

EPA National Lead Laboratory Accreditation Program Laboratory Quality System Requirements (LQSR) Revision 3.0 (July 5, 2007) Working Document

NOTES:

- This working document is intended as a checklist for the assessor when conducting Testing Laboratory Accreditation Assessments according to the EPA Laboratory Quality System Requirements (LQSR) Revision 3.0 (July 5, 2007).
- 2. Please make notes in the <u>Comments</u> column any deficiencies in the laboratory's management system identified during the assessment (see item #3). These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations. At a minimum should be 1 comment per major element of the checklist. (e.g. 4.1, 4.2, 5.8, 5.10 etc)
- 3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.
- 4. Assess the system only to the relevant standard and to the requested scope of accreditation. Do not be concerned with system requirements stemming from:
 - · Company- or facility-imposed policies
 - Subcontractors
 - Other sources
- If additional questions arise during the assessment, indicate them (and the appropriate responses)
 either in the blank working document pages at the end of this document or in the empty rows
 included in some of the sections.
- 6. Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."
- 7. If, at any time, the assessment team requires assistance in the interpretation of the requirements of Laboratory Quality System Requirements (LQSR) Revision 3.0 (July 5, 2007), contact the PJLA office immediately.

Assessment Number:	
Client:	
Address:	
Contact/Management Rep.:	
Lead Assessor:	
Assessment Team:	

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	MANAGEMENT REQ	UIREM	IENTS	
4.1 Or	ganization			
4.1.5 LQSR 4.1	b) have arrangements to ensure that its management & personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work or other conflicts of interest??			
LQSR 4.1 4.2.3	f) have an organization chart (or other means) that identifies key personnel, responsibilies, authorities, and interrelationships of staff?			
LQSR 4.1.1.1 4.1.1.2	h) have technical management ("Technical Manager(s)" or however named) with overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations Is the technical manager (or managers, however named): • qualified by the appropriate education, training, and experience (or a combination thereof) in the laboratory's measurement technologies to: • design and implement the management system • identify departures for the quality management system or its procedures and initiate action to prevent or minimize them • responsible for all technical operations • available to address technical issues or laboratory staff and customers • able to assess and document the competence of personnel (see 5.2.1) • able to ensure adequate			

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PJLA				
LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	supervision of all laboratory technical personnel (4.1.1.2).			
4.1.5	i) appoint a member of staff as quality manager (however named)?			
	Does this quality manager have:			
LQSR 4.1.2.1	Is the quality manager (however named):			
4.1.2.2	 qualified by the appropriate education, training, and experience (or a combination) to identify the departures from the quality management system or its procedures and initiate action to prevent or minimize them? knowledgeable in the quality management system and the technical and management system procedures? responsible and authorized to implement and oversee the quality management system, implement new quality assurance and control practices, plan/perform periodic audits of the quality management system, perform periodic review of test reports prior to issue and ensure the laboratory quality management system deficiencies (however named) are documented and that corrective actions are implemented? 			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
LQSR 4.1	I) identify a responsible laboratory official (or officials) authorized to release test reports on behalf of the laboratory. Note: In a laboratory with only one person, that person will be responsible for the release of the report. That person may serve as the technical manager or the quality manager but not both. In the case of a laboratory with only one person, one of these positions shall be contracted out. See LQSR sections 4.14, 5.4.6 and 5.10.3.			
4.2 M	anagement System			
4.2.2 LQSR 4.2	Are the lab's management system policies and objectives defined in a Quality Management Systems Manual (QMSM, a.k.a."quality manual"- however named)?			
LQSR 4.2.2	Has the quality policy statement been issued under the authority of top management (i.e., the CEO, President, Executive Director, etc.)			
LQSR 4.2.a, 4.2.2.e	e) the laboratory management's commitment to compliance with this standard (i.e. the LQSR) and to continually improve the effectiveness of the management system?			
4.2.6	Does the quality manual define the roles and responsibilities of the technical and quality managers, including the roles which ensure compliance with the LQSR?			
4.3 D	ocument Control			
4.3.1 LQSR 4.2.1.a	Has the laboratory established and maintained procedures to control all documents that form part of its management system (internally generated or from external sources) such as regulations, standards, other normative documents, test and calibration methods, as well as			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	drawings, software, specifications, instructions and manuals?			
4.3.2.2 LQSR 4.2.1.d, 4.2.3, 4.3.4	b) documents are periodically reviewed at least annually and where necessary, revised to ensure continuing suitability and compliance with applicable requirements?			
LQSR 4.2.5.b	Do the quality manual and the related quality documents include or address at least the following: title page, table of contents, management requirements and all the elements of the LQSR 4.1-5.10?			
4.5 St	ubcontracting of Tests			
4.5.1 LQSR 4.5	When a laboratory subcontracts work for lead testing included in laboratory's NLLAP scope, whether because of unforeseen reasons (workload, need for further expertise or temporary incapacity) or on a continuing basis (permanent subcontracting, agency or franchising arrangements), is the subcontractor accredited by an NLLAP recognized accreditation body for the method(s) in question?			
4.5.2 LQSR 4.5	Does the laboratory advise the customer of the arrangement in writing? Does the laboratory gain the approval of the customer, preferably in writing?			
4.6 Pt	urchasing Services and Supplies			
LQSR 4.6.1.2	Are reagents and standards inspected, dated and initialed or otherwise evaluated to verify compliance to purchasing documented specifications?			
LQSR 4.6.1.2	Are expiration dates assigned to each reagent and standard (by the supplier			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	or by the laboratory)?			
	Are reagents and standards <i>not</i> used beyond assigned expiration dates or <i>not</i> used if damaged or contaminated or suspected to be damaged or contaminated?			
LQSR 4.6.1	Are requirements for reagents and standards specified in the quality manual and/or technical procedures?			
LQSR 4.6.1.1	Are reagents used at least American Chemical Society (ACS) reagent grade or the quality specified by the analytical method?			
4.8 Co	omplaints			
LQSR 4.8	Does the policy include a notice to the effect "Any complaint about the quality of the reported results may be referred to the accrediting body if such complaints cannot be resolved directly with the customer"?			
4.9 Cd	ontrol of Nonconforming Testing			
4.9.1	b) an evaluation of the significance of the nonconforming work is made?			
LQSR 4.10	Is no data reported until the cause of the problem is determined and corrected, or the laboratory demonstrates the root cause of the nonconformance was a "random event"?			
4.9.1 LQSR 4.11.1	d) where necessary, the customer is notified and work is recalled? Is the customer informed of the corrective action? Are reports corrected/amended?			
4.11 Co	orrective Action			
4.11.5 LQSR	When complaints, nonconformities or any other circumstances raise doubts with regards to the			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.8	laboratory's compliance with its own policies and procedures, the LQSR, the quality management system or the quality of the laboratory's analyses, are the areas of the activities promptly audited in accordance with 4.14?			
4.13 Cd	ontrol of Records			
LQSR 4.13.1	Do records of all procedures to which a sample is subjected (sampling, preparation, and testing) include (but not limited to): • sample identification, receipt, acceptance or rejection and log-in • sample storage and tracking including shipping receipts, where applicable • sample preparation, instrument printouts, and calculations, where applicable • sample analysis logs • standard and reagent origin, receipt, preparation and use • equipment and instrument operating conditions • calibration criteria, frequency and acceptance criteria • data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conditions • method performance criteria • quality control protocols and assessment • storage and retention • sample disposal procedures and schedule?			
LQSR 4.13.2	Are the following laboratory quality management system and test records retained: • all original raw data (hard copy or electronic) for sampling and testing to include: calibrations, samples, quality control			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	measurements, work sheets and data output/instrument response readout records a written description or reference to the specific method used including the specific steps in the calculations used to derive the reportable analytical values copies of the final reports archived standard operating procedures correspondence relating to laboratory work activities performance evaluation results and raw data data review and cross checking			
LQSR 5.10.2	Along with the final report, does the laboratory maintain a sample case file or an equivalent which contains the information required in the LQSR for a minimum of five years?			
LQSR 4.13.b.	Do the records include a history of the locations of mobile laboratory and FSMO operations, including a specific description of where sample and testing work activity was performed?			
4.13.1.2	Are all records legible?			
LQSR 4.13. f.	Are all handwritten records and corrections made using permanent ink?			
LQSR 4.13. c.	Are all records retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss? Is access to archived records controlled with an access log or equivalent?			
LQSR 4.13.b.	Are the retention times established?			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Are all laboratory records associated with work activities retained for a minimum of five (5) years			
LQSR 4.13.3	Do records stored or generated by computer have hard copy or write protected back up copies?			
4.13.2.1 LQSR 4.13	Do the records for each test contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original or otherwise verified? Does the record keeping system allow the historical retrieval of all laboratory activities that were used to produce the particular test report?			
4.13.2.1 LQSR 4.13.e.	Do the records include the identity of personnel responsible for the			
4.14 In	ternal Audits			
LQSR 4.13.d.	In the event of going out of business does the laboratory have a plan to ensure its records are maintained or transferred according customer instructions or applicable regulations?			
4.14.1 LQSR	Does the laboratory periodically, in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this standard?			
4.14	Is the cycle for internal auditing to be			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	completed at least annually?			
LQSR 4.14	In a one person operation are the audits conducted by the person or a contractor?			
	If done by the individual, does the person follow recognized guidance (ISO 19011, ASTM, ANSI, etc)?			
	If conducted by a contractor, is the contractor competent?			
4.15 Ma	anagement Reviews			
4.15.1	In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?			
LQSR 4.15	Are management reviews conducted at least once per year?			
	TECHNICAL REQU	IREME	NTS	
5.2 Pe	ersonnel (Not required for surveillance	unless	critical	changes have occurred)
LQSR 5.2.1.1	Do training records include: a description of program contents, duration of training, trainer qualifications, and objective evidence of analyst/technician has successfully demonstrated competence in selecting and/or collecting samples or prepared or tested known reference samples of the matrices of concern?			
	Have analysts and/or technicians completed a minimum of four (4) independent test runs of sample preparation (if applicable) and/or instrument analysis for each matrix?			
	Does each independent run consist of at least five (5) samples of known lead			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	content, one of which is a certified reference material or proficiency testing material – separated by sufficient time to evaluate the performance of any previous independent run(s)? For sample preparation training, do the recoveries of the associated reference materials or proficiency samples meet			
	the requirements of Table 3 (see Appendix B of this checklist)?			
	For instrumental analysis training, do the recoveries of the associated reference materials or proficiency samples for each run meet the requirements of Table 3 or 4, as appropriate (see Appendix B of this checklist)?			
	NOTE: For some analytical testing technologies it may not be possible to separate the sample preparation techniques from instrumental analyses. In such cases, the training requirements shall be based on the minimum requirements stated for both analysts and technicians.			
	Are the reference materials/proficiency test samples used similar to matrices the analyst/technician will encounter in routine lead sample analysis and cover the sample mass/concentration range for which the analytical SOP has been validated?			
	Have analyst/technicians periodically demonstrated their ability to proficiently test samples for lead at least every six (6) months?			
LQSR 5.2.1.2. 1	Are all mobile laboratory and FSMO personnel designating sampling areas for lead based risk assessment in target housing and/or child occupied facilities certified by the EPA or an			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	authorized state or tribal program pursuant to Sec. 402 of the Toxic Substance Control Act (TSCA)?			
LQSR 5.2.1.2. 2	Are all mobile and FSMO technicians evaluated by a qualified supervisor for their first two NLLAP related job sites?			
5.2.4 LQSR 4.1	Does the laboratory maintain current job descriptions for all positions including mobile laboratories and FSMOs? NOTE: Job descriptions, as a minimum, should define: • responsibilities for performing tests/calibrations • responsibilities for planning and evaluation of results of tests/calibrations • responsibilities for reporting interpretations • responsibilities for method modifications and development and validation of new methods • expertise/experience required • qualifications/training programs-managerial duties			
5.3 Acco	mmodation and Environmental Condition	ons		
LQSR 5.3	Do fixed site or mobile laboratory operations have the space, equipment, instruments, ventilation, utility services, storage space, safety equipment, and documentation and references to analyze for lead concentrations in the area of concern (see 29 CFR § 1910.1450)?			
LQSR 5.3	Do FSMOs have appropriate facilities to maintain integrity of sampling or testing equipment when not in use?			
LQSR 5.3.1.1	Are portable testing activities, sample collection and field testing conducted to minimize risk of cross contamination?			
LQSR 5.3.1.1	At fixed site and mobile laboratory facilities, is wipe sampling of sample			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	preparation and testing area surfaces conducted at least on a quarterly basis to determine the surface contamination level of lead?			
	Are sample preparation and analysis suspended until the surface contamination is below the specified maximum allowable concentration of 50% of the lowest regulatory limit for dust wipe samples? (see 40 CFR Part 745 Final Rule, Federal Register, Vol. 61, no 169, August 29, 19696, page 4573)			
	For FSMOs are appropriate contamination control blank samples run to monitor potential lead contamination as outlined in the quality manual?			
LQSR 5.3.1.2	Are lab ware cleaning procedures specified in a written standard operating procedure or instruction?			
	Does the procedure include, where applicable, the frequency for monitoring lead concentrations in cleaning baths, the monitoring of glassware contamination during the analysis of reagent or other blanks, and periodic analysis of disposable lab ware contamination by analyzing reagent or other blanks?			
	NOTE: To assess possible contamination, glassware used for the method blanks should be processed through acid baths used for lab ware cleaning.			
5.4 Test I	Methods and Method Validation			
LQSR 5.4.1a	Prior to using methods for sample analysis has the laboratory confirmed and documented its proficiency?			
LQSR 5.4.1.a	Is competency demonstrated over the lead concentration and sample mass			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	ranges for each matrix in the scope?			
LQSR 5.4.1.b	If sample preparation and analysis methods are not specified by regulatory programs, does the laboratory, whenever possible, used validated procedures published federal agencies (USEPA, HUD, NIOSH, etc.), state agencies, or national or international recognized consensus organizations such as the ASTM? NOTE: Acceptable methods are cited in 40 CFR Part 745 – Lead Based Activities.			
LQSR 5.4.1.b	For each method has the laboratory demonstrated a quantitation limit less than or equal to 20% of the lowest relevant action level or regulatory limit for paint and soil, and 50% of the lowest level for dust wipes?			
LQSR 5.4.1	Does the laboratory have records of method performance demonstration and validation for laboratory developed or modified procedures? Do these include method detection limit (MDL) and bias and precision?			
LQSR 5.4.3.1	Sampling, test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following:			
	 method detection limit scope and application summary of the method definitions applicable matrix or matrices applicable lead concentration range applicable sample mass range method performance (bias and precision) interferences safety considerations 			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	 reagents and standards equipment and supplies sample collection (where applicable) sample preservation and storage (where applicable) sample preparation including grinding, homogenization, and sub sampling (where applicable) instrument calibration/verification quality control procedures detailed step-by-step procedures calculations data acceptance criteria corrective actions for out-of-control data contingencies for handling out of control data references NOTE: Attachments or other references to SOPs may be used to meet the above. 			
LQSR 5.4.1.c	Does the laboratory validate the following to confirm that the methods are fit for the intended use? - new or non-standard methods - lab-designed/developed methods - standard methods used outside their intended scope - amplifications/modifications of standard methods			
LQSR 5.4.1.c	Do the methods meet the performance requirements of LQSR 5.4.1.b above?			
LQSR 5.4.1.c	If methods are validated by a third party do they meet the performance requirements of LQSR 5.4.1.b above? Has the laboratory determined its competency in following third party validated methods as described in LQSR 5.4.1.a (see above)?			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
LQSR 5.4.4	Are the laboratory's statistically determined minimum method performances within those provided in LQSR Tables 3 and 4? (see Appendix B of this checklist)			
LQSR 5.4.4.1	Are method detection limits (MDLs) established, statistically verified and monitored as needed for each methods and matrix?			
	For methods with stated MDLs, has the laboratory demonstrated and documented its ability to meets these MDLs?			
	Has the documented SOP for determining MDLs shown the laboratory can demonstrate the ability to detect the lead level below the action level in the matrix of concern?			
LQSR 5.4.4.2	Are the quantitation limits less than a value at least 2 times but no greater than 10 times the respective MDL?			
LQSR 5.4.4.3	Are the bias and precision determined for each analytical method? Are the bias and precision documented?			
	Do the bias and precision meet the minimum criteria in LQSR Tables 3 and 4? (see Appendix B of this checklist)			
LQSR 5.4.4.4	Does the laboratory use documented procedures and appropriate techniques for representative subsampling of sample aliquots from submitted samples?			
LQSR 5.4.4.5	Are data reduction and review conducted by a qualified person? Does this reduction and review include (but limited to): comparison of quality control data, computation verification, transcription of data, and adherence to			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	the SOPs?			
	Where appropriate, are computations verified and transcription of data double checked?			
	Is the review process documented and records retained with the final report for at least 5 years?			
	NOTE: Qualified persons can be technicians, analysts, the quality manager, technical manager, or a responsible person described in LQSR 4.0. In the case of a one person laboratory, the review process shall be contracted out to an independent person or firm that is competent in terms of experience and training.			
LQSR 5.4.1.c	Are acceptable operating characteristics for non-numerical or pass/fail technologies or methods appropriate to the associated regulatory limits?			
	NOTE: For example, the measured values including its 95% uncertainty of measurement must be less than the associated regulatory limit.			
LQSR 5.4.1.d	Do the methods used for composite dust wipe samples address the increase in sample mass?			
	Has the laboratory met the minimum performance requirements in LQSR 5.4.1.b and demonstrated its competency in 5.4.1.a?			
5.5 Ec	quipment			
5.5.1	In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of the LQSR are met?			
LQSR 5.5	i) organization performing the repair, contact, phone number			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
LQSR 5.4.4	j) date put into service			
LQSR 5.5.1	Are instruments that are routinely calibrated verified daily or prior to analyzing samples? Are acceptance criteria determined and documented? NOTE: Such checks may include: instrument sensitivity, noise levels,			
	instrument response, and interference levels to be compared to historical performance levels.			
LQSR 5.5.1	Are instrument calibration/performance verifications done using reference standard materials of the same matrix as the materials being measured (if available)?			
LQSR 5.5.1	Are QC limits and frequencies determined and implemented? If not, are types of samples, minimum frequencies and required acceptance limits shown in LQSR Tables 1 and 2			
LQSR 5.5.1.a	met? (see Appendix A of this checklist) Does the laboratory have a system of equipment calibration (where applicable)?			
LQSR 5.5.2.a	Do all calibration curves bracket the expected sample concentrations? Are calibration standards distributed evenly across the range? Are calibration curves dated, labeled and included at least the following: • applicable method • instrument identification • analysis date • lead concentrations • instrument response identification of personnel responsible			
LQSR	Are the axes of the curves labeled?			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.5.2.b	For electronic systems that automatically compute the calibration curve are the curve equations and correlation coefficient recorded?			
LQSR 5.5.2.c	Are the criteria for the acceptance of a calibration curve established and documented?			
LQSR 5.5.2.d	For linear curves is the extent of the linear range verified and are calibration standards limited to that range?			
LQSR 5.5.2.1	Initial Calibration: Prior to the analysis of samples (as appropriate) are at least three calibration standards which span or bracket the sample concentrations and an initial calibration blank (ICB) used to construct the calibration curve? Are calibration acceptance criteria stated? Are new calibration curves established whenever out of control conditions are indicated? If a linear fit is used is linearity evaluated using the calibration standards? Are acceptance criteria stated (see			
	LQSR Table 1 and 2, Appendix A of this checklist)? NOTE: For those technologies and software requiring fewer calibration standards manufacturer recommendations are to be followed.			
LQSR 5.5.2.2	Independent Calibration Verification (ICV): Is an independent calibration standard analyzed daily or prior to analyzing a sample?			
	Are minimum performance criteria contained in LQSR Tables 1 and 2			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	(Appendix A of this checklist) met? For instruments that produce a numerical result is the ICV standard at a lead level in the range of the customer specified levels of concern or action levels such as regulatory limits? For instruments that produce a pass/fail result (except for positive or negative screening): Is the ICV Positive (ICV-P) lead level no more than 20% above the applicable regulatory limit? Is the ICV Negative (ICV-N) not less than 20% below the applicable regulatory limit?			
LQSR 5.5.2.3	Continuing Calibration Verification: Are continuing calibration verification (CCV) standards analyzed per the SOP? Is the CCV standard prepared from an independent reference standard or from the same standards used to prepare the instrument calibration curve? Are acceptance criteria stated (see LQSR Table 1 and 2, see Appendix A of this checklist)?			
LQSR 5.5.2.3. a	Are at least two CCV standards analyzed every 12 hours, or according to the instrument manufacturer's recommendation, or at a predetermined SOP frequency – whichever is most frequent?			
LQSR 5.5.2.3. b	For instruments that produce a numerical result, are the concentration of these standards determined by the operating range of the instrument, the regulatory limits, and/ method specified levels?			
LQSR 5.5.2.3.	For instruments that produce a pass/fail result, are the concentration			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
С	of these standards determined by the operating range of the instrument, the regulatory limits, and/ method specified levels?			
	For instruments that produce a pass/fail result (except for positive or negative screening): • Do the QC samples have lead levels no more than 20% above the applicable regulatory limit for the CCV Positive (CCV-P)? Do the QC samples have lead levels not less than 20% below the applicable regulatory limit for CCV Negative (CCV-N)?			
LQSR 5.5.2.3. d	When two consecutive CCV checks are outside acceptable limits is a new calibration curve established?			
	When a CCV is confirmed outside the limits are the samples affected reanalyzed after the new curve is established, evaluated and accepted?			
	Is sample analysis suspended and not restarted until a new curve is established and verified?			
LQSR 5.5.2.4	Are continuing calibration blank (CCB) standards analyzed in accordance with the testing SOP?			
5.6 M	easurement Traceability			
Note: Mu	st include evidence of traceability for a	II aspe	cts of 5	.6
5.6.2.1.	For laboratories performing their own calibration, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI)?			
5.6.2.1.	Does a laboratory performing its own calibration establish traceability of its own measurement standards and measuring instruments to the SI by			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)	
	means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI measurement units?				
5.6.2.1. 1 NIST 5.6.1	Is the link to SI units achieved by reference to national measurement standards (when available: NIST or another BIPM signatory)?				
LQSR 5.6.1	Do reference materials have an expiration date assigned? Are reference materials <i>not</i> used past their expiration date? Are reference materials <i>not</i> used if damaged, contaminated or suspected of being damaged or contaminated?				
LQSR 5.6.1	Are records of all reference standards, reference materials, and reagents including certificates of analysis, purity, origin and traceability, as provided by the manufacturer, maintained for a period of at least 5 years?				
5.7 Sa	ampling				
LQSR 5.7	When collecting dust, paint and soil samples as part of testing for lead, is the sampling performed in accordance to 40 CFR 745 – Lead Based Paint Activities?				
LQSR 5.7.1	If the laboratory is responsible for supplying sampling media, is the media evaluated, as appropriate, for lead contamination? Is the evaluation process defined in an SOP and the results recorded?				
5.8 Ha	5.8 Handling of Test Items				
LQSR 5.8.1	Are the procedures available to sample collecting personnel?				
LQSR 5.8.2	Does the laboratory have a system for uniquely identifying test items?				

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
LQSR 5.8.2.5	Are multiple aliquots of a sample assigned a different ID code (e.g. a prefix or a suffix)?			
LQSR 5.8.2.1	Is there full and complete documentation including sample identification, the location and date of sampling, sample matrix, and special remarks concerning the sample? Does sample labeling include unique			
	field identification? Are appropriate sample containers used?			
	Is there adequate sample for analysis?			
LQSR 5.8.2.2	Is there a permanent record such as a log book or equivalent electronic record to document the receipt of all samples? Does the record contain:			
	Is all associated documentation such as memos, transmittal forms for the sample retained?			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
LQSR 5.8.2.3	For samples that do not meet acceptance criteria:			
	Does the laboratory retain correspondence and records concerning final disposition of the sample or fully document the decision to proceed with the analysis of the compromised or suspect samples?			
	Is the condition of such samples noted on the chain of custody documentation or the laboratory receiving records?			
	Is the associated test result appropriately "qualified" on the final report?			
LQSR 5.8.2.4	Are legally defensible chain of custody protocols required by customers, federal, state, tribal, or other programs?			
	If the chain of custody is not required is it encouraged or recommended?			
	Do chain of custody (if followed) records establish an intact, continuous record of the physical possession, storage and disposal of collected samples?			
LQSR 5.8.1	Are appropriate space, equipment and procedures provided for sample receipt, storage and processing?			
LQSR 5.8.2.5	Does the laboratory comply with all applicable federal, state, tribal, or local regulations regarding environmental containment and waste disposal?			
5.9 As	ssuring the Quality of Test Results			
5.9.1	b) participation in inter-laboratory comparison or proficiency-testing programs, specifically the ELPAT program?			
	Assessor must show evidence that this is taking place.			

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PJLA		<u> </u>		<u> </u>
LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
LQSR 5.9.1	Does the laboratory continually evaluate its performance, analyze bias and precision for each matrix and participate quarterly in the ELPAT proficiency program for each matrix analyzed? Does the laboratory seek feedback whenever possible for the client supplied duplicates, spikes, and/or blanks? Does the laboratory's system process control and performance monitoring use statistical process control (SPC) techniques? Do the SPC methods specify warning and action limits and the monitoring of trends over time? If there is insufficient data to determine the QC frequency and/or action limits, does the laboratory use the frequencies and criteria in LQSR Tables 3 and 4 (see Appendix B of this checklist)? Are the QC procedures stated in quality documents such as the QMSM and/or specific SOPs? Do these procedures address, as appropriate: • duplicate or "side by side" field sample analyses • spiked and blank sample analyses • spiked field sample analyses • control charts or equivalent • calibration standards • laboratory control samples • internal standards			
LQSR 5.9.1.1	Laboratory Control Samples (LCS)			

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LQSR	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness
Req.	Characteristic	res	NO	(if applicable)
	Are LCS samples (of the same matrix of the test samples) prepared and analyzed with a minimum frequency of one (1) per twenty (20) field samples or batch? For instruments that produce a numerical result is the LCS at a lead level near the level of concern or action level and shall not require extensive pretreatment dilution or concentration? For instruments that produce a pass/fail result (except for positive or negative screening): Is the LCS lead level no more than 20% above the applicable regulatory limit? Is the LCS lead level not less than 20% below the applicable regulatory limit? Does not require extensive pretreatment dilution or concentration?			
LQSR 5.9.1.1	Matrix Spike (Split/Spike) Field Samples Are matrix spikes analyzed with a minimum frequency of 5% of the samples for each matrix type per batch? For fewer than 20 samples in a batch is at least one matrix spike for each matrix spike analyzed? Are matrix spikes prepared using a split field sample (before digestion)? Is the level of lead enough to result in a lead concentration of the prepared sample of five (5) times the sample's observed lead level, or five (5) times the MDL, whichever is greater?			

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PJLA				
LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Are matrix spike analyses performed using field samples (whenever possible) to monitor potential field sample matrix interferences? For field samples too small or difficult			
	to homogenize does the laboratory select alternative QC options (such as duplicate laboratory control samples of the same matrix)?			
LQSR 5.9.1.1	Are method blanks containing all reagents (and for dust wipes, the representative blank wipe) subjected to all preparation steps and processed and analyzed along with the samples?			
	Is the method blank frequency at least 5% of the sample for each matrix per batch of samples?			
	For fewer than 20 samples in a batch is at least one method blank for each matrix per batch analyzed?			
	Are method blanks or other QC results NOT used to correct sample results?			
LQSR 5.9.1.2	Precision Determination - Split Field Samples			
	Are split field samples for precision determination analyzed with a minimum frequency of 5% of the samples for each matrix type per batch?			
	For fewer than 20 samples is at least one split field sample for each matrix spike analyzed?			
	If there is insufficient sample or the analytical technology is does not allow for split samples, does the laboratory use alternative QC procedures (such as the analysis of duplicate laboratory control samples with the appropriate			

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PJLA				
LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	matrix material)?			
5.10 R	eporting the Results			
LQSR 5.10.2	a title (e.g. "Test Report", "Report of Results", or "Laboratory Results"			
LQSR 5.10.2	d) the customer's name and address or project name, as applicable?			
LQSR 5.10.2 LQSR 5.10.2.1	i) the test results with, where appropriate, the units of measurement? REQUIREMENT: Reporting zero concentration is not permitted. The laboratory is required to determine a minimum positive finite lead level appropriate for the technology used. Measured values below this level shall be reported with a qualifier "less than" ("<") this positive level. For pass/fail technologies a clear statement of measurement capability with associated uncertainty shall be reported.			
5.10.3.1 LQSR 5.10.2.n	d) where appropriate and needed, opinions and interpretation including if quality control results did not meet requirements?			
LQSR 5.10.2.r	f) identification of inconclusive results and the reason that they are determined to be inconclusive			
LQSR 5.10.2.r	g) identification of the NLLAP accrediting body			
LQSR 5.10.3	Report Review Do final reviews undergo a documented final review prior to the release? Is the reviewer qualified? NOTE: A qualified person can be a technician, analyst, quality manager,			

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LQSR Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	technical manager, or a responsible person as defined by the LQSR. In a one person laboratory or where a qualified person is not available for review, the review is the review contracted out to a competent independent person or firm? Is the review process documented and signed by the reviewer? Are records of the review retained with the final report for a minimum of five (5) years?			

Additional Notes:

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Appendix A

Table 1 Summary of Instrument Calibration Performance Requirements for an instrument which produces a numerical result

QC SAMPLE	FREQUENCY	ACCEPTANCE LIMITS
Independent Calibration Verification (ICV)	Once per day after calibration	Within ±10 % of known value
Initial Calibration Blank (ICB)	Once per run at the beginning of the run	Absolute value not more than 50 % of the lowest regulatory limit for the sample matrix analyzed or minimum level of concern
Continuing Calibration Verification (CCV)	At the beginning and end of a sample run, as well as every 12 hours, or according to instrument manufacturer's recommendations, or according to instrument Performance Characteristic Sheet (PCS), or at a predetermined SOP frequency whichever is most frequent	Within ±20 % of known value
Interference Check Sample (ICS) (where applicable)	At the beginning and end of each run or twice every 12 hours	Within 20 % of known value
Continuing Calibration Blank (CCB)	After each ICS and CCV	Absolute value not more than 50 % of the lowest regulatory limit for the sample matrix analyzed or minimum level of concern

In the absence of sufficient data for statistical determination of adequate QC limits and frequency, the types of QC samples, minimum frequencies and the required minimum acceptance limits shown in this table shall be met, as appropriate.

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Appendix A

Table 2 Summary of Instrument (or Equivalent) Performance Requirements for an instrument (or equivalent) which produces Pass-Fail result

QC SAMPLE	FREQUENCY	ACCEPTANCE LIMITS
Independent Calibration Verification - Positive (ICV-P) (sample lead level no more than 20 % above the applicable regulatory limit; omit for positive screen technologies)	Once per run at the beginning of the run	Positive
Independent Calibration Verification - Negative (ICV-N) (sample lead level no less than 20 % below the applicable regulatory limit; omit for negative screen technologies)	Once per run at the beginning of the run	Negative
Initial Calibration Blank (ICB)	Once per run at the beginning of the run	Negative
Continuing Calibration Verification Positive (CCV-P) (sample lead level no more than 20 % above the applicable regulatory limit; omit for positive screen technologies)	At the end of a run as well as every 12 hours, or according to the manufacturer's recommendations, or according to instrument PCS, or at a predetermined SOP frequency, whichever is most frequent	Positive
Continuing Calibration Verification Negative (CCV-N) (sample lead level no less than 20 % below the applicable regulatory limit; omit for negative screen technologies)	At the end of a run as well as every 12 hours, or according to the manufacturer's recommendations, or according to instrument PCS, or at a predetermined SOP frequency, whichever is most frequent	Negative
Interference Check Sample (ICS) (where applicable)	At the beginning and end of each run or twice every 12 hours	Result consistent with lead level
Continuing Calibration Blank (CCB)	After each ICS and CCV	Negative

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Appendix B

Table 3 Summary of QC Sample Performance Requirements for an instrument which produces a numerical result

QC SAMPLE	FREQUENCY	ACCEPTANCE LIMITS
Laboratory Control Sample	One per 20 samples or batch (min. frequency 5 %)	Within ±20 % of known value
Matrix Spike Sample	One per 20 samples or batch (min. frequency 5 %)	Within ±25 % of calculated value
Duplicate Sample	One per 20 samples or batch (min. frequency 5 %)	Within ±25 % Relative % Difference (RPD)
Method Blank	One per 20 samples or batch (min. frequency 5 %)	Absolute value not more than 50 % of the lowest regulatory limit for the sample matrix analyzed or minimum level of concern

In the absence of sufficient data for statistical determination of adequate QC limits and frequency, the types of QC samples, minimum frequencies and the required minimum acceptance limits shown in this table shall be met, as appropriate.

Table 4 Summary of QC Sample Performance Requirements for an Instrument (or equivalent) which Produces Pass-Fail Results

QC SAMPLE	FREQUENCY	ACCEPTANCE LIMITS
Laboratory Control Sample Positive LCS-P (sample lead level no more than 20 % above the applicable regulatory limit; omit for positive screen technologies)	One per 20 samples or batch (min. frequency 5 %)	Positive
Laboratory Control Sample Negative LCS-N (sample lead level no less than 20 % below the applicable regulatory limit; omit for negative screen technologies)	One per 20 samples or batch (min. frequency 5 %)	Negative
Duplicate Laboratory Control Sample LCS-P or LCS-N	One per 20 samples or batch (min. frequency 5 %)	Positive or Negative, depending on the choice of lead level and the capability of the technology
Method Blank	One per 20 samples or batch (min. frequency 5 %)	Negative

In the absence of sufficient data for statistical determination of adequate QC limits and frequency, the types of QC samples, minimum frequencies and the required minimum acceptance limits shown in this table shall be met, as appropriate.

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