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	C221 – Specific Checklist: Current DoD QSM Gray Box Requirements	Document Revised: December 20, 2011
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This checklist is intended for use in association with A2LA assessments, and is not to be publicly distributed. Use of this document is restricted to A2LA employees, contractors, and applicant and accredited. Any other use of this document is prohibited.

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The following pages present the criteria from the Department of Defense Environmental Laboratory Accreditation Program (current DoD ELAP) Quality System Manual (QSM) Gray Box Requirements. **The DoD ELAP program requires that laboratories also meet ISO/IEC 17025:2005, “General requirements for the competence of testing and calibration laboratories” and the 2003 NELAC Chapter 5 requirements. The 17025:2005 and 2003 NELAC requirements are included in the A2LA C205 checklist.** The laboratory’s policies and procedures must meet these requirements. Requirements that include the need for a **written** policy, procedure or arrangement are **shaded**.

Laboratory Instructions: This checklist must be completed and submitted as part of the application for accreditation in order to help both the laboratory and assessor(s) prepare for the assessment. **Correct completion of this checklist may save a significant amount of assessment time and cost.** Complete the document reference identifiers in the checklist's second column (labeled "Reference") for all **shaded** requirements. The appropriate “reference” must identify the document (quality manual, laboratory manual, SOPs, etc) and include a “locator” to facilitate identification of the appropriate portion(s) of the relevant document (page number, section number, etc.) The management system documentation and supporting records must be available for the assessor's review.

Assessor Instructions: Review the laboratory’s documented management system to verify compliance with the applicable DoD ELAP documentation requirements. Assess to verify that the documented quality system is indeed implemented as described. Place a tick mark in the yes (Y), no (N), or not applicable (NA) space for each checklist item. In those instances where NA is selected, please comment on the justification for NA. Record comments related to any requirement on the space provided. Record comments related to tests on separate sheets and/or on the method review matrix. All deficiencies must be identified and explained in the assessor deficiency report. Assess the laboratory’s technical competence to perform specific tests or specific types of tests. **Please also complete the separate C104 – General Checklist: Reference to A2LA Accredited Status-A2LA Advertising Policy, C105 – General Checklist: A2LA Policy on Measurement Traceability, and C106 – General Checklist: Proficiency Testing for ISO/IEC 17025 Laboratories checklists. The laboratories themselves are not required to complete C104-C106 prior to the assessment.** IMPORTANT NOTE: An asterisk (*) in the comments section indicates that the assessor must document the specific objective evidence reviewed in association with that requirement. Objective evidence information is mandatory for those clauses.

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 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):	
AcO:			

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Personnel Information (Names, Titles, and Responsibilities):

Technical Management: _____

Quality Manager (QM): _____

Deputy QM: _____



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Requirement	Reference	{RESERVED FOR ASSESSORS ONLY}			Comments
		Compliance			
		Y	N	NA	
DoD1 All DoD-specific clarifications, requirements, guidance, and references are contained in the gray boxes.					
DoD2 Terms and Definitions: DoD QSM Glossary (Clarification) The DoD QSM Glossary can be found in Appendix B of the current DoD Quality System Manual. It includes terms from the NELAC glossary. Clarifications and supplemental terms used in the DoD QSM are included as gray boxes in the glossary.					
DoD3 Organization: Technical Director Qualifications (Guidance) The Technical Director (however named) is a full-time member of the environmental laboratory staff who exercises day-to-day supervision of laboratory operations and reporting of results for the appropriate fields of accreditation. The actual title for the position may include, but is not limited to, laboratory director, technical director, laboratory supervisor, or laboratory manager. A laboratory may appoint one or more Technical Directors for the specific fields of accreditation for which they are seeking accreditation. Duties shall include monitoring standards of performance in quality control and quality assurance and monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data. An individual shall not serve as Technical Director in more than one environmental laboratory without authorization from the Accreditation Body.					



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<p>Circumstances to be considered in the decision to grant such authorization shall include, but are not limited to, the extent to which operating hours of the laboratories overlap, adequacy of supervision in each laboratory, and the availability of environmental laboratory services in the area served. If the Technical Director is absent for a period of time exceeding 15 consecutive calendar days, he/she shall designate another full-time staff member meeting the qualifications listed below to temporarily perform this function. If this absence exceeds 65 consecutive calendar days, the Accreditation Body shall be notified in writing.</p> <p>The education and experience requirements for Technical Director are provided below, according to the type of laboratory services offered. Persons who do not meet the education requirements listed below, but possess the requisite experience shall qualify as Technical Director(s) subject to the following conditions: the person must be serving as Technical Director for those fields of accreditation on the date the laboratory applies for accreditation and must have been a Technical Director for those fields of accreditation in that laboratory or another accredited laboratory continuously for the previous 12 months or more, and the person will be approved as Technical Director for only those fields of accreditation for which he/she has been functioning as technical director in that laboratory for the previous 12 months or more. The requirement for 12 months' experience is waived during the first 12 months the Accreditation Body offers a particular field</p>					



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<p>of accreditation.</p> <p>Education and Experience:</p> <p>Environmental Laboratory (classical wet chemistry) Bachelor’s degree in the chemical, environmental, biological or physical sciences, or engineering, with at least 24 college credit hours in chemistry and at least two years of experience in the environmental analysis of representative inorganic and organic analytes for which the laboratory seeks or maintains accreditation. A master’s or doctoral degree in one of the above disciplines may be substituted for one year of experience.</p> <p>Environmental Laboratory (limited to inorganic chemical analysis other than metals and perchlorate analysis) Associate degree in the chemical, physical, or environmental sciences, or two years of equivalent and successful college education, with a minimum of 16 college credit hours in chemistry and at least two years of experience performing such analyses.</p> <p>Environmental Laboratory Engaged in Microbiological or Biological Analysis (general) Bachelor’s degree in microbiology, biology, chemistry, environmental sciences, physical sciences, or engineering with a minimum of 16 college credit hours in general microbiology and biology and at least two years of experience in the specific analytical procedures for which the laboratory seeks or maintains accreditation. A master’s or doctoral degree in one of the above disciplines may be substituted for one year of</p>					



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		Y	N	NA	
<p>experience. Microbiological Analysis (limited to fecal coliform, total coliform, and standard plate count) Associate degree in an appropriate field of science (or applied sciences) with a minimum of four college credit hours in general microbiology. Two years of equivalent and successful college education, which include the microbiology requirement, may be substituted for the Associate Degree. In addition, the Technical Director shall have one year of experience in environmental analysis. Radiological Analysis Bachelor's degree in chemistry, physics, or engineering with 24 college credit hours of chemistry with two or more years of experience in the radiological analysis of environmental samples. A master's or doctoral degree in one of the above disciplines may be substituted for one year experience. Microscopic Examination of Asbestos and/or Airborne Fibers i) For procedures requiring the use of a transmission electron microscope: Bachelor's degree, successful completion of courses in the use of the instrument, and one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals. ii) For procedures requiring the use of a polarized light microscope: Associate degree or two years of college study, successful completion of formal coursework in polarized light microscopy, and</p>					



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<p>one year of experience, under supervision, in the use of the instrument. Such experience shall include the identification of minerals.</p> <p>iii) For procedures requiring the use of a phase contrast microscope: Associate degree or two years of college study, documentation of successful completion of formal coursework in phase contrast microscopy, and one year of experience, under supervision, in the use of the instrument.</p> <p>Radon in Air Associate degree (or two years of college) and one year of experience in radiation measurements, including at least one year of experience in the measurement of radon and/or radon progeny.</p>					



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<p>DoD4 Organization: Responsibility for Implementation, Maintenance, and Improvement of the Quality System (Requirement) The Quality Manager shall have the authority and be responsible for:</p> <ul style="list-style-type: none"> • Implementing, maintaining, and improving the quality system; • Ensuring that all personnel understand their contributions to the quality system; • Ensuring communication takes place at all levels within the laboratory regarding the effectiveness of the quality system; • Evaluating the effectiveness of training; and • Using available tools, such as audit and surveillance results, control charts, proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends and continually improve the quality system. 					
<p>DoD5 Quality System: Documentation (Requirement) Copies of all quality systems documentation provided to DoD for review must be in English.</p>					
<p>DoD6 Quality System: Commitment to Continual Improvement (Requirement) The quality policy shall also include a statement of management’s commitment to continually improve the quality system. Management shall provide evidence of this commitment, which includes, but is not limited to, communicating to staff at all levels the importance of:</p> <ul style="list-style-type: none"> • Meeting customer requirements; 					



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<ul style="list-style-type: none"> • Operating in accordance with statutory and regulatory requirements; and • Operating in accordance with the laboratory’s documented ethics policy. 					
<p>DoD7 Quality System: Key Staff (Clarification) At a minimum, the following laboratory management staff (however named) shall be considered key staff:</p> <ol style="list-style-type: none"> 1. Management (e.g., President, Chief Executive Officer, Chief Operating Officer, Laboratory Director); 2. Technical managers (e.g., Technical Director, Section Supervisors); 3. Quality managers; 4. Support systems and administrative managers (e.g., LIMS manager, purchasing manager, project managers); and 5. Client services managers. <p>The quality manual shall describe the reporting relationship between key personnel and other staff. Job descriptions of key personnel shall describe their responsibilities.</p>					
<p>DoD8 Quality System: Procedures for Audits and Data Review (Requirement) The procedures for audits and data review shall specify which records must be included in the review.</p>					
<p>DoD9 Document Control: Reviewing and Updating Quality Manual (Requirement) The quality manual shall be reviewed at least annually, and updated if necessary, to ensure it remains up-to-</p>					



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<p>date. All such reviews shall be documented and made available for assessment. The document control procedures shall describe how affected personnel are notified of changes to quality systems documents and supporting procedures, including technical procedures.</p>					
<p>DoD10 Subcontracting of Environmental Tests: Requirements for Subcontractors (Requirement) Laboratories must ensure that subcontracted laboratories meet the requirements of the DoD QSM. Subcontracted laboratories must be accredited by DoD or its designated representatives. Subcontracted laboratories must receive project-specific approval from the DoD client before any samples are analyzed. These requirements also apply to the use of any laboratory under the same corporate umbrella, but at a different facility or location.</p>					
<p>DoD11 Purchasing Services and Supplies: Items that May Affect Quality (Requirement) Records for services and supplies that may affect the quality of environmental tests must include the following, where applicable:</p> <ul style="list-style-type: none"> • Date of receipt; • Expiration date; • Source; • Lot or serial number; • Calibration and verification records; and • Certifications. <p>(Guidance) Examples of services and supplies that may</p>				*	



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affect the quality of environmental tests include, but are not limited to, balance calibration, solvents, standards, and sample containers.					
<p>DoD12 Service to the Client: Opportunities for Proactive Communication (Requirement)</p> <p>The laboratory shall maintain and document timely communication with the client for the purposes of seeking feedback, both positive and negative, and clarifying customer requests. Feedback shall be used and analyzed to improve the quality system, testing activities, and service to the client.</p> <p>(Guidance) Examples of situations for which immediate clarification or feedback should be sought from the client include the following:</p> <ul style="list-style-type: none"> • The client has specified incorrect, obsolete, or improper methods; • Methods require modification to ensure achievement of project-specific objectives contained in planning documents (e.g., difficult matrix, poor-performing analyte); • Project-planning documents (e.g., Quality Assurance Project Plan (QAPP) or Sampling and Analysis Plan (SAP)) are missing or requirements in the documents (e.g., action levels, detection and quantification capabilities) require clarification; or • The laboratory has encountered problems with sampling or analysis that may impact results (e.g., improper preservation of sample). 					
DoD13 Control of Records: Archiving of SOPs					



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(Requirement) All SOPs shall be archived for historical reference, per regulatory or client requirements.					
DoD14 Control of Records: Date and Time (Requirement) Both date and time of preparation and analysis are considered essential information, regardless of the length of the holding time, and shall be included as part of the laboratory report. If the time of the sample collection is not provided, the laboratory must assume the most conservative time of day (i.e., earliest).					
DoD15 Internal Audits: Schedule and Personnel (Requirement) The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year. Audit personnel shall be trained and qualified in the specific quality system element or technical area under review.					
DoD16 Management Reviews (Clarification) Internal audits and management reviews are separate activities.					
DoD17 Personnel: Job Descriptions (Requirement) Job descriptions shall include the following, as appropriate: • Duties relative to scheduling and performing tests and evaluating results; • Duties relative to the development, validation, and approval of new methods or method modifications;					



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<ul style="list-style-type: none"> • Required experience, qualifications, and training; and • Managerial duties. 					
<p>DoD18 Required Program Elements: Detecting and Deterring Improper, Unethical, or Illegal Actions (Requirement)</p> <p>The laboratory shall have a documented program to detect and deter improper, unethical, or illegal actions. To facilitate the implementation of this program, the following text:</p> <ol style="list-style-type: none"> 1) defines improper and unethical, or illegal actions; 2) outlines elements of detection/deterrence programs for improper, unethical, or illegal actions; and 3) provides examples of improper laboratory practices. <p>Data shall be produced according to the project-specific requirements as specified in the final, approved project-planning documents, such as the approved QAPP, when these documents are provided to the laboratory.</p> <p>Improper actions are intentional or unintentional deviations from contract-specified or method-specified analytical practices that have not been authorized by DoD. Unethical or illegal actions are the deliberate falsification of analytical or quality control results, where failed method or contractual requirements are made to appear acceptable.</p> <p>Detecting and deterring improper, unethical, or illegal actions begins with a zero-tolerance philosophy established by management. Improper, unethical, or illegal actions are detected through the implementation</p>					



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<p>of surveillance protocols. The following are the minimum elements of an acceptable program for detecting and deterring improper, unethical, or illegal actions:</p> <ul style="list-style-type: none"> • An ethics policy must be read and signed by all personnel; • Initial and annual ethics training must be conducted as described in Section 5.2.7; • Internal audits must be conducted as described in Section 4.13; • Analysts must explain and sign-off on all manual changes to data (see also Box 29); • Where available in the instrument software, all electronic tracking and audit functions must be enabled (see also Box 44); • The laboratory must have a “no-fault” reporting policy that encourages laboratory personnel to report suspected improper, unethical, or illegal activities, without fear of retribution; and • The laboratory must have a designated data integrity officer or ombudsman to whom personnel may confidentially report suspected instances of improper, unethical, or illegal activities. <p>The following practices are prohibited:</p> <ul style="list-style-type: none"> • Fabrication, falsification, or misrepresentation of data. <ul style="list-style-type: none"> – Creating data for an analysis that was not performed (dry lab). – Creating information for a sample that was not collected (dry lab). 					



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<ul style="list-style-type: none"> – Using external analysts, equipment, and/or laboratories to perform analyses when not allowed by contract. • Improper clock setting (time traveling) or improper date/time recording. – Resetting the internal clock on an instrument to make it appear that a sample was analyzed within holding time when in fact it was not. – Changing the actual time or recording a false time to make it appear that holding times were met, or changing the times for sample collection, extractions, or other steps to make it appear that holding times were met. • Unwarranted manipulation of samples, software, or analytical conditions. – Unjustified dilution of samples. – Manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria. – Changing the instrument conditions for sample analysis from the conditions used for standard analysis (e.g., changing EM voltage). – Unwarranted manipulation of computer software (e.g., forcing calibration or QC data to meet criteria, removing computer operational codes such as the “M” flag, inappropriately subtracting background, or improperly manipulating the chromatographic baseline). – Turning off, or otherwise disabling, electronic instrument audit/tracking functions. • Misrepresenting or misreporting QC samples. 					



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		Y	N	NA	
<ul style="list-style-type: none"> – Representing spiked samples as being digested or extracted when this was not performed. – Substituting previously generated runs for a non-compliant calibration or QC run to make it appear that an acceptable run was performed. – Failing to prepare or analyze method blanks and the laboratory control sample (LCS) in the same manner that samples were prepared or analyzed. – Tampering with QC samples and results, including special treatments for QC samples (e.g., running extra rinse blanks prior to QC samples), over-spiking, and adding surrogates after sample extraction. – Performing multiple calibrations or QC runs (including continuing calibration verifications (CCVs), LCSs, spikes, duplicates, and blanks) until one meets criteria, rather than taking needed corrective action, and not documenting or retaining data for the other unacceptable data. – Deleting or failing to record non-compliant QC data to conceal the fact that calibration or other QC analyses were non-compliant. <ul style="list-style-type: none"> • Improper calibrations. – Discarding mid-level points in the initial calibration to meet calibration criteria. – Discarding points from a Limit of Detection (LOD) study to force the calculated LOD to be lower than the actual value. – Using an initial calibration that does not correspond to the actual run sequence to make continuing calibration 					



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		Y	N	NA	
<p>data look acceptable when in fact it was not.</p> <ul style="list-style-type: none"> – Performing improper manual integrations, including peak shaving, peak enhancing, or baseline manipulation to meet QC criteria or to avoid corrective action. • Concealing a known analytical or sample problem. • Concealing a known improper or unethical behavior or action. • Failing to report the occurrence of a prohibited practice or known improper or unethical act to the appropriate laboratory or contract representative, or to an appropriate government official. 					
<p>DoD19 Accommodation and Environmental Conditions: Preventing Cross-Contamination (Requirement) When cross-contamination is a possibility, samples suspected of containing high concentrations of target analytes shall be isolated from other samples. Samples or extracts designated for volatile organics analysis must be segregated from other samples and extracts. Samples suspected of containing high concentrations of volatile organics shall be further isolated from other volatile organics samples. Storage blanks shall be used to determine if cross-contamination may have occurred. Laboratories shall have documented procedures and criteria for evaluating storage blanks, appropriate to the types of samples being stored.</p>					



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<p>DoD20 Environmental Test Methods and Method Validation: Annual Reviews (Requirement) All technical SOPs (e.g., sample preparation, analytical procedures, sample storage, sample receipt, etc.) shall be reviewed for accuracy and adequacy annually and whenever method procedures change, and updated as appropriate.</p>					
<p>DoD21 Environmental Test Methods and Method Validation: Modifications to Published Methods (Requirement) Where published methods are specified as required for a project, requirements contained within that method shall be followed. Any modifications to existing method requirements require project-specific approval by DoD personnel.</p>					
<p>DoD22 Environmental Test Methods and Method Validation: Content of SOPs (Requirement) In addition to items 1) through 23) above, the SOP must discuss or reference equipment/instrument maintenance, computer hardware and software, and troubleshooting.</p>					
<p>DoD23 Environmental Test Methods and Method Validation: Target Analytes (Requirement) The laboratory shall analyze those target analytes identified by the client on a project-specific basis. If project-specific information is not available, then the list of analytes published in the method shall be used.</p>					
<p>DoD24 Environmental Test Methods and Method Validation: Appropriate Method Validation Techniques</p>					



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<p>(Requirement) The laboratory must establish procedures for documenting the validation of new methods before they are used in the laboratory. Appropriate method validation techniques include the following:</p> <ul style="list-style-type: none"> • Testing of reference standards or reference materials; • Comparison of results to those achieved using other validated, standard methods; and • Interlaboratory comparisons. <p>When the above techniques are not feasible, the following options must be used:</p> <ul style="list-style-type: none"> • Systematic assessment of factors that could influence the result; and/or • Assessment of the precision and bias of the result based on the science of the method and practical experience. 					
<p>DoD25 Environmental Test Methods and Method Validation: Requirements for Initial and Ongoing Demonstrations of Capability (Requirement) The laboratory shall have a procedure for performing the initial and continuing demonstration of capability (DOC) for methods used. The DOC shall include verification of method sensitivity, precision, and bias in each quality system matrix of concern. (Guidance) A laboratory may employ quarterly Limit of Detection (LOD) verification (see Box D-13) to verify method sensitivity and quarterly Limit of Quantitation (LOQ) verification (see Box D-14) to verify precision and bias at the LOQ. A laboratory may use laboratory</p>					



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QC samples (such as LCS) to verify precision and bias of the quantitation range.					
DoD26 Environmental Test Methods and Method Validation: Change in Personnel, Instrument, Test Method or Sample Matrix (Clarification) “Change” refers to any change in personnel, instrument, test method, or sample matrix that potentially affects the precision and bias, sensitivity, or selectivity of the output (e.g., a change in the detector, column type, matrix, or other components of the sample analytical system, or a method revision). Requirements for demonstration of capability are further addressed in Appendix C.					
DoD27 Environmental Test Methods and Method Validation: Definition of Work Cell (Requirement) Each member of the work cell must demonstrate proficiency in his/her area(s) of responsibility. A work cell may not be defined as a group of analysts who perform the same step in the same process (for example, extractions for Method 8270) represented by one analyst who has demonstrated proficiency for that step.					
DoD28 Environmental Test Methods and Method Validation: Estimating Measurement Uncertainty (Clarification) The laboratory is only responsible for estimating the portion of measurement uncertainty that is under its control. As stated in Section 5.10.3.1.c, test reports shall include a statement of the estimated uncertainty of					



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measurement only when required by client instruction. If a DoD project requires measurement uncertainty to be reported, the laboratory shall report the estimated uncertainty based on project-specific procedures or, if not available, any other scientifically valid and documented procedures. The estimated measurement uncertainty can be expressed as a range (\pm) around the reported analytical results at a specified confidence level. A laboratory may report the in-house, statistically-derived LCS control limits based on historical LCS recovery data as an estimate of the minimum laboratory contribution to measurement uncertainty at a 99% confidence level.					
DoD29 Environmental Test Methods and Method Validation: Manual Integrations (Requirement) When manual integrations are performed, raw data records shall include a complete audit trail for those manipulations (i.e., the chromatograms obtained before and after the manual integration must be retained to permit reconstruction of the results). This requirement applies to all analytical runs including calibration standards and QC samples. The person performing the manual integration must sign and date each chromatogram and document the rationale for performing manual integration (electronic signature is acceptable).					
DoD30 Environmental Test Methods and Method Validation: Software Verification (Requirement) The quality system shall address all aspects of electronic data management. At a minimum, a sample data set					



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<p>shall be used to test and verify the operation of all automated data reduction processes (including data capture, manipulation, transfer, and reporting). This shall be done any time new software (including commercially available software) is installed or programming code is modified or manipulated. (Guidance) For more information about these topics, see Good Automated Laboratory Practices (EPA 2185, 1995).</p>						
<p>DoD 31 Equipment: Minimum Performance Checks and Acceptance Criteria for Support Equipment (Requirement) Method-specific requirements must be followed for verifying the accuracy of support equipment. In the absence of method-specific requirements, the minimum requirements are as follows:</p>						
Performance Check	Frequency	Acceptance Criteria	Y	N	NA	Comments (Reserved for A2LA Assessor)
<p>Balance calibration check using two traceable standard weights that bracket the expected weight</p>	<p>Daily or before use</p>	<p>Top-loading balance: ± 2% or ± 0.02 g, whichever is greater Analytical balance: ± 0.1% or ± 0.05 mg, whichever is greater</p>				
<p>Verification of standard weight, using weights traceable to the SI through</p>	<p>Every 5 years</p>	<p>Certificate of Calibration from accredited</p>				



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an NMI such as NIST.		calibration laboratory or NMI			
Monitoring of refrigerator/freezer temperature	Daily (i.e., 7 days per week)	Refrigerators: 0 °C to 6 °C Freezers: ≤-1 °C			
Thermometer calibration check, using a thermometer traceable to the SI through a NMI such as NIST, at two temperatures that bracket the target temperature(s)	Liquid in glass: Before first use and quarterly Electronic: Before first use and quarterly	Apply correction factors or replace thermometer			
Volumetric labware	Class B: Before first use Class A and B: Upon evidence of deterioration	Bias: Mean within ± 2% of nominal volume Precision: RSD ≤ 1% of nominal volume (based on 10 replicate measurements)			
Non-volumetric labware (Applicable only when used for measuring initial sample volume or final extract/digestate volume)	By lot before first use or upon evidence of deterioration	Bias: Mean within ± 3% of nominal volume Precision: RSD ≤ 3% of stated value (based on 10 replicate measurements)			
Mechanical volumetric	Before first use and quarterly	Bias: Mean within			



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<p>pipettes</p>	<p>or upon evidence of deterioration</p>	<p>± 2% of nominal volume Precision: RSD ≤ 1% of nominal volume (based on 10 replicate measurements) [Note: for variable volume pipettes, the nominal volume is the largest user-selectable volume setting]</p>				
<p>Drying oven temperature check</p>	<p>Before and after use</p>	<p>Within ± 5% of set temperature</p>				
<p>DoD32 Equipment: Second Source Standards for Initial Calibration Verification (Requirement) The requirements listed below apply when project-specific or method-specific requirements do not exist.</p> <ul style="list-style-type: none"> • The initial calibration verification shall be successfully completed prior to analyzing any samples; • The use of a standard from a second lot is acceptable when only one manufacturer of the standard exists (note: manufacturer refers to the producer of the standard, not the vendor); and • The concentration of the second source standard shall be at or near 						



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the midpoint of the calibration range. Acceptance criteria for the initial calibration verification must be at least as stringent as those for the continuing calibration verification.					
<p>DoD33 Equipment: Quantitative Values in a Calibration Curve (Requirement)</p> <p>The LOQ and the highest calibration standard of a multi-level calibration curve establish the quantitation range (see Box D-14 for requirements pertaining to the LOQ). For metals analysis with a single-point calibration, the LOQ and the calibration standard establish the quantitation range, which must lie within the linear dynamic range.</p> <p>When sample results exceed the quantitation range, the laboratory shall dilute and reanalyze the sample (when sufficient sample volume permits) to bring results within the quantitation range. For metals analysis with a single-point calibration, the laboratory may report a sample result above the quantitation range if the laboratory runs and passes a CCV that exceeds the sample result but is within the linear dynamic range.</p> <p>Results outside the quantitation range shall be reported as estimated values, qualified using appropriate data qualifiers (see Box 47) and explained in the case narrative.</p>					
<p>DoD34 Equipment: Calibration Points (Requirement)</p> <p>The initial calibration range shall consist of a minimum of five calibration points for organic analytes and three calibration points for inorganic analytes and IH samples (unless otherwise stated in the method). All reported target analytes and surrogates (if applicable) shall be included in the initial calibration. Reported results for all target analytes and surrogates shall be quantified using a multipoint calibration curve. Exclusion of calibration points without technical</p>					



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justification is not permitted.					
<p>DoD35 Equipment: Continuing Calibration Verification Frequency (Clarification) When the method specifies that CCVs shall be run at specific sample intervals, the count of these samples shall be of field samples only.</p>					
<p>DoD36 Equipment: CCV Acceptance Criteria (Requirement) The following criteria must be met:</p> <ul style="list-style-type: none"> • The concentration of the CCV standard shall be between the low calibration standard and the midpoint of the calibration range; • The source of the CCV standard should be the same as the source for the initial calibration standard(s); and • The baseline for evaluating the CCV is the initial calibration curve, except for the evaluation of retention times in organic chromatographic methods, which may be based on comparison with the retention times in the initial CCV. 					
<p>DoD37 Equipment: Corrective Action for Noncompliant CCV (Requirement) The laboratory shall reanalyze CCVs and all samples analyzed since last successful calibration verification. If reanalysis is not possible, the laboratory must notify the client prior to reporting data associated with a noncompliant CCV. If these data are reported, the data must be qualified and explained in the case narrative.</p>					



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<p>DoD38 Measurement Traceability: Lot Numbers (Requirement) Records for standards, reagents, and reference materials shall include lot numbers.</p>					
<p>DoD39 Handling of Samples: Subsampling Procedures (Requirement) Sample-handling procedures shall address laboratory practices for performing subsampling and documenting the presence of extraneous materials (e.g., rocks, twigs, vegetation) present in samples in the case of heterogeneous materials. To avoid preparing non-representative subsamples, the laboratory shall not “target” a specific sample weight (i.e., the laboratory shall not manipulate the sample material so the sample aliquot weighs exactly 1.00 g ± 0.01 g). The handling of multiphase samples shall be addressed in specific subsampling procedures, as appropriate. The laboratory’s subsampling procedures shall comply with recognized consensus standards (for example, ASTM standards or EPA’s Guidance for Obtaining Representative Laboratory Analytical Subsamples from Particulate Laboratory Samples (EPA/600/R-03/027)) where available.</p>					
<p>DoD40 Handling of Samples: Temperature Measurement (Requirement) The temperature measurement, when applicable, shall be</p>					



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verified through the use of one or more temperature blank(s) for each transport container, such as a cooler. If a temperature blank is not available, other temperature measurement procedures may be used (e.g., the use of an IR gun to monitor the surface temperature of sample containers).					
<p>DoD41 Handling of Samples: Checking Chemical Preservation (Requirement) Chemical preservation must be checked at the time of sample receipt for all samples, unless it is not technically acceptable to check preservation upon receipt. If any of the following conditions exist, chemical preservation must be checked at a later time, or rechecked in the laboratory:</p> <ul style="list-style-type: none"> • Continued preservation of the sample is in question (e.g., the sample may not be compatible with the preservation); • It is not technically acceptable to check preservation upon receipt (e.g., in the case of VOA samples); or • Deterioration of the preservation is suspected. 					
<p>DoD42 Handling of Samples: Sample Disposal (Requirement) The laboratory shall maintain appropriate documentation and records demonstrating that samples have been properly disposed of, in accordance with Federal, State, and local regulations.</p>					
DoD43 Assuring the Quality of Environmental Test and					



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<p>Calibration Results: Proficiency Testing (PT) Program (Requirement) Laboratories that perform environmental work for DoD must participate in a PT program, as defined in NELAC Chapter 2. Refer to the complete Chapter 2 and appendices for additional explanation and the NELAC website for current lists of fields of proficiency testing, PT Providers, and analyte acceptance criteria. Outside Contiguous United State (OCONUS) environmental laboratories must use a PT provider that can demonstrate compliance with ISO Guide 34:2000, ISO Guide 43:1997, and ISO/IEC 17025:2005. Laboratories performing Industrial Hygiene and/or any analysis under the Environmental Lead program must participate in the appropriate PT program administered by the American Industrial Hygiene Association (AIHA). Consult the DoD client for information and requirements about other PT programs. LABORATORY ENROLLMENT IN PT PROGRAM(S) Required Level of Participation Laboratories (Contiguous United States (CONUS) plus Alaska and Hawaii, and U.S. territories, e.g., Puerto Rico, Guam, etc.) performing environmental analysis in the United States for DoD, must obtain PT samples from a Proficiency Testing Oversight Body (PTOB)/Proficiency Testing Provider Accreditor (PTPA)-approved PT Provider. OCONUS laboratories, including those in U.S. territories, must use a PT Provider that can demonstrate compliance</p>					



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<p>with ISO Guide 34:2000, ISO Guide 43:1997, and ISO/IEC 17025:2005. Each laboratory shall participate in at least two PT studies for each field of proficiency testing per year unless a different frequency is required for a given program. Laboratories performing industrial hygiene and/or environmental lead analysis for DoD, must participate in the IHPAT and/or ELPAT, which requires participation in four PT studies for each field of proficiency testing per year.</p> <p>PT CRITERIA FOR LABORATORY ACCEPTABILITY Initial or Continuing PT Studies</p> <p>For environmental analyses, a laboratory shall successfully complete two initial or continuing PT studies for each requested field of proficiency testing within the most recent three rounds attempted. For initial acceptance, the laboratory must successfully analyze two sets of PT studies, the analyses to be performed at least 15 calendar days apart from the closing date of one study to the shipment date of another study for the same field of proficiency testing. For continuing acceptance, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart. Failure to meet the semiannual schedule is regarded as a failed study.</p> <p>For industrial hygiene analyses, the laboratory is rated proficient for the applicable field of testing/method(s) if there are no more than 25% cumulative outliers reported in the last four consecutive PT rounds in which the laboratory has participated at the time of accreditation, or there are no</p>					



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<p>outliers reported in the last two consecutive PT rounds. The laboratory must receive a passing score if not more than 25% of the reported results are outliers. A laboratory is rated proficient for the associated field of testing/Method if the laboratory has a passing score for the applicable PT analyte class in two of the last three consecutive PT rounds. A laboratory is rated non-proficient for the applicable field of testing/method if the laboratory has failing scores. For environmental lead analysis, the laboratory is rated proficient for the applicable field of testing/method(s) if there are no more than 25% cumulative outliers reported in the last four consecutive PT rounds in which the laboratory has participated at the time of accreditation, or there are no outliers reported in the last two consecutive PT rounds.</p> <p>Failed Studies and Corrective Action</p> <p>If a laboratory fails a PT study, it shall determine the cause for the failure and take any necessary corrective action. The laboratory shall provide documentation describing both the cause for the failure and the corrective action taken to the pertinent accreditation authorities. In addition, if a laboratory fails two out of the three most recent environmental PT studies for a given field of proficiency testing or is rated as non-proficient by AIHA, its performance is considered unacceptable and the laboratory shall then meet the requirements of initial acceptability for the fields of testing before analyzing any further DoD samples.</p>					



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<p>Pass/Fail Criteria for Environmental Analyte Group PT Samples (excerpted from NELAC Appendix C.5.3) Proficiency testing pass/fail evaluations for Analyte Group PT studies shall be determined as follows: To receive a score of “Pass”, a laboratory must produce acceptable results as defined in Section C.1 for 80% of the analytes in an Analyte Group PT Study. Greater than 20% “Not Acceptable” results shall result in the laboratory receiving a score of “Fail” for that group of analytes. A “Not acceptable” result for the same analyte in two out of three consecutive PT studies shall also result in the laboratory receiving a score of “Fail” for that analyte. The PCB analyte group is exempt from the 80% pass/fail criteria.</p>					
<p>DoD44 Assuring the Quality of Environmental Test and Calibration Results: Internal Data Review (Requirement) Internal data review shall consist of a tiered or sequential system of verification, consisting of at least three tiers, with each check performed by a different person. The three tiers must include at a minimum, 100% review by the analyst, 100% verification review by a technically qualified supervisor or data review specialist, and a final administrative review. The analyst and verification review must include at least the following procedures: 1. Determination of whether the results meet the laboratory-specific quality control criteria; 2. Checks to determine consistency with project-specific</p>					



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<p>measurement quality objectives (MQOs);</p> <p>3. Checks to ensure that the appropriate sample preparatory and analytical SOPs and methods were followed, and that chain-of-custody and holding time requirements were met;</p> <p>4. Checks to ensure that all calibration and quality control requirements were met; and</p> <p>5. Checks for complete and accurate explanations of anomalous results, corrective action, and the use of data qualifiers in the case narrative.</p> <p>The final administrative review shall verify that previous reviews were documented properly and that the data package is complete.</p> <p>In addition, the quality manager or designee shall review a minimum of 10% of all data packages for technical completeness and accuracy. This review is part of the QA program and does not need to be completed before the data package is issued to the client.</p> <p>If electronic audit trail functions are available, they must be in use at all times, and associated data must be accessible.</p> <p>If the instrument does not have an audit trail, the laboratory must have procedures to document the integrity of the data.</p>					
<p>DoD45 Assuring the Quality of Environmental Test and Calibration Results: Analyzing Quality Control Data (Requirement)</p> <p>Quality control samples must be processed in the same manner as field samples. They must be analyzed and reported with their associated field samples. If QC results</p>					



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are outside method-specified or project-specified criteria, planned action shall be taken to correct the problem and prevent incorrect results from being reported. (Guidance) For additional guidance on batch-specific QC samples, refer to the Quality Assurance Matrix contained in the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP).					
DoD46 Reporting the Results: Holding Times (Requirement) Both date and time of preparation and analysis are considered essential information (see Box 14).					
DoD47 Reporting the Results: Use of Data Qualifiers (Requirement) Laboratories must have a documented procedure for communicating with the client for the purpose of establishing project-specific data reporting requirements, including 1) conventions for reporting results below the LOQ and 2) specifications for the use of data qualifiers. The basis for the use of all data qualifiers must be adequately explained in the test report. In the absence of project-specific requirements, the minimum standard data qualifiers to be used by laboratories are listed below: U – Analyte was not detected and is reported as less than the LOD or as defined by the client. The LOD has been adjusted for any dilution or concentration of the sample (* see Example, below).					



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<p>J – The reported result is an estimated value (e.g., matrix interference was observed or the analyte was detected at a concentration outside the quantitation range, see Box 33).</p> <p>B – Blank contamination. The recorded result is associated with a contaminated blank (see Box D-1).</p> <p>N – Non-target analyte. The analyte is a tentatively identified compound using mass spectrometry.</p> <p>Q – One or more quality control criteria failed (e.g., LCS recovery, surrogate spike recovery or CCV).</p> <p>The laboratory may use additional data qualifiers, or different letters or symbols to denote the qualifiers listed above, as long as they are appropriately defined and their use is consistent with project-specific requirements (e.g., this document, the contract, and project-planning documents).</p> <p>[Note: These data qualifiers are for laboratory use only. Data usability must be determined by the project team.]</p> <p>(Guidance) *Example: Detection limit (DL) = 2, Limit of Detection (LOD) = 4, Limit of Quantitation (LOQ) = 15, sample is undiluted.</p> <p>Sample #1: Analytical result: Not detected; Reported result: <4 U</p> <p>Sample #2: Analytical result: 2; Reported result: 2 J</p> <p>Sample #3: Analytical result: 10; Reported result: 10 J</p> <p>Sample #4: Analytical result: 15; Reported result: 15</p>					



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<p>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:</p> <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 amount measured in any sample or 1/10 the regulatory limit (whichever is greater); • 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>					
<p>DoD D-2 Positive and Negative Controls: LCS Spiking Compounds (Requirement)</p> <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 					



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preparation of multiple LCSs to avoid interferences. • The concentration of the spiked compounds shall be at the project-specific concentration of concern. If this is not specified, it shall be at or below the midpoint of the calibration curve.					
DoD D-3 Positive and Negative Controls: LCS Control Limits (Requirement) A laboratory shall establish in-house limits that: <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 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.					



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DoD D-4 Positive and Negative Controls: LCS Marginal Exceedance (ME) Limits (Requirement) The marginal exceedance limit is four (4) standard deviations around the mean.					
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.					
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 indicative of non-random behavior.					
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.					
DoD D-8 Positive and Negative Controls: MS/MSD Spiking Compounds (Requirement)					



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<p>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.</p>					
<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>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>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).</p>					



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Duplicate analysis should be performed at a minimum frequency of once per preparatory batch per matrix type.					
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.					
DoD D-13 Limit of Detection (LOD): Determination and Verification (Requirement) 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: 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 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.					



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<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. 					
<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</p>					



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requirements and must be reported. If the method is modified, precision and bias at the new LOQ must be demonstrated and reported.					
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.					
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, 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.					

Document Revision History

Date	Description
12/20/2011	Added CAB Information Block