EPA LQSR 4.0 Working Document

ASSESSMENT INFORMATION	
Assessment Number	**Date(s)**
CAB name:	
Lead Assessor:	
Team Members:	
☐ Accreditation Assessment ☐ Reassessment ☐ EOA Reason:	
Location of Assessment: ☐ Onsite ☐ Virtual ☐ Remote Desk Review	

Instructions:

This checklist is to be used in conjunction with the ISO/IEC 17025 LF-56 Working Document and Supplement.

The assessment team is to use this checklist to evaluate the design and utilization of the management system as related to the standard requirements.

The checklist is a tool for recording the objective evidence used by the assessment team in the determination of conformance of standard requirements during the assessment.

Assessments shall be conducted using the standard, not this checklist.

Refer to the standard for complete clauses and related notes.

***** ON ACCREDITATION AND REACCREDITATION ASSESSMENTS, ALL CLAUSES OF THE STANDARD MUST BE COVERED AND DOCUMENTED ON THE THIS CHECKLIST *****

Clause	Summary of Requirement The checklist is a tool for recording the evidence of the assessment activity. **Assessments shall be conducted using the standard, not this checklist**. Refer to the standard for complete clause	Document(s) CAB QM w/section Policy/SOP/WI	Conformity Determination C/NC/NA	Objective Evidence Reviewed to Make Determination Assessor Identify documents/records/observations of practices/ results of interviews, etc. used to determine how the laboratory is/is not meeting the clause
LQSR 4 4.1	**Organization and Management**			
LQSR 4 4.1	Does the laboratory organization and management conform to ISO/IEC 17025 and ASTM E1583 and include job descriptions for all positions as well as an organizational chart identifying key personnel, their responsibilities, lines of supervision, and authority?			
LQSR 4 4.1.1	Does the Technical Manager meet the qualifications and responsibilities as defined by ISO/IEC 17025 and ASTM E1583, ensuring that adequate supervision is provided for all technical personnel?			
LQSR 4 4.1.2	Does the Quality Manager (or an appropriately contracted individual) satisfy the qualifications and responsibilities required by ISO/IEC 17025 and ASTM E1583?			
ASTM 1583-21 Section 5	**Organization**			
ASTM 1583-21 5.1	Is the laboratory legally identifiable, organized, and operating in accordance with this practice?			
ASTM 1583-21 5.2	Does the laboratory meet all organizational structure requirements, including:			
ASTM 1583-21 5.2.1	An appropriate organizational structure and quality assurance program?			
ASTM 1583-21 5.2.2	Capability demonstration upon request?			
ASTM 1583-21 5.2.3	Staff protection from undue pressure or inducement?			

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ASTM 1583-21 5.2.4	Maintenance of independence, judgment, and integrity?			
ASTM 1583-21 5.2.5	Clear awareness by staff of responsibilities and limitations?			
ASTM 1583-21 5.2.6	Employment of a competent technical manager?			
ASTM 1583-21 5.2.7	Employment or engagement of a conflict-free quality manager?			
LQSR 4 4.2	**Quality Management System**			
LQSR 4 4.2	Has the laboratory established a quality management system in conformance with ISO/IEC 17025 and/or ASTM E1583, with all items available for on-site inspection or audit?			
LQSR 4 4.2.1	Is there a documented quality management system that is reviewed annually, updated as needed, and maintained under the responsibility of the quality manager (or equivalent)?			
LQSR 4 4.2.2	Does laboratory management define, document, and communicate a quality policy statement that outlines the objectives and commitment to compliance with the required standards?			
LQSR 4 4.2.3	Is there a quality manual that documents the quality management system, including roles and responsibilities of the technical and quality managers, and is it updated and approved at least annually?			
ASTM 1583-21 6.1	Does the laboratory maintain an appropriate internal quality assurance program?			

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ASTM 1583-21 6.2	Does the quality manual adequately document:			
ASTM 1583-21 6.2.1	Organizational structure?			
ASTM 1583-21 6.2.2	Operational and functional duties related to quality?			
ASTM 1583-21 6.2.3	General quality procedures, including staff training?			
ASTM 1583-21 6.2.4	Specific procedures for each test?			
ASTM 1583-21 6.2.5	Proficiency testing and analytical quality control?			
ASTM 1583-21 6.2.6	Corrective actions and feedback mechanisms?			
ASTM 1583-21 6.2.7	Procedures for addressing technical complaints?			
ASTM 1583-21 6.2.8	Provisions for permitted departures from procedures?			
ASTM 1583-21 6.2.9	Procedures for corrections/amendments to reports?			
LQSR 4 4.3	**Document Control**			
LQSR 4 4.3.1	Does the laboratory have procedures for controlling all internal and external documents related to the quality management system in conformance with ISO/IEC 17025?			

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LQSR 4 4.3.2	Are all documents reviewed, approved, and identified, including page count or document end, as required by ISO/IEC 17025?			
LQSR 4 4.3.3	Are changes to documents made and noted in accordance with ISO/IEC 17025, with revised documents re-issued promptly?			
LQSR 4 4.3.4	Does the laboratory review and revise its quality management system documents annually in accordance with ISO/IEC 17025?			
LQSR 4 4.4	**Review of Request, Tender or Contract**			
LQSR 4 4.4	Does the laboratory have a procedure for reviewing requests, tenders, or contracts that conforms to ISO/IEC 17025 and ensures communication with the customer regarding any changes?			
LQSR 4 4.5	**Subcontracting of Tests**			
LQSR 4 4.5	Does the laboratory subcontract tests only when necessary and with customer approval, ensuring that subcontractors are accredited by an NLLAP recognized body?			
ASTM 1583-21 6.6	Does the laboratory ensure subcontractors meet relevant competence and compliance criteria?			
LQSR 4 4.6	**Purchasing Services and Supplies**			
LQSR 4 4.6	Are there policies and procedures in place for selecting and purchasing services and supplies (including reagents) in accordance with ISO/IEC 17025, with specifications			

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	documented in the quality manual or technical procedures?			
LQSR 4 4.7	**Service to the Customer**			
LQSR 4 4.7	Does the laboratory maintain effective communication and cooperation with the customer throughout the testing process, including notification of delays or deviations?			
LQSR 4 4.8	**Complaints**			
LQSR 4 4.8	Is there a documented process for receiving, evaluating, and resolving complaints in conformance with ISO/IEC 17025, including provisions for referral to the accrediting body if unresolved?			
LQSR 4 4.9	**Improvements**			
LQSR 4 4.9	Does the laboratory continually improve the effectiveness of its quality management system using quality objectives, audit results, data analysis, and corrective/preventive actions?			
LQSR 4 4.10	**Control of Nonconforming Work**			
LQSR 4 4.10	Are documented policies and procedures in place to control nonconforming work, ensuring that no data is reported until issues are resolved or justified as random events?			
LQSR 4 4.11	**Corrective Action**			

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LQSR 4 4.11.1	Does the laboratory have a corrective action policy and procedure in conformance with ISO/IEC 17025 and ASTM E1583 that includes notifying affected customers and amending results when necessary?			
LQSR 4 4.11.2	Does the corrective action process begin with an investigation to determine the root cause(s) of any nonconformance?			
LQSR 4 4.11.3	Once root causes are identified, are appropriate corrective actions selected and implemented to mitigate and prevent recurrence?			
LQSR 4 4.11.4	Are corrective actions monitored to ensure they are effective in addressing the identified problems?			
LQSR 4 4.11.5	Are special audits conducted when there is doubt regarding compliance with internal policies or relevant standards?			
LQSR 4 4.12	**Preventive Action**			
LQSR 4 4.12	Does the laboratory implement preventive actions to address potential sources of nonconformance in line with ISO/IEC 17025?			
LQSR 4 4.13	**Records**			
LQSR 4 4.13	Are records maintained for each laboratory activity to allow for repetition or verification, in accordance with ASTM E1583?			
LQSR 4 4.13.1	Does the laboratory maintain sample records documenting all procedures (sampling, preparation, testing) for at least five years?			

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LQSR 4 4.13.2	Are all raw data, final reports, SOPs, and related documents retained as part of the laboratory's quality management system?			
LQSR 4 4.13.3	Are electronic records secured with appropriate backup procedures to ensure data integrity and compliance with record keeping requirements?			
LQSR 4 4.14	**Internal Audits**			
LQSR 4 4.14	Does the laboratory perform internal audits at least annually in compliance with ISO/IEC 17025 and ASTM E1583, with audit findings documented?			
ASTM 1583-21 6.3	Does the laboratory arrange regular audits of its quality management system?			
ASTM 1583-21 6.5	Are audit findings and corrective actions fully documented?			
LQSR 4 4.15	**Management Reviews**			
LQSR 4 4.15	Are management reviews of the quality system conducted at least once a year to ensure continuing suitability, effectiveness, and timely implementation of necessary improvements?			
ASTM 1583-21 6.4	Is the quality management system periodically reviewed by management?			
LQSR 4 5.1	**Personnel**			
LQSR 4 5.1	Does laboratory management ensure that all personnel involved in lead sampling and testing are educated,			

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	trained, experienced, and competent in accordance with ISO/IEC 17025 and ASTM E1583?			
LQSR 4 5.1.1	Do analysts and technicians possess the necessary education, training, and experience to perform tests, operate equipment, evaluate results, and sign test reports when authorized?			
LQSR 4 5.1.1.1	Are minimum qualifications and training requirements met by analysts and technicians, including completion of training programs and demonstration of proficiency through independent test runs?			
LQSR 4 5.1.1.2	Are mobile laboratory and FSMO personnel certified as required by EPA or state/tribal programs, and are they evaluated by competent supervisors for their initial job sites?			
ASTM 1583-21 7.1	Does the laboratory have sufficient personnel with required education, training, knowledge, and experience?			
ASTM 1583-21 7.2	Is the training of personnel regularly updated?			
ASTM 1583-21 7.3	Are records of personnel qualifications and authorizations maintained?			
LQSR 4 5.2	**Accommodation And Environmental Conditions**			
LQSR 4 5.2	Does the laboratory operate in facilities that are suitable for lead testing and comply with environmental conditions as required by ISO/IEC 17025 and ASTM E1583?			
LQSR 4 5.2.1	Are contamination control measures implemented, including laboratory dust wipe checks and labware cleaning, to prevent external contamination?			

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LQSR 4 5.2.1.1	Are dust wipe checks conducted at least quarterly to ensure surface contamination is below the allowable limit before proceeding with sample analysis?			
LQSR 4 5.2.1.2	Are cleaning procedures for labware clearly specified in an SOP, including frequency and monitoring of potential contamination?			
ASTM 1583-21 8.1	Does the laboratory have all necessary facilities?			
ASTM 1583-21 8.1.1	Are space, lighting, environmental control, and monitoring adequate?			
LQSR 4 5.3	**Test and Sampling Methods**			
LQSR 4 5.3	Are test methods and sampling procedures in conformity with ISO/IEC 17025 and ASTM E1583, including validation, performance demonstration, and proper documentation?			
LQSR 4 5.3.1	Are acceptable test methods or SOPs used that have been validated for method detection limits, bias, and precision, and are only used after demonstrating proficiency?			
LQSR 4 5.3.2	Does the laboratory validate and document method performance in accordance with ISO/IEC 17025 and ASTM E1583?			
LQSR 4 5.3.3	Are SOPs available to all personnel at work locations and do they address critical aspects such as detection limits, equipment calibration, quality control, and corrective actions?			

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LQSR 4 5.3.4	Does the laboratory establish method performance characteristics that meet or do not exceed the minimum performance standards specified?			
LQSR 4 5.3.5	Are method detection limits established, statistically verified, and monitored for each method and matrix as required?			
LQSR 4 5.3.5.1	Are quantitation limits set at values at least 1.6 times but no more than 10 times the method detection limit?			
LQSR 4 5.3.5.2	Are bias and precision determined for each analytical method, with results documented and maintained on file?			
LQSR 4 5.3.6	Is subsampling conducted in accordance with ASTM E1583 for preparing sample aliquots?			
LQSR 4 5.3.7	Does the data reduction and review process include quality control comparisons, verification of computations, and double-checking of data transcription?			
LQSR 4 5.3.7.1	Are procedures in place for estimating the uncertainty of measurement, with all components identified and reported appropriately?			
ASTM 1583-21 8.1.2	Are standard methods for lead determination consistently applied?			
ASTM 1583-21 10.1	Are instructions available for equipment use, specimen handling, and testing procedures?			
ASTM 1583-21 10.2	Are methods validated for precision and accuracy through appropriate evaluation?			
ASTM 1583-21 10.3	Are testing methods readily available to staff?			

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ASTM 1583-21 10.4	Are deviations from standard methods validated and documented for accuracy and precision?			
ASTM 1583-21 10.5	Are calculations related to test results checked appropriately?			
ASTM 1583-21 10.6	Are computerized systems validated initially and periodically for continued validity?			
LQSR 4 5.4	**Equipment**			
LQSR 4 5.4	Is the laboratory furnished with appropriate equipment that is maintained and used only by authorized personnel in accordance with ISO/IEC 17025 and ASTM E1583?			
LQSR 4 5.4.1	Are instruments calibrated daily or prior to analysis and verified using matrix-matched reference materials to ensure acceptable performance?			
LQSR 4 5.4.2	Are calibration performance standards established for instruments, including initial calibration, independent calibration verification, continuing calibration verification, and continuing calibration blank, with specified acceptance criteria?			
LQSR 4 5.4.2.1	Are at least three calibration standards and an initial calibration blank used to construct a calibration curve before sample analysis?			
LQSR 4 5.4.2.2	Is an independent calibration verification standard analyzed daily or before sample analysis, with results meeting the specified criteria?			
LQSR 4 5.4.2.3	Are continuing calibration verification standards analyzed at the designated frequency and do they comply with the acceptance limits?			

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LQSR 4 5.4.2.4	Is a continuing calibration blank analyzed as specified in the SOP to confirm blank response and absence of carryover?			
ASTM 1583-21 8.1	Does the laboratory have all necessary equipment?			
ASTM 1583-21 8.2	Does the laboratory maintain equipment appropriately?			
ASTM 1583-21 8.2.1	Are maintenance instructions available?			
ASTM 1583-21 8.2.2	Are detailed equipment records maintained?			
LQSR 4 5.5	**Measurement Traceability**			
LQSR 4 5.5	Does the laboratory maintain an established system for ensuring measurement traceability of equipment, reference materials, and standards?			
LQSR 4 5.5.1	Are reference standards and materials certified, traceable to NIST (or equivalent), and used within their expiration dates?			
LQSR 4 5.5.2	Is documentation maintained for the preparation of reagents and calibration solutions, including details on preparation date, identity, concentration, and expiration date?			
ASTM 1583-21 8.2.3	Are calibration records maintained appropriately?			
ASTM 1583-21 9.1	Is all measurement and testing equipment calibrated by accredited organizations?			

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ASTM 1583-21 9.2	Is analytical equipment calibration verified daily before use?			
ASTM 1583-21 9.3	Does the calibration program maintain traceability to certified national or international standards?			
ASTM 1583-21 9.4	Are calibration and verification procedures performed according to test methods?			
LQSR 4 5.6	**Sampling and Sampling Handling (ASTM 1583-21)**			
LQSR 4 5.6	Does the laboratory perform sampling in accordance with 40 CFR Part 745, ISO/IEC 17025, and ASTM E1583, ensuring proper sample handling, acceptance, and documentation?			
LQSR 4 5.6.1	Are sampling media evaluated for lead contamination as per ASTM E1792-20 and specified in a written SOP?			
LQSR 4 5.6.1.1	Is there a written sample acceptance policy that outlines criteria for documentation, labeling, container use, and adequate sample quantity?			
LQSR 4 5.6.1.2	Does the laboratory maintain permanent logs documenting sample receipt with all required details?			
LQSR 4 5.6.1.3	Are procedures in place to document and resolve doubts about sample suitability, including communication with the customer?			
LQSR 4 5.6.1.4	Are chain of custody protocols established to ensure the secure handling, storage, and disposal of samples?			
LQSR 4 5.6.1.5	Is there a documented system to uniquely identify and track samples, subsamples, and related extracts or digestates?			

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ASTM 1583-21 11.1	Does the laboratory have a documented system for uniquely identifying specimens?			
ASTM 1583-21 11.2	Are specimens protected from deterioration or damage during handling?			
ASTM 1583-21 11.3	Are there clear procedures for receipt, storage, retention, and disposal of specimens?			
ASTM 1583-21 11.4	Are appropriate statistical methods documented and used when subsampling?			
ASTM 1583-21 Section 12	**Records**			
ASTM 1583-21 12.1	Are comprehensive records maintained for at least five years?			
ASTM 1583-21 12.2	Are records and test reports kept secure and confidential?			
LQSR 4 5.7	**Assuring The Quality Of Test Results**			
LQSR 4 5.7	Does the laboratory ensure the quality of test results through internal quality control, proficiency testing, and statistical process control?			
LQSR 4 5.7.1	Are quality control procedures implemented, including the use of duplicate samples, spiked samples, blind samples, and control charts, to monitor test validity?			
LQSR 4 5.7.1.1	Are Laboratory Control Samples (LCS) analyzed at the required frequency to determine bias in a manner consistent with the sample matrix?			
LQSR 4 5.7.1.2	Is precision determined through split or duplicate sample analyses with acceptable relative percent differences?			

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LQSR 4 5.7.2	Are control charts or a quality control database used to record QC data and monitor laboratory performance in real time?			
LQSR 4 5.7.3	Are procedures established to identify and address out-of-control situations when QC sample results fall outside acceptance limits?			
LQSR 4 5.8	**Reporting The Results**			
LQSR 4 5.8	Are test results reported in conformance with ISO/IEC 17025 and ASTM E1583, including details of the accrediting body?			
LQSR 4 5.8.1	Is there a method to report results below the quantitation limit with an appropriate qualifier (e.g., ‚Äòless than‚Äô a positive finite value), rather than reporting zero?			
LQSR 4 5.8.1.1	Are opinions and interpretations in test reports provided in accordance with ISO/IEC 17025?			
LQSR 4 5.8.2	Do all final test reports undergo a documented review and approval process by a qualified, independent reviewer?			
LQSR 4 5.8.3	Are procedures in place for making corrections or additions to test reports that comply with ISO/IEC 17025 and ASTM E1583, including proper identification of subcontracted work?			
ASTM 1583-21 13.1	Do laboratory reports present clear, accurate, and unambiguous results?			
ASTM 1583-21 13.2	Do laboratory reports contain required information, including:			

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ASTM 1583-21 13.2.1	Laboratory name and address?			
ASTM 1583-21 13.2.2	Unique report identification?			
ASTM 1583-21 13.2.3	Client name and address?			
ASTM 1583-21 13.2.4	Description and identification of specimens?			
ASTM 1583-21 13.2.5	Receipt and test dates?			
ASTM 1583-21 13.2.6	Identification and limits of test methods?			
ASTM 1583-21 13.2.7	Sampling procedure description?			
ASTM 1583-21 13.2.8	Documentation of deviations or exclusions from standard procedures?			
ASTM 1583-21 13.2.9	Measured and derived results, supported by tables or graphs?			
ASTM 1583-21 13.2.10	Measurement uncertainty statement?			
ASTM 1583-21 13.2.11	Identification of responsible technical personnel?			
ASTM 1583-21 13.2.12	Statements regarding airborne particulate analyses (cassette wall deposits)?			
ASTM 1583-21 13.3	Are corrections and additions to reports managed according to documented requirements?			

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ASTM 1583-21 13.3.1	Are corrected reports issued in compliance with these requirements?			
ASTM 1583-21 13.3.2	Are clients promptly notified in writing of any event affecting the validity of results?			