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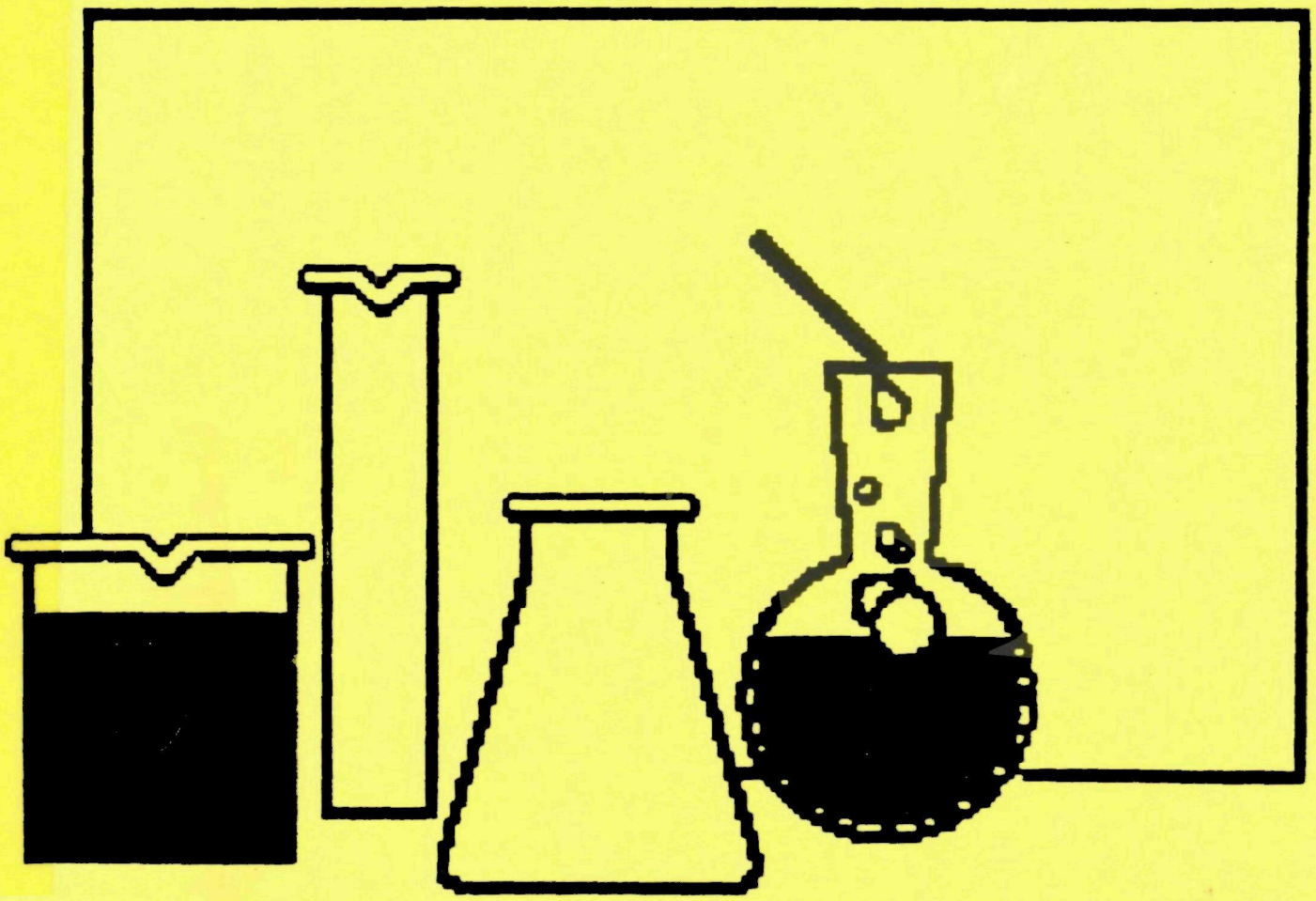

LABORATORY ACCREDITATION PROGRAM GUIDELINES: MEASUREMENT OF LEAD IN PAINT, DUST, AND SOIL

Final Report

Prepared by the
Task Group on
Methods and Standards
of the
Federal Interagency Lead-Based Paint Task Force

Distributed By

U.S. Environmental Protection Agency
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NOTICE

In 1989, the U.S. Environmental Protection Agency (EPA) and the Department of Housing and Urban Development (HUD) formed an Interagency Task Force to evaluate issues related to the reduction of lead-based paint exposure to children. This eighteen member Interagency Task Force operates to exchange information, coordinate activities, and conduct joint projects aimed at reducing childhood poisoning from exposure to lead-based paint. One effort of the Task Force is aimed at improving the measurement of lead in a variety of media including blood, paint, dust, and soil. Specific activities include improving the accuracy and precision of analytical methods for the laboratory, the development of standard reference materials for lead in environmental media, and establishing the evaluation components of a laboratory proficiency testing and accreditation program. This report presents the guideline recommendations of the Interagency Task Force for the establishment of a national laboratory accreditation program for the analysis of Pb in paint, dust, and soil samples. These recommendations, as well as others provided by the scientific community, are being considered by EPA in an effort to develop a national laboratory accreditation program for the analysis of Pb in paint, dust, and soil samples.

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REPORT ON GUIDELINES FOR ESTABLISHMENT OF A LABORATORY ACCREDITATION PROGRAM FOR THE MEASUREMENT OF LEAD IN PAINT AND THE ENVIRONMENT

EXECUTIVE SUMMARY

This report summarizes the results of meetings that were held to discuss guidelines and recommendations for conducting an intergovernmental agency laboratory accreditation program (LAP) for the chemical analysis of lead in paint, dust, and soil.

The main factors to consider in establishing a LAP are the administrative structure, quality assurance policy, performance evaluation materials, method protocols, site inspections, and administrative rules.

This report suggests guidelines for structuring a LAP for lead in paint, dust and soil. It is recommended that existing programs be utilized as much as possible, but uniformity of requirements between the programs is needed. This can be accomplished by establishing an organization that monitors and coordinates the activities of the laboratory accreditors. The development of uniform requirements will create the potential for reciprocity between accrediting organizations in the LAP.

The implementing agency will have to establish from already existing models, concepts of quality assurance to be expected from the accredited laboratories. Training programs to propagate this policy will have to be established. It is also recommended that annual symposia for representatives of the accredited laboratories and other members of the environmental community be established for the purpose of updating methods and standards.

While test method protocols used by any given laboratory must be clearly identified and detailed, it is not recommended specific methods be mandated. It is believed a comprehensive and rigorous performance evaluation material program coupled with laboratory site inspections can verify laboratory capabilities. It is expected the fees paid by the laboratories participating in the LAP will cover a substantial part of the program's cost; however, additional support from the lead agency may be necessary.

It is recommended the lead agency establish an advisory committee consisting of representatives of the users of the accredited laboratories, the accredited laboratories, the laboratory accreditors, accreditor monitor, and lead agency. This committee would review specific procedures and requirements developed by the lead agency from the guidelines established in this report.

INTRODUCTION

The Interagency Lead-Based Paint Task Force has formulated a Task Group on Methods and Standards. At the September 1991 Interagency Task Force meeting, the Group was asked to perform a brief study on accreditation procedures for laboratories performing analyses of paint, dust and soil samples for lead. To that end, a Special Committee was assembled to include representatives from the various government agencies that have particular interest in laboratory accreditation. (See list of members at the beginning of this report.) The Special Committee on Laboratory Accreditation limited its consideration to the analysis of lead in paint, dust, and soil. It was decided the best way to proceed was to discuss briefly the attributes of existing laboratory accreditation programs and to generate functional guidelines that could be used for the establishment of a laboratory accreditation program (LAP) for the analysis of lead in paint, dust, and soil.

The reason for establishing a LAP for lead is based upon the desire to obtain lead compositional data of known and appropriate quality, so proper decisions may be made regarding the protection of those exposed to lead in paint, soil or dust. A LAP provides recognition of competent laboratories, and if properly implemented, improves the overall quality of compositional measurement.

The reference list at the end of this report contains a number of documents from which information has been obtained. The review prepared by Research Triangle Institute[1] is of particular interest. Laboratory accreditation programs[2] are presently in place for the analysis of lead in blood, air and water. The Center for Disease Control monitors the performance of lead analysis in blood. NIOSH, through its Proficiency Analytical Testing (PAT) Program with the American Industrial Hygiene Association (AIHA), evaluates laboratory performance for lead in air particulates. EPA's Office of Ground Water and Drinking Water monitors laboratory performance for the analysis of lead in drinking water.

It is up to laboratories to choose under which LAP(s) they may wish to participate, and this choice may depend in large part on the types of samples (e.g., blood, air, or water), the laboratory needing accreditation is most concerned. In view of the anticipated magnitude of the lead analysis program for paint, dust, and soils, it is desirable to have an accreditation program which will be employed universally so each laboratory will respond to the same set of requirements.

There is always a compromise that must occur between the comprehensiveness of the LAP rules and their cost of implementation. Because the cost of accreditation is usually paid for by the user of the analytical services, those laboratories participating in a more comprehensive accreditation program may be at a competitive disadvantage. In addition, many laboratories are overburdened with responses to the multi-variate regulations required for the various LAP's. For these reasons, it is important for the various

accreditors to normalize their rules and regulations. Several standards organizations have provided guidelines[3,4], and these can provide the impetus toward effective normalization. It might be important to establish some organization that has the mission to assist in such a rules leveling between LAP's. There are efforts both in the United States by the EPA Committee on National Accreditation of Environmental Laboratories (CNAEL) and internationally by the International Association of Environmental Testing Laboratories (IAETL) to establish uniform laboratory requirements across all environmental testing.[5] The guidelines set forth here attempt to establish some uniformity between LAP's for lead analysis of paint, dust, and soil.

This report breaks down the LAP function into sections involving administration, training programs, quality assurance, performance evaluation materials, method protocols, site visits, and administrative rules. While these guidelines were explicitly developed to deal with accreditation of laboratory based operations, it is clear these guidelines may be implemented for all types of chemical analysis for lead whether field or laboratory based, however, the Special Committee considered the accreditation of field based analytical operations such as portable XRF or test kit field evaluations to be beyond the mandate of this assignemnt. In some instances, the guidelines attempt to be quite specific, but in other cases, it is felt some of the rules need to be established by the accreditation advisory groups with proper representation of the affected parties.

ADMINISTRATIVE STRUCTURE

Input for the basic administrative structure for the LAP came from guidance provided by ISO Guide 25[4] and the experience of members of the Special Committee which included representatives from HUD, NIOSH, EPA, NIST and CPSC.

Lead Organization

To establish an effective LAP for lead, it is desirable to have a clear articulation of the authority under which such a program would operate. Congress in its appropriation bill for FY 1991 included language directing EPA to establish a federally based laboratory accreditation program for lead. HUD received directions to determine the need to remove leaded paint from housing, and to decide through dust analysis, if the abatement of lead contamination was effective. OSHA has continuing responsibility for evaluating lead exposures and cleanup in the workplace. DHHS has a mandate to evaluate the lead levels in human blood, especially children. It would be desirable to have normalized and consistent rules for LAP's in all of these areas. Figure 1 depicts a straightforward mode by which an effective LAP for lead can be implemented.

The lead organization, whether it be EPA, HUD, OSHA, or DHHS, would be responsible for administering the program. In some instances, it might be possible if it is within the mandate of one organization to delegate this responsibility to another. For

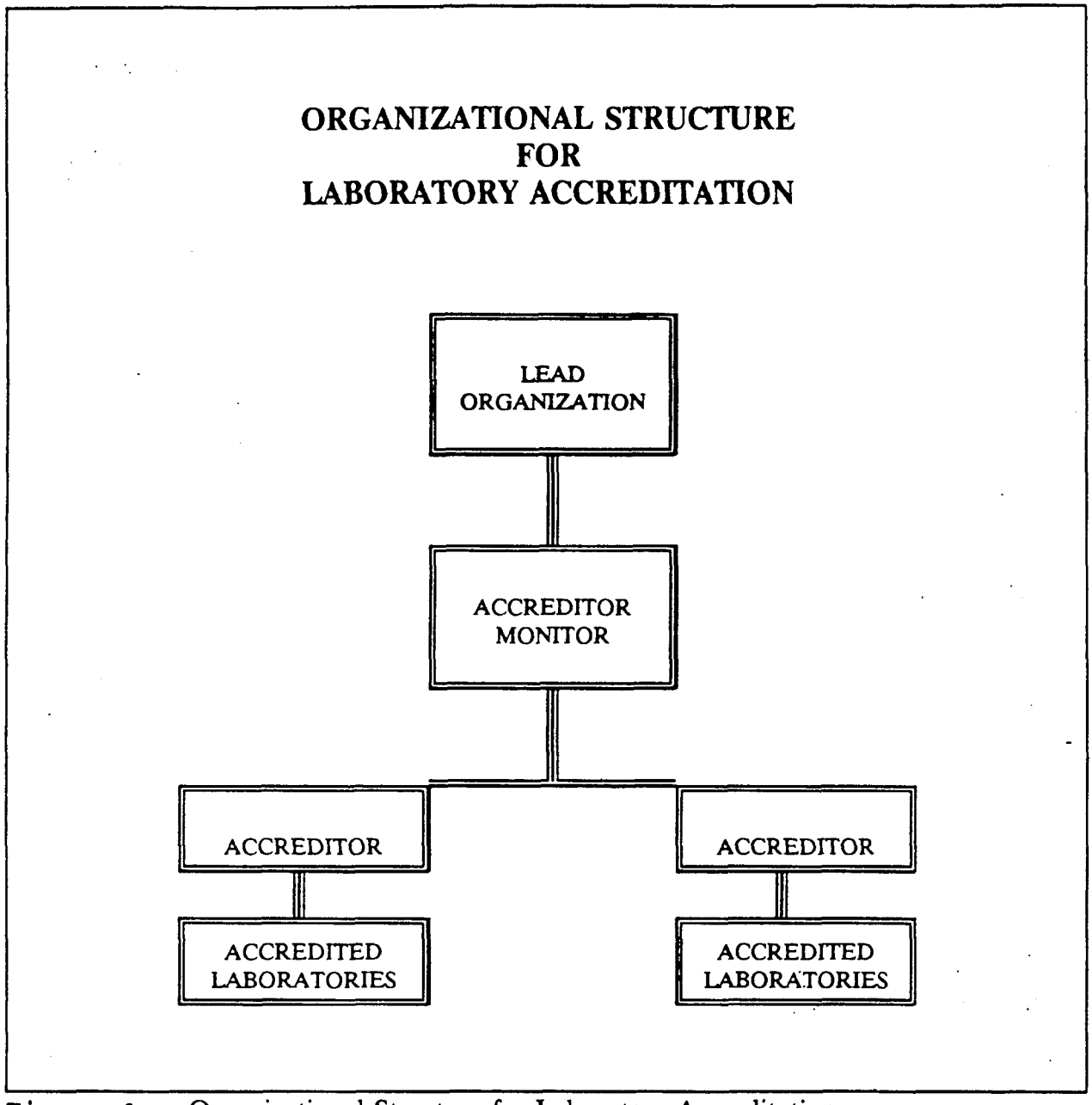

Figure 1 - Organizational Structure for Laboratory Accreditation

example, HUD may request EPA to operate a LAP from which HUD can utilize laboratory services.

Accreditor Monitor

Either as part of the lead organization or as a recognized agent of the lead organization, a monitor of accreditors should be established. This subunit is responsible for seeing that there is uniformity among the accreditors in the LAP. It is recommended that this unit be responsible for developing uniform accreditation criteria. An additional responsibility would be the establishment of reciprocity between the accreditors. The national LAP should take maximum advantage of existing accreditation programs both in the private professional sector and at the public state government level; thereby, saving the cost of establishing an entirely new program. To the extent state programs exist, attempts should be made to establish uniformity across the state accreditation programs for lead analysis.

Advisory Committee

The lead organization should establish an advisory committee for the purpose of formulating technical specifications for the LAP. For example, such a committee can assist the lead organization in implementing many of the recommended technical requirements listed in the sections of this report. This committee should contain representation from the lead organization, accreditor monitor, accreditor(s), accredited laboratories, and users of the laboratory' services. This committee, with the lead organization's support, should establish a team-like environment by sponsoring at least one meeting per year open to all parties affected by the LAP to discuss methods, standards, and uniform requirements.

Financial Support

In general, the LAP should be financially supported from fees obtained from the accredited laboratories. For some aspects of the LAP, it will be necessary to provide start-up funding, and in other parts continuous funding may be necessary. For example, initial funding will be required for the production of performance evaluation and primary reference materials (see below), and for establishing training programs. Continuous funding will be required for monitoring accreditor operations, as well as for activities involving the advisory committee.

ESTABLISHMENT OF QUALITY ASSURANCE AND TRAINING PROGRAMS

Quality Assurance System

Quality assurance requires that the laboratory establish and maintain a quality assurance system that is represented by the combination of good laboratory practices, proper data processing, final result reporting procedures, and well-documented methods. Good Laboratory Practices (GLP's) have been adopted by many countries to ensure the scientific reliability and quality of test data for chemicals that have the potential to adversely affect human health and the environment. Food, drug, and environmental regulatory agencies in various countries, including the U.S. Food and Drug Administration and the U.S. Environmental Protection Agency, have cooperated to develop a uniform set of good laboratory practices.[6] In manufacturing and service industries, a series of international guides covering quality systems from initial design/development to final inspection and testing and servicing of products has been developed and is in wide use.[7] As a result of the development and widespread use of these new and improved quality requirements, ISO Guide 25[4] which is the basis of many national laboratory accreditation programs covering many fields of testing was revised in 1990 to take into account OECD GLP and ISO Guide 9000 requirements.

It is particularly important to recognize the need for data security since computer processing and storage of the data are preferred.[8]

In addition, it is suggested that establishment of quality assurance in a laboratory be implemented in steps. Before the accreditation procedure begins, it should be possible for a laboratory to participate in the analysis of performance evaluation materials as part of a routine proficiency testing procedure as implemented by a laboratory accreditor. This would permit laboratories that are not yet certain that they can meet the necessary qualifications for accreditation to gain important information concerning their ability to analyze lead environmental samples.

Training Programs

It is important to provide training opportunities in quality assurance for the accredited laboratory staff. In some instances, existing courses that are given in conjunction with specific standards organizations can be utilized. Additional courses will be required for site inspectors and for accreditors in order to establish the uniformity of requirements intended via these guidelines. It is suggested that the lead agency give consideration to the use of instructional computer generated video tapes to support the various training programs.

PERFORMANCE EVALUATION MATERIALS

Because of the importance of performance evaluation to a laboratory accreditation program, an effective lead analysis program will make available quality performance evaluation materials (PEM's). PEM's provide a practical test of quality performance. Properly designed PEM's can make it possible to evaluate a wide variety of methods including field methods and test kits, as well as laboratory based methods. Furthermore, PEM's can serve as suitable comparator materials for the development of new methods. In the following paragraphs, key attributes of a system for the preparation of PEM's are presented along with recommendations for the lead LAP.

Real Materials

Most PEM's that are used for laboratory accreditation are not similar to the routine samples that are measured. For example, some accreditation systems provide reference materials of water solutions containing the elements of interest at concentration levels that approximate those of routine samples after chemical processing. This procedure does not test the quality of the sample preparation. It is recommended that the PEM be a real world material, and made as close as possible to those materials that are routinely analyzed. The PEM's are to be prepared in small lot quantities, with each lot containing lead at different levels. The level of lead in each lot is quantitated prior to distribution by submitting representative samples to laboratories known to provide reliable measurements (reference laboratories). The quality assurance of the laboratory preparing the PEM's should be carefully and continually evaluated. It is important that the laboratory accreditor work closely with the PEM producer to assure that the best possible materials are provided for the program.

Distribution

The mode and frequency of distribution of the PEM's is very important. The PEM's can be delivered to the laboratory to be tested in single or double-blind mode. Submission of PEM's is usually done single blind where the laboratory is aware that the samples are PEM's, but is unaware of the concentration of the analyte(s). In this case, laboratories usually analyze these samples more carefully than routine samples. In the case of the double-blind mode, the laboratory is unaware of either which sample is the PEM or the concentration levels of the analyte(s). This mode ensures that the PEM's are analyzed with approximately the same care as routine samples, thereby giving a truer estimate of the measurement quality. Distribution of PEM's in this mode is somewhat more costly than single blind. The routine mode for distribution of PEM's should be single blind. Even though the cost of distributing double-blind materials is higher than for single blind, it is suggested that occasionally, selected materials be distributed in the double blind

mode to a small representative sample of the accredited laboratories, with appropriate followup if problems arise.

Primary Reference Materials

It is important to establish primary reference materials (PRM's) for the most frequently analyzed PEM's. The accuracy of the measurement of lead content should be greater than for the PEM's. The PRM serves as a benchmark whose certified concentration is well known, and therefore provides a different function than that of a PEM. The PEM producers and the accredited laboratories as well, will use these materials to reduce systematic errors in their measurements.

Specifications

It is necessary in some instances to design a PEM for a specific method of chemical analysis. This means that special design criteria must be established. For example, if lead in dust is to be measured by X-ray fluorescence, then the PEM must be made homogeneous to at least the target accuracy of the method for a sample size of a few tens of milligrams. These and other specifications along with a large number of production-oriented criteria need to be established on a case-by-case basis.

Financial Support

The cost of fulfilling the above requirements will be significant, but compromising the quality of the reference materials defeats the core function of the LAP. It will be necessary for the lead agency to support prototype production of reference materials, and to provide support for production PEM's if necessary.

METHOD PROTOCOLS

A crucial component in a laboratory accreditation program is the choice of the methods which are to be used to analyze for lead in environmental samples. Choice of method will depend on a large number of criteria: composition of sample matrix, concentration range, amount of necessary sample preparation, detection limit, dynamic range, precision, potential interferences, ease of use, cost, etc. Based on these considerations, some general guidelines on the choice of methods for the lead analysis program are proposed.

Selection Strategy

The primary concern will be the analysis of three types of environmental sources: paint, dust, and soil. It is recommended that the choice of method for lead analysis be left up to the laboratory seeking accreditation, since a number of methods have been shown to

perform well. Methods that are able to handle all three sample matrices are strongly encouraged to help reduce costs and improve data quality. This is especially important when considering digestion procedures. A strategy for the selection of suitable methods for these matrices should be guided by (at a minimum) the following considerations:

1. **Target extraction efficiency and precision** (95 percent confidence limit) should be quantitative with total uncertainties for standard reference materials (SRM's), 10 percent relative; for real-world samples, sieved only, 25 percent (NOTE: EPA/CLP program allows 15 percent), sieved and ground, 10 percent.

2. **Target working range** (using NIOSH model, for example) is for the detection limit: 0.1 x action concentration (or level of concern), and for the upper limit: 10 x action concentration (or level of concern). NOTE: Action concentration should be based on health effects data. Unfortunately, these data are not available for any of the three materials.

3. **Interferences (and their remedies) will depend on the sample matrix, digestion procedure, and instrumentation employed for analysis.** The type of sample matrix should be reported to the laboratory performing the analysis. Recommendations can be made on digestion procedures based on the type of sample matrix.

4. **Cost per sample.** Due to the large volume of samples expected, this will be very important information to provide to the users of the proposed accreditation program. Cost considerations will be a result of such factors as; equipment and materials costs, training required (skill level) and the availability of trained personnel, through-put rate (usually limited by rate of sample digestion), ease of use of the methodology, special precautions required, and disposal of wastes.

Compendium of Methods

As a starting point, a compendium of method protocols from such organizations as EPA, NIOSH, ASTM, RTI, and others should be assembled. The performance of a number of candidate methods is currently being evaluated by many investigators. Protocols for methods which are found to perform well should be made available to user/consumers.*

Quality Assurance/Quality Control

There should be a strong quality assurance/quality control (QA/QC) component in the lead analysis accreditation program. It is emphasized that realistic sample matrices should be used for QA/QC samples. Recommended minimal considerations to ensure

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* It is the intent of the Task Group on Methods and Standards to provide such a compendium of methods and standards.

good laboratory practice are that 5 percent of the samples should be blanks, both reagent and field types where possible; 5 percent-duplicates which are independently prepared samples run as "blinds"; one reference material per batch**; and 5 percent are instrument check solutions which are a known spiked solution or spiked sample matrix. The spike must be prepared from a standard stock which is different from the calibration standard stock, and should have a lead concentration that is within the range of the samples to be run.

It is noted that both the PRM and the check solution should have "real-time evaluation" with quantitative lead recovery within 10 percent relative. Control charts are also recommended.

Field Methods

Field collection techniques are not specified here because field collection methodologies are rapidly changing and improving due to identification of problems in ongoing studies. As results from further research become available, we will be in a better position to recommend more specific sampling protocols for field analysis.

The choice of laboratory technique (consisting of digestion and instrumental analysis) will depend on the sample matrix. Also, field analysis techniques are not addressed here as they will probably fall under "Training" or "Certification of Abatement Personnel." Decisions on what technique is to be used, be it a field technique or laboratory method, will depend on the purpose of the sampling (e.g., screening vs. quantitative). For any field analytical method, which is to be used for quantitative purposes, the performance criteria that the field method satisfies should be the same as those criteria recommended above for laboratory methods. The issue of sample collection in the field is extremely important, but at present remains in its formative stages. It is too early in the process of method development to address this issue, and it is recommended that the field sampling protocols outlined in the HUD guidelines be followed.[9]

SITE INSPECTIONS

Assessment of a laboratory to be accredited by a skilled and knowledgeable person is considered to be mandatory. Most of the existing LAP's use site inspections. There are a number of advantages to having a well-trained inspector visit the laboratory. The quality of the facilities, equipment, written procedures, and personnel can be perceived in ways that are impossible by other means. A properly conducted site inspection can result in improvement in performance of the laboratory, because the

** This reference material is often referred to as a secondary reference material whose concentration is established from and is traceable to a PRM.

inspector can suggest improvements in procedure. In addition to the obvious factor that the inspector determines the existence of specific methods and equipment, it is possible to verify from laboratory records that PEM's have been rotated among analysts and instruments, and that special precautions have not been taken in the analysis of these samples. The fact that the assessor can witness all or part of the analysis using a PEM, provides added assurance that performance evaluation results are representative of typical analytical performance. The assessor can provide important feedback to various groups within the government that are conducting analytical research on any problems that the accredited laboratories are having in using the analytical methods.

Assessment Requirements

On-site assessments, the appointment of assessors, the training and qualifications of assessors, and the laboratory accreditation program's quality assurance program for on-site assessments should follow the general requirements of appropriate international guides for laboratory accreditation programs such as ISO Guides 54 and 55.[10,11] This will provide a common base from which cooperation among various accreditation programs in closely related areas could occur. This is important because some laboratories that perform environmental lead analyses also operate in other fields of testing and are subjected to multiple laboratory accreditations. This would facilitate the use of a single assessor with training and experience in multiple fields to conduct simultaneous site visits for more than one laboratory accreditation program at considerable cost savings to the laboratory.

Frequency of Inspections

The frequencies of site assessments for similar laboratory accreditation programs range from once every two years to once every three years with the option of more frequent site visits if other information indicates that problems exist. It is recommended that on-site assessments be performed at least once every three (3) years.

Qualifications of Inspectors

Similar laboratory accreditation programs require assessors to have experience in the field and in laboratory quality assurance techniques. It is recommended that assessors have a bachelors degree in chemistry, at least five (5) years' analytical chemistry experience with senior position responsibilities, and at least two (2) years' specific knowledge of laboratory quality assurance and inorganic environmental analyses. Masters or Ph.D. degrees in chemistry or closely related fields may reduce the number of required years of experience in analytical chemistry. The assessor should also complete a short course on laboratory quality assurance, accreditation program procedures, and lead analytical requirements which includes an examination of competence. The assessor should also accompany an experienced assessor on at least one site visit before being

qualified. Experienced assessors may initially be drawn from lists of assessors that are currently performing assessments and have taken the required training course.

Other laboratory accreditation programs have schemes to rate the effectiveness of assessors. The accreditation program should have a scheme to either rate assessor reports or to obtain feedback from participating laboratories on the usefulness and completeness of assessor laboratory evaluations and recommendations. This should be part of the laboratory accreditation program's own quality assurance system that conforms to the requirements of Section 8 of ISO/IEC Guide 54.[10]

ADMINISTRATIVE RULES

Examples of rules for accreditation are listed below. Some items are from NIST 4493[12] that reflect NVLAP operating requirements. Selection of specific rules should be the responsibility of the lead agency with advice from the advisory group described above. There are a number of pertinent references.[13,14]

Federal Register Notice

Conclusions related to the lead agency's decisions associated with the lead LAP (including lists of accredited laboratories) should be published in the Federal Register.

Public Notices

Means should be available for disseminating widely adequate and impartial LAP information to the private sector.

Expert Advice

Input based on specialist's skills and knowledge shall be utilized in the development of technical requirements. The use of an advisory group as described above, and public workshops or reviews is an important consideration.

Federal Agencies

Coordination, consultation, and communication with appropriate department components shall be maintained.

Notice of Laboratory Accreditation, Schedule, and Fees

Details of Lead Laboratory Accreditation Program shall be announced in the Federal Register. FR Notice would include processes to be implemented both for organizations

seeking status as accrediting organizations and for individual laboratories seeking status as accredited laboratories.

Fees

A fully reimbursable fee structure for all services performed by the accreditation entity should be the objective of the programs once operational. It is envisioned some measure of federal funding may be required to support the initial stages of implementing the program. This could include initial funding for the development of performance evaluation materials (PEM's); proficiency testing of federal laboratories; the use of federal agency staff in monitoring accreditor operations and in serving on the technical advisory committee.

Denial, Suspension, Revocation, and Voluntary Termination of Accreditation

Conditions need to be stipulated in an unequivocal manner and formulated with a suitable appeals procedure for fairness and objectivity.

Termination

When determination of the need for accreditation no longer exists, a public notice and period for commentary shall be provided prior to the evaluation and decision for termination.

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