MODULE 2C
ENVIRONMENTAL LEAD LABORATORY ACCREDITATION PROGRAM (ELLAP) REQUIREMENTS

2C.1 SCOPE

The AIHA-Laboratory Accreditation Programs (AIHA-LAP), LLC's Environmental Lead Laboratory Accreditation Program (ELLAP) is intended for accreditation of laboratories performing lead analysis in the following Fields of Testing (FoTs): airborne particulates, composited wipes, dust wipes, paint chips and soil. A FoT may also be referred to as a "matrix" in this module. Laboratory accreditation in this program is based upon a review of the laboratory management systems as defined in Module 2A and this program specific module, and successful participation in the appropriate proficiency testing program, as defined in Module 6.

2C.2 LEAD IN PAINT/SOIL/DUST WIPE ACCREDITATION REQUIREMENTS

AIHA-LAP, LLC has a Memorandum of Understanding (MOU) with the United States EPA (U.S. EPA) to implement the Laboratory Quality System Requirements (LQSR) of National Lead Laboratory Accreditation Program (NLLAP). Laboratories that are ELLAP accredited for lead analysis of dust wipes, paint chips and soil are also recognized by EPA as capable of performing analysis of paint, soil and/or settled dust wipe samples collected from or during lead-based paint activities as defined in 40 CFR Part 745. ELLAP accreditation requires participation in the AIHA PAT Program, LLC proficiency testing program for lead for each FoT where proficiency samples exist. The laboratory shall maintain proficiency in the FoT(s) for which it is accredited. Unless otherwise noted, where there are discrepancies between the requirements in Module 2A and the LQSR, the requirements in the LQSR shall take precedent.

The specific criteria for determining lead (Pb) contamination are maintained in the Laboratory Quality System Requirements (LQSR) revision 3.0 published by the EPA National Lead Laboratory Accreditation Program (NLLAP).

This document is available from: U.S. Environmental Protection Agency Ariel Rios Building (7404T) Office of Pollution Prevention and Toxics 1200 Pennsylvania Ave., N.W. Washington D.C. 20460 Phone: (202) 566-0500

http://www.epa.gov/lead/national-lead-laboratory-accreditation-program-laboratory-quality-system-requirements-revision

2C.3 LEAD IN AIR ACCREDITATION REQUIREMENTS

2C.3.1 Technical Manager

2C.3.1.1 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.

2C.3.1.2 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.

2C.3.2 Quality Manager

2C.3.2.1 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.

2C.3.2.2 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.

2C.3.3 Accuracy and Precision Determinations for Air Samples

When analyzing air samples, method spike/method spike duplicate samples shall be prepared using two (2) blank collection media spiked at the same level. These samples shall be analyzed with a minimum frequency of five (5) percent of the samples per batch. If there are fewer than twenty samples in a batch, at least one set of method spike/method spike duplicates for each matrix per batch, shall be analyzed.

2C.3.4 Matrix Blanks

When analyzing air filter samples, a matrix blank shall be prepared using representative blank media and analyzed at a frequency of five (5) percent. If there are fewer than twenty (20) samples in a batch, at least one matrix blank for each matrix shall be analyzed. Unless otherwise specified by the method or client contract, matrix blanks shall not be used to correct sample results.

2C.3.5 Laboratory Control Samples (LCS)

A matrix based reference material shall be run with a minimum frequency of five (5) percent of the samples for each matrix per batch of samples. If there are fewer than twenty (20) samples in a batch, at least one sample for each matrix shall be analyzed. The LCS is carried through the entire procedure with each sample batch, from digesting through analysis as if it were a field sample. LCSs shall only be used for analysis with the same batch of samples for which it was digested. Use of a previously digested LCS for analysis with future sample batches is unacceptable. The LCS shall be a solid matrix matched material with an established concentration obtained from a source independent of the instrument calibration and traceable to NIST or other similar reference material.

2C.3.6 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 that is based on procedures published or recognized nationally (e.g., 40CFR Part 136 Appendix B).

2C.3.7 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 2C.1 and 2C.2 shall be met, as appropriate.

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.

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.

A criterion for the acceptance of a calibration curve, (for example, an acceptable correlation coefficient) shall be established and documented.

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.

2C.3.8 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 2C.1 and 2C.2).

2C.3.9 Independent Calibration Verification

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

2C.3.10 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 2C.1 and 2C.2 for minimum performance acceptance criteria).

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.

2C.3.11 Continuing Calibration Blank

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

Table 2C.1: Summary of Instrument Calibration Performance Requirements for an instrument which produces a numerical result

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

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

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

QC Sample	Frequency	Acceptance Limits
Independent Calibration Verification - Positive (ICV-P) (sample lead level no more than 20% above the applicable regulatory limit; omit for positive screen technology)	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

2C.4 Lead in Composited Wipes Accreditation Requirements

For composited wipes, all requirements for wipes listed in the LQSR apply. In addition, the laboratory shall meet the PT requirements as outlined in Policy Module 6 and the Scope/PT Table.