

## **EPA NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM**

### **LABORATORY QUALITY SYSTEM REQUIREMENTS (LQSR) REVISION 3.0 (July 05, 2007)**

The requirements in this document apply to all lead testing laboratories participating in the Environmental Protection Agency's (EPA) National Lead Laboratory Accreditation Program (NLLAP). In addition to meeting the Laboratory Quality System Requirements (LQSRs), the lead testing laboratory must also successfully participate in the Environmental Lead Proficiency Analytical Testing (ELPAT) Program.

NLLAP was established by the EPA Office of Pollution Prevention and Toxics (OPPT) under the legislative directive of Title X, the Lead-Based Paint Hazard Reduction Act of 1992 Sections 405 (a) and (b) requiring EPA to set minimum standards for laboratory analysis of lead in paint films, soil and dust.

Concerning any future revisions to the NLLAP Laboratory Quality System Requirements, laboratories currently participating in NLLAP will be given a period of eighteen months from the posting of the revision on the <http://epa.gov/lead/nllap.htm> to conform to any new requirements stated in the revision. For further information concerning NLLAP, please address your request in writing to:

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# NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM (NLLAP)

## LABORATORY QUALITY SYSTEM REQUIREMENTS

### INTRODUCTION AND PURPOSE

This document identifies the minimum requirements for use by accreditation organizations when evaluating laboratories performing environmental testing activities under NLLAP and is based on requirements of International Organization for Standardization and International Electrochemical Commission (ISO/IEC) Standard 17025: 2005 (E) "General requirements for the competence of testing and calibration laboratories". NLLAP recognizes laboratories that perform quantitative and/or qualitative analytical testing of paint chip (film), dust, and/or soil samples for lead analysis. NLLAP requires recognized laboratories to employ quality assurance/quality control systems that meet the requirements described in this document, to monitor for potential sample matrix and environmental interferences as well as laboratory operational deficiencies.

#### 1.0 SCOPE

The requirements described within this document must be met for an organization to attain recognition under the NLLAP as a lead testing laboratory, hereafter referred to in this document as a laboratory. An organization requesting recognition under this program shall possess a laboratory operation capable of performing sampling and lead testing. A laboratory shall have distinct staffing, instrumentation, sampling and test methods, as appropriate, and depending upon the type laboratory may have physical facilities and may use field test kits. Laboratory accreditation under this program shall be based on its meeting the requirements listed in this document.

#### 1.1 LABORATORY TYPES

For the purposes of NLLAP, a **laboratory** is defined as an operation that performs sampling and/or quantitative and/or qualitative analytical testing of paint chip (film), dust, and/or soil samples for lead analysis regardless of the number of personnel or the extent of the scope of testing activities.

NLLAP recognizes three types of laboratory operations: fixed-site, mobile and field sampling and measurement organization (FSMO). These types of laboratory operations are defined as follows:

Fixed-Site:                   An operation that performs analytical lead testing at a permanent location

under controlled environmental conditions.

Mobile Facility: A transportable, self contained operation that can perform analytical lead testing under controlled environmental conditions.

Field Sampling and Measurement

Organization (FSMO): An operation that performs on-site sampling and lead testing using portable testing technologies.

A laboratory may include one, two or all three of these types of operations. In cases where a laboratory does not perform one or more of the operations addressed above, the requirements relating to those activities do not apply.

## **2.0 NORMATIVE REFERENCES**

The following normative documents were used in the writing of this set of requirements.

NLLAP LQSR Rev. 2.0 08/01/96.

ISO/IEC Standard 17025: 2005 (E) "General requirements for the competence of testing and calibration laboratories".

40 CFR Part 745 - Lead-Based Paint Activities.

Performance Characteristics Sheets (PCS), available at:  
<http://www.hud.gov/utilities/intercept.cfm?/offices/lead/guidelines/hudguidelines/Allpcs.pdf>

## **3.0 TERMS AND DEFINITIONS**

A list of Acronyms and a Glossary of Terms used in this document is in Appendix 1.

## **4.0 MANAGEMENT REQUIREMENTS**

### **4.1 ORGANIZATION AND MANAGEMENT**

The laboratory management shall accept legal responsibility for its actions and ensure that appropriate communication processes are established within the laboratory so that communication takes place regarding the effectiveness of the laboratory quality management system. In addition, policies and procedures needed to ensure that management and personnel

are free from any conflicts of interest that might adversely affect the quality of work performed shall be documented and implemented in the quality management system manual (QMSM). Procedures shall be implemented to ensure confidentiality of customer information and protection of proprietary rights.

The laboratory shall have job descriptions for all positions and an organizational chart or other means of identifying the functions of key personnel, their responsibilities, lines of supervision, and authority. Laboratory management shall be responsible for all personnel employed by the laboratory including those assigned to mobile laboratories and/or FSMOs and for ensuring that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the quality management system.

The laboratory shall also appoint (or contract out) one member of the staff to act as quality manager. The quality manager shall have the responsibility and authority for assuring implementation of the quality management system at all times, and shall be free of any conflict of interest.

All NLLAP recognized laboratories shall identify a responsible laboratory official who is authorized to release test reports on behalf of the laboratory. In a laboratory with one person, that person will be the responsible official for the release of the test report. That person may either serve as the technical manager or the quality manager, but cannot serve as both. In the case of a laboratory with only one employee, one of these positions shall be contracted out. See Sections 4.14, 5.4.6 and 5.10.3 below for requirements on one-person firms regarding internal audits and the release of test reports.

The following specific personnel requirements shall apply to NLLAP recognized laboratories. In laboratories with a limited number of personnel, individuals may be assigned more than one duty (except that no individual may be both the technical manager and the quality manager).

#### **4.1.1 Technical Manager**

##### **4.1.1.1 Qualifications**

The individual who functions as the technical manager (however named) of the laboratory shall have appropriate education, training, and experience, or combination thereof for the measurement technologies used by the laboratory, to 1) be able to design and implement the management system, and 2) enable that individual to identify the occurrence of departures from the implemented quality management system or test procedures and to initiate actions to prevent or minimize such departures.

#### **4.1.1.2 Responsibilities**

The technical manager or their designee shall be responsible for all technical operations and shall be available to address technical issues for laboratory staff and customers concerning NLLAP related analyses.

The technical manager shall ensure and document the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. The competence determination shall be based on appropriate education, training, experience and/or demonstrated skills.

The technical manager shall ensure that adequate supervision is provided for all laboratory technical personnel.

#### **4.1.2 Quality Manager**

##### **4.1.2.1 Qualifications**

The individual who functions as the quality manager (or however named) of the laboratory shall have the education, training, and experience, or combination thereof, to enable that individual to identify the occurrence of departures from the implemented quality management system and to initiate actions to prevent or minimize such departures. The quality manager shall be knowledgeable of the quality management system and the technical and management system procedures used.

##### **4.1.2.2 Responsibilities**

The quality manager shall have defined responsibility and authority to implement and oversee the quality management system, implement new quality assurance and control practices, perform periodic audits of the quality management system, perform periodic review of test reports prior to issue, and to ensure laboratory quality management system deficiencies are documented and that corrective actions are implemented.

#### **4.2 QUALITY MANAGEMENT SYSTEM**

The laboratory quality management system shall include all the policies and procedures required by this document and the performance of the activities covered by its scope of accreditation. The quality management system manual (QMSM) shall contain all the required policies and must either contain or cite the related quality documentation and procedures to help ensure and document the quality of the analytical data.

The QMSM and related quality documentation shall state the laboratory's policies and operational procedures established in order to meet the requirements of this document.

All items in the laboratory's quality system shall be available for on-site inspection or audit by EPA NLLAP personnel and by accreditation organizations participating in NLLAP or, if applicable, to federal/state/tribal program certifying officials.

Laboratory management shall:

- a. Provide evidence of its commitment to the development and implementation of the quality system and continually improving the effectiveness of the quality management system;
- b. Ensure the integrity of the quality management system is maintained when changes to the quality system are planned and implemented; and
- c. Communicate to the organization the importance of meeting customer as well as statutory and regulatory requirements.

#### **4.2.1 Quality Management System Establishment and Maintenance**

The laboratory shall establish and maintain a quality management system to ensure the quality of its testing.

- a. The elements of this system shall be documented;
- b. The quality documentation shall be available for use by laboratory personnel;
- c. The laboratory management shall ensure that these policies and objectives are documented in a QMSM and communicated to, understood, and implemented by laboratory personnel; and
- d. The QMSM shall be reviewed annually, updated as needed and maintained under the responsibility of the quality manager or however named. (see 4.3.4 below)

#### **4.2.2 Quality Policy Statement**

Laboratory management shall define and document the objectives and policies of the quality management system. These policies and objectives shall be documented in a QMSM. The overall policy on quality management shall be provided in the QMSM, and shall denote the standard of performance to be obtained and maintained. The chief executive (person authorized

to make decisions e.g. president, executive director) shall issue the quality policy statement. It shall include:

- a. A statement of the standard of service the laboratory management intends to provide;
- b. The purpose of the quality management system;
- c. A requirement that all personnel involved with testing activities within the laboratory acquaint themselves with quality management system documentation and implement the policies and procedures used in their work;
- d. The commitment of the laboratory to good professional laboratory practice and quality of service to the customer; and
- e. The laboratory management's commitment to compliance with the requirements of this document.

#### **4.2.3 Quality Management System Manual (QMSM)**

The QMSM shall include the defined roles and responsibilities of the technical manager and the quality manager, including each of their responsibility for ensuring compliance with the requirements of this document. The quality management system shall include an organizational chart identifying key personnel, responsibilities, lines of authority, and interrelationships of staff. The QMSM shall include or make reference to the supporting procedures including technical procedures and shall outline the structure of the documentation used in the management system.

The QMSM and related quality documents shall include or address at least the following elements:

- Title Page
- Table of Contents
- Management requirements
- Organization (4.1)
- Quality Management System (4.2)
- Document control (4.3)
- Review of requests, tenders and contracts (4.4)
- Subcontracting of tests and calibrations (4.5)
- Purchasing services and supplies (4.6)
- Service to the customer (4.7)
- Complaints (4.8)

- Control of nonconforming testing and/or calibration work (4.9)
- Improvement (4.10)
- Corrective action (4.11)
- Preventive action (4.12)
- Control of records (4.13)
- Internal audits (4.14)
- Management reviews (4.15)
- Technical requirements
- General (5.1)
- Personnel (5.2)
- Accommodation and environmental conditions (5.3)
- Test and calibration methods and method validation (5.4)
- Equipment (5.5)
- Measurement traceability (5.6)
- Sampling (5.7)
- Handling of test and calibration items (5.8)
- Assuring the quality of test and calibration results (5.9)
- Reporting the results (5.10)

The QMSM shall be updated whenever necessary and reviewed and approved by management at least annually. The QMSM shall be accessible to all laboratory personnel.

### **4.3 DOCUMENT CONTROL**

#### **4.3.1 General**

The NLLAP recognized laboratory shall establish and maintain procedures for the control of all documents (both internal and external documents) that form the quality management system. Examples of external documents that may be included are standards, regulations, normative documents, test and/or calibration methods, drawings, specifications, instructions, and manuals. The laboratory document control system shall ensure that all standard operating procedures, manuals, and/or documents clearly indicate the time period during which the procedure or document was in force.

#### **4.3.2 Document Approval and Issue**

All documents in the laboratory shall be reviewed and approved before their release for use by authorized personnel. A system shall be implemented for identification of the current revision status of quality system documents to prevent use of invalid or obsolete documents.

Quality system documents generated by a laboratory shall be clearly identified. Included

in the identification shall be the issue date, revision identification and the total number of pages or a clearly marked document end.

### **4.3.3 Document Changes**

Document changes shall be reviewed by the same personnel that reviewed the original document, unless otherwise indicated. Where possible, changes to the document shall be noted in the document or in an attachment. Documents may be amended by hand pending re-issue of the most current version, where permitted. A revised document shall be re-issued as soon as practicable.

A system shall be established and used to record changes made in computerized systems.

### **4.3.4 Document Review and Revision.**

The laboratory shall outline in its QMSM or document control standard operating procedure (SOP), the process for adopting and revising of quality management system documents. This process shall address when and how the laboratory's documents are reviewed, identify the sign off authority, and state that the laboratory documents are reviewed at least annually and/or revised as needed.

## **4.4 REVIEW OF REQUEST, TENDER OR CONTRACT**

Procedures shall be established by the laboratory for the review of requests, tenders, or contracts. The policies and procedures shall ensure that:

- a. The requirements including the methods to be used are adequately defined, documented, and understood;
- b. The laboratory has the capability and resources to meet the requirements; and
- c. The appropriate test method is selected and capable of meeting the customer's requirements.

Differences between the customer's request and the contract offered to the customer shall be resolved based on the QMSM policies and procedures before any work commences. The contract shall be acceptable to both the laboratory and customer. Changes made at the contract review shall be recorded and maintained. Contract review shall also cover work to be subcontracted by the laboratory. If the contract requires amendment after work has begun, the same contract review process shall be repeated and amendments communicated to all necessary personnel. The customer shall be informed of any deviations from the contract.

#### **4.5 SUBCONTRACTING OF TESTS**

An NLLAP recognized laboratory shall only subcontract work when necessary and with the approval of the customer. Work shall only be performed by another NLLAP recognized laboratory. The laboratory shall be able to demonstrate that the subcontractor is accredited by an NLLAP recognized accrediting body for the methods in question. A list of all subcontractors used for tests shall be compiled along with records of the evaluation of the subcontractors' qualifications.

#### **4.6 PURCHASING SERVICES AND SUPPLIES**

The laboratory shall implement policies and procedures for the selection and purchase of services and supplies that impact the quality of tests. Only services and supplies that satisfy and maintain the quality needed to produce acceptable test results shall be purchased. The laboratory shall have procedures for the purchase, receipt and storage of reagents and laboratory consumables that impact the quality of tests.

Purchasing documents shall clearly describe the product ordered. The laboratory shall ensure that supplies purchased are not used until properly inspected or otherwise verified for compliance with standard specifications or method requirements.

##### **4.6.1 Reagents and Standards**

Requirements for reagents and standards shall be specified in the documented QMSM and/or technical procedures.

###### **4.6.1.1 Reagent Grades Used**

Reagents shall be at least American Chemical Society (ACS) reagent grade or of the quality specified by the analytical methods in use by the laboratory.

###### **4.6.1.2 Reagents and Standards Tracking**

Upon receipt, purchased reagents and standards shall be inspected, dated and initialed or otherwise evaluated to verify the purchasing document specifications have been met. An expiration date shall be assigned to each reagent and standard. Reagents and standards shall not be used beyond assigned expiration dates nor used if damaged or contaminated or suspected to be damaged or contaminated.

When available, the laboratory shall maintain certificates of analysis or other documentation on the manufacturer's statement of purity, of the origin and traceability of all reagents and standards.

#### **4.7 SERVICE TO THE CUSTOMER**

The NLLAP recognized laboratory shall cooperate with the customer. This may include providing the customer or customer's representative reasonable access to areas of the laboratory to witness work performed for that customer or providing test or sample items needed by that customer for purposes of verification. The laboratory should also maintain contact with the customer throughout the period of work and inform the customer of any delays and/or deviations in performance of the tests. Laboratories are also encouraged to seek feedback from the customer for improvement of the quality system.

#### **4.8 COMPLAINTS**

The laboratory shall have documented policy and procedures for the resolution of complaints received from customers or other parties about the laboratory's activities or results. The policy shall include the notice that "Any complaint about the quality of reported results may be referred to the accrediting body if such complaints cannot be resolved directly with the customer." See the NLLAP web page at: [www.epa.gov/lead/nllap.htm](http://www.epa.gov/lead/nllap.htm) for the contact information of the recognized accrediting bodies. A record shall be maintained of all complaints and of the actions taken by the laboratory. Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with policies its own procedures, the requirements of this document, the quality management system and/or the quality of the laboratory's analyses, the laboratory shall ensure that those areas of activity are promptly audited.

#### **4.9 IMPROVEMENTS**

The laboratory shall continually improve the effectiveness of its quality management system through the use of its quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

#### **4.10 CONTROL OF NONCONFORMING TESTS**

The laboratory shall have documented policy and procedures for handling nonconforming tests and for describing and recording actions taken when nonconforming tests are identified. No data shall be reported until the cause of the problem is determined and corrected, or the laboratory demonstrates that the root cause of the nonconformance was a random event. The laboratory shall maintain records of all nonconforming tests or out-of-control events, the determined cause(s), and corrective action(s) taken. The laboratory shall respond to customer

complaints and maintain records of corrective action. Once corrective action(s) have been implemented, the laboratory shall monitor the results to make sure the actions taken have been effective at addressing the problem(s) of nonconformance.

## **4.11 CORRECTIVE ACTION**

### **4.11.1 General**

A policy and procedure for corrective action shall be established and implemented for use by appropriate laboratory authorities when nonconforming work is identified. Required changes to the operational procedures resulting from corrective action investigations shall be properly documented and implemented. When reported results have been affected by nonconforming tests all affected customers shall be contacted and informed of the corrective action taken and the amended results (see 5.10.4).

### **4.11.2 Cause Analysis**

Corrective action procedures shall begin with an investigation to determine the root cause(s) of the problem.

### **4.11.3 Corrective Actions**

Once the root causes have been identified, the laboratory shall identify possible corrective actions. The action(s) most likely to eliminate the problem and prevent its recurrence shall be selected and implemented.

### **4.11.4 Monitoring the Corrective Actions**

Once corrective action(s) have been implemented, the laboratory shall monitor the results to make sure the actions taken have been effective at addressing the problem(s) that caused the nonconformance.

### **4.11.5 Special Audits**

If there is doubt that the laboratory is complying with its own policies and procedures or those of relevant standards, then the laboratory shall ensure that the appropriate areas of activity are audited.

#### **4.12 PREVENTIVE ACTION**

Needed improvements and potential sources of nonconformance, either technical or concerning the quality management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such, nonconformities and to take advantage of the opportunities for improvement.

#### **4.13 RECORDS**

The records for each laboratory activity shall contain sufficient information so that it may be repeated or otherwise verified. The record keeping system shall allow historical retrieval of all laboratory activities that were used to produce the associated test report. The record keeping system shall facilitate the retrieval of all records. Additional record keeping guidance is available from ASTM: E 2239 “Standard Practice for Record Keeping and Record Preservation for Lead Hazard Activities.”

- a. All records (including those pertaining to calibration and test equipment, certificates, and reports) shall be safely stored, held secure and treated as confidential;
- b. All records of the laboratory associated with its work activities shall be retained for a minimum of five years. All hardware and software necessary for the historical retrieval of data must be maintained by the laboratory. These records shall include a history of the locations of mobile laboratory and FSMO operations, including a specific description of where the sampling and testing work activity was performed and these records shall be maintained for at least five years;
- c. Access to archived records shall be controlled using an access log. All records shall be stored and retained in readily accessible facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Records may be in hard paper copy or electronic media;
- d. In the event that a laboratory goes out of business, the laboratory shall have a plan to ensure that its records are maintained or transferred according to the customer's instructions and applicable regulations;

- e. The records shall include the identity of all personnel involved in sampling (if known), sample preparation, calibration, analysis, final reporting. Also, a record of the signature and initial for the name of employees shall be created and maintained; and
- f. Entries in records shall not be obliterated by methods such as erasures, overwritten files, or markings. All corrections and/or amendments to records shall be made with a single strike out line through the error and/or the correct data or value added alongside, as appropriate. All handwritten data shall be recorded using permanent ink. The individual making the correction shall sign (or initial) and date the correction.

#### **4.13.1 Sample Records**

A record of all procedures to which sample is subjected (sampling, preparation and testing) while in the possession of the laboratory shall be maintained for a period of at least five years as a readily retrievable hard copy or electronic media that can be generated without change. These records shall include, but are not limited to, records of:

- a. Sample identification, receipt, acceptance or rejection and log-in;
- b. Sample storage and tracking including shipping receipts, where applicable;
- c. Sample preparation, instrument printouts, and calculations, where applicable;
- d. Sample analysis logs;
- e. Standard and reagent origin, receipt, preparation, and use;
- f. Equipment and instrument operating conditions;
- g. Calibration criteria, frequency and acceptance criteria;
- h. Data and statistical calculations, review, confirmation, interpretation, assessment, and reporting conventions;
- i. Method performance criteria;
- j. Quality control protocols and assessment;

- k. Storage and retention; and
- l. Sample disposal procedures and schedule.

#### **4.13.2 Laboratory Quality Management System and Test Records**

In addition to documenting all the above mentioned activities, the following shall be retained:

- a. All original raw data, hard copy or electronic, for sampling and testing activities to include: calibrations, samples, and quality control measurements, work sheets and data output/instrument response readout records;
- b. A written description or reference to the specific method used which includes a description of the specific steps in the calculation used to translate parametric observations into a reportable analytical value;
- c. Copies of final reports;
- d. Archived standard operating procedures;
- e. Correspondence relating to laboratory work activities;
- f. All corrective action reports, audits, and audit responses;
- g. Performance evaluation results and raw data; and
- h. Data review and cross checking.

#### **4.13.3 Electronic Data**

Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage or retrieval of data, the laboratory shall ensure that:

- a. Electronic computer records can satisfy the record keeping requirement without hard copy files if hard copies can be generated without changing the information;
- b. The computer programs are validated before they are used and whenever the programs are changed;

- c. Computer file backup procedures are completed in accordance with a predetermined schedule;
- d. Records that are stored or generated by computers have a hard copy or write-protected backup copies.

#### **4.14 INTERNAL AUDITS**

At least annually, the laboratory shall, in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to ensure that operations comply with the requirements of this document and the established quality management system. The quality manager shall be responsible for the planning and implementation of such audits. Such audits shall be carried out by trained and qualified staff that are, whenever possible, independent of the activities to be audited. All relevant information pertaining to the audit activity shall be recorded. In a one-person organization, the annual audits may be conducted by the one member of the laboratory if that person follows independent third-party guidance for conducting a quality system audit, such as ISO 19011, Guidelines for quality and/or environmental management systems auditing or similar third party guidance published by organizations such as ASTM (American Society for Testing and Materials) or ANSI (American National Standards Institute) and creates and maintains a written audit report of the audit findings in its record system. Alternatively, the one-person organization may choose to contract out the internal audit to an independent person or firm that is competent and has the experience and training to conduct an audit of a quality system.

When the audit finds doubt on the correctness or validity of the laboratory test results, timely corrective action shall be taken by the laboratory. If the audit indicates that laboratory results may have been affected, customers shall be notified and informed of the corrective action taken and the amended results.

#### **4.15 MANAGEMENT REVIEWS**

The quality system adopted to satisfy the requirements of the NLLAP LQSR shall be reviewed at least once a year by the laboratory management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements (see 4.9). Such reviews shall be carried out by the laboratory management in accordance with a predetermined schedule and procedure. The review shall take account of:

- The suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- The outcome of recent internal audits;
- Corrective and preventive actions;

- Assessments by external bodies;
- The results of interlaboratory comparisons or proficiency tests;
- Changes in the volume and type of the work;
- Customer feedback;
- Complaints;
- Recommendations for improvement
- Other relevant factors, such as quality control activities, resources and staff training.

All relevant information pertaining to the management review shall be recorded. The laboratory management shall ensure that necessary changes or improvements are carried out within an appropriate and agreed timescale.

## **5.0 TECHNICAL REQUIREMENTS**

### **5.1 GENERAL**

Many factors contribute to the correctness and reliability of lead measurements performed by a laboratory. These factors include contributions from:

- Human factors (personnel) (5.2)
- Accommodation and environmental conditions (5.3)
- Test and sampling methods (5.4)
- Equipment (5.5)
- Measurement traceability (5.6)
- Sampling (5.7)
- Sample handling (5.8)

These factors shall be taken into account by the laboratory in developing test and calibration methods, in training personnel, and in the selection of equipment used.

### **5.2 PERSONNEL**

Laboratory management shall ensure that all laboratory personnel performing NLLAP recognized analyses are educated, trained, experienced, skilled and competent in performing lead sampling and testing activities, as appropriate. Staff assigned to operate equipment, perform tests, evaluate results, and sign test reports shall be qualified and authorized in writing by management to do so. When using staff in training, adequate supervision shall be provided. A record of all employees and their associated competence, training, skills, experience, authorizations and professional qualifications shall be clearly defined, documented, and maintained on file. The criteria and training requirements for laboratory personnel shall be

clearly defined, documented, and readily available. Training records shall include a description of training program contents, the duration of the training, qualifications of the trainer, and evidence that the analyst and/or technician has successfully demonstrated their competence, such as described in Section 5.2.1.1.

Goals for the laboratory training program shall be formulated by laboratory management and a training program shall be in place to address the training needs of laboratory employees and shall be relevant to the present and anticipated needs of the laboratory. The effectiveness of the training shall be evaluated. The laboratory shall maintain current job descriptions for managerial, technical, and key support staff involved in sampling and testing activities, as appropriate.

The NLLAP recognized laboratory shall use permanently employed staff or those under contract to the laboratory. When additional support or technical personnel (such as temporary employees) are needed, the laboratory shall ensure that such personnel are competent, supervised and work within the quality management system.

### **5.2.1 Analysts and Technicians**

Personnel who function as analysts and/or technicians (however named) in the laboratory shall have the education, training, experience and/or demonstrated skills or combination thereof, to enable them to adhere to the implemented quality system and to competently perform test procedures, operate laboratory equipment, evaluate test results and sign test reports (when authorized).

#### **5.2.1.1 Minimum Qualifications and Training for Analysts and Technicians**

**5.2.1.1.1** NLLAP analysts and/or technicians shall have hands on experience conducting lead sampling and testing activities, as appropriate, before being authorized to work on NLLAP related samples.

**5.2.1.1.2** Analysts and technicians shall complete an external and/or internal training program for lead sampling and testing activities, as appropriate, prior to performing those activities on NLLAP related samples. Courses on sample selection, collection, preparation (when applicable) and instrumental analysis may be taken separately or combined. The criteria and training requirements for laboratory personnel shall be clearly defined, documented and maintained on file. A description of the training program content, the duration of the training, qualifications of the trainer, and objective evidence that the analyst and/or technician has successfully selected and/or collected samples and prepared and

tested, as appropriate, known reference samples of the matrices of concern within the specified acceptance criteria must be maintained by the laboratory.

- 5.2.1.1.3** The analyst and/or technician trainee shall complete a minimum of four independent test runs of sample preparation (when applicable) and/or instrumental analysis for each matrix. An independent run is defined as analysis of at least five samples of known lead content, one of which is a certified reference material or proficiency testing material and is separated by a period of time sufficient to evaluate the performance of any previous independent run. For sample preparation training, the recoveries of the associated reference materials or proficiency training samples for each run must be within the requirements of Table 3. For instrumental analysis training, the recoveries of the associated reference materials or proficiency training samples for each run must be within either Table 3 or 4 as applicable.

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 upon the minimum requirements stated for both analysts and technicians.

The reference material/proficiency test samples utilized shall: 1) be similar to matrices the analyst and/or technician will encounter during routine lead sample analysis, and 2) cover the sample mass/concentration range for which the analytical SOP has been validated.

- 5.2.1.1.4** Analyst and/or technicians shall periodically demonstrate their ability to proficiently test samples for lead at least every six months.

### **5.2.1.2 Additional Requirements for Mobile and FSMO Personnel**

- 5.2.1.2.1** All mobile laboratory and FSMO personnel involved in the selection of samples or sampling areas as a part of a lead-based paint risk assessment and/or clearance testing in target housing and/or child occupied facilities shall also be certified by EPA or an authorized state or tribal program as a risk assessor/inspector/sampling technician as pursuant to Section 402 of the Toxic Substance Control Act (TSCA) and its implementing regulations.

- 5.2.1.2.2** All mobile or FSMO technicians shall be evaluated by a competent supervisor for their first two NLLAP-related job sites.

### **5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS**

Any fixed site or mobile laboratory operation shall have, as appropriate, the space, equipment, instruments, ventilation, utility services, storage space, safety equipment, and documentation and references necessary to accomplish the analyses for lead concentrations in the matrices of concern (see 29 CFR § 1910.1450 for information). FSMOs shall have appropriate storage facilities to maintain the integrity of the testing equipment when not in use.

Temperature, humidity, ventilation, dust, and vibration shall be controlled and/or monitored to meet instrument and/or sample analysis requirements. Tests shall be terminated when environmental conditions jeopardize the results of the test.

Incompatible activities in the laboratory shall be separated to prevent cross-contamination. Access to areas affecting the quality of test and/or calibrations shall be controlled. The integrity of the laboratory shall be maintained with good housekeeping practices. For laboratories operating portable testing technologies, sample collection and field testing shall be conducted so as to minimize the chance of cross-contamination. Site access shall be controlled to the extent possible while sampling and testing are taking place. Activities at the site shall be conducted to minimize the possibility of creating a hazard during or after testing, or contaminating the site from sampling and testing.

#### **5.3.1 Contamination Control**

##### **5.3.1.1 Laboratory Dust Wipe Checks**

For fixed-site and mobile laboratory facilities, contamination control by wipe sampling of sample preparation and testing area surfaces shall be conducted at least quarterly to determine surface concentration levels of lead. Sample preparation and analysis is not to proceed until surface contamination is below the specified maximum allowable concentration of 50 percent (%) of the lowest regulatory limit for dust wipe samples (See 40 CFR Part 745 Final Rule, Federal Register, Vol. 61, no. 169, August 29, 1996, page 45793). For FSMO, appropriate contamination control blank samples shall be run in order to monitor potential lead contamination as outlined in the QMSM.

##### **5.3.1.2 Labware Cleaning**

Cleaning procedures for labware shall be specified by the laboratory in a written Standard Operating Procedures (SOP). The procedure shall include, where applicable, a specified frequency for monitoring of lead concentrations in cleaning baths, the monitoring of glassware contamination during the analysis of reagent or other blanks, and periodic monitoring of disposable labware contamination by analyzing of reagent or other blanks. To assess possible

contamination, glassware used for the method blanks should be processed through acid baths used by the laboratory for labware cleaning.

## **5.4 TEST AND SAMPLING METHODS**

### **5.4.1. Acceptable Methodology**

The test methods or written SOPs, dated and approved by the appropriate authority, shall be available for use where work activities are performed. The laboratory shall have demonstrated that the test and/or sampling methods used are suited for the intended use. In addition the laboratory shall have records of method performance demonstration and validation for developed or modified laboratory procedures, which include method detection limit (MDL), bias and precision.

- a. Methods shall not be used for sample analysis until the laboratory has confirmed and documented its proficiency in using these methods. Competency in using test methods shall be demonstrated over the lead concentration and sample mass ranges for each matrix stated by the method, as appropriate;
- b. Where sample preparation and analysis methods are not specified by regulatory programs, the laboratory shall, whenever possible, use validated procedures published by federal agencies such as EPA, HUD or NIOSH, state agencies, or nationally or internationally recognized consensus standards organizations such as ASTM International. For methods under consideration for analytical testing the laboratory shall demonstrate it can achieve a quantitation limit equal to or less than 20 % of the lowest relevant action level or regulatory limit of interest for paint and soil and 50 % of the lowest action level for dust wipe samples. Laboratory SOPs for sample analysis may require additional QC procedures to those stated in the published methods in order to meet requirements of this document.

Acceptable sampling methods are cited in 40 CFR Part 745 - Lead-Based Paint Activities;

- c. New, alternative or modified analytical methods and/or new testing technologies may be used by a laboratory if they have been validated by the laboratory or a third party, and shown to meet the minimum performance requirements stated in 5.4.1(b). The method validation must be documented by the laboratory or qualified third party. In the case where validation is done by a party other than the laboratory, the laboratory shall confirm its competency utilizing the method as described above in Section 5.4.1(a).

Acceptable operating characteristics for non-numerical or pass-fail technologies (positive or negative screen technologies) shall be appropriate to the associated regulatory limits (e. g., the measured value including its 95 % uncertainty of measurement must be less than the associated regulatory limit); and

- d. When a laboratory offers analyses of composite dust wipe samples, the laboratory analytical method for composite dust wipe samples shall address increase of sample mass. The laboratory shall meet the minimum performance requirements stated in 5.4.1(b) and demonstrate its competency utilizing the method as described above in Section 5.4.1(a).

#### **5.4.2 Method Validation and Performance Demonstration Procedures**

A list of guidance documents that should be helpful in dealing with method validation and performance demonstration that include good professional laboratory principles and practices are listed below:

- AOAC International operates method validation programs. Information on these programs is available at: <http://www.aoac.org/vmeth/page1.htm>
- U.S. EPA Office of Solid Waste “Guidance for Method Development and Method Validation for the RCRA Program, June 1995” at: [www.epa.gov/SW-846/methdev.htm](http://www.epa.gov/SW-846/methdev.htm)
- “Guidelines for Collaborative Study Procedure to Validate Characteristics of a Method of Analysis,” *J. Assoc. Off. Chem.*, Vol. 72, No.4, 1989, p. 694
- "Meeting the Traceability Requirements of ISO 17025-An Analyst's Guide," 2nd Edition, at: [www.vam.org.uk/](http://www.vam.org.uk/)
- “Preparation of Calibration Curves-A Guide to Best Practice,” September 2003, LGC/VAM/2003/032, at: [www.vam.org.uk/](http://www.vam.org.uk/)
- “New Eurachem/CITAC guidance on traceability of chemical measurements: A paradigm for practical traceability,” April 2003, LGC/VAM/2003/016, at: [www.vam.org.uk/](http://www.vam.org.uk/)
- “Quantifying Uncertainty in Analytical Measurement, 2nd Edition,” QUAM2000-1, 2000, at: [www.vam.org.uk/](http://www.vam.org.uk/)

- “EURACHEM/CITAC Guide: Traceability in Chemical Measurement-A Guide to Achieving Comparable Chemical Measurement,” 2003, at: [www.vam.org.uk/](http://www.vam.org.uk/)
- “In-house method validation: A guide for chemical laboratories,” 2003, at: [www.vam.org.uk/](http://www.vam.org.uk/)
- “A Practical Guide to Analytical Method Validation,” Analytical Chemistry 1996, (68) 305A-309A, published at: <http://pubs.acs.org/hotartcl/ac/96/may/may.html>
- “The Fitness for Purpose of Analytical Methods-A Laboratory Guide to Method Validation and Related Topics,” EURACHEM Guide 1998, at: [www.eurachem.ul.pt/](http://www.eurachem.ul.pt/)
- “Standard Practice for Determining the Precision of ASTM Methods for Analysis and Testing of Industrial and Specialty Chemicals,” ASTM International Practice Designation E 180, at: [www.astm.org](http://www.astm.org)
- “Standard Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method,” ASTM International Practice Designation E 691 at: [www.astm.org](http://www.astm.org)
- “Standard Guide for Demonstrating and Assessing Whether a Chemical Analytical Measurement System Provides Analytical Results Consistent with Their Intended Use,” ASTM International Guide Designation D 6956-03 at: [www.astm.org](http://www.astm.org)
- “Standard Guide for Conducting Ruggedness Tests,” ASTM International Guide Designation E 1169 at: [www.astm.org](http://www.astm.org)
- “Standard Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data” ASTM International Guide Designation E 1323 at: [www.astm.org](http://www.astm.org)
- “Standard Guide for Statistical Procedures to Use in Developing and Applying Test Methods,” ASTM International Guide Designation E 1488 at: [www.astm.org](http://www.astm.org)

### **5.4.3 Sample Preparation and Analysis Procedures**

#### **5.4.3.1 Standard Operating Procedures (SOPs)**

All method SOPs shall be available to all personnel at the locations where work activities are performed and shall include information addressing the following areas, as appropriate:

- 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
- Reagents and standards
- Equipment and supplies
- Sample collection (where applicable)
- Sample preservation and storage (where applicable)
- Sample preparation including grinding, homogenization, and subsampling (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

Laboratory SOPs which do not address all of the areas stated above shall be amended in accordance with the laboratory's SOP on document control, revision /change, which may permit the use of attachments in order to meet this requirement or reference other quality system documents as appropriate. All operating procedures relevant to the work being conducted shall be available for use where the work activities are performed.

#### **5.4.4 Method Performance Characteristics**

The acceptable minimum method performance characteristics provided in Tables 3 and 4 of this document shall be replaced by the laboratory's own statistically determined performance characteristics and shall not be greater than values stated in Tables 3 and 4.

##### **5.4.4.1 Method Detection Limits**

Method detection limits (MDLs) shall be established, statistically verified and monitored, as needed for each method and matrix of concern. For methods with stated MDLs, demonstration of ability to achieve such MDLs is required and shall be documented. MDLs shall be determined using a documented SOP showing that the laboratory can equivocally demonstrate the ability to see the lead level below the action level in the matrix of concern.

##### **5.4.4.2 Quantitation Limits**

The quantitation limit shall be "less than" (" $<$ ") a value at least 2 times but no greater than 10 times the method detection limit as determined in Section 5.4.4.1.

##### **5.4.4.3 Bias and Precision**

Bias and precision shall be determined for each analytical method. The method evaluation results shall be documented and kept on file. Acceptable minimum method performance criteria for bias and precision can be found in Tables 3 and 4 of this document.

#### **5.4.5 Sample Aliquots**

Where subsampling (obtaining sample aliquots from a submitted sample) is carried out as part of the analytical method, the laboratory shall use documented procedures and appropriate techniques to obtain representative subsamples.

#### **5.4.6 Data Reduction and Review Process**

The data reduction and review process shall be conducted by a qualified person and include, but not necessarily be limited to: comparison of quality control data against established acceptance limits, computation verification, transcription of data, and adherence to the procedures established in the laboratory SOPs. Where appropriate, computations shall be verified and transcription of data double checked. Qualified persons can be technicians, analysts, the quality manager, or technical manager, or the responsible person described previously in Section 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 and has the experience and training necessary to conduct the review.

The review process shall be documented and signed by the reviewer, and shall be retained on file with a copy of the final report for a minimum of five years.

#### **5.4.6.1 Estimate of Uncertainty of Measurement**

Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement (UoM). The laboratories shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. A reasonable estimate shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of previous experience and validation data and requirements of the customers.

In those cases where a well-recognized test method specifies limits to the values of the major sources of UoM and specifies the form of presentation to calculate results, the laboratory is considered to have satisfied this section by following the test method and reporting instructions (see 5.10.2 ).

### **5.5 EQUIPMENT**

The laboratory shall be furnished with the proper equipment to perform the necessary tests. Should the laboratory need to use equipment outside its permanent control, it shall ensure that all NLLAP requirements for equipment and instrumentation are met. All equipment used for sample preparation or for instrumental analysis shall be maintained and calibrated in accordance with manufacturer instructions, as well as any specifications stated in the analytical methods. Standards used for calibration shall be traceable to National Institute of Standards and Technology (NIST) standards (when available). Equipment is to be used by authorized personnel only.

Each item of equipment shall be uniquely identified when possible and records shall be maintained for each major instrument, including records of in-house preventive maintenance and service. The calibration/verification frequency for each instrument shall be established and documented. The documentation shall include descriptions of the problem or service, dates and types of repair, organization and person performing repair, and contact phone number shall be recorded. Instruments that are found to be out of calibration or defective shall be taken out of service until repaired and demonstrated to be functioning within documented acceptance limits. The record shall identify the instrument by make, model number, serial number, and when available, the date placed in service.

To prevent contamination or deterioration, the laboratory shall have procedures for the safe handling, transport, storage, use, and maintenance of measurement equipment. Equipment that has been mishandled, operates outside expected limits, or provides suspect results shall be removed from service and marked accordingly until it can be repaired, recalibrated, and returned to service. Likewise, equipment that goes outside the control of the laboratory for any period of time must be checked and shown to provide satisfactory performance before being returned to service.

All equipment used to collect, prepare and test samples for lead shall have SOPs for their calibration/verification and maintenance and shall be readily available for use where these activities are performed.

### **5.5.1 Instrument Calibration and Performance Quality Checks**

Instruments that are routinely calibrated shall be verified daily or prior to analyzing samples. Acceptable instrument performance shall be demonstrated daily or prior to use. Such checks may include evaluation of instrument sensitivity, noise levels, instrument response and interference levels to be compared to historical performance values. Acceptance criteria shall be determined, documented and used.

All instrument calibration/performance verification shall be performed using matrix matched reference standard materials of the same matrix as the samples being measured, when available. These standard materials shall be traceable to NIST standards (when available). 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 Tables 1 and 2 shall be met, as appropriate.

### **5.5.2 Instrument Calibration Performance Requirements**

Instruments and equipment used for testing that have a significant effect on the accuracy of the result shall be calibrated prior to use. The laboratory shall have an established system for equipment calibration, where applicable. See "Preparation of Calibration Curves-A Guide to Best Practice," September 2003, LGC/VAM/2003/032, [www.vam.org.uk/](http://www.vam.org.uk/) for the guidance.

- a. All calibration curves shall cover (bracket) the expected sample concentration range with the concentrations of the calibration standards evenly distributed across the range. The calibration curves shall be dated, labeled and include at least the following information: applicable method, instrument identification, analysis date, lead concentrations, instrument response, and identify the personnel responsible for the calibration.

- b. When used, the axis of the calibration curve shall be labeled. For electronic data processing systems that automatically compute the calibration curve, the equation for the curve and the correlation coefficient must be recorded. The equation for the line and the correlation coefficient shall also be recorded when the calibration curve is prepared manually.
- c. A criterion for the acceptance of a calibration curve, (for example, an acceptable correlation coefficient) shall be established and documented.
- d. When linear fit is used, the extent of the linear range shall be verified (if possible) and the calibration standards shall be limited to that range.

#### **5.5.2.1 Initial Calibration**

A minimum of three calibration standards, which bracket the sample concentrations, and an initial calibration blank (ICB) shall be analyzed and used to construct a calibration curve prior to the analysis of samples, as appropriate. Calibration acceptance criteria shall be stated. New calibration curves shall be prepared whenever an out of control condition is indicated. For those technologies and software packages requiring fewer calibration standards, follow the manufacturer's recommendations (e. g., the instrument operations manual).

When linear fit is used, linearity shall be evaluated by using the calibration standards. Acceptance criteria shall be stated (See Tables 1 and 2).

#### **5.5.2.2 Independent Calibration Verification**

An independent calibration verification (ICV) standard shall be analyzed daily or prior to analyzing samples. See Tables 1 and 2 for minimum performance acceptance criteria.

For an instrument which produces a numerical result, the ICV standard shall be at a lead concentration in the range of customer specified lead levels of concern or action levels such as regulatory limits.

For an instrument (or equivalent) which produces a pass-fail result, the ICV positive (ICV-P) with lead level no more than 20 % above the applicable regulatory limit (omit for positive screen technologies) and/or negative (ICV-N) with lead level no less than 20 % below the applicable regulatory limit (omit for negative screen technologies).

### **5.5.2.3 Continuing Calibration Verification**

Continuing calibration verification (CCV) standards shall be analyzed in accordance with the SOP. The CCV standard may be prepared from independent reference standards or from the same standards used to prepare the instrument calibration curve. Acceptance criteria shall be stated (See Tables 1 and 2 for minimum performance acceptance criteria).

- a. At least two standards shall be analyzed every 12 hours, or according to instrument manufacturer's recommendations, or at a predetermined SOP frequency whichever is most frequent.
- b. For an instrument which produces a numerical result, the concentration of these standards shall be determined by the confirmed operating range of the instrument, regulatory limits and/or method specified levels.
- c. For an instrument (or equivalent) which produces a pass-fail result, the concentration of these standards shall be determined by the confirmed operating range of the instrument, regulatory limits and/or method specified levels. The QC samples must contain lead levels no more than 20 % above the applicable regulatory limit for the Continuing Calibration Verification positive (CCV-P) (omit for positive screen technologies), and no less than 20 % below the applicable regulatory limit for the Continuing Calibration Verification negative (CCV-N) (omit for negative screen technologies).
- d. A new calibration curve shall be established if two consecutive test results of one continuing calibration check are outside acceptable limits. When the continuing calibration check is confirmed to be outside acceptable limits, the samples affected by the unacceptable check shall be reanalyzed after a new calibration curve has been established, evaluated, and accepted. Sample analysis shall not continue or be restarted until a new calibration curve is established and verified.

### **5.5.2.4 Continuing Calibration Blank (CCB)**

Continuing Calibration Blank (CCB) standards shall be analyzed in accordance with the testing SOP.

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

<b>QC SAMPLE</b>	<b>FREQUENCY</b>	<b>ACCEPTANCE LIMITS</b>
Independent Calibration Verification (ICV)	Once per day after calibration	Within $\pm 10$ % 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 $\pm 20$ % 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.*

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

<b>QC SAMPLE</b>	<b>FREQUENCY</b>	<b>ACCEPTANCE LIMITS</b>
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

## **5.6 MEASUREMENT TRACEABILITY**

All equipment that has a significant effect on the accuracy or validity of the test result shall be calibrated prior to use. The laboratory shall have an established system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials and equipment.

NLLAP recognized laboratories shall establish and use a program for the calibration of equipment to ensure traceability to the *Système International d'Unités* (International System of Units, or SI) units of measurement. Traceability of measurement shall be ensured through the use of calibration services from organizations demonstrating competence, traceability and measurement capability. The laboratory shall obtain and retain in its record system calibration certificates from these organizations showing the link to a primary standard and containing the measurement results including measurement uncertainty and/or a statement of compliance with an identified metrological specification.

### **5.6.1 Reference Standards and/or Reference Materials**

Property values for reference materials shall be traced to SI units of measurement wherever possible. The reference standards and materials values shall be certified and traceable to NIST or verified against NIST standards (when available). Intermediate calibration checks shall be carried out according to defined procedures and schedules. To protect the integrity of the reference standards, the laboratory shall have procedures in place to ensure their proper handling, transport, storage, and use of reference materials. Reference materials shall have an expiration date assigned.

Reference materials shall not be used beyond assigned expiration dates nor used if damaged or contaminated or suspected to be damaged or contaminated. The laboratory shall maintain records pertaining to all reference standards, reference materials and reagents to include certificates of analysis, purity, their origin and traceability, as provided by the manufacturer, for a period of at least five years.

### **5.6.2 Documentation of Reagent and Calibration Solution Preparation**

Documentation of intermediate and working standard and reagent solution preparations shall be kept to provide traceability and shall include the date of preparation, identity and concentration or purity of parent material, assigned expiration date and preparer's initials. All prepared reagents and standards shall be uniquely identified and the contents shall be clearly identified.

## **5.7 SAMPLING**

When the laboratory collects dust, paint and/or soil samples as a part of testing for lead, the sampling shall be performed in accordance with federal regulations in 40 CFR Part 745 - Lead-Based Paint Activities.

### **5.7.1 Sampling Media**

Where the laboratory is responsible for supplying sampling media, the media shall be evaluated, as appropriate, for lead contamination. The evaluation process shall be defined in a SOP and results of evaluations shall be recorded.

## **5.8 SAMPLE HANDLING**

The laboratory shall have written SOPs for transportation, receipt, handling, protection, retention, and/or disposal of the samples, including provisions necessary to protect the integrity of the samples.

### **5.8.1 Sample Control**

Appropriate space, equipment and procedures shall be provided for sample receipt, storage and processing.

### **5.8.2 Sample Acceptance, Documentation and Tracking Procedures**

These procedures shall include a laboratory identification system that uniquely identifies each sample and/or batch of samples received by the laboratory.

#### **5.8.2.1 Sample Acceptance Policy**

The laboratory shall have a written sample acceptance policy that clearly outlines the circumstances under which samples will be accepted (without issuing results with a qualifier in the associated data report). Data from any samples which do not meet the following criteria must be clearly flagged defining the nature and substance of the variation. This sample acceptance policy shall be made available to sample collecting personnel and shall include, but is not limited to, the following areas of concern:

- a. Full and complete documentation, which shall include sample identification, the location, date of collection, sample matrix and any special remarks concerning the sample;

- b. Sample labeling shall include unique field identification.
- c. Use of appropriate sample containers; and
- d. Adequate quantity of sample for analysis.

#### **5.8.2.2 Sample Receipt Logs**

The laboratory shall utilize a permanent record, such as a log book or electronic record, to document receipt of all samples. The following information must be recorded:

- a. Date of laboratory receipt of sample;
- b. Sample collection date (if known);
- c. Unique laboratory ID code (5.8.2.5);
- d. Field ID code supplied by sample submitter;
- e. Sample matrix;
- f. Requested analyses, including method number, if applicable;
- g. Signature or initials of sample receiver (where applicable); for electronic sample logging systems, the identity of the sample receiver; and
- h. Comments resulting because of sample rejection.

All associated documentation, such as memos or transmittal forms that are transmitted to the laboratory by the sample transmitter shall be retained.

#### **5.8.2.3 Documentation on Questionable Samples**

Where there is any doubt as to the suitability of the sample for testing, the sample does not conform to the description provided, or the analysis required is not fully specified, the laboratory shall consult the customer for further instruction before proceeding. If the sample does not meet the sample acceptance criteria, the laboratory shall:

- Retain correspondence and/or records of conversations concerning the final disposition of rejected samples or fully document any decision to proceed with the analysis of compromised samples;

- The condition of these samples shall, at a minimum, be noted on the chain of custody or transmittal form and laboratory receiving documents; and
- The associated test result shall be appropriately "qualified" on the final report.

#### **5.8.2.4 Sample Custody Procedures**

The use of legally-defensible chain of custody (COC) protocols is strongly recommended and may be required by customers and/or federal/state/tribal programs (see ASTM D 4840 Standard Guide for Sample Chain of Custody Procedures). Chain of custody records shall establish an intact, continuous record of the physical possession, storage and disposal of collected samples.

#### **5.8.2.5 Sample Tracking**

The laboratory shall have a documented system for uniquely identifying the items to be analyzed, to ensure traceability of items and to ensure that there can be no confusion regarding the identity of such items at any time. This system shall include identification of all samples, subsamples, and subsequent extracts and/or digestates. The laboratory shall have policies and procedures to uniquely identify samples and batches recovered by the laboratories and procedures for retention and disposal. Multiple aliquots of a sample that have been received for testing must be assigned a different ID code (such as a prefix or suffix).

The laboratory sample retention and disposal policies shall be documented and used. Laboratories shall comply with all applicable federal, state and local regulations regarding environmental contamination and waste disposal.

### **5.9 ASSURING THE QUALITY OF TEST RESULTS**

The laboratory is responsible for ensuring the quality of the test results through the monitoring of the testing process. Such monitoring plans shall include:

- Internal quality control approaches using statistical techniques;
- Participation in interlaboratory comparisons or proficiency testing programs;
- Regular use of reference materials;
- Replication of tests using the same or different methods
- Re-testing.

The laboratory quality control (QC) program shall include the continual evaluation of its performance: determinations of bias and precision for each matrix analyzed; and participation in

the ELPAT Program for each matrix analyzed. Also laboratories are encouraged to participate in interlaboratory comparisons and/or other proficiency testing programs.

Because the client may also be providing duplicates, spikes and/or blanks as part of their own sampling protocol, the laboratory should seek client feedback, whenever possible, on the laboratory's performance after reports are provided to the client; any information obtained should be included in the laboratory QC performance evaluation.

Laboratory system process control and system performance monitoring shall be accomplished using statistical process control (charts or data base) for monitoring the laboratory's performance with QC sample analysis results. The statistical process control method used shall specify warning and action limits for acceptance or rejection of the QC data and shall be used to monitor performance trends within the quality management system over time. In the absence of a statistically sufficient data base to determine the necessary frequency for QC samples and/or action limits for acceptance or rejection of QC data, the laboratory shall use of the frequencies and criteria for QC samples stated in Tables 3 and 4.

*Note: Tables 3 and 4 contain the required minimum performance criteria and frequency for QC sample analysis (frequency determinations are usually based on system process control data produced by the laboratory for the method in question). The laboratory shall establish its own performance criteria for QC samples (uncertainty of measurement), which shall not be greater than stated in tables 3 and 4.*

### **5.9.1 Quality Control Procedures.**

The laboratory shall have QC procedures for monitoring the validity of lead tests undertaken. The QC procedures shall be stated in the quality documents such as QMSM and/or in each method SOP addressing, as appropriate:

- Duplicate or "side-by-side" field sample analyses
- Spiked and blank sample analyses
- Blind samples
- Split/spiked field sample analyses
- Control charts or equivalent
- Calibration standards
- Laboratory control samples
- Internal standards

The resulting QC data, where appropriate, shall be recorded in such a way that trends are detectable and statistical techniques shall be applied to the reviewing of the results.

### 5.9.1.1 Bias Determination

Laboratory Control Samples (LCS). LCSs (External Reference) are used to determine the degree of bias shall be of the same matrix as the test samples, and shall be prepared and analyzed with a minimum frequency of one per twenty field samples or batch, whichever is most frequent. A batch is defined as a set of samples which are processed (for example, homogenized, digested and analyzed) in one operation.

*Note: LCS sources include but are not limited to: proficiency testing samples from the ELPAT Program, commercially available certified reference materials (CRM), or materials of known concentration determined using definitive methods. All external reference sample materials shall be NIST traceable.*

For an instrument which produces a numerical result, the lead concentration of the LCS shall be near the level of concern or action level and whenever possible shall not require extensive pretreatment dilution or concentration prior to analysis.

For an instrument (or equivalent) which produces a pass-fail result, the lead concentration of the LCS shall be near the level of concern or action level, but no more than 20 % above the applicable regulatory limit (omit for positive screen technologies) or no less than 20 % below the applicable regulatory limit (omit for negative screen technologies) and whenever possible shall not require extensive pretreatment dilution or concentration prior to analysis.

Matrix Spike (Split/Spiked) Field Samples. In an effort to evaluate potential matrix interference, a matrix spike sample shall be analyzed with a minimum frequency of 5 % of the samples for each matrix type per batch of samples. If there are fewer than twenty samples in a batch, at least one matrix spike for each matrix per batch shall be analyzed.

Matrix spike samples shall be prepared using a split field sample (before any digestion process when possible) and the level of lead spiked shall be enough to result in a final lead concentration of the prepared sample of five times the sample's observed lead concentration, or five times the method detection limit, whichever is greater.

Matrix spike analyses shall be performed using field samples (whenever possible) in order to monitor for potential field sample matrix interferences. For field samples too small or difficult to homogenize and split in order to obtain samples for matrix spike evaluation or replicate analyses, the laboratory shall select alternative QC options. One of these alternative options includes the analysis of duplicate laboratory control samples, prepared with the appropriate matrix material, for each batch.

**Method Blanks.** A method blank containing all reagents (and in the case of dust wipes, the representative blank wipe) and subject to all preparation steps shall be processed and analyzed along with the samples. Method blanks shall be analyzed with a minimum frequency of 5 % of the samples for each matrix per batch of samples. If there are fewer than twenty samples in a batch, at least one method blank for each matrix per batch shall be analyzed. Method blanks (or other QC results) shall not be used to correct sample results.

### 5.9.1.2 Precision Determination

A split field sample (the initial sample being split into two fractions before digestion and analysis) for precision determination shall be analyzed with a minimum frequency of 5 % of the samples for each matrix type per batch of samples. If there are fewer than twenty samples in a batch, at least one test sample for each matrix per batch shall be analyzed. For analyses where there is not a sufficient amount of field sample for splitting or the analytical technology does not allow for split samples, the laboratory shall use alternative QC procedures in an effort to monitor the laboratory's precision of analysis. One of these options is the analysis of duplicate laboratory control samples, prepared with the appropriate matrix material, for each batch in order to monitor laboratory performance.

**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 $\pm 20$ % of known value
Matrix Spike Sample	One per 20 samples or batch (min. frequency 5 %)	Within $\pm 25$ % of calculated value
Duplicate Sample	One per 20 samples or batch (min. frequency 5 %)	Within $\pm 25$ % 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.*

### **5.9.2 Control Charts or Quality Control Data Base**

Control charts or a quality control data base shall be used to record quality control data and track laboratory performances with respect to the associated acceptance limits for each matrix. The performance tracking of critical QC samples shall be done as close as possible on a real time basis.

### **5.9.3 Procedures for determination of out of control situations**

The laboratory shall implement general procedures to be followed to determine when quality control data is out of control. These procedures shall address the following:

- a. Assigning responsibility for assessing each QC data type;
- b. Assigning responsibility for initiating and/or recommending corrective actions;
- c. Defining how the analyst should treat a data set if the associated QC measurements are unacceptable; and
- d. Specifying how out-of control situations and subsequent corrective actions are to be documented.

When QC sample results fall outside the acceptance limits, the affected batch of samples shall be reanalyzed, whenever possible. The re-analysis shall begin with the sample preparation stage, when applicable, and shall include a new set of QC samples, when possible. When feasible, a lead laboratory may arrange for the re-collection or re-taking of field samples.

## **5.10 REPORTING THE RESULTS**

### **5.10.1 General**

Results of test activities carried out by the NLLAP recognized laboratory shall be reported clearly and objectively. These test results shall be reported in a test report that includes all the information needed for the interpretation of the test results and required by the test method used, as well as any additional information requested by the customer. The test report should indicate any test results that are inconclusive and explain briefly why the result is considered inconclusive.

When tests are performed for internal customers, or by customer request, the results may be reported in a simplified manner upon written agreement with the customer. In this case, the

information listed in 5.10.2 that is not reported shall be easily accessed in the laboratory that performed the tests.

### **5.10.2 Test Reports**

Final test reports shall contain, at a minimum, the information outlined below. The customer may request additional information to be included in the report. Along with the final test report, the laboratory shall maintain a sample case file or be able to assimilate the sample case information described in this document for a period of at least five years after the final test report is issued. It is also recommended that the document include a clause stating that the test report is not to be reproduced except in full without written approval of the laboratory.

Each report shall include at least the following information:

- a. title, e.g., “Test Report”, or “Report of Results” or “Laboratory Results”;
- b. name and address of laboratory, location where the analysis was carried out, if different from the address of the laboratory, and name and phone number of contact person for questions;
- c. unique identification of the report (such as serial number) and of each page, the total number of pages, and a clear identification of the end of the report;
- d. name and address of customer, where appropriate, and project name if applicable;
- e. description, condition, and clear identification of the analyzed samples;
- f. date of receipt of the sample(s);
- g. identification of the validated analytical method used;
- h. any deviations from, additions to, or exclusions from the analytical method, and any other information relevant to a specific analytical method, such as environmental conditions including the use of relevant data qualifiers;
- i. identification of the standard(s) or specification(s) relevant to the test (when required by customer);
- j. where necessary, a statement of compliance/non compliance with requirements and/or specifications;

- k. analytical test results, supported by tables, graphs, sketches, and photographs as appropriate, with units of measurement; and any failures identified; and identification of the quantitation limit and reporting units (such as mg/kg with identification of whether data is calculated on a dry weight or wet weight basis);
- l. a signature and title, or an equivalent identification, of the person(s) accepting responsibility on behalf of the laboratory for the content of the report (however produced), and date of issue;
- m. where relevant, a statement to the effect that the results relate only to the items analyzed;
- n. where appropriate and needed, opinions and interpretations including synopsis of analytical quality control results focusing on any quality control sample measurements that did not meet the method specified requirements;
- o. reference to sampling procedure, where relevant;
- p. statement on the estimated uncertainty of the measurement when the uncertainty affects reported lead result or is required by the customer (see section 5.4.6.1);
- q. significant figures reported for each value shall correctly represent the estimated uncertainty of the reported measurement;
- r. identification of inconclusive test results and reason why the result is considered inconclusive; and
- s. identification of the NLLAP recognized accrediting body.

In addition to the requirements listed above, test reports containing the results of sampling shall include the following, if available:

- a. the date of sampling;
- b. location(s) of sampling, including any relevant diagrams, sketches, or photographs;
- c. reference to the specific sampling plan used;
- d. detailed environmental conditions present during sampling that may affect the interpretation of the test results;

- e. identification of the sampling method or procedure used; and
- f. protocols or specifications used for the sampling methods or procedures, as well as any deviations from, additions to, or exclusions from the specification concerned.

#### **5.10.2.1 Reporting Results Below the Quantitation Limit**

Report of zero concentration is not permitted. Laboratories shall establish a method of limiting the lower reported values to a positive finite lead level that is appropriate for the technology being used. Measured lead levels below this positive finite value shall be reported with a qualifier “less than” (“<”) this positive finite value.

For pass-fail technologies, clear statement of measurement capability with associated uncertainty shall be reported to the customer.

#### **5.10.2.2 Opinions and Interpretations**

When opinions and interpretations are included in the test report, the laboratory shall be able to show that it has documented the basis upon which the opinions and interpretations have been made. Examples of opinions and interpretations that might be included in a test report are recommendations on how to use results, guidance for improvement, and conformity of results with requirements.

#### **5.10.3 Report Review and Approval Process**

All final test reports shall undergo the documented data review process before release to the customer. If a qualified person who was not involved in the physical preparation or analysis of samples in question is available to review the final report, than that person shall conduct the review. Qualified persons can be technicians, analysts, the quality manager, or technical manager, or the responsible person described previously in Section 4.0.

In the case of a one person laboratory, or where a qualified person is not available for the review, the review process shall be contracted out to an independent person or firm that is competent and has the experience and training necessary to conduct the review.

The review process shall be documented and signed by the reviewer, and shall be retained on file with a copy of the final report for a minimum of five years.

#### **5.10.4 Test Report Corrections Process**

##### **5.10.4.1 Corrections and Amendments to Test Reports**

If corrections or additions to a test report are made, they shall be documented and the report reissued as an amended report.

Once a test report has been issued, material amendments shall be made only in the form of a further document or data transfer that is clearly identified as a supplement to the original. When issuance of a complete new report is warranted, it shall be uniquely identified and shall contain a reference to the original it replaces.

##### **5.10.4.2 Test Results Obtained from Subcontractors**

Test results obtained from subcontractors shall be clearly identified in the test report. The subcontracted laboratory or organization must be currently NLLAP recognized for the subcontracted test methods in question.

##### **5.10.4.3 Electronic Transmission of Results**

When transmitting test results via telex, facsimile, telephone, or other electronic or electromagnetic means, the requirements in 4.13.3 of this document must be met. Data transfers shall be subject to appropriate checks in a systematic manner.

**APPENDIX I**

**ACRONYMS AND GLOSSARY OF TERMS  
ASSOCIATED WITH THE NLLAP**

**Acronyms**

A2LA	American Association for Laboratory Accreditation
ACS	American Chemical Society
AIHA	American Industrial Hygiene Association
ASTM	American Society for Testing and Materials
ANSI	American National Standards Institute
CCB	Continuing Calibration Blank
CCV	Continuing Calibration Verification
CDC	Centers for Disease Control and Prevention
COC	Chain of Custody
ELPAT	Environmental Lead Proficiency Analytical Testing
EPA	Environmental Protection Agency
FSMO	Field Sampling and Measurement Organization
HUD	Housing and Urban Development
ICB	Initial Calibration Blank
ICV	Independent Calibration Verification
ICS	Interference Check Standard
ID	Identification
ISO	International Organization for Standardization
ISO-IEC	International Organization for Standardization and International Electrochemical Commission
LCS	Laboratory Control Sample
MDL	Method Detection Limit
MOU	Memorandum of Understanding
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLLAP	National Lead Laboratory Accreditation Program
OPPT	Office of Pollution Prevention and Toxics
PCS	Performance Characteristic Sheet
PE	Performance Evaluation
PT	Proficiency Testing
QA	Quality Assurance
QC	Quality Control
QMSM	Quality Management System Manual
RE	Relative Error

RPD	Relative Percent Difference
SAP	Sample Analysis Plan
SI	<i>Système International d'Unités</i> (International System of Units)
SOP	Standard Operating Procedure
SRM	Standard Reference Material Produced by NIST
TSCA	Toxic Substances Control Act
UoM	Uncertainty of Measurement

## Glossary

Accreditation:	A formal recognition that an organization (e.g., laboratory) is competent to carry out specific tasks or specific types of analyses.
Accredited laboratory:	A laboratory that has been evaluated and given approval to perform a specified analysis or task, usually for a specific property or analyte and for a specified period of time.
Acceptance limits:	Data quality limits specified by the National Lead Laboratory Accreditation Program for analytical method performance.
Accuracy:	The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. See <u>Precision</u> and <u>Bias</u> .
Aliquot:	See <u>Subsample</u> .
Batch:	A quantity of material produced or processed (for example, homogenized, digested and analyzed) in one operation, considered to be a uniform, discrete unit.
Bias (trueness):	The systematic error manifested as a consistent positive or negative deviation from the known true value.
Blind sample:	A subsample submitted for analysis with a composition and identity known to the submitter but unknown to the analyst and used to test the analyst's or laboratory's proficiency in the execution of the measurement process.
Calibrate:	To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the calibration standards should bracket the range of planned measurements. See <u>Calibration curve</u> .
Calibration blank:	See <u>Initial calibration blank</u> .
Calibration-check:	See <u>Calibration verification</u> .

Calibration-check standard:	See <u>Calibration verification</u> .
Calibration curve:	The graphical relationship between the known values for a series of calibration standards and instrument responses.
Calibration drift:	The difference between the instrument response and a reference value after a period of operation without recalibration. See <u>Continuing calibration verification</u> .
Calibration standard:	A substance or reference material used to calibrate an instrument.
Calibration solution:	See <u>Calibration standard</u> .
Calibration verification:	See <u>Initial or continuing calibration verification</u> .
Certified Reference Material:	A reference material that has one or more of its property values established by a technically valid procedure and is accompanied by or traceable to a certificate or other documentation issued by a certifying body. See <u>Certification</u> and <u>Reference material</u> .
Chain of custody (COC):	An unbroken trail of accountability that insures the physical security of samples, data, and records.
Check sample:	An uncontaminated sample matrix spiked with known amounts of analytes, usually from the same source as the calibration standards. It is generally used to establish the stability of the analytical system, but may also be used to assess the performance of all or a portion of the measurement system. See also <u>Quality control sample</u> .
Composite sample:	A sample composed as a result of collection of more than one sample of the same medium (e.g., dust) from the same type of surface (e.g., floor, interior window sill, or window trough) so that multiple samples can be analyzed as a single sample.

Continuing Calibration Blank (CCB):	A standard solution which has no analyte and is used to verify blank response and freedom from carryover. The CCB should be analyzed after the CCV and after the Interference Check Standard (ICS).
Continuing Calibration Verification (CCV):	A standard solution (or set of solutions) used to verify freedom of excessive instrumental drift. The concentration of the standard solution should be near mid-range of the linear curve. The CCV should be matrix matched to acid content present in sample digestates. The CCV should be analyzed before and after all sample digests.
Control chart:	A graph of some measurement plotted over time or sequence of sampling, together with control limit(s) and, usually, a central line and warning limit(s).
Control sample:	See <u>Laboratory control sample</u> .
Corrective action:	Action taken to correct a deficiency noted in a technical systems audit. See <u>Deficiency</u> and <u>Systems audit</u> .
Deficiency:	A failure to fully comply with the requirements of NLLAP usually noted during a technical systems audit. See <u>NLLAP</u> and <u>Systems audit</u> .
ELPAT:	Environmental Lead Proficiency Analytical Testing Program. Successful participation in this proficiency testing program on a quarterly basis is required for all EPA/NLLAP recognized laboratories. ELPAT Program is administered by AIHA in cooperation with NIOSH and EPA.
Initial calibration blank (ICB):	A standard solution that contains no analyte and is used for initial calibration and zeroing instrument response. The ICB must be matrix matched to acid content present in sample digestates. The ICB should be measured during calibration and after calibration.
Independent calibration verification (ICV):	A standard solution (or set of solutions) used to verify calibration

standard levels. Concentration of the analyte should be near mid-range of the calibration curve which is made from a stock solution having a different manufacturer or manufacturer lot identification than the calibration standards. The ICV must be matrix matched to acid content present in sample digestates. The ICV should be measured after calibration and before measuring any sample digestates.

Instrument:	An instrument which produces a quantitative (numerical result) performs a measurement of lead that can be quantified numerically or an instrument (or equivalent) which produces qualitative (pass-fail) result performs a measurement that indicates the absence or presence of lead relative to a given threshold level.
Interference check standard (ICS):	A standard solution (or set of solutions) used to verify accurate analyte response in the presence of possible interferences from other analytes present in samples. The ICS must be matrix matched to the reagent content present in sample digestates.
Internal quality control:	The routine activities and checks, such as periodic calibrations, duplicate analyses, and spiked samples, that are included in normal internal procedures to control the bias and precision of measurements.
Internal standard:	A standard added to a test portion of a sample in a known amount and carried through the entire demonstration procedure as a reference for calibration and controlling the precision and bias of the applied analytical method.
Laboratory:	Any operation that performs quantitative and/or qualitative analytical testing of paint chip (film), dust, and/or soil samples for lead analysis regardless of the number of personnel or the extent of the scope of testing activities.
Laboratory control sample (LCS):	A matrix-based reference material with an established concentration obtained from a source independent of the instrument calibration and traceable to NIST or other reference materials. The LCS is carried through the entire procedure from digestion through analysis as a field sample. The purpose of the

LCS is to evaluate bias of the method.

Laboratory systems  
audit:

See Systems audit.

Lot:

A set of samples submitted together for laboratory analysis which can be treated as one or more batches.

Matrix:

The component or substrate which contains the analyte of interest.

Matrix spike:

See Spiked sample.

Method blank:

A mixture of all reagents used for the digestion of paint, soil, or dust matrices but without the matrix. This blank, is carried through all steps of the analysis starting with the digestion step. This blank evaluates the process for contamination from the laboratory.

Method performance:

A general term used to document the characteristics of a method. These characteristics usually include method detection limits, linearity, precision and bias. The minimum acceptable criteria for method performance characteristics are determined and/or verified as part of method validation, method measurement uncertainty determination and method performance demonstrations.

Method detection  
limit (MDL):

The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99 % probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.

NLLAP:

National Lead Laboratory Accreditation Program. This EPA program recognizes laboratories which have demonstrated they are capable of analyzing paint chip (film), dust and/or soil samples for lead.

NLLAP requirements:

Requirements specified by the EPA National Lead Laboratory Accreditation Program (NLLAP) in order to be accredited for lead analysis in paint chip (film), dust, and/or soil matrices by an EPA-recognized laboratory accreditation organization. (NLLAP requirements are designed to be used for accreditation purposes and should not be used for purpose of verification/validation of any

specific technology).

Precision (repeatability):	The degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.
Proficiency testing:	A systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant.
Quality assurance (QA):	An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality within a stated level of confidence.
Quality control (QC):	The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.
Quality manager:	The manager of the quality system. The quality manager is independent of the analyst and reports directly to management.
Quantitation Limits:	The maximum or minimum levels or quantities of a target analyte that can be quantified to a specified accuracy.
Reference material:	A material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or assigning values to materials.
Reference standard:	See <u>Calibration standard</u> .
Relative percent difference:	A term defined as:

$$RPD = | R_1 - R_2 | / R_{ave} \times 100 \%$$

where  $| R_1 - R_2 |$  represents the absolute difference in two values and  $R_{ave}$  represents the average of the two values.

Run:	A set of consecutive sample measurements.
Sample:	An aliquot taken from a painted surface (paint), surface (dust), or soil in accordance with 40 CFR 745 that was physically removed from its matrix for analysis by a laboratory.
Sample log:	The document where sample identification, condition, etc is noted when samples arrive at the laboratory. The log is part of the sample tracking system. See <u>Sample tracking</u> .
Sample tracking:	A system of following a sample from receipt at the laboratory, through sample processing and analysis, and to final reporting. The system includes unique numbering or bar coding labels and the use of a sample log.
Site inspection/assessment:	An on-site visit to a laboratory for the purpose of conducting a systems audit.
Spiked sample:	A sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.
Split samples:	Two or more representative portions taken from a sample or subsample and analyzed by different analysts or laboratories. Split samples are used to replicate the measurement of the variable(s) of interest.
Standard operating procedure (SOP):	A written document that details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.
Standard reference material (SRM):	A certified reference material produced by the U.S. National Institute of Standards and Technology and characterized for

absolute content independent of analytical method.

- Standardization: The process of establishing the quantitative relationship between a known mass of target material (e.g., concentration) and the response variable (e.g., the measurement system or instrument response). See Calibrate and Calibration curve.
- Stock solution: A concentrated solution of analyte(s) or reagent(s) prepared and verified by prescribed procedure(s), and used for preparing working standards or standard solutions.
- Subsample: A representative portion of a sample.
- Systems audit: A thorough systematic on-site, qualitative review of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system.
- Traceability: An established property of the result of a measurement, to stated references (usually national or international standards) at a stated level of uncertainty through an unbroken chain of comparisons.
- Validation: The process of substantiating specified performance criteria.