

The following pages present the criteria from the 2003 NELAC Appendix D requirements and the related current DoD ELAP QSM Gray Box requirements in a checklist format as they relate to chemical testing. The laboratory’s policies and procedures must meet these requirements. Each DoD Gray box is prefaced with DoD and the associated gray box number. Management system documentation and supporting records must be available for the assessor’s review.

To the best of my knowledge, all laboratory document references below as well as actual laboratory practice have been assessed for compliance with the relevant clauses of 2003 NELAC Chapter 5 Appendix D and the current DoD ELAP QSM Gray Box Requirements. I hereby attest that all ‘Yes’ marked compliance clauses, whether initialed or not, meet the aforementioned requirements. Any areas of noncompliance have been fully described in the Assessor Deficiency Report.

CAB Name:			
Address:			
Contact:			
Phone:		Email:	
Master Code:		Assessment ID:	
Certificate(s):		Conformity Standard:	
Assessment Dates:		Assessment Type:	
Assessor(s):		Assessor Signature(s):	
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Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			
		Compliance			Comments
		Y	N	NA	
D.1.1 Positive and Negative Controls					
a) Negative Control - Method Performance Purpose: The method blank is used to assess 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.					
Frequency: The method blank shall be analyzed at a minimum of 1 per preparation batch. 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 20 environmental samples.					
Composition: The method blank shall consist of a matrix that is similar to the associated samples and is known to be free of the analytes of interest.					



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Evaluation Criteria and Corrective Action: While the goal is to have no detectable contaminants, each method blank must 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:					
1. The concentration of a targeted analyte in the blank is at or above the reporting limit as established by the test method or by regulation, AND is greater than 1/10 of the amount measured in any sample.					
2. The blank contamination otherwise affects the sample results as per the test method requirements or the individual project data quality objectives.					
3. When a blank is determined to be contaminated, the cause must be investigated and measures taken to minimize or eliminate the problem. Samples associated with a contaminated					
DoD D-1 Positive and Negative Controls: Evaluation Criteria for Blanks (Requirement) For DoD samples, the method blank will be considered to be contaminated if: <ul style="list-style-type: none"> • The concentration of any target analyte in the blank exceeds 1/2 the reporting limit and is greater than 1/10 the 					



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<p>amount measured in any sample or 1/10 the regulatory limit (whichever is greater);</p> <ul style="list-style-type: none"> • The concentration of any common laboratory contaminant in the blank exceeds the reporting limit and is greater than 1/10 the amount measured in any sample or 1/10 the regulatory limit (whichever is greater); or • The blank result otherwise affects the samples results as per the test method requirements or the project-specific objectives. <p>If the method blank is contaminated as described above, then the laboratory shall reprocess affected samples in a subsequent preparation batch, except when sample results are below the LOD. If insufficient sample volume remains for reprocessing, the results shall be reported with appropriate data qualifiers.</p>					
b) Positive Control - Method Performance					
1) Laboratory Control Sample (LCS)					
<p>Purpose: 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</p>					



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results reported with appropriate data qualifying codes.					
Frequency: The LCS shall be analyzed at a minimum of 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 20 environmental samples.					
Composition: The LCS is a controlled matrix, known to be free of analytes of interest, spiked with known and verified 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:					
The components to be spiked shall be as specified by the mandated test method or other regulatory requirement or as requested by the client. In the absence of specified spiking components the laboratory shall spike per the following:					



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		Y	N	NA	
For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.					
For those test methods that have extremely long lists of analytes, a representative number may be chosen. The analytes selected should 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 2 year period.					
a) For methods that include 1-10 targets, spike all components;					
b) For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater;					
c) For methods with more than 20 targets, spike at least 16 components.					
DoD D-2 Positive and Negative Controls: LCS Spiking Compounds (Requirement) <ul style="list-style-type: none"> • All target analytes must be spiked in the LCS (with the exception of PCB analysis, which is spiked per the method). Target analytes are identified by the client on a project-specific basis. This may require the preparation of multiple LCSs to avoid interferences. • The concentration of the spiked compounds shall be at the 					



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project-specific concentration of concern. If this is not specified, it shall be at or below the midpoint of the calibration curve.					
Evaluation Criteria and Corrective Action: The results of the individual batch LCS are calculated in percent recovery. The laboratory shall document the calculation for percent recovery.					
The individual LCS is compared to the acceptance criteria as published in the mandated test 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.					
<p>DoD D-3 Positive and Negative Controls: LCS Control Limits (Requirement)</p> <p>A laboratory shall establish in-house limits that:</p> <ul style="list-style-type: none"> • Are statistically-derived using scientifically valid and documented procedures; • Meet the limits specified by the project or as stated in the method, if available; • Are updated on an annual basis, or as stated in the method, and re-established after major changes in the analytical process (e.g., new instrumentation); • Are based on at least 30 data points generated under the same analytical process; • Do not exclude failed LCS recovery data and statistical outliers from the calculation, unless there is a 					



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documented and scientifically valid reason (e.g., bad LCS standard, leaking purging cell); Control limits may not be greater than ± 3 times the standard deviation of the mean LCS recovery. Control charts shall be maintained and used to detect trends and prevent out-of-control conditions. Control limits shall be continually monitored for shifts in mean recovery, changes in standard deviation, and development of trends.					
A 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 a LCS determined to be “out of control” should be considered suspect and the samples reprocessed and re-analyzed or the data reported with appropriate data qualifying codes.					
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. A ME is defined as being beyond the LCS control limit (3 standard deviation), but within the ME limits. ME limits are between 3 and 4 standard deviations around the mean.					
DoD D-4 Positive and Negative Controls: LCS Marginal Exceedance (ME) Limits (Requirement)					



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		Y	N	NA													
The marginal exceedance limit is 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 11 analytes.																	
DoD D-5 Positive and Negative Controls: Target Analytes (Requirement) DoD does not allow any target analyte to exceed its LCS control limits, even marginally. It is inappropriate to control batch acceptance on poor-performing analytes.																	
The number of allowable marginal exceedance is as follows: Analytes in LCS- Analytes in ME of LCS limit <table style="margin-left: 20px; border: none;"> <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> </table>	>90	5	71-90	4	51-70	3	31-50	2	11-30	1	<11	0					
>90	5																
71-90	4																
51-70	3																
31-50	2																
11-30	1																
<11	0																
DoD D-6 Positive and Negative Controls: Random Marginal Exceedance (Clarification) DoD considers the same analyte exceeding the LCS control limit two (2) out of three (3) consecutive LCS to be																	



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indicative of non-random behavior.					
c) Sample Specific Controls					
The laboratory must document procedures for determining the effect of the sample matrix on method performance. These procedures relate to the analyses of matrix specific Quality Control (QC) samples and are designed as data quality indicators for a specific sample using the designated test 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, evaluating and reporting results based on performance of the QC samples.					
Matrix Spike; Matrix Spike Duplicates:					
Purpose: 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					



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and would not normally be used to determine the validity of the entire batch.					
Frequency: The frequency of the analysis of matrix specific samples shall be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the required mandated test method.					
DoD D-7 Positive and Negative Controls: MS/MSD Frequency (Requirement) Each preparation batch of samples must contain an associated MS and MSD (or sample duplicate, see Box D-11) using the same matrix collected for the specific DoD project. The requirements for MS/MSD are not applicable to all methods (e.g., asbestos, certain air-testing samples, classic chemistry, and industrial hygiene samples). If adequate sample material is not available, then the lack of MS/MSDs shall be noted in the case narrative. Additional MS/MSDs may be required on a project-specific basis.					
Composition: The components to be spiked shall be as specified by the mandated test 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:					
For those components that interfere with an accurate assessment such as spiking simultaneously with technical chlordane, toxaphene and PCBs, the spike should be chosen that represents the chemistries and elution patterns of the components to be reported.					



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For those test 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 2 year period.					
a) For methods that include 1-10 targets, spike all components; b) For methods that include 11-20 targets, spike at least 10 or 80%, whichever is greater; c) For methods with more than 20 targets, spike at least 16 components.					
DoD D-8 Positive and Negative Controls: MS/MSD Spiking Compounds (Requirement) The MS and MSD must be spiked with all target analytes (with the exception of PCB analysis, which is spiked per the method). The concentration of the spiked compounds shall be at or below the midpoint of the calibration range or at the appropriate concentration of concern. (Guidance) Multiple spiked samples may need to be prepared to avoid interferences.					
Evaluation Criteria and Corrective Action: 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) and relative percent difference (RPD). The laboratory shall document the calculation for relative percent difference.					



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<p>DoD D-9 Positive and Negative Control: Calculation of Relative Percent Difference (RPD) (Requirement) For DoD, relative percent difference (RPD) between original and duplicate analyses must be calculated as follows:</p> $RPD = \frac{ C_o - C_D }{\frac{C_o + C_D}{2}} \times 100\%$ <p>where CO and CD are the concentrations of the original and duplicate, respectively.</p>					
<p>Results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should 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 reported with appropriate data qualifying codes.</p>					
<p>DoD D-10 Positive and Negative Controls: MS/MSD Acceptance Criteria (Requirement) The results of all MS/MSDs must be evaluated using the same acceptance criteria used for the LCS.</p>					
<p>d) Matrix Duplicates:</p>					



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Purpose: 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 provides a usable measure of precision only when target analytes are found in the sample chosen for duplication.					
Frequency: The frequency of the analysis of matrix duplicates may be determined as part of a systematic planning process (e.g. Data Quality Objectives) or as specified by the mandated test method.					
DoD D-11 Positive and Negative Controls: Sample Duplicate Frequency (Requirement) If the known concentration of concern is greater than five times the LOQ, a sample duplicate may be analyzed in place of the MSD. A matrix spike is still required (see Box D-8). Duplicate analysis should be performed at a minimum frequency of once per preparatory batch per matrix type.					
Composition: Matrix duplicates are performed on replicate aliquots of actual samples. The composition is usually not known.					



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Evaluation Criteria and Corrective Action: The results from matrix duplicates are primarily designed to assess the precision of analytical results in a given matrix and are expressed as relative percent difference (RPD) or another statistical treatment (e.g., absolute differences). The laboratory shall document the calculation for relative percent difference or other statistical treatments.					
Results are compared to the acceptance criteria as published in the mandated test 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 reported with appropriate data qualifying codes.					
e) Surrogate Spikes:					
Purpose: Surrogates are used most often in organic chromatography test methods and are chosen to reflect the chemistries of the targeted components of the method. Added prior to sample preparation/extraction, they provide a measure of recovery for every sample matrix.					
Frequency: Except where the matrix precludes its use or when not available, surrogate compounds must be added to all samples, standards, and blanks for all appropriate test methods.					



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Composition: 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.					
Evaluation Criteria and Corrective Action: The results are compared to the acceptance criteria as published in the mandated test method. Where there are no established criteria, the laboratory should determine internal criteria and document the method used to establish the limits. Surrogates outside the acceptance criteria must 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 should include appropriate data qualifiers.					
DoD D-12 Positive and Negative Controls: Surrogate Spike Acceptance Criteria (Requirement) Surrogate spike results shall be compared with project-specific acceptance criteria specified by the client. If project-specific criteria are not available, the laboratory shall compare the results with its in-house criteria.					
D.1.2 Limit of Detection and Limit of Quantitation					



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<p>All procedures used must be documented. Documentation must include the quality system matrix type. All supporting data must be retained.</p>					
<p>D.1.2.1 Limit of Detection (LOD)</p> <p>The laboratory shall utilize a test method that provides an LOD that is appropriate and relevant for the intended use of the data. An LOD is not required for a test method when test results are not reported outside of the calibration range. LOD's shall be determined by the protocol in the mandated test method or applicable regulation. If the protocol for determining LOD's is not specified, the selection of the procedure must reflect instrument limitations and the intended application of the test method.</p>					
<p>DoD D-13 Limit of Detection (LOD): Determination and Verification (Requirement)</p> <p>A laboratory shall establish a detection limit (DL) using a scientifically valid and documented procedure for each suite of analyte-matrix-method, including surrogates. The detection limit shall be used to determine the LOD for each analyte and matrix as well as for all preparatory and cleanup methods routinely used on samples, as follows:</p> <p>After each detection limit determination, the laboratory must immediately establish the LOD by spiking a quality system matrix at approximately two to three times the</p>					



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<p>detection limit (for a single-analyte standard) or one to four times the detection limit (for a multi-analyte standard). This spike concentration establishes the LOD. It is specific to each combination of analyte, matrix, method (including sample preparation), and instrument configuration. The LOD must be verified quarterly. The following requirements apply to the initial detection limit/LOD determinations and to the quarterly LOD verifications.</p> <ul style="list-style-type: none"> • The apparent signal to noise ratio at the LOD must be at least three and the results must meet all method requirements for analyte identification (e.g., ion abundance, second-column confirmation, or pattern recognition.) For data systems that do not provide a measure of noise, the signal produced by the verification sample must produce a result that is at least three standard deviations greater than the mean method blank concentrations. • If a laboratory uses multiple instruments for a given method the LOD must be verified on each. • If the LOD verification fails, then the laboratory must repeat the detection limit determination and LOD verification at a higher concentration or perform and pass two consecutive LOD verifications at a higher concentration and set the LOD at the higher concentration. • The laboratory shall maintain documentation for all detection limit determinations and LOD verifications. 					



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a) The LOD shall be initially determined for the compounds of interest in each test method in a quality system matrix in which there are not target analytes nor interferences at a concentration that would impact the results or the LOD must be determined in the quality system matrix of interest.					
b) LODs must be determined each time there is a change in the test method that affects how the test is performed, or when a change in instrumentation occurs that affects the sensitivity of the analysis.					
c) The laboratory must have established a procedure to relate LOD with LOQ.					
d) The LOD must be verified annually for each quality system matrix, method and analyte according to the procedure specified in C.3.					
D.1.2.2 Limit of Quantitation (LOQ)					
Any established LOQ must be above the LOD.					
The LOQ must be verified annually for each quality system matrix, method and analyte according to the procedure specified in C.3. Alternatively, the annual LOQ verification is not required if the LOD is reevaluated or verified according to D.1.2.d above.					



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<p>DoD D-14 Limit of Quantitation (LOQ): Establishment and Verification of LOQ (Requirement) For DoD projects, the LOQ must be set within the calibration range prior to sample analysis. At a minimum, the LOQ must be verified quarterly. The laboratory procedure for establishing the LOQ must empirically demonstrate precision and bias at the LOQ. The LOQ and associated precision and bias must meet client requirements and must be reported. If the method is modified, precision and bias at the new LOQ must be demonstrated and reported.</p>					
D.1.3 Data Reduction					
<p>The procedures for data reduction, such as use of linear regression, shall be documented.</p>					
D.1.4 Quality of Standards and Reagents					
a) The source of standards shall comply with 5.5.6.2.2.2.					
b) Reagent Quality, Water Quality and Checks:					



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1) Reagents - 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 test method shall not be used. The labels on the container should be checked to verify that the purity of the reagents meets the requirements of the particular test method. Such information shall be documented.					
2) Water - The quality of water sources shall be monitored and documented and shall meet method specified requirements.					
DoD D-15 Quality of Standards and Reagents: Water Quality in Method SOPs (Requirement) The quality (e.g., purity) specifications for all standards and reagents (including water) shall be documented or referenced in SOPs.					
3) The laboratory will verify the concentration of titrants in accordance with written laboratory procedures.					



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D.1.5 Selectivity					
a) The laboratory shall evaluate by following the checks established within the method, which may include mass spectral tuning, second column confirmation, ICP interelement interference checks, chromatography retention time windows, sample blanks, spectrochemical absorption or fluorescence profiles, co-precipitation evaluations, and electrode response factors.					
b) A confirmation shall be performed to verify the compound identification when positive results are detected on a sample from a location that has not been previously tested by the laboratory. Such confirmations shall be performed on organic tests such as pesticides, herbicides, or acid extractable or when recommended by the analytical test method except when the analysis involves the use of a mass spectrometer. Confirmation is required unless stipulated in writing by the client. All confirmation shall be documented.					
DoD D-16 Selectivity: Analyte Confirmation (Requirement) When reporting data for methods that require analyte confirmation using a secondary column or detector, project-specific reporting requirements shall be followed. If project-specific requirements have not been specified,					



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<p>follow the reporting requirements in the method. If the method does not include reporting requirements, then report the results from the primary column or detector, unless there is a scientifically valid and documented reason for not doing so. Results that are unconfirmed, or for which confirmation was not performed, shall be identified in the test report, using appropriate data qualifier flags, and explained in the narrative. The laboratory shall use method-specified acceptance criteria for analyte confirmation. If method-specific criteria do not exist, the laboratory shall develop acceptance criteria and document them in the SOP.</p>					
c) The laboratory shall document acceptance criteria for mass spectral tuning.					
D.1.6 Constant and Consistent Test Conditions					
a) The laboratory shall assure that the test instruments consistently operate within the specifications required of the application for which the equipment is used.					
<p>b) Glassware Cleaning - Glassware shall be cleaned to meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the test method shall be documented in laboratory records and SOPs.</p>					

Document Revision History

Date	Description
12/20/2011	Added CAB Information Block