

NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM

Memorandum of Understanding on Collaboration between the Office of Pollution Prevention and Toxics of the U.S. Environmental Protection Agency and the [Organization's Name]

I. Purpose

The purpose of this Memorandum of Understanding (MOU) between the Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics (OPPT) and [Organization's Name] is to recognize [ORGANIZATION'S NAME] as a laboratory accrediting organization working in cooperation with the EPA National Lead Laboratory Accreditation Program (NLLAP). Laboratories that are accredited by [ORGANIZATION'S NAME] for the analysis of lead in paint, dust, and soil matrices will be recognized by the NLLAP as being capable of performing adequate analyses for lead in paint, dust and soil matrices.

II. Background

In an effort to establish a national accreditation program for laboratories conducting analyses for lead in paint, dust and soil matrices associated with the evaluation and control of lead-based paint hazards, EPA/OPPT has drawn upon the capabilities of private and public laboratory accrediting organizations. In order to assure the public that a laboratory accrediting organization is capable of performing an adequate assessment of participating laboratories, EPA enters into MOUs with accrediting organizations in recognition of their capability to perform adequate laboratory assessments meeting criteria set forth in the International Organization for Standardization and International Electrochemical Commission (ISO/IEC) 17025: 2005 (E) "General requirements for the competence of testing and calibration laboratories", and EPA's Laboratory Quality System Requirements, Revision 3.0 (LQSR 3.0).

III. Definitions

The following definitions are specific to this MOU:

Accreditation – A formal recognition that a laboratory is competent to perform analyses of lead in paint, dust and/or soil matrices associated with the evaluation and control of lead-based paint hazards. Competence will be based on successful performance in both a proficiency testing (PT) program and systems audit (inclusive of an on-site assessment) by programs/organizations recognized by NLLAP as an Accrediting Organization.

Accreditation Organization (AO) – An organization that is recognized by EPA's NLLAP Program as being capable of performing assessments of laboratories requesting accreditation for the analysis of lead in paint, dust and soil matrices.

Assessor – A person who is trained to perform a systematic evaluation of a laboratory on behalf of a laboratory Accreditation Organization.

Environmental Lead Proficiency Analytical Testing Program (ELPAT Program) – The PT program recognized by the NLLAP. Participation on a quarterly basis in this program is necessary for all laboratories seeking accreditation by an NLLAP recognized laboratory accrediting organization.

EPA National Lead Laboratory Accreditation Program (NLLAP) – A voluntary laboratory accreditation program through which EPA recognizes private sector and public laboratory accreditation organizations capable of performing adequate laboratory assessments as a part of their accreditation program of laboratories requesting accreditation for the analysis of lead in paint, dust and/or soil matrices associated with the evaluation and control of lead-based paint hazards.

Laboratory – An operation that performs sampling, quantitative, or qualitative analytical testing (or any combination thereof) of paint, or dust or soil matrices for lead analysis regardless of the number of personnel or the extent of the scope of testing activities.

IV. Authority

Under Title X, Section 405(b) of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (Section 405(b) of the Toxic Substances Control Act), EPA is required to establish protocols, criteria, and minimum performance standards for laboratory analysis of lead in paint, soil, and dust matrices. It also requires EPA to determine if effective voluntary laboratory accreditation programs are in place and operating on a nationwide basis. If such programs are not operating effectively within two years (October 28, 1994), EPA is to establish a laboratory certification program for all laboratories which demonstrate an ability to accurately analyze for lead in paint, dust and soil matrices.

V. Basis and Substance of Understanding

The general consensus standards for AOs are set forth in ISO/IEC 17011: 2004, "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies". The general consensus standards for laboratories performing environmental testing activities under NLLAP are stated ISO/IEC 17025: 2005 (E) "General requirements for the competence of testing and calibration laboratories".

To determine that [ORGANIZATION'S NAME] voluntary programs meet the goals of the NLLAP and the standards and criteria in LQSR 3.0, which identifies the criteria for use by AOs when evaluating laboratories performing environmental testing activities under NLLAP and is based on requirements of ISO/IEC 17025: 2005(E), EPA reviewed [ORGANIZATION'S NAME] organizational policies, laboratory evaluation practices and standards. Specifically, EPA reviewed the following

[**ORGANIZATION'S NAME**]’s standards related to laboratory accrediting procedure and ELPAT program, and found them to be consistent with the NLLAP goals and the criteria in LQSR 3.0:

- {List of [**Organization's Name**] standard documents (titles and dates of publication) reviewed}

Through this MOU, [**ORGANIZATION'S NAME**] agrees that laboratories are accredited only to analyze for lead in paint, dust and soil matrices, using standards stated in LQSR 3.0.

Specifically, [**ORGANIZATION'S NAME**] agrees:

1) to notify EPA NLLAP officials in writing within five working days of the action by [**ORGANIZATION'S NAME**] in the event that a laboratory loses its accreditation status.

2) to notify EPA NLLAP officials within 30 days after [**ORGANIZATION'S NAME**] makes a decision to implement changes in [**ORGANIZATION'S NAME**] organizational policies or management that could affect the NLLAP.

3) to establish and implement a continuing education program for Assessors using the most current revision, including amendments of the EPA developed curriculum guidance document entitled "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations For Assessor Training Programs – Revision 1.0" (EPA document No. 747-R-92-005), or [**ORGANIZATION'S NAME**]’s own training curricula, which addresses the areas covered in the EPA guidance document. In cases where [**ORGANIZATION'S NAME**] develops its own training curricula, [**ORGANIZATION'S NAME**] agrees that before using the curricula, the curricula will first be approved by EPA OPPT’s National Chemicals Division (NPCD). [**ORGANIZATION'S NAME**] agrees to notify the NPCD MOU Implementation Officer if [**ORGANIZATION'S NAME**] utilizes the assessor training program of another accrediting organization recognized by the NLLAP. Copies of the document "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs – Revision 1.0" can be obtained from the National Lead Information Center Clearinghouse by calling 1-800-424-LEAD.

4) to perform a systems audit on applicant laboratories which includes an on-site assessment by [**ORGANIZATION'S NAME**] Assessors and to ascertain that the applicant laboratories’ general and environmental program requirements are consistent with the criteria in LQSR 3.0.

5) that [**ORGANIZATION'S NAME**] Assessors will fill out a checklist for each on-site assessment. The checklist utilized may be the example provided in the EPA publication "Pb-Based Paint Laboratory Accreditation: Curriculum Recommendations for Assessor Training Programs – Revision 1.0" or one developed by [**ORGANIZATION'S NAME**] and approved by the NPCD MOU Implementation Officer that addresses the areas covered by the example. [**ORGANIZATION'S NAME**] further agrees to keep the laboratory checklists on file for 10

years as a part of the accreditation documentation.

6) to allow EPA representatives to accompany **[ORGANIZATION'S NAME]** Assessors during an on-site visit to observe the performance of **[ORGANIZATION'S NAME]** Assessor in the field.

7) only to accredit laboratories that perform successfully (rated proficient or "P" in the ELPAT as administered by American Industrial Hygiene Association Proficiency Analytical Testing Programs, LLC (AIHA PAT Programs, LLC). **[ORGANIZATION'S NAME]** further agrees that accreditation will be contingent upon participation in the ELPAT program on a quarterly basis as new rounds of PT samples are made available. **[ORGANIZATION'S NAME]** agrees that it will be responsible for making arrangements with AIHA PAT Programs, LLC in order to secure the ELPAT data of participating laboratories.

8) to reevaluate laboratories accredited by **[ORGANIZATION'S NAME]** at a minimum of once every three years. This reevaluation will include a systems audit and an on-site visit. **[ORGANIZATION'S NAME]** agrees to subject laboratories that have been cited as having performed inadequately based on customer complaints or poor performance in the ELPAT program to more frequent reevaluation.

9) to provide accreditation information to the NPCD MOU Implementation Officer within 45 days of approving a laboratory accreditation including: (a) accreditation effective date, (b) accreditation expiration date, and (c) matrices for which the laboratory is accredited. **[ORGANIZATION'S NAME]** also agrees to provide: a list of all current accredited laboratories to the NPCD MOU Implementation Officer at least once every three months and a continual update of the laboratory's accreditation standing over time as reassessments and performance evaluation reviews are conducted

10) to maintain records for a period of five years of the terms of accreditation of each accredited laboratory including all complaints received from customers of the accredited laboratory. **[ORGANIZATION'S NAME]** agrees to make this information available to EPA upon request.

11) if necessary, to delegate full or partial responsibility for laboratory assessment only to another NLLAP recognized organization.

12) to only accredit a laboratory that practices the sub-contracting of routine sample analysis of lead in paint, soil or dust matrices if the sub-contracting is limited exclusively to another NLLAP recognized laboratory.

13) to participate in meetings with EPA at least once every two years in an effort to help provide an evaluation of NLLAP.

The OPPT as the overseeing EPA Office of the NLLAP, agrees:

1) to recognize **[ORGANIZATION'S NAME]**, pursuant to the terms of this MOU, as a

laboratory accrediting organization for the NLLAP. Laboratories accredited by [ORGANIZATION'S NAME] for the NLLAP will be recognized by EPA as capable of analyzing for lead in paint, dust, or soil matrices during the period of their accreditation. A list of laboratories, which have been accredited, will be made available to the public by EPA.

2) to provide guidance and interpretation of NLLAP protocols, criteria, and performance standards, and provide written notice to [ORGANIZATION'S NAME] when NLLAP protocols, criteria, and performance standards have been amended.

3) to conduct evaluations of [ORGANIZATION'S NAME] as a laboratory AO for the NLLAP at least once every three years, or more frequently if needed. These evaluations will be the responsibility of OPPT's NPCD, Program Assessment and Outreach Branch (PAOB). Evaluation criteria will be based on the criteria, standards, and terms set forth in Section V above.

VI. Management and Implementation

The NLLAP is managed as a part of the OPPT's NPCD Lead Program. The responsibility for implementing and support of the program lies with NPCD personnel.

Inquiries concerning the NLLAP and this MOU can be addressed to the NPCD MOU Implementation Officer at:

National Program Chemicals Division (7404T)
Program Assessment and Outreach Branch
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460

VII. Funding

All costs incurred by [ORGANIZATION'S NAME] to accredit laboratories are the responsibility of [ORGANIZATION'S NAME]. This includes costs for training of its Assessors and costs for obtaining PT samples and data for the accredited laboratories. [ORGANIZATION'S NAME] has the discretion to recover any costs by assessing fees to participating laboratories for its services.

All commitments made by EPA in this agreement are subject to the availability of appropriated funds. Nothing in this agreement, in and of itself, obligates EPA to expend appropriations or to enter into any contract, assistance agreement, interagency agreement, or to incur other financial obligations. [ORGANIZATION'S NAME] agrees not to submit a claim for compensation for services rendered to EPA in connection with any activities it carries out in furtherance of this MOU. This MOU does not exempt [ORGANIZATION'S NAME] from EPA policies governing competition for assistance agreements. Any endeavor involving reimbursement or contribution of funds between the parties to this agreement will be handled in accordance with applicable laws, regulations, and procedures, and will be subject to separate subsidiary agreements that will be effected in writing by representatives of both parties.

VIII. Revision or Termination

This MOU shall enter into force upon signature, and shall remain in force for 3 years, at which time a reevaluation of the NLLAP recognized laboratory accrediting organization's program will be done by EPA staff in NPCD. This MOU may be amended by written agreement of both parties at any time prior to its expiration or termination. The parties shall seek to resolve any dispute concerning the MOU through good faith discussions. The MOU may be terminated at any time upon sixty days' written notice by either party to the other.

IX. MOU Implementation Officers

Whenever this MOU provides for notice, such notice may be satisfied upon delivery by mail, facsimile, or e-mail to the respective MOU Implementation Officers listed below:

[MOU Implementation Officer]
USEPA/OPPT/NPCD (7404T)
Program Assessment and Outreach Branch
U.S. Environmental Protection Agency
Washington, D.C. 20460
Tel:
Fax:
Email:

[Organization's Decision Official]
[Title]
[Organization's Name]
[Organization's Address]
Tel:
Fax:
Email:

Organizational Approval

The following decision officials are authorized to enter into the NLLAP MOU between EPA and **[ORGANIZATION'S NAME]**:

Decision Official on Behalf of EPA/OPPT

[Name of Office Director]
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Date

Decision Official on Behalf of **[ORGANIZATION'S NAME]**

[Organization's Decision Official]
[Title]
[Organization's Name]

Date

