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MODULE 2C

ENVIRONMENTAL LEAD LABORATORY ACCREDITATION PROGRAM (ELLAP) SPECIFIC ADDITIONAL REQUIREMENTS

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2C.1 SCOPE

The American Industrial Hygiene Association 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 (FoT): airborne particulates, 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 defined in Modules 6A and 6C.

The ELLAP adheres to standards and guidelines documented in the following publications: ISO/IEC 17011:2004 for the accrediting body; ISO/IEC 17025:2005 for the participating laboratories; the American Society for Testing and Materials (ASTM) "Standard Guide for Laboratory Accreditation Systems" (E994); ASTM "Standard Guide for Evaluating Laboratories Engaged in the Determination of Lead in Paint, Dust, Airborne Particulates, and Soil Taken from and Around Buildings and Related Structures" (E1583); and the "Report on Guidelines for Establishment of a Laboratory Accreditation Program for the Measurement of Lead in Paint and the Environment" (The DeVoe Report), prepared by the Special Committee on Laboratory Accreditation, Task Group on Methods and Standards of HUD-EPA Lead Based Paint Task Force (March, 1992).

The Environmental Lead Laboratory Accreditation Program (ELLAP) also conforms to the current version of Laboratory Quality System Requirements (LQSR) of the EPA 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 must maintain proficiency in the FoT(s) for which it is accredited.

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2C.2 FACILITIES

Mobile and field operations laboratories shall maintain records of the locations where analyses are performed.

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2C.3 PERSONNEL

Laboratory personnel shall consist, at a minimum, of a Technical Manager and a qualified individual not directly involved with the analysis of the samples set. They are to review and concur on the data for use in the final report. See Policy Module 9 for definition of "Qualified Individual (for data review)."

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2C.3.1 Technical Manager

Qualifications of the TM in addition to those in 2A are at least three (3) years of nonacademic analytical chemistry laboratory experience, of which at least two (2) years shall be metals

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analysis experience. For laboratories performing lead in air analysis, the Technical Manager shall possess knowledge of IH chemistry calculations with respect to lead in air principles and calculations.

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2C.3.2 Laboratory Analytical Staff

The environmental lead program distinguishes two titles for those conducting analytical procedures within the laboratory. An analyst is one who has a bachelor's degree in chemistry or a related science. A technician is one who does not have a degree in chemistry or a related science.

2C.3.2.1 All analysts and technicians shall complete a training course (an in-house course is acceptable) for lead or applicable metals analysis prior to performing analysis on laboratory samples. Courses on sample preparation and instrument analysis may be taken separately or combined. The criteria and training requirements for laboratory personnel shall be clearly defined, documented and maintained on file. The laboratory must maintain a description of the training program content, duration of the training, qualifications of the trainer, and objective evidence that the analyst/technician has successfully analyzed unknown reference samples for the FoT(s) of concern within specified acceptance criteria. The dates of authorization to perform specific tasks shall be recorded.

Deleted: The Technical Manager shall be available at least 50 percent of the laboratory operating hours to address technical issues for laboratory staff and customers concerning NLLAP related analyses. The Technical Manager shall authorize and document that all analyses for which the laboratory is accredited are completed by personnel with appropriate education and/or technical background. The Technical Manager shall ensure that adequate supervision is provided for all laboratory technical personnel. The Technical Manager may function as the Quality Manager so long as he/she does not act in the position of the sample analyst/technician analyzing the samples. The Technical Manager or their designee shall function as the approved signatory.

2C.3.2.2 All analysts and technicians shall have demonstrated ability to produce reliable results through accurate analysis of certified reference materials (CRMs), proficiency testing samples, or in-house quality control samples. This demonstration shall be performed and documented at a minimum of every six (6) months.

2C.3.2.3 All analysts and technicians shall have a minimum of twenty (20) business days of hands-on experience conducting analyses in an inorganic/metals laboratory before initiation of work on NLLAP related samples. All of these performance criteria must be documented in the laboratory files.

2C.3.2.4 All analysts and technicians shall be trained with the SOPs in use in the laboratory and with the instrument and equipment operation manuals. All analysts and technicians shall complete a minimum of four (4) independent test runs of sample preparation and/or instrumental analysis for each FoT. Independent runs are defined as analytical runs consisting of at least five (5) samples of known content, one of which is a certified reference material (CRM) or proficiency testing material, 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 materials for each run must be within +/- 10% of the certified value, 75% of the time. For instrumental analysis training, the recoveries of the associated reference materials or proficiency training samples for each run must be within +/- 10% of the certified value, 75% of the time. The reference/proficiency test samples utilized shall be representative of the FoT(s) and mass ranges that the analyst will encounter during routine sample analysis.

2C.3.2.5 All mobile and field operations facilities laboratory personnel conducting



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analyses onsite at field job locations shall be trained and certified as inspectors of target housing and child-occupied facilities as defined in 40 CFR 745, Subpart L, Title X Section 404/404, Lead Based Paint Activities. All mobile and field operations facilities personnel shall have the capability to communicate with their Technical Manager while onsite at a job location. In addition, all mobile and field operations facilities technicians shall be accompanied by a qualified individual, as defined under 40 CFR 745, Subpart L, for their initial two (2) NLLAP related job sites.

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2C.4 ANALYTICAL METHODS

In addition to the requirements in Module 2A, the following requirements apply to lead testing procedures under the ELLAP.

2C.4.1 Each method under consideration for analytical testing shall demonstrate a reporting limit (at least twice the method detection limit, MDL) equal to or less than 20% of the lowest relevant action level or regulatory limit of interest, except for lead wipes. The reporting limit for lead wipes must be equal to or less than 50% of the lowest relevant action limit. As of the revision date of this policy module, national limits of interest are: paint = 0.06%; soil = 400 ppm; wipe = 40 ug/ft². State regulatory limits may be lower than national limits. Applicable state limits must be checked before analyzing samples.

2C.4.1.1 Environmental lead laboratories shall only report levels below the method reporting limit as “<” (less than) and reference the reportable limit. The reporting of zero concentration is not permitted.

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2C.4.2 Analytical reagents shall be of ACS grade or better.

2C.4.3 Initially, and at least annually thereafter, the following shall be established and statistically verified for each method/matrix/instrument combination as part of the method validation process:

2C.4.3.1 Linear calibration ranges.

2C.4.3.2 Method Detection Limits (MDLs). For methods with stated MDLs, demonstration of ability to achieve such MDL is required. The required method for conducting and calculating MDLs is defined in 40 CFR Part 136, Appendix B.

2C.4.3.3 Whenever there is a change in methodology or instrumentation, linear calibration ranges and MDLs shall be re-established or re-determined and verified.

2C.4.4 The daily working calibration curve, as specifically described in the applicable SOP, shall fall within the established linear calibration range.

2C.4.5 For wipe samples, the MDL shall be determined using wipe materials meeting ASTM E1792, “Standard Specification for Wipe Sampling Materials for Lead in Surface Dust”, or with wipe materials meeting specifications issued by EPA (reference EPA publication, “Interpretive Guidance for the Federal Program TSCA Sections 402/403”, March 14, 2002 and/or subsequent EPA published guidance).



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Note: If the laboratory is unable to verify that the wipe materials submitted to the laboratory for lead analysis meet the ASTM E1792 or specifications issued by EPA, then the laboratory may choose to qualify the report to indicate the following:

- 1) MDLs and resulting Reporting Limits have been derived using either wipe materials meeting ASTM E1792 or wipe materials that meet the specifications issue by EPA, stating whichever materials were used; or,
- 2) The laboratory has been unable to verify that the wipe samples submitted conform to ASTM E1792 or specifications issued by the EPA; or
- 3) MDLs and resulting Reporting Limits may not be relevant or applicable to the reported results.

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2C.4.6 For applicable methodologies, a minimum of three (3) calibration standards (ICP-AES is an exception) which bracket the sample concentrations, and a blank shall be analyzed each day of use to construct a calibration curve. Instrument performance at the minimum reporting limit concentration shall be verified, with acceptance criteria documented. All calibration curves shall be dated and labeled with applicable method, instrument identification, analysis date, analyte concentrations, and instrument response. Acceptance criteria in terms of the relative percent difference (RPD) of response factors or correlation coefficient shall be stated. New calibration curves shall be prepared whenever an out of control condition is indicated and/or after new calibration standards and/or reagents are prepared.

2C.4.7 For inductively coupled plasma - atomic emission spectroscopy (ICP-AES) analyses, where possible, a minimum of a two-point calibration plus a blank should be performed. For the samples to be analyzed, linearity shall be confirmed by the calibration standards, measuring concentrations encompassing the concentration range of interest. Instrument performance at the minimum reporting limit concentration shall be verified, with acceptance criteria documented.

2C.4.8 An Initial Calibration Verification (ICV) standard shall be measured after calibrating and before measuring any sample. The ICV is a standard solution (or set of solutions) used to verify calibration standard levels. The concentration of the analyte shall be near the regulatory level of concern. The ICV shall be made from a stock solution having a different manufacturer or different manufacturer lot identification than the calibration standards. The ICV shall be matrix matched to acid content present in the sample digestates. Acceptance criteria shall be stated.

2C.4.9 For ICP-AES only, an Interference Check Standard (ICS) shall be analyzed at the beginning and end of each run or twice every eight (8) hours. The ICS is a standard solution (or set of solutions) used for ICP-AES to verify an accurate analyte response in the presence of possible spectral interferences from other analytes present in the samples. Laboratories should refer to EPA SW-846, Method 6010 for guidance on concentrations. The ICS shall be matrix matched to acid content present in the sample digestates. Acceptance criteria shall be stated.

2C.4.10 A Continuing Calibration Verification (CCV) standard shall be analyzed in accordance with the specified test method. The CCV is a standard solution (or set of solutions) used to verify freedom of excessive instrumental drift. The concentration shall be near the mid-range of the linear curve. The CCV should be matrix matched to acid content present in the sample digestates. Acceptance criteria shall be stated.



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2C.4.11 Each day that a matrix is analyzed, a matrix spiked sample (reporting limit verification) at a concentration equal to or below the stated reporting limit shall be digested and analyzed to demonstrate acceptable recovery of lead. The acceptance criteria shall be +/- 20% of the actual value. A liquid spike is acceptable.

2C.4.12 In accordance with NLLAP requirements, all unique SOPs including any modifications of standard methodologies shall be submitted in their entirety to AIHA-LAP, LLC. Use of a standard method requires submission of verification data, and use of any nonstandard methodologies requires submission of validation data for review and subsequent approval.

2C.4.13 Any laboratory wishing to change or add a technology and/or method for one or more FoTs shall provide AIHA-LAP, LLC with the new or additional SOP for approval forty (40) business days prior to use on NLLAP samples. In addition to the SOP, use of a standard method requires submission of validation data for review and subsequent approval. AIHA-LAP, LLC shall determine if any additional laboratory assessment is required.

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2C.5 INTERNAL QUALITY CONTROL PROCEDURES

As part of the quality assurance program for each FoT for which the laboratory is accredited, the laboratory shall adhere to all stated QA/QC requirements as published in the method(s) used. A synopsis of analytical quality control results, focusing on any quality control sample measurements that do not meet the method specified requirements, shall be included in the test report.

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2C.5.1 Accuracy Determinations for Lead in Soil and Paint Chip Samples

Matrix spikes shall be analyzed with a minimum frequency of five (5) percent of the samples for each matrix per batch of samples (samples processed at a single time). If there are fewer than twenty (20) samples in a batch, at least one spiked sample for each matrix per batch shall be analyzed.

2C.5.2 Precision Determinations for Lead in Soil and Paint Chip Samples

Duplicate samples shall be analyzed with a minimum frequency of five (5) percent of the samples for each matrix per batch of samples (samples processed at a single time). If there are fewer than twenty (20) samples in a batch, at least one sample for each matrix per batch shall be analyzed. If the analyte is not detected in the sample, duplicate matrix spike samples may be analyzed.

2C.5.3 Accuracy and Precision Determinations for Lead Dust Wipe and Air Samples

When analyzing wipe samples and/or air samples, method spike/method spike duplicate samples shall be prepared using two (2) blank collection media spiked at the same level. The method spike/method spike duplicate for dust wipes must be prepared by adding a known amount of a solid paint, dust or soil certified reference material (CRM) to representative blank dust wipe media (ELPAT paint or soil material may be substituted for a CRM). 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.



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2C.5.4 Method Blanks (Reagent Blanks)

If a method requires sample pretreatment that is not applied to calibration standards, a method blank containing all reagents and subject to all preparation steps shall be processed with the samples. Method blanks shall be analyzed with a minimum frequency of five (5) percent 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. The use of method blanks provides a measurement of laboratory and/or reagent contamination. Method blanks shall not be used to correct sample results.

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2C.5.5 Matrix Blanks

When analyzing wipe and/or 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. Matrix blanks shall not be used to correct sample results.

2C.5.6 Initial Calibration Blanks (ICB)

The ICB is a standard solution that contains no analyte and is used for initial calibration and for zeroing instrument response. The ICB shall be matrix matched. The ICB shall be measured during and after calibration.

2C.5.7 Continuing Calibration Blanks (CCB)

The CCB is a standard solution that has no analyte and is used to verify blank responses and freedom from carryover. The CCB shall be analyzed after each CCV and after the ICS.

2C.5.8 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. Liquid spikes may not be used for preparing LCSs, except for the air matrix.

2C.5.9 Acceptance Limits

In the absence of sufficient data for the statistical determination of adequate acceptance limits, the QC sample frequencies and acceptance limits listed in Table 2C-1 are required under ELLAP. Laboratory determined statistical acceptance limits and frequencies must be at least as stringent as these interim limits.

2C.5.10 Contamination Control

Wipe sampling shall be conducted at least quarterly to determine surface levels of lead in the laboratory. The laboratory shall define the areas to be sampled and the level of acceptable contamination. The wipe samples shall be collected on all laboratory surfaces that are



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associated with lead analysis such as around balances, sample preparation and analysis areas, and the inside of hoods and microwaves. The acceptable contamination level must be below the lowest regulatory level and may be set at the limit of detection. Any contaminated area must be cleaned and the area re-sampled to verify cleanliness before any analytical work is performed in the affected area. Documentation of all wipe data and corrective actions is required.

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2C.6 SUBCONTRACTING FOR ANALYSIS OF SUBMITTED SAMPLES

Subcontracting of routine sample analyses for which the laboratory is accredited is not permitted unless the laboratory selected for subcontract work is accredited under this program or a program recognized by EPA under the NLLAP program. If accreditation is suspended for any FoT, as defined in AIHA-LAP, LLC Policy Module 4, then the laboratory must inform AIHA-LAP, LLC in writing within ten (10) business days, of procedures for any samples that are received by the laboratory for analysis in the suspended FoT(s).

2C.7 DOCUMENTATION AND RECORD KEEPING

All laboratory records shall be maintained for a period of at least ten (10) years. If a laboratory is going out of business, it shall have a plan for transferring records to customers for lead analyses performed under NLLAP.

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Table 2C-1 Minimum QC Procedure Frequencies and Acceptance Limits for ELLAP

QC SAMPLE	FREQUENCY	ACCEPTANCE LIMITS
Independent Calibration Verification (ICV)	Once per run after calibration	Within +/- 10% of the known value
Initial Calibration Blank (ICB)	Once per run at the beginning of the run	Absolute value not more than 10% of the regulatory limit or minimum level of concern
Continuing Calibration Verification (CCV)	Every 10 samples and at the end of the run	Within +/- 10% of the known value for ICP or FAAS Within +/- 20% of the known value for GFAA
Interference Check Sample (ICS)	Beginning and end of each run or twice every 8 hours	Within +/- 20% of the known value
Continuing Calibration Blank (CCB)	After each ICS and CCV	Absolute value not more than 10% of the regulatory limit or minimum level of concern
Laboratory Control Sample (LCS)	One per 20 samples or batch (5%)	Within +/- 20% of the known value
Matrix Spike	One per 20 samples or batch (5%)	Within +/- 25% of the known value
Duplicate Sample	One per 20 samples or	≤ 25% RPD for the duplicate pair



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	batch (5%)	
Method Blank (Reagent Blank)	One per 20 samples or batch (5%)	Absolute value not more than 10% of the regulatory limit or the minimum level of concern
Reporting Limit Verification	Once per day	Within +/- 20% of known value

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