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Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs

Revision 1.0

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Revision 1.0

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May 14, 1993

DISCLAIMER

This document has been reviewed and approved for publication by the Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency. The use of trade names or commercial products does not constitute Agency endorsement or recommendation for use.

NOTICE

This document provides recommendations for site assessor training curricula for assessors of laboratories that analyze Pb in paint film or chips, Pb-based paint contaminated soils, and deposited dust (vacuum dust and wipe samples). These recommendations will form the basis of the training curricula EPA will establish for accrediting organizations that seek recognition as participants in the EPA National Lead Laboratory Accreditation Program (NLLAP). Two training course curricula for assessors were developed. The Level One Course is an extensive course of 3 to 5 days for the beginning assessor, and the Level Two Course is of 12 hours duration for the experienced assessor from related fields. Specific lesson plans should be developed by the accrediting organization, addressing the curricula recommendations presented in this document.

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Midwest Research Institute (MRI) was requested by the Environmental Protection Agency (EPA) to develop recommended curricula for the training of on-site assessors. These on-site assessors will perform on-site assessments of laboratories seeking accreditation for the analysis of lead (Pb) in paint, soil, and deposited dust, including vacuumed dust and wipe samples, from EPA-recognized accreditation organizations as part of the EPA National Lead Laboratory Accreditation Program (NLLAP).* These curricula were developed with the cooperation of the Technical Programs Branch, Office of Pollution Prevention and Toxics (OPPT), under EPA Contract No. 68-DO-0137. A working meeting was held in Gaithersburg, Maryland, from June 22 to 24, 1992, with a group of metals laboratory accreditation experts to gather information for the basis of this report. The affiliations of the working group and the role of each organization are presented below.

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MRI was responsible for the planning and the conduct of the working meeting held in Gaithersburg, Maryland, from June 22 to 24, 1992. Dr. Larry Lowry, who was the Work Assignment Leader, had primary responsibility for conducting the meeting and writing the final reports with input from working group members and Mr. Paul Constant, Dr. Gary Dewalt, and Mr. Jack Balsinger from MRI.

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* In order to avoid confusion in the terms lead (for Pb) and lead (for leader), the following conventions are used. Pb will be used for the heavy metal and lead will be used for all other uses. The terms, Auditor, Assessor, and Site Visitor, are used interchangeably. The term, Assessor, which is the term preferred by the ISO (International Organization for Standardization), is used in this report. The term, paint, in this document refers to dried paint film or paint chips and not to liquid, uncured paint.

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EXECUTIVE SUMMARY

The hazards of Pb-based paint have become a leading public health issue of the 1990s, and Pb-paint abatement of homes is a high priority among many different health and environmental organizations. The Environmental Protection Agency (EPA) estimates there are several hundred laboratories, not currently performing analysis, that will be involved in new, extensive Pb-abatement programs.

Following the lead of the Interagency Lead-Based Paint Task Force (U.S. EPA, 1992a), the EPA Office of Pollution Prevention and Toxics (OPPT) is establishing the National Lead Laboratory Accreditation Program (NLLAP). The NLLAP will provide federal oversight for state and private sector laboratory accreditation programs involved in the accreditation of laboratories analyzing paint, soil, and dust samples associated with the abatement and control of Pb-based paint contaminated housing. The NLLAP will recognize accrediting organizations that meet EPA minimum requirements through a Memorandum of Understanding (MOU). Each NLLAP-recognized accrediting organization will administer its laboratory accreditation program under NLLAP oversight. In order to be recognized by the NLLAP, laboratories must meet the following criteria:

- The laboratory must successfully undergo a systems audit inclusive of an on-site assessment by an analytical laboratory accrediting organization recognized by EPA through an MOU.

- The laboratory must successfully participate in the Environmental Lead Proficiency Analytical Testing (ELPAT) program.*

The purpose of this document is to recommend criteria for site assessor training curricula for assessors of laboratories that analyze Pb in paint, dust, and soil. These recommendations will form the basis of the training curricula that EPA will establish for

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* The Environmental Lead Proficiency Analytical Testing (ELPAT) Program is a cooperative effort to improve and evaluate the performance of laboratories involved in the analysis of Pb in paint, dust, and soil matrices. The National Institute for Occupational Safety and Health (NIOSH) performs ELPAT data analysis under a Memorandum of Understanding (MOU No. PW593570-01-0) with the U.S. Environmental Protection Agency (EPA). The American Industrial Hygiene Association (AIHA) contracts for ELPAT sample production and administers the ELPAT program as permitted under a Cooperative Research and Development Agreement (CRADA No. NIOSH-92-1) with NIOSH covering cooperation in analytical research and proficiency test programs.

accrediting organizations which seek EPA recognition through an MOU as a part of the NLLAP.

These recommendations for site assessor training programs were prepared following a working meeting of experts in metals analysis from government and from independent laboratories. Two training course curricula were developed.

The Level One Course is an extensive course of 3 to 5 days duration for the beginning assessor. The course consists of seven modules, including a written examination and an on-site assessment internship. The seven modules cover: (1) a general overview of the accreditation process; (2) the technical aspects of Pb sampling and analysis; (3) the assessment process or how to conduct an assessment; (4) the interpersonal skills needed to conduct an assessment; (5) a practical role-playing exercise; (6) a written examination; and (7) an on-site assessment internship.

The Level Two Course is a 12-hour course for the experienced assessor from qualified NLLAP-recognized accrediting organizations. This course covers three modules, including modules (1) and (2) from the Level One Course. A written examination is also included. The two courses are designed so that they can be taught concurrently.

Both courses have minimum education/experience requirements for prospective students and instructors. The courses make extensive use of a checklist that is based on the ISO Guide 25, the international standard (ISO/IEC Guide 25, 1990). The courses should be taught by a team that includes an experienced assessor and an experienced inorganic chemist familiar with Pb analyses in dust and paint matrices.

The two courses are generic in scope and require supplemental instruction on policies and procedures specific for individual NLLAP-recognized accrediting organizations.

The NLLAP-recognized accrediting organization will conduct all modules of the course. The accrediting organization will certify the assessor and have the option of hiring the graduates of the program. The NLLAP-recognized accrediting organization will also be responsible for monitoring the assessor's performance following completion of the training program and for conducting continuing education programs annually.

SECTION 1

INTRODUCTION

1.1 BACKGROUND

The hazards of Pb-based paint have become a leading public health issue of the 1990s, and Pb-paint abatement of homes is a high priority among many different health and environmental organizations. The Environmental Protection Agency (EPA) estimates there are several hundred laboratories, not currently performing analysis, that will be involved in new, extensive Pb-abatement programs.

1.2 EPA RECOGNITION OF LABORATORIES

Following the lead of the Interagency Lead-Based Paint Task Force (U.S. EPA, 1992a), the EPA Office of Pollution Prevention and Toxics (OPPT) is establishing the National Lead Laboratory Accreditation Program (NLLAP). The NLLAP will provide federal oversight for state and private sector, laboratory accreditation programs involved in the accreditation of laboratories analyzing paint, soil, and dust samples associated with the abatement and control of Pb-based paint contaminated housing.

The NLLAP will recognize accrediting organizations that meet NLLAP minimum requirements through a Memorandum of Understanding (MOU). Each NLLAP-recognized accrediting organization will administer its laboratory accreditation program under NLLAP oversight. In order to be recognized by NLLAP, laboratories must meet the following criteria:

- The laboratory must successfully undergo a systems audit inclusive of an on-site assessment by an analytical laboratory accrediting organization recognized by EPA through an MOU.

- The laboratory must successfully participate in the Environmental Lead Proficiency Analytical Testing (ELPAT) program. (See footnote on page xi.)

The completion of a proficiency testing-based program alone is not sufficient proof that a laboratory can perform successfully on real world samples. The proficiency testing sample, even though it is a matrix-based material, will usually receive special treatment in the laboratory. The systems audit is necessary to ensure that a laboratory has the required staff, methods, facilities, quality assurance plans, and other essentials necessary to perform the analysis within a stated level of confidence.

1.3 PURPOSE

The purpose of this document is to recommend criteria for site assessor training curricula for assessors of laboratories that analyze Pb in paint, dust and soil. These recommendations will form the basis of the training curricula that EPA will establish for accrediting organizations which seek recognition by NLLAP through an MOU.

Because of the need to maintain flexibility, this curriculum is intended to be a working guideline rather than a program outlining specific requirements. At this time, there are no standard EPA-validated analysis methods for Pb in paint, soil, and deposited dust (including wipe samples and vacuumed samples). In addition, there are no standardized wipe-sampling media. As standardized methods are developed, they will be incorporated into the training program and replace some of the generic sections in the current program.

1.4 APPROACH

Curricula recommendations for site assessor training programs were prepared following a working meeting of experts in metals analysis from government and from independent laboratories. Two training course curricula were developed.

The Level One Course is an extensive course of 3 to 5 days duration for the beginning assessor. The minimum qualifications for admission are (1) a B.S. degree in chemistry or related science, (2) a minimum of 3 years nonacademic analytical laboratory experience, two of which are in metals analysis, (3) documented experience with laboratory quality assurance/quality control procedures, and (4) good interpersonal skills. The course consists of seven modules, including a written examination and an on-site assessment internship. The seven modules cover: (1) a general overview of the accreditation process; (2) the technical aspects of Pb sampling and analysis; (3) the assessment process or how to conduct an assessment; (4) the interpersonal skills needed to conduct an assessment; (5) a practical role-playing exercise; (6) a written examination; and (7) an on-site assessment internship.

The Level Two Course is a 12-hour course for the experienced assessor from qualified NLLAP-recognized accrediting organizations. The qualifications for admission are (1) the general educational and experience requirements for assessors, as specified by NLLAP-recognized accrediting organizations, (2) experience in conducting assessments with a minimum of three assessments per year for the most recent 2-year period, and (3) a letter of recommendation from the assessor's accrediting organization. This course covers three modules, including modules (1) and (2) from the Level One Course. A written examination is included. The two courses are designed so that they can be taught concurrently.

Both courses have minimum education/experience requirements for prospective students and instructors. The courses make extensive use of a checklist based on the ISO Guide 25, the international standard (ISO/IEC Guide 25, 1990). The checklist will

be provided to the laboratory prior to the site visit for a self-assessment and returned to the designated assessor. The designated assessor will use the same checklist to perform the on-site assessment. The courses should be taught by a team that includes an experienced assessor and an experienced inorganic chemist familiar with Pb analyses in dust, soil, and paint matrices. The two courses, which are generic in scope, require supplemental instruction on policies and procedures specific for individual NLLAP-recognized accrediting organizations.

The NLLAP-recognized accrediting organization will conduct the final phase of the training: the on-site assessment internship. The accrediting organization will certify the assessor and have the option of hiring the graduates of the program. The NLLAP-recognized accrediting organization will also be responsible for monitoring the assessor's performance following completion of the training program and for conducting continuing education programs annually.

A continuing education course (refresher course) will be required for all assessors. It would be offered annually and required every two years. It should be taught by the specific NLLAP-recognized accrediting organization and would include updates on (1) policies of the NLLAP-recognized accrediting organization, (2) regulations update, (3) health issues associated with Pb, and (4) new technical aspects of sampling and analysis. The curriculum would be based on case discussions and problem resolution.

The remainder of this document contains the Level One Course (Section 2), the Level Two Course for the experienced assessor (Section 3), and the continuing education module (Section 4). A discussion of various administrative issues is in Section 5. Section 6 gives a list of references. Two appendices include (A) a list of acronyms and glossary of terms, and (B) the site assessor checklist.

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SECTION 2

LEVEL ONE COURSE—THE BEGINNER COURSE

2.1 COURSE OUTLINE

This beginner course is open to individuals possessing a minimum set of qualifications as outlined in a variety of publications, including ASTM standard E-994 (ASTM E-994, 1990), the Registrar Accreditation Board (1992), the Interagency Lead-based Paint Task Force (U.S. EPA, 1992a), and ISO guides (ISO/IEC 58, 1992). It runs for 3 to 5 days, depending on the type and number of case studies and the number of hands-on classroom exercises used. Qualifications for assessor candidates are given in Section 2.2. Qualifications for instructors are given in Section 2.3. The course is also open to individuals with an interest in the assessment process, but who have no interest in becoming qualified assessors. Educational/experience requirements for these "observer" students would be waived, as would be the examination and on-site internship. The major modules of this course are outlined below.

2.1.1 Module I. General Overview of the Accreditation Process

This 2-hour module covers the generic aspects of the accreditation process, the history of the health effects of Pb, and the current status of Pb paint abatement issues and legislation. This section should be taught by a current assessor or individual familiar with laboratory accreditation and Pb analysis.

An additional 2-hour session is required to acquaint the prospective assessor with the specific accreditation policies and procedures. This program should be taught by a representative of the NLLAP-recognized accrediting organization, because the accreditation process can be expected to be different for each NLLAP-recognized accrediting organization.

2.1.2 Module II. Technical Aspects of Pb Sampling and Analysis

This 8-hour module, which covers the technical aspects of Pb sampling and analysis, is aimed at the laboratory chemist. It covers all aspects of laboratory issues related to sampling, analysis, and reporting of data for Pb in paint, soil, and deposited dust matrices. This module should be taught by a chemist with experience in analyses of these matrices for Pb.

Additional information is incorporated in this module by reference. The EPA report, "Pb-Based Paint Laboratory Operations Guidelines: Analysis of Pb in Paint, Dust, and Soil," (U.S. EPA, 1992b) describes many of the issues related to sampling and analysis of paint, soil, and deposited dust for Pb from a laboratory perspective. It contains specific sections on quality assurance and provides guidance on selection of digestion and analysis methods. This EPA report should be utilized in the training curriculum.

2.1.3 Module III. The Assessment Process, or How to Conduct an Assessment

This 8-hour module addresses the assessment process and all steps required to perform a successful assessment. Included are pre-assessment steps, the conduct of the on-site assessment, reporting requirements, and assessor performance ratings. This section should be taught by an experienced assessor. The following items should be included:

- Pre-assessment review of documents
- Pre-assessment communication with the laboratory
- Preparation for the assessment, including which documents to take
- Conduct of the on-site assessment to include the following:
  - Opening conference
  - Pre-assessment walk through
  - Use of checklist
  - Documentation of sample tracking (through use of an audit sample or tracking of samples)
  - Interviews with key personnel
  - On-site report writing, as required by the accrediting organization
  - Closing conference
- Assessor reporting requirements
- Assessor performance rating from the laboratory and NLLAP-recognized accrediting organization

2.1.4 Module IV. Interpersonal Skills

This 4-hour module includes the important aspects of how to conduct an assessment and lists of do's and don'ts appropriate for a professional objective assessor. This component is possibly the most important module because technical expertise is in vain if the assessor does not have good interpersonal skills. This module should be taught by an experienced assessor or an individual knowledgeable in and experienced with interpersonal skills training.

2.1.5 Module V. Practical Role-playing Exercise

This module includes a practical role-playing application of the assessment process. A variety of approaches can be used, such as mock site visits, case studies with role-playing by students, or video cases with role-playing. The objective is to apply skills learned in the lecture portion of the course. The length of this module can vary from a few hours to a full day, depending on the format of the role-playing exercise. This module should be taught by an experienced assessor.

2.1.6 Module VI. Written Examination

A 1-hour written examination must be administered to document the successful completion of the course. Guidelines for passing the course were established as described later in this document, along with recommendations for remedial action in the event of failure. Observer students would not be eligible for the written examination or assessor status.

2.1.7 Module VII. On-site Internship with a Certified Assessor

This module covers the practical application of the assessment process in an actual laboratory. The recommended criteria include a minimum of two on-site visits, one as an active intern, the second as a primary assessor with the assistance of a supervising assessor from the specific NLLAP-recognized accrediting organization. This module is not part of the generic course and must be administered by an assessor from an NLLAP-recognized accrediting organization. Successful completion of the on-site internship should result in certification from an NLLAP-recognized accrediting organization.

2.2 QUALIFICATIONS OF ASSESSOR CANDIDATES

Assessor candidates should meet the following minimum requirements:

- A B.S. degree in chemistry or related science.
- Minimum of 3 years nonacademic analytical laboratory experience, two of which are in metals analysis.

- Documented experience with laboratory quality assurance/quality control procedures.

- Good interpersonal skills.

Prospective students who are interested in the assessment process, but do not wish to become assessors, would be admitted as "observer" students. Such students would not be eligible for the written examination or any recognized assessor status.

2.3 QUALIFICATIONS OF COURSE INSTRUCTORS

Team teaching of these courses is most effective because many diverse areas are included in the curriculum. Instructors must meet the requirements for admission to the Level One course. In addition, they must have experience as current assessors for environmental metals laboratories (minimum of three assessments per year for the most recent 2-year period) and familiarity with Pb-analysis techniques and quality assurance for the specific matrices. Experience with or knowledge of the ISO Guide 25 testing laboratory requirements is essential. Instructors who teach interpersonal skills may not be required to be assessors or inorganic chemists, provided that they have knowledge and experience in interpersonal skills training.

The initial cadre of instructors may be drawn from current assessors in related fields, along with experienced Pb chemists. As the cadre of trained assessors in this specific field increases, requirements for instructors may be raised to include successful completion of these courses as a student and demonstrated experience in assessment with these Pb-based matrices.

2.4 MODULE I. GENERAL OVERVIEW OF THE ASSESSMENT PROCESS (4 HOURS)

The course objective is to provide the student with an overview of the assessment process, including introductions to the health effects of Pb exposure, the current status of legislation, and issues related to laboratory accreditation.

2.4.1 Generic Overview Module Applicable to All Assessors and Accrediting Organizations (2 Hours)

The overview module includes generic aspects of Pb laboratory operations associated with matrices of paint, soil, and deposited dust, and is applicable to all accrediting organizations. It includes the following topics:

- History of government regulatory processes related to Pb and Pb paint laboratory issues, including discussion of the HUD Guidelines for Pb abatement (HUD, 1990).

` History of health effects of Pb on children and the need for laboratory measurements and a laboratory accreditation program. Some discussion of the Centers for Disease Control (CDC) statement, "Preventing Lead (Pb) Poisoning in Young Children," should be included (CDC, 1991).

` General requirements for accreditation as an "NLLAP-recognized" laboratory.

- A systems audit inclusive of an on-site assessment by an accrediting organization recognized by NLLAP.

- Participation in the ELPAT program (see footnote xi for explanation). Note: It is not necessary to be accredited by an NLLAP-recognized accrediting organization to participate in this program.

` General requirements of accreditation through an NLLAP-recognized accrediting organization based on the ISO Guide 25 (ISO/IEC Guide 25, 1990) criteria, as well as:

- Application Procedures.

- On-Site Assessment, including frequency.

- Participation in ELPAT program, including frequency.

- Audit of assessor performance as specified by ISO Guide 58 and the accrediting organization.

- Requirements for "need-based" assessment, such as failed ELPAT rounds, change in director or management, or failure to respond to deficiencies.

- Requirements for removal of accreditation, such as repeated failure to correct deficiencies noted on an audit, repeated failure of ELPAT rounds, or fraud.

- Ethics of assessors

2.4.2 Accreditation Organization Procedures

This 2-hour module, which is a required supplement to the general module, is designed to familiarize the student with the policies and procedures of a specific accrediting organization, since these requirements vary by organization. This module would be presented by a representative of an NLLAP-recognized accrediting organization. The lecture would cover the following topics:

- Specific organization and policies of the accrediting organization.
- Application process, including fees.
- Review of the application.
- Time schedules and basic information on the process.
- Detailed requirements for staff, facilities, etc.
- Advertising limitations to specific matrices and Pb.
- Reporting requirements to accrediting organization.
- Responsibility for communicating accreditation requirements to applicant.
- Responsibility at the accrediting organization for answering administrative and technical questions.
- Addition of other criteria to the program.
- Communication of new changes (new equipment, staff) to the accrediting organization.
- Specific criteria for "need-based" assessment, such as failed ELPAT results, change in director or management, or failure to respond to deficiencies.
- Specific criteria for removal of accreditation, such as repeated failure to correct deficiencies noted on an audit, repeated failure of ELPAT rounds, or fraud.

2.5 MODULE II. TECHNICAL ASPECTS OF Pb SAMPLING AND ANALYSIS (8 HOURS)

The objective of this module is to provide the assessor student, who should have a basic knowledge of operation of a metals laboratory, with a detailed knowledge necessary to perform a complete and objective site assessment of laboratories performing analysis of Pb in paint chips, soil, and deposited dust (including dust wipes and vacuumed dust.)

2.5.1 General Overview

This module covers subsampling of the sample and the analysis and reporting of data for Pb in paint, soil, and deposited dust matrices. This module should be taught by a chemist with experience in analyses of these matrices for Pb. Note: This module

provides a recommended curriculum, but the actual minimum laboratory requirements are specified by NLLAP.

Additional information is incorporated in this module by reference. The EPA report, "Pb-Based Paint Laboratory Operation Guidelines: Analysis of Pb in Paint, Dust, and Soil" (U.S. EPA, 1992b), describes many of the issues related to sampling and analysis of paint, soil, and deposited dust for Pb from a laboratory perspective. It contains specific sections on quality assurance and provides guidance on selection of digestion and analysis methods. Many of the recommendations in the Laboratory Operations Guidelines are being incorporated as laboratory quality system requirements for the NLLAP. This module should highlight those NLLAP requirements. When the NLLAP quality system requirements are finalized, a notice of their availability will be placed in the *Federal Register.*

2.5.2 Facilities and Personnel Qualifications

2.5.2.1 Facilities—

These laboratory guidelines apply to fixed location, temporary, and mobile laboratories.

A laboratory must have the space, equipment, instruments, ventilation, utility services, storage, safety equipment, and manuals necessary to accomplish Pb analyses of paint, soil, and deposited dust. The facility should have restricted access for security reasons and controlled access to sample preparation areas to reduce contamination. Other recommendations are listed in the TSCA Good Laboratory Practices Standards (U.S. EPA, 1989). Minimum recommendations for metals laboratories include:

- Appropriate area for sample receipt, processing, and storage (secured, controlled temperature).

- A laboratory hood for digestion of samples that meets the requirements specified in the Industrial Hygiene Ventilation Manual of the American Conference of Governmental Industrial Hygienists (ACGIH, 1991).

- An adequate number of grounded electrical circuits that meet local electrical codes and ensure stable electrical supply to instruments and data systems. Uninterrupted power supplies may be needed in some areas to protect data systems.

- Ambient temperature and humidity control adequate to insure reliable operation of instrumentation and sample/digest stability.

- Cross-contamination control procedures to prevent sample contamination and contamination of work areas. Controlled access to sample preparation

areas and other procedures to minimize sample contamination. Documentation of effectiveness of contamination control by use of surface wipe samples.

` A glassware-cleaning facility with SOPs and monitoring requirements.

` Procedures for disposal of hazardous waste in compliance with local, state, and federal regulations.

2.5.2.2 Personnel and Qualifications—

The laboratory management must provide technical and quality managers who operate the laboratory in conformance with ISO Guide 25 (ISO/IEC Guide 25, 1990) and the accrediting organization requirements. Following are the personnel and minimum qualifications that are needed.

Technical Manager, or however named

This individual must have a B.S. degree in Chemistry, or related field, with a minimum of 3 years' nonacademic laboratory experience, two of which are in metals analysis. This individual is responsible for the technical effort and must be available to the analyst at the laboratory at least 50% of the normal work day. The technical manager may also serve as the inorganic chemistry supervisor.

Quality Manager, or however named

This individual must have a B.S. degree in a basic science and have at least 1 year of nonacademic analytical chemistry experience and training in statistics, or 4 years nonacademic analytical chemistry experience and training in statistics. Experience or knowledge of ISO Guide 25 is required. The quality manager should be separated from the analytical chemistry operations. In some small laboratories, the technical manager may also function as the quality manager, as long as this person is not involved in the direct supervision of the lead analyst/technician doing the routine sample analysis.

Inorganic Chemist, Spectroscopist, or however named

This individual must have a B.S. degree in Chemistry, or related field, with a minimum of 1 year in metals analysis in a nonacademic laboratory. Training in specific metals methods used in the laboratory must be documented; proficiency in analysis must also be documented. This category includes the following persons:

` Inductively Coupled Plasma-Emission Spectroscopist
Experience: 1 year minimum recommended (nonacademic)
Training: Satisfactory completion of a short course on Inductively Coupled Plasma Emission Spectrometry (ICP-AES). An in-house training program is acceptable.

` Flameless Atomic Absorption Spectroscopist
Experience: 1 year minimum recommended (nonacademic)
Training: Satisfactory completion of a short course on Graphite Furnace Atomic Absorption Spectrometry (GFAA). An in-house training program is acceptable.

` Flame Atomic Absorption Spectroscopist
Experience: 1 year minimum recommended (nonacademic)
Training: Satisfactory completion of a short course on Flame Aspiration Atomic Absorption Spectrometry (FLAA). An in-house training program is acceptable.

Analyst, Technician, or however named

Two years of technical education at the college level is recommended. This individual must have documented training in specific metal methods used in the laboratory and must have documented proficiency in performing assigned tasks. This category includes the following persons:

` Inorganic Sample Preparation Technician
Experience: 3 months minimum recommended (nonacademic)

` Routine Sample Analyst (instrumentation)
Experience: 6 months minimum recommended (nonacademic)

The above staff must have documented training on instruments specific to the laboratory and have demonstrated proficiency in these techniques. Junior staff, such as analysts or technicians, must work under the direct supervision of a degreed chemist in one of the "Chemist/Spectroscopist" categories. Junior staff may also work under the supervision of the Technical Manager or a sample analyst/technician who has performed successfully over a period of 3 years in the analysis of metals, using the same technologies that will be used for the analysis of Pb-containing samples.

2.5.3 Quality Assurance Program

Quality assurance programs are required for laboratories that analyze paint, soil, and deposited dust for Pb. The ISO Guide 25 (ISO/IEC Guide 25, 1990), the internationally accepted quality system for testing laboratories should serve as the basis for the laboratory quality system. There are several good general references for quality assurance programs listed in the bibliography. The reference by Liabastre (Liabastre,

1992) is recommended as it addresses all aspects of quality assurance for environmental assessment laboratories. The reference by Ratliff (Ratliff, 1990) is also recommended. Information specific for laboratories that analyze paint, soil, and deposited dust for Pb is located in the HUD Interim Guidelines (HUD, 1990) and in the various other referenced publications.

2.5.3.1 The Quality System—

The laboratory must have a quality system documented in a quality manual. The manual should document the policies and objectives of the quality system. The specific program requirements are found in individual accrediting organization policies. The major components of a typical quality system, which are listed below, should be addressed and documented in a quality manual and in related supporting documents. The components are listed according to ISO Guide 25 headings (ISO/IEC Guide 25, 1990).

- QA management should be directed by a full-time employee with power to oversee the situation, identify problems, and make corrections, while being independent of the analyses.
- A quality policy statement, including objectives and commitments by top management.
- Organization and management structure of the laboratory, its place in any parent organization, and relevant organizational charts.
- Relationship between management, technical operations, support services, and the quality program.
- Procedures to control and maintain documentation of the quality manual and related supporting documents.
- Job descriptions of key staff and reference to other staff.
- The introduction of new employees to the quality manual and the requirement that all employees periodically review the manual.
- A documented training program for employees that includes site-specific SOPs.
- Identification of the laboratory sign-off person for reports.
- Traceability of calibration standards to SRMs.
- Scope of the laboratory operation and services offered.

- Procedures for review of incoming work to assure adequate facilities and staff.

- Reference to the calibration, verification, and test procedures used.

- Procedures for handling calibration and test items.

- SOPs for sample log-in procedures.

- SOPs for sample preparation, including debris removal, substrate removal, drying, grinding, sieving, and mixing.

- SOPs for sample and subsample identification, including digests and extracts.

- SOPs for the preparation of working standards and calibration solutions.

- SOPs for digestion procedures, methods of analysis, and calibration procedures.

- SOPs for major equipment calibration, reference standards used, and maintenance of equipment.

- References to verification practices, including interlaboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes.

- SOPs for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur.

- Arrangements for exemptions permitting departures from documented policies/procedures as specified in SOPs.

- References to procedures for dealing with complaints.

- References to procedures for protecting confidentiality of results.

- SOPs for data audit and review.

- Quality system audits must be conducted to ensure that the documented quality system is implemented as written.

2.5.3.2 Review of the Quality System—

The quality system requires frequent inspection and audits to ensure its effectiveness. The following are recommendations for quality system audits.

- Quality system audits should be conducted at regular intervals by trained and qualified staff to verify the system is implemented as written. Discrepancies found should be corrected, and any client whose reported data are affected should be notified in writing immediately.

- The quality system should be reviewed at least once per year by management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

- All audit and review findings, and any corrective actions that arise from them, should be brought to the attention of the Quality Manager and resolved in a timely manner.

2.5.3.3 Quality Control—

The quality manual and related supporting documents must contain the following sections on quality control:

Quality Control System

- QC procedures required by applicable federal or state environmental or public health agencies should be listed, documented, and followed.

- A sample tracking system should be maintained.

- Control chart data or equivalent should be maintained for each analytical technique. See *Handbook for SRM Users* (Taylor, 1985) for recommendations on control charting.

- Supervisory personnel should review the data calculations and QC results (internal data review).

- Deviations or deficiencies in QC should be documented and reported to management immediately.

- A documented corrective action plan should be implemented when analytical results fail to meet QC criteria.

- QC data should be retrievable for all analytical results.

Calibration and Quality Checks

- Standard calibration curves should be prepared to adequately cover the expected concentration ranges of the samples and the expected "action levels" of Pb (HUD, 1990).

- Standard calibration curves should be prepared using at least three standards and one blank, unless otherwise specified by the method.

- New calibration curves should be prepared whenever out-of-control conditions are indicated and after new reagents are prepared and used.

- Method detection limits should be determined and documented (40 *CFR* 136, Appendix B).

- The laboratory should ensure the quality of results by implementing and reviewing quality checks, as appropriate, but not limited to:

    - Internal quality control charting based upon statistical techniques. This is most useful for identifying trends and out-of-control incidents.

    - Regular use of standard reference materials and certified reference materials as primary reference materials.

    - Participation in the ELPAT Pb-proficiency testing program.

    - Replicate testings using the same or different methods.

    - Retesting of retained items as needed.

SOPs

- The QC procedures (SOPs) should be specific to each test technology and matrix addressing the following:

    - Reagent and method blanks

    - Glassware cleaning

    - Trip and field blanks

    - Sampling and subsampling

    - Replicate/duplicate analysis

    - Spiked and blank sample analysis

    - Blind samples

    - Quality control samples

    - Control charts

- Calibration standards
- Reference samples and SRMs
- Internal standards

2.5.3.4 Quality Control Practices—

The laboratory quality control program should include the continual evaluation of its performance (system process control) for each matrix, which includes the determination of accuracy and precision. One possible method used for laboratory system process control is the use of control charts to monitor the performance of a specific QC sample. Control charts should specify warning and action limits. In the absence of a statistically sufficient data base to determine the necessary frequency for QC samples, the laboratory should default to the use of a set frequency for QC samples stated in its analytical standard operating procedure.

Quality control practices can be broken down into those processes that are affected by the instrumentation and those that are related to the sample matrix. The following recommendations for matrix-based quality control practices applicable to AA or ICP-AES should be used in the absence of laboratory-based process control data.

Precision and Accuracy Determinations

Accuracy studies are performed to determine how close a measurement comes to an actual or accepted reference value. Accuracy can be expressed as percent recovery and evaluated by analysis of matrix spike samples. A matrix spike is an aliquot of a sample fortified (spiked) with a known quantity of the analyte of interest and subjected to the entire analytical procedure. The spike must be prepared from a standard stock, which is different from the calibration standard stock, and should have a Pb concentration that is within the range of the sample to be run.

Precision is evaluated by the reproducibility of analyses. Precision is commonly expressed as standard deviation or relative percent difference (RPD) and can be evaluated by the analysis of replicate samples. Replicate sample analyses are one or more additional analyses on separate portions of a given sample in order to assist in the evaluation of method variance. Most commonly, two replicate analyses (defined as a duplicate analysis) are performed.

In the analysis of soil, dust (vacuum), and paint chips matrices, samples may be too small and difficult to homogenize and split in order to obtain samples for matrix spike evaluations or replicate analysis. For these sample matrices, the laboratory should select alternate QC options, such as the analysis of duplicate laboratory control samples per batch.

Paint Chips, Soil, and Vacuumed Dust Samples.

Accuracy determination. Matrix spiked samples should be analyzed with a minimum frequency of 5% of the samples for each matrix, per batch of samples (samples processed at a single time). If there are fewer than 20 samples in a batch, at least one spiked sample for each matrix per batch should be analyzed.

Precision determination. Replicate (duplicate) samples should be analyzed with a minimum frequency of 5% of samples for each matrix per batch of samples. If there are fewer than 20 samples in a batch, at least sample for each matrix per batch should be analyzed. In the event the analyte is not detected in the sample, replicate matrix spike samples may be analyzed.

Dust Wipe Samples—Accuracy and Precision Determinations.

When analyzing wipe samples, method spike samples are prepared using blank collection media and analyzed with a minimum frequency of 5% of samples for each matrix per batch of samples. If there are fewer than 20 samples per batch, at least 1 method spike/spike duplicate set should be run per batch. The matrix samples are to be prepared using a Pb-based paint NIST SRM applied directly to the wipe. It is recommended that the client submit blank wipes representative of the lots to be used in the field for lead contamination analysis prior to field sampling.

Method Blanks

When using methods requiring sample pretreatment not performed on calibration standards, a method blank containing all reagents and subject to all preparation steps shall be processed and analyzed along with the samples. Method blanks should be analyzed with a minimum frequency of 5% of the samples for each matrix per batch of samples. If there are fewer than 20 samples in a batch, at least 1 method blank for each matrix per batch should be analyzed. The use of method blanks provides a measurement of laboratory and/or reagent contamination. Method blanks are not to be used to correct sample results.

External Reference or Laboratory Control Sample Analysis

At least one reference or laboratory control sample (LCS) should be analyzed with each matrix per batch of samples with a minimum frequency of 5%. If there are fewer than 20 samples per batch, then at least 1 LCS should be run per batch per matrix type. The concentration of the LCS should be within the working range of the method and should not require extensive pretreatment, dilution, or concentration prior to analysis. Sources of these samples include but are not limited to: NIST Standard Reference Materials, commercially available certified reference samples, or samples prepared from different sources of analyte than calibration standards and whose

concentrations were determined using definitive methods. If available, all these reference materials shall be NIST traceable.

Recommended QC Sample Criteria

The following recommendations for analytical instrument quality control practices should be used in the absence of laboratory-based process control data.

Acceptable performance limits for analytical instrumentation, as well as each method, should be established based upon the continuing statistical evaluation of the data generated by the analysis of quality control samples, unless specific minimum acceptance limits are established by the method. The laboratory's calculation procedures for statistically derived acceptance limits should be documented. Some methods have listed acceptance criteria for applicable analytes based upon determinations by a single laboratory, the compilation of data from many laboratories, or limits that are assumed or expected. These limits may be too broad to define accurate acceptance criteria for routine use. These limits are best used as guidelines during the initial phases of method use and are superseded when the laboratory has collected sufficient self-generated data for proper statistical evaluation.

In the absence of sufficient data for the determination of QC sample frequency and acceptance criteria, the following minimum QC sample frequencies and acceptance limits are required (where applicable) for analytical SOPs employing AA or ICP-AES instrumentation:

QC sample	Frequency	Acceptance limits
Initial calibration verification (ICV)	Once per run after calibration	Within ±10% of known value
Initial calibration blank (ICB)	Once per run at the beginning of run	Absolute value not more than 20% of the regulatory limit or level of concern
Continuing calibration verification (CCV)	Before and at the end of a sample run, as well as every 10 samples	Within ±10% of known value for ICP or FLAA; within ±20% for GFAA
Interference check sample (ICS)	Beginning and end of each run or twice every 8 hr	Within 20% of known value
Continuing calibration blank (CCB)	After each ICS and CCV	Absolute value not more than 20% of the regulatory limit or level of concern

QC sample	Frequency	Acceptance limits
Laboratory control sample (LCS)	1 per 20 samples or batch (5%)	Within ±20% of known value
Matrix spike	1 per 20 samples or batch (5%)	Within ±25% of known value
Duplicate sample	1 per 20 samples or batch (5%)	Within ±25% relative percent difference (RPD)
Method blank	1 per 20 samples a batch (5%)	Absolute value not more than 20% of the regulatory limit or level of concern

A detailed recommended analysis protocol is listed in Section 2.5.14.

2.5.4 Required Standard Operating Procedures (SOPs)

All methods, including sample collection, subsampling, digestion, and analysis, must have laboratory-generated Standard Operating Procedures (SOPs). There are no standard methods from EPA or other organizations/agencies with published validations for the analysis of Pb in paint and deposited dust matrices. There is a standard method for digestion of soils (U.S. EPA SW 846 Method 3050). Modifications of methods must be documented in revised SOPs. Minor modifications (for example, the use of more acid) should be specified in SOPs and include the reasons to make such adjustments. No deviations should be permitted during routine sample analysis beyond those limits specified in the laboratory SOP, but deviation within stated limits is acceptable. Guidelines for the preparation of SOPs have been published by the EPA Office of Solid Waste (U.S. EPA, 1990c). Elements of SOPs are listed in the companion EPA report on laboratory practices (U.S. EPA, 1992b).

2.5.5 Field Sampling of Paint Films, Soils, and Dust Wipes, Including Vacuumed Dust

Although the laboratory staff is often not involved in field sampling, they need to understand the process in order to advise the client, if asked, and to better understand the heterogeneity of samples submitted to the laboratory. The HUD Interim Guidelines (HUD, 1990) provide a general summary of sampling requirements for Pb from abatement projects. The companion EPA report on laboratory practices also provides a summary of field sampling recommendations (U.S. EPA, 1992b). The laboratory should provide guidance only in the form of a written SOP or a copy of specific sampling guidelines.

2.5.6 Sample Preparation Steps Prior to Analysis (Subsampling).

This section covers the handling of the sample after it is received from the field and prior to digestion. Cleanup activities (removal of rocks, substrate, hair, etc.) and subsampling or aliquoting of the bulk sample into uniform portions suitable for analysis are also covered. Subsection 2.5.7 gives recommendations for sample tracking and storage.

2.5.6.1 Solids—General Considerations—

Particle size distribution, debris, and stratification of solid samples is a major problem. The following general considerations apply to all solid samples.

- Samples must be examined for debris, such as hair, paper clips, pins, and insects, prior to subsampling the sample. Debris should be removed with tweezers or by screening through a course #4-mesh (4 to 7 mm) sieve.

- Samples of dust or finely ground paint or soil are subject to stratification from vibration in the laboratory. Therefore, thorough mixing is essential prior to removing an aliquot for analysis.

- A representative sample must be obtained. A device such as a "riffle" box, or equivalent, should be used for separating and allocating fractions of dust or soil that have been ground to a #10-mesh (1.9 mm) and sieved. A riffle box randomly aliquots one-half of the sample to one side and one-half of the sample to the other. Several passes may be necessary to reach usable sample sizes for digestion.*

- Humidity control is very important in sampling of solids, particularly if results are expressed on a weight basis. Oven drying at 105` C to a constant weight is recommended.

2.5.6.2 Wipe Samples—

The handling of wipes in the laboratory must be detailed by an SOP. Wipes are used to collect deposited dust over a defined surface area. In most cases, the Pb content in the wipe material is unknown and appears to vary from lot to lot and among sources. The pickup efficiency (ability to pick up and retain dust on the wipe material) and the digestibility properties are also unknown. Research on the development of standardized wipes is in progress. Until such time as some "standardized wipe" is developed, the laboratory must perform the following tests on each type of wipe submitted.

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* Use of a riffle box to separate coal and coke is described in ASTM Method (D5).

- Determine the Pb background level in the "blank" wipe submitted with the samples. Ideally, Pb background levels of wipe samples should be determined prior to sample collection. If the background level is greater than 5 µg Pb per wipe, blank correction may be necessary. Blank correction can be used if the blank is < 20% of the regulatory limit or level of concern. If blank correction is used, it must be documented on the report. It should be noted that blank values of 5 µg per wipe are insignificant at HUD clearance recommendations of 200 µg per wipe collected over a 1 sq ft area.

- Perform a recovery study of a spiked wipe (extractable Pb) using the laboratory standard digestion technique. The digestion technique does not have to destroy wipe fibers (total Pb), but it should be able to digest Pb from dust deposited on the wipe (extractable Pb).

Results should be expressed per wipe or per area sampled. If the area is less than 1 sq ft, results should be corrected and reported as µg Pb/sq ft.

2.5.6.3 Paint Chips—

Appropriate steps must be taken to ensure uniformity of the sample before subsampling. The presence of "substrate" compromises the results, particularly if the results are presented on a weight basis. The handling of paint chips must be covered by an SOP. Because paint chips containing substrate present special problems, the following should be addressed:

- Attempts should be made to remove the paint from substrate. If the paint cannot be removed from the substrate, the analytical report must include an annotation that results may be invalid. Substrate contamination of paint must be noted because large amounts of nonlead containing substrate will produce low-Pb concentrations and may lead to false negative results.

Paint chips relatively free of substrate should be handled as follows:

- Cut paint chips into small pieces with scissors or a knife.

- Grind up the pieces of paint chips into a powder with a mortar and pestle or other nonmetal contaminating material to improve digestibility. Paints with a high latex content may not be suitable for grinding due to their tendency to form "gummy" residues.

2.5.6.4 Dust-Vacuumed Samples—

There are no defined procedures for preparation of vacuumed dust samples. An SOP must be developed covering the steps listed below.

` Dust samples should be sieved (#10 mesh, 1.9 mm) to remove debris (metal, glass, hair, pins, etc.) prior to digestion because this debris is not dust.

` Dust samples must be subjected to humidity control. If dust is moist, it should be dried in an oven at 105` C to a constant weight. Cross-contamination during drying can be reduced by placing dust samples in covered drying bottles.

2.5.6.5 Soils—

The handling of soil samples must be covered by an SOP that addresses:

` Screening to remove debris, including metal, glass, plant material, rocks, plaster, and bricks. If large paint chips are present in the soil, these should be removed and digested separately.

` Drying of the soil at 105` C to a constant weight to control for variable moisture content.

` Grinding to a fine mesh (#10 mesh) to aid digestion.

` Thorough mixing prior to analysis to avoid stratification.

2.5.7 Sample Tracking and Storage

A sample tracking system must be detailed in an SOP and referred to in the QA manual. A subsampling system of unique numbers must be used for all digests and dilutions of the original sample so that original sample identification is not lost. If computer log-in procedures are used, the sample log-in procedure must include hard copy backup of computer log-in records. Although a legal chain of custody is not usually required, a client may demand it in some cases that may involve potential litigation.

The SOP must detail the specifics for storage of unused samples during the analysis cycle and after completion of analysis. Digests can be kept for 2 to 4 weeks, as long as digest volumes are monitored gravimetrically for evaporation loss. Holding times for matrix samples are not a problem. It is recommended that the laboratory establish an automatic discard date for digests and samples, such as 90 days after reporting to the client, unless contacted by the client.

The requirements for storage of samples and digests include:

` Secure storage in a locked or controlled-access area.

- Uniform environmental conditions must be maintained, such as a cool, dry storage area.

- Storage of digests require special conditions. Fluid loss in digests by evaporation must be monitored gravimetrically.

2.5.8 Sample Digestion Procedures

At this time, there are no standard EPA-approved digestion methods for paint and dust matrices. EPA SW-846 Method 3050 is approved for soils, but not necessarily for analysis of Pb in soils contaminated with paint chips. There are three basic sample digestion techniques that have been applied, often with some modification, to digest paint chips, dust (wipes and collected dust), and soil samples. These methods are outlined below and cited in Section 2.5.10. However, little published information is available to document the suitability of these digestion methods.

- Dry ashing, followed by wet digestion with HNO_3 or HNO_3/H_2O_2

- Wet digestion using a hot plate with HNO_3 or HNO_3/H_2O_2

- Microwave digestion with HNO_3, HNO_3/HCl, or HNO_3/H_2O_2

Dry ashing is not recommended because it is difficult to control and has the possibility of uneven heating and splatter/cross-contamination of samples. Therefore "wet digestion" techniques are preferable. "Wet digestion" techniques using HNO_3 alone are not generally recommended because digestion may be incomplete. Wet digestion techniques, such as U.S. EPA SW-846 Method 3050, a validated method for soils, are suggested and may be suitable for digestion of most samples. But this method has not been validated for other matrices. NIOSH Method 7082 is also suitable for digestion of dust samples. Perchloric acid has also been used in combination with nitric acid with acceptable results. However, since the use of perchloric acid requires special safety precautions (i.e., a perchloric acid hood), it is generally not recommended.

Research is currently underway to develop a standard digestion procedure that would work with all matrices using 200-250 mg of sample. The ASTM has prepared draft wet digestion methods for wipes, dust, soils, and paint chips, which are currently undergoing review and testing. Digestion acids must be chosen with analytical instrumentation in mind because of incompatibility of HCl with GFAA instrumentation. Whatever digestion technique is used, it is recommended that the digest be filtered or centrifuged prior to instrumental analysis. The specified digestion procedure must be documented in an SOP.

2.5.9 Instrumentation

There are three general types of instrumentation suitable for analysis of Pb in paint, soil, and dust matrices. These are listed below and are available from a variety of vendors in many different configurations.

2.5.9.1 Atomic Absorption Spectrometry Using Direct Flame Aspiration—

This instrumentation, which is widely available with and without autosamplers, has adequate sensitivity for most samples, depending on dilution volumes used in the digestion process. Following are characteristics of Atomic Absorption Spectrometry Using Direct Flame Aspiration (FLAA):

- Instrument detection limits: Instrument detection limits are adequate for most samples, but are the highest of the three techniques considered in this guide. Since direct aspiration is required, a minimum of 5 mL of digest is needed for aspiration and measurement of a stable signal.

- Principal interference: Light scattering and molecular absorption by matrix components are common for measurements near detection limit and can cause a false positive signal. They can best be corrected using methods such as a continuum source or Zeeman background correction schemes. Correction using alternate nonabsorbing Pb lines is possible, but not optimal. Matrix enhancement, or suppression of the Pb absorbance signal, is possible at all concentration levels and can be corrected by using the method of standard additions.

- Cost: Initial instrument cost is low and consumables, such as acetylene gas, are inexpensive.

- Sample throughput: Sample throughput is good using either autosamplers or manual aspiration and can be several samples per minute.

- Maintenance and potential downtime: Routine maintenance is limited to periodic cleaning of the aspirator, mixing chamber, and burner, as well as external optics as necessary. Of the three methods, maintenance and potential downtime is lowest.

- Principal Pb lines: The 283.3-nm line is preferred because of less molecular absorption and scattering. The 217.0-nm line, however, is more sensitive and can be used if a continuous source background correction is employed.

- Range of analysis: The linear range of analysis is approximately two orders of magnitude, from about 0.2 µg Pb/mL to 20 µg Pb/mL, but can be extended by rotating the burner head.

` Potential problem areas: The method detection capabilities are borderline for wipes below HUD "Clearance" levels. For such samples, the 217.0-nm line and background correction must be used.

2.5.9.2 Atomic Absorption Spectrometry Using the Graphite Furnace—

This instrumentation is widely available and is the most sensitive technique of the three techniques. Throughput is good with autosamplers and sample size requirements are very small. The following are characteristics of Atomic Absorption Spectrometry Using the Graphite Furnace (GFAA):

` Instrument detection limits: Detection limits are the lowest of the three instrumental techniques. Because only 20 µL of sample is used for analysis, digest volume requirements are the smallest (10-25 µL). If the laboratory is also involved with blood Pb determinations, GFAA is the instrumentation of choice.

` Principal interference: Light scattering and molecular absorption by matrix components are common for most measurements and can cause a false positive signal. They can best be corrected by methods such as a continuum source (Deuterium Arc) or Zeeman or Smith-Hieftje background correction schemes. Matrix enhancement or suppression of the Pb-absorbance signal is often significant and can be corrected by using the method of standard additions. Matrix modifiers, such as magnesium nitrate, lanthanum nitrate, palladium, or ammonium dihydrogen phosphate, minimize loss of Pb during the sample charring step and allow higher charring temperatures. This also minimizes, but does not eliminate, matrix enhancement or suppression effects. Chloride arising from the use of HCl in a digestion can cause significant interferences in GFAA.

` Cost: Initial instrument cost is intermediate. Maintenance and consumable costs are significant, since the graphite furnace tubes must be replaced approximately every 500 firings and argon gas must constantly flow through the system to prevent oxidation of the graphite.

` Sample throughput: Autosamplers are required to increase precision and throughput. Manual sample introduction is tiresome and often irreproducible. Throughput is approximately one sample every 2 to 3 min.

` Maintenance and potential downtime: The primary difference between maintenance of GFAA and FLAA is the alignment and cleaning of furnace components of the former. Because of the complexity of some graphite furnace systems, downtime may be greater than with FLAA.

` Principal Pb lines: The 283.3-nm line is preferred because of less interference. The 217.0-nm line, however, is more sensitive and may be used as needed, provided the interference and noise are not severe.

- Range of analysis: The linear range of analysis for an intermediate sample size is from about 0.001 µg Pb/mL to 0.1 µg Pb/mL, but can be varied by adjusting sample size and dilution.

- Potential problem areas: Matrix interference and contamination.

- Advantages: This instrumentation is widely available and is the most sensitive technique of the three. Throughput is good with auto-samplers and sample size requirements are very small.

2.5.9.3 Inductively Coupled Plasma Emission Spectrometry—

This instrumentation is available in many laboratories and offers the advantage of simultaneous multielement determinations. Sensitivity for Pb is intermediate, but adequate for all Pb matrix samples. Sample volume requirements are moderate because the digest is aspirated into the plasma torch.

- Instrument detection limits: Instrument detection limits, which are similar to FLAA, are adequate for most samples, but may present analysis difficulties at the lowest level of wipe samples. Because the direct aspiration rate of inductively coupled plasma emission spectrometry (ICP-AES) is less than FLAA, less sample is required. If other elements are desired in environmental samples, this is the instrumentation of choice.

- Principal interference: Spectral interferences caused by radiation from lines of other elements present in the sample are most common and can be corrected by several methods. Background correction can be performed by selecting wavelengths near the Pb line, or an alternate Pb line can be used. It is important to include an interfering element check sample that contains high levels of suspected elements (aluminum, titanium, chromium, calcium, or iron).

- Cost: Initial instrument cost is high, but major consumable cost is only argon gas, unless the instrument is operated incorrectly and the torch is destroyed.

- Sample throughput: Sample throughput is intermediate between FLAA and GFAA. Samples that are directly aspirated require a longer period for equilibration and washout. Throughput is typically slightly less than one sample per minute.

- Maintenance and potential downtime: Maintenance costs are the highest of all the instruments discussed because of the complicated design of ICP-AES instruments and the requirements for critical alignment of components.

- Principal Pb lines: Usually the 220.35-nm line is used, although an alternate line is at 217.0 nm.

- Range of analysis: The linear range of analysis for the 220.35-nm line is from about 0.2 µg Pb/mL to 3,000 µg Pb/mL.

- Potential problem areas: Spectral interferences from high levels of other metals and insufficient washout of the mixing chamber can occur after the analysis of a sample of high Pb concentration.

- Advantages: This instrumentation is available in many laboratories and offers the advantage of simultaneous multielement determinations. Sensitivity for Pb is intermediate, but adequate for all Pb matrix samples. Sample volume requirements are moderate because the digest is aspirated into the plasma torch.

2.5.9.4 Other Instrumentation—

In addition to these instruments, there are others that are not currently recommended. X-ray fluorescence (XRF) is currently being evaluated for laboratory use and may be suitable. However, sample preparation steps, including sample loading, can significantly affect precision and bias. On the other hand, the results are not affected by inclusion of substrate with the sample. Inductively Coupled Plasma-Mass Spectrometry (ICP-MS), although a powerful and sensitive technique, is not recommended at this time because of a lack of need for this level of instrumentation sophistication and costs. Anodic stripping voltametry may be suitable, provided that the method is compatible with digestion techniques. Methods using spectrophotometric instrumentation for Pb, such as the dithizone method, are not recommended because of the potential for contamination and interference. The latter method also may not be compatible with digestion procedures.

2.5.10 Analytical Methods

This section gives a list of published methods and discusses calibration standards applicable to paint, soils, and deposited dust matrices. References from agencies of the Federal Government can be obtained from the National Technical Information Service (NTIS), (703) 487-4650.

2.5.10.1 Lists of Methods—

AOAC 5.009 (1984) - Lead in Paint Using Direct Aspiration Atomic Absorption.

ASTM D-3335-85a - Test Method for Low Concentrations of Lead, Cadmium, and Cobalt in Paint by Atomic Absorption Spectrometry (direct aspiration).

ASTM D 3618 - Test Method for the Detection of Lead in Paint/Dried Paint Films.

U.S. EPA Reference Method for the Determination of Lead in Suspended Particulate Matter Collected from Ambient Air (40 *CFR* Part 50, Appendix G)

NIOSH 7082, Lead in Air Collected on Cellulose Ester Filters. Nitric acid/hydrogen peroxide hot plate digestion followed by direct aspiration atomic absorption at 283.3 nm.

NIOSH 7105, Lead in Air Collected on Cellulose Ester Filters, Nitric acid/ Hydrogen Peroxide Hot Plate Digestion Followed by GFAA.

NIOSH 7300, Elements in Air Collected on Cellulose Ester Filters, Nitric/ Perchloric Acid Hot Plate Digestion Followed by ICP-AES at 220.4 nm.

*U.S. EPA SW-846 Method 7420, Pb - Atomic Absorption, Direct Aspiration (U.S. EPA, 1990c).

*U.S. EPA SW-846 Method 7421, Pb - Atomic Absorption, Graphite Furnace (U.S. EPA 1990c).

*U.S. EPA SW-846 Method 6010A, Metals - Inductively Coupled Plasma Emission Spectroscopy (U.S. EPA 1990c).

* These methods do not include a digestion technique and are for digests of Pb prepared by one of the digestion techniques listed above.

*U.S. EPA SW-846 Method 3050A - Acid Digestion of Sediments, Sludges and Soils (Metals) (U.S. EPA 1990c).

*U.S. EPA SW-846 Method 3051 - Microwave Assisted Acid Digestion of Sediments, Sludges, Soils and Oils (Metals) (U.S. EPA 1990c).

In addition to these cited methods, the ASTM E36 subcommittee is working on several standard methods for Pb. These include GFAA, FLAA, and ICP-AES. These draft methods include digestion techniques for paint, dust, wipes, and soil, and use hot plate wet digestion techniques or microwave digestion methods. These draft methods are not yet available for distribution.

2.5.11 Calibration

2.5.11.1 Primary Standards—

Primary standards are solutions of standards that are traceable to aqueous-based SRMs from NIST and that must be used for instrument calibration. The preparation of primary standards must be detailed in an SOP. The SOP must detail the traceability of the primary standard to primary calibrant SRMs from NIST.

The NIST aqueous 10,000 ppm Pb (in 10% HNO_3) SRM is suitable for calibrant material and must be used to check laboratory working standards. The SRM is available as SRM 3128 (50 mL of a 10 mg/mL solution in 10% HNO_3). Matrix-based SRMs are not primary standards and are not suitable for instrument calibration.

2.5.11.2 Working Standards—

Stock primary standards must be prepared from material traceable to NIST SRM 3128. These stock standards are stable, but are subject to evaporation and loss of Pb to the container wall. The possible loss of solvent can be monitored by weighing the stock solution at regular intervals. The preparation of stock and working standards, including storage conditions, must be detailed in an SOP. Acids used in standards must match the acids used in the matrix. Purchased stock standards must include certifications that standards are traceable to SRM-3128.

Working standards should be prepared from stock primary standard solutions of 1000 to 10,000 ppm Pb. Working standards are used for initial calibration of the instrument and to verify the calibration at intervals dependent on the instrumental method. The recommended minimum intervals are at the beginning, midpoint, and at

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* These methods are general digestion techniques for the matrices listed. The mild conditions used in SW-846 methods must be evaluated for their efficiency in digesting these matrices. They must be combined with an analytical method such as the EPA SW-846 Methods 6010A, 7420, or 7421 for completion of analysis.

the end of a batch of samples (usually 20 samples) run on any particular day. Results that are reportable must be in the calibration range.

2.5.11.3 Matrix-Based Quality Control Samples—

A variety of matrix-specific materials (LCS) contain Pb and can be used for quality control samples. These internal QC samples must be independent of the instrument calibrant and used only to monitor the performance of the entire process, including the digestion step.

2.5.11.4 SRMs from NIST—

NIST prepares a variety of SRMs. These reference materials are rigorously characterized and analyzed by definitive methods. They are expensive and are not intended to be used for routine quality control. They are intended to be used in the development and validation of methods and as a real-world tool to evaluate method performance. Examples of NIST SRMs available for Pb-based matrices are listed in the table below. Certificates are available from NIST.

SRM	Description and date	Certified Pb value
1579a	Powdered Pb-based paint, Feb. 3, 1992	11.995% ± 0.031
—[a]	Powdered Pb-based paint (in progress)	4.0%
—[a]	Powdered Pb-based paint (in progress)	0.5%
1648	Urban particulate matter, Nov. 16, 1978	0.655% ± 0.008
2704	Buffalo River sediment, July 9, 1990	161 µg/g ± 17
2709	Baseline agricultural soil, Oct. 16, 1992	18.9 µg/g ± 0.5
2710	Highly contaminated soil, Oct. 16, 1992	5532 µg/g ± 80
2711	Moderately contaminated soil, Oct. 16, 1992	1162 µg/g ± 31
2579	Lead paint film on Mylar sheet, set of 5, July 7, 1992	3.53 mg/cm^2 ± 0.24 1.63 mg/cm^2 ± 0.08 1.02 mg/cm^2 ± 0.04 0.29 mg/cm^2 ± 0.01 < 0.0001 mg/cm^2

[a] These NIST SRMs are under development.

2.5.11.5 Other Reference Materials—

Reference materials from other sources are available, but they are not NIST-certified and may be less well-defined and characterized. However, they may be suitable for use as internal quality control materials.

There are three CRADA certified materials available. They are labeled: "This product was verified for accuracy and stability under a cooperative research and development agreement (CRADA) with the U.S. Environmental Protection Agency." They are manufactured by Resource Technology Corporation, Laramie, Wyoming, and are available from Fisher Scientific. These reference materials have also been certified by A2LA. These materials are not characterized like SRMs and cannot be used as substitutes for NIST SRMs. ELPAT samples may be available for use in evaluation of method performance (call 703-849-8888).

2.5.12 Reports and Record Management

Reporting and record-keeping requirements are outlined in the HUD Interim Guidelines (HUD, 1990).

> "All information relating to field sample analysis and QA/QC sample analysis, along with information on laboratory facilities, equipment, methods, and procedures must be documented by the laboratory, so that an analytical event can be recreated for an audit or investigation."

The HUD Interim Guidelines (HUD, 1990) recommend that the following general categories of records should be kept.

- Cover page information including methods, dates, instruments, digestions, and sign-offs by the laboratory director.
- Sample information including identification, blanks, QC samples, sample weights, dilution factors, and batch identification.
- Results of initial precision and accuracy runs.
- Results of calibration including sources of standards and detection limits.
- Results of blanks including type of blank and any corrections used.
- Results of calibration verification checks.
- Results of tests for accuracy and precision.
- Data reduction and reporting procedures including data calculations, outliers, and data archiving.

More details are given in the HUD Interim Guidelines (HUD, 1990). The client may have more specific needs, so the laboratory should be prepared to provide that data.

There are no regulatory requirements for record retention for these matrices. The HUD Interim Guidelines and NLLAP requirements suggest 10 years. Record-retention policies must be established with the client, with the realization that there may be future regulatory requirements.

2.5.13 Proficiency Testing and Data Quality

2.5.13.1 Proficiency testing—

Laboratories must demonstrate proficiency in the Environmental Lead Proficiency Analytical Testing (ELPAT) Program to be "recognized" by NLLAP. (See footnote on p. xi.) Laboratories may participate in this program independently without participating in an NLLAP-recognized accrediting organization program.

Note: Proficiency testing (PT) matrix materials, including ELPAT samples, are not to be used for instrument calibration or primary standards. These materials have not been subjected to rigorous characterization for their target concentrations. PT materials and SRMs that are fine powders are subject to significant stratifications from vibration in the laboratory. Therefore, thorough mixing is essential prior to removing an aliquot for analysis.

2.5.13.2 Rejection Criteria and Corrective Action—

The following guidelines are recommended as minimum rejection criteria that require corrective action prior to release of data. Data should be thoroughly evaluated, even if one of these criterion is out of range, and corrective action taken prior to release of data.

- Within day or intra-day variation of the calibration curve as measured by CCV is greater than ±10%.
- Any blank that exceeds 20% of the regulatory limit or minimum limit of concern.
- Spike recoveries of extractable Pb less than 75% or greater than 125% at the midrange concentration.
- Matrix-based quality control or check sample (also called control or laboratory control sample) outside 80-120% of stated value.

` Unacceptable precision (> ±25% RPD) of duplicate samples (two aliquots of the same bulk sample carried through the entire procedure.) Precision is based on the concentration of the sample and the method detection limit.

Corrective actions include reanalysis of QC check samples. If these QC samples are out of range, then repeat entire analysis, including recalibrations and all QC samples.

2.5.14 General Recommendations, Analysis Protocol

The analysis protocol for a digest may be specified in individual method citations. Individual laboratory SOPs must provide specifics. The quality control program should be based on the laboratory's continuous evaluation of its performance (system process control). In the absence of laboratory generated process controls, the recommendations in Section 2.5.3.4 should be used regarding frequency of blanks, calibration, and controls.

Since Pb is ubiquitous in the environment and in the laboratory, rigorous steps must be specified in an SOP on how contamination control is to be achieved during subsampling, digestion, and analysis. Cross-contamination must be documented by monitoring of surfaces, glassware, and reagents. A protocol to reduce cross-contamination from Pb is described by T. J. Murphy (Murphy, 1976).

The following are general recommendations for an analysis protocol:

` The instrument should be calibrated daily with an aqueous working standard traceable to an aqueous-based SRM (SRM 3128).

` Stock working standards for Pb (10,000 ppm) are stable. However, evaporation should be monitored by periodic weighing to document and correct for evaporative losses. Sealed containers help control evaporation loss; however, loss to container walls is possible.

` The daily calibration curve should consist of one initial calibration blank and at least three standards covering the concentration range of the samples.*

` The 3-standard calibration curve should have a correlation coefficient of at least 0.995.

` The calibration curve should be verified by the periodic use of continuing calibration blank and continuing calibration verification samples throughout the run.

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* Calibration requirements are both instrument and method specific. SOPs for specific analytical methods should be followed.

- The LCS (matrix-based and near the midpoint of the calibration curve) should be ±20% of stated value.

- One spiked matrix sample or duplicate matrix sample should be included per batch of up to 20 samples. A suitable duplicate matrix sample would be split digest samples because duplicate field samples cannot be collected.

- Instrument drift should be documented and corrected using CCV and CCB according to the method SOP.

- Interference check samples (ICS-AES) for ICP instrumentation (background shifts and interelement interference) should be determined prior to performing analyses to correct for potential interferences from components in the sample matrix. The ability of the instrument to measure lead in the presence of potential interference should be determined at the beginning, during the run, and after the sample is run. Correction factors should be applied, if available, on the specific ICP-AES instrument in use.

- Background correction for GFAA using simultaneous methods (e.g., Zeeman, Smith-Hieftje, Deuterium Arc) should be used at all times.

- Matrix modifiers, used in GFAA, should be verified to be free of Pb contamination.

- Matrix-based SRMs at action levels, if available, should be used to verify working standards and CRMs at monthly intervals.

- All samples exceeding the upper limits of the calibration range should be diluted to fit within the calibration range.

- The SOP should provide for a means to control carryover following samples with high concentrations (memory effect). Reruns of samples following a high sample is recommended.

- The SOP should provide for possible resampling of the submitted sample if the result is at or above an "action level" to confirm a "positive" result.

- Sample analysis priorities: Although the following scenario has been suggested, consideration should also be given to development of an analysis protocol using randomization of samples and blanks to minimize bias.

    - Assemble all samples, standards, blanks, and background samples.

    - Analyze those samples expected to contain Pb first.

- If a significant amount of Pb is found, analyze blanks and background samples to determine if there is contamination.

- Blank collection media (wipes) should also be analyzed to determine the background Pb levels.

- QC data should be control charted in order to monitor trends and QC excursions. The SOP must specify what is done in the event of unacceptable trends or excursions.

Table 1 shows the recommended process quality control blanks and control materials to be included in each batch. Table 2 shows the recommended instrumental QC standards and their specifications.

TABLE 1. QUALITY CONTROL SAMPLES AND PROCESS CONTROL

QC samples	Definition	Frequency
Method blanks	Type 1 water—digest as a sample with addition of all reagents. Should reflect the maximum treatment given any one sample within the batch.	1 per 20 samples, a minimum of 1 per batch
Spiked samples	A portion of a sample is fortified with all the target analytes before preparation and analyzed independently.	1 per 20 samples per matrix type, a minimum of 1 per batch
Spiked sample duplicates	A portion of a same sample used for the spiked sample is fortified with all the target analytes before preparation.	1 per 20 samples per matrix type, a minimum of 1 per batch
Reference material (standard reference)	A material of known composition, where analyte levels are certified by the manufacturer. These materials should be traceable to NIST standards.	1 per batch of samples

TABLE 2. RECOMMENDED INSTRUMENTAL QC STANDARDS AND SPECIFICATIONS

Name	Use	Specification
ICB—Initial calibration blank	Used for initial calibration and zeroing instrument response.	Calibration standard that contains no analyte. Must be measured during calibration and after calibration. Measured value to be less than 5 times the instrumental detection limit.
Calibration standards	Used to calibrate instrument. The high standard rerun is used to check for high response rollover.	Must be matrix matched to acid content present in sample digestates. Must be measured prior to measuring any sample digestates. Correlation coefficient of ` 0.995, as measured using linear regression on instrument response (y) versus concentration (x). The highest level calibration standard must be measured after calibration. The measured value to fall within ±10% of known value.
ICV—Initial calibration verification	Used to verify calibration standard levels.	Concentration of analyte to be near midrange of linear curve. The ICV is made from a stock solution having a different manufacturer or manufacturer lot identification than the calibration standards. Must be measured after calibration and before measuring any sample digestates. Measured value to fall within ±10% of known value.

TABLE 2 (CONTINUED)

Name	Use	Specification
ICS—Interference check sample (for ICP-AES only)	Used to verify accurate analyte response in the presence of possible spectral interferences from other analytes present in samples.	Concentration of analyte to be less than 25% of the highest calibration standard, concentrations of interferant will be 200 µg/mL of Al, Ca, Fe, and Mg. Must be analyzed at least twice, once before and once after all sample digestates. Measured analyte value to fall within ±20% of known value.
CCV—Continuing calibration verification	Used to verify freedom from excessive instrumental drift.	Concentration to be near midrange of linear curve. Must be analyzed before and after all sample digestates and at a frequency not less than every 10 sample digestates. Measured value to fall within ±10% of known value for ICP-AES or FLAA (±20% for GFAA), run 1 every 10 samples.
CCB—Continuing calibration blank	Used to verify blank response and freedom from carryover.	Calibration standard that contains no analyte. Must be analyzed after the CCV and after the ICS. Measured value to be less than 5 times the instrumental detection limit.

2.5.15 Safety, Health and Hazardous Waste

An introduction to laboratory safety and health, particularly as it applies to heavy metals, should be given. Safety and health aspects of laboratory operations are delineated in the OSHA Laboratory Standard "Occupational Exposures to Hazardous Chemicals in Laboratories" (29 *CFR* 1910.1450, Chemical Hygiene Plan). The assessor should note the existence of such a plan and specify that the evaluation is only an acknowledgement of the existence of a safety and health plan and not an evaluation of the effectiveness of such programs. Failure to communicate this to the laboratory may result in the mistaken assumption that the assessment found that the laboratory complied with health and safety regulations. A subsequent citation by OSHA or a laboratory accident could result in liability to the assessor.

Certain Pb materials may be classified as hazardous waste. A solid waste containing more than 200 ppm of Pb may fail the TCLP (Toxicity Characterization Leaching Procedure) used to define a hazardous waste (U.S. EPA SW-846 Method 1310 for TCLP, followed by Methods 3050/6010). By failing the TCLP, a waste is classified as hazardous and, consequently, requires special handling and disposal. Therefore, steps must be detailed in an SOP for the handling of potentially hazardous waste to include compliance with applicable local, state, and federal regulations.

Digests, which are acidic in nature, also contain Pb and perhaps other metals. These digests must be disposed of according to local state and federal regulations.

2.6 MODULE III. THE ASSESSMENT PROCESS, OR HOW TO CONDUCT AN ASSESSMENT (8 HOURS)

The objective of this module is to provide the student with a working knowledge of how to perform a site assessment, including planning, conducting the assessment, and preparation of reports.

2.6.1 Instructor Qualifications

This section should be taught by an experienced assessor or a trainer of a previous assessor training program for an accrediting organization. The practical experience of the trainer is essential to provide a "real world" rather than a theoretical perspective to the course.

2.6.2 Pre-Assessment Review

Prior to scheduling an on-site assessment, the assessor will receive a package of information from the NLLAP-recognized accrediting organization that will include the documents listed below. These documents need to be reviewed prior to making arrangements for a site assessment.

- Personal responsibilities, qualifications of laboratory staff, key contacts, and phone numbers.
- Application for accreditation.
- Evaluation of ELPAT data and corrective actions, if available.
- Quality manual and SOPs.
- Previous site assessment reports (if available).
- Previous laboratory in-house audits.
- Laboratory response to previous deficiencies, if applicable.

2.6.3 Pre-Assessment Preparation—How to Pack Your Bags

The assessor should be familiar with the following documents and take copies as appropriate. The assessor should take all items that may be needed and not assume that the laboratory will supply needed items.

- Policies and guidelines of the accreditation organization.
- 29 *CFR* 1910.1450 (OSHA Laboratory Standard).
- Policy for interpretation of proficiency test results as specified by ELPAT and the accreditation organization.
- Lists of methods and some selected methods.
- QA references, such as ISO Guide 25, as educational guides.
- References to QA programs.
- Accrediting organization forms.
- "Portable office" supplies, including paper clips, notes, pads, tape, binders, notebook PC, etc.
- Letter of introduction from the accrediting organization.
- Expense statements from the accrediting organization.
- Safety glasses and other required safety equipment.
- Sample for sample tracking as required by accreditation organization.

- Copies of the checklist.

- Copies of correspondence with the laboratory regarding the audit.

- Copies of the laboratory response to previous deficiencies and complaints.

- Criteria/requirements for accreditation.

- NLLAP requirements.

2.6.4 Pre-Assessment Communication to Laboratory

The assessor should open a clear line of communication with the laboratory in order to conduct an efficient assessment with minimum disruption of laboratory personnel. The following topics are needed for an effective assessment:

- Plan the agenda so that the laboratory knows how long the assessor will be there and with whom the assessor needs to talk. Provide an anticipated closing conference time. Remain flexible in scheduling.

- Send a letter of introduction from the accrediting organization and have copies of the expense statement, the checklist, and the agenda.

- Obtain a list of key contacts from the laboratory, including phone numbers.

- Determine who will attend the opening conference.

- Determine specific assessment plans from evaluation of previously submitted materials.

- Request information on convenient food, lodging, and transportation from the laboratory.

- Request the use of a copy machine to make copies of reports for the laboratory director.

- When applicable, notify the laboratory of specific problem areas found on the application or from client-filed complaints that will be investigated.

- Confirm, by telephone, arrival date 1 to 2 days before departure.

- Inquire about safety requirements and personal protective equipment needs.

2.6.5 Steps of the Assessment

The key to conducting a quality assessment with minimum disruption of laboratory staff and maximum cooperation from laboratory management is to follow the steps outlined below. It must be stressed that the assessor is a fact finder, not a decision maker. The ultimate decision on accreditation is made by the accrediting organization. The assessor is not a consultant to the laboratory. The assessor must be thoroughly prepared and conduct himself/herself in a professional manner at all times.

2.6.5.1 Opening Conference (Entry Briefing)—

Following are suggestions for the initial conference with the laboratory personnel:

` Meet with laboratory authorized representatives.

` Confirm agenda outline (work time, breaks, lunch, etc.).

` Explain the general procedures for the assessment and emphasize that the assessor's role is to gather facts, not make decisions.

` Confirm the accuracy of organization charts and matrices for which the laboratory seeks accreditation.

` Request files on problems reported by clients associated with the Pb program.

` Request current copies of SOPs and QA manuals for comparison with those sent for pre-assessment review. (These may have been updated since the application was submitted or after the self-evaluation checklist was sent.)

` Notify attendees of needs to evaluate areas of concerns revealed during pre-assessment review, such as qualifications of director, problems in QA manual, etc.

` Identify spokesperson for the laboratory.

` Request a quiet room to review documents and prepare reports.

` Request an escort.

` Obtain an attendance roster.

` Conduct a pre-assessment walk through for general orientation.

2.6.5.2 Checklist —

A checklist is used to develop the basic framework of the on-site assessment. It is based on the general criteria required in the ISO 25 Guide (ISO/IEC Guide 25, 1990)

with added specifics applicable to spectroscopy (atomic absorption and ICP-AES) procedures used for Pb paint laboratory work. The checklist should be sent to the laboratory for a self-evaluation prior to the actual site visit. It is then returned to the designated site assessor before the actual site visit.

The checklist serves as a specific guide to the assessor in evaluating problem areas. Three check-offs (yes, no, and N/A) are at the top of the column, and space for assessor comments is provided. It serves (1) as the basis for preparation of an assessor report and (2) to document the areas of the laboratory operation specifically evaluated by the assessor. The advantages of using this checklist include self-evaluation by the laboratory, an opportunity to correct a problem before a site visit, and the avoidance of surprises that may arise during the site assessment. The checklist also allows the assessor to do an independent review with less on-the-spot questioning of technical staff during the assessment. The checklist is extensive and will require significant time on the part of the laboratory staff to perform a self-evaluation. A copy of the checklist is included in Appendix B.

2.6.5.3 Documentation of Sample Tracking—

This step is used to document the flow of samples through the system and to trace samples from their receipt in the laboratory to the data report leaving the laboratory. The specifics of sample tracking depend on the policies of the NLLAP accrediting organization. The assessor could bring an actual audit sample that is observed through the system. Some accrediting organizations also perform a paper tracking of a randomly selected sample through the system.

2.6.5.4 Interviews with Key People—

It is essential to talk to key people involved in the analysis of samples and those responsible for quality assurance. Persons interviewed should include those who have performed the analysis, such as the Pb technician, the metals area supervisor, the QA person, and other specialists, as identified in the pre-assessment review and in the opening conference. Documents should be reviewed and compared with those provided in the pre-assessment package.

2.6.5.5 On-site Reports—

The NLLAP-recognized accrediting organization determines the need for on-site reports. If such reports are required, the assessor should find quiet time to prepare draft reports prior to the closing conference. If the accrediting organization requires on-site reports, the following are recommended:

- Assessor's reports (handwritten) that include a narrative review of findings during the site visit and the positive aspects of the laboratory operation. Copies of the checklist also should be included.

` Deficiencies noted during the site assessment that require responses from the laboratory within a specified time. There should be reference or citations provided that relate to specific requirements.

` Draft reports, including deficiency reports, should be acknowledged, signed off by both parties, and distributed to the laboratory key contact. This step is essential to avoid surprises, provides immediate documentation of the assessment, and allows laboratories to begin corrective actions, if needed, right away.

Some accrediting organizations may not want the assessor to provide feedback in written form to the laboratory until the accrediting organization has reviewed the assessor's report. In this case, no written reports would be provided on site.

2.6.5.6 Closing Conference—

The closing conference with the same personnel that attended the opening conference should be conducted in a firm, professional way to include positive observations as well as observed deficiencies. Important points to include are the following:

` There should be no surprises for the laboratory manager, if at all possible.

` Reports should be thoroughly reviewed to be sure that all parties understand the contents. It may be necessary to actually read the report to ensure a clear understanding. Obtain sign off from the laboratory key contact and assessor on each copy of the reports distributed to laboratory personnel.

` Indicate that a response is required for each identified deficiency within a specified time, as noted on the report.

` Avoid serving as a consultant. Identify deficiencies and report requirements only. Do not recommend solutions, only requirements.

` Discuss complaints by customers and resolution of those complaints.

` Review steps and schedule for corrective actions by the laboratory and for decisions by the accrediting organization. (The assessor is not the decision maker!)

` Execute other documents required by the NLLAP-recognized accrediting organization, such as expense reports.

2.6.5.7 Final Reports and Decision by Accrediting Organization—

Final reports (typewritten), prepared after the site visit, are sent to the laboratory and to the accrediting organization within a specified period of time, which is determined by the accrediting organization. The deficiencies noted on this report that require corrective action must have a suspense date. The laboratory must correct or respond to the deficiencies by the suspense date. It must be emphasized that the assessor does not make on-site decisions as to pass or failure of a laboratory.

The accrediting organization reviews responses to deficiencies according to their specific policy. The assessor usually reviews the response to the deficiency report and assists the accrediting organization in making a decision to provide/deny/revoke accreditation, depending on accrediting organization policy. Grounds for failure include lack of adequate, timely responses to deficiencies, lack of acceptable responses to complaints from clients, and lack of acceptable performance in required proficiency testing programs. A follow-up site assessment might be required before a final decision is reached.

2.6.5.8 Assessor Performance Rating—

Assessors, to be effective, should be subjected to an objective performance-rating system. The specifics are determined by the accrediting organization, but should include the following minimum requirements:

- Feedback from the laboratories that were assessed on the competence and thoroughness of the assessment with the precaution that ratings from assessed laboratories are not always based on the assessors' effectiveness. A poorly performing laboratory could provide a biased response to a thorough assessment.

- The accrediting organization should develop an assessor evaluation and rating program based on the quality and timeliness of the reports submitted and the degree of preparation prior to the conduct of the assessment.

2.7 MODULE IV. INTERPERSONAL SKILLS (4 HOURS)

The objective of this module is to provide the student with the skills and tips on the psychology of assessment, an area equally as important as the technical aspects of Pb analysis.

2.7.1 General Overview

This module includes the important aspects of how to conduct an assessment (the psychology of assessment). It includes professional conduct, assessor ethics, lists of do's and don'ts appropriate for a professional objective assessor, and pitfalls to avoid during an assessment. There are numerous references cited in the bibliography (e.g., Bunker, 1984a; Bunker, 1984b; Samel, 1992; Vassals, 1977).

2.7.2 Professional Conduct of the Assessor

- Maintain a positive, professional attitude at all times.
- Exhibit gentle firmness and dignity; be polite.
- Maintain objectivity at *all* times—be independent.
- Dress as a professional appropriate for the laboratory director or supervisor—sweats, "tennies," golf shirts, or jeans are unacceptable.
- Observe and note rather than dictate and criticize.
- Document observations on the checklist and do not rely on memory.
- Provide constructive criticism as appropriate; provide references to NLLAP requirements.
- Solicit constructive criticism of the assessment process.
- Adjust the agenda to meet changing needs of the laboratory, such as increased workload, and so forth.
- Understand the assessment process and answer questions fully.

2.7.3 Assessor Ethics

- The assessor is a fact finder, not a decision maker. Observe and note; do not serve as a consultant.
- Disclose any apparent conflicts of interest, such as assessor business connections, prior to the visit.
- Do not be an assessor and a consultant for the same laboratory.
- Treat all information as confidential and do not transfer information from laboratory to laboratory.
- Do not accept gratuities or free meals, unless there is no choice (a company lunchroom provided as a benefit to employees with no provision for cash payments).

2.7.4 Do

- Follow laboratory safety procedures, and leave the area when requested.

- Bring your own safety glasses.
- Prepare yourself for local customs, such as dress codes, meal schedules, breaks, and so forth.
- Allow time for the laboratory to adjust to the assessment process.
- Arrive in a fully alert, rested state. The overtired assessor or the assessor with a hangover is unacceptable.
- Provide positive reinforcements to laboratory personnel as appropriate.
- Listen attentively and take notes.
- Express appreciation for laboratory cooperation.
- Observe and practice appropriate body language.

2.7.5 Do Not

- Criticize equipment, suppliers, or the accrediting organization.
- Become argumentative.
- Do the analysis—keep hands off laboratory equipment and personnel.
- Chew gum, use beepers or musical watches.
- Tell jokes or behave too casually.
- Smoke or chew tobacco.
- Become involved in laboratory personnel problems.
- Make specific recommendations on supplies or equipment (product endorsement).
- Make derogatory comments about individuals.
- Discuss the assessment with personnel not involved in the assessment.
- Allow personal viewpoints to affect the assessment.
- Socialize with the client.

2.7.6 Beware of Tactics by the Laboratory to Sidetrack the Assessor

Reports by Bunker (Bunker, 1984a,b) provide many details on this topic. Some of the highlights are listed.

- The "everything is beautiful" tactic, where only the positive attributes of the laboratory are discussed. Actively seek out the weak points.
- The "name, rank, and serial number" tactic, where no information is volunteered. Be prepared to ask specific questions in advance.
- The "bury the assessor in detail" tactic, where unnecessary detail is provided to derail the assessment. Filter the details out and do not get sidetracked.
- The "Don't tell me how to run my lab!" tactic. Be firm, point out requirements and deficiencies, but do not become argumentative.

2.7.7 Assessor Pitfalls

- Do not expect any one person to have complete knowledge—talk to others.
- Do not get side-tracked in areas outside the scope of the assessment, such as regulatory policies, for example.
- Beware of the chronic complainer or lobbyist, who may use the assessor as a tool to get a personal problem advanced to management.
- Cover all areas, using the checklist as a guide, not just those specific areas that interest you.
- Avoid "rabbit" conclusions during a specific evaluation. Get all the facts, including views from others, before concluding that a deficiency exists.
- Do not become part of the laboratory problem; remain detached and professional.
- Do not accept the laboratory staff's word about a specific situation; personally evaluate the situation.

2.8 MODULE V. PRACTICAL ROLE-PLAYING EXERCISE (8-16 HOURS)

The objective of this module is to provide the student with practical, role-playing exercises to reinforce the lecture material and to provide some insight into actual assessments.

2.8.1 General Overview

This module discusses a role-playing, practical application of the assessment process. A variety of approaches can be included in role-playing, such as mock site visits could be conducted; case studies could be presented with role-playing by students; or video cases could be presented. The objective in role-playing is to apply skills learned in the lecture portion of the course.

The role-playing exercise provides a better understanding of the assessment process and builds assessor confidence. The length of this module can vary from a few hours to a full day, depending on the format of the role-playing exercise. The specific format is intentionally left vague to encourage the development of innovative role-playing exercises.

2.8.2 Points to Emphasize in a Role-Playing Exercise

The following points should be emphasized in a role-playing exercise:

- Entrance/exit sessions.
- Interviews of technicians and QA personnel.
- Potential conflicts/disagreements with laboratory staff.
- Preparation of a mini-report based on a presented case.
- Critique by observers of the role play.

2.8.3 Examples of Practical Role-playing Exercises

- Case studies constructed from experience and planned to illustrate actual and potential problems.
- An actual class visit to a local laboratory. A field trip is a good role-playing exercise, but may have a negative impact on the visited laboratory.
- Video case reports and practical role-playing exercises including the use of the checklist and report preparation (assessor's report and deficiency lists).

` Mock visit to a laboratory through a variety of media, such as slides, video, and so forth.

` Mock interviews or role-playing with laboratory personnel (director, chemist, QA coordinator, lawyer, etc.) using student role players.

2.9 MODULE VI. WRITTEN EXAMINATION (1 HOUR)

The object of this module is to examine the student for retained knowledge and problem-solving skills in preparation for actual on-site internship.

2.9.1 General Overview

A written examination should be administered to document the successful completion of the course. The examination should include essay and practical problem-solving exercises covering all aspects of the course. The questions for the written examination should be as objective as possible. In order to pass the course, the student must provide acceptable understanding of each module in the course. Acceptable understanding cannot be rigidly defined as a percent score because tests could be constructed so all participants get at least 70% correct on each module. If, in the judgement of the instructor(s) or accrediting organization, the student fails any module, the student should be given the opportunity to retake those modules. Any student that fails more than three modules should not pass the course and should not be given the opportunity to retake specific modules. Of course, the student could retake the entire course with appropriate fees paid.

The student assessor, who meets the qualifications standards in Section 2.2, will be given a certificate of successful completion after the examination has been graded. Successful completion of the written exam does not qualify the student as an assessor. Completion of an on-site internship conducted by the NLLAP-recognized accrediting organization is required before the student is certified as an NLLAP-recognized assessor.

"Observer" students, identified in Section 2.2, who are not qualified to become assessors because of their lack of education/experience, will not be allowed to take the examination, and will not be recognized as NLLAP assessors. No certificate of completion would be issued.

2.10 MODULE VII. ON-SITE INTERNSHIP

The objective of this module is to perform actual on-site assessments as an intern under the direction of an experienced assessor according to the policies and procedures of an NLLAP-recognized accrediting organization.

2.10.1 General Overview

Because on-site assessments are conducted under specific rules of the NLLAP-recognized accrediting organization, actual on-site assessments are not part of this lecture and discussion training program. However, actual on-site assessments are a required part of the total training curriculum for recognition as an NLLAP-recognized assessor. Certification as an experienced assessor is based on the requirements of the NLLAP-recognized accrediting organization.

2.10.2 Minimum Requirements for On-Site Internship

The following are recommended minimum requirements for the on-site internship:

- Two on-site visits, one as an active observer (intern), the second as a primary assessor, with the assistance of a supervising assessor who would accompany the intern.

- Feedback to the NLLAP-recognized accrediting organization on the effectiveness of the assessor trainee from the assessed laboratory and from the supervising assessor.

- Certification by the NLLAP-recognized accrediting organization following successful completion of the internship.

SECTION 3

LEVEL TWO COURSE—UPDATE FOR THE EXPERIENCED ASSESSOR

3.1 COURSE OUTLINE

This course is a 12-hour course aimed at current laboratory assessors from qualified NLLAP-recognized accrediting organizations. It includes two modules: (1) General Overview of the Accreditation Process, and (2) Technical Aspects of Pb Sampling and Analysis. This course is nearly identical to the Level One Course. However, there are different admission qualifications and examination requirements. The Level Two course will be restricted to current or experienced assessors who have conducted three assessments per year in the most recent 2 years. The assessor student must meet minimum requirements, including the conduct of recent assessments for a NLLAP-recognized accreditation organization and a letter of recommendation from that organization.

The course includes a 2-hour module covering the generic aspects of the accreditation process, the history of the health effects of Pb, and the current status of Pb-paint abatement issues and legislation. This 2-hour module is identical to the General Overview module from the Level One course, as presented in Subsection 2.4.

An additional 2-hour module would be required to acquaint the experienced assessor with the specific accreditation policies and procedures for an NLLAP-recognized accrediting organization for paint, soil, and deposited dust matrices. This program should be taught by a representative of the NLLAP-recognized accrediting organization, because the accreditation process will be different for each accrediting organization.

The 8-hour module on the technical aspects of Pb sampling and analysis is identical to the Technical Aspects module from the Level One course as presented in Subsection 2.5. It covers all aspects of laboratory issues related to sampling, analysis, and reporting of data for Pb in paint, soil, and deposited dust matrices.

An examination would be administered to document the successful completion of the course. No on-site assessment would be required because the student must be a current laboratory assessor to take this Level Two course. It is assumed that the experienced assessor knows how to conduct an on-site assessment. An experienced assessor may be assigned as a mentor for the new assessor at the discretion of the NLLAP-recognized accrediting organization.

3.2 QUALIFICATIONS FOR ADMISSION

The qualifications for admission are

- The general educational and experience requirements for assessors, as specified in Section 2.2 and by NLLAP-recognized accrediting organizations.

- Experience in conducting assessments with a minimum of 3 assessments per year for the most recent 2-year period.

- A letter of recommendation from the assessor's accrediting organization.

3.3 WRITTEN EXAMINATION

The objective of the written examination is to test the student for retained knowledge. The written examination must be administered to document the successful completion of the course. The questions should be as objective as possible. In order to pass the course, the student must provide acceptable understanding of each module. Acceptable understanding cannot be rigidly defined as a percent score because the test could be constructed so that all participants scored at least 70%. If the student fails any module, the student would not pass the course, and would have to retake the course and pass another examination.

The student assessor, who meets the qualifications standards in Subsection 3.2, would be given a certificate of successful completion after passing the examination. Successful completion of the written exam should qualify the student as a Pb assessor.

No on-site assessment internship period would be required; however, an experienced assessor from an NLLAP-recognized accrediting organization could be assigned as a mentor to answer any questions that may arise during initial site assessments. The experienced assessor who successfully completed the course would then be evaluated by the NLLAP-recognized accrediting organization for possible employment.

SECTION 4

CONTINUING EDUCATION REFRESHER COURSE FOR ALL ASSESSORS

4.1 OBJECTIVE

The objective of this module is to ensure that properly trained and certified assessors have frequent opportunities to upgrade their understanding of the accrediting process, the technical aspects of Pb methods, and practical aspects of the conduct of an assessment. An added benefit is the opportunity to discuss problems and creative solutions with peers.

4.2 OUTLINE OF CONTINUING EDUCATION PROGRAM (1 DAY)

Continuing education would be required of all assessors. Programs would be offered annually and required every 2 years for assessor recertification. Programs would be for a full day. These updates should address the following topics:

- New policies of the accrediting organization and the NLLAP.
- New or updated federal and state regulations and legislation related to both laboratory accreditation and Pb-paint abatement.
- New findings regarding the hazards of Pb to human health, particularly laboratory workers.
- Technical update on sampling and analysis methods.
- Sharing of experiences of current assessors by means of case studies and discussion groups.

The continuing education course should be documented internally at the accreditation organization, and result in recertification from the board of directors of the accrediting organization.

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SECTION 5

ADMINISTRATIVE ISSUES

5.1 WHO OFFERS THE COURSES?

These courses should be taught by an NLLAP-recognized accrediting organization with their specific requirements added to a core curriculum. The course should follow ISO Guide 25, the international standards guidelines. Alternately, the course could be taught by a third party as a generic course. After completion of the generic course, a supplemental course (2-hour module) would be required to familiarize the student assessor with the policies and procedures of the specific accrediting organization. This 2-hour module should be taught by an experienced official from the accrediting organization. A chemist familiar with Pb analyses in paint, soil, and deposited dust matrices should teach the technical aspects of Pb analysis.

The on-site assessment internship, required in the Level One course, is the responsibility of the accrediting organization. Continuing education courses are also the responsibility of the accrediting organization.

In order for the instructors and the training organization to be recognized by NLLAP, the training organization should submit a lesson plan, along with resumes of the instructors, for EPA review as part of the NLLAP MOU package. Initial offerings of courses must be evaluated by NLLAP-recognized accrediting organizations that hire assessors as to the effectiveness of the training programs. Such constructive feedback to accrediting organizations, and in turn to EPA, will result in improvements in the training programs.

5.2 HIRING, USE, AND DISMISSAL OF ASSESSORS

Assessors are employed by the NLLAP-recognized accrediting organization, thus all decisions on personnel matters, including hiring and firing, are the responsibility of that accrediting organization. Specific areas that the accrediting organization must address are listed.

- The accrediting organization has the final say in all personnel matters regarding assessors.

- The accrediting organization should provide a system of monitoring assessor performance.

- The accrediting organization should develop a policy regarding the minimum number of assessments (e.g., 1 assessment in 2 years) in order to maintain assessor status.

- The accrediting organization should have a documented means for removal of ineffective assessors.

- The accrediting organization should have an appeals procedure to ensure fair and equitable treatment of grievances brought by assessors.

SECTION 6

LIST OF REFERENCES

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APPENDIX A

ACRONYMS AND GLOSSARY OF TERMS

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APPENDIX A

ACRONYMS AND GLOSSARY OF TERMS

ACRONYMS

AA	Atomic Absorption
A2LA	American Association for Laboratory Accreditation
ACIL	American Council of Independent Laboratories
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
AOAC	Association of Official Analytical Chemists
APHA	American Public Health Association
ASTM	American Society for Testing and Materials
ASQC	American Society for Quality Control
ASTPHLD	Association of State and Territorial Public Health Laboratory Directors
AWWA	American Water Works Association
CCB	Continuing Calibration Blank
CCV	Continuing Calibration Verification
CERCLA	Comprehensive Environmental Responsibility, Compensation and Liability Act
CDC	Centers for Disease Control
CMD	Chemical Management Division
CNAEL	Committee on National Accreditation of Environmental Laboratories
CRADA	Cooperative Research and Development Agreement
CLP	Contract Laboratory Program
CRM	Certified Reference Material
EDL	Estimated Detection Limit
ELLAC	Environmental Lead Laboratory Accreditation Committee (AIHA)
ELPAT	Environmental Lead Proficiency Analytical Testing (AIHA/NIOSH)
EMPC	Estimated Maximum (Protocol) Concentration
FLAA	Direct Flame Aspiration Atomic Absorption Spectrometry
GFAA	Graphite Furnace Atomic Absorption Spectrometry
GLP	Good Laboratory Practices Standards (TSCA)
ICB	Initial Calibration Blank
ICP-AES	Inductively Coupled Plasma Emission Spectrometry
ICP-MS	Inductively Coupled Plasma-Mass Spectrometry
ICV	Initial Calibration Verification
ICS	Interference Check Standard
IDL	Instrument Detection Limit
IMVL	Interlaboratory Method Validation Study
ISO	International Organization for Standardization
LCS	Laboratory Control Sample
LOQ	Limit of Quantitation
LSA	Laboratory Systems Audit
MCL	Maximum Contaminant Level
MDL	Method Detection Limit

MOU	Memorandum of Understanding
MRI	Midwest Research Institute
NATA	National Association of Testing Authorities (Australia)
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLLAP	National Lead Laboratory Accreditation Program
NTIS	National Technical Information Service
NVLAP	National Voluntary Laboratory Accreditation Program
OSW	Office of Solid Waste (U.S. EPA)
PE	Performance Evaluation
PM	Preventive Maintenance
PT	Proficiency Testing
PQL	Practical Quantitation Limit
QA	Quality Assurance
QAMS	Quality Assurance Management Staff
QAPjP	Quality Assurance Project Plan
QAPP	Quality Assurance Program Plan
QC	Quality Control
QM	Quality Manual
RCRA	Resource Conservation and Recovery Act
RE	Relative Error
RPD	Relative Percent Difference
SAP	Sample Analysis Plan
SARA	Superfund Amendments and Re-authorizations Act of 1986
SOP	Standard Operating Procedure
SRM	Standard Reference Material Produced by NIST
TCLP	Toxicity Characteristic Leaching Procedure
TPB	Technical Programs Branch
TQM	Total Quality Management
TSCA	Toxic Substances Control Act
XRF	X-Ray Fluorescence
WAL	Work Assignment Leader (L. K. Lowry)
WAM	Work Assignment Manager (J. Scalera)
WPCF	Water Pollution Control Federation

GLOSSARY

Accreditation:	A formal recognition that an organization (e.g., laboratory) is competent to carry out specific tasks or specific types of tests. See also Certification.
Accredited laboratory:	A laboratory that has been evaluated and given approval to perform a specified measurement 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 Precision and Bias.
Aliquot:	See Subsample.
Analytical blank:	See Digestion blank.
Bias:	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 Calibration curve.
Calibration blank:	See Initial calibration blank.
Calibration-check:	See Calibration verification.
Calibration-check standard:	See Calibration verification.
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 Continuing calibration verification.
Calibration standard:	A substance or reference material used to calibrate an instrument.

Calibration solution:	See Calibration standard.
Calibration verification:	See Initial or continuing calibration verification.
Certification:	The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service usually for a specified time. See also Accreditation.
Certified Reference Material (CRM):	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 Certification and Reference material.
Chain of custody:	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 Quality control 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 to be near mid-range of 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 and periodically throughout the analyses of 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 Laboratory control sample.

Corrective action:	Action taken to correct a deficiency noted in a technical systems audit. See Deficiency and Technical systems audit.
Deficiency:	A failure to fully comply with the requirements of the NLLAP program, usually noted during a technical systems audit. See NLLAP and Technical systems audit.
Digestion 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.
Duplicate analyses or measurements:	The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation, or storage internal to the laboratory.
Duplicate samples:	Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis.
External quality control:	Activities that are routinely initiated and performed by persons outside of normal operations to assess the capability and performance of a measurement process.
Field blank:	A clean sample of matrix (e.g., paint, soil, dust, wipe) carried to the sampling site, exposed to the sampling conditions (e.g., bottle caps removed), returned to the laboratory, treated as an environmental sample, and carried through all steps of the analysis. For example, clean quartz sand, non-Pb containing paint, or a clean wipe could be used as a field blank. The field blank, which should be treated just like the sample, evaluates possible site contamination sources such as airborne contaminants.
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.

Initial calibration verification (ICV):	A standard solution (or set of solutions) used to verify calibration standard levels. Concentration of analyte to be near mid-range of linear 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 maintenance log:	A chronological record of preventive and emergency maintenance performed on an analytical instrument. The logs include record of calls, service technician summaries, records of calibration etc.
Interference check standard (ICS):	A standard solution (or set of solutions) used for ICP-AES to verify accurate analyte response in the presence of possible spectral interferences from other analytes present in samples. The concentration of analyte to be less than 25% of the highest calibration standard, concentration of interferant will be 200 µg/Ml of Al, Ca, Fe, and Mg. The ICS must be matrix matched to acid content present in sample digestates.
Internal quality control:	See Intralaboratory quality control.
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.
Intralaboratory precision:	A measure of the method/sample specific analytical variation within a laboratory, usually given as the standard deviation estimated from the results of duplicate/replicate analyses.
Intralaboratory 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 accuracy and precision of measurements.
Laboratory blank:	See Digestion blank.
Laboratory control sample (LCS):	A matrix-based reference material with an established concentration obtained from a different outside source 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 Technical systems audit.

Matrix blank: A sample of the matrix (paint chips, soil, dust) but without the analyte (Pb). This sample goes through the complete analysis including digestion.

Method blank: See Digestion blank.

Method performance: A general term used to document the characteristics of a method. These characteristics usually include method detection limits, linearity, precision, accuracy and bias.

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.

Mobile laboratory: A mobile laboratory is a self-contained, mobile facility that moves under its own power or is conveyed on a trailer, and does not remain at a site for more than two years.

NLLAP requirements: Requirements specified by the EPA National Lead Laboratory Accreditation Program (NLLAP) in order to be accredited for lead analysis in paint, soil and dust matrices by an EPA-recognized laboratory accreditation organization.

Precision: 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.

Primary standard: A substance or device with a property or value that is unquestionably accepted (within specified limits) in establishing the value of the same or related property of another substance or device.

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 assurance program:	See Quality assurance.
Quality assurance coordinator:	See Quality manager.
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.

Reagent blank: See Digestion blank.

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 Calibration standard.

Relative percent difference: A term defined as

$$RDP \quad \frac{| R_1 \quad R_2 |}{\overline{R}} \times 100$$

where $| R_1 - R_2 |$ represents the absolute difference in two values and $\overline{R}$ represents the average of two values.

Replicate analysis or measurements: The analysis or measurement of the variable of interest performed identically on two or more subsamples of the same sample within a short time interval. See Duplicate analysis or measurement.

Replicate sample: Two or more samples representing the same population characteristic, time, and place, which are independently carried through all steps of the sampling and measurement process in an identical manner. Replicate samples are used to assess total (sampling and analysis) method variance. Often incorrectly used in place of the term "replicate analysis." See Duplicate samples and Replicate analysis.

Report sign-off: The Technical Manager or designee authorized to review and sign analysis reports.

Reproducibility:	The extent to which a method, test or experiment yields the same or similar results when performed on subsamples of the same sample by different analysts or laboratories.
Rinseate blank:	A sample of a "used" cleaning fluid rinse solution, also called an equipment blank. Rinseate blank examples include a final rinse of the device used to collect soil or vacuumed dust or to clean the scoop used to collect soil or vacuumed dust. The rinseate blank is used in rinsing collection media and equipment prior to use to monitor possible cross contamination. The rinseate blank goes through the complete analysis, including the digestion.
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 Sample tracking.
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.
Secondary standard:	A standard whose value is based upon comparison with a primary standard.
Site blank:	See Field blank.
Site visit:	An on-site visit to a laboratory for the purpose of conducting a technical systems audit.
Site visitor:	A person who conducts technical system audits. The terms site visitor, auditor and assessor are often used interchangeably. See Technical systems audit.
Spiked matrix:	See Spiked sample.
Spiked reagent blank:	A specified amount of reagent blank fortified with a known mass of the target analyte, usually used to determine the recovery efficiency of the method.

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 addition:	The procedure of adding known increments of the analyte of interest to a sample to cause increases in detection response. The level of the analyte of interest present in the original sample is subsequently established by extrapolation of the plotted responses.
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.
Stratification:	The division of a target population into subsets or strata which are internally more homogeneous with respect to the characteristic to be studied than the population as a whole.
Subsample:	A representative portion of a sample. A subsample may be taken from any laboratory or a field sample.

Substrate:	This term has a very specialized use in the Pb-abatement area. It refers specifically to the material to which paint is attached, such as wallboard, concrete, wood, steel, etc.
Systems audit:	See Technical systems audit.
Technical 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.
Trip blank:	A clean sample, including collection media, that is carried to the sampling site and transported back to the laboratory for analysis **without being opened**. This blank is analyzed as a regular sample through all steps. The trip blank evaluates the integrity of the sample container.
Validation:	The process of substantiating specified performance criteria.
Working standard:	See Secondary standard.

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APPENDIX B

ASSESSOR CHECKLIST FOR LABORATORIES ENGAGED IN THE ANALYSIS OF Pb IN PAINT, SOILS, AND DEPOSITED DUST (INCLUDING WIPE SAMPLES AND VACUUMED DUST)

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ASSESSOR CHECKLIST FOR LABORATORIES ENGAGED IN THE ANALYSIS OF Pb IN PAINT, SOILS AND DEPOSITED DUST, INCLUDING WIPE SAMPLES AND VACUUMED DUST

Checklist DISTRIBUTION AND INSTRUCTIONS

This checklist should be distributed to the laboratory personnel prior to the on-site assessment. The laboratory should perform a self-assessment and check off each item examined. The laboratory should use an "x" for the check-off column. Comments should be entered in the space provided for all "no" entries and initialed. The completed checklist should be signed by the responsible laboratory person and returned to the assigned assessor for his/her review prior to the scheduled site assessment. The assessor will use this completed checklist to evaluate the laboratory. The assessor will check each item using a tick mark ` and add comments to each question as appropriate. The assessor will initial any comments and sign the completed checklist. Copies of the completed checklist should be provided to the laboratory during the closing conference. The checklist should not be filled out in pencil.

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ASSESSOR CHECKLIST

1. Background: Record comments or answers to the information-type questions in the space provided. The numbering of the checklist follows the corresponding paragraph numbers of ISO Guide 25-1990.

2. Name of Laboratory: _____

   Address: _____ City: _____ State: ____

   Telephone: _____ FAX: _____

3. Personnel Information (Names, Education, Training, Responsibilities):

3.1 Laboratory Manager:_____

3.2 Principal Chemists: _____

_____

_____

3.3 Technicians: (summarize qualifications and numbers)_____

_____

_____

3.4 Quality Assurance Officer: _____

3.5 Manager of Sample Control: _____

3.6 Statistician: _____

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		Yes	No	N/A
4.0	**ORGANIZATION AND MANAGEMENT**			
4.1	Is the laboratory legally identifiable?			
	Comments:			
4.2	Does the laboratory have managerial staff with the authority and resources needed to discharge their duties?			
	Comments:			
4.3	Has the laboratory specified and documented in job descriptions the responsibility, authority, and interrelationship of all personnel who manage, perform, or verify work affecting the quality of tests?			
	Comments:			
4.4	Does the laboratory provide supervision by persons familiar with the test methods and procedures, the objectives of the test, and the assessment of the results?			
	Comments:			
4.5	Does the laboratory have a technical manager (however named) who has overall responsibility for the technical operations?			
	Comments:			
4.6	Does the laboratory have a quality manager (however named) who has responsibility for implementation of the quality system who functions independently from those who are responsible for generation of the data?			
	Comments:			
4.6.1	Does the QA manager have the power to oversee the situation, identify problems, and make corrections?			
	Comments:			
4.7	Does the laboratory have deputies in case of absence of the technical or quality manager?			
	Comments:			

		Yes	No	N/A
5.0	**QUALITY SYSTEM, AUDIT, AND REVIEW**			
5.1	Is the quality system documented in a quality manual?			
	Comments:			
5.1.1	Is the quality manual and related supporting documents available for use by laboratory personnel?			
	Comments:			
5.1.2	Are the quality policies and objectives communicated to, understood, and implemented by all laboratory personnel concerned?			
	Comments:			
5.1.3	Is the quality manual kept current under the responsibility of the quality manager?			
	Comments:			
5.1.4	Are new employees introduced to the quality manual and how often do employees review the manual? Describe in comments below.			
	Comments:			
5.1.5	Does the laboratory have an in-house training program? Describe the type and frequency of training in comments below.			
	Comments:			
5.1.6	Is the quality system reviewed at least once per year by management to ensure its continuing suitability and effectiveness?			
	Comments:			
5.2	Does the quality manual and related supporting documents contain:			
5.2.1	A quality assurance policy statement, including objectives and commitments, by top management?			
	Comments:			
5.2.2	Organization charts that describe the management structure of the laboratory and its place in any parent organization?			
	Comments:			
5.2.3	Job descriptions of key staff and reference to job descriptions of other staff?			

		Yes	No	N/A
	Comments:			
5.2.4	Identification of laboratory's approved signatories for reports?			
	Comments:			
5.2.5	Procedures for achieving traceability of measurements?			
	Comments:			
5.2.6	The laboratory's scope of testing?			
	Comments:			
5.2.7	Procedures for reviewing methods, facilities, and resources necessary to complete proposed new work prior to initiation of new work?			
	Comments:			
5.2.8	Standard operating procedures for instrumental analysis techniques used?			
	Comments:			
5.2.9	Procedures for sample handling?			
	Comments:			
5.2.10	Reference to reagents and reference standards used?			
	Comments:			
5.2.11	Standard operating procedures for instrument calibration?			
	Comments:			
5.2.12	Reference to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes?			
	Comments:			
5.2.13	Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur?			
	Comments:			
5.2.14	Arrangements for exceptions permitting departures from documented policies/procedures?			

		Yes	No	N/A
	Comments:			
5.2.15	Procedures for audit and review?			
	Comments:			
5.3	Are audits of laboratory activities conducted to verify compliance with the quality system?			
	Comments:			
5.3.1	Are audits conducted to ensure that analysts actually follow SOPs?			
	Comments:			
5.3.2	Are all audit and review findings and any corrective actions that arise from them documented?			
	Comments:			
5.4	Does the laboratory ensure the quality of results by implementing and reviewing internal quality control schemes using, whenever possible, statistical techniques?			
	Comments:			
5.4.1	Are control chart data maintained?			
	Comments:			
5.4.2	Do records indicate what corrective action has been taken when results fail to meet QC criteria?			
	Comments:			
5.4.3	Does the laboratory regularly use NIST SRMs or other certified reference materials?			
	Comments:			
5.4.4	Are QC data for all analytical results retrievable?			
	Comments:			
5.4.5	Are method detection limits documented?			
	Comments:			
5.4.6	Are routine analyses of reagents used for dilutions and digestions performed?			

		Yes	No	N/A
	Comments:			
5.4.7	Do supervisory personnel review the data calculations and QC results?			
	Comments:			
5.4.8	Are deviations or deficiencies in QC documented and reported to management?			
	Comments:			
5.5	Does the laboratory participate in the ELPAT proficiency testing program for each matrix that is routinely run in the laboratory?			
	Comments:			
5.5.1	Are ELPAT samples treated as regular samples and analyzed with the same method and by the same analyst who performs routine analyses?			
	Comments:			
5.5.2	Environmental lead laboratories must participate in the NIOSH/AIHA environmental lead proficiency analytical testing (ELPAT) program. Please attach copies of the two most recent ELPAT results and provide a summary of your investigation and findings regarding the laboratory's handling of any "not acceptable" results.			
	Comments:			
5.6	Are there QC procedures (SOPs) which address the following:			
5.6.1	Reagent and method blank analysis?			
	Comments:			
5.6.2	Glassware cleaning?			
	Comments:			
5.6.3	Sampling and subsampling?			
	Comments:			

		Yes	No	N/A
5.6.4	Replicate/duplicate analyses?			
	Comments:			
5.6.5	Spiked and blank sample analysis?			
	Comments:			
5.6.6	Blind samples?			
	Comments:			
5.6.7	Control charts?			
	Comments:			
5.6.8	Calibration standards?			
	Comments:			
5.6.9	Reference samples?			
	Comments:			
5.6.10	Internal standards?			
	Comments:			
5.7	Is at least the following minimum QC practiced in the laboratory:			
5.7.1	One method blank in 20 (5% or one per batch).			
	Comments:			
5.7.2	One method spike in 20 (5% or one per batch).			
	Comments:			
5.7.3	One duplicate or spiked duplicate in 20 (5% or one per batch).			
	Comments:			
5.7.4	One laboratory control sample (consists of a representative matrix spiked with the target analytes) in 20 (5% or one per batch).			
	Comments:			
5.7.5	Has the laboratory established control limits for all the above types of QC samples?			
5.7.6	If yes, can the laboratory demonstrate the basis for the established limits?			

		Yes	No	N/A
	Comments:			
6.0	**PERSONNEL**			
6.1	Does the laboratory have sufficient personnel, with the required education, training, knowledge, and experience for their assigned functions?			
	Comments:			
6.2	Do laboratory personnel have the following minimum education, experience and training:			
6.2.1	Supervisory Inorganic Chemist responsible for technical effort.			
	Name:_____ Experience: ____			
	Degree: B.S. Chemistry or related science			
	Recommended Experience: 3 years, nonacademic, 2 years metals analysis.			
	Comments:			
6.2.2	Inductively Coupled Plasma-Atomic Emission Spectroscopist			
	Name:_____ Experience: ____			
	Degree: B.S. Chemistry, or related science			
	Recommended Experience: 1 year minimum			
	Training: Satisfactory completion of a short course on ICP.			
	Comments:			
6.2.3	Flameless Atomic Absorption Spectroscopist			
	Name:_____ Experience: ____			
	Degree: B.S. Chemistry, or related science			
	Recommended Experience: 1 year minimum			
	Training: Satisfactory completion of a short course on GFAA			
	Comments:			

		Yes	No	N/A
6.2.4	Flame AA Spectroscopist			
	Name:_____ Experience: ____			
	Degree: B.S. Chemistry, or related science			
	Recommended Experience: 1 year minimum			
	Comments:			
6.2.5	Inorganic Sample Preparation Technician			
	Name:_____ Experience: ____			
	Recommended Experience: 3 months minimum			
	Comments:			
6.2.6	Routine Sample Analyst			
	Name:_____ Experience: _____			
	Recommended Experience: 6 months minimum			
	Comments:			
6.3	Are records maintained on the qualifications, training, skills and experience of the technical personnel?			
	Comments:			
6.4	Is there documented evidence of analyst proficiency for each test method performed?			
	Comments:			
7.0	**FACILITIES AND ENVIRONMENT**			
7.1	Does the laboratory:			
7.1.1	Use distilled/demineralized water that it can demonstrate to be essentially free of lead?			
	Comments:			
7.1.2	Routinely check and record the conductivity of distilled/demineralized water (for a continuous system, check should be per batch or daily)?			
	Comments:			
7.1.3	Provide separate contamination-free work areas for sample preparation and sample analysis?			
	Comments:			

		Yes	No	N/A
7.1.4	Provide facilities for separate storage of samples, digests, acids, reference materials, and standards with temperature and humidity control as required?			
	Comments:			
7.1.5	Have glassware cleaning facilities suitable for metals analysis?			
	Comments:			
7.2	Does the laboratory have a Chemical Hygiene Plan as specified by the OSHA Laboratory Standard (29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories")?			
	Comments:			
7.2.1	Does the laboratory provide exhaust hoods for sample digestion and vent hoods for instrumentation with sufficient flow to prevent cross-contamination?			
	Comments:			
7.2.2	Does the laboratory provide safety equipment as specified in the Chemical Hygiene Plan, such as safety showers, eyewash stations, chemical spill kits?			
	Comments:			
7.2.3	Does the laboratory provide personal protective equipment as specified in the Chemical Hygiene Plan, such as gloves, face shields, acid resistant aprons?			
	Comments:			
7.3	Are material safety data sheets readily available to the laboratory analyst?			
	Comments:			
7.4	Does the laboratory have documented procedures and facilities in place for storage, and disposal of chemical wastes, including acids and lead?			
	Comments:			

		Yes	No	N/A
8.0	**EQUIPMENT/INSTRUMENTATION** Note: Supplemental information on equipment should be listed in the table at the end of this checklist.			
8.1	Is the laboratory furnished with all items of equipment required for the analysis of Pb in paint, dust, and soil?			
	Comments:			
8.2	What type of equipment does the laboratory have for digestion? Identify types of heating units used for digestion below and provide complete details in equipment supplement.			
	( ) Hot plate ( ) Microwave Oven ( ) Other, specify			
8.2.1	If a hot plate is used for digestion, does it have temperature control within requirements as stated in the method SOPs?			
	Comments:			
8.2.2	If a microwave oven is used for digestion, does the unit have variable power levels that meet requirements as stated in method SOPs?			
	Comments:			
8.2.2.1	Has the microwave unit been calibrated according to manufacturer's recommendations?			
	Comments:			
8.2.2.2	How often has the unit been calibrated and does the schedule follow that described in the SOP?			
	Comments:			
8.3	What type of analytical instrument does the laboratory use? Identify types of instruments below and provide complete details in equipment supplement.			
	( ) FLAA ( ) GFAA ( ) ICP-AES ( ) Other, specify			
8.3.1	If a FLAA Spectrophotometer is used, is there a detailed SOP describing its operation and calibration?			
	Comments:			
8.3.1.1	Does the FLAA have a monochromoter, wavelength range, and lamps specified in the method SOP?			
	Comments:			

		Yes	No	N/A
8.3.1.2	Are fuels and oxidants commercial grade?			
	Comments:			
8.3.1.3	Is there a filter moisture trap between the air source and the spectrophotometer?			
	Comments:			
8.3.1.4	Are fuel tank pressures greater than instrument operating pressure?			
	Comments:			
8.3.1.5	Are flash-back arresters and heaters in use where needed?			
	Comments:			
8.3.1.6	Are burner heads specified in the method SOP used?			
	Comments:			
8.3.1.7	Are burner head gases removed by ventilation?			
	Comments:			
8.3.1.8	Is the burner head clean and free of build-up?			
	Comments:			
8.3.2	If the laboratory has GFAA, is there a detailed SOP describing its operation and calibration?			
	Comments:			
8.3.2.1	What type of GFAA background correction is used? ( ) Deuterium Arc ( ) Smith-Heiftje ( ) Zeeman			
	Comments:			
8.3.2.2	How often is the graphite tube changed and the chamber cleaned (every _____)? Is this documented?			
	Comments:			
8.3.3	Lamps used for FLAA and GFAA may be of various types. Are they: single element __; multi-element __; electrodeless __			
	Comments:			

		Yes	No	N/A
8.3.3.1	Are back-up lamps available as spare parts?			
	Comments:			
8.3.4	If the laboratory has ICP-AES, is there a detailed SOP covering its use and calibration?			
	Comments:			
8.3.4.1	Is a background correction technique in use and documented according to the SOP?			
	Comments:			
8.3.4.2	Has the absence of spectral interference for analytes of interest been checked, corrected, and documented?			
	Comments:			
8.3.4.3	Has salt build-up on the nebulizer been controlled?			
	Comments:			
8.3.4.4	When a matrix interference is encountered, are procedures specified in the SOP used to correct/eliminate potential interference?			
	Comments:			
8.3.4.5	Is the spectrometer equipped with an argon gas supply?			
	Comments:			
8.3.4.6	Are high purity grade or equivalent nitric and hydrochloric acids and deionized (distilled) water used for sample processing and standards preparation?			
	Comments:			
8.4	General equipment requirements:			
8.4.1	Are analytical balance/pan balances calibration covered by an SOP?:			
	Comments:			
8.4.1.2	Do records document regular calibration using certified weights?			
	Comments:			
8.4.1.3	Do records show annual servicing and calibration for all balances?			

		Yes	No	N/A
	Comments:			
8.4.2	Labware:			
8.4.2.1	Does the laboratory have deionized/distilled Class A water and an SOP describing the checks on conductivity and lead contamination?			
	Comments:			
8.4.2.2	Is there documentation of the lack of contamination on glassware used for metals analysis?			
	Comments:			
8.4.3	Conductivity meter:			
8.4.3.1	Do records show a calibration check daily, or before each use, whichever is less frequent?			
	Comments:			
8.4.4	Autopipetors/dilutors:			
8.4.4.1	Does the laboratory keep records showing delivery volumes are checked at least monthly?			
	Comments:			
8.5	Does the laboratory maintain records on each major item of equipment? Do the records include:			
8.5.1	The name of the equipment?			
	Comments:			
8.5.2	The manufacturer's name, model number, and serial number or other unique identification?			
	Comments:			
8.5.3	Condition when received (e.g., new, used, reconditioned)?			
	Comments:			
8.5.4	Date received and date placed in service?			
	Comments:			

		Yes	No	N/A
8.5.5	Copy of the manufacturer's instruction manual(s) readily available to the analyst?			
	Comments:			
8.5.6	Dates and results of instrument calibrations and date scheduled for the next calibration?			
	Comments:			
8.5.7	Detailed maintenance SOPs, including names and telephone numbers to call for service?			
	Comments:			
8.5.8	Detailed log of preventive maintenance and service calls which include dates and repair records?			
	Comments:			
8.6	Has any equipment that has been damaged, or produces unacceptable results, been taken out of service until it has been repaired and then shown by calibration, verification, or test to perform satisfactorily prior to being placed back into service?			
	Comments:			
9.0	**CALIBRATION/STANDARD OPERATING PROCEDURES**			
9.1	Is all instrumentation having an effect on the accuracy and validity of tests calibrated before being put into service?			
	Comments:			
9.1.1	Is the initial calibration and instrument checkout documented as instruments are brought into service, either when new or after repair?			
	Comments:			
9.1.2	Are instrument calibration records kept near the instrument and are they used by the analyst?			
	Comments:			
9.2	Are calibration standards traceable to NIST standard reference materials?			
	Comments:			
9.2.1	Are NIST standard reference materials used for calibration or traceability studies only and for no other purpose?			

		Yes	No	N/A
	Comments:			
9.2.2	Are separate reference materials dedicated to calibration purposes only and not used as LCS?			
	Comments:			
9.3	Do SOPs that provide for method calibration contain the following information:			
9.3.1	Are standard curves prepared to adequately cover the expected concentration ranges of the samples?			
	Comments:			
9.3.2	For methods using AAS, are standard calibration curves made up of a reagent blank, and a minimum of three standards covering the concentration range of the samples?			
	Comments:			
9.3.3	Are new curves prepared whenever out-of-control conditions are indicated and after new reagents are prepared?			
	Comments:			
9.3.4	When analyses are performed, is the standard curve verified (checked) by use of at least a method blank and one standard?			
	Comments:			
9.3.4.1	Are these checks within ±10% of the original values?			
	Comments:			
10.0	**METHODS**			
10.1	Method Selection. Does the laboratory:			
10.1.1	Use recognized (EPA recommended) methodologies and instrumentation for each analysis performed, if such methods are available?			
	Comments:			

		Yes	No	N/A
10.1.2	Select methods mandated by legal requirements, recognized published methods, or methods developed and validated by the laboratory?			
	Comments:			
10.1.3	Have site-specific SOPs for sample analysis?			
	Comments:			
10.1.4	Use alternative analytical techniques that have undergone an approved validation study?			
	Comments:			
10.1.5	Make available to the client fully documented and validated non-standard method information?			
	Comments:			
10.1.6	Require that modifications to test method SOPs be documented and approved by the Technical Manager (or however named) before being implemented?			
	Comments:			
10.1.7	Make available to analysts SOPs, standards, manuals, and reference data relevant to the work of the laboratory?			
	Comments:			
10.1.8	Regularly update SOPs and document changes in the QA manual?			
	Comments:			
10.1.9	Have method performance criteria (method detection limits, precision, accuracy, linearity, etc.) been documented in an SOP?			
	Comments:			
10.1.10	Have demonstrated acceptable performance for each analytical test method using performance evaluation samples?			
	Comments:			

		Yes	No	N/A
10.2	Standards and Calibration. Does the laboratory:			
10.2.1	Have SOPs for standards preparation?			
	Comments:			
10.2.2	Use reagent grade or higher purity chemicals to prepare standards?			
	Comments:			
10.2.4	Use NIST SRMs (SRM 3128, Pb in 10% nitric acid) as a primary standard?			
	Comments:			
10.2.5	Prepare fresh analytical standards at a frequency consistent with good QC?			
	Comments:			
10.2.6	Properly label reference materials/reagents with concentrations, date of preparation, expiration date, and the identity of the person preparing the reagent?			
	Comments:			
10.3	Does the analytical run contain, where applicable:			
10.3.1	An initial calibration blank?			
	Comments:			
10.3.2	A method blank?			
	Comments:			
10.3.3	A matrix-based laboratory control sample?			
	Comments:			
10.4	Are sample pretreatment and preservation documentation available to the analyst?			
	Comments:			
10.5	Is the method of standard addition in use where needed?			
	Comments:			

		Yes	No	N/A
10.6	Are method calculation and data transfers checked by someone other than the analyst?			
	Comments:			
11.0	**HANDLING OF TEST SAMPLES**			
11.1	Does the laboratory have a documented system for uniquely identifying the sample to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time?			
	Comments:			
11.2	Upon receipt, does the laboratory record the condition of the sample, including the presence of debris, substrate, and any abnormalities that may affect the quality of the analytical result?			
	Comments:			
11.2.1	If there is any doubt as to the item's suitability for analysis, or if the item does not conform to the description provided, or if the test required is not fully specified, does the laboratory consult with the client for further information before proceeding?			
	Comments:			
11.2.2	Does the laboratory establish whether the sample has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory (e.g., screening out debris, grinding to a fine mesh, removing substrate)?			
	Comments:			
11.3	Does the laboratory have documented procedures for the retention or safe disposal of samples?			
	Comments:			
11.4	Follow documented chain-of-custody procedures, when required by the client?			
	Comments:			

		Yes	No	N/A
12.0	**RECORDS**			
12.1	Has the laboratory established and maintained a records system that ensures that:			
12.1.1	All observations and calculations are recorded in a permanent manner (such as laboratory notebooks, pro forma work sheets, or magnetic media) at the time they are made and that the units of measurement in which observations are recorded are stated?			
	Comments:			
12.1.2	Original records are uniquely identified and traceable to the samples to which they refer and to any analysis reports based upon them?			
	Comments:			
12.1.3	Records are traceable, retrievable, and legible and include sufficient information and explanation such that they can be readily interpreted by staff other than those responsible for their generation?			
	Comments:			
12.1.4	Records contain sufficient information to permit identification of possible sources of error and to permit, where feasible and necessary, satisfactory repetition of the analysis under the original conditions?			
	Comments:			
12.1.5	Records contain sufficient details of any significant departures from specified procedures, including authorizations for such departures?			
	Comments:			
12.1.6	Records are checked for data transcription or calculation errors?			
	Comments:			
12.1.7	Records identify the person or persons responsible for their generation and for the checking of data transcriptions and calculations?			
	Comments:			

		Yes	No	N/A
12.1.8	Corrections or amendments to test records are made in a manner that does not obliterate the original data and are signed or initialled by the person responsible?			
	Comments:			
12.2	Are all records and reports safely stored, held secure and in confidence for the client?			
	Comments:			
12.3	Are hard copy analysis records protected from loss damage, misuse or deterioration and retained for a designated period in a manner that permits retrieval?			
	Comments:			
12.4	Are analysis records that are created and/or retained on magnetic media (e.g., computer disks) or photographic media (e.g., microfiche) stored in a manner that protects them from the hazards that affect such media, and is provision made for the printing of such records when required?			
	Comments:			
13.0	**REPORTS**			
13.1	Are the laboratory's results of each analysis that is carried out reported accurately, clearly, unambiguously?			
	Comments:			
13.2	Does each report include at least the following information:			
13.2.1	A title (e.g., "Analysis Report")			
	Comments:			
13.2.2	The name and address of laboratory and location where the analysis was carried out, if different from the address of the laboratory?			
	Comments:			
13.2.3	A unique identification number for the report, for each page, and the total number of pages?			
	Comments:			
13.2.4	The name and address of client?			
	Comments:			

		Yes	No	N/A
13.2.5	Reference to the field sampling procedure, if known by the laboratory?			
	Comments:			
13.2.6	A description and unambiguous identification of the sample tested?			
	Comments:			
13.2.7	A characterization and condition of the samples?			
	Comments:			
13.2.8	The date of receipt of the samples and date(s) of performance of the tests, including digestion dates, and analysis dates, if different?			
	Comments:			
13.2.9	An identification of the sample digestion and instrumental analysis methods used?			
	Comments:			
13.2.10	Description of any deviations from, additions to, or exclusions from the SOPs, relevant to a specific analysis?			
	Comments:			
13.2.11	Measurements, and derived results, supported by tables, and graphs as appropriate, including identification of any missing data?			
	Comments:			
13.2.12	A statement of the estimated uncertainty of the analysis result?			
	Comments:			
13.2.13	A signature and title, or equivalent identification, of person(s) accepting responsibility for the content of the report (however produced), and date of issue?			
	Comments:			

		Yes	No	N/A
13.3	Does the laboratory notify clients promptly, in writing, of any event, such as the identification of defective measuring or test equipment that casts doubt on the validity of results given in any test report or amendment to a report?			
	Comments:			
13.4	Has the laboratory ensured the confidentiality of data when clients require transmission of test results by telephone, telex, facsimile, or other electronic or electromagnetic means, by use of documented procedures for electronic data transmission?			
	Comments:			
14.0	**COMPLAINTS**			
14.1	Does the laboratory have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities?			
	Comments:			
14.2	Does the laboratory maintain records of all complaints and of the actions taken by the laboratory?			
	Comments:			
14.3	Where a complaint, or any other circumstance, raises doubt concerning the laboratory's compliance with the laboratory's policies or procedures, or with the applicable requirements, or otherwise concerning the quality of its tests, does the laboratory ensure that those areas of activity and responsibility involved are promptly audited according to requirements listed in the quality manual?			
	Comments:			

SUPPLEMENTAL INFORMATION ON MAJOR EQUIPMENT

Instrument	Manufacturer	Model	Serial Number	Installation Date
ICP-AES				
Data System				
AA (Flame)				
Data System				
AA (GFAA)				
Data System				
Microwave Digestion Unit				

Comments on Instruments and Data Systems: