations from the mean of historical data, but no wider than the LCS acceptance criteria with an additional 20% allowance above and below?</p> <p>Additionally, is the lower limit greater than or equal to 10% recovery?</p>		
M4: 5.2.4.c	In the event the verification fails, does the laboratory redetermine the LOQ and, if necessary, the DL and/or LOD; or implement its nonconforming work procedure, until the requirements are met?		
M4: 5.2.4.d	<p>Does the laboratory procedure for establishing the LOQ include how precision and bias are determined at the LOQ for each combination of analyte-matrix-method and meet the requirements of this section?</p> <p>Is the LOQ and associated precision and bias within the laboratory established acceptance criteria and meet customer-provided requirements, when available, and reported in each data package?</p> <p>If the method is modified, is precision and bias at the new LOQ demonstrated?</p>		
M4: 5.2.4.e	If there are multiple instruments that will be assigned the same LOQ, then are these LOQ verification spikes distributed across all the instruments and the results included in the precision and bias determination?		
M4: 5.2.4.f	<p>Does the laboratory verify the LOQ quarterly, at a minimum?</p> <p>Is the precision and bias updated annually, at a minimum, using any additional LOQ verification sample results?</p>		
M4: 5.2.4.g	In situations where methods are set up and used on an infrequent basis, the laboratory may choose to perform Ongoing LOQ verifications on a one-per-batch		Permission



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	basis, before sample analysis, in lieu of quarterly verification.		
M4: 5.2.4.g	Does the verification data meet requirements and is it reported to the customer?		
M4: 5.2.4.g	Whichever verification frequency is chosen, is it continued for a minimum of 12 months?		
M4: 5.2.5	Does the laboratory provide the following when DL, LOD, and LOQ summary information is requested:		
M4: 5.2.5.a	indication of which analyte/matrix/prep method/analytical method and instrument used;		
M4: 5.2.5.b	DL;		
M4: 5.2.5.c	claimed LOD;		
M4: 5.2.5.d	concentration of initial LOD spike and verification spike, if different;		
M4: 5.2.5.e	statement of compliance with analyte identification requirements;		
M4: 5.2.5.f	signal-to-noise value or statement of compliance with requirements;		
M4: 5.2.5.g	claimed LOQ;		
M4: 5.2.5.h	concentration of LOQ spike;		
M4: 5.2.5.i	recovery or result of LOQ spike;		
M4: 5.2.5.j	calculated precision and bias at the LOQ that incorporates historic and current data;		
M4: 5.2.5.k	accuracy acceptance criteria at the LOQ;		
M4: 5.2.5.l	description of precision and bias calculations; and		
M4: 5.2.5.m	if specifically requested, raw data to support parameters reported?		
M4: 5.3	Evaluation of Method Precision and Bias		
M4: 5.3.1	Does the laboratory determine the precision and bias of a method for each analyte of concern for each quality system matrix or follow a documented alternate procedure when the analyte cannot be spiked into the sample matrix and QC samples are not commercially available?		
M4: 5.3.2	Does the laboratory have a procedure for determining precision and bias?		
M4: 5.3.3	Does the laboratory process the samples through the entire measurement system for each analyte of interest?		
M4: 5.3.4	Are precision and bias measurements evaluated across the analytical calibration range of the method?		
M4: 5.3.5	Does the laboratory compare results of the precision and bias measurements with criteria established by the		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	customer, criteria given in the reference method, and/or criteria established by the laboratory?		
M4: 5.4	Evaluation of Selectivity Does the laboratory evaluate selectivity by following the checks established within the method, which may include mass spectral tuning, second column confirmation, inter-element interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, and electrode response factors?		
M4: 6.0	Demonstration of Capability (DOC)		
M4: 6.1	General		
M4: 6.1.1	Does an individual who performs any activity involved with preparation and/or analysis of samples have constant, close supervision (as defined in the laboratory's training procedure) until a satisfactory initial DOC is completed?		
M4: 6.1.2	Thereafter, does the individual perform ongoing DOCs?		
M4: 6.1.3	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 year before applying for accreditation, and there have been no significant changes in instrument type or method, is the ongoing DOC acceptable as an initial DOC? Does the laboratory maintain records to demonstrate that an initial DOC is not required?		
M4: 6.1.4	Is all data applicable to the DOC retained and readily available at the laboratory?		
M4: 6.2	Initial DOC Does everyone successfully perform an initial DOC prior to using any method, any time there is a change in instrument type or method that could potentially affect the precision and bias, sensitivity, or selectivity of the output, or any time that a method has not been performed by the individual in a 12-month period?		
M4: 6.2.1	Does the laboratory have a procedure for performing an initial DOC?		
M4: 6.2.2	Does the laboratory maintain records of each initial DOC in a manner such that the following information is readily available for each individual:		
M4: 6.2.2.a	individual(s) involved in preparation and/or analysis;		
M4: 6.2.2.b	matrix;		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 6.2.2.c	analyte(s), class of analyte(s);		
M4: 6.2.2.d	identification of method(s) performed;		
M4: 6.2.2.e	identification of laboratory-specific procedures used for analysis, including revision number;		
M4: 6.2.2.f	date(s) of analysis; and		
M4: 6.2.2.g	summary of analyses, including information outlined in Section 6.2.3.c?		
M4: 6.2.3	<p>If the reference method or regulation does not specify how to perform an initial DOC, the following procedure is acceptable.</p> <p>It is the responsibility of the laboratory to document that other approaches to initial DOC are adequate.</p>		Clarifying Statement
M4: 6.2.3	For methods where spiking is not a viable option (e.g., leaching procedures), does the laboratory approach include observation and evaluation of negative controls?		
M4: 6.2.3.a	<p>Does the analyte(s) spike in a volume of clean quality system matrix sufficient to prepare four aliquots at the concentration specified in the reference method, or if unspecified, at a concentration of one to four times the LOQ?</p> <p>Is the quality system matrix like the associated samples?</p> <p>For analysis of metals in solids, materials such as washed sand or non-reactive beads are acceptable as a matrix.</p>		
M4: 6.2.3.b	Are at least four aliquots prepared and analyzed according to the method?		
M4: 6.2.3.c	<p>Using all the results, is the mean recovery in the appropriate reporting units and the standard deviations of the sample (in the same units) for each analyte of interest calculated?</p> <p>Where it is not possible to determine mean and standard deviations, such as for presence/absence and logarithmic values, does the laboratory assess performance against established and documented criteria?</p>		
M4: 6.2.3.d	Is the information from 6.2.3.c above compared to the corresponding acceptance criteria for precision and accuracy in the method, if applicable, or in laboratory-generated acceptance criteria if there are not acceptance criteria in the method?		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	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, is the performance considered unacceptable for that analyte?		
M4: 6.2.3.e	When one or more of the tested analytes fail at least one of the acceptance criteria, does the analyst proceed according to i) or ii) below:		
M4: 6.2.3.e.i	Locate and correct the source of the failure and repeat the DOC procedure for all analytes of interest?		
M4: 6.2.3.e.ii	Repeat the DOC procedure for all analytes that failed to meet criteria?		
M4: 6.2.3.f	Repeated failure, however, confirms a general problem with the measurement system. If repeated failure occurs, does the laboratory locate and correct the source of the failure, and repeat the DOC procedure for all analytes?		
M4: 6.2.3.g	When an analyte not currently found on the laboratory's list of accredited analytes is added to an existing accredited method, is an initial demonstration performed for that analyte?		
M4: 6.3	Ongoing DOC		
M4: 6.3.1	Does the laboratory have a procedure for ongoing DOC that includes how the laboratory will identify data associated with ongoing DOCs?		
M4: 6.3.1	It is the responsibility of the laboratory to document that other approaches to ongoing DOC are adequate.		Clarifying Statement
M4: 6.3.1	For methods where spiking is not a viable option (e.g., leaching procedures), does the laboratory approach include observation and evaluation of negative controls?		
M4: 6.3.1	Does the individual demonstrate on-going capability by routinely meeting the QC requirements of the reference method, laboratory procedure, customer requirements, and/or this standard. If the method has not been performed by the individual in a 12-month period, is an initial DOC performed?		
M4: 6.3.2	Is this on-going demonstration one of the following:		
M4: 6.3.2.a	acceptable performance of a blind sample or a blind proficiency testing sample on a similar method using the same technology;		
M4: 6.3.2.b	another initial DOC;		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 6.3.2.c	<p>at least four consecutive laboratory control samples (LCS) with acceptable levels of precision and accuracy;</p> <p>Does the laboratory determine the acceptable limits for precision and accuracy, and those limits are within laboratory-developed LCS acceptance criteria?</p> <p>Does the laboratory tabulate or be able to readily retrieve four consecutive passing LCSs or reference samples for each method for each individual performed within the last 12-month period?</p>		
M4: 6.3.2.d	<p>following a procedure for reviewing records of QC samples meeting the QC requirements of the method, laboratory procedure, customer requirements, and/or this standard; or</p> <p>Is a review of these records done to identify patterns and determine if implementation of the nonconforming work procedure and/or retraining is necessary?</p>		
M4: 6.3.2.e	<p>if a) through d) are not technically feasible, then is analysis of real-world samples with results within a pre-defined acceptance criterion (as defined by the laboratory or method) performed?</p>		
M4: 7.0	Technical Requirements		
M4: 7.1	<p>Calibration</p> <p>If more stringent standards or requirements are included in a mandated method or by regulation, does the laboratory demonstrate that such requirements are met?</p> <p>If it is not apparent which requirements are more stringent, then are the requirements of the regulation or mandated method followed?</p>		
M4: 7.1.1	<p>Initial Calibration</p> <p>Is each reported analyte associated with an acceptable initial calibration?</p> <p>If the initial calibration is not acceptable, does the laboratory implement its nonconforming work procedure, and all associated samples reanalyzed?</p> <p>The following items are required elements of initial calibration:</p>		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.1.1.a	<p>Are the details of the initial calibration including calculations, integrations, acceptance criteria, and associated statistics included or referenced in the procedure?</p> <p>When initial calibration procedures are referenced then the referenced procedures, are these references retained by the laboratory?</p>		
M4: 7.1.1.b	<p>Are sufficient raw data records retained to permit reconstruction of the initial calibration?</p>		
M4: 7.1.1.c	<p>Does the laboratory use the most recent initial calibration analyzed prior to the analytical batch, unless otherwise specified by the method?</p>		
M4: 7.1.1.d	<p>Does the laboratory perform calibrations for reported analytes with Certified Reference Materials (CRM) specifically identified as such in an accompanying Certificate of Analysis from a Reference Material Producer (RMP) accredited to ISO 17034 or Standard Reference Materials (SRM) from a National Metrology Institute (NMI), when available?</p>		
M4: 7.1.1.e	<p>Does the laboratory have a written procedure addressing removal and replacement of calibration standards?</p> <p>Does the procedure comply with the following requirements?</p>		
M4: 7.1.1.e.i	<p>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 individual analytes in interior levels is not permitted.</p>		Permission
M4: 7.1.1.e.ii	<p>The laboratory may remove one entire calibration standard 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.</p>		Permission
M4: 7.1.1.e.ii	<p>If a laboratory chooses to remove a calibration level from the interior of the calibration, does it remove that calibration level for all analytes?</p>		
M4: 7.1.1.e.ii	<p>Is the removal of a calibration level from the interior of the curve not used to compensate for lack of maintenance or repair to the instrument?</p>		
M4: 7.1.1.e.iii	<p>Does the laboratory adjust the LOQ and quantitation range of the calibration based on the concentration of the remaining high and low calibration standards?</p>		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence										
M4: 7.1.1.e.iv	Does the laboratory ensure that the remaining initial calibration levels are sufficient to meet the minimum requirements for the number of initial calibration levels as mandated by this standard, the method, and/or regulatory requirements?												
M4: 7.1.1.e.v	The laboratory may replace a calibration level provided that:		Permission										
M4: 7.1.1.e.v.a	the laboratory analyzes the replacement standard within 24 hours of the original calibration standard analysis for that calibration level;		Permission										
M4: 7.1.1.e.v.b	the laboratory replaces all analytes of the replacement calibration standard if a level within the interior of the calibration is replaced; and		Permission										
M4: 7.1.1.e.v.c	the laboratory shall limit the replacement to one calibration level.		Permission										
M4: 7.1.1.e.vi	Does the laboratory record a technically valid reason for either removal or replacement of any interior calibration level?												
M4: 7.1.1.f	<p>For regression or average response/calibration factor calibrations, are the minimum number of non-zero calibration standards as specified in the table below?</p> <table border="1" data-bbox="326 1052 886 1255"> <thead> <tr> <th>Type of Calibration Curve</th> <th>Minimum Number of Calibration Standards</th> </tr> </thead> <tbody> <tr> <td>Threshold Testing</td> <td>1</td> </tr> <tr> <td>Average Response</td> <td>5</td> </tr> <tr> <td>Linear Fit</td> <td>5</td> </tr> <tr> <td>Quadratic Fit</td> <td>6</td> </tr> </tbody> </table> <p>Refer to Table footnotes "a", "b", and "c" in M4: 7.1.1.f for further explanation.</p>	Type of Calibration Curve	Minimum Number of Calibration Standards	Threshold Testing	1	Average Response	5	Linear Fit	5	Quadratic Fit	6		
Type of Calibration Curve	Minimum Number of Calibration Standards												
Threshold Testing	1												
Average Response	5												
Linear Fit	5												
Quadratic Fit	6												
M4: 7.1.1.g	Is the lowest non-zero calibration standard at or below the lowest concentration for which quantitative data are to be reported without qualification?												
M4: 7.1.1.h	<p>Is the highest calibration standard at or above the highest concentration for which quantitative data from undiluted samples are reported without qualification?</p> <p>When the undiluted results exceed the calibration range, does the laboratory dilute and reanalyze the sample to bring results uncorrected for dilution within the calibration range, if sufficient sample material is available?</p> <p>If results are outside the calibration range and reanalysis is not possible, are the results reported with appropriate data qualifiers?</p>												



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.1.1.h.i	For methods utilizing inductively coupled plasma analysis, the laboratory may report a sample result with a response above the calibration range if the laboratory analyzes and passes (within 10% of the true value) a high-level check standard that exceeds the sample concentration but is within the linear dynamic range (provided the high-level check standard is analyzed in the same manner as the sample and evaluated with the same calibration).		Permission
M4: 7.1.1.i	Are sample results quantitated from the initial calibration and not quantitated from any continuing calibration verification unless otherwise required by regulation, method, or program?		
M4: 7.1.1.j	Is criteria for the acceptance of an initial calibration documented?		
M4: 7.1.1.k	Does the laboratory use and document a measure of relative error in the calibration?		
M4: 7.1.1.k.i	For calibrations evaluated using an average response factor, is the determination of the relative standard deviation (%RSD) the measure of the relative error?		
M4: 7.1.1.k.ii	For calibrations evaluated using correlation coefficient or coefficient of determination, does the laboratory evaluate relative error by either:		
M4: 7.1.1.k.ii.a	<p>Measurement of the Relative Error (%RE)</p> <p>Is the Relative Error (%RE) calculated by the equation under M4: 7.1.1.k.ii.a in the Standard?</p> <p>Is this calculation performed for two calibration standards: the standard at or near the mid-range of the initial calibration and a standard less than or equal to the LOQ?</p> <p>Does the Relative Error at both levels meet the criteria specified in the method?</p> <p>If no criterion for the lowest calibration level is specified in the method, is the criterion, and the procedure for deriving the criterion specified in the laboratory procedure; or</p>		
M4: 7.1.1.k.ii.b	<p>Measurement of the Relative Standard Error (%RSE)</p> <p>Is the Relative Standard Error (%RSE) calculated by the equation in the Standard under M4: 7.1.1.k.ii.b?</p> <p>Does the %RSE meet the criterion specified in the method?</p>		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	<p>If no criterion is specified in the method, is the maximum allowable %RSE numerically identical to the requirement for %RSD in the method.?</p> <p>If there is no specification for %RSE or %RSD in the method, then is the %RSE specified in the laboratory procedure?</p>		
M4: 7.1.1.l	When procedures are employed that specify calibration with a single calibration standard and a zero point (blank or zero, however specified by the procedure), does the following occur:		
M4: 7.1.1.l.i	Are the zero point and single calibration standard within the linear range analyzed at least daily and used to establish the slope of the calibration?		
M4: 7.1.1.l.ii	<p>To verify adequate sensitivity, is a standard analyzed at or below the lowest concentration for which quantitative data are to be reported without qualification?</p> <p>Is this standard analyzed before sample analysis with each calibration and does it meet the recovery acceptance criteria at the LOQ established by the method or in Appendix B, whichever is more stringent?</p>		
M4: 7.1.1.m	<p>For analysis of Aroclors which use a linear through origin model (or average response factor), does the laboratory perform an initial multi-level calibration for a subset of Aroclors (e.g., a mixture of 1016/1260) and use a one-point initial calibration for pattern recognition for the remaining Aroclors?</p> <p>If one of the remaining Aroclors is identified, is a multi-level calibration performed for the specific Aroclor detected, and the sample extract reanalyzed using the multi-level calibration for quantitation?</p>		
M4: 7.1.1.n	If calibrations for reported analytes are not performed with a CRM specifically identified as such in an accompanying Certificate of Analysis from a RMP accredited to ISO 17034 or SRM from a NMI, then does the laboratory use standards from an authoritative source and verify all initial calibrations with a standard from an authoritative, independent, second source?		
M4: 7.1.1.n	The use of a calibration material from a second lot obtained from the same manufacturer, independently prepared from different source materials, is acceptable for use as a second-source standard.		Clarifying Statement



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.1.1.n	Is the concentration of the second-source standard calibration verification standard at the mid-range or lower?		
M4: 7.1.1.n	Does the calibration verification meet the acceptance criteria of the reference method, or if not specified in the reference method, the acceptance criteria for continuing calibration verification is used?		
M4: 7.1.1.o	Does the laboratory explain in the case narrative when calibrations are not performed with a CRM or SRM and an initial calibration verification using a second-source standard is required?		
M4: 7.1.1.p	For those methods where reporting non-detected analytes based on successful completion of a sensitivity check is allowed, the requirements of this standard do not prohibit the practice.		Clarifying Statement
M4: 7.1.1.q	Are surrogates associated with an acceptable calibration?		
M4: 7.1.1.q	The laboratory may quantitate surrogates using a single-level calibration.		Permission
M4: 7.1.1.q	Do the calibration of the surrogates meet the requirements of the analytes, or for a single-level calibration, the %RSD for each surrogate is less than or equal to 20%?		
M4: 7.1.2	<p>Continuing Calibration Verification</p> <p>Is the validity of the initial calibration verified before sample analyses by a calibration verification with each analytical batch?</p> <p>The following items are essential elements of continuing calibration verification.</p>		
M4: 7.1.2.a	Are the details of the continuing calibration verification procedure, calculations, and associated statistics included or referenced in the procedure?		
M4: 7.1.2.b	Is calibration 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 may be used?		
M4: 7.1.2.c	Is the concentration of the continuing calibration verification sample (CCV) greater than or equal to the low calibration standard and less than or equal to the mid-range?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.1.2.d	Is instrument calibration verification performed at the beginning and end of each analytical batch, and at the frequency defined in the method except:		
M4: 7.1.2.d.i	when a second source initial calibration verification that passes the continuing calibration verification criteria is used in place of CCV;		
M4: 7.1.2.d.ii	when a LCS is used in place of a CCV (but not as a replacement for a failing CCV) for methods where the calibration goes through the same process as the LCS?		
M4: 7.1.2.e	Are sufficient raw data records retained to permit reconstruction of the calibration verification? Do continuing calibration verification records explicitly connect the continuing calibration verification data to the initial calibration?		
M4: 7.1.2.f	Are criteria for the acceptance of a continuing calibration verification established? If the continuing calibration verification results obtained are outside the established acceptance criteria, are the following steps taken?		
M4: 7.1.2.f.i	If a cause for the calibration verification failure is identified that impacts only the CCV, then does analysis proceed if a second CCV is analyzed immediately (within one hour and no samples analyzed) and the result is within acceptance criteria? Are samples analyzed previously considered valid if bracketed by a passing CCV? Does the laboratory maintain records of the cause for the failure of the first calibration verification result?		
M4: 7.1.2.f.ii	If a cause for the calibration verification failure is not isolated to the CCV or not identified, then does the laboratory implement its nonconforming work procedure and repeat the CCV and all associated samples since the last successful CCV?		
M4: 7.1.2.f.iii	Qualifying data for a failed CCV is only appropriate when the affected samples cannot be reanalyzed.		Clarifying Statement
M4: 7.1.2.f.iii	Does the laboratory notify the customer before reporting data associated with a failed CCV?		
M4: 7.1.2.f.iv	Are data associated with an unacceptable CCV qualified if reported, but not reported if prohibited by the customer, a regulatory program or regulation?		
M4: 7.1.2.f.iv.a	When the CCV acceptance criteria are exceeded high (i.e., high bias) and there are associated samples with analytes that are non-detects, then those non-detect		Permission



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	results may be reported with a data qualifier and sample reanalysis is not required.		
M4: 7.2	Quality Control		
M4: 7.2	Does the laboratory have QC procedures for monitoring the validity of environmental tests undertaken as specified in this Section?		
M4: 7.2.1	Negative Control – Method Performance: Method Blank		
M4: 7.2.1.a	The method blank is used to assess the samples in the preparation batch for possible contamination during the preparation and processing steps.		Clarifying Statement
M4: 7.2.1.b	Is the method blank processed along with and under the same conditions as the associated samples to include all steps?		
M4: 7.2.1.c	Are procedures in place to determine if a method blank is contaminated?		
M4: 7.2.1.d	Are any affected samples associated with a contaminated method blank reprocessed for analysis or the results reported with an appropriate data qualifier?		
M4: 7.2.1.e	Is the method blank analyzed at a minimum of one per preparation batch?		
M4: 7.2.1.f	When no separate preparation method is used (e.g., volatiles in water), is the preparation batch 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 20 environmental samples, not including method blanks, LCS, matrix spikes and matrix duplicates?		
M4: 7.2.1.g	Does the method blank consist of a quality system matrix similar to the associated samples and known to be free of analytes of interest?		
M4: 7.2.1.g	For analysis of metals in solids, materials such as washed sand or non-reactive beads are acceptable as a matrix.		Clarifying Statement
M4: 7.2.1.h	Method blanks are not applicable for certain analyses (e.g., pH, conductivity, flash point, and temperature).		Clarifying Statement
M4: 7.2.1.i	For chromatographic analyses, when samples that are extracted together are analyzed on separate instruments or in separate analytical shifts, is the method blank associated with those samples (i.e., extracted with the samples) analyzed on at least one of those instruments? Is a method blank, solvent blank, or instrument blank analyzed on all other instruments on which the set of		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	samples was analyzed to demonstrate the instrument is not contributing contaminants to the samples?		
M4: 7.2.2	Positive Control – Method Performance: Laboratory Control Sample		
M4: 7.2.2.a	The LCS is used to evaluate the performance of the total measurement system.		Clarifying Statement
M4: 7.2.2.a	Is the LCS processed along with and under the same conditions as the associated samples and include all steps?		
M4: 7.2.2.b	Is the LCS analyzed at a minimum of one per preparation batch?		
M4: 7.2.2.c	Exceptions are allowed for those analytes for which no spiking solutions are available (e.g., pH, color, odor, temperature, dissolved oxygen, or turbidity).		Clarifying Statement
M4: 7.2.2.d	In instances for which no separate preparation method is used (e.g., volatiles in water), is the preparation batch 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 20 environmental samples, not including method blanks, LCS, matrix spikes, and matrix duplicates?		
M4: 7.2.2.e	Is the LCS a quality system matrix similar to the associated samples, known to be free of analytes of interest, spiked with known concentrations of analytes?		
M4: 7.2.2.e	For analysis of metals in solids, materials such as washed sand or non-reactive beads are acceptable as a matrix.		Clarifying Statement
M4: 7.2.2.f	Alternatively, does the LCS consist of a media containing known and verified concentrations of analytes or a Certified Reference Material? Are all analyte concentrations within the calibration range of the methods?		
M4: 7.2.2.g	Are the components to be spiked as specified by the reference method or regulation, or as requested by the customer? In the absence of specified spiking components, does the laboratory spike as follows:		
M4: 7.2.2.g.i	Are all reported analytes spiked in the LCS?		
M4: 7.2.2.g.ii	Is the concentration of the spiked compounds at or below the mid-range of the calibration if customer-provided concentrations are not specified?		
M4: 7.2.3	Sample-Specific Controls		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.2.3	Does the laboratory document procedures for determining the effect of the sample matrix on method performance?		
M4: 7.2.3	<p>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.</p> <p>These controls alone are not used to judge laboratory performance.</p> <p>Examples of matrix-specific QC include Matrix Spike (MS), Matrix Spike Duplicate (MSD), matrix duplicate (MD), and surrogate spike.</p>		Clarifying Statement
M4: 7.2.3	Does the laboratory have procedures in place for tracking, managing, and handling matrix-specific QC criteria, including spiking appropriate components at appropriate concentrations, calculating percent recovery (%R), relative percent difference (RPD), and other appropriate statistical measures; and evaluating and reporting results based on performance of the QC samples?		
M4: 7.2.3.a	<p>Matrix Spikes and Matrix Spike Duplicates</p> <p>Matrix-specific QC samples indicate the effect of the sample matrix on the precision and accuracy of the results generated using the selected method.</p> <p>The information from these controls is sample/matrix specific and would not normally be used to determine the validity of the entire preparation batch.</p>		Clarifying Statement
M4: 7.2.3.a.i	Does each preparation batch of samples contain an associated MS and MSD using the same matrix collected for the specific project if recommended or required by the method or the applicable B-Table?		
M4: 7.2.3.a.i	The requirements for MS/MSD are not applicable to all methods.		Clarifying Statement
M4: 7.2.3.a.i	If adequate sample material is not available, then is the lack of MS/MSDs noted in the case narrative, and then, is a LCS Duplicate (LCSD) used to determine precision?		
M4: 7.2.3.a.i	Additional MS/MSDs may be required by a customer.		Clarifying Statement
M4: 7.2.3.a.ii	Is the MS and MSD spiked with all reported analytes (except for Aroclor analysis, which is spiked per the method)?		
M4: 7.2.3.b	Matrix Duplicates		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.2.3.b.i	Does each preparation batch of samples contain a MD when precision is not monitored through the analysis of a MS/MSD pair?		
M4: 7.2.3.b.i	<p>MDs are defined as replicate aliquots of the same sample taken through the entire analytical procedure.</p> <p>The results from this analysis indicate the precision of the results for the specific sample using the selected method.</p> <p>The MD may provide a usable measure of sample homogeneity.</p> <p>It may also provide a measure of precision when target analytes are present.</p>		Clarifying Statement
M4: 7.2.3.b.i	If adequate sample material is not available, is the lack of MD noted in the case narrative, and then is a LCSD used to determine precision?		
M4: 7.2.3.b.ii	Is the frequency of the analysis of a MD specified by the customer or method?		
M4: 7.2.3.b.iii	Are matrix duplicates performed on replicate aliquots of actual samples?		
M4: 7.2.3.b.iii	The composition is usually not known.		Clarifying Statement
M4: 7.2.3.c	Surrogate Spikes		
M4: 7.2.3.c.i	Except where the matrix precludes its use or when not commercially available, are surrogate compounds added to all samples, standards, and blanks for all appropriate methods?		
M4: 7.2.3.c.ii	Are surrogates chosen to reflect the chemistries of the targeted components of the method?		
M4: 7.2.3.c.ii	Often this is accomplished by using deuterated analogs of select compounds.		Clarifying Statement
M4: 7.2.3.c.iii	Are surrogates added before sample preparation/extraction?		
M4: 7.2.4	Data Reduction		
M4: 7.2.4	Does the laboratory have a procedure for data reduction, and those records maintained?		
M4: 7.2.5	Reagent Quality, Water Quality, and Checks		
M4: 7.2.5.a	<p>In methods where the purity of reagents is not specified, is analytical reagent grade or better used?</p> <p>Are reagents of lesser purity than those specified by the method not used?</p>		
M4: 7.2.5.b	Does the quality of water sources meet recommendations or requirements of the reference method, if applicable?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	Does the laboratory monitor that the water sources meet the requirements and maintain records?		
M4: 7.2.5.c	Does the laboratory verify the concentration of titrants in accordance with written laboratory procedures and does it maintain records?		
M4: 7.2.5.d	Is the quality (e.g., purity) specifications for all standards and reagents (including water) included or referenced in procedures?		
M4: 7.2.6.	Selectivity		
M4: 7.2.6.	Does the laboratory validate selectivity by following the checks established within the method and/or Appendix B?		
M4: 7.2.6.a	For chromatography methods where confirmation is recommended or required in the reference method or Appendix B, are all results greater than the DL confirmed?		
M4: 7.2.6.a	Confirmation techniques include further analysis using a second column with dissimilar stationary phase, using a second detector type, or by other recognized confirmation techniques. HPLC UV-Diode Array detectors are not considered confirmation for a UV detector.		Clarifying Statement
M4: 7.2.6.a.i	Do confirmation techniques using the same detector type (e.g., second-column confirmation) meet the same calibration and QC criteria as the initial or primary analysis?		
M4: 7.2.6.a.ii	Is the RPD of results from the primary and confirmation technique using the same detector type less than or equal to 40%?		
M4: 7.2.6.a.iii	If using a second column for confirmation, does the laboratory identify the primary column for each target analyte? If results are reported from the second column due to interference, QC failure, or customer requirements, does the laboratory discuss the circumstances in the case narrative?		
M4: 7.2.6.a.iv	If using a mass spectrometer for confirmation, does the laboratory have a procedure that includes acceptance criteria for selectivity and sensitivity?		
M4: 7.2.6.a.v	When reporting data for methods that require analyte confirmation, are customer reporting requirements followed?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	<p>If customer requirements are not available, does the laboratory follow the reporting requirements in the method?</p> <p>If the method does not include reporting requirements, does the laboratory report the results from the primary column or detector, unless there is a scientifically valid and documented reason for not doing so, and is concurrence obtained from the customer?</p>		
M4: 7.2.6.a.vi	<p>Is the customer notified of any results that are unconfirmed and the results identified in the test report using data qualifiers and described in the case narrative?</p> <p>Is analyte presence only reported if both original and confirmation signals are positive or if confirmation signal cannot be discerned from interference?</p>		
M4: 7.3	Data Acceptance/Rejection Criteria		
M4: 7.3.1	Negative Control – Method Performance: Method Blank		
M4: 7.3.1.a	<p>While the goal is to have no detectable contaminants, is each method blank exhibiting potential contamination evaluated as to the nature of the interference and the effect on the analysis of each sample within the preparation batch?</p> <p>Is a method blank considered contaminated if:</p>		
M4: 7.3.1.a.i	The concentration of any target analyte (chemical of concern) in the blank exceeds 1/2 the LOQ or 1/10th the amount measured in any associated sample, whichever is greater; or		
M4: 7.3.1.a.ii	The concentration of any target analyte identified as a common laboratory contaminant in the blank exceeds the LOQ or 1/10th the amount measured in any associated sample, whichever is greater?		
M4: 7.3.1.b	When a method blank is contaminated, does the laboratory reprepare and analyze the MB and all affected QC and field samples in the associated preparation batch if sufficient sample material is available?		
M4: 7.3.1.b	Samples are affected if the sample result is greater than the DL and less than 10X the amount detected in the MB.		Clarifying Statement
M4: 7.3.1.b	If the affected samples cannot be reprepared and analyzed, is a qualifier applied to affected analyte results of all samples in the associated preparation batch and explained in the case narrative?		



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.3.2	Positive Control – Method Performance: Laboratory Control Sample		
M4: 7.3.2.a	<p>Does the laboratory calculate results of the individual preparation batch LCS in %R or other appropriate statistical technique that allows comparison to established acceptance criteria?</p> <p>Does the laboratory include the calculation in the procedure?</p>		
M4: 7.3.2.b	Does the laboratory evaluate the LCS against acceptance criteria provided by the customer?		
M4: 7.3.2.c	<p>In the absence of customer-provided LCS acceptance criteria, does the laboratory evaluate the LCS against its laboratory-developed acceptance criteria?</p> <p>Does the laboratory develop processes or procedures to incorporate these limits?</p>		
M4: 7.3.2.d	<p>When LCS results are outside of acceptance criteria, does the laboratory reprepare and analyze the LCS and all affected QC and field samples in the associated preparation batch for the analytes outside acceptance criteria if sufficient sample material is available?</p> <p>If the samples cannot be reprepared and analyzed, is a qualifier applied to affected analyte results of all samples in the associated preparation batch and explained in the case narrative?</p>		
M4: 7.3.2.d.i	When the LCS acceptance criteria are exceeded high (i.e., high bias) and there are associated samples with analytes that are non-detects, then those non-detect results may be reported with a data qualifier and sample re-preparation and analysis is not required.		Permission
M4: 7.3.2.e	Regardless of which limits are used for LCS evaluation, does the laboratory develop acceptance criteria for all analytes on its scope of accreditation that:		
M4: 7.3.2.e.i	are statistically derived based on the laboratory's historical data, using scientifically valid and documented procedures;		
M4: 7.3.2.e.ii	meet the limits within the reference method, if available;		
M4: 7.3.2.e.iii	are updated on at least an annual basis or as recommended or required in the reference method, whichever is more frequent, and re-established after major changes in the measurement system (e.g., new instrumentation);		
M4: 7.3.2.e.iv	are based on at least 30 data points generated under the same measurement system;		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.3.2.e.v	do not exclude failed LCS recovery data and statistical outliers from the calculation, unless there is a scientifically valid and documented reason (e.g., incorrectly made standard, instrument malfunction);		
M4: 7.3.2.e.vi	are not outside ± 3 times the standard deviation of the mean LCS recovery; and		
M4: 7.3.2.e.vii	are used for trend analysis, and preparation batch control if applicable?		
M4: 7.3.2.f	Are control charts or data analysis software maintained and used to detect trends and prevent out-of-control conditions? Are control limits monitored at least quarterly for shifts in mean recovery, changes in standard deviation, and development of trends?		
M4: 7.3.2.f	The laboratory may choose representative compounds for control charts for the purpose of trend analysis.		Permission
M4: 7.3.2.f	Is the basis for selecting representative compounds documented and scientifically valid?		
M4: 7.3.2.g	Does the laboratory review control charts at a specified frequency for out-of-control conditions and initiate corrective actions when appropriate?		
M4: 7.3.2.g	Data analysis software may also be used for the statistical evaluation of data for trends.		Permission
M4: 7.3.2.h	Does the laboratory use its laboratory developed LCS control limits for the purpose of trend analysis?		
M4: 7.3.2.h	The laboratory may use those control limits as a component in estimating measurement uncertainty.		Permission
M4: 7.3.2.i	Marginal Exceedances: If many analytes are in the LCS, it becomes statistically likely that a few will be outside acceptance criteria. This may not indicate that the system is out of control, therefore corrective action may not be necessary. This ME approach is relevant for methods with long lists of analytes.		Clarifying Statement
M4: 7.3.2.i	Is the ME approach not applied to target analyte lists with fewer than 11 analytes?		
M4: 7.3.2.i.i	Does the laboratory have a procedure for monitoring the application of ME allowances to the LCS?		
M4: 7.3.2.i.ii	Sporadic marginal exceedances are allowed for those analytes outside the 3 standard deviation control limits but still within 4 standard deviations.		Clarifying Statement
M4: 7.3.2.i.iii	The number of allowable MEs is based on the number of analytes in the LCS.		Clarifying Statement



PJLA

DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence														
	<p>If more analytes exceed the LCS acceptance criteria than is allowed, or if any one analyte exceeds four standard deviations, the LCS fails, and corrective action is necessary.</p> <p>The number of allowable marginal exceedances is as follows:</p> <table border="1" data-bbox="326 590 764 892"> <thead> <tr> <th>Number of Analytes in LCS</th> <th>Number Allowed as Marginal Exceedances</th> </tr> </thead> <tbody> <tr> <td>> 90</td> <td>5</td> </tr> <tr> <td>71 – 90</td> <td>4</td> </tr> <tr> <td>51 – 70</td> <td>3</td> </tr> <tr> <td>31 – 50</td> <td>2</td> </tr> <tr> <td>11 – 30</td> <td>1</td> </tr> <tr> <td>< 11</td> <td>0</td> </tr> </tbody> </table>	Number of Analytes in LCS	Number Allowed as Marginal Exceedances	> 90	5	71 – 90	4	51 – 70	3	31 – 50	2	11 – 30	1	< 11	0		
Number of Analytes in LCS	Number Allowed as Marginal Exceedances																
> 90	5																
71 – 90	4																
51 – 70	3																
31 – 50	2																
11 – 30	1																
< 11	0																
M4: 7.3.2.i.iv	The same analyte exceeding the LCS acceptance criteria in two out of three consecutive preparation batches is indicative of non-random behavior.		Clarifying Statement														
M4: 7.3.2.i.iv	If this occurs, does the laboratory implement its nonconforming work procedure and the LCS and associated samples reprepared and analyzed?																
M4: 7.3.2.i.v	Are sporadic MEs are not allowed for target analytes (i.e., chemicals of concern identified by the customer) without customer approval?																
M4: 7.3.2.j	Laboratory Control Sample Duplicate																
M4: 7.3.2.j.i	<p>If sufficient sample material was not available for a MS/MSD or MD and a LCSD was used to measure precision of analytical results, does the laboratory evaluate the LCSD recovery and RPD using acceptance criteria provided by the customer, or if customer requirements are not provided, using the appropriate Appendix B Table?</p> <p>If these acceptance criteria are not available, does the laboratory evaluate the LCSD recovery and RPD using the reference method, or if not specified in the reference method, using laboratory-developed limits?</p>																
M4: 7.3.2.j.ii	<p>If LCSD results are outside of acceptance criteria, does the laboratory reprepare and analyze the LCSD and all affected QC and field samples in the associated preparation batch for the analytes outside acceptance criteria if sufficient sample material is available?</p> <p>If the samples cannot be reprepared and analyzed, is a qualifier applied to the affected analyte results of all</p>																



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	samples in the associated preparation batch and explained in the case narrative?		
M4: 7.3.3	Sample-Specific Controls		
M4: 7.3.3.a	Matrix Spike; Matrix Spike Duplicates		
M4: 7.3.3.a	The results from matrix spike/matrix spike duplicate are primarily designed to assess the precision and accuracy of analytical results in each matrix and are expressed as percent recovery (%R), RPD, or other appropriate statistical technique that allows comparison to established acceptance criteria.		Clarifying Statement
M4: 7.3.3.a	Does the laboratory include in a procedure the calculation for %R, RPD or other statistical treatment used?		
M4: 7.3.3.a.i	Does the laboratory evaluate MS/MSD recoveries using the same acceptance criteria used for the LCS?		
M4: 7.3.3.a.ii	Does the laboratory evaluate the MS/MSD RPD against customer requirements, or if not specified, with the appropriate Appendix B Table for the technology? If these acceptance criteria are not available, does the laboratory evaluate the MS/MSD RPD to the reference method, or if not specified, with its laboratory-developed limits?		
M4: 7.3.3.a.iii	If MS/MSD results or MS/MSD RPD are outside the acceptance criteria, and an assignable cause isolated to only the MS or MSD is identified, does the laboratory reanalyze the MS or MSD or reprepare and analyze the MS or MSD if sufficient sample material is available, as indicated by the cause? Otherwise, is a qualifier applied to affected analyte results in the parent sample and explained in the case narrative?		
M4: 7.3.3.b	Matrix Duplicates The results from matrix duplicates are primarily designed to assess the homogeneity of the sample chosen. If that sample is homogenous, it may also describe the precision of analytical results in each matrix.		Clarifying Statement
M4: 7.3.3.b	These may be expressed as RPD or another statistical treatment (e.g., absolute differences).		Permission
M4: 7.3.3.b.i	Does the laboratory include in a procedure the calculation for RPD or other statistical treatments?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
M4: 7.3.3.b.ii	<p>Does the laboratory evaluate the MD RPD against customer requirements, or if not specified, with the appropriate Appendix B Table?</p> <p>If these acceptance criteria are not available, does the laboratory evaluate the MD RPD to the reference method, or if not specified, with its laboratory-developed limits?</p>		
M4: 7.3.3.b.iii	<p>If the MD RPD is outside of acceptance criteria, and an assignable cause isolated to only the MD is identified, does the laboratory reanalyze the MD or reprepare and analyze the MD if sufficient sample material is available, as indicated by the cause?</p> <p>Otherwise, is a qualifier applied to affected analyte results in the parent sample and explained in the case narrative?</p>		
M4: 7.3.3.c	Surrogate Spikes		
M4: 7.3.3.c.i	<p>Does the laboratory evaluate the surrogate spike recoveries using acceptance criteria provided by the customer, or if customer requirements are not provided, using the appropriate Appendix C limits?</p> <p>If these acceptance criteria are not available, does the laboratory evaluate surrogate spike recoveries using acceptance criteria developed from LCS recovery data?</p>		
M4: 7.3.3.c.ii	<p>If surrogate results are outside the acceptance criteria, and an assignable cause isolated to only the surrogates is identified in a field sample, does the laboratory reprepare, and analyze the field sample if sufficient sample material is available?</p> <p>Otherwise, does the apply a qualifier to analyte results associated with the surrogates outside acceptance criteria and explained in the case narrative?</p>		
M4: 7.4	Sample Handling		
M4: 7.4.1	<p>Does the laboratory implement procedures for checking sample preservation using readily available techniques, such as pH or chlorine, before, or during sample preparation or analysis?</p> <p>For volatile organic analysis, is chemical preservation checked after analysis?</p>		
M4: 7.4.2	Is a storage blank stored with all volatile organic samples, regardless of suspected concentration levels?		



DoD/DOE QSM 6.0 Clause	Requirement	Conformity C / NC / NA	Comments/Objective Evidence
	<p>Are storage blanks used to determine if cross-contamination may have occurred?</p> <p>If cross-contamination greater than ½ LOQ (Methylene chloride, Acetone, 2-Butanone, greater than LOQ) is found in the storage blank, does the laboratory implement the nonconforming work procedure?</p> <p>Does the laboratory have procedures and acceptance criteria for evaluating storage blanks appropriate to the types of samples being stored?</p> <p>Are the storage blanks stored in the same manner as the customer samples?</p> <p>Are the storage blanks analyzed every 14 days, at a minimum?</p>		