MEMORANDUM OF AGREEMENT BETWEEN THE U.S. ENVIRONMENTAL PROTECTION AGENCY AND THE [ORGANIZATION'S NAME]

National Lead Laboratory Accreditation Program

I. Purpose

The purpose of this Memorandum of Agreement (MOA) entered into on _______ by the U.S. Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics, Existing Chemicals Risk Management Division and the [ORGANIZATION'S NAME] is to recognize [ORGANIZATION'S NAME] as a voluntary laboratory accrediting organization working in cooperation with EPA National Lead Laboratory Accreditation Program (NLLAP). Laboratories that are accredited by [ORGANIZATION'S NAME] for the analysis of lead in the matrices of paint films, dust and soil will be recognized by EPA under NLLAP as being capable of performing adequate analyses for lead in paint films (chips), dust and soil samples.

II. Background

In an effort to establish a national, voluntary accreditation program for laboratories conducting analyses for lead in paint films, dust and soil matrices associated with the evaluation and control of lead-based paint hazards, EPA 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 MOAs with accrediting organizations. The MOA serves as a recognition of the accrediting organization's capability to perform adequate laboratory assessments and meet the criteria set forth in EPA's Laboratory Quality System Requirements, Revision 3.0 (LQSR 3.0).

III. Definitions

The following definitions are specific to this MOA:

Accreditation – A formal recognition that a laboratory is competent to perform analyses of lead in paint films, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards. Competence will be based on successful performance in both a proficiency testing program and systems audit (inclusive of an on-site assessment) by accrediting programs/organizations recognized by NLLAP. Accrediting Organization (AO) – An organization that seeks recognition from EPA as an accreditation body capable of performing assessments of laboratories requesting accreditation for the analysis of leadin collected paint films, dust and soil samples associated with the evaluation and control of lead-based paint hazards.

<u>Assessor</u> – A person who is trained to perform a systematic evaluation of a laboratory on behalf of a laboratory accrediting organization.

<u>Environmental Lead Proficiency Analytical Testing Program (ELPAT)</u> – The proficiency testing (PT) program recognized by NLLAP. Participation on a quarterly basis in this program is mandatory for all laboratories accredited by an NLLAP-recognized laboratory accrediting organization.

<u>EPA National Lead Laboratory Accreditation Program</u> – A voluntary laboratory accreditation program through which EPA recognizes private sector and public laboratory accrediting organizations capable of performing adequate laboratory assessments as a part of their accreditation program of laboratories that conduct analyses of lead in paint films, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards.

<u>Laboratory</u> – An operation that performs sampling and/or quantitative and/or qualitative analytical testing of paint films, dust, and/or soil samples for lead analysis regardless of the number of personnel.

IV. Authority

Under Section 405(b) of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2685(b), EPA is required to establish protocols, criteria, and minimum performance standards for laboratory analysis of lead in paint films, dust and soil. Section 405(b) of TSCA 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 that demonstrate an ability to accurately test paint films, dust and soil samples for lead.

V. Basis and Substance of Understanding

The general consensus standards for AOs are set forth in the International Organization for ISO/IEC 17011:2017, "Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies." The general consensus standards for laboratories performing environmental testing activities are stated in the ISO/IEC 17025:2017(E), "General requirements for the competence of testing and calibration laboratories."

The standards and criteria of NLLAP are defined in LQSR 3.0, which identifies the minimum criteria for use by AOs when evaluating laboratories performing environmental testing activities under NLLAP and is based on the criteria in 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] standards related to laboratory accrediting procedures and PT program and found them to be consistent with NLLAP goals and the criteria in LQSR 3.0 as well as ISO/IEC 17011:2017 and ISO/IEC17025:2017(E):

• List of [ORGANIZATION'S NAME] standard documents (titles and dates of publication) reviewed}

Through this MOA, [ORGANIZATION'S NAME] agrees that laboratories are accredited to test paint films, dust and soil for lead, using guidelines provided in LQSR 3.0.

Specifically, [ORGANIZATION'S NAME] agrees:

- 1) To notify the EPA MOA Implementation Officer in writing within five working days if [ORGANIZATION'S NAME] withdraws a laboratory's accreditation.
- 2) To notify the EPA MOA Implementation Officer within 30 days after [ORGANIZATION'S NAME] makes a decision to implement changes in its organizational policies or management that could affect NLLAP.
- 3) To establish and implement a continuing education program for Assessors using the most current version (including any 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. [ORGANIZATION'S NAME] agrees to notify the EPA MOA Implementation Officer if [ORGANIZATION'S NAME] utilizes the assessor training program of another accrediting organization recognized by NLLAP. Copies of the document "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs Revision 1.0" can be

- downloaded at https://www.epa.gov/lead/pb-based-paint-laboratory-accreditation-curricula-recommendations-assessor- training-programs or may be obtained from the National Lead Information Center by calling 1-800-424-LEAD [5323].
- 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 minimum criteria stated in LQSR 3.0 and ISO/IEC 17025:2005(E) or future versions thereof.
- 5) That [ORGANIZATION'S NAME] Assessors will fill out a checklist for each on-site assessment. The checklist utilized may be the sample provided in the EPA publication "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs Revision 1.0," or onedeveloped by [ORGANIZATION'S NAME] and approved by the EPA MOA Implementation Officer that addresses the areas covered by the sample. [ORGANIZATION'S NAME] further agrees to keep the laboratory checklists on file for five years as a part of the accreditation documentation.
- 6) To allow EPA to accompany [ORGANIZATION'S NAME] Assessors during an on-site visit to observe the performance of [ORGANIZATION'S NAME] Assessors in the field.
- 7) Only to accredit laboratories that perform successfully (rated proficient or "P") in the ELPAT Program as administered by American Industrial Hygiene Association-Proficiency Analytical Testing 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 EPA MOA 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 currently accredited laboratories to the EPA MOA 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 during 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) To delegate exclusively full or partial responsibility of laboratory assessment only to another NLLAP-recognized AO, should the need arise. If the situation requires such delegation, [ORGANIZATION'S NAME] will notify the EPA MOA Implementation Officer within 30 days.
- 12) To accredit only a laboratory that practices the sub-contracting of routine sample analysis of lead in paint films, or dust 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 to provide an evaluation of NLLAP.
- 14) To require laboratories accredited by **[ORGANIZATION'S NAME]** under NLLAP to use proper labeling for any materials used to market its status as an EPA-recognized NLLAP laboratory. Marketing materials include but are not limited to the laboratory's website, print publications and/or lead dust wipe sampling kit packaging, if applicable. NLLAP laboratories may use the terminology, "EPA-Recognized TestingLab" or "EPA-Recognized NLLAP Lab" to denote its status to the public.

Through this MOA, EPA agrees:

- 1) To recognize [ORGANIZATION'S NAME], pursuant to the terms of this MOA, as a laboratory accrediting organization for NLLAP. Laboratories accredited by [ORGANIZATION'S NAME] for NLLAP will be recognized by EPA as capable of analyzing for lead in the specified matrix of paint films, dust, or soil samples during the period of their accreditation. A list of laboratories that have been accreditedwill 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 performancestandards have been amended.
- 3) To conduct an evaluation 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 EPA. Evaluation criteria will be based on the requirements stated in this section.

VI. Management and Implementation

The NLLAP is managed as a part of the EPA Lead Program. The responsibility for implementing and supporting the program lies with EPA's Existing Chemicals Risk Management Division personnel.

Inquiries concerning NLLAP and this MOA should be addressed to the EPA MOA Implementation Officer (see Section IX of this MOA).

This MOA does not create any right or benefit, substantive or procedural, enforceable by law or equity, by persons who are not party to this agreement, against [ORGANIZATION'S NAME] or EPA, their officers or employees, or any other person. This MOA does not direct or apply to any person outside of [ORGANIZATION'S NAME] and EPA.

VII. Funding

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

As required by the Antideficiency Act, 31 U.S.C. §§ 1341 and 1342, 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 MOA. This MOA 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 byrepresentatives of both parties.

VIII. Revision or Termination

This MOA shall enter into force upon signature and shall remain in force for three years from the date specified in Section I of this MOA, at which time a reevaluation of the NLLAP-recognized laboratory accrediting organization's program will be performed by EPA. It 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 MOA through good faith discussions. The MOA may be terminated at any time upon 60 days' written notice by either party to the other. Should this MOA be terminated, all NLLAP

laboratories accredited by **[ORGANIZATION'S NAME]** will be notified at least 30 days prior to the termination date by **[ORGANIZATION'S NAME]** of such status and will be directed to seek NLLAP accreditation from other EPA-recognized NLLAP Accrediting Organizations.

IX. MOA Implementation Officers

[ORGANIZATION'S NAME]

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

Tony Shorter Information Technology Specialist U.S. Environmental Protection Agency OPPT/PMOD (7407M)	[Organization's Decision Official] [Title]
1200 Pennsylvania Avenue, N.W. Washington, DC 20460	[Organization's Name] [Organization's Address]
Tel: 202-564-7638	Tel:
Fax: 202-564-7480	Fax:
Email: shorter.tony@epa.gov	Email:
Organizational Approval The following decision officials are authorized [ORGANIZATION'S NAME]: Decision Official on Behalf of EPA:	to enter into the NLLAP MOA between EPA and
[Name of Division Director] Existing Chemicals Risk Management Division	Date
Decision Official on Behalf of [ORGANIZATIO	ON'S NAME]:
[Organization's Decision Official]	Date